

**POSITRON EMISSION
TOMOGRAPHY**

APPENDIX A. Revised and Updated Standards and Criteria for Positron Emission Tomography (PET) services



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.