



**STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
DIVISION OF HEALTH PLANNING
312 Rosa L Parks Blvd
Suite 2100 William R. Snodgrass Building
Nashville, Tennessee 37243
Phone (615) 532-3161 Fax (615) 532-8532**

**M.D. GEOTZ, JR.
COMMISSIONER**

**JEFF OCKERMAN
DIRECTOR**

February 23, 2009

To: All Interested Members of the Public

Health Services and Development Agency Members
Ms. Melanie Hill, HSDA Executive Director
500 Deaderick Street, Suite 850
Nashville, TN 37243

Re: State Health Plan; Proposed 2009 Standards and Criteria for Cardiac Catheterization Services

Dear Agency Members, Ms. Hill, and members of the public:

Enclosed please find the Proposed 2009 Certificate of Need Standards and Criteria for Cardiac Catheterization Services ("Proposed Standards").

The Division of Health Planning has pursued an extensive process to revise the Certificate of Need Standards and Criteria for Cardiac Catheterization Services, including interviewing providers throughout Tennessee and submitting detailed questionnaires to expert parties regarding the clinical components of these Proposed Standards. In addition to seeking written comments on these Proposed Standards, the Division is also holding a public meeting on them in Nashville on March 3 and encourages all interested parties to attend (see attached public meeting announcement for more information).

After receiving your feedback and making any necessary revisions, we anticipate including the final Standards and Criteria for Cardiac Catheterization Services ("Final Standards") in the first edition of the State Health Plan. Thus, once the first edition of the State Health Plan is adopted by the Governor, the Final Standards will be part of the State Health Plan along with the previously revised final standards for positron emission tomography (PET) services. As a part of the State Health Plan, the Final Standards will be utilized by the HSDA in considering CON applications. In addition, because the State Health Plan is to be the State's guide to aligning policies and priorities to improve health, the Final Standards will contain policy recommendations pertaining to all existing and future providers of cardiac catheterization services. Draft policy recommendations are included in the Proposed Standards for your comment as well.

The Division is eager to work with stakeholders on these recommendations and approaches to their implementation. The detail contained in these Proposed Standards is evidence of the significant public involvement already obtained in their development.

We have included rationale statements explaining the reasoning behind each policy recommendation and the Proposed Standards, which should assist you in providing feedback to us. We value and welcome your thoughts and ask that you send your comments by Monday, March 16, 2009 to Eric Harkness, planning and research coordinator, by mail or email at eric.harkness@state.tn.us.

Thank you for your time and assistance. We look forward to hearing from you.

Sincerely,

Jefferson H. Ockerman
Director, Division of Health Planning

Attachments

cc: Commissioner Dave Goetz
Deputy Commissioner Mike Morrow
Eric Harkness

Tennessee Division of Health Planning

State Health Plan Cardiac Catheterization Services Proposed 2009 Standards and Criteria February 23, 2009

The following are proposed Standards and Criteria and Policy Recommendations for Cardiac Catheterization Services. Once adopted by the governor, these shall become effective immediately as a part of the State Health Plan. However, applications for cardiac catheterization services submitted to the Health Services and Development Agency prior to the adoption date shall be considered using the Guidelines for Growth, 2000 Edition standards and criteria.

The Division of Health Planning values and welcomes comments from stakeholders on these proposed standards and criteria. Please send comments by Monday, March 16 to Eric Harkness, planning and research coordinator, by mail or email at eric.harkness@state.tn.us.

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 catheterizations, therapeutic catheterizations, and electrophysiological (EP) studies.

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.

Electrophysiological (EP) Study: An invasive procedure that tests the heart's electrical system. 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.

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.

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	Alations, 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 Procedure or Case: For the purposes of these standards and criteria and for measuring laboratory capacity, a “procedure” or “case” shall mean one visit to a cardiac catheterization laboratory or another procedure room by one patient. Even if multiple procedures are performed between admission and discharge to the laboratory or procedure room, only the highest weighted diagnostic-equivalent procedure will be counted in a case to determine laboratory capacity.

