

POSITRON EMISSION TOMOGRAPHY

Special Exemption from Certificate of Need which requires approval from the West Virginia Health Care Authority.

Those providing Positron Emission Tomography (PET) services, which meet the following criteria, will not be required to address the standards below.

West Virginia Code § 16-2D-11(c)(5) states:

Shared health services between two or more hospitals licensed in West Virginia providing health services made available through existing technology that can reasonably be mobile. This exemption does not include providing mobile cardiac catheterization.

West Virginia Code § 16-2D-11(c)(9) states:

The replacement of major medical equipment with like equipment, only if the replacement major medical equipment cost is more than the expenditure minimum.

The expenditure minimum is updated annually by the West Virginia Health Care Authority (Authority) and can be found on the Authority's webpage at www.hca.wv.gov.

Like Equipment means medical equipment in which functional and technological capabilities are similar to the equipment being replaced; and the replacement equipment is to be used for the same or similar diagnostic, therapeutic, or treatment purposes as currently in use; and it does not constitute a substantial change in health services or a proposed health service.

Major Medical Equipment means a single unit of medical equipment or a single system of components with related functions which is used for the provision of medical

and other health services and costs in excess of the expenditure minimum. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services if the clinical laboratory is independent of a physician's office and a hospital and it has been determined under the Title XVIII of the Social Security Act to meet the requirements of paragraphs ten and eleven, Section 1861(s) of such act, Title 42 U.S.C. §1395x. In determining whether medical equipment is major medical equipment, the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition of such equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

Those meeting the requirements of § 16-2D-11(c)(5) or § 16-2D-11(c)(9) will be eligible for a special exemption from Certificate of Need (CON), which requires approval from the Authority. Pursuant to W. Va. C.S.R. § 65-29, applicants must submit an exemption application justifying how the proposed location will meet the definition of serving a medically underserved population.

The exemption application is available on the Authority's webpage at: www.hca.wv.gov.

Those that do NOT meet the criteria for the exemption specified in W. Va. Code § 16-2D-11(c)(5) or § 16-2D-11(c)(9), must address the standards below.

I. INTRODUCTION

Positron Emission Tomography or "PET" is a non-invasive diagnostic technology which enables the body's physiological and biological processes to be observed through the use of positron emitting radiopharmaceuticals which are injected into the body and whose interaction with body tissues and organs is able to be pictured through a computerized positron transaxial reconstruction tomography scanner. The radiopharmaceuticals are positron-emitting isotopes.

II. DEFINITIONS

Applicant means the Facility that provides the PET service.

Cyclotron means a nuclear accelerator, which is used to generate the radiopharmaceuticals that are injected into a patient to enable computerized images to be generated through the use of a PET scanner to provide physiological and biochemical information about the patient. Cyclotrons are two types: Positive ion and negative ion.

Facility means acute care facility.

Fixed PET means a stationary PET service, which includes two major elements: A Cyclotron that produces the radiopharmaceuticals, and a PET scanner which includes a data acquisition system and a computer.

Mobile PET – means a mobile unit that includes a data acquisition system and a computer. The radiopharmaceuticals are transported to the mobile unit from an existing Cyclotron. Mobile PET unit must be shared between two or more acute care facilities.

PET Study or Scan means the gathering of data during a single patient visit from which one or more images may be constructed of a single anatomical region of the patient's body.

III. NEED METHODOLOGY

A. FIXED PET UNITS

NEW SERVICE/ADDITIONAL EQUIPMENT

An Applicant proposing the acquisition of a Fixed PET unit must document that it has performed more than 950 procedures on a Mobile PET unit within

the last twelve (12) month period and can project a total of 1,250 procedures annually on the Fixed PET unit.

An Applicant proposing the acquisition of an additional Fixed PET unit must document that each existing Fixed PET unit has performed 1,250 procedures annually. In addition, the Applicant must demonstrate it has performed a minimum of 950 procedures on a Mobile PET unit.

An exception to the quantitative need methodology may be granted if an Applicant can present clear and convincing evidence that approval of a new or additional Fixed PET unit is a superior alternative to the provision of Mobile PET services.

IV. QUALITY

The proposed Fixed PET service must function as a component of a comprehensive diagnostic service. The Facility must have accessible the following modalities and capabilities on site or through contractual arrangements:

1. Computed Tomography - whole body;
2. Magnetic resonance imaging - brain and whole body;
3. Nuclear medicine - cardiac, SPECT;
4. Conventional radiography.

An Applicant proposing to provide Fixed PET services must address the following quality related criteria in its application for a Certificate of Need:

1. The application must contain written assurances that the service will be offered in a physical environment that conforms to federal standards,

manufacturer's specification, and licensing agencies' requirements. The following areas are to be addressed:

- a. quality control and assurance of radiopharmaceuticals production of generator or cyclotron-produced agents;
 - b. quality control and assurance of PET tomograph and associated instrumentation;
 - c. radiation protection and shielding; and,
 - d. radioactive emissions to the environment.
2. The Applicant must affirm that the PET unit is registered with the West Virginia Bureau for Public Health for the proposed site, plans, and equipment before services begin.
 3. The Applicant shall document access to a supply of cyclotron-produced radiopharmaceuticals from an off-site medical cyclotron and a radiopharmaceuticals production facility within an appropriate transport radius.
 4. The Applicant must affirm that the U.S. Food and Drug Administration has certified the proposed PET equipment for clinical use.
 5. The Applicant must document the PET training and experience of the operational staff. The following staff must be available to the Fixed PET/unit:
 - a. A licensed physician who is Board Certified or Board eligible in Radiology of Nuclear Medicine.

- b. Qualified PET radiochemist or radiopharmacist personnel, available to the Facility during service hours.
 - c. Qualified engineering and physics personnel, available to the Facility during service hours, with training and experience in the operation and maintenance of the PET equipment.
 - d. Qualified radiation safety personnel, available to the Facility, with training and experience in the handling of short-lived positron emitting nuclides.
 - e. Certified nuclear medicine technologists with expertise in computed tomographic nuclear medicine imaging procedures.
 - f. Other appropriate personnel shall be available during service hours which may include certified nuclear medicine technologists, computer programmers, nurses, and radio-chemistry technicians.
6. The Applicant must require that the provider be accredited by The Joint Commission, Det Norske Veritas (DNV), or another accepted accreditation body.
7. The Applicant must demonstrate how medical emergencies within the Fixed PET unit will be managed in conformity with accepted medical practice.
8. The Applicant must affirm that protocols based on national standards, will be established to assure that all clinical PET procedures performed are medically necessary and cannot be performed as well by other, less expensive, established modalities.
9. The Applicant must have a referral system that includes a feedback mechanism for providing patient information to the referring physician.

10. The Applicant must maintain current listings of appropriate PET procedures that may be clinically appropriate. The listing will be made available for use by referring physicians.

V. COST

Applicants shall demonstrate the financial feasibility of the proposal by providing an analysis of the cost-effectiveness of the proposed project to include:

1. A three (3) year projection of revenues and expenses for the project;
2. Evidence that sufficient capital is available to initiate and operate the proposed project;
3. Evidence that financing arrangements are reasonable and secure;
4. Documentation that all indigent persons needing the service can be served without jeopardizing the viability of the project;
5. Demonstration that the applicant is willing to participate in reasonable utilization management programs sponsored by peer review or managed care organizations; and,
6. That the charges and costs used in projecting financial feasibility are equitable in comparison to prevailing rates for similar services in similar hospitals as defined by the Authority.

VI. OTHER

The applicant must provide additional information, as may be requested by the Authority, regarding demographics data, financial data, and clinical data for patients receiving the service.