Technology and Equipment Committee Agency Report Adjusted Need Petition for Positron Emission Tomography Equipment in the 2025 State Medical Facilities Plan

Petitioner:

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Request:

Mission Hospital petitions the State Health Coordinating Council (SHCC) to convert the general positron emission tomography (PET) need determination in HSA I in the *Proposed 2025 State Medical Facilities Plan (SMFP)* to a specific need determination for one fixed cardiac PET scanner in HSA I.

Background Information:

Chapter Two of the *SMFP* notes that during the summer, the Agency accepts petitions that "involve requests for adjustments to need determinations in the *Proposed SMFP*. Petitioners may submit a written petition requesting an adjustment to the need determination in the *Proposed SMFP* if they believe that special attributes of a service area or institution give rise to resource requirements that differ from those provided by the standard methodologies and policies." Any person may submit a certificate of need (CON) application for a need determination in the *SMFP*. The CON review could be competitive and there is no guarantee that the Petitioner would be the approved applicant.

The *SMFP* need determination methodology for dedicated fixed PET scanners calculates scanner need for the six health service areas (HSAs) in the state. Mission Hospital is in HSA I, which consists of 26 counties in the western part of the State (see Appendix A of the *SMFP*). The need determination methodology generates a need for one additional fixed dedicated PET scanner when an existing dedicated fixed PET scanner is being used at a minimum of 80% of capacity (i.e., 2,400 procedures) during the current reporting year. Needs can be generated based on utilization at a single facility, but the need determination is for the service area as a whole. The maximum need determination in any year for a given service area is two PET scanners.

The SMFP provides additional methods for fixed dedicated PET scanner need determinations for hospital-based cancer centers that have at least two linear accelerators (LINAC) but no PET

scanner. Mission Hospital has two LINACs and a PET scanner, so this part of the methodology does not apply to the Petitioner.

Analysis/Implications:

The *Proposed 2025 SMFP* shows four PET providers in HSA I. Each facility has one existing or approved scanner. Catawba Valley Medical Center (CVMC) and Frye Regional Medical Center ("Frye") jointly own a PET scanner, which is located at CVMC in Catawba County. Messino Cancer Center ("Messino") in Asheville operates a PET scanner that began serving patients on May 1, 2023, when five months remained in the reporting year. AdventHealth Hendersonville ("AdventHealth") received a CON on March 5, 2024 to develop a PET scanner at the hospital in Henderson County. When this last scanner is developed, HSA I will have two PET scanners in Buncombe County, one in Catawba County and one in Henderson County.

The CONs issued to Messino and AdventHealth were both based on standard need determinations in the 2021 and 2023 SMFPs, respectively. In both cases, the need determinations were generated by the greater than 80% utilization at Mission Hospital. HSA I has a need determination in the *Proposed 2025 SMFP* based on 95.4% utilization of the PET scanner at Mission Hospital (see Table 1).

Table 1. Excerpt from Table 15F-1 from the Proposed 2025 State Medical Facilities Plan

Table 15F-1: Utilization of Existing Dedicated Fixed PET Scanners

A	В	C	D	E	F	G
HSA	Facility	Planning Inventory	2022-2023 Procedures	Facility Utilization Rate	Facility Deficit	Need Determination
I	AdventHealth Hendersonville *	1				
	Catawba Valley Medical Center / Frye Regional					
	Medical Center	1	1,649	54.97%	0	
	Messino Cancer Center	1	192	6.40%	0	
	Mission Hospital	1	2,862	95.40%	1	
	HSA I Totals	4	4,703		1	1

Source: Proposed 2025 SMFP

The Petitioner implies that the existing scanners focus on oncology. Messino is a cancer center and, presumably, only serves oncology patients. Both CVMC and Frye have active cardiology programs and treat cancer patients. However, the Agency has no data on the breakdown of the specialty areas in which PET procedures are performed (e.g., oncology, cardiology, neurology) at any facility.

The Agency does have data on overall PET utilization, which shows substantial increases throughout the state over the past five years for both fixed and mobile scanners (see Figure 1). The numbers beside the lines represent the number of procedures in each year. The figure also shows that, throughout the period, mobile PET procedures make up about 20% of all PET procedures. The data table below the chart shows the annual percent growth for the time period indicated.

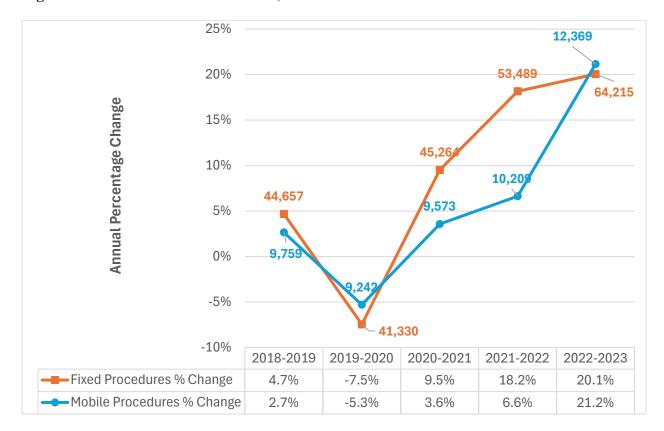


Figure 1. PET Procedures 2018-2023, Statewide

Source: 2020-Proposed 2025 State Medical Facilities Plan

Utilization in HSA I also increased during this same period (see Figure 2.) The percentage change in PET procedures for CVMC/Frye shows a pattern similar to the statewide pattern. However, the pattern at Mission shows that the growth rate has been smaller. Note that the number of procedures at Mission has been rather stable for the past two to three years. This observation suggests that Mission has been operating at or near capacity for several years. The 95.4% utilization figure reported in the *Proposed 2025 SMFP* would support this observation, as would the utilization rates reported in the previous four SMFPs, which ranged from 83.6% to 97.3%.



Figure 2. Fixed PET Procedures 2018-2023, Health Service Area I

Source: 2020-Proposed 2025 State Medical Facilities Plan

The Petitioner provides evidence that Mission Hospital is a primary provider of comprehensive cardiac care for the region and states that it is uniquely suited to have a dedicated cardiac PET scanner. However, as mentioned above, CVMC and Frye also provide a range of cardiac services. The Petitioner also points out that Mission's oncology PET utilization is decreasing. Mission attributes this change to the opening of Messino Cancer Center. Based on these changes and future expectations, the Petitioner estimates that it would perform approximately 2,100 oncology scans and a bit over 1,000 cardiac PET scans annually, for a total of about 3,100 scans.

CON regulation 10A NCAC 14C .3703 (a) (7) requires that a CON applicant "shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project" (Proposed 2025 SMFP, p. 417). Because each facility in HSA I currently has one PET scanner, an existing provider would have to propose to perform at least 4,160 total scans to obtain a second scanner. As the Petitioner notes, Mission's projection of 3,100 scans falls short of the required 4,160 scans for two scanners but exceeds the volume for a single PET scanner.

Agency Recommendation:

As mentioned previously, Chapter 2 of the *SMFP* outlines the criteria for Spring and Summer petitions. Spring petitions address policies and methodologies. Summer petitions request changes to need determinations based on unique aspects of service areas that the relevant standard methodology does not consider. Mission does not identify special characteristics of HSA I that merit the application of a different approach to assess its need for PET scanners than that used to assess PET scanner need for all HSAs statewide. Mission states that it is in a unique position to offer a cardiac PET program in HSA I. It also states that its current PET scanner is in an outpatient oncology center, a location that would be inconvenient for cardiology patients. However, this rationale does not provide the requisite support to allow the Agency to recommend changing a standard need determination to a need determination for a dedicated cardiac PET scanner.

The *SMFP* does not include fixed PET scanner need determinations for specific types of scanners/facilities. The Agency supports the standard methodology for PET scanners. Given available information and comments received by the August 7, 2024 deadline, and in consideration of factors discussed above, the Agency recommends denial of the petition.