STATE OF TENNESSEE

STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

POSITRON EMISSION TOMOGRAPHY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Positron Emission Tomography (PET) services. Existing providers of PET services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for PET 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 PET services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Positron Emission Tomography (PET): A noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body (source: The Centers for Medicare and Medicaid Services). PET differs from other nuclear medicine modalities in the type of radiation emitted and in the type of scanner required to detect it. By measuring the distributions of certain radiotracers in the body some time after they have been administered, PET can be used to diagnose physical abnormalities and to study body functions in normal subjects.

PET Unit: Diagnostic equipment (often referred to as a "scanner") that uses a positron camera (tomograph) to produce cross-sectional tomographic images (this process is often referred to as a "scan"). The images are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2-(F-18) Fluoro-D-Glucose (FDG) which are administered intravenously to the patient. The radioactive tracers may be produced on-site, e.g. with a cyclotron, or may be ordered from commercial distributors. As a result, factors such as equipment cost, geographic distribution and availability of distributors, and other related factors (regulatory compliance/certification) should be considered by the Agency in its review of all PET applications.

First developed in the 1970s, initial PET scanners were dedicated machines performing only that service. PET scanners can be either fixed (stationary) or mobile. Current technological adaptations include hybrid machines, such as combined PET-CT (computed tomography) scanners that are capable of performing a variety of nuclear medicine studies.

PET Procedure: A PET diagnostic scan or combination of scans performed on a single patient during a single visit. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition.

Stationary PET Unit: A non-moveable PET unit housed at a single permanent location.

Mobile PET Unit: A PET unit and transporting equipment that is moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the Continental United States.

Capacity: The measure of the maximum number of PET scans per PET unit per year based upon the type of PET equipment to be used (i.e., stationary or mobile).

Stationary PET Unit Capacity: Total capacity of a stationary PET unit is 2,000 procedures per year and is based upon a daily operating efficiency of eight procedures per day x 250 days of operation per year. The optimal efficiency for a stationary PET unit is 80 percent of total capacity, or 1,600 procedures per year.

Mobile PET Unit Capacity: Total capacity of a mobile PET scanner is 400 annual procedures per day of operation per week and is based upon a daily operating efficiency of at least eight (8) procedures per day x number of days in operation per week x approximately 50 weeks per year. The optimal efficiency of a mobile PET unit is based upon the number of days per week that it is in operation. For each day of operation per week, the optimal efficiency is 320 procedures per year, or 80 percent of total capacity.

PET Unit Service Area: The counties, or portions thereof, representing a reasonable area in which a health care institution intends to provide PET unit services, including, but not limited to, oncology and cardiology diagnostic and treatment services, and in which at least 75% of its service recipients reside. A PET unit should be located at a site that allows reasonable access for residents of the service area.

Service Area Capacity: The estimate of the number of PET units needed in a given service area. The estimate is based upon an optimal efficiency of 1,600 procedures per year for a stationary PET unit and an optimal efficiency of 320 annual procedures per day of operation per week for a mobile PET unit, and the quantitative estimate of the number of patients who potentially could benefit from PET diagnostic services, especially those patients pertaining to the following categories:

- those patients where the use of PET unit services is essential to the diagnosis, treatment, or surveillance of cancer, including, but not limited to, diagnosis codes approved by the Centers for Medicare and Medicaid Services (CMS);
- those patients who are either non-emergent candidates for open heart surgery or therapeutic cardiac catheterization procedures;
- those patients with a diagnosis of partial complex epilepsy for whom surgical intervention is being considered; and
- any other patient population that may benefit from the accessibility to stationary or mobile PET unit services as a result of expanded clinical applications and changes in the reimbursement of PET service by third party payors, including those pertaining to programs administered by the CMS.

In addition to the above determinants of service area capacity, applicants should consider demographic patterns, including the results of estimates of population health risk factors and population-based cancer, heart disease, or other applicable clinical incidence rates.

The data should be consistent with data prepared by the Tennessee Department of Health. Applicants should also document the extent, if any, of diagnostic oncology, cardiac and neurological medical services in the proposed service area in its determination of the need for PET unit services.

Standards and Criteria

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

   For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

   Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

   Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

   The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.

   a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

   b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

   c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

8. 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 cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; 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.

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. Theses 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.

POLICY RECOMMENDATIONS FOR IMPROVING THE PROVISION OF CARDIAC CATHETERIZATION SERVICES

The 2009 State Health Plan expresses *Five Principles for Achieving Better Health.* 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 development, recruitment, and retention of a sufficient and quality health care workforce*

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

In light of these principles, the 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 (HSDA) in considering applications for such services. However, these recommendations extend beyond the current certificate of need (CON) program and are not to be considered standards and criteria by the HSDA in granting CON applications.

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 of 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

[1] View website: https://www.ncdr.com/

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 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, the Division recommends that all providers of adult cardiac catheterization services ensure that each physician participating in its program is performing 75 procedures 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 procedures 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. The Division sees this effort closely connected with Policy Recommendation 2.

Rationale: The American College of Cardiology recommends that interventional cardiologists perform at least 75 procedures per year and that pediatric cardiologists perform at least 50 procedures 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.

STATE OF TENNESSEE

STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

OPEN HEART SURGERY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide open heart surgery services. Rationale statements for each standard are provided in an appendix. Existing providers of open heart surgery services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for such services.

