Comments in Opposition to Mission Hospital's Petition To Convert the General PET Need Determination to a Specific Need Determination for One Fixed Cardiac PET Scanner in HSA I in the 2025 State Medical Facilities Plan

COMMENTER

Margaret R. Pardee Memorial Hospital 800 North Justice Street Hendersonville, North Carolina 28791

James Kirby, II, MHA, MBA President and Chief Executive Officer (828) 696-1144 james.kirby@unchealth.unc.edu

INTRODUCTION

The *Proposed 2025 SMFP* identifies a need for a dedicated fixed PET scanner for HSA I. Margaret R. Pardee Memorial Hospital (Pardee) is located in Henderson County within HSA I. Pardee respectfully requests that the State Health Coordinating Council (SHCC) deny Mission's request for a specific need determination for one fixed cardiac PET scanner and retain the need for a general PET scanner as reflected in the *Proposed 2025 SMFP*. As outlined below, Pardee believes there are numerous reasons to deny the Mission petition.

PARDEE'S RATIONALE FOR PETITION DENIAL

1. The *Proposed 2025 SMFP* Need Determination Allows Applicants to Propose a Cardiac Specific PET Scanner

The need determination in the *Proposed 2025 SMFP* does not require the applicant to provide specific services. More specifically, the current need determination does not prohibit applicants from proposing a cardiac specific PET scanner. Based on Mission's history of applying for multi-specialty PET services and the Agency's history of finding applicants that offer a broader range of services to be more effective, a general PET scanner need determination is ideal.

In its 2021 and 2023 HSA I PET CON applications, Mission proposed PET services that included oncology, cardiac, and neurologic patients. With the current need determination for a general PET scanner, Mission can apply for a cardiac specific PET scanner, or it can propose to serve cardiac patients in addition to other specialties. The current need does not prevent Mission from proposing cardiac PET services.

The Agency has historically prioritized a PET scanner with a broad scope of services relative to a single specialty scanner. For example, based on the 2023 HSA II PET Scanner Review, "the application proposing to provide the broadest scope of services with the proposed equipment is the more effective alternative regarding this comparative factor." The two applicants that proposed to provide PET services to oncology, cardiac, and neurologic patients were deemed most effective in that review. This is consistent with the comparative factors utilized in the last two HSA I PET reviews. For example, in the 2021 HSA I PET review, Mission was determined to be the more effective alternative as it proposed oncology, cardiac, and

neurologic services while Messino only proposed oncology and neurologic services.¹ In the 2023 HSA I PET review, Mission and AdventHealth Hendersonville were found equally effective in regard to this factor as they each proposed to serve oncology, cardiac, and neurologic patients.² The Agency has historically found applicants that include cardiac PET services to be more effective in terms of scope of services; thus, the current need determination does not prevent Mission from proposing cardiac PET services.

2. The HSA I Need Determination is Driven by Oncology Utilization

Based on the *Proposed 2025 SMFP*, there is a need determination for one dedicated fixed PET scanner within HSA I which was generated by Mission Hospital's 95.40 percent facility utilization rate.³ According to its petition, Mission's high utilization generated the PET need determinations in the *2021*, *2023*, and *Proposed 2025 SMFPs* for HSA I.

On page 1 of its petition, Mission states the following:

"Mission Cancer Center's existing fixed PET/CT scanner is used to diagnose and stage over 4,200 cancer patients annually and while primarily used for oncology, is also used for neuroendocrine scans. Mission's PET/CT scanner is essential for diagnosing and planning treatments for cancerous tumors in conjunction with Mission's oncology services.... The demand for PET imaging in recent years is evident in the scanner's utilization. In fiscal year 2022, Mission Hospital's PET utilization exceeded 97%. In fiscal year 2023, Mission Hospital operated at 95.4% of capacity, as reported in the proposed 2025 SMFP, <u>which generated the need</u>." (emphasis added)

As outlined by its own statements, the service area need was generated by a PET/CT scanner primarily utilized for oncology services. This data does not support the need for a cardiac specific PET scanner.

3. Mission Does Not Demonstrate a Need for a Cardiac Specific PET scanner

Mission does not provide evidence to support a cardiac specific need determination. The 1,000 cardiac PET procedures it cites in its petition are inadequate to generate a need determination or to meet the applicable PET performance standards.

On page 2 of its petition, Mission states, "based on this high level of cardiac patient demand, <u>Mission</u> <u>Hospital projected to provide over 1,000 cardiac PET scans</u> in its 2023 CON application for a second PET unit." The following image is from page 71 of its 2023 CON application.

¹ 2021 HSA I PET Scanner Review, p. 58.

² 2023 HSA I PET Scanner Review, p. 63.

³ Proposed 2025 SMFP, p. 364.

Projected Cardiac PET/CT Scans						
	2025	2026	2027			
Population	938,011	943,914	949,300			
Advisory Board Rate	1.30	1.58	1.64			
Cases	1,219	1,492	1,558			
Capture Rate	55.0%	65.0%	70.0%			
Mission Cases	671	970	1,091			
Other NC	7	11	12			
Out of State	4	6	7			
Total Service Area	682	987	1,109			

Step 5	
Proiected Cardiac PET/CT	Scar

As shown above, Mission calculated there would be demand for 1,558 total cardiac PET/CT cases in HSA I in 2027. Mission estimated that it would capture 70 percent, or 1,091 of these HSA I cases, and serve 1,109 cases total.

