

## PETITION FOR AN ADJUSTMENT TO A NEED DETERMINATION

### Petition to Add a Dedicated Cardiac PET Need Determination in Health Service Area (“HSA”) I to the 2025 State Medical Facilities Plan (“SMFP”)

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#### **Petitioner**

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#### **Statement of the Proposed Change**

Table 15F-4 in the Draft 2025 SMFP shows a need for one additional fixed PET scanner for Health Service Area I (“HSA I”). Mission Hospital (“Mission”) respectfully petitions the State Health Coordinating Council (“SHCC”) to convert the general PET need determination in the draft 2025 SMFP in HSA I to a specific need determination for one fixed cardiac PET scanner in HSA I.

#### **Background on Mission Hospital’s PET Services**

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. Mission Hospital offers the largest cancer center in western North Carolina, and its high utilization generated the PET need determinations in the 2021, 2023, and Draft 2025 SMFPs. Mission Hospital applied for, but was not awarded, an additional PET/CT scanner in both 2021 and 2023 to address Mission’s capacity constraints for oncology scans and to develop a new cardiac PET program that would be the first of its kind in the region.

The demand for PET imaging in recent years is evident in the scanner’s utilization. In fiscal year 2023, 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, which generated the need. However, the FY 2023 data only considers one quarter of data for the operation of the Messino Cancer Center’s new PET and does not consider the new PET for AdventHealth Hendersonville approved in 2023, as will be discussed in detail below. When these two new providers are fully accounted for, there is no need for another general fixed PET scanner in HSA I. However, a specific cardiac PET scanner at Mission would truly help address a unique need in the HAS for cardiac PET services that cannot be met by the other 3 providers in the area.

#### **Background on HSA I PET Services**

In addition to Mission Hospital, Catawba Regional/Frye Medical Center in Hickory, Catawba County, is a longstanding provider of fixed PET services in HSA I. As noted above, Mission Hospital’s high PET utilization generated a need determination in HSA I in both the 2021 and 2023 SMFPs.

In response to the 2021 SMFP need determination, Messino Cancer Center (“Messino”) applied to fill the need for a third fixed PET unit in HSA I dedicated to serving only oncology services and was approved. Messino’s unit came online mid-2023 and its initial months of utilization are reflected in the draft 2025 SMFP. In response to the 2023 SMFP Need determination, AdventHealth Hendersonville was approved for the CON to meet the need for a fourth fixed PET unit in the service area. AdventHealth currently does not have the cardiac patient base or specialized cardiology staff to develop a cardiac PET program.

The draft 2025 SMFP now identifies the need for a fifth fixed PET unit to serve HSA I based on the FY 2023 utilization of the existing PET unit at Mission Hospital. The current PET/CT need methodology is based on the historic utilization of existing individual providers and does not net out the capacity of approved providers or the available capacity of existing units with lower volume. For example, in HSA I there are now 4 existing and approved PET units. Collectively these units have a capacity of 12,000 scans (4 x 3,000 capacity per unit). In fiscal year 2023, these existing and approved units collectively provided 4,703 scans as reflected in the draft 2025 SFMP. With 4,703 scans and a capacity of 12,000 scans, the existing and approved units are together operating at just 39% of capacity. With so much unused capacity focused on oncology PET, there is simply no need for another general PET unit in HSA I.

**With the full year impact of Messino’s new PET unit, Mission is on track to provide just 2,136 PET scans. This equates to just 71% of capacity.** Mission Hospital’s oncology PET demand no longer supports a need determination in the 2025 SMFP. However, Mission Hospital’s PET utilization remains too high to develop a cardiac PET program, as will be described.

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. Mission Hospital is the only regional medical center with clinical resources and an extensive cardiac patient base capable of offering cardiac PET imaging. In both 2021 and 2023, the general PET need determination was granted to oncology focused PET units. These decisions did not meet the service area’s need for a cardiac PET program.

### **Background on Mission Hospital’s Cardiac Program**

For over 50 years, Mission Heart has been the regional leader in cardiac and cardiothoracic surgical care, providing specialized clinical experience and compassionate care to patients in western North Carolina. As the region’s only tertiary and quaternary care medical center, Mission offers comprehensive cardiac services, including interventional cardiology (including cardiac catheterization, electrophysiology, and stents) and cardiac surgery (including transcatheter aortic valve replacement, left ventricular assist device placement, structural heart, and bypass surgeries). Mission consistently achieves the best cardiac outcomes in the region. Its accomplishments, accreditations, and awards include, but are not limited to:

- The highest inpatient survival rates in North Carolina, with the No. 1 survival rate for heart attack patients;
- One of America’s 50 Top Cardiovascular Hospitals by PINC AI/IBM Watson Health 16 times since 2000, including 2024;
- Prestigious Three-Star Ranking by the Society of Thoracic Surgeons in CABG, AVG/CABG and Lobectomy;
- Regional leader in “Door to Balloon” time and excels in post-discharge care, with heart attack and heart failure patients less likely to be readmitted than the national average;
- Healthgrades America’s 100 Best Hospitals for Cardiac Care Award (2024, 2023, 2022) and 100 Best Hospital for Coronary Intervention Award (2024).

Mission partners with Asheville Cardiology Associates and Asheville Heart for cardiothoracic surgery, providing a team-oriented approach to cardiac care for residents in western North Carolina and beyond. Mission and Asheville Cardiology Associates have two cardiologists that are specifically trained in cardiac PET imaging along with three who specialize in cardiac MRI and eight who specialize in cardiac CT. Given this extensive expertise, Mission is uniquely qualified to develop a dedicated cardiac PET program in HSA I. In 2023, Mission performed:

- 27,095 Adult Echocardiograms
- 2,779 Stress Echocardiograms/Treadmill
- 2,348 Cardiac CT scans
- 1,201 Cardiac MRI scans
- 3,469 Pediatric Cardiac Imaging Studies

As a result of the experience outlined above, Mission Hospital is uniquely qualified to provide insight regarding the cardiac diagnostic needs of HSA I and the importance of this petition to cardiac patients in western North Carolina. Based on this high level of cardiac patient demand, **Mission Hospital projected to provide over 1,000 cardiac PET scans** in its 2023 CON application for a second PET unit. Along with the approximately 2,100 oncology scans at Mission after the impact of Messino, 3,100 scans (over 100% of capacity) is too much volume for a single PET scanner and too much to implement a cardiac PET program without negatively impacting PET availability to Mission’s oncology patients.

### **Reason for the Requested Adjustment**

#### *Chronic Conditions and Diseases that Impact the Demand for PET Services*

While the service area’s existing PET scanners are primarily used for diagnosing and staging of cancer patients, PET is also a crucial tool for other areas of diagnostic imaging due to its ability to visualize blood flow to organs and tissues. This makes PET units valuable for assessing heart perfusion, effects of heart attacks, brain abnormalities, and normal brain and heart functions.

According to the Centers for Disease Control and Prevention (“CDC”), based on 2022 data, the leading cause of death in North Carolina is heart disease, followed by cancer. This mirrors the trends in HSA I, where heart disease and cancer are the top causes of death. Until 2019, cancer was the leading cause of death in HSA I. However, starting in 2018, when heart disease became the new leading cause of death in the service area, heart disease trends now underscore the growing unmet demand for cardiac PET services in HSA I<sup>1</sup>. As heart disease continues to grow, access to cardiac PET services and to advancements in PET technology will become even more important, particularly for tertiary and quaternary care providers handling the sickest patients. Earlier detection of both acute and chronic cardiac conditions through PET is vital for effective diagnosis, staging, and treatment.

#### *Advances in PET Cardiac Imaging*

For over 25 years, PET has significantly advanced the understanding of cardiac physiology and pathophysiology. Research, including a comprehensive review from the University of Michigan Health System published in Academic Radiology, highlights PET’s superiority over perfusion imaging, CT

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<sup>1</sup> North Carolina State Center for Health Statistic

angiography (“CTA”), and MR angiography (“MRA”). Some of the main uses for cardiac PET imaging include:

- Screening for cardiovascular disease in symptomatic individuals or those with risk factors like family history or high cholesterol.
- Monitoring heart condition and treatment efficacy in patients diagnosed with coronary artery disease (“CAD”).
- Evaluating previously detected blockages to determine candidacy for coronary stents or bypass surgery.
- Assessing tissue damage and scarring post-heart attack to identify optimal treatment.

Additionally, cardiac PET imaging is increasingly important for diagnosing and managing cardiac sarcoidosis, a manifestation of systemic sarcoid disease that significantly impacts morbidity and mortality. Despite challenges in diagnosing cardiac sarcoidosis, PET Imaging is now recognized as an excellent tool for early diagnosis, prognostication, and patient follow up.

As research continues to expand the clinical applications of PET for cardiac imaging, it will be used more and more frequently in diagnosing chronic heart conditions. Mission is already seeing a frequent need for access to this modality for its cardiac patients. However, the anticipated rise in clinical applications as well as demand will further necessitate the need for access to cardiac PET services in HSA I.

#### *There is a Need for Cardiac PET Scan Services*

The current PET methodology used by the SHCC does not consider or provide a mechanism to assess or determine the need for specialized cardiac PET services.

Mission has identified a critical need for a dedicated cardiac fixed PET scanner to serve HSA I. At present, no existing facility in HSA I offers cardiac PET services, and it is becoming a standard of care for cardiac diagnostics. The current PET scanner at Mission is primarily used for oncology procedures, along with some neurology procedures, which utilize different protocols and radiotracers than those required for cardiac PET procedures. This limitation, coupled with the high demand for oncology PET procedures and its physical location in an outpatient oncology facility, has prevented Mission from expanding its service offerings to cardiac PET. There is currently no other fixed PET provider in western North Carolina that has the expertise and patient base to develop such a program.

The need determination for a general fixed PET unit will not meet the needs of this service area for cardiac PET services nor bring a meaningful increase in access to PET services. The service area currently has four existing and/or approved fixed PET units that are primarily, and some exclusively, used for oncology imaging. All of the providers, except Mission, have adequate capacity available to meet their needs now and into the future. However, a fixed cardiac PET scanner in HSA I will offer unique diagnostic capabilities that are currently unavailable in HSA I.

As shown below, each HSA in the State has at least one cardiac PET program except for HSA I. The Top 5 cardiac programs in the state, as measured by open-heart surgery volume, are also shown on this list and include all listed providers except for Novant New Hanover Regional Medical Center, which is not a top 5 cardiac programs but is the largest cardiac program in HSA V. Mission is the second largest cardiovascular provider in the state. Of the Top 5 cardiovascular surgery providers in the State and the largest in each

HSA, only Mission does not offer a cardiac PET program and only Mission does not have two or more PET/CT units.

**Top North Carolina Cardiovascular Providers and Cardiac PET Programs**

Facility	HSA	Open Heart Surgery Procedures	Offers Cardiac PET/CT	Number of PET Units	Number of PET Scans	PET Utilization Rate
Duke University Hospital	HSA V	1,286	Yes	3	7,442	82.7%
Mission Hospital	HSA I	1,254	No	1	2,862	95.4%
Atrium Wake Forest Baptist	HSA II	925	Yes	2	4,248	70.8%
ECU Health Medical Center (fka Vidant)	HSA VI	865	Yes	2	3,849	64.2%
Atrium Carolinas Medical Center	HSA III	803	Yes	2	5,686	94.8%
Novant New Hanover Regional Med Center*	HSA V	466	Yes	2	4,130	68.8%

*Draft 2025 SMFP, Table 7B Open-Heart Surgery Procedures, Table 15F-1 Utilization of Existing Dedicated Fixed PET Scanners*

*Facility websites*

*\*Novant New Hanover was approved in 2022 (Project ID-#O12143-21) for a second PET unit in part to be able to develop at cardiac PET program.*

Currently, patients needing cardiac PET must leave HSA I to access these diagnostic capabilities as no other provider in the service area has these capabilities or provides cardiac PET imaging. Mission sees this unmet need every day and hears the stories from its physicians who must refer patients outside of western North Carolina for cardiac PET imaging. More often than not, patients in HSA I have to forgo cardiac PET services due to patient condition, cost of travel, extent of illness, or other mobility limited issues. Patients in western North Carolina simply do not have access to cardiac PET services. Currently, patients who live in Asheville would have to drive at least 2 hours plus to the nearest cardiac PET programs at Atrium Health Carolinas Medical Center or Atrium Health Wake Forest Baptist. Patients who live in far western HSA I, such as Murphy, NC, would have to travel drive at least 4 hours plus to the nearest cardiac PET programs at Atrium Health Carolinas Medical Center.

The limitation of the need determination in the 2025 SMFP to a cardiac-specific fixed PET unit in HSA I would ensure that HSA I residents gain access to cardiac diagnostic capabilities which are both needed and currently unavailable in HSA I. The limitation of the need determination to a cardiac PET scanner in HSA I will open access to cardiac PET imaging that has been severely constrained and inequitable for HSA I residents. The cardiac PET will promote cost effective access and quality health care for needed cardiac imaging in HSA I, for residents who are currently medically underserved in relation to residents in other HSAs that have tertiary hospitals with cardiac PET programs.

*The Existing PET Providers can Adequately Serve HSA I Oncology Patient Demand*

Since the inception and widespread implementation of PET more than two decades ago, it has been primarily and historically used for cancer diagnostics as well as other various diagnostic capabilities including neurology. Its use in HSA I has been no different. Mission Hospital and Catawba Valley Medical Center/Frye Regional Medical Center were the original providers of fixed PET services to HSA I. In the last 3 years, two additional providers of PET services have received DHR approval. Messino Cancer Center implemented its CON in 2023, and its initial utilization is reflected in the 2025 Draft SMFP. In total, there are four existing and approved fixed PET scanners in HSA I as shown in Table 15F-1 below.

**Table 15F-1: Utilization of Existing Dedicated Fixed PET Scanners, 2023**

A	B	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	
	<b>HSA I Totals</b>	<b>4</b>	<b>4,703</b>		<b>1</b>	<b>1</b>

Source: Draft 2025 SMFP

An aggregate view of the four fixed PET providers shows no overall need for fixed PET services in HSA I. After Mission Hospital, the most highly utilized provider is Catawba Regional/Frye Medical Center, which most recently operated its PET unit at approximately 55% of the SMFP’s identified capacity, far from the 80% capacity threshold needed to trigger additional need. Overall, the four existing and approved units operated at 39.19% capacity, leaving abundant availability to diagnose service area patients needing oncologic PET diagnostics and other more historically common PET scans.

Facility	2022-2023 Procedures	SMFP Capacity	% of Capacity
AdventHealth Hendersonville	-	3,000	0.00%
Catawba Regional/Frye Medical Center	1,649	3,000	54.97%
Messino Cancer Center	192	3,000	6.40%
Mission Hospital	2,862	3,000	95.40%
<b>Total</b>	<b>4,703</b>	<b>12,000</b>	<b>39.19%</b>

Source: Draft 2025 SMFP

There is simply a lack of significant additional demand for oncology PET services. While there is some organic growth with population growth and new PET applications, the overall base of oncology PET services is relatively stable. The majority of the patient scan volume that will be served by Messino and AdventHealth will come from taking Mission Hospital’s patients or the patients served by smaller mobile PET programs in the region. There is now more than sufficient capacity for oncology PET services in HSA I. Messino has already taken PET scan volume from Mission Hospital to the extent that Mission’s volume does not generate a need for an additional general oncology PET program.

**Adverse Effects If Petition is Not Approved**

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. Currently, Mission is not able to offer cardiac PET imaging as its existing PET scanner is constrained by the continued demand for oncologic PET services. Other existing providers in the service area, who have lower PET utilization, are limited by their physician specialties, level of care, size of cardiac patient base, and clinical expertise. They simply do not have the resources or patient base to support a cardiac PET program.

The lack of access to cardiac PET services is adversely impacting patients in HSA I. Patients currently must leave the service area to obtain cardiac PET scans, with some patients opting to forgo the diagnostics altogether, rather than endure the inconvenience and added transportation costs. The ongoing need for

cardiac PET imaging services that existed in 2022 and 2023, along with Mission's demand for PET oncology utilization will continue into the future. Mission's sickest and most complex cardiac patients should not have to go without treatment due to the lack of necessary equipment and a program to meet their needs. The cardiac PET demand will only increase in the future as more cardiologists are turning to cardiac PET diagnostics as a standard of care. The lack of access to cardiac PET services will persist, grow and continue to negatively affect patient care and outcomes in HSA I.

If the general PET need remains in the DRAFT 2025 SMFP, Mission will once again apply to be able to obtain sufficient capacity for its cardiac PET program. However, given the Agency's past two decisions to award a PET unit to a new market entrant providing oncology PET, it is possible the Agency could do so again. This would severely dilute the utilization of existing and approved PET providers with a limited number of oncology PET patients spread over five oncology focused PET programs, rather than the four current providers. This would prevent the development of a cardiac PET program once again.

The addition of a specialized cardiac PET need determination will allow the expansion of PET service offerings to include cardiac PET services within HSA I. This adjustment would keep pace with advancements in PET technology and ensure that high-volume oncology PET services are not disrupted, while meeting the growing cardiac needs in the service area.

### **Alternatives Considered**

#### **Alternative: Maintain Status Quo**

One option was to maintain the status quo and for Mission to apply again for approval for the general fixed PET need determination proposed in the draft 2025 SMFP. This is not an effective alternative, as it does not ensure that an approved provider of fixed PET services will meet the growing need and demand for cardiac PET diagnostics in HSA I. HSA I has more than enough existing capacity for oncology PET services as shown above. More general oncology PET imaging is not what the service area residents need.

#### **Best Alternative: Petition the SHCC for a Dedicated Cardiac PET Need Determination**

The best alternative is to limit the need determination to a cardiac fixed PET unit in HSA I. This approach ensures that cardiac PET services will be provided in the service area, addressing the growing unmet need for such services as PET technology continues to advance. It will also allow the existing PET scanners in the service area to continue meeting the increasing demand for oncology diagnostics and procedures without disruption. The addition of a dedicated cardiac PET need determination is the most effective solution to ensure comprehensive PET services availability in HSA I, meeting both the current and future needs of the service area.

The limitation of the PET need determination to a dedicated cardiac unit also prevents the unnecessary addition of a fifth general purpose oncology scanner that will be underutilized. The only scenario in which a fifth PET unit in the area is not underutilized and unnecessarily duplicative of the four existing and approved units, is if the unit is approved to develop a cardiac PET program at a health care provider that is able to demonstrate they have the clinical expertise and patient base to develop and support such a program.

### **Proposed Adjustment Would Not Result in Unnecessary Duplication**

Mission's petition for the addition of a specific fixed cardiac PET scanner need determination would not result in unnecessary duplication of services since HSA I does not currently have a provider of cardiac PET services. Approval of the petition will expand access to PET services in HSA I and address unmet need, ensuring that patients have access to essential cardiac imaging without redundancy in service offerings.

### **The Request is Consistent with the Basic Principles**

The petition aligns with SMFP's Basic Principles regarding safety, quality, access, and value as outlined below.

#### **Safety and Quality**

Adding a dedicated cardiac fixed PET scanner in HSA I will significantly enhance quality and safety. Currently, cardiac PET services are unavailable within the service area, forcing residents to travel outside the service area or forgo the procedure altogether. This unmet demand among cardiology patients highlights the need for a specific fixed PET scanner, which is essential for quality, comprehensive cardiac imaging. By addressing this gap, the SHCC can ensure that HSA I patients receive timely and accurate cardiac imaging, reducing the risk associated with delayed or missed diagnoses.

#### **Access**

Approval of the petition will greatly improve access to cardiac PET services in HSA I. The current limited PET services do not meet the demand of cardiology patients. A dedicated cardiac PET scanner will allow HSA I residents to access comprehensive care without having to travel outside of the service area – as much as 2-4 hours travel for many western North Carolina residents - or forgo care due to lack of local accessibility. Enhanced access will particularly benefit patients in HSA I and rural areas, and those with disabilities or financial hardships, who often face significant barriers to travel for medical care.

#### **Value**

This petition also promotes value for patients. Those currently leaving the service area for a cardiac PET scan incur costs associated with taking time off work and traveling, and they experience delays in diagnosis, each of which do not add to the quality of their care. Moreover, insufficient local access may lead patients to opt for less effective imaging studies, resulting in suboptimal treatments and outcomes and repeated testing and diagnostics. Access to high-quality imaging services without the added burdens of travel and delayed diagnosis will also improve patient outcomes and overall healthcare value.

In summary, the proposal to limit the PET need determination in the 2025 SMFP to a dedicated cardiac fixed PET scanner in HSA I will enhance safety, quality, access, and value, making it a necessary and beneficial adjustment for the service area.

### **Conclusion**

Mission petitions the SHCC to limit the specific PET need determination in HSA I in the 2025 SMFP to a dedicated cardiac fixed PET scanner for HSA I. This change is essential as PET is becoming a standard of care in the diagnosis of cardiac conditions and as to prevent the development of unnecessary and duplicative



oncology PET capacity. The existing and approved units in HSA I will continue to be utilized for the primary purpose of oncologic diagnostics. Approval of the proposed specific need determination will ensure that the residents of HSA I get access to fixed cardiac PET diagnostics closer to home.