These proposed standards and criteria will become effective immediately upon approval and adoption by the governor. However, applications to provide open heart surgery services that are deemed complete by HSDA prior to the approval and adoption of these standards and criteria shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

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

The following procedures also are considered open heart surgery:

- Procedures being performed on the heart through smaller incisions

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

Open Heart Surgery Service: An organized surgical program that serves inpatients of a hospital that has a suitable operating room or suite of operating rooms, equipment, staff, intensive care unit, and all support services required to perform open heart surgery. The open heart surgery service shall be located in an acute care hospital that is licensed by the State of Tennessee and that has an authorized therapeutic cardiac catheterization service.

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

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

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

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

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

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

Standards and Criteria

1. **Determination of Need:** The need for open heart surgery services is determined by applying the following formula to four age ranges of the population and summing the result of each calculation. The applicant should apply this formula to the following age ranges: 0 through14; 15 through 44; 45 through 64; and 65 and above. The formula serves to derive the number of open heart surgery cases which may be needed in a proposed service area.

    N = U x (P + O).

    where:

    N = number of cases needed in a service area;

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

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

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

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

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

2. **Minimum Volume Standard:** The applicant should demonstrate that the proposed service utilization will be a minimum of 200 adult surgery cases per year by its third year of operation for adult open heart surgery services. The applicant should demonstrate that the proposed service utilization will be a minimum of 100 pediatric open heart surgery cases per year by its third year of operation for pediatric open heart surgery services. Annual volume shall be measured based upon a two-year average which shall begin at the conclusion of the applicant's first year of operation.

3. **Current Service Area Utilization:** The applicant should document that all existing providers of open heart surgery services within the proposed service area and within a 50 mile radius each performed at least 300 adult open heart surgery cases per year (or 130 pediatric open heart surgery

cases per year) during the most recent 12 month period for which data are available. To characterize existing providers located within Tennessee, the applicant should use data provided by the Hospital Discharge Data System (HDDS) maintained by the Tennessee Department of Health. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

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

4. **Orderly Development of Applicant's Cardiac Care Services:** The applicant should document that it has operated a fully functioning therapeutic cardiac catheterization laboratory for at least one year and that this laboratory complies with the minimum volume standards set forth in the Standards and Criteria for Cardiac Catheterization Services. The applicant should also document the number of heart surgery cases and—if applicable—cardiac catheterization cases that have been referred out of the hospital during the most recent three year period of available data.

5. **Adverse Impact on Existing Providers:** A new open heart surgery program should not be approved if the new program will cause the annual caseload of existing programs within the service area to drop below 300 adult cases or 130 pediatric cases. The patient origin study conducted for Standard 2, an analysis of patient origin data collected for Standard 4, and the referral data documented for Standard 5 should be used to determine whether such an adverse impact on existing providers is likely to occur.

6. **Open Heart Surgery Continuum of Care:** The applicant should document that it will provide the following resources to properly support an open heart surgery program based upon projected volume levels. Included in such documentation should be a letter of support from the applicant's governing board of directors documenting the full commitment of the applicant to develop and maintain the facility resources, equipment, and staffing to provide a full continuum of open heart surgery care and supportive services. The applicant should also document the financial costs of maintaining these resources and its ability to sustain them to ensure quality treatment of patients in the open heart surgery continuum of care.

a) Access to specialists as required in the areas of Interventional Cardiology, Renal, Nephrology, Pulmonary Medicine, Neurology, Infectious Disease, and Endocrinology;
b) At least one dedicated open heart surgery Operating Room;
c) Operative services—available 24 hours per day, seven days per week for emergent cases—including Perfusion, Cardiac Anesthesia, and a specially trained Cardiac Operating Room Team;
d) Support services, including Blood Bank, Patient Dialysis, Respiratory Therapy, and Physical Therapy;
e) Post-Operative care that includes a Cardiovascular Intensive Care Unit/Open Heart Recovery Unit, a Cardiac Step-Down Unit, and Cardiac Rehabilitation; and
f) Ventricular Assist Device (VAD) capabilities.

7. **Adequate Staffing:** The applicant should document a plan for recruiting and maintaining a sufficient number of professional and technical staff to provide the services listed in Standard 7. The applicant should also document an ongoing educational plan for all staff included in the open heart surgery program.

8. **Staff and Service Availability for Emergent Cases:** The applicant should document the capability to mobilize surgical and medical support teams rapidly (within 30 minutes) for emergency cases 24 hours per day, seven days per week. The applicant should also address staff availability and Operating Room space availability for emergencies during peak operating hours.

9. **Treatment of Pediatric Patients:** Open heart surgery on pediatric patients may not be limited to pediatric facilities. However, a facility treating pediatric patients should have a pediatric cardiac surgeon, specialized pediatric staff, and offer services in the continuum of care as noted in Standard 7 for pediatric patients; additionally, such an applicant should document its intention to comply with the American Academy of Pediatrics' Guidelines for Pediatric Cardiovascular Centers.

10. **Minimum Physician Requirements to Initiate a New Service:** The applicant should document the availability of, or present a plan for recruiting, at least two qualified cardiac surgeons certified by the American Board of Thoracic Surgery. For adult open heart surgery services, a qualified cardiac surgeon will have performed a minimum of 200 adult open heart surgery cases in the two years prior to the application. For pediatric open heart surgery services, a qualified cardiac surgeon will have performed a minimum of 100 pediatric open heart surgery cases in the two years prior to the application. In both adult and pediatric open heart surgery services programs, at least one cardiac

surgeon should have a minimum of five years of cardiac surgical experience.

11. **Maintenance of Physician Skill:** The applicant should establish processes to ensure that its adult open heart surgeons will perform at least 100 adult open heart surgery cases annually across all practice locations and/or that its pediatric open heart surgeons will perform at least 50 pediatric open heart surgery cases annually across all practice locations.

12. **Clinical Guidelines:** The applicant should agree to document ongoing compliance with the most recently published *Guidelines for Coronary Artery Bypass Graft Surgery* adopted by the American College of Cardiology and the American Heart Association. Where providers are not in compliance, they should maintain appropriate documentation stating the reasons for noncompliance and the steps the provider is taking to ensure quality. As of the adoption of these Standards and Criteria, the latest edition may be found here under the heading "Guidelines": http://www.acc.org/qualityandscience/clinical/topic/topic.htm.

13. **Licensure:** Open heart surgeries should only be performed in acute care hospitals that are licensed by the State of Tennessee.

14. **Accessibility:** The maximum travel time to hospitals providing open heart surgery services should be within a one-way driving time of 90 minutes for at least 90 percent of the population of Tennessee.

15. **Elective Surgery:** The applicant should document that elective open heart surgery services will be available within two weeks from the date of the patient's decision to undergo surgery.

16. **Quality Control and Monitoring:** The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system which benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant hospital. Demonstrated active participation in the STS National Database is encouraged and shall be considered evidence of meeting this standard.

17. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

Rationale for Revised and Updated Standards and Criteria for Open Heart Surgery Services

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

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

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

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

3. **Current Service Area Utilization.** This Standard supports Standards 2 and 5 by asking the applicant to demonstrate that a sufficient number of potential open heart patients reside within the applicant's service area and that the potential redistribution of patients in the service area will not adversely affect the quality of care provided by existing providers. Respondents to the Questionnaire and the Proposed Standards agreed that this Standard is reasonable.

4. **Orderly Development of Applicant's Cardiac Care Services.** Because providing open heart surgery services is such a resource intensive endeavor, the Division takes the position that it is not appropriate for a brand new hospital to provide the service. Instead, the Division believes that the hospital should demonstrate its capability to administer an open heart surgery program through successful management of less intensive cardiac services. In addition, graduating from a therapeutic cardiac catheterization service to an open heart surgery program will help provide an initial base of patients. Respondents to the Questionnaire and the Proposed Standards agreed that this Standard is reasonable.

5. **Adverse Impact on Existing Providers.** For the reasons stated in the rationale for Standard 2, the Division believes that causing an existing open heart surgery program's volume to drop below a certain threshold will affect the economic viability and quality of that program. Respondents to the Questionnaire and Proposed Standards generally agreed that this Standard is reasonable, though many suggested lowering the volume threshold from 350 to 300, which the Division has done for this Final Standard.

6. **Open Heart Surgery Continuum of Care.** The Division seeks to ensure that applicants to provide open heart surgery services have fully planned for the programmatic and financial implications of maintaining a successful program. In addition, a commenter on the Proposed Standards suggested adding a statement to this Standard to help ensure that the applicant's board of directors fully understands the resource commitment to maintain a successful program.

7. **Adequate Staffing.** State Health Plan Principle for Achieving Better Health Number 5 reads, "The state should support the development, recruitment, and retention of a sufficient and quality health care workforce." This Standard asks the applicant to support this principle through providing the HSDA with a well thought out staffing recruitment and educational plan.

8. **Staff and Service Availability for Emergent Cases.** Respondents to the Questionnaire and Proposed Standards agreed that providers of open heart surgery cases should be prepared to quickly provide surgical services in an emergency situation.

9. **Treatment of Pediatric Patients.** In certain circumstances, it may be appropriate for a hospital other than a children's hospital to provide open heart surgery services to a pediatric patient. Respondents to the Questionnaire and Proposed Standards generally agreed that this Standard is reasonable. Additionally, one commenter recommended including a statement regarding intention to comply with the American Academy of Pediatrics' Guidelines for Pediatric Cardiovascular Centers, which the Division has included in the Final Standard.

10. **Minimum Physician Requirements to Initiate a New Service.** Respondents to the Questionnaire and Proposed Standards agreed that hospitals should not initiate new open heart surgery programs with an inexperienced medical staff. Respondents agreed that the minimum thresholds set by this Standard are reasonable.

11. **Maintenance of Physician Skill.** The issue of ongoing accountability to the CON Standards and Criteria for successful CON applicants is not yet resolved. However, currently the CON program does have the authority to ensure proper planning is in place before a new service is initiated. This Standard seeks to ensure that applicants have established procedures that will result in its open heart surgeons having an adequate volume of cases to maintain a high level of quality

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

12. **Clinical Guidelines.** This Standard mimics a similar standard in the Standards and Criteria for the Initiative of Cardiac Catheterization Services. It also supports State Health Plan Principle Number 4: "Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers." Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.

13. **Licensure.** Practicing open heart surgery in a facility not monitored by an official accreditation/licensure process harms patience confidence in the quality of care. Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.

14. **Accessibility.** This Standard supports State Health Plan Principle Number 2: "Every citizen should have reasonable access to health care." Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.

15. **Elective Surgery.** This Standard was adopted by the Guidelines for Growth, 2000 Edition, and is maintained in these Final Standards. Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.

16. **Quality Control and Monitoring.** This Standard supports State Health Plan Principle Number 4: "Principle for Achieving Better Health Number 4: "Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers." Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable, though some commenters asked that the Division specifically mention the STS National Database as the ideal quality monitoring system, which the Division has included in this Final Standard. The Division hopes that, eventually, every open heart surgery program in Tennessee will participate in the STS National Database, however the Division does not believe it is appropriate to mandate participation in the program.

