

**Technology and Equipment Committee  
Agency Report  
Petition for Proposed Policy TE-5:  
Plan Exemption for Dedicated Cardiac PET  
for Open Heart Surgery Providers  
Proposed 2026 State Medical Facilities Plan**

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***Petitioner:***

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***Request:***

Mission Hospital (Mission”) requests that the State Health Coordinating Council (SHCC) include a policy to allow open-heart surgery (OHS) providers to acquire a dedicated cardiac positron emission tomography (PET) scanner without regard to a need determination in the *State Medical Facilities Plan (SMFP)*. The proposed policy requires the applicant to be an existing or approved provider of OHS and that the cardiac PET scanner can only be used for cardiac PET scanning.

***Background Information:***

Chapter Two of the *SMFP* provides that “[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” The annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring.

The *SMFP* need determination methodology for dedicated fixed PET scanners calculates the need for additional scanners for the six health service areas (HSAs) in the state. The methodology calculates a facility deficit when use of the existing dedicated fixed PET scanner(s) is a minimum of 80% of capacity (i.e., 2,400 procedures) during the current reporting year. While deficits are based on the utilization of scanners at a single facility, if a need determination is generated, it is for the service area as a whole, and anyone may submit a certificate of need (CON) application. The maximum need determination in any year for a given service area is two PET scanners.

**Prior PET Need Determinations in HSA I**

Mission’s PET scanner volume generated the last two PET need determinations in HSA I. However, two other providers received the CONs. The Agency approved a CON application

submitted by Messino Cancer Center for the 2021 PET scanner need determination because it was a new provider and projected more cost efficiency than Mission. The Agency also approved a CON submitted by AdventHealth Hendersonville to develop a PET scanner pursuant to the 2023 SMFP need determination because it proposed more geographic distribution of PET services, projected lower cost than Mission, and included a new provider.

#### PET Need Determinations in the 2025 SMFP

The 2025 SMFP has five PET need determinations:

- 1 in HSA I
- 1 in HSA II
- 1 in HSA III. This need was generated by Part 2 of the methodology, which is based on the existence of a hospital-based major cancer treatment facility, program, or provider that does not own or operate a dedicated fixed PET scanner. The need determination is for the service area; the provider that is the subject of Part 2 of the methodology may or may not receive the CON.
- 2 in HSA IV

In 2024, Mission petitioned the SHCC for an adjusted need determination to change the standard need determination in the 2025 SMFP from a need for a dedicated fixed PET scanner to a need for a dedicated fixed *cardiac* PET scanner. However, the SMFP's Access basic principle supports need determinations that address the general needs of the service area. The SHCC denied the petition on the basis that need determination methodologies do not address specialized applications.

#### ***Analysis/Implications:***

The Petitioner proposes the following policy:

##### **Policy TE-5: Plan Exemption for Dedicated Cardiac PET for Open Heart Surgery Providers**

1. It is a licensed North Carolina acute care hospital or hospital campus that has the following characteristics:
  - a. has licensed acute care beds;
  - b. provides emergency care coverage 24 hours a day, seven days a week;
  - c. has Certificate of Need approval or other authorization (grandfathered) to provide Open Heart Surgery as recognized in Chapter 7B of this plan.
2. The proposed dedicated Cardiac PET scanner and associated equipment will perform at least 1,040 PET procedures during the third full operating year.
3. The proposed dedicated Cardiac PET scanner will be located:
  - a. on the main campus of the hospital as defined in G.S. § 131E-176(14n); or
  - b. on an acute care hospital campus that operates under the main hospital's license.
4. The proposed Cardiac PET scanner and associated equipment will be dedicated to providing cardiac PET procedures and will serve non-cardiac patients in an emergency situation such as temporary downtime for other PET scanners owned or operated by the applicant.

*The performance standards in 10A NCAC 14C.3703 are not applicable.*

Mission's request has three major themes:

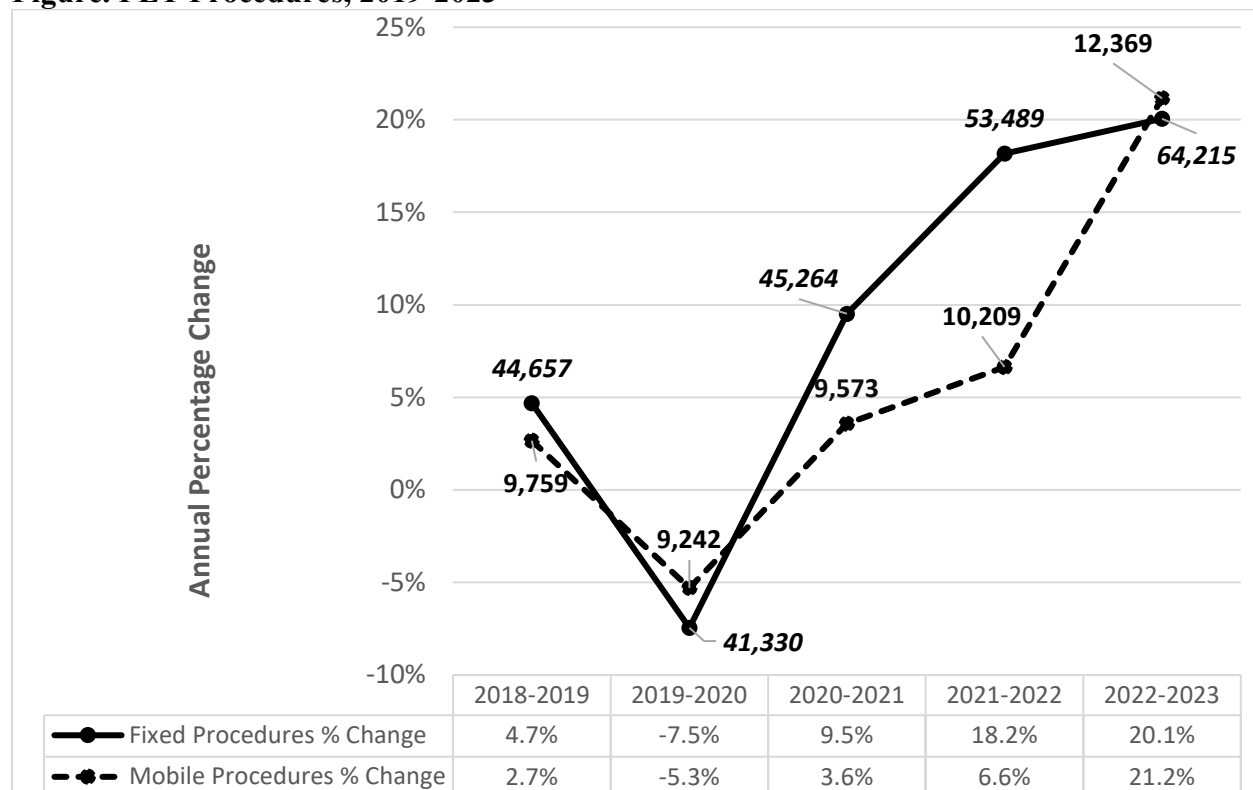
- PET is superior to other technologies available for the diagnosis of cardiac conditions;

- the demand for PET scanners is increasing; and
- most of the PET utilization in North Carolina is in oncology. As a result, it is often inconvenient for OHS patients and providers to access PET services.

The Petitioner first presents a thorough discussion of the value of PET in cardiac diagnosis. The Agency acknowledges that PET is becoming a valuable, and possibly essential, tool in the diagnosis of cardiac conditions. This may be especially true for OHS programs, because they treat the most complex conditions.

The second theme is exemplified by the Figure below, which illustrates that the demand for both fixed and mobile PET services has increased dramatically in North Carolina in the past five years. The State experienced a 44% increase in fixed PET procedures since 2019 and a 27% increase in mobile procedures. Based on a recent study of Medicare patients,<sup>1</sup> it is likely the state's increase reflects the national trend. The study also noted a decrease in the use of Single Photon Emission Computed Tomography (SPECT), although it remained the predominant diagnostic tool. The Agency has no data on the types of patients served by SPECT or PET. Thus, is it not possible to address whether there has been an increase in the use of either SPECT or PET in cardiology applications in North Carolina. The Agency also cannot ascertain the proportion of OHS patients who had PET scans before or after surgery.

**Figure. PET Procedures, 2019-2023**



Source: 2021 – 2025 State Medical Facilities Plans

<sup>1</sup> Al-Mallah, Mouaz, et al. (2024). *Journal of Nuclear Cardiology* 41: 102030.  
[https://www.journalofnuclearcardiology.org/article/S1071-3581\(24\)00712-8/fulltext](https://www.journalofnuclearcardiology.org/article/S1071-3581(24)00712-8/fulltext). Retrieved 3/7/2025

The third theme of the petition posits that most of the PET usage in North Carolina is in oncology. While this assumption may be accurate, as noted above, the Agency has no data on the types of patients served by PET scanners. However, comparing the number of PET scans to the number of open-heart surgeries, it seems clear that the PET scanners are used for more than OHS cases (See Table).

To further examine the third theme, the Petitioner reviewed hospital websites and contacted some hospitals to obtain information on the use of cardiac PET. To share the results of their research, Mission created the Table, below, from the *SMFP* data. This data was self-reported by owners of PET scanners and submitted to the Agency through the 2024 Hospital License Renewal Applications. (The Agency reordered the facilities alphabetically and added a column for the HSA in which the facility is located.) The Table shows that 22 hospitals provided OHS in 2023, for a total of 10,400 procedures. Five hospitals did not have either PET services or cardiac PET services. The remaining 17 offered cardiac PET imaging.

**Table. Analysis of OHS Providers and PET Utilization/Capacity (adapted from Mission Hospital Petition)**

Licenses #	Providers	HSA	Open Heart Surgery	PET Services (2025 SMFP)			OHS Volume (2025 SMFP)	
				Planning Inventory	2022-2023 Procedures	PET Utilization	2022	2023
H0031	Atrium Health Cabarrus	III	Yes	1	1,417	47.2%	195	337
H0042	Atrium Health Pineville	III	Yes	Not Available			270	344
H0011	Atrium Health Wake Forest Baptist	II	Yes	2	4,248	70.8%	840	925
H0213	Cape Fear Valley Medical Center	V	Yes	1	1,352	45.1%	124	139
H0201	CarolinaEast Medical Center	VI	Yes	1	1,576	52.5%	222	255
H0071	Carolinas Medical Center	III	Yes	2	5,686	94.8%	777	803
H0105	CaroMont Regional Medical Center	III	Yes	1	1,282	42.7%	268	283
H0159	Cone Health	II	Yes	1	2,750	91.7%	601	546
H0233	Duke Regional Hospital	IV	Yes	Not Available			97	91
H0015	Duke University Hospital	IV	Yes	3	7,442	82.7%	1,259	1,286
H0104	ECU Health Medical Center*	VI	Yes	2	3,849	64.2%	805	865
H0100	FirstHealth Moore Regional Hospital / First Imaging of the Carolinas#	V	No	1	2,091	69.7%	234	228
H0053/ H0223	Frye Regional Medical Center / Catawba Valley Medical Center^^	I	Yes	1	1,649	55.0%	177	207
H0052	High Point Regional Health	II	Yes	1	583	19.4%	19	30
H0036	Mission Hospital	I	Yes	1	2,862	95.4%	1,099	1,254
H0209	Novant Health Forsyth Medical Center**	II	Yes	2	2,907	48.5%	436	500
H0221	Novant Health New Hanover Regional Medical Center	V	Yes	2	4,130	68.8%	433	466
H0010	Novant Health Presbyterian Medical Center	III	Yes	1	2,275	75.8%	360	450
H0065	Rex Hospital	IV	Yes	2	4,772	79.5%	520	490
H0064	Southeastern Regional Medical Center	V	Yes	1	1,169	39.0%	53	43
H0157	University of North Carolina Hospitals	IV	Yes	2	5,375	89.6%	351	339
H0199	WakeMed Hospital / Wake PET Services^	IV	Yes	1	1,660	55.3%	487	519
	<b>TOTAL</b>			<b>29</b>	<b>59,075</b>		<b>9,637</b>	<b>10,400</b>

Source: 2025 SMFP

\* CON issued to convert fixed PET to mobile PET December 13, 2022. CON Project ID: Q-012223-22. PET scanner is across the street from the hospital.

\*\*CON issued for second PET March 29, 2024. CON Project ID: G-012432-23

^ OHS program based on WakeMed Hospital (H0199). PET based at affiliate 210 PET Imaging in Cary, NC.

^^ Frye Regional Medical Center is an OHS provider; Catawba Valley Medical Center is not.

# OHS program based on First Health Moore Regional Hospital (H0100). PET based at affiliate First Imaging of the Carolinas

The Petitioner's research identified five facilities without PET or cardiac PET services (in addition to the Petitioner). Two facilities offer OHS but have no access to a fixed or mobile PET scanner: Atrium Health Pineville (HSA III); and Duke Regional Hospital (HSA IV). Three hospitals offer OHS but do not have a cardiac PET scanner: Atrium Health Cabarrus (HSA III); FirstHealth Moore Regional Hospital (HSA V); and High Point Regional Hospital (HSA II). The *2025 SMFP* has need determinations in all these HSAs except HSA V. Thus, four of the five hospitals without a dedicated cardiac PET scanner would have the opportunity to apply for a PET scanner in 2025. If the providers awarded the CON deem it the best option, they would then be able to assign the new PET scanner to the cardiology service.

***Agency Recommendation:***

As shown above, the *2025 SMFP* has a PET need determination in HSA I. Thus, the Petitioner has another opportunity to submit a CON application for a PET scanner. The CON-approved applicant will have the ability to develop the scanner in the manner described in its CON application, whether it be for general or specialized use.. Therefore, given available information and comments submitted by the March 19, 2025 deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition.