

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 23, 2026
Findings Date: January 23, 2026

Project Analyst: Yolanda W. Jackson
Co-Signer: Gloria C. Hale

COMPETITIVE REVIEW

Project ID #: B-12675-25
Facility: Margaret R. Pardee Memorial Hospital
FID #: 943324
County: Henderson
Applicants: Henderson County Hospital Corporation
Project: Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

Project ID #: B-12684-25
Facility: Novant Health Asheville PET
FID #: 250780
County: Buncombe
Applicants: Novant Health Long Shoals Imaging, LLC
Novant Health, Inc.
Project: Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

Project ID #: B-12685-25
Facility: Mission Hospital
FID #: 943349
County: Buncombe
Applicants: MH Mission Hospital, LLLP
Project: Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

Project ID #: B-12688-25
Facility: AdventHealth Asheville
FID #: 220475
County: Buncombe
Applicants: AdventHealth Asheville, Inc.
Adventist Health System Sunbelt Healthcare Corporation
Project: Change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds) to acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C – All Applications

Need Determination

The 2025 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional PET scanners in North Carolina by service area. Application of the need methodology in the 2025 SMFP identified a need for one additional fixed PET scanner in Health Service Area (HSA) I service area. Four applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) proposing to develop a total of four new fixed PET scanners. However, pursuant to the need determination, only one fixed PET scanner may be approved in this review.

Policies

There are two policies in the 2025 SMFP that are applicable to this review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 30 of the 2025 SMFP, states:

“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop

and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

Policy GEN-4 applies all applicants in this review.

Policy GEN-5: Access to Culturally Competent Healthcare, on pages 30-31 of the 2025 SMFP, states:

“A certificate of need (CON) applicant applying to offer or develop a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities. The delivery of culturally competent healthcare requires the implementation of systems and training to provide responsive, personalized care to individuals with diverse backgrounds, values, beliefs, customs, and languages. A certificate of need applicant shall identify the underserved populations and communities it will serve, including any disparities or unmet needs of either, document its strategies to provide culturally competent programs and services, and articulate how these strategies will reduce existing disparities as well as increase health equity.

CON applications will include the following:

The applicant shall, in its CON application, address each of the items enumerated below:

Item 1: *Describe the demographics of the relevant service area with a specific focus on the medically underserved communities within that service area. These communities shall be described in terms including, but not limited to: age, gender, racial composition; ethnicity; languages spoken; disability; education; household income; geographic location and payor type.*

Item 2: *Describe strategies it will implement to provide culturally competent services to members of the medically underserved community described in Item 1.*

Item 3: Document how the strategies described in Item 2 reflect cultural competence.

Item 4: Provide support (e.g., best-practice methodologies, evidence-based studies with similar communities) that the strategies described in Items 2 – 3 are reasonable pathways for reducing health disparities, increasing health equity and improving the health outcomes to the medically underserved communities within the relevant service area.

Item 5: Describe how the applicant will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities in underserved communities.”

Policy *GEN-5* applies to all applicants in this review.

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

Henderson County Hospital Corporation (hereinafter referred to as “UNC Health Pardee” or “the applicant”) proposes to acquire one fixed PET scanner pursuant to the 2025 SMFP need determination for one fixed PET scanner in HSA I.

Need Determination. The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA I PET scanner service area.

Policy GEN-4. The proposed capital expenditure for this project is approximately \$4.4 million. In Section B, page 26, the applicant describes the project’s plan to improve energy efficiency and conserve water.

Policy GEN-5. In Section B, pages 27-31, the applicant describes how the project will provide access to culturally competent healthcare.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more than one fixed PET scanner that is determined to be needed in the service area.

- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-4* because the applicant includes a written statement describing the project’s plan to ensure improved energy efficiency and water conservation.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-5* because the applicant demonstrates how the project will provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

Novant Health Long Shoals Imaging, LLC and Novant Health, Inc. (hereinafter referred to as “Novant Health” or “the applicant”) propose to acquire one fixed PET scanner pursuant to the 2025 SMFP need determination for one fixed PET scanner in HSA I.

Need Determination. The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA I PET scanner service area.

Policy GEN-4. The proposed capital expenditure for this project is approximately \$7.0 million. In Section B, pages 26-28, the applicant describes the project’s plan to improve energy efficiency and conserve water.

Policy GEN-5. In Section B, pages 29-34, the applicant describes how the project will provide access to culturally competent healthcare.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more than one fixed PET scanner that is determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-4* because the applicant includes a written statement describing the project’s plan to ensure improved energy efficiency and water conservation.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-5* because the applicant demonstrates how the project will provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

MH Mission Hospital, LLLP (hereinafter referred to as "Mission Hospital" or "the applicant") proposes to acquire one fixed PET scanner pursuant to the 2025 SMFP need determination for no more than two fixed PET scanners in HSA I.

Need Determination. The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA I PET scanner service area.

Policy GEN-4. The proposed capital expenditure for this project is approximately \$4.9 million. In Section B, page 31, the applicant describes the project's plan to improve energy efficiency and conserve water.

Policy GEN-5. In Section B, pages 32-46, the applicant describes how the project will provide access to culturally competent healthcare.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more than one fixed PET scanner that is determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-4* because the applicant includes a written statement describing the project's plan to ensure improved energy efficiency and water conservation.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-5* because the applicant demonstrates how the project will provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

AdventHealth Asheville, Inc. and Adventist Health System Sunbelt Healthcare Corporation (collectively referred to as "AdventHealth" or "the applicant") propose to acquire a fixed PET scanner at AdventHealth Asheville pursuant to the 2025 SMFP need determination which is a change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds).

Need Determination. The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA I PET scanner service area.

Policy GEN-4. The proposed capital expenditure for this project is approximately \$5.5 million. In Section B, page 27, the applicant describes the project's plan to improve energy efficiency and conserve water.

Policy GEN-5. In Section B, pages 28-40, the applicant describes how the project will provide access to culturally competent healthcare.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more than one fixed PET scanner that is determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-4* because the applicant includes a written statement describing the project's plan to ensure improved energy efficiency and water conservation.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-5* because the applicant demonstrates how the project will provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

UNC Health Pardee
Novant Health
Mission Hospital

NC
 AdventHealth

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination for one fixed PET scanner to be located at the main campus of Margaret H. Pardee Memorial Hospital (UNC Health Pardee) in Henderson County. The proposed PET scanner will be the first at UNC Health Pardee and serve oncology patients as well as patients from a range of other specialties, including neurology and cardiology.

Currently, UNC Health Pardee provides mobile PET services through a vendor-operated mobile service contracted with Alliance. The mobile PET scanner is on site every Sunday and two half Fridays each month. UNC Health Pardee has requested additional time from the mobile vendor; however, the vendor has not been able to provide additional days or times of service.

Patient Origin

On page 363, the 2025 SMFP defines the service area for a fixed PET scanner as “the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” The applicant proposes to locate the fixed PET scanner in Henderson County, which is in HSA I. Thus, the service area for this facility is HSA I. Facilities may also serve residents of counties not included in their service area.

The applicant does not currently offer fixed PET services at UNC Health Pardee. Therefore, there is no historical patient utilization. However, UNC Health Pardee does provide mobile PET services through a contract with Alliance and the proposed project involves a shift of existing patients receiving mobile PET services at UNC Health Pardee.

The following table illustrates the historical patient origin for mobile PET services.

Mobile PET Services	UNC Health Pardee	
	Last Full FY 07/01/2023 to 06/30/2024^	
County	# of Patients	% of Total
Henderson	633	68.4%
Transylvania	91	9.8%
Buncombe	75	8.1%
Polk	44	4.8%
Rutherford	25	2.7%
Other*	57	6.1%
Total	925	100.0%

Source: Section C, page 36.

*Other includes Greenville, SC, Haywood, McDowell, Jackson, Madison, Spartanburg, SC, Macon, Park, CO, Brunswick, Mecklenburg, Other NC counties, and Other States.

^SFY 2024 represents the last full year of comprehensive data available during application preparation. While SFY 2025 volume data was available and used for baseline projections, other required year-end financial and utilization data for the table above remained unavailable due to ongoing close-out processes.

The following table illustrates the projected patient origin for the proposed fixed PET services.

Fixed PET Services	UNC Health Pardee					
	1st Full FY		2nd Full FY		3rd Full FY	
	07/01/2027 to 06/30/2028		07/01/2028 to 06/30/2029		07/01/2029 to 06/30/2030	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Henderson	1,453	68.4%	1,636	68.4%	1,845	68.4%
Transylvania	209	9.8%	235	9.8%	265	9.8%
Buncombe	172	8.1%	193	8.1%	218	8.1%
Polk	102	4.8%	115	4.8%	129	4.8%
Rutherford	58	2.7%	65	2.7%	74	2.7%
Other*	130	6.1%	146	6.1%	165	6.1%
Total	2,123	100.0%	2,391	100.0%	2,696	100.0%

Source: Section C, page 38.

*Other includes Greenville, SC, Haywood, McDowell, Jackson, Madison, Spartanburg, SC, Macon, Park, CO, Brunswick, Mecklenburg, Other NC counties, and Other States.

In Section C, page 38, the applicant provides the assumptions and methodology used to project its patient origin. The assumptions for fixed PET services are based on State Fiscal Year (SFY) 2024 patient origin data for mobile PET services with percentages applied to the number of PET procedures to be performed during the first three full fiscal years of the project. The applicant assumes that one procedure equals one patient.

The applicant’s assumptions are reasonable and adequately supported because the projected patient origin percentages are consistent with imaging utilization across other specialties at UNC Health Pardee and which vary less than one percent based on historical data.

Analysis of Need

In Section C, pages 41-55, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- **The Expansion of Clinical Applications and Superior Quality of PET Imaging.** The applicant states that when PET imaging is compared to Single Photon Emission Computed Tomography (SPECT), PET imaging provides better resolution. The applicant states that while both imaging modalities produce detailed three-dimensional images of target organs, SPECT relies on gamma-ray emitting radioisotopes to collect this information whereas PET involves the tracking of positrons, small particles released as the radiotracer breaks down. The applicant states that this characteristic difference is largely responsible for the higher sensitivity of PET imaging, and the greater precision it brings to the detection and diagnosis of various conditions.

The applicant states that PET scanning has additional applications beyond oncology, neurology and cardiology. The applicant states that PET scans can detect several inflammatory conditions that affect the chest and the inflammation they cause.

The applicant states that while fluorodeoxyglucose (FDG) PET may be utilized for imaging related to cancer and even dementia, it also may be utilized in evaluating and detecting infectious disorders (e.g., fever of unknown origin and abscess localization).

- **Need for Additional PET Capacity in HSA I.** The applicant states that the need for the proposed fixed PET scanner is supported by the overall population growth in HSA I and additional demographic factors. The applicant states the growing multicounty population of residents age 65 and older will require more access to services in the future, as older residents typically use healthcare services more frequently than younger residents and experience a higher incidence of heart disease, neurological diseases, and various types of cancer.

The applicant states that according to data compiled by the North Carolina State Center for Health Statistics, both HSA I and the multicounty region served by UNC Health Pardee demonstrate significant health challenges. The applicant states that the health challenges for HSA I residents include cancer, heart disease and Alzheimer's Disease and create a substantial demand for advanced diagnostic services, including PET imaging.