17. **Data Requirements.** This Standard seeks to improve quality through transparency in accordance with accepted rules, regulations, and contracts. Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.

STATE OF TENNESSEE

STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

EXTRA-CORPOREAL SHOCK WAVE LITHOTRIPSY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide extra-corporeal shock wave lithotripsy (ESWL) services. Rationale statements for each standard are provided in an appendix. Existing providers of ESWL services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for such services.

These proposed standards and criteria will become effective immediately upon approval and adoption by the governor. However, applications to provide ESWL services that are deemed complete by the HSDA prior to the approval and adoption of these standards and criteria shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Lithotripsy: Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy is the non-invasive procedure that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient relative to where the stone is located and the shock waves are focused on the stone, which is shattered by the force.

Procedure: A “procedure” is the single provision of ESWL services as reported by its ICD9 code or the ESWL services facility’s internal financial code that corresponds to the ESWL services CPT code.

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

Standards and Criteria

1. **Determination of Need:** The need for ESWL services is determined by applying the following formula:

   N = (U x P) + O

   N = number of ESWL services procedures needed in a Service Area;

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

   P = projection of population (in thousands) in the service area as determined by the Tennessee Department of Health for Tennessee counties and the United States Census Bureau for non-Tennessee counties; and

   O = the number of out-of-state resident procedures performed within the applicant's Service Area in the same time frame used to determine U based upon publically reported data. The applicant should document the methodology used to count volume in out-of-state resident procedures and, if different from the definition of "procedure" described in these standards and criteria, should distinguish out-of-state procedures from in-state cases.

   The need shall be based upon the Service Area's current year's population projected three years forward.

2. **Minimum Volume Standard:** Applicants proposing to acquire and operate an ESWL services unit must project a minimum utilization of at least 250 procedures per year by the third year of operation, based on full-time use of an ESWL unit. The applicant must also document and provide data supporting the methodology used to project the patient utilization. An application to provide ESWL services on a part-time basis shall convert its projected use to that of a full-time equivalent ESWL unit.

3. **Current Service Area Utilization:** The applicant should document that all existing providers of ESWL services within the proposed Service Area each performed at least 300 ESWL procedures per year during the most recent 12 month period for which data are available. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. To characterize existing providers located within Tennessee, the applicant should use data provided by the Health Services and Development Agency. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

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

4. **Adverse Impact on Existing Providers:** An application for ESWL services should not be approved if the new program will cause the annual caseload of existing ESWL programs within the Service Area to drop below an average of 300 procedures. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. The patient origin study conducted for Standard 2, an analysis of patient origin data collected for Standard 3, and the referral data documented for Standard 3 should be used to determine whether such an adverse impact on existing providers is likely to occur.

5. **Adequate Staffing and Services:** The applicant should document a plan for recruiting and maintaining a sufficient number of qualified professional and technical staff to provide the ESWL services and must document the following:

   a. The existence of an active radiology service and an established referral urological practice;
   b. The availability within 90 minutes' drive time of acute inpatient services for patients who experience complications; and
   c. The fact that all individuals using the equipment meet the training and credentialing requirements of the American College of Surgeons' Advisory Council for Urology.

The applicant should also document an ongoing educational plan for all staff included in the ESWL services program.

6. **ESWL Equipment:** Only applications that provide for the provision of ESWL services using equipment that has been approved by the United States Food and Drug Administration for clinical use shall be approvable.

7. **Quality Control and Monitoring:** The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system that benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant.

8. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the HSDA with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

9. **Transfer and/or Affiliation Agreements:** If an applicant is not a designated Level 1 trauma center, an applicant must document an acceptable plan for the development of transfer and/or affiliation agreements with hospitals in the service area (this criterion does not preclude the development of transfer agreements with facilities outside the applicant's Service Area).

10. **Access:** In addition to the factors set forth in HSDA Rule 0720-11-.01 (1) (listing the factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant:

    a. That is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

    b. That documents that the service area population experiences a prevalence and/or incidence of urinary stones or other clinical conditions applicable to extra-corporeal shock wave lithotripsy services that is substantially higher than the State of Tennessee average; or

    c. That is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program.

Rationale for Revised and Updated Standards and Criteria for Extra-Corporeal Shock Wave Lithotripsy Services

Definitions for "Lithotripsy," "Procedure," and "Service Area" are provided in the standards and criteria.

1. **Determination of Need**: The formula for determination of need is based on a state utilization rate formula for ESWL services, rather than one unit per 250,000 people. Data available in the future may enable the need determination to be based on regional utilization rates. The need determination also takes into account out-of-state residents' utilization of Tennessee-based ESWL services. Need is based upon population projected three years forward, instead of the current four years provided by the Guidelines for Growth, reflecting the comparatively low capitalization requirements to institute ESWL services.

2. **Minimum Volume:** Based on the responses to the Questionnaire and the comments at the public meeting, it appears that a reasonable minimum annual volume projection for an ESWL unit by its third year of operation is 250 procedures, which allows for future growth in services (the former Guidelines for Growth also required a projection of 250 procedures). An application to provide ESWL services on a part-time basis is converted to a full-time equivalent ESWL unit projected use.

