F. POSITRON EMISSION TOMOGRAPHY SCANNERS

Introduction

A ***positron emission tomography (PET) scanner,*** as defined in G.S. § 131E-176(19a), means "equipment that utilizes a computerized radiographic technique that employs radioactive substances to examine the metabolic activity of various body structures."

The first PET scanners were dedicated machines performing only that service, supported by cyclotrons on-site. However, PET scanners now include hybrid machines, performing a variety of nuclear medicine studies and supported by new tracer production facilities housing cyclotrons in stand-alone facilities. Many PET scanners are configured with a single gantry to accommodate computed tomography (CT) to acquire sequential PET and CT images during the same exam. All these machines are PET scanners as defined in G.S. § 131E-176(19a), but they vary widely in their capabilities.

Definitions

Dedicated PET scanners can be fixed or mobile. ***Mobile*** PET scanner means a dedicated PET scanner and its transporting equipment that is moved, at least weekly, to provide services at two or more host facilities. A ***fixed*** PET scanner is one that is not mobile.

A fixed PET scanner's ***service area*** is the HSA in which it is located (*Table 15F-1*). Appendix A identifies the multicounty groupings that comprise the HSAs. A mobile PET scanner's service area is statewide. A ***statewide service area*** is defined as a planning area that encompasses the entire state when determining need. For mobile equipment, the definition does not imply that a CON applicant is required to project that it will provide mobile services in a certain number of counties, HSAs, or regions. Similarly, once developed, the equipment does not have to serve a certain number of counties, HSAs, or regions.

Changes from Previous Plan

This section contains no substantive changes from the previous State Medical Facilities Plan (SMFP). However, it contains technical changes that do not alter the methodology. The table labeled as 15F-1 in the previous SMFP has been reorganized. Also, the tables labeled as 15F-2 and 15F-3 in the previous SMFP have been consolidated into a single table (now Table 15F-2). The chapter narrative has been revised to align with these changes. Finally, Step 7 in Part 2 of the Application of the Methodology has been clarified.

Assumptions of the Methodology

1. The methodology concerns dedicated fixed PET scanners only. Dedicated scanners do not perform other nuclear medicine procedures.

2. The facility has a deficit when its overall utilization of dedicated fixed PET scanners is at or above 80% of capacity during the current reporting year. For the purpose of need determination calculations, the annual capacity of a dedicated fixed PET scanner is 3,000 procedures; 80% capacity is 2,400 procedures. [1]

[1] Beginning with the 2009 SMFP, the fixed PET scanner capacity was reduced from 2,600 procedures to 2,400 procedures annually. However, the mobile PET scanner capacity was not revised, and remains at 2,600 procedures annually.

Application of the Methodology

Part 1 *(Table 15F-1)*:

~~Determine the planning inventory of all fixed PET scanners in the state by summing the number of existing fixed PET scanners in operation, the number of CON-approved fixed PET scanners under development, and the number of fixed PET scanners available pursuant to need determinations pending review or appeal (*Column C*).~~

Step 1: For each facility that operates a fixed PET scanner, enter the inventory of existing scanners (*Column C*). ~~determine the total number of procedures performed on all fixed PET scanners located at the facility for the current reporting year (*Column D*).~~

Step 2: Enter adjustments for the number of CON-approved fixed PET scanners under development and the number of fixed PET scanners available pursuant to need determinations pending review or appeal (*Column D*).

Step 3: Sum the results of Step 1 and Step 2 to arrive at the Planning Inventory (*Column E*). Enter the number of procedures for each facility for the current reporting period in Column F.

Step 4: Multiply the number of fixed PET scanners at each facility by 3,000 procedures to determine the PET scanner capacity at each facility.

Step 5: Divide the total number of PET scanner procedures performed at each facility, as determined in Step ~~1~~ 4, by the PET scanner capacity ~~calculated in Step 2~~. Multiply the results by 100 to convert the numbers to obtain the total ~~a~~ utilization percentage (*Column G ~~E~~*). A facility has a deficit if its total utilization is 80% or greater (*Column H ~~F~~*). A negative one (-1) will appear in Column H for need determinations from previous SMFPs.

Step 6: For each HSA, ~~To calculate the need determination for the service area,~~ add all deficits listed in Column H ~~*F* and adjust the sum by the number of placeholders for need determinations in previous SMFPs~~. A negative one is treated as a zero in this calculation. ~~total~~ The result is the service area's total facility deficit. The service area's facility deficit is the need determination for an additional fixed PET scanner except as provided in Step 7 for both parts of the methodology combined (*Column I ~~G~~*).

Part 2:

Step 7: Identify each major cancer treatment facility, program, or provider in the state, defined as providers that own or operate two linear accelerators that performed over 12,500 ESTV procedures during the current reporting year (*Table 15C-1*).

Step 8: A service area has a need determination for one additional fixed PET scanner if a major cancer treatment facility, program, or provider identified in Step 5 is hospital-based (i.e., on a hospital's license) and does not own or operate a dedicated fixed PET scanner, except as provided in Step 7 for both parts of the methodology combined.

Step 9: The maximum need determination for a single HSA in any one year will be no more than two additional fixed PET scanners regardless of the numbers generated individually by each part of the methodology (*Table 15F-1, Column I ~~F~~*).

Unless otherwise specified by the methodology, calculations do not use rounded values. However, fractional values are rounded automatically when displayed.

The SMFP does not have a methodology to project need for additional mobile PET scanners. Table 15F-2 presents the utilization of mobile PET scanners. A summer petition is required to place a need determination in the upcoming SMFP. If the need determination is approved, any person may apply for a CON to acquire the mobile PET scanner.