- **The Need for Fixed PET Imaging Services at UNC Health Pardee Hospital.** The applicant states that the mobile PET unit at UNC Health Pardee is only onsite a few days per month. The applicant states that the utilization of the mobile PET unit has increased by a compound annual growth rate (CAGR) of 20.3 percent from SFY 2022 to SFY 2025 and that it expects that demand for PET services at UNC Health Pardee will remain high and continue to grow rapidly.

The applicant states that there are operational challenges associated with the existing mobile PET unit. The applicant states that the proposed fixed PET scanner at UNC Health Pardee will provide consistent, regular available PET imaging services, significantly reducing current wait times and scheduling delays, and the dedicated space within the UNC Health Pardee Hospital facility will provide a more comfortable and convenient setting for care compared to the mobile unit's complex routing process.

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2025 SMFP for one additional PET scanner in HSA I, which includes Henderson County.
- The applicant provided reasonable and clearly identified information to support the need for a fixed PET scanner at UNC Health Pardee based on the existing and projected incidence of diseases for which patients benefit from PET services in the service area.
- The applicant used reasonable and clearly identified demographic data to make assumptions supporting identification of the population to be served, the projected growth of that population, and the need the identified population has for the proposed

PET services.

Projected Utilization

In Section Q, Form C.2a, page 110, and Form C.2b, page 111, the applicant provides historical and projected utilization, as illustrated in the following tables.

UNC Health Pardee Historical Utilization			
Mobile PET	Last Full FY	Interim Full FY	Interim Full FY
	07/01/2023 – 06/30/2024	07/01/2024- 06/30/2025	07/01/2025- 06/30/2026
# of Pet Scanners	Mobile	Mobile	Mobile
# of Procedures	925	919	1,068

UNC Health Pardee Projected Utilization				
Fixed PET	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	07/01/2026- 06/30/2027	07/01/2027- 06/30/2028	07/01/2028- 06/30/2029	07/01/2029- 06/30/2030
# of Pet Scanners	1	1	1	1
# of Procedures	1,457	2,123	2,391	2,696

Source: Section Q, page Form C.2.b, page 111.

In Section Q, pages 112-117, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The proposed project is expected to become operational on March 1, 2027. UNC Health Pardee’s fiscal year corresponds to the state fiscal year from July 1 to June 30. The first full fiscal year of the proposed project will be July 1, 2027 to June 30, 2028, or SFY 2028. The first three project years will be SFY 2028, SFY 2029 and SFY 2030.

Historical Utilization of the Mobile PET Scanner at UNC Health Pardee

UNC Health Pardee currently provides mobile PET services through its contract with Alliance. The applicant began by analyzing the historical PET procedures performed on the contracted mobile PET scanner to project future PET procedures on the proposed fixed PET scanner.

Table 1: Historical Mobile PET Procedures at UNC Health Pardee						
	SFY22	SFY23	SFY24	SFY25	SFY22-SFY24 CAGR*	SFY22-SFY25 CAGR*
# of Procedures	528	723	925	919	32.4%	20.3%

Source: Section Q, page 112.

*CAGR=Compound Annual Growth Rate

The applicant states that historical PET procedures performed at UNC Health Pardee on the contracted mobile unit grew at a CAGR of 32.4 percent from SFY 2022 to SFY 2024. The applicant states that during the period from June 2024 to July 2025, adverse weather

conditions and vendor cancellations disrupted mobile PET service at UNC Health Pardee multiple times, resulting in the loss of at least 10 operational days and further restricted mobile capacity. The applicant states that volume was down in SFY 2025 as a result of the restricted capacity and reduced the overall growth rate to a CAGR of 20.3 percent from SFY 2022 to SFY 2025.

Projected Fixed PET Procedures at UNC Health Pardee

The applicant states that it projects fixed PET procedures for the categories of oncology, neurology, and cardiology separately due to the distinct methodologies required for each service line. The applicant states that currently the vast majority of its mobile PET scans are oncology procedures which allows for straightforward projections based on historical utilization patterns. The applicant states that neurology procedures represent a small percentage of the current volume and cardiology procedures are not currently performed on the mobile unit. The projected growth in neurology and cardiology procedures will therefore require different analytical approaches.

Oncology PET Utilization

The applicant assumes that oncology procedures on the proposed fixed PET scanner will grow at an overall CAGR of 16.2 percent given that the majority of historical PET procedures on the mobile PET unit are oncology-related as shown in the table below.

	SFY25	SFY26	SFY27	SFY28 (PY1)	SFY29 (PY2)	SFY30 (PY3)	SFY26-SFY30 CAGR
Oncology Procedures	919	1,068	1,240	1,441	1,674	1,945	16.2%

Source: Section Q, page 113.

The applicant believes this growth rate is reasonable because it represents half of the CAGR of 32.4 percent achieved by UNC Health Pardee’s mobile PET services from SFY 2022 to SFY 2024. The applicant states that the growth rate is also reasonable because it represents a lower projected growth rate compared to the 20.3 percent CAGR achieved from SFY 2022 to SFY 2025. The applicant states that while this rate is slightly higher than the statewide growth rate of 13.0 percent, the rate aligns with the PET procedure growth rate across HSA I from Federal Fiscal Year (FFY) 2022 to FFY 2024 of 16.0 percent as shown in the table below.

	FFY22	FFY23	FFY24	FFY22 - FFY24 CAGR
HSA I Totals	4,301	4,703	5,786	16.0%
Statewide Totals	55,147	64,215	70,463	13.0%

Source: Section Q, page 113; 2024 SMFP, 2025 SMFP and Proposed 2026 SMFP.

Cardiac PET Utilization

The applicant does not currently provide cardiology PET procedures. However, the applicant states that it anticipates providing cardiac PET imaging on the proposed fixed PET scanner. The applicant relied on recently published data analyzing trends in cardiac PET use among the Medicare population as shown in the table below.

Table 4: Medicare Cardiac PET Use Rate			
	FFY18	FFY22	FFY18 – FFY22 CAGR
PET MPI^ Procedures	169,334	212,106	
Total Medicare Beneficiaries*	62,900,000	68,200,000	
Use Rate per 1,000 Medicare Patients	2.69	3.11	3.7%

Source: Section Q, page 114. <https://pubmed.ncbi.nlm.nih.gov/39233112/>

*[Data Analysis Brief: Medicare-Medicaid Dual Enrollment Trends 2006-2018](#)

^MPI=myocardial perfusion imaging

The applicant assumes a 3.7 percent CAGR to project the cardiac PET use rate. The applicant converted the projected FFY cardiac PET use rates to SFY cardiac PET use rates through SFY 2030 to align with internal data and the three project years as shown in the table below.

Table 5: Projected Cardiac PET Use Rate*									
	FFY22	FFY23	FFY24	FFY25	FFY26	FFY27	FFY28	FFY29	FFY30
Projected Cardiac PET Use Rate	3.11	3.22	3.34	3.47	3.59	3.72	3.86	4.00	4.15
	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27	SFY28	SFY29	SFY30
Projected Cardiac PET Use Rate^	--	3.20	3.31	3.43	3.56	3.69	3.83	3.97	4.11

Source: Section Q, page 115.

*Per 1,000 Medicare patients

^Projected cardiac PET use rates were converted from FFY to SFY using the following formula: $SFY = (3/12) \times FFY(n) + (9/12) \times FFY(n+1)$

The applicant increased the SFY cardiac PET use rate by 3.7 percent annually and applied it to the projected population of residents age 65 and older in HSA I, projecting total cardiac procedures for this cohort to SFY 2030. The applicant assumes that it will perform one-third of the projected cardiac PET procedures upon approval of the proposed project and that patients age 65 and older are expected to constitute the majority of cardiac procedure volume. Patients under the age of 65 are also expected to use the services. The applicant reviewed North Carolina industry data related to cardiac catheterization procedures which indicated that approximately 60 percent were performed on patients under 65 and approximately 40 percent were performed on patients over 65. The applicant states that while this demographic ratio serves as a reasonable basis for projections, the applicant applied a ratio derived from historical utilization of the existing mobile PET service, projecting that patients 65 and older will constitute 80 percent of overall cardiac PET volume and patients under 65 will make up another 20 percent as shown in the table below.

Table 7[6]: UNC Health Pardee Projected Cardiac PET Procedures					
	FY26	FY27	FY28 (PY1)	FY29 (PY2)	FY30 (PY3)
HSA I 65% Projected Population	363,263	370,367	376,728	382,693	388,007
Cardiac PET Use Rate per 1,000 Medicare Patients	3.56	3.69	3.83	3.97	4.11
Projected Cardiac PET Procedures in HSA I for Patients 65+	1,294	1,367	1,442	1,519	1,596
Projected Cardiac PET Procedures at UNC Health Pardee for Patients 65+		152	481	506	532
Projected Cardiac PET Procedures at UNC Health Pardee (All Patients)		191	603	635	668

Source: Section Q, page. 115.

Neurology PET Utilization

The applicant based projections for neurology PET utilization on its existing population of patients with Alzheimer’s Disease which grew by 2.3 percent. The applicant states that the Henderson County age 65 and older population also grew by 2.3 percent. The applicant assumes that only one-third of its current Alzheimer’s Disease patients will receive PET imaging procedures. The applicant states that this assumption is supported by study findings that amyloid PET scans are ordered for approximately one-third of patients seen in settings that provide care for cognitive, behavioral neurology, and memory disorders. The projections for neurology PET utilization are shown in the table below.

Table 8[7]: UNC Health Pardee Projected Neurology PET Utilization						
	SFY25	SFY26	SFY27	SFY28 (PY1)	SFY29 (PY2)	SFY30 (PY3)
UNC Health Pardee Alzheimer’s Disease Patients Total Volume	221	226	231	237	242	248
UNC Health Pardee Alzheimer’s Patients Total PET Volume			26	79	81	83

Source: Section Q, page 116.

Performance Standards

The table below summarizes UNC Health Pardee’s projected PET utilization.

Table 9[8]: UNC Health Pardee Projected PET Utilization					
	SFY26	SFY27	SFY28 (PY1)	SFY29 (PY2)	SFY30 (PY3)
Oncology PET Projected Volume	1,068	1,240	1,441	1,674	1,945
Cardiac PET Projected Volume		191	603	635	668
Neurology PET Volume (Alzheimer’s Disease)		26	79	81	83
Total PET Procedures Volume	1,068	1,457	2,123	2,391	2,696
Fixed Units		1	1	1	1
Procedures per Fixed Unit		1,457	2,123	2,391	2,696
Performance Standard	2,080	2,080	2,080	2,080	2,080
Percentage of Performance Standard		70%	102%	115%	130%

Source: Section Q, page 117.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant used historical utilization data for its contracted mobile PET scanners to project future utilization of PET services for oncology because the majority of its current mobile PET scans are for oncology procedures.
- The applicant makes reasonable assumptions regarding projected PET utilization for cardiology based on its review of trends of cardiac PET use among the Medicare population, North Carolina industry data related to cardiac catheterization procedures, and historical utilization of its existing mobile PET services.
- The applicant makes reasonable assumptions regarding projected PET utilization for neurology based on its existing population of patients with Alzheimer’s Disease which is conservative given the PET scanner will be used for additional neurological conditions as well.

All three competing applicants in this review provided comments questioning the reasonableness of UNC Health Pardee’s projected utilization stating that it did not take into account AdventHealth Hendersonville’s approved PET scanner to be developed in Henderson County, the same county that UNC Health Pardee proposes to locate its PET scanner.

The Agency concludes that the applicant’s projected utilization of its proposed fixed PET scanner is reasonable and adequately supported based on the need discussed on pages 41-55 of the application which is summarized in these findings, and the following analysis:

- UNC Health Pardee is located in Henderson County.
- The applicant projects the same *percentage* of patients will utilize its proposed PET services as it did historically for mobile PET services provided at its facility.
- The applicant states, on page 46 of its application, that it is a major provider of primary and specialty care across Henderson, Buncombe, Polk and Transylvania counties where it has robust clinical programs in oncology, neurology, and cardiology.

Access to Medically Underserved Groups

In Section C, pages 60-61, the applicant states:

“Consistent with all UNC Health facilities, UNC Health Pardee provides services to all people in need of medical care and will continue to do so following the proposed project. As stated in UNC Health’s Notice of Nondiscrimination ..., ‘UNC Health and its affiliated Network Entities comply with applicable Federal civil rights laws and do not discriminate, exclude, or treat people less favorably based on race, color, national origin, age, disability, or sex.’

UNC Health provides reasonable accommodations to people with disabilities, including free aids and services to communicate effectively such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). UNC Health also provides free language services to people whose primary language is not English, such as qualified interpreters and translation services, and information written in other languages....

Low income persons, Medicare beneficiaries, and Medicaid recipients will continue to receive care regardless of ability to pay. UNC Health Pardee provides financial counseling and assistance programs, and patients receive appropriate medical screening and stabilizing treatment for emergency conditions in compliance with Federal EMTALA regulations ...”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons*	--
Racial and ethnic minorities	8.0%
Women	60.8%
Persons with disabilities*	--
Persons 65 and older	61.1%
Medicare beneficiaries	61.9%
Medicaid recipients	9.6%

Source: Section C, page 61.

*UNC Health Pardee does not track this data.

The applicant states that while UNC Health Pardee does not maintain data that includes the number of low income or disabled persons it serves, low income and handicapped persons are not denied access to the proposed services.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement that it will provide services to all people in need of medical care and will continue to do so following the proposed project.
- In Exhibit C.6, the applicant provides a copy of its Non-Discrimination Policy.
- In Section B, pages 27-31, the applicant explains how it will provide access to culturally competent healthcare.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in a medical office building (MOB) in Arden, Buncombe County.

Patient Origin

On page 363, the 2025 SMFP defines the service area for a fixed PET scanner as “*the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” Thus, the service area for this facility is HSA I. Facilities may also serve residents of counties not included in their service area.

Novant Health Asheville PET does not currently offer fixed PET services. Therefore, there is no historical patient utilization.

The following table illustrates projected patient origin.

Fixed PET Services	NH Asheville PET					
	1st Full FY		2nd Full FY		3rd Full FY	
	CY2029		CY2030		CY2031	
	County	# of Patients	% of Total	# of Patients	% of Total	# of Patients
Buncombe	465	43.67%	753	43.67%	1,083	43.67%
Haywood	127	11.91%	205	11.91%	295	11.91%
Henderson	81	7.65%	132	7.65%	190	7.65%
McDowell	63	5.90%	102	5.90%	146	5.90%
Macon	58	5.49%	95	5.49%	136	5.49%
Madison	51	4.79%	83	4.79%	119	4.79%
Transylvania	35	3.33%	57	3.33%	83	3.33%
Jackson	34	3.15%	54	3.15%	78	3.15%
Yancey	26	2.45%	42	2.45%	61	2.45%
Mitchell	25	2.34%	40	2.34%	58	2.34%
Rutherford	16	1.52%	26	1.52%	38	1.52%
Burke	12	1.11%	19	1.11%	28	1.11%
Polk	9	0.88%	15	0.88%	22	0.88%
Swain	9	0.82%	14	0.82%	20	0.82%
Avery	7	0.64%	11	0.64%	16	0.64%
Caldwell	6	0.53%	9	0.53%	13	0.53%
Graham	5	0.47%	8	0.47%	12	0.47%
Cherokee	5	0.47%	8	0.47%	12	0.47%
Clay	3	0.29%	5	0.29%	7	0.29%
Cleveland	1	0.12%	2	0.12%	3	0.12%
Catawba	1	0.06%	1	0.06%	1	0.06%
Watauga	1	0.06%	1	0.06%	1	0.06%
Other NC Counties*	4	0.41%	7	0.41%	10	0.41%
Out of State/Unknown	20	1.98%	34	1.98%	49	1.98%
Total	1,064	100.0%	1,723	100.0%	2,481	100.0%

Source: Section C, page 39.

*Other NC Counties includes patients from Wayne, Mecklenburg, Chatham, Lincoln and Union counties.

In Section C, pages 37-38, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states that the patient origin for the proposed PET scanner is based on CY2024 payor mix of outpatient PET scans conducted on Mission’s fixed PET/CT scanner in HSA I. The applicant used Hospital Industry Data Institute (HIDI) data for Mission as its basis for patient origin because it is a fixed PET/CT provider in Buncombe County and its origin shows the largest contingent of its patients originating from Buncombe County.

Analysis of Need

In Section C, pages 41-58, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- **The Need for Additional PET Scanner in HSA I Under 2025 SMFP PET Scanner Methodology.** The 2025 SMFP identified a need for one additional fixed PET scanner in HSA I.
- **Growing Demand for PET Services in HSA I.** The applicant states that the number of PET procedures performed in North Carolina and HSA I has increased in recent years. The applicant analyzed HIDI data which indicates that while the HSA I facility use rate is below statewide average, the resident use rate for HSA I is above the statewide average. The applicant states that this data indicates patients are leaving HSA I to receive PET/CT scans and supports the need for the proposed fixed PET scanner.
- **Projected Population Growth in HSA I.** The applicant states that population in Buncombe County is expected to grow by over 44,000 residents in the next fifteen years and given this growth and its role as the largest population center in HSA I, Buncombe County is the right place for an additional PET scanner in HSA I.
- **Projected Aging of the HSA I Population.** The applicant states that the projected growth in the number of residents age 65 and older in HSA I increases the need for the PET scanner because this segment of the population relies most heavily on PET imaging for the diagnosis and treatment of disease. By 2030, residents age 65 and older in HSA I will reach a quarter of the HSA's population.
- **Cancer Incidence in HSA I.** The applicant states that cancer is the second leading cause of death in HSA I and lung cancer accounts for more than twice as many deaths as any other cancer in HSA I. The applicant states that expanding access to PET scans in HSA I will aid in the detection and treatment of lung cancer.
- **A New Non-Hospital Based PET Site That Will Serve Patients With Diagnoses That Reflect the Increasing Uses for PET Scans.** The applicant states that PET/CT technology is increasingly being used to diagnose coronary artery disease, heart attacks, and brain disorders. The applicant states that its proposed PET scanner will be available to physicians to refer all clinically appropriate patients in the service area and give equal access to all physicians whose patients need a PET scan. In addition, as an outpatient service, it will offer a lower cost alternative than hospital-based PET/CT scanners for many residents with commercial insurers.
- **Documented Support From Healthcare Providers in the Service Area.** The applicant has submitted letters of support from health service providers in HSA I in Exhibit 4.1.

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2025 SMFP for one additional PET scanner in HSA I, which includes Buncombe County.
- The applicant used reasonable and clearly identified demographic and disease incidence data to make assumptions supporting identification of the population to be served, the projected growth of that population, and the need the identified population has for the proposed PET services.

Projected Utilization

In Section Q, Form C.2b, page 121, the applicant provides projected utilization, as illustrated in the following table.

NH Asheville PET Projected Utilization			
	1st Full FY	2nd Full FY	3rd Full FY
	CY2029	CY2030	CY2031
# PET scanners	1	1	1
# of Procedures	1,064	1,723	2,481

Source: Section Q, Form C.2b.

In Section Q, pages 122-127, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant proposes to develop one fixed PET scanner at an MOB in Buncombe County in HSA I. NH Asheville PET is expected to be open January 1, 2029.

Step 1: Calculate Past PET Growth Rates in HSA I and North Carolina

The applicant used data published in the SMFP for fixed and mobile PET scans in HSA I and statewide. The table below shows data from the 2022 SMFP through the draft 2026 SMFP on PET volumes by provider for HSA I providers and all providers in North Carolina.

PET Site	County	PET Procedures, FFY (Ending September)					20-24 CAGR
		2020	2021	2022	2023	2024	
Fixed Scanners							
Messino Cancer Centers	Buncombe				192	2,111	
Mission Hospital	Buncombe	2,695	2,808	2,919	2,862	1,893	-8.45%
Catawba Valley Medical Center	Catawba	1,082	1,140	1,382	1,649	1,779	13.24%
<i>Fixed Totals</i>		3,777	3,948	4,301	4,703	5,783	11.24%
<i>Growth Rate</i>			4.5%	8.9%	9.3%	23.0%	
<i>% Fixed</i>		57%	56%	56%	52%	58%	

Mobile Scanners, By Site	County	2020	2021	2022	2023	2024	20-24 CAGR
Atrium Health Cleveland	Cleveland	806	839	808	977	1,241	11.39%
Margaret R. Pardee Memorial Hospital	Henderson	504	532	562	767	918	16.17%
Blue Ridge Morganton	Burke	274	322	301	361	431	11.99%
Caldwell Memorial Hospital	Caldwell	183	201	282	436	409	22.27%
Wilkes Regional Medical Center	Wilkes	6	153	269	361	382	182.47%
Lifepoint Haywood Regional	Haywood	188	187	182	210	284	10.86%
Lifepoint Westcare Health System	Jackson	251	318	346	393	282	2.95%
Lifepoint Rutherford Regional	Rutherford	174	154	149	145	165	-1.32%
AdventHealth Hendersonville	Henderson	244	242	241	278	-	
Watauga Medical Center	Watauga	196	188	219	423	-	
<i>Mobile Totals</i>		2,826	3,136	3,359	4,351	4,112	9.83%
<i>Annual Growth Rate</i>			11.0%	7.1%	29.5%	-5.5%	
<i>% Mobile</i>		43%	44%	44%	48%	42%	
HSA I Total PET Scans							
		6,603	7,084	7,660	9,054	9,895	10.64%
<i>Annual Growth Rate</i>			7.3%	8.1%	18.2%	9.3%	
Total North Carolina PET Scans		51,654	54,837	65,356	77,351	83,406	12.73%

Source: Section Q, page 123.

Step 2: Project Future Total PET Scans in HSA I

As shown in the table above, the CAGR for HSA I total PET scans for 2020-2024 is 10.64%. The applicant assumes the future number of PET scans in HSA I will grow at 75% of the 2020-2024 CAGR for PET scans, which is 7.98%. The applicant applies the 7.98% annual growth rate to the base year (FFY 2024) PET scans performed on HSA I scanners, as illustrated in table below.

Projected Total HSA I PET Scans (FY)								
	2025	2026	2027	2028	2029	2030	2031	2032
Total HSA I PET Scans	10,685	11,538	12,459	13,453	14,527	15,686	16,938	18,290

Source: Section Q, page 124.

Step 3: Convert Fiscal Year to Calendar Year

The applicant's fiscal year is the calendar year. Therefore, the applicant must convert fiscal year (FY) data to calendar year (CY) data to project the first three project years. To convert FFY to CY, the applicant took 75% of the FFY and added 25% of the next future FFY.

Projected Total HSA I PET Scans, by Calendar Year (CY)							
	2025	2026	2027	2028	Year 1 2029	Year 2 2030	Year 3 2031
Total HSA I PET Scans	10,898	11,768	12,708	13,722	14,817	15,999	17,276

Source: Section Q, page 124.

Step 4: Project Future Fixed PET Scans in HSA I

The table in Step 1 shows that the average percentage of PET scans performed on fixed equipment during the period between 2020 and 2024 was 55.87%. The applicant used the average percentage of 55.87% to project future PET scans performed on fixed equipment to provide projected fixed HSA I PET scans.

Projected Total HSA I PET Scans, by Calendar Year (CY)							
	2025	2026	2027	2028	Year 1 2029	Year 2 2030	Year 3 2031
Total HSA I PET Scans (Step 3)	10,898	11,768	12,708	13,722	14,817	15,999	17,276
% Fixed	55.87%	55.87%	55.87%	55.87%	55.87%	55.87%	55.87%
HSA I Fixed Scans	6,089	6,575	7,100	7,666	8,278	8,939	9,652

Source: Section Q, page 125.

Step 5: Project NH Asheville PET Scans (Apply Expected NH Asheville PET Market Share to Future HSA I Fixed PET Volume)

The applicant is the majority owner of Open MRI & Imaging of Asheville, a provider of diagnostic imaging services to Western North Carolina residents. Open MRI & Imaging of Asheville states that it will encourage its referring providers to use the new service and if it receives referrals for PET/CT scans, it will refer those patients to Novant Health’s proposed PET scanner.

The applicant states that Open MRI & Imaging of Asheville served 19,808 patients from HSA 1 in 2024, and those patients accounted for 97.41% of the patients it saw. The table below shows Open MRI & Imaging of Asheville’s market share for fixed MRI scans in Buncombe County in FY2020-2024.

Open MRI & Imaging of Asheville’s Fixed MRI Market, FY2020-2024						
	FY2020	FY2021	FY2022	FY2023	FY2024	FY20-24 Total
Asheville Open MRI Fixed MRI Scans	10,264	11,114	12,625	13,511	14,254	61,768
Total Buncombe County Fixed MRI Scans	29,027	33,954	38,191	39,890	39,228	180,290
Asheville Open MRI Market Share	35.36%	32.73%	33.06%	33.87%	36.34%	34.26%

Source: Section Q, page 125. 2022-Draft2026 SMFP, Chapter 15.

As shown in the table above, Open MRI & Imaging of Asheville market share for the period of FY20-24 was 34.26%. The applicant assumes that it will achieve 75% of Open MRI & Imaging of Asheville’s market share (34.26%) by its third year of operation (.75 x 34.26=25.70). The applicant states that this is reasonable given that both are part of the Novant Health system and will share a referral network and it is a lower market share than Messino Cancer Centers achieved in its first full fiscal year of operations.

The applicant states that it will achieve 50% of the year-three market share in the first year, 75% in the second year and 100% in the third year. The table below shows the ramp up of the

projected market share and applies the projected market share to the total HSA I fixed PET/CT scans projected in Step 4.

	Year 1	Year 2	Year 3
	2029	2030	2031
Fixed PET Scans in HSA I (Step 4)	8,278	8,939	9,652
Year 3 Market Share	25.70%	25.70%	25.70%
Percent of Year 3 Market Share	50%	75%	100%
NH Asheville PET Market Share	12.9%	19.3%	25.7%
NH Asheville PET Scans	1,064	1,723	2,481

Source: Section Q, page 126. 2022-Draft 2026 SMFP, Chapter 15.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant used PET scans for HSA I to project future utilization.
- The applicant assumes that future PET/CT scans in HSA I would grow at 75% of the 2020-2024 CAGR for PET/CT scans, which is 7.98%.
- The applicant uses Open MRI and Imaging of Asheville’s market share for fixed MRI scans to project its market share for fixed PET scans because they are both a part of the Novant Health system and will share a referral network.

All three competing applicants in this review provided comments questioning NH Asheville’s use of the fixed MRI market share of its affiliated fixed MRI provider in Buncombe County, Open MRI and Imaging of Asheville (Open MRI), to project market share of its proposed fixed PET scanner in operating year three. In addition, all three competing applicants provided comments stating that NH Asheville lacked a referral base for its proposed fixed PET services and that these issues do not support the applicant’s projected utilization. The Agency concludes that the applicant’s projected utilization of its proposed fixed PET scanner is reasonable based on the need discussed on pages 41-58 of the application which is summarized in these findings, and the following analysis:

- The applicant states, on page 56 of its application, that Open MRI has established relationships with many area physicians and advanced practice providers who refer their patients for imaging. The applicant further states that in 2024, Open MRI’s imaging services were provided to patients from 648 unique referring providers and provides a table on page 56 showing 40 specialties from which Open MRI received referrals in 2024. The Agency believes it is reasonable, based on publicly available information which states that MRI scans do detect tumors that may be cancerous and, in addition, that Open MRI has been in operation twenty years in Buncombe County, to conclude that Open MRI’s existing referral base, including primary care providers, would have relationships with other appropriate providers in the service area, including oncologists and neurologists, to which patients could be referred. In turn, those specialists would be able to order follow-up PET scans.
- The applicant provides support for its market share on page 126, citing Messino Cancer Centers’ experience in providing fixed PET services in Buncombe County as a non-hospital-based fixed PET services provider beginning in FFY2023 – in which its PET utilization increased from 192 PET procedures to 2,111 from FFY2023 (partial year) through FFY2024, respectively. The applicant states that its market share is lower than what Messino Cancer Center achieved in its first full year of operation, FFY2024, which was 36.5%.

- The applicant states, on page 50, its proposed PET scanner will not be tied to any one physician practice and that equal access will be provided to all physicians whose patients need a PET scan.
- The applicant provides a letter of support from Messino Cancer Centers, provided in Exhibit C-4.1, that indicates patients from its Center would be referred to the applicant’s PET services. The letter states, in part, *“If approved, Novant Health’s proposed PET scanner will give patients (including those referred by Messino Cancer Centers’ physicians) faster and more convenient access to essential treatment, helping ensure timely and seamless support for their personalized care plans.”*

Access to Medically Underserved Groups

In Section C, page 63, the applicant states:

“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will continue to have access to Novant Health Asheville PET/CT (NH Asheville PET) as clinically appropriate. Novant Health does not discriminate based on race, ethnicity, age, gender, or disability.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	N/A
Racial and ethnic minorities	4.9%
Women	43.8%
Persons with disabilities	N/A
Persons 65 and older	69.0%
Medicare beneficiaries	70.7%
Medicaid recipients	5.78%

Source: Section C, page 63.

The applicant states that the percentage of patients expected to be Medicare or Medicaid beneficiaries and the demographic mix for the proposed PET/CT scanner are based on calendar year 2024 data for outpatient PET/CT scans conducted on Mission Hospital’s fixed PT/CT scanner. The applicant states that it did not include Messino Cancer Center’s PET/CT data because it is not included in the HIDi database.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The use of Mission’s Hospital’s fixed PET/CT scanner demographic mix is reasonable given its location in Buncombe County.

- Novant Health has nondiscrimination policies in place and NH Asheville PET will operate under Novant Health's policies.
- In Section B, pages 29-34, the applicant explains how it will provide access to culturally competent healthcare.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in its existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive (Mission 5 Vanderbilt Park) in Asheville, Buncombe County. Mission has one existing PET scanner located at Mission Hospital Cancer Center (Mission Cancer Center) on Mission's main campus. The proposed second PET scanner will be located at approximately a 6-minute (2 mile) drive from Mission's main campus. The proposed unit will offer oncologic PET studies which are currently offered at Mission Cancer Center, as well as cardiac PET imaging that is currently not offered in the service area.

Patient Origin

On page 363, the 2025 SMFP defines the service area for a fixed PET scanner as "*the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*" The applicant proposes to locate the fixed PET scanner in Buncombe County, which is in HSA I. Thus, the service area for this facility is HSA I. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate the historical patient origin for Mission Cancer Center PET services and the projected patient origin for Mission-5 Vanderbilt Park and Mission Cancer Center.

Mission Cancer Center		
PET Services	Last Full FY CY2024	
County	# of Patients	% of Total
Buncombe	683	39.6%
Haywood	191	11.1%
Henderson	124	7.2%
McDowell	97	5.6%
Macon	86	5.0%
Madison	72	4.2%
Transylvania	54	3.1%
Jackson	52	3.0%
Yancey	42	2.4%
Mitchell	36	2.1%
Rutherford	24	1.4%
Burke	15	0.9%
Swain	14	0.8%
Polk	12	0.7%
Cherokee	9	0.5%
Caldwell	8	0.5%
Graham	6	0.3%
Clay	5	0.3%
Other NC Counties*	18	1.0%
Out of State	175	10.2%
Total	1,723	100.0%

Source: Section C, page 59.

*Other NC Counties include Avery, Catawba, Cleveland, Lincoln, Mecklenburg, Union, Watauga and Wayne Counties.

Mission – 5 Vanderbilt Park						
PET Services	1st Full FY		2nd Full FY		3rd Full FY	
	CY2028		CY2029		CY2030	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Buncombe	679	39.6%	777	39.6%	840	39.6%
Haywood	190	11.1%	217	11.1%	235	11.1%
Henderson	123	7.2%	141	7.2%	153	7.2%
McDowell	96	5.6%	110	5.6%	119	5.6%
Macon	86	5.0%	98	5.0%	106	5.0%
Madison	72	4.2%	82	4.2%	89	4.2%
Transylvania	54	3.1%	61	3.1%	66	3.1%
Jackson	52	3.0%	59	3.0%	64	3.0%
Yancey	42	2.4%	48	2.4%	52	2.4%
Mitchell	36	2.1%	41	2.1%	44	2.1%
Rutherford	24	1.4%	27	1.4%	30	1.4%
Burke	15	0.9%	17	0.9%	18	0.9%
Swain	14	0.8%	16	0.8%	17	0.8%
Polk	12	0.7%	14	0.7%	15	0.7%
Cherokee	9	0.5%	10	0.5%	11	0.5%
Caldwell	8	0.5%	9	0.5%	10	0.5%
Graham	6	0.3%	7	0.3%	7	0.3%
Clay	5	0.3%	6	0.3%	6	0.3%
Other NC Counties	18	1.0%	20	1.0%	22	1.0%
Out of State	174	10.2%	199	10.2%	215	10.2%
Total	1,715	100.0%	1,961	100.0%	2,120	100.0%

Source: Section C, page 60.

Mission Cancer Center and Mission – 5 Vanderbilt Park Combined						
PET Services	1st Full FY		2nd Full FY		3rd Full FY	
	CY2028		CY2029		CY2030	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Buncombe	1,411	39.6%	1,560	39.6%	1,678	39.6%
Haywood	395	11.1%	436	11.1%	469	11.1%
Henderson	256	7.2%	283	7.2%	305	7.2%
McDowell	200	5.6%	222	5.6%	238	5.6%
Macon	178	5.0%	196	5.0%	211	5.0%
Madison	149	4.2%	164	4.2%	177	4.2%
Transylvania	112	3.1%	123	3.1%	133	3.1%
Jackson	107	3.0%	119	3.0%	128	3.0%
Yancey	87	2.4%	96	2.4%	103	2.4%
Mitchell	74	2.1%	82	2.1%	88	2.1%
Rutherford	50	1.4%	55	1.4%	59	1.4%
Burke	31	0.9%	34	0.9%	37	0.9%
Swain	29	0.8%	32	0.8%	34	0.8%
Polk	25	0.7%	27	0.7%	29	0.7%
Cherokee	19	0.5%	21	0.5%	22	0.5%
Caldwell	17	0.5%	18	0.5%	20	0.5%
Graham	12	0.3%	14	0.3%	15	0.3%
Clay	10	0.3%	11	0.3%	12	0.3%
Other NC Counties	37	1.0%	41	1.0%	44	1.0%

Mission Cancer Center and Mission – 5 Vanderbilt Park Combined						
PET Services	1st Full FY		2nd Full FY		3rd Full FY	
	CY2028		CY2029		CY2030	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Out of State	361	10.2%	400	10.2%	430	10.2%
Total	3,559	100.0%	3,936	100.0%	4,233	100.0%

Source: Section C, page 61.

In Section C, page 59, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because the applicant projects its PET patient origin based on the historical patient origin for PET services at Mission. The applicant states that the historical percentage breakdown by county for FY2024 was used to disperse the projected PET scans for oncology PET services for the first three years by county to determine the total projected PET for the first three years of operation.

Analysis of Need

In Section C, pages 62-78, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- **2025 SMFP Need Determination.** The applicant states that Mission’s PET utilization drove the need for an additional fixed PET scanner as published in the 2025 SMFP.
- **There is Steady Population Growth and Significant Aging in the Service Area.** According to data from the North Carolina Office of State Budget and Management (NC OSBM), the service area is expected to grow by 3.4% from 2025 to 2030. The 65 and older population is projected to grow at the fastest rate of all age groups for that same period, with a total increase of 9.2%. The applicant states that oncologic and cardiac conditions are most common in middle-aged to elderly people and with this population growing significantly, the demand for PET services will increase accordingly.
- **There is a Diagnostic Deficit for Cardiology Patients in HSA I Despite Rising Unmet Need.** Heart disease and cancer are the two leading causes of death in North Carolina and within Buncombe County. The applicant states that Cardiac PET has emerged as a vital diagnostic tool for evaluating coronary artery disease (CAD), assessing myocardial perfusion and viability, and guiding complex cardiovascular treatment planning. The applicant states that 13 of the 18 counties in the service area have heart disease death rates that exceed both the state and national averages. The applicant states that in HSA I and across the state, access to PET remains disproportionately skewed towards oncology-focused providers, limiting availability for other specialties, especially cardiology. The applicant states that cardiac PET capabilities are needed in HSA I to support optimal diagnostic evaluation and improve outcomes for high-risk cardiac patients.
- **There is a Growing Incidence of Cancer in the State and Service Area.** Cancer incidence and mortality rates exceed the state average in eight counties in HSA I. The applicant states that PET remains the standard for care in diagnosing, staging and monitoring cancers. The applicant states that the demand for oncology PET is substantial and continues to rise, driven by increasing cancer incidence and a growing reliance on advanced molecular imaging to inform treatment decisions.

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2025 SMFP for one additional PET scanner in HSA I, which includes Buncombe County.
- The applicant provided reasonable and clearly identified information to support the need for a fixed PET scanner at its HOPD in Buncombe County based on the existing and projected incidence of diseases for which patients benefit from PET services in the service area.
- The applicant used reasonable and clearly identified demographic data to make assumptions supporting identification of the population to be served, the projected growth of that population, and the need the identified population has for the proposed PET services.

Projected Utilization

In Section Q, Forms C.2a and C.2b, pages 140-143, the applicant provides historical and projected utilization, as illustrated in the following tables.

Mission Cancer Center Historical and Interim Utilization				
	Last Full FY	Interim Full FY	Interim Full FY	Partial Interim FY
	CY2024	CY2025	CY2026	01/01/2027 to 06/30/2027
# PET scanners	1	1	1	1
# of Procedures	1,723	1,826	1,936	1,001

Source: Section Q, Forms C.2a, page 140.

Mission Cancer Center Projected Utilization				
	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	07/01/2027 to 12/31/2027	CY2028	CY2029	CY2030
# PET scanners	1	1	1	1
# of Procedures	899	1,846	1,975	2,113

Source: Section Q, Form C.2b, page 141.

Mission – 5 Vanderbilt Park Projected Utilization				
	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	07/01/2027 to 12/31/2027	CY2028	CY2029	CY2030
# PET scanners	1	1	1	1
# of Procedures	524	1,713	1,961	2,120

Source: Section Q, Form C.2b, page 142.

In Section Q, pages 144-149, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant proposes to develop one fixed PET scanner at an HOPD located in Asheville pursuant to the need determination in the 2025 SMFP for one additional PET scanner in HSA I. Currently, Mission Hospital has one existing fixed PET scanner located at the hospital’s main campus in Asheville.

The proposed PET unit is expected to be operational by July 1, 2027, and the first three full years of operations are CY2028-2030.

The applicant projected PET service utilization for the existing and the proposed PET units.

Step 1: Review Historical Mission PET/CT Utilization

Mission has consistently exceeded the SMFP PET performance of 2,080 scans per scanner. Mission experienced a slight decline in PET volume beginning in CY2023, coinciding with the opening of Messino Cancer Center’s PET scanner. AdventHealth Hendersonville is expected to bring a PET scanner online in CY2025. The applicant does not expect this addition to impact Mission’s PET volumes because AdventHealth does not have medical staff working with or referring PET patients to Mission.

The table below shows Mission Hospital’s Cancer Center PET scanner utilization from CY2018 through annualized CY2025.

Figure1: Mission Cancer Center – Historical PET Scan Volume								
	CY2018	CY2019	CY2020	CY2021	CY2022	CY2023*	CY2024	CY2025** Annualized
Mission PET CT Scans	2,261	2,586	2,611	2,826	2,946	2,735	1,723	1,826

Source: Section Q, page 145

*Messino PET scanner came online in 2023.

**CY2025 is annualized based on 5 months of actual data.

The table below shows the combined volume of Mission Hospital and Messino Cancer Center’s PET units.

Figure 2: Historical Service Area PET Utilization Trend (FY-SMFP)						
SMFP	2022	2023	2024	2025	Draft 2026	
Data Year	FY2020	FY2021	FY2022	FY2023	FY2024	FY2020- FY2024 CAGR %
Mission	2,695	2,808	2,919	2,862	1,893	
Messino	-	-	-	195	2,111	
Total	2,695	2,808	2,919	3,057	4,004	10.4%
Annual Growth		4.2%	4.0%	4.7%	31.0%	

Source: Section Q, page 145 and 2022-Draft 2026 SMFPs.

The applicant states that Mission’s annualized CY2025 utilization is on track to reflect a 6.0% growth rate even with the shift of Messino oncology referrals in FY2023 and FY2024 because Mission’s demand for PET scans in oncology, cardiac, and neurology is increasing.

The table below shows the growth trends in PET/CT scans.

Figure 3: Growth Trends in PET/CT Scans	
Mission 2024-2025 Growth Rate	6.0%
Service Area Fixed Scanners (2020-2024)	10.4%
Statewide Rate	15.0%

Source: Section Q, page 146.

Step 2: Mission Baseline PET Projections

The applicant applied a CAGR of 7% to its annualized CY2025 PET volumes to establish a baseline projection. The applicant states the projected growth rate of 7% is conservative given the service area growth rate of 10.4% and statewide growth in demand of 15%. The table below shows the total volume of oncology and neurology PET patients to be served during the Interim Years and Project Years 1-3.

Figure 4: Mission Baseline Projected PET/CT Scans (Oncology and Neurology)							
	CY2025	CY2026	CY2027	CY2028	CY2029	CY2030	Projected CAGR
Mission Baseline PET CT Scans (Oncology and Neurology)	1,826	1,954	2,091	2,237	2,394	2,562	7.0%

Source: Section Q, page 146.

Step 3: Cardiac PET Projections

The applicant states that cardiac PET services are currently not offered by any providers in HSA I. The applicant looked at the 2025-2031 population projections obtained from NC OSBM and the Advisory Board rates to project potential utilization.

To calculate projected cardiac cases for the service area, the applicant multiplied the population of the corresponding year by the appropriate Advisory Board rate and divided it by 100,000. The Advisory Board provides cardiac PET use rates for 2024, 2029 and 2034. The applicant estimated the interim year use rates based on the Advisory Board’s growth rate. The applicant used one half of the estimated 2027 rate to reflect the fact that Mission’s proposed cardiac PET scanner would be online for just half of CY2027.

The applicant applied a projected capture rate to these cardiac cases to determine Mission’s expected cardiac PET utilization. Mission is the only provider of tertiary cardiac services in western North Carolina. Therefore, Mission serves the majority of cardiac-related patients in the region. (Example for 2028: 1,676 demand x 70% capture rate = 1,174 scans)

The applicant includes 1.0% volume from Other NC Counties and 10.2% from Out of State based on Mission’s FY2024 patient origin to account for in-migration.

Figure 5: Project Cardiac PET/CT Scans				
	Partial Year	First Full FY	2nd Full FY	3rd Full FY
	7/1 - 12/31/2027	CY2028	CY2029	CY2030
Population	959,657	966,017	972,251	978,449
Advisory Board Rate	0.88	1.74	1.76	1.78
Cases	844	1,676	1,711	1,746
Capture Rate*	35.0%	70.0%	80.0%	85.0%
Mission Cases	296	1,174	1,369	1,484
Other NC	3	14	16	17
Out of State	34	134	157	170
Total Service Area	333	1,322	1,542	1,671

Source: Section Q, page 147.

*Capture rate for 2027 reflects ramp up and partial year of operation.

Step 4: Summary of Total PET Projected Utilization by Location

The table below shows the combined projected baseline scans (oncology and neurology) and cardiac PET projections.

Figure 6: Mission Total Projected Utilization				
	Interim	First Full FY	2nd Full FY	3rd Full FY
	7/1/2027 - 12/31/2027	CY2028	CY2029	CY2030
Baseline Scans (Oncology and Neurology)	1,090	2,237	2,394	2,562
Cardiac PET Scans	333	1,322	1,542	1,671
Total Scans	1,423	3,559	3,936	4,233
Performance Standard				4,160

Source: Section Q, page 148.

The applicant states that the existing PET at Mission Cancer Center will continue to serve oncology and neurology patients. The proposed PET scanner at Mission 5 Vanderbilt Park will primarily focus on serving cardiac PET scans but will also serve oncology and neurology when necessary. The applicant projects that 17.5% of Oncology/Neurology scans will shift to the new proposed PET scanner. The table below summarizes the utilization for the existing PET scanner at Mission Cancer Center and the proposed PET scanner at Mission 5 Vanderbilt Park.

Figure 7: Mission Health System Summary of Projected PET Utilization by Location			
	1st Full FY CY2028	2nd Full FY CY2029	3rd Full FY CY2030
Mission Cancer Center			
Projected Oncology/Neurology PET/CT Scans	2,237	2,394	2,562
% Redirection to Mission 5 Vanderbilt Park	17.5%		
PET/CT Scans Shifted Mission 5 Vanderbilt Park	392	419	448
PET/CT Scans Remaining at Mission Cancer Center	1,846	1,975	2,113
Mission 5 Vanderbilt Park			
PET/CT Scans Redirected from Mission Cancer Center	392	419	448
Projected New Cardiac PET/CT Scans	1,322	1,542	1,671
Total Mission 5 Vanderbilt Park PET/CT Scans	1,713	1,961	2,120
Total Mission Health System PET Scans	3,560	3,936	4,233
Number of Units	2	2	2

Source: Section Q, page 148.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant used the historical utilization at Mission to project future utilization.
- The applicant assumes a CAGR of 7%, which is less than the service area growth rate in PET scans of 10.4% and the statewide growth in demand of 15%.
- The proposed PET scanner will mainly be focused on service cardiac PET scans. However, the applicant projects that 17.5% of Oncology/Neurology PET procedures will shift from Mission Cancer Center to the proposed fixed PET scanner.

In response to comments made by the other applicants in this review, the applicant states that it did consider the PET service under development at AdventHealth Hendersonville and determined there would not be an impact on its projected utilization because of each hospital’s physician referral base. In addition, in response to comments regarding the reasonableness of its cardiac PET market share, the applicant states that Mission is the only provider in the region that provides open heart surgery and EP studies and would be the only provider providing cardiac PET services.

Considering the need determination in the 2025 SMFP, the applicant’s analysis of need on pages 62-78, growth of PET scans in the service area, and its responses to comments, the Agency concludes that the applicant’s projected utilization is reasonable and adequately supported.

Access to Medically Underserved Groups

In Section C, page 84, the applicant states:

“Mission Hospital provides services to all people in need of medical care regardless of race, color, religion, nationality, or ability to pay. Additionally, as the only trauma center in the region and a safety net hospital, Mission Hospital serves many underserved and uninsured individuals.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons*	79.7%
Racial and ethnic minorities	4.4%
Women	43.5%
Persons with Disabilities+	Not Available
Persons 65 and older	69.3%
Medicare beneficiaries	65.5%
Medicaid recipients	5.2%

Source: Section C, page 85.

*Includes Self-Pay/Charity and Medicaid Patients

+Data not tracked

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant has a facility in the service area currently providing PET services to residents in the service area including underserved groups.
- In Section B, pages 32-46, the applicant explains how it will provide access to culturally competent healthcare.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire a fixed PET scanner at AdventHealth Asheville pursuant to the 2025 SMFP need determination which is a change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds).

AdventHealth Asheville is conditionally approved to develop a new acute care hospital with 93 acute care beds in Weaverville in Buncombe County. The project is currently under appeal. The proposed fixed PET service is the only service component proposed in this application. The proposed service will be developed in an outpatient building located on the campus of

AdventHealth’s conditionally approved hospital in Weaverville and the proposed fixed PET scanner will operate under the license of the conditionally approved hospital.

If the proposed project is approved, it will be AdventHealth’s second fixed PET scanner in HSA I. AdventHealth Hendersonville is approved to develop a fixed PET scanner at its hospital in Henderson County (Project ID# B-12331-23). The applicant states that the project is currently under development and expected to become operational in 2026.

Patient Origin

On page 363, the 2025 SMFP defines the service area for a fixed PET scanner as “the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” Thus, the service area for this facility is HSA I. Facilities may also serve residents of counties not included in their service area.

The applicant does not provide fixed PET services at AdventHealth Asheville. Therefore, there is no historical patient utilization.

The following table illustrates projected patient origin.

AdventHealth Asheville						
Fixed PET Scanner	1st Full FY		2nd Full FY		3rd Full FY	
	CY2029		CY2030		CY2031	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Avery	0	0.0%	10	0.7%	21	1.0%
Buncombe	307	34.9%	496	34.3%	712	34.0%
Cherokee	16	1.8%	35	2.4%	56	2.7%
Clay	7	0.8%	14	1.0%	23	1.1%
Graham	8	1.0%	13	0.9%	19	0.9%
Haywood	69	7.9%	111	7.7%	159	7.6%
Henderson	202	23.0%	290	20.0%	390	18.7%
Jackson	49	5.5%	78	5.4%	112	5.4%
Macon	21	2.4%	45	3.1%	73	3.5%
Madison	46	5.3%	62	4.3%	80	3.8%
McDowell	23	2.7%	50	3.4%	80	3.8%
Mitchell	15	1.7%	24	1.7%	34	1.6%
Polk	10	1.2%	22	1.5%	35	1.7%
Rutherford	34	3.9%	73	5.1%	117	5.6%
Swain	14	1.6%	23	1.6%	32	1.5%
Transylvania	0	0.0%	19	1.3%	40	1.9%
Yancey	39	4.4%	52	3.6%	67	3.2%
Other*	18	2.0%	29	2.0%	42	2.0%
Total	880	100.0%	1,447	100.0%	2,091	100.0%

Source: Section C, page 72.

*Other includes the remaining counties in HSA I and other states.

In Section Q, pages 122-135, the applicant provides the assumptions and methodology used to project its patient origin. However, the applicant's assumptions and methodology are not reasonable and adequately supported.

Two competing applicants in this review provided comments questioning the reasonableness of the applicant's patient origin since it includes patients from counties that are closer to its approved, but yet to be developed, PET scanner in Henderson County. Given the location of the approved AdventHealth Hendersonville PET scanner in Henderson County and the location of the AdventHealth Asheville hospital in Weaverville in northern Buncombe County, which based on its most recently approved change of scope application and the existing PET scanners in Asheville in Buncombe County, it is not reasonable to project that a total of nearly 31 percent of AdventHealth Asheville's PET patients will come from Rutherford, Macon, Transylvania, Polk and Henderson counties. Patients from those counties would have to bypass the PET scanner at AdventHealth Hendersonville which the applicant states will be operational in 2026 or bypass two existing PET scanners in Asheville to receive PET scans at AdventHealth Asheville in northern Buncombe County.

Therefore, the Agency concludes that the applicant's patient origin of its proposed fixed PET scanner is not reasonable and adequately supported.

Analysis of Need

In Section C, pages 49-70, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- **2025 SMFP Need Determination.** The applicant states that the utilization of fixed PET scanners within HSA I during FY2023 resulted in the need determination for one fixed PET scanner in HSA I and any person can apply for the CON to meet the need, not just the health service facility or facilities that generated the need.
- **Increasing Demand for PET Services.** According to data from the North Carolina Office of State Budget and Management (NC OSBM), from FY2016 through FY2024, the statewide PET utilization rate increased by more than 70 percent, rising from 4.46 to 7.60 PET procedures per 1,000 population. The applicant states that PET imaging volume in HSA I has experienced growth driven by expanding clinical applications, rising provider demand and broader patient access to fixed PET services. The applicant states that the number of fixed PET procedures in HSA I has increased by 46% between FY2021 and FY2024.
- **Geographic Access.** The applicant states that the existing and approved fixed PET scanners within HSA I are concentrated in the southern and eastern portions of the region and this creates a geographic gap in access for residents of the more remote northwestern counties. Patients in these areas must travel significant distances to access PET imaging which contributes to delayed diagnosis, missed appointments, and disparities in access to time-sensitive imaging for cancer, neurological and cardiac conditions.
- **Population Demographics.** The NC OSBM projects the total population of the service area will grow at a CAGR of 0.7 percent over the next six years. The population age 65+ is expected to grow at a CAGR of 1.6 percent over the next six years, more than double the total population growth rate. PET scans are most frequently used to diagnose and monitor

conditions that disproportionately affect older adults, including cancer, cardiac disease and neurodegenerative disorders.

Cancer remains the most common clinical indication for PET imaging and rising cancer incidence will directly contribute to increasing demand for PET services. The applicant states that many of the counties in HSA I cancer incidence rates exceed the statewide average and this underscores the need for expanded access to fixed PET imaging in HSA I. Many of the counties in HSA I report heart disease mortality rates higher than the statewide average. The applicant states that the demand for PET imaging for cardiac indications is expected to increase across the service area given the high burden of heart disease combined with the aging population. The applicant states that several counties in HSA I exhibit Alzheimer’s prevalence rates near or above the statewide average of 11.6% for adults age 65 and older. PET imaging plays an important role in the evaluation of Alzheimer’s disease. The applicant states that the correlation between age and Alzheimer’s disease, combined with increasing access to PET imaging, supports the need for expanded PET capacity.

However, the information is not reasonable and adequately supported because although the applicant discusses the need for a PET scanner to serve residents in more remote northwestern counties to address a gap in PET services access, it does not discuss why over 30 percent of its projected patients from southern and western counties would bypass its approved PET scanner in Henderson County and two existing PET scanners in central Buncombe County to receive PET scans. Therefore, the applicant does not adequately support the need its identified population has for the proposed PET services.

Projected Utilization

In Section Q, Forms C.2b, pages 120-121, the applicant provides projected utilization, as illustrated in the following tables.

The following table provides projected utilization for the proposed fixed PET scanner.

AdventHealth Asheville Projected Utilization			
	1st Full FY	2nd Full FY	3rd Full FY
	CY2029	CY2030	CY2031
# PET scanners	1	1	1
# of Procedures	880	1,447	2,091

Source: Section Q, Forms C.2b, page 120.

The following tables provide projected utilization for the approved fixed PET scanner under development at AdventHealth Hendersonville.

AdventHealth Hendersonville Projected Utilization			
	Partial Year	1st Full FY	2nd Full FY
	CY2026	CY2027	CY2028
# PET scanners	1	1	1
# of Procedures	456	858	1,457

Source: Section Q, Forms C.2b, page 121.

AdventHealth Hendersonville Projected Utilization			
	3rd Full FY: CY2029	CY2030	CY2031
# PET scanners	1	1	1
# of Procedures	2,124	2,124	2,124

Source: Section Q, Forms C.2b, page 121.

In Section Q, pages 122-135, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant proposes to develop one fixed PET scanner at its conditionally approved hospital campus in Buncombe County, AdventHealth Asheville.

Step 1: Population Projections

The applicant reviewed the population projections for the counties in HSA I for 2025 through 2031 based on data from the NCOSBM.

Step 2: PET Procedure Use Rate

The applicant examined the statewide PET utilization rate from FY2016 to FY2024, calculated using annual PET procedure volumes reported in the SMFP and population estimates published by the NC OSBM. The applicant states that statewide PET utilization rate increased by more than 70 percent, rising from 4.46 to 7.60 PET procedures per 1,000 population.

North Carolina PET Use Rate				
Fiscal Year	State Population	Number of PET Procedures	PET Use Rate/1000	PET Use Rate/1,000 % Change
FY2016	10,080,436	45,006	4.46	6.8%
FY2017	10,181,491	48,066	4.72	5.7%
FY2018	10,284,335	52,167	5.07	7.4%
FY2019	10,381,670	54,416	5.24	3.3%
FY2020*	10,472,893	50,572	4.83	-7.9%
FY2021	10,573,149	54,837	5.19	7.4%
FY2022	10,702,014	63,698	5.95	14.8%
FY2023	10,846,274	77,351	7.13	19.8%
FY2024	10,978,531	83,406	7.60	6.5%

Source: Section Q, page 123.

*Utilization and use rate were negatively impacted by COVID-19 public health emergency.

The applicant states that the statewide PET use rate serves a practical and evidenced based benchmark for projecting future PET volumes in regional markets. The statewide PET use rate increased by a rate of 6.5% from FY2023 to FY2024. Therefore, the applicant projects the statewide PET use rate will increase by a rate of 6.5%, illustrated as follows:

North Carolina PET Procedure Use Rate (per 1,000 population)							
	2025	2026	2027	2028	2029	2030	2031
PET Use Rate	8.09	8.62	9.18	9.78	10.42	11.10	11.83

Source: Section Q, page 125.

Step 3: Projected PET Procedure Demand Based on PET Use Rate

The following table projects future PET scan procedure based on the statewide PET use rate applied to the projected population of the respective counties.

Projected PET Procedure Demand Based on PET Use Rate			
County	2029	2030	2031
Alexander	383	409	436
Alleghany	122	130	139
Ashe	277	295	314
Avery	183	195	208
Buncombe	3,074	3,308	3,560
Burke	957	1,020	1,087
Caldwell	866	923	984
Catawba	1,849	1,990	2,142
Cherokee	324	348	373
Clay	132	143	154
Cleveland	1,087	1,166	1,249
Graham	84	90	95
Haywood	693	743	797
Henderson	1,346	1,450	1,561
Jackson	485	521	560
Macon	420	452	486
Madison	232	248	266
McDowell	467	498	530
Mitchell	151	160	170
Polk	207	220	234
Rutherford	687	732	780
Swain	141	150	160
Transylvania	354	378	403
Watauga	575	612	652
Wilkes	699	746	796
Yancey	195	208	222
Total*	8,994 [15,990]	9,649 [17,135]	10,351 [18,358]

Source: Section Q, page 126.

Note: Formula (Step 1 Population ÷ 1000) x Step 2 PET Use Rate

*Applicant's numbers appear to be a typographical error. Corrected numbers are shown in brackets.

Step 4: AdventHealth Asheville PET Market Share

The applicant states that its PET market share projections are grounded in a thorough analysis of historical utilization patterns, demonstrated patient origin data, geographic access gaps and provider alignment trends within HSA I. The applicant states that its projected PET market share reflects an evidence-based approach that accounts for geographic access, anticipated referral patterns, population growth and documented support. The applicant states that it anticipates steady growth in PET utilization across 22 counties with strong adoption in counties that have historically experienced limited access to fixed PET services (i.e., Madison and Yancey Counties).

Projected PET Market Share			
County	2029	2030	2031
Avery	0.0%	5.0%	10.0%
Buncombe	10.0%	15.0%	20.0%
Cherokee	5.0%	10.0%	15.0%
Clay	5.0%	10.0%	15.0%
Graham	10.0%	15.0%	20.0%
Haywood	10.0%	15.0%	20.0%
Henderson	15.0%	20.0%	25.0%
Jackson	10.0%	15.0%	20.0%
Macon	5.0%	10.0%	15.0%
Madison	20.0%	25.0%	30.0%
McDowell	5.0%	10.0%	15.0%
Mitchell	10.0%	15.0%	20.0%
Polk	5.0%	10.0%	15.0%
Rutherford	5.0%	10.0%	15.0%
Swain	10.0%	15.0%	20.0%
Transylvania	0.0%	5.0%	10.0%
Yancey	20.0%	25.0%	30.0%

Source: Section Q, page 131.

Step 5: AdventHealth Hendersonville [Asheville] Fixed PET Procedures

The following table summarizes AdventHealth Asheville’s projected fixed PET procedures based on the projected annual market share (Step 4) applied to the projected PET demand (Step 3).

AdventHealth Asheville Fixed PET Procedures			
County	2029	2030	2031
Avery	0	10	21
Buncombe	307	496	712
Cherokee	16	35	56
Clay	7	14	23
Graham	8	13	19
Haywood	69	111	159
Henderson	202	290	390
Jackson	49	78	112
Macon	21	45	73
Madison	46	62	80
McDowell	23	50	80
Mitchell	15	24	34
Polk	10	22	35
Rutherford	34	73	117
Swain	14	23	32
Transylvania	0	19	40
Yancey	39	52	67

Source: Section Q, page 132.

Formula: Step 4 Market Share x Step 3 Projected PET Procedure Demand

Existing fixed PET providers in the county routinely serve patients from outside HSA I due to Buncombe County’s geographic proximity to both Tennessee and South Carolina, as well as seasonal travel patterns and the area’s status as a regional destination for care. The applicant states that historically, approximately 2.2% of patients receiving care at Mission Hospital and 2.4% of patients at Messino Cancer Centers originated from outside HSA I. Therefore, the applicant projects 2.0% in-migration for its proposed fixed PET scanner at AdventHealth Asheville.

AdventHealth Asheville Projected Fixed PET Procedures During First Three Project Years			
County	2029	2030	2031
Avery	0	10	21
Buncombe	307	496	712
Cherokee	16	35	56
Clay	7	14	23
Graham	8	13	19
Haywood	69	111	159
Henderson	202	290	390
Jackson	49	78	112
Macon	21	45	73
Madison	46	62	80
McDowell	23	50	80
Mitchell	15	24	34

AdventHealth Asheville			
Projected Fixed PET Procedures During First Three Project Years			
County	2029	2030	2031
Polk	10	22	35
Rutherford	34	73	117
Swain	14	23	32
Transylvania	0	19	40
Yancey	39	52	67
Subtotal	862	1,418	2,050
In-migration (2.0%)	18	29	42
Total	880	1,447	2,091

Source: Section Q, page 132.

Formula: Step 4 Market Share x Step 3 Projected PET Procedure Demand

AdventHealth Hendersonville is approved to develop a fixed PET scanner at its hospital in Henderson County (Project ID# B-12331-23). This project is currently under development and expected to become operational in 2026.

The following table shows the projected fixed PET scanner utilization for AdventHealth Hendersonville submitted as part of Project ID# B-12331-23.

AdventHealth Hendersonville				
Approved Fixed PET Utilization				
	Partial Year	Year One	Year Two	Year Three
	2026	2027	2028	2029
Fixed PET Procedures	456	858	1,457	2,124

Source: Project ID# B-12331-23 AdventHealth Hendersonville CON Application and provided in Section Q, page 134.

The applicant has held projected utilization constant at 2,124 procedures annually.

AdventHealth Hendersonville	
Fixed PET Procedures	
Year	Fixed PET Procedures
2026	456
2027	858
2028	1,457
2029	2,124
2030	2,124
2031	2,124

Source: Section Q, page 135.

However, projected utilization is not reasonable and adequately supported based on the following:

Two competing applicants in this review provided comments questioning the reasonableness of the applicant’s patient origin since it includes patients from counties that are closer to its approved, but yet to be developed, PET scanner in Henderson County. Given the location of the approved AdventHealth Hendersonville PET scanner in Henderson County and the location of the AdventHealth Asheville hospital in Weaverville in northern Buncombe County, which

based on its most recently approved change of scope application and the existing PET scanners in Asheville in Buncombe County, it is not reasonable to project that a total of nearly 31 percent of AdventHealth Asheville's PET patients will come from Rutherford, Macon, Transylvania, Polk and Henderson counties. Patients from those counties would have to bypass the PET scanner at AdventHealth Hendersonville which the applicant states will be operational in 2026 or bypass two existing PET scanners in Asheville to receive PET scans at AdventHealth Asheville in northern Buncombe County.

Since patient origin is not reasonable, the numbers of PET procedures (one PET procedure equals one patient) projected to be performed in each of the first three operating years after project completion are also not reasonable. While it is conceivable that some patients from Rutherford, Macon, Transylvania, Polk and Henderson counties may receive PET scans at AdventHealth Asheville, it is not reasonable to project that nearly 31 percent of the procedures, or 655, will come from those counties. The applicant projects it will perform a total of 2,091 PET procedures in the third full operating year after project completion. Therefore, if only 12 or more patients from those counties receive their PET procedure at any of the three closer PET locations, the applicant will not meet the required performance threshold of 2,080 PET procedures in the third operating year.

Therefore, the Agency concludes that the applicant's projected utilization of its proposed fixed PET scanner is not reasonable and adequately supported.

Access to Medically Underserved Groups

In Section C, page 73, the applicant states:

“Access by medically underserved groups is not expected to be different from what was projected in the previously approved applications because AdventHealth does not propose a change to the scope of inpatient acute care services.

All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will have access to AdventHealth Asheville, including the proposed fixed PET scanner, as clinically appropriate. AdventHealth does not discriminate based on race, ethnicity, age, gender, or disability.”

The applicant states, in Section C, page 73, that it does not expect access by medically underserved groups to be different from what was projected in its previously approved application.

However, the applicant does not adequately describe the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services because the applicant's percentages of medically underserved groups include a significant percentage of patients originating from counties that are closer to its approved PET scanner in Henderson County and to two existing PET scanners in Asheville, Buncombe County. Since that is not reasonable and adequately supported, the applicant's estimated percentages are questionable.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA – All Applications

None of the applicants propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C
UNC Health Pardee
Novant Health
Mission Hospital

NC
AdventHealth

Project ID # B-12675-25 / Margaret R. Pardee Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner to be located on the main campus of UNC Health Pardee.

In Section E, pages 71-72, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- **Maintain the Status Quo.** The applicant currently uses a contracted mobile PET unit provided by Alliance. The applicant states that it could continue to rely exclusively on the

- mobile PET unit. The applicant states that its patients have faced extended wait times of two weeks or longer due to the limited hours which is particularly problematic for oncology patients where imaging is often critical to treatment schedules and outcomes. The applicant states that the current routing process to the mobile unit is especially burdensome for elderly patients and patients with limited mobility. The applicant states the demand for PET imaging will continue to increase given the growth in the age 65 and older population in HSA I. Therefore, maintaining the status quo is a less effective alternative.
- **Develop the PET Scanner at Another Location.** The applicant states that it considered developing the fixed PET scanner at another location other than the main hospital campus. The applicant states UNC Health Pardee's main campus houses the only comprehensive cancer center in Henderson County, which represents a primary source of referrals for PET imaging. The applicant states that separating PET services from the cancer center would unnecessarily complicate care coordination and force patients to travel to multiple locations for comprehensive treatment. The applicant states that patients of UNC Health Pardee's cardiology and neurology programs would also utilize the proposed fixed PET scanner and would similarly be impacted with regards to continuity of care. The applicant states that developing the fixed PET scanner at an alternate location would require either significant renovations of existing UNC Health Pardee facilities not designed for PET imaging or construction of a new facility specifically to house the PET scanner. The applicant states that both options would be more resource-intensive than utilizing the identified space at the main hospital campus. Therefore, developing the PET scanner at another location would be a more costly and less effective alternative.

On pages 71-72, the applicant states that its proposal is the most effective alternative because it will allow for coordination of care for patients treated at its cancer center as well as patients of its cardiology and neurology programs and it is more cost effective to use the space identified at the main hospital campus than an alternate location which would require significant renovation or construction of a new facility.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in a MOB in Arden, Buncombe County.

In Section E, pages 73-74, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- **Obtain a Different PET/CT Scanner.** The applicant considered other PET/CT scanners before choosing the Siemens Biograph Vision 450. The applicant states that it consulted with area radiologists and chose the Siemens Biograph Vision because it satisfies the basic principles of the SMFP, including promotion of safety, delivery of high-quality services and provision of the full scope of PET/CT services. Therefore, this is a less effective alternative.
- **Develop the Proposed Scanner at a Different location Within HSA I.** The applicant states that it considered locating the proposed PET scanner at a site outside of Arden/the greater Asheville area. The applicant states that Arden is within a 90-minute drive for many residents in HSA I and the MOB where the proposed PET scanner will be located is easily accessible to major area thoroughfares. In addition, Buncombe County and the Asheville Area serve as the major commercial and healthcare hub in western North Carolina. Therefore, this is a less effective alternative.
- **Not Develop the Project (Maintain the Status Quo).** The applicant states that it rejected this alternative because it would not meet the additional need for a fixed PET scanner identified in the 2025 SMFP. The applicant state that this alternative would not address the current scheduling delays or offer residents another non-hospital based, new provider in the area. Therefore, this is a less effective alternative.

On page 74, the applicant states that its proposal is the most effective alternative because it will offer area residents another non-hospital based, new provider in the area and the MOB where the proposed PET scanner will be located is easily accessible to major area thoroughfares.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in its existing HOPD in Asheville, Buncombe County for no more than two fixed PET scanners in HSA I.

In Section E, pages 95-96, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- **Maintain the Status Quo.** The applicant could have decided that it would continue only providing PET scans on the current scanner located at the Mission Cancer Center. However, the scheduling difficulties that patients and providers currently face would continue to be an issue and would worsen as demand grows for PET services without access to additional PET scanner capabilities. Therefore, maintaining the status quo is not an effective alternative.
- **Placing a New PET Scanner Within Mission Hospital.** The applicant states that there is available space in Mission Hospital for an additional PET scanner. However, the applicant determined that this option is not the most cost-effective alternative. The applicant states that locating the proposed PET scanner within the existing hospital's imaging suite would require a much larger and more costly renovation than the proposed project due to the constraints of existing building infrastructure. Additionally, the path of installation for the PET scanner at the hospital would be much greater in comparison to the proposed location and trigger the requirement to comply with NC building code I-2 Construction and the *Guidelines for Design and Construction of Hospitals*. The applicant states that locating an ambulatory service within the inpatient setting adds to the challenges of parking and navigating a large building, which negatively impacts patient access and patient experience. Therefore, the applicant determined that locating a fixed PET scanner within Mission Hospital would be less effective and a more costly alternative.
- **Placing a New PET Scanner at Mission Cancer Center.** The applicant considered placing the proposed PET scanner at Mission Cancer Center. However, this location would not be able to serve the growing utilization of PET scans in the diagnosis of heart disease. The applicant states that Mission Cancer Center does not have additional space to conduct stress testing associated with these scans, while cancer related PET scans may be

performed in the cardiovascular setting as all the appropriate resources would be available. Therefore, this is a less effective alternative.

On page 96, the applicant states that its proposal is the most effective alternative because placing the proposed PET scanner at Mission 5 Vanderbilt Park Drive was determined to be the most patient-centric and cost-effective alternative site. The applicant states that the facility is adjacent to the main Asheville Cardiology Associates clinic, providing patients and providers with convenient access to a full complement of advanced cardiovascular diagnostic imaging and there is space in the facility to accommodate a PET scanner and associated support functions, thereby not requiring new construction and minimizing necessary renovations.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire a fixed PET scanner at AdventHealth Asheville pursuant to the 2025 SMFP need determination which is a change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds).

In Section E, pages 80-81, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- **Maintain the Status Quo.** The applicant could have decided that it would not pursue development of a fixed PET scanner. The applicant states that maintaining the status quo is inconsistent with the 2025 SMFP and would deny patients timely, convenient access to

fixed PET services and fail to address the capacity shortfall identified by the state. Therefore, maintaining the status quo is not an effective alternative.

- **Develop a Fixed PET Scanner at Another Location.** Another alternative is to develop a fixed PET scanner in another location in HSA I. The applicant states that developing the fixed PET scanner at another location would create operational inefficiencies and increase development costs, as it would require duplicative site preparation, infrastructure investments and staffing resources. Therefore, the applicant determined that locating a fixed PET scanner at another location would be less effective and a more costly alternative.

On page 81, the applicant states that its proposal is the most effective alternative because co-locating PET services at the AdventHealth Asheville hospital allows for economies of scale, optimized resource utilization, and enhanced patient convenience, particularly for those undergoing complex diagnostic workups or preparing for treatment planning.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant did not adequately demonstrate the need it has for the proposed project, including patient origin, projected utilization, and access to medically underserved groups is based on reasonable and adequately supported assumptions. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. A proposal that does not adequately demonstrate the need it has for the proposed project cannot be the most effective alternative.
- The applicant did not demonstrate in the application as submitted that it was conforming with the Criteria and Standards for Positron Emission Tomography Scanner promulgated in 10A NCAC 14C .3700(a). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. A proposal that cannot meet required performance standards cannot be the most effective alternative.
- The application is not conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

UNC Health Pardee
Novant Health
Mission Hospital

NC
AdventHealth

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner to be located on the main campus of UNC Health Pardee.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 118, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contract(s)	\$2,005,500
Architect/Engineering Fees	\$280,500
Medical Equipment	\$1,686,505
Furniture	\$28,600
Consultant Fees (Program Manager, Equipment Planner)	\$130,737
Other (IS Equip, Moving, Permitting, 10% Project Contingency)	\$281,160
Total	\$4,413,002

In Section Q, page 119, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Construction and architect/engineering costs are based on the experience of the of the project architect with similar projects.
- Medical equipment and furniture costs are based on vendor quotes and the experience of UNC Health Pardee with similar projects.
- Other fees including IS equipment, transition/moving expenses, permitting and a 10% contingency are based upon UNC Health Pardee's prior experience with similar projects.

In Section F, pages 75-76, the applicant states there will be no start-up costs or initial operating expenses because the proposed project does not involve a new service or a new facility, as UNC Health Pardee is an existing facility and currently provides PET services through a mobile vendor.

Availability of Funds

In Section F, page 74, the applicant states that the capital cost will be funded with the accumulated reserves of UNC Health Pardee. In Exhibit F.2-1, the applicant provides a letter dated August 15, 2025, signed by the Chief Financial Officer of UNC Health Pardee documenting UNC Health Pardee’s commitment to fund the capital cost for the proposed project from its existing accumulated cash reserves. In Exhibit F.2-2, the applicant provides a copy of the audited financial statements for UNC Health Pardee. For the year ending June 30, 2024, UNC Health Pardee had sufficient accumulated reserves to fund the capital needs of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate UNC Health Pardee official confirming the availability of the funding proposed for the capital needs of the proposed project and the commitment to use those funds to develop the proposed project.
- The applicant provides documentation of sufficient accumulated reserves to fund the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, page 121, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

UNC Health Pardee Fixed PET Scanner	1st Full FY	2nd Full FY	3rd Full FY
	07/01/2027 – 06/30/2028	07/01/2028 – 06/30/2029	07/01/2029 – 06/30/2030
Total Procedures (Form C.2b)	2,123	2,391	2,696
Total Gross Revenues (Charges)	\$22,398,376	\$25,972,074	\$30,167,403
Total Net Revenue	\$5,267,851	\$6,108,345	\$7,095,040
Average Net Revenue per Procedure	\$2,481	\$2,555	\$2,632
Total Operating Expenses (Costs)	\$3,363,580	\$3,963,744	\$4,397,223
Average Operating Expense per Procedure	\$1,584	\$1,658	\$1,631
Net Income	\$1,904,271	\$2,144,601	\$2,697,817

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 124. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Patient Services Gross Revenue is based on CY 2024 payor mix and average charge by payor for the service through the project years.
- The percentage of total patients is based on CY2024 payor mix for the service.

- The applicant assumes that 25 percent of remaining self-pay patients with shift to Medicaid due to the expansion of Medicaid in North Carolina.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in a MOB in Arden, Buncombe County.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 128, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contract(s)	\$2,810,314
Architect/Engineering Fees	\$200,000
Medical Equipment	\$3,015,056
Non-Medical Equipment	\$140,085
Furniture	\$132,475
Consultant Fees	\$80,000
Other (Contingency Costs)	\$637,793
Total	\$7,015,723

In Section Q, page 129, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit F-1.1, the applicant provides the fixed PET equipment quotation.
- The applicant states that medical equipment includes all medical equipment necessary for PET/CT scanner.
- In Exhibit K-3.1, the applicant provides the architect's cost certification letter and the architect states that construction costs are based on his review, experience and the assistance of the general contractor.
- In Exhibit K-3.1, the architect states that architectural and engineering fees are estimated to be \$200,000.
- The applicant states that Other includes a contingency of 10% of construction costs and owners expenses.

In Section F, page 77, the applicant projects that start-up costs will be \$145,150 and initial operating expenses will be \$235,720 for a total working capital of \$380,870. On pages 77-78, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states that start-up costs include rental expenses, staffing, medical and other supplies, pharmacy costs, and central office overhead.
- The applicant states that it expects to hire the Nuclear Medicine Supervisor three months before opening and other staff one month before opening to allow for orientation and initial training.
- The applicant states that the initial operating costs are based on all operating cash flow losses related with operating NH Asheville PET while the cash outflow exceeds cash inflow.

Availability of Funds

In Section F, pages 75-76 and pages 78-79, the applicant states that the capital and working capital needs will be funded with the accumulated reserves of Novant Health, Inc. In Exhibit F-2.1, the applicant provides a letter dated August 7, 2025, signed by the Executive Vice President and Chief Financial Officer of Novant Health, Inc. documenting Novant Health's commitment to fund the capital and working capital costs for the proposed project from its existing accumulated cash reserves. In Exhibit F-2.2, the applicant provides a copy of the audited financial statements for Novant Health. For the year ending December 31, 2024, Novant Health had sufficient accumulated reserves to fund the capital needs of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides a letter from the appropriate Novant Health official confirming the availability of the funding proposed for the capital and working capital needs of the proposed project and the commitment to use those funds to develop the proposed project.
- The applicant provides documentation of sufficient accumulated reserves to fund the capital and working capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, page 130, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

NH Asheville PET- PET/CT