3. **Current Service Area Utilization:** Converting part-time ESWL unit utilization numbers to full-time equivalents, the average number of ESWL procedures performed by ESWL units in Tennessee in 2009 was 589. The Questionnaire responses and the public meeting comments showed strong and reasonable interest in ensuring greater accessibility to ESWL services statewide, as is contemplated by the State Health Plan's Principle No. 2 for Achieving Better Health ("Every citizen should have reasonable access to health care"). This standard states that each existing Service Area ESWL unit should have performed at least 300 procedures in the most recent 12 month period in order for an application to show need for ESWL services in the Service Area. This standard also requires an applicant to provide patient origin data analysis.

4. **Adverse Impact:** This standard suggests that existing ESWL programs in a Service Area should not drop below a projected annual utilization number of 300 procedures as a result of the granting of an application to provide ESWL services. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit.

5. **Staffing/Services**: Availability of acute inpatient services within a 90 minute drive time has been added, replacing the current undefined "proximity" guideline,

thus providing a more definite access-to-care standard. The Guidelines for Growth referenced the "American Lithotripsy Society," which no longer exists. That reference has been replaced by one to the "American College of Surgeons' Advisory Council for Urology."

6. **Equipment:** This standard reflects the one in the former Guidelines for Growth.

7. **Quality:** This standard reflects the connection to the State Health Plan's Principle No. 4 for Achieving Better Health, "Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers."

8. **Data:** The ability to measure improvements in access to care and in cost of care can only be discerned by having access to necessary data. This standard reflects the continuing need for accurate data.

9. **Transfer Agreements:** This standard differs from the Guidelines for Growth in providing that an applicant that is a Level 1 Trauma Center need not provide a transfer and/or affiliation agreement.

10. **Access:** To ensure reasonable access to ESWL services in underserved areas, as is contemplated by the State Health Plan's Principle No. 2 for Achieving Better Health ("Every citizen should have reasonable access to health care"), the HSDA may choose to give special consideration to applicants that meet these particular conditions.

STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

MAGNETIC RESONANCE IMAGING SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Magnetic Resonance Imaging (MRI) services. Existing providers of MRI services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for MRI services.

These standards and criteria are effective immediately as of Decenber 21, 2011, the date of approval and adoption by the Governor of the State Health Plan changes for 2011. Applications to provide MRI services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Capacity: The measure of the maximum number of MRI procedures per MRI unit per year based upon the type of MRI equipment.

Dedicated Breast MRI Unit: An MRI unit that is configured to perform only breast MRI procedures and is not capable of performing other types of non-breast MRI procedures.

Dedicated Extremity MRI Unit: An MRI unit that is utilized for the imaging of extremities only and is of open design with a field of view no greater than 25 centimeters.

Magnetic Resonance Imaging (MRI): A noninvasive diagnostic modality in which electronic equipment is used to create tomographic images of body structure. The MRI

scanner exposes the target area to nonionizing magnetic energy and radio frequency fields, focusing on the nuclei of atoms such as hydrogen in the body tissue. Response of selected nuclei to this stimulus is translated into images for evaluation by the physician.

MRI Procedure: A single, discrete MRI study performed on a single patient during a single visit. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition, including the development of a selected set of CPT codes, which shall not include research-only CPT codes for purposes of determing capacity and need.

MRI Study: An MRI scan defined by a CPT procedure code.

MRI Unit: Medical imaging equipment (often referred to as a "scanner") that uses nuclear magnetic resonance to create tomographic images of body structure. MRI units may be differentiated by magnetic field strength ("tesla" or "T"), and also by construction or orientation. A "closed" scanner typically uses a higher strength magnet and an "open" scanner typically uses a lower strength magnet. There are also "multi-position" or "stand-up" scanners (often used for spine and joint evaluation, where weight-bearing is required) and limited-use scanners, such as those designed only to scan the breast or extremities (e.g., elbows, wrists, toes, etc.).

Mobile MRI Unit: An MRI unit and transporting equipment that is moved or able to be moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the United States.

Mobile MRI Unit Capacity: Total capacity of a mobile MRI unit is 600 annual procedures per day of operation per week and is based upon a daily operating efficiency of 12 procedures per day x 50 weeks per year, multiplied by the number of days per week that the equipment is used. The optimal efficiency of a mobile MRI unit is based upon the number of days per week that it is in operation. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of total capacity.

Dedicated Multi-position MRI Unit: An MRI unit that permits the patient to be scanned in various positions, such as sitting, standing, bending, or leaning, as well as lying down, for the purpose of providing weight-bearing scans.

Service Area: The contiguous counties or portions thereof representing a reasonable area in which an applicant intends to provide MRI unit services and in which at least 75% of its service recipients reside. An MRI unit should be located at a site that allows reasonable access for residents of the service area.

Service Area Capacity: The estimate of the number of MRI units needed in a given service area. The estimate is based upon an optimal efficiency of 2,880 procedures per

year for a stationary MRI unit and an optimal efficiency of 480 annual procedures per day of operation per week for a mobile MRI unit

Specialty MRI Unit: A Dedicated Breast, Extremity, or Multi-position MRI unit.

Stationary MRI Unit: A non-moveable MRI unit housed at a single permanent location.

Stationary MRI Unit Capacity: Total capacity of a stationary MRI unit is 3600 procedures per year and is based upon a daily operating efficiency of 1.20 procedures per hour, 12 hours per day x 5 days a week x 50 weeks of operation per year. The optimal efficiency for a stationary MRI unit is 80 percent of total capacity, or 2,880 procedures per year.

Standards and Criteria

1. Utilization Standards for non-Specialty MRI Units.
    a. An applicant proposing a new non-Specialty stationary MRI service should project a minimum of at least 2160 MRI procedures in the first year of service, building to a minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2880 procedures per year by the third year of service and for every year thereafter.
    b. Providers proposing a new non-Specialty mobile MRI service should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.
    c. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.
    d. Mobile MRI units shall not be subject to the need standard in paragraph 1 b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's Service Area are not adequate and/or that there are special circumstances that require these additional services.
    e. Hybrid MRI Units. The HSDA may evaluate a CON application for an MRI "hybrid" Unit (an MRI Unit that is combined/utilized with another medical equipment such as a megavoltage radiation therapy unit or a positron emission tomography unit) based on the primary purposes of the Unit.

2. Access to MRI Units. All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the Service Area's population. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRI units that service the non-Tennessee counties and the impact on MRI unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

3. Economic Efficiencies. All applicants for any proposed new MRI Unit should document that althernate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

4. Need Standard for non-Specialty MRI Units.

   A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per MRI unit is based upon the following formula:

   Stationary MRI Units: 1.20 procedures per hour x twelve hours per day x 5 days per week x 50 weeks per year = 3,600 procedures per year

   Mobile MRI Units: Twelve (12) procedures per day x days per week in operation x 50 weeks per year. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.

5. Need Standards for Specialty MRI Units.
   a. Dedicated fixed or mobile Breast MRI Unit. An applicant proposing to acquire a dedicated fixed or mobile breast MRI unit shall not receive a CON to use the MRI unit for non-dedicated purposes and shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:
      i. It has an existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound, and MRI unit equipment, and that is trained to interpret

images produced by an MRI unit configured exclusively for mammographic studies;

ii. Its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit are in compliance with the federal Mammography Quality Standards Act;

iii. It is part of or has a formal affiliation with an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the proposed service area; and

iv. It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.

b. Dedicated fixed or mobile Extremity MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Extremity MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Extremity MRI Unit and a CON granted for this use should so state on its face.

c. Dedicated fixed or mobile Multi-position MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Multi-position MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity.Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Multi-position MRI Unit and a CON granted for this use should so state on its face.

6. Separate Inventories for Specialty MRI Units and non-Specialty MRI Units. If data availability permits, Breast, Extremity, and Multi-position MRI Units shall not be counted in the inventory of non-Specialty fixed or mobile MRI Units, and an inventory for each category of Specialty MRI Unit shall be counted and maintained separately. None of the Specialty MRI Units may be replaced with non-Specialty MRI fixed or mobile MRI Units and a Certificate of Need granted for any of these Specialty MRI Units shall have included on its face a statement to that effect. A non-Specialty fixed or mobile MRI Unit for which a CON is granted for Specialty MRI Unit purpose use-only shall be counted in the specific Specialty MRI Unit inventory and shall also have stated on the face of its Certificate of Need that it may not be used for non-Specialty MRI purposes.

7. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRI Unit is safe and effective for its proposed use.

   a. The United States Food and Drug Administration (FDA) must certify the proposed MRI Unit for clinical use.

   b. The applicant should demonstrate that the proposed MRI Procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

   c. The applicant should demonstrate how emergencies within the MRI Unit facility will be managed in conformity with accepted medical practice.

   d. The applicant should establish protocols that assure that all MRI Procedures performed are medically necessary and will not unnecessarily duplicate other services.

   e. An applicant proposing to acquire any MRI Unit or institute any MRI service, including Dedicated Breast and Extremity MRI Units, shall demonstrate that it meets or is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, including staff education and training programs.

   f. All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.

   g. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with

its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

8. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

9. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," 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 is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or

    c. 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; or

    d. Who is proposing to use the MRI unit for patients that typically require longer preparation and scanning times (e.g., pediatric, special needs, sedated, and contrast agent use patients). The applicant shall provide in its application information supporting the additional time required per scan and the impact on the need standard.

Rationale for Revised and Updated Standards and Criteria for Magnetic Resonance Imaging Services

Definitions

Specialty MRI Units. The Office of Health Planning recognizes that certain MRI Units dedicated for breast, extremity, and multi-position purposes do not reach the level of utilization that standard MRI Units do. Consequently, definitions for these Specialty Units have been created and specific standards for each have been developed.

MRI Procedure. To provide for uniform procedure reporting, the Health Services and Development Agency is responsible for setting CPT code reporting requirements consistent with the definition of MRI Procedure. Research CPT codes are excluded from capacity and need calculations.

Capacity. The Office solicited operating schedule information from owners/operators of MRI Units. From this information, while total capacity of a non-Specialty MRI Unit could conceivably be based on an operating schedule of 24 hours per day, 7 days per week, usual practice does not cover such extended hours of operation. It appears that physician offices and outpatient diagnostic centers more usually operate their MRI Units Monday-Friday; inpatient facilities typically operate Monday-Friday, with the potential to operate on Saturdays as needed. There are exceptions, however, with both outpatient and inpatient MRI Units operating more than five days a week. Hours of operation vary and seem to not be dependent upon outpatient or inpatient use, usually from 12 to 16 hours per day. Utilization and operating practices can and do vary widely.

Additionally, from the information received, the length of time per scan varies depending on a variety of circumstances, including protocols in place, whether a patient is sedated or needs longer time to be placed in the unit, whether the scan is with or without contrast, etc. A scan may take as little as 30 minutes or as long as 80 (or more) minutes. Typically, due to sedation and/or contrast requirements, an inpatient facility will take longer to perform its scans. However, Tennessee does not collect sufficient data on these scans in order to develop a total capacity formula based on them.