Cardiac Catheterization Laboratory Capacity: The capacity of dedicated and multipurpose cardiac catheterization laboratories is equal to 1300 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 90 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 18 years of age. Pediatric cardiac catheterization laboratories may 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. Some mobile laboratories may be permanently fixed at an acute care hospital with on-site open heart surgery availability.

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 (260 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 must 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 shall 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.

Policy Recommendations

The Draft 2009 State Health Plan expresses *Five Health Plan Principles*. These include:

1. The purpose of the State Health Plan is to improve the health of Tennesseans
2. Every citizen should have reasonable access to health care
3. The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system
4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers
5. The state should support the recruitment and retention of a sufficient and quality health care workforce

Note that Health Plan Principles 2-5 are derived from the policy statements contained in TCA § 68-11-1625(b). The State Health Plan Advisory Committee advised the addition of Health Plan Principle 1.

In light of these principles, the Draft 2009 State Health Plan sets forth the following policy recommendations specifically relating to the provision of cardiac catheterization services in Tennessee. These recommendations are the result of extensive dialog between the Division of Health Planning, other state departments and agencies, and members of the provider community throughout Tennessee. They are intended to provide direction to all providers of cardiac catheterization services and to the Health Services and Development Agency in considering applications for such services. In order to implement these recommendations, the Division intends to work with providers of cardiac catheterization, the Tennessee Department of Health, and other health planning stakeholders to pursue necessary information, dialog, and action steps and to identify measurable objectives.

1. **Access to Emergency Services:** Every citizen in Tennessee experiencing the onset of emergency symptoms related to ST-Segment Elevation Myocardial Infarction (STEMI) should be able to receive emergent coronary intervention within 90 minutes of presenting to an emergency department. In addition, every citizen in Tennessee should be within 90 minutes driving time of a hospital offering appropriate services for such a condition.

Rationale: The first part of this recommendation recognizes the importance of prudently administering emergency care for STEMI patients. A “door to balloon time” of 90 minutes is consistent with nationally recognized guidelines. The second part of this recommendation refers to the accessibility therapeutic cardiac catheterization services. In meetings with providers throughout Tennessee, participants stressed the importance of receiving emergency cardiac care in a timely manner. The Division recommends that the CON program help ensure

that citizens in Tennessee have ready access to high quality emergency cardiac catheterization services.

- 2. Assuring the Monitoring of Health Care Quality:** In order to assure citizens in Tennessee that health care quality is monitored, all providers of cardiac catheterization services should participate in a systematic quality-monitoring program that allows comparability of quality (outcomes) and performance (efficiency) among providers. The State of Tennessee recognizes the National Cardiovascular Data Registry (NCDR)¹ as the gold standard for such a program. In addition, the State of Tennessee should consider how best to develop a reasonable quality review program that could include the NCDR or another approach deemed more appropriate for Tennessee.

Rationale: Meetings with providers throughout Tennessee revealed widespread interest in a focused effort to improve the quality of cardiac care in our state. Providers pointed to the NCDR as the best system available to monitor and help improve quality. However, participation in the NCDR is data intensive and requires substantial staff time. The Division believes that quality monitoring and improvement efforts are vital to improving our health and health care system; however, the Division is also sensitive to the burdens such efforts can place on providers to the detriment of their patients. In addition, several providers suggested that the State should convene a group of practitioners that could review sensitive quality information and advise the State accordingly. The Division agrees that such a group could contribute to quality improvement efforts, though the Division does not have a position on the makeup of this group or how it would interact with the State. The Division's preferred first step in this matter is to consult with the Department of Health on the development of a reasonable quality monitoring and improvement system that will collect appropriate data for analysis without overly burdening providers.

- 3. Accommodating a Clarified Definition of Cardiac Catheterization Services:** The Certificate of Need program in Tennessee has lacked clarity on the definition of cardiac catheterization services, including whether electrophysiological (EP) studies specifically qualify as a cardiac catheterization service. Based upon numerous provider interviews and consultation with the Tennessee Hospital Association, the Division of Health Planning has determined that, for the purpose of the Certificate of Need program, EP studies are a cardiac catheterization service. Both procedures involve similar clinical methods, similar sets of expertise, and similar—if not the same—equipment. Given this clarification of the definition of cardiac catheterization services, the State of Tennessee, led by the Division of Health Planning and the Department of Health, should review the ramifications for the licensure system and for existing providers of EP services—particularly those providers who initiated EP services without receiving a CON for cardiac catheterization services. This review may result in a revision of these

¹ View website: <https://www.ncdr.com/>

standards and criteria for cardiac catheterization services to further specify specific standards for EP procedures.

Rationale: Several respondents to the Questionnaire on Cardiac Catheterization Services for the Revision of Certificate of Need Standards and Criteria (Questionnaire) strongly urged the Division to clarify the definition of cardiac catheterization services and decide whether or not to include EP studies in the definition. With assistance from the Tennessee Hospital Association, the Division sought guidance from experts and current providers, the majority of whom agreed that EP studies are a cardiac catheterization service due to the reasons mentioned in the recommendation. Should this clarified definition have any ramifications for any current providers of EP studies, the Division intends to work with all appropriate parties to address any resulting concerns.

4. **Assuring Health Care Quality Through Maintaining Physician Skill:** Tennesseans should be assured that providers of cardiac catheterization services provide quality care. In order to comply with nationally recognized guidelines intended to maintain physician proficiency, all providers of adult cardiac catheterization services should ensure that each physician participating in its program is performing 75 cases per year based on a two-year average; all providers of pediatric cardiac catheterization services should ensure that each physician participating in its program is performing 50 pediatric cases per year based on a two-year average. These cases do not necessarily have to be performed at the same facility. The data needed to verify operator volumes is currently collected by the Department of Health through its Hospital Discharge Data System.

Rationale: The American College of Cardiology recommends that interventional cardiologists perform at least 75 cases per year and that pediatric cardiologists perform at least 50 cases per year to maintain proficiency. Respondents to the Questionnaire agreed that maintaining individual physician volume is relevant to providers of all types of cardiac catheterization services. The Division recognizes that many physicians operate at multiple facilities, which is reflected in this recommendation. In addition, the Division suggests that the implementation of this recommendation be included in the future, broader discussion of developing a quality improvement program referenced in Policy Recommendation 2.

5. **Improving Aggregate Utilization Data:** To promote an accurate understanding of the services available in Tennessee and to meet the data needs resulting from these revised standards and criteria, the Certificate of Need program requires more specific cardiac catheterization utilization data than is currently reported in the Joint Annual Report (JAR). Data needed includes summary level information on the number and type of procedures performed (including diagnostic cardiac catheterizations, elective and emergent therapeutic cardiac catheterizations, electrophysiological (EP) studies, percutaneous coronary intervention (PCI), and possibly other procedures); indications of whether the procedure was performed

in a laboratory authorized under the CON program or in another setting (such as general operating room); each patient's county of residence; and revenue, ICD-9, and procedure codes.

The Division plans to work with the Department of Health, the HSDA, and stakeholders of the CON program to survey the universe of cardiac catheterization data already available to the State. This survey will include the Hospital Discharge Data System, the Joint Annual Report, and other sources identified as relevant. Based upon this survey, the Division may identify needed modifications or additions to current reporting streams. However, since some of these changes may take some time to implement, after considering currently available data the Division may recommend a temporary approach to more quickly collect data needed by the CON program. For instance, all providers of cardiac catheterization could voluntarily report the above summary level information to the HSDA through its Equipment Registry or to the Department of Health Division of Health Statistics as an addendum to the JAR.

Rationale: Once finalized, these standards and criteria will require additional data to properly consider an application to provide cardiac catheterization services. The Division intends to work with all relevant stakeholders to develop a rational and reasonable data compilation process to serve the CON program. The Division has held initial discussions with the Department of Health in preparation of this effort.