Based on the PET need determination calculation, a facility has a deficit, and generates a need, if its total utilization is 80 percent or greater. For need determination calculations, the annual capacity of a dedicated fixed PET scanner is 3,000 procedures; thus, 80 percent capacity is 2,400 procedures.⁴ Mission's projected volume of 1,109 total cardiac PET/CT procedures in 2027 is less than half of the volume required to generate a need.

To meet performance standards under 10A NCAC 14C .3703, an applicant must project that its existing, approved, and proposed fixed PET scanners will perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation. Mission's projected cardiac PET/CT procedures for 2027 are 53 percent of the volume required and would not meet the performance standard.

Mission provides no discussion in its petition that projected volumes for cardiac PET procedures have materially changed since its 2023 application. In fact, it simply quotes the volume it included in that application. Mission provides no evidence to support a cardiac specific need determination or that it can generate sufficient cardiac specific volume to meet the performance standard.

4. Cardiac PET Procedures Can Be Performed in the Service Area

According to page 6 of its petition, Mission states "without the limitation to the need determination for a fixed cardiac PET scanner in HSA I, access to cardiac PET imaging will likely remain unavailable in the service area." Denial of this petition does not prevent cardiac PET imaging within the service area.

First, according to page 49 of the recently approved AdventHealth Hendersonville 2023 CON application, "development of a fixed PET scanner on its main campus will enable AdventHealth Hendersonville to provide a wider range of PET procedures to its patients, including <u>cardiac</u> and PSMA PET procedures" <u>(emphasis added)</u>. This would indicate that AdventHealth plans to provide cardiac PET imaging within HSA I.

⁴ *Proposed* 2025 SMFP, p. 362-363.

Second, as discussed previously, applicants proposing to meet the need in the *Proposed 2025 SMFP* can apply to provide cardiac PET procedures, either as an exclusive service or as part of a broader range of services. As discussed above, Mission's 2021 and 2023 CON applications proposed PET services that included cardiac patients. Again, the need determination in the *Proposed 2025 SMFP* does not prevent cardiac PET imaging.

5. There is a Need for an Additional PET Scanner in HSA I

Pardee agrees with the *Proposed 2025 SMFP* that there is a need for an additional fixed PET scanner in HSA I and disagrees with Mission's statement that "with so much unused capacity focused on oncology PET, there is simply no need for another general PET unit in HSA I."

In its petition, Mission attempts to mismatch current volumes with future capacity to create the illusion of underutilized resources. AdventHealth Hendersonville was issued a CON for a PET scanner in early 2024 that is not yet operational. Further, according to Mission's petition, Messino only operated for a portion of FFY 2023 so Messino's volumes in the *Proposed 2025 SMFP* are limited. Including capacity for facilities that are not fully operational, as Mission does in its petition, artificially deflates utilization rates for the HSA.

Based on the *Proposed 2025 SMFP*, the two existing PET scanners, Mission and Catawba Valley, operated at an average utilization rate of 75 percent. Based on Messino and AdventHealth Hendersonville's CON applications, they project to operate at 73 and 71 percent utilization, respectively.⁵ There is no evidence to support Mission's claim that the four scanners in HSA I will operate at 39 percent utilization.

Further, compared to the other HSAs, HSA I has the highest population per fixed PET scanner as shown below. This would indicate a need for an additional scanner within the service area. With a fifth scanner, HSA I's population per pet scanner (296,906) would be similar to the current state average.

HSA	2024 Population	Fixed Pet Scanners	Population / Pet	Rank
1	1,484,531	4	371,133	1
2	1,771,010	7	253,001	6
3	2,469,370	8	308,681	3
4	2,347,470	9	260,830	5
5	1,515,719	5	303,144	4
6	1,396,006	4	349,002	2
Total	10,984,106	37	296,868	

Source: NC OSBM, Proposed 2025 SMFP

⁵ AdventHealth Hendersonville Fixed PET Scanner CON application, p. 115. Messino Cancer Center Fixed PET Scanner CON application, p. 114.

6. Mission Can File a Spring Petition to Request a Revision to the PET Need Determination Methodology

In its petition, Mission states, "the current PET methodology used by the SHCC does not consider or provide a mechanism for assessing or determining the need for specialized PET services such as cardiac PET."

In the current PET methodology, steps one through four calculate need determinations for the defined service areas based on facility deficits. In steps five and six, the methodology considers additional factors for major cancer treatment facilities based on linear accelerator procedures.

If Mission believes that cardiac PET scanners warrant additional consideration by the SHCC, it should file a spring petition to request a revision to the PET need determination methodology.

Summary

Pardee acknowledges that the Technology and Equipment Committee, the SHCC, and Planning staff have an extremely difficult task of effecting the right balance between ensuring enough capacity where appropriate without unnecessary duplication. As outlined above, Mission does not adequately support its petition to convert the general PET need determination to a cardiac specific need in HSA I. Pardee requests that the SHCC deny Mission's petition and encourages the SHCC to retain the need for a general PET scanner in HSA I as reflected in the *Proposed 2025 SMFP*.

Thank you.