We are basing a total non-Specialty MRI unit capacity number on the performance of 1.20 scans per hour, Monday through Friday utilization, 12 hours a day, 50 weeks a year, for a total capacity number of 3,600. Using an 80% optimal efficiency number, we arrive at 2,880 as the number of scans a year that a typical stationary non-Specialty MRI Unit should be able to perform.

Standards and Criteria Regarding Certificate of Need Applications for Magnetic Resonance Imaging Services

1. **Exceptions to Utilization Standards:** Exceptions to the standard number of procedures has been retained for new or improved technology and diagnostic applications, and for mobile MRI Units in operation fewer than 150 days of service per year. Applications for hybrid MRI Units (e.g., MRI Units combined with PET Units or MRT Units) may be assessed under the primary use of the hybrid unit.

2. **Other Access Issues:** The provision of health care doesn't recognize state boundaries. Accordingly, applicants may include non-Tennessee counties in proposed service areas if that data are available.

3. **Economic Efficiencies:** To support the goal of reducing health care costs, applicants should document that other options have been investigated and found less advantageous.

4. **Specialty MRI Units Standards:** Dedicated Breast MRI Units have a proposed total capacity estimate of 2,000 procedures per year. Dedicated Extremity and Dedicated Multi-position MRI Units do not have a defined estimate; an applicant must demonstrate total capacity as well as its estimated annual utilization that, by the third year, will be at least 80% of total capacity.

5. **Inventories:** Given that there are proposed different standards for Specialty and non-Specialty MRI Units, separate inventories should be maintained. Additionally, a CON granted for the institution of a Specialty MRI Unit should not be permitted to be used for non-Specialty MRI purposes; it is recommended that any CON granted for Specialty MRI purposes so state on its face.

6. **Quality of Care:** Specific staffing, training, and education standards are included to help ensure patient safety and quality of care provided.

STATE OF TENNESSEE

STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

MEGAVOLTAGE RADIATION THERAPY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Megavoltage Radiation Therapy (MRT) Services. Existing providers of MRT services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for MRT services.

These standards and criteria are effective immediately as of December 21, 2011, the date of approval and adoption by the Governor of the State Health Plan changes for 2011. Applications to provide MRT services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

External Beam Radiation Therapy (EBRT). Radiation therapy delivered by an MRT Unit from outside the body.

Linear Accelerator. A type of EMRT Unit that delivers a beam of high energy x-rays (photon or electron particles) from an external source to the location of the patient's tumor and/or other tissue being irradiated. Linear accelerators may deliver conventional EBRT, intensity modulated radiation therapy, image-guided radiation therapy, and SRT services. Linear accelerators are the only MRT Unit type specifically listed in Tennessee Code Annotated Section 68-11-1607 (a)(4) as requiring a CON in order for services to be initiated.

Linear Accelerator Service Area Capacity: The estimate of the number of Linear Accelerator MRT units needed in a given service area, based upon an Optimal Capacity of 7,688 procedures per year.

MRT Procedure: Each discrete MRT treatment related to services performed on a single patient during a single visit, designated by CPT code. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition, including the development of a selected set of CPT codes.

MRT Unit: Medical equipment that performs radiation therapy.

Proton Beam Therapy Unit. A type of EBRT MRT Unit that uses proton beams rather than photon beams. Although not specifically listed as requiring a CON, the cost of initiating proton beam therapy services likely falls above the capital expenditure threshold set forth in TCA Section 68-11-1607 (2).

Radiation Therapy. A medical procedure that allows non-invasive treatment of tumors and cancer cells using X-rays, gamma rays, and charged particles. The radiation may be delivered by a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, also called brachytherapy).

Radiation Therapy is also known as **Stereotactic Radiotherapy (SRT)** when used to target lesions in the brain and as **Stereotactic Body Radiotherapy (SBRT)** when used to target lesions in the body.

Service Area: For linear accelerators that do not perform SRT or SBRT procedures, the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services and in which at least 120,000 people reside and where the applicant is able to reach the optimal capacity set forth below. Otherwise, a Service Area shall be the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services.

Standards and Criteria

1. Utilization Standards for MRT Units.
   a. Linear Accelerators not dedicated to performing SRT and/or SBRT procedures:
      i. **Full capacity of a Linear Accelerator** MRT Unit is 8,736 procedures, developed from the following formula: 3.5 treatments per hour, times 48 hours (6 days of operation, 8 hours per day, or 5 days of operation, 9.6 hours per day), times 52 weeks.
      ii. **Linear Accelerator Minimum Capacity:** 6,000 procedures per Linear Accelerator MRT Unit annually, except as otherwise noted herein.

iii. **Linear Accelerator Optimal Capacity:** 7,688 procedures per Linear Accelerator MRT Unit annually, based on a 12% average downtime per MRT unit during normal business hours annually.
iv. An applicant proposing a new Linear Accelerator should project a minimum of at least 6000 MRT procedures in the first year of service in its Service Area, building to a minimum of 7,688 procedures per year by the third year of service and for every year thereafter.

b. For Linear Accelerators dedicated to performing only SRT procedures, full capacity is 500 annual procedures.

c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, full capacity is 850 annual procedures.

d. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for Linear Accelerators develop. An applicant must demonstrate that the proposed Linear Accelerator offers a unique and necessary technology for the provision of health care services in the proposed Service Area.

e. Proton Beam MRT Units. As of the date of the approval and adoption of these Standards and Criteria, insufficient data are available to enable detailed utilization standards to be developed for Proton Beam MRT Units.

2. Need Standards for MRT Units.

a. For Linear Accelerators not dedicated solely to performing SRT and/or SBRT procedures, need for a new Linear Accelerator in a proposed Service Area shall be demonstrated if the average annual number of Linear Accelerator procedures performed by existing Linear Accelerators in the proposed Service Area exceeds 6,000.

b. For Linear Accelerators dedicated to performing only SRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT procedures in a proposed Service Area exceeds 300, based on a full capacity of 500 annual procedures.

c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT/SBRT procedures in a

proposed Service Area exceeds 510, based on a full capacity of 850 annual procedures.

d. Need for a new Proton Beam MRT Unit: Due to the high cost and extensive service areas that are anticipated to be required for these MRT Units, an applicant proposing a new Proton Beam MRT Unit shall provide information regarding the utilization and service areas of existing or planned Proton Beam MRT Units' utilization and service areas (including those that have received a CON), if they provide MRT services in the proposed Service Area and if that data are available, and the impact its application, if granted, would have on those other Proton Beam MRT Units.

e. An exception to the need standards may occur as new or improved technology and equipment or new diagnostic applications for MRT Units develop. An applicant must demonstrate that the proposed MRT Unit offers a unique and necessary technology for the provision of health care services in the proposed Service Area.

3. <u>Access to MRT Units.</u>
   a. An MRT unit should be located at a site that allows reasonable access for residents of the proposed Service Area.

   b. An applicant for any proposed new Linear Accelerator should document that the proposed location of the Linear Accelerator is within a 45 minute drive time of the majority of the proposed Service Area's population.

   c. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRT units that service the non-Tennessee counties and the impact on MRT unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

4. <u>Economic Efficiencies.</u> All applicants for any proposed new MRT Unit should document that lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

5. <u>Separate Inventories for Linear Accelerators and for other MRT Units.</u> A separate inventory shall be maintained by the HSDA for Linear Accelerators, for Proton Beam Therapy MRT Units, and, if data are available, for Linear Accelerators dedicated to SRT and/or SBRT procedures and other types of MRT Units.

6. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRT Unit is safe and effective for its proposed use.
    a. The United States Food and Drug Administration (FDA) must certify the proposed MRT Unit for clinical use.

    b. The applicant should demonstrate that the proposed MRT Units shall be housed in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

    c. The applicant should demonstrate how emergencies within the MRT Unit facility will be managed in conformity with accepted medical practice. Tennessee Open Meetings Act and/or Tennessee Open Records Act.

    d. The applicant should establish protocols that assure that all MRT Procedures performed are medically necessary and will not unnecessarily duplicate other services.

    e. An applicant proposing to acquire any MRT Unit shall demonstrate that it meets the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) or a similar accrediting authority such as the National Cancer Institute (CNI). Additionally, all applicants shall commit to obtain accreditation from ASTRO, ACR or a comparable accreditation authority for MRT Services within two years following initiation of the operation of the proposed MRT Unit.

    f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

    g. All applicants should provide evidence of any onsite simulation and treatment planning services to support the volumes they project and any impact such services may have on volumes and treatment times.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

8. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," 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 is a “safety net hospital” or a “children’s hospital” as defined by the Bureau of TennCare Essential Access Hospital payment program; or

c. 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.

Comments:

1. The Office of Health Planning recognizes the need to review MRT Services standards and criteria on a frequent basis due to the evolving nature of the technology involved.

2. It is anticipated that the Tennessee Cancer Registry data, maintained by the Department of Health, will in the future become available for use by applicants to support the need for new MRT Units.

Rationale for Revised and Updated Standards and Criteria for Megavoltage Radiation Therapy Services

Definitions

Linear Accelerator Units. The Office of Health Planning recognizes that Linear Accelerators performing SRT and/or SBRT procedures do not reach the level of utilization of Linear Accelerators that do not perform these procedures. Consequently, standards have been developed that endeavor to recognize these significant differences in utilization.

Proton Beam Therapy Units. Given the increasing interest in proton beam therapy units, surprisingly little data exist on optimal capacity and geographic service areas. However, the Office thought it important to include a specific category for proton beam therapy units to help inform the application and decision-making process.

MRT Procedure. To provide for uniform procedure reporting, the Health Services and Development Agency is responsible for setting CPT code reporting requirements.

Capacity. The Health Services and Development Agency staff solicited operating schedule information from owners/operators of MRT Units and the number of procedures performed annually. The capacity numbers were developed from this information.

Standards and Criteria Regarding Certificate of Need Applications for Magnetic Resonance Imaging Services

1. **Exceptions to Utilization Standards:** Exceptions to the standard number of procedures have been added for new or improved technology and treatment applications. The Office recognizes the rapidly advancing technological changes in this area and the need for flexibility on the part of the HSDA in making its decisions.

2. **Other Access Issues:** The provision of health care doesn't recognize state boundaries. Accordingly, applicants may include non-Tennessee counties in proposed Service Areas if that data are available. Proton Beam Therapy Units are anticipated to require extremely large Service Areas that may include other states' counties.

3. **Economic Efficiencies:** To support the goal of reducing health care costs, applicants should document that other options have been investigated and found less advantageous.

4. **Inventories:** If data are available, separate inventories should be maintained for Linear Accelerators based on procedures performed as well as for other types of MRT Units.

5. **Quality of Care:** Reference to specific recognized authorities' recommendations on staffing, training, and education standards are included to help ensure patient safety and quality of care are provided.