6. **Minimum Volume Standards and Program Quality:** All providers of cardiac catheterization services should strive to meet the appropriate minimum procedure volume standards prescribed by these or subsequent standards and criteria. The Division will work with the Department of Health to assess what steps could be taken should a provider fall below these minimum standards to assure program quality and integrity until the standard is met.

Rationale: Several respondents to the Questionnaire stated that all providers of cardiac catheterization services should be required to meet minimum volume requirements, not just new applicants. The Division agrees that volume standards should apply to all providers and intends to work with all relevant stakeholders to develop a reasonable review process in conjunction with Policy Recommendations 2 and 4.

7. **Developing Economic Efficiencies Through Increasing Efficiency and Accuracy of Information:** Capitalizing on and organizing the wealth of information generated through the health care system is key to increasing economic efficiency. All providers of cardiac catheterization services should strive to support the development of e-prescribing and electronic health records. Understanding that many delicate issues must be resolved before widespread adoption of these technologies may take place, providers should engage in the

public process currently addressing these issues and pursue opportunities when feasible and where available.

Rationale: The Division had considered requiring applicants to comment on their current or intended use of e-prescribing and electronic health records. Respondents to the Questionnaire suggested that such comments would only add to the paperwork of filing an application without providing much benefit. The Division acknowledges this concern. However, the Division still encourages all providers to participate (and understands that many already do) in the public processes that are developing these technologies.

8. **Accountability for Existing Freestanding Providers:** The Division advises that it will work with the Department of Health to create a process through which existing freestanding providers of cardiac catheterization services that are not on a hospital campus receive oversight from a proper authority. This oversight should be extended to future freestanding providers of cardiac catheterization services.

Rationale: In revising these standards and criteria, the Division learned of a small number of freestanding providers of cardiac catheterization services that, as a result of legislative inconsistencies, are not required to be licensed by the Department of Health or any other proper authority. The Division believes that, in the interest of assuring the provision of quality care to the public, the Division should consult with the Department Health and the HSDA on how to resolve this matter and welcomes comments from stakeholders on appropriate action.

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:** Applicants shall document their intent to cooperate with the Department of Health to achieve and maintain compliance with these standards and criteria.

Rationale: 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. By agreeing to document their intent to cooperate with the Department of Health to achieve and maintain compliance with these standards and criteria, applicants affirm the importance of these standards and criteria and their intent to uphold them.

2. **Facility Accreditation:** Applicants shall provide documentation that the facility is fully accredited or is pursuing accreditation by the Joint Commission or another appropriate accrediting authority recognized by the Centers for Medicare and Medicaid Services (CMS).

Rationale: The accreditation process includes a review of each facility's laboratories and services, including cardiac catheterization, though these services typically do not receive specific accreditation. 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." The Division believes that accreditation is especially important for free standing facilities that are not located on an acute care facility's campus.

3. **Emergency Transfer Plan:** Applicants for cardiac catheterization services located in a facility without open heart surgery capability must provide a formalized written protocol for immediate and efficient transfer of patients to the nearest open heart surgical facility (within 60 minutes) that is reviewed/tested on a regular (quarterly) basis.

Rationale: 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:** Applicants shall 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 will agree to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee, which may be developed per Policy Recommendation 2.

Rationale: 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:** Applicants shall 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.

Rationale: 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:** Applicants shall agree to document ongoing compliance with the latest clinical guidelines of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence (ACCF/AHA/SCAI Guidelines). Where providers are not in compliance, they shall 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.

Rationale: Respondents to the Questionnaire agreed that the ACCF/AHA/SCAI 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 ACCF/AHA/SCAI 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. **Minimum Physician Requirements to Initiate a New Service:** The initiation of a new cardiac catheterization program shall require at least two cardiologists with at least one cardiologist having performed an average of 75 procedures over the most recent five year period of the type of service proposed (i.e., diagnostic or therapeutic) and an average of 50 procedures over the most recent five year period for a pediatric cardiologist. All participating cardiologists in the proposed program must be board certified or board eligible in cardiology and any relevant cardiac subspecialties.

Rationale: In meetings with providers throughout Tennessee, the Division heard a concern that new programs should not be initiated solely by inexperienced physicians. This standard is consistent with the recommendations of the ACC/SCA&I Expert Consensus Document on Cardiac Catheterization Laboratory Standards.

8. **Staffing Recruitment and Retention:** The applicant shall 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.

Rationale: 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.

9. **Definition of Need for New Services:** A need shall be determined to exist 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 1300 cases) for the proposed service area.

Rationale: 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.

10. **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.

Rationale: 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.

11. **Access:** An applicant for new or expanded cardiac catheterization services shall foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances by the following:

- A. Providing a written policy regarding the provision of any services provided by or on behalf of the applicant shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay.
- B. Providing a written commitment that services for indigent and charity patients will be offered at a standard consistent with the facility's overall charity care policy.
- C. Providing a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

Rationale: Access to health care is a main principle of the State Health Plan and should be reflected in the CON process. Respondents to the Questionnaire mostly agreed that subsection C is reasonable and would not disadvantage providers in negotiations with MCOs.

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

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

1. **Minimum Volume Standard:** Such applicants shall 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 diagnostic cardiac catheterization cases may count towards meeting this minimum volume standard.

Rationale: Questionnaire respondents generally agreed that 300 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.

2. **High Risk/Unstable Patients:** Such applicants must (a) delineate the steps, based on 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.

Rationale: 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.

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:

1. **Minimum Volume Standard:** Such applicants shall demonstrate that the proposed service utilization will be a minimum of 400 diagnostic and/or therapeutic cardiac catheterization procedures per year by its third year of operation. At least 75 of these procedures per year should be therapeutic cardiac catheterization procedures. 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 diagnostic and therapeutic cardiac catheterization procedures shall count towards meeting this minimum volume standard.

Rationale: Questionnaire respondents generally agreed that 400 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.

2. **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 must document and maintain strict compliance with the Criteria for the Performance of Primary PCI at Hospitals Without On-Site Cardiac Surgery contained in the most recent ACC/AHA/SCAI Practice Guideline Update for Percutaneous Coronary Intervention.

Further, therapeutic procedures shall not be permitted 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.

Rationale: 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.

3. **Staff and Service Availability:** Therapeutic services should be available on an emergency basis 24 hours per day, 7 days per week through a staff call schedule. In addition, all laboratory staff should be available within 30 minutes of the activation of the laboratory.

Rationale: Respondents to the Questionnaire generally favored including this standard, which is consistent with nationally recognized guidelines. A cardiac catheterization laboratory offering therapeutic services that only operates during convenience hours does not provide sufficient access for the public and can result in lost time during an emergency.

4. **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, shall demonstrate that its diagnostic cardiac catheterization unit has been utilized for an average minimum of 300 procedures per year for the two most recent years as reflected in the data supplied to and/or verified by the Department of Health.

Rationale: 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

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

1. **Minimum Number for New Service:** Such applicants shall demonstrate that the proposed service utilization will be a minimum of 100 diagnostic and/or therapeutic cardiac catheterization procedures 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 diagnostic and therapeutic cardiac catheterization procedures shall count towards meeting this minimum volume standard.

Rationale: This standard is consistent with national guidelines on the provision of pediatric cardiac catheterization services.

2. **Physician Requirements:** Pediatric cardiac catheterization services shall be performed only by board certified or board eligible physicians specializing in pediatric cardiac care.

Rationale: This standard is consistent with the most recent ACC/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards.

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

Rationale: This standard is consistent with the most recent ACC/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards.

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

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

1. **Minimum Number for New Service:** Such applicants shall demonstrate that the proposed service utilization will be a minimum of 60 cardiac catheterization procedures 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 procedures per day of operation per year is acceptable. Only diagnostic cardiac catheterization procedures may count towards meeting this minimum volume standard.

Rationale: 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.

2. **Limitations on Procedure Types in Mobile Facilities:** No therapeutic or pediatric cardiac catheterization procedures shall 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 affecting the fixed laboratory.

Rationale: 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 affecting fixed laboratories.

3. **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 shall 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: 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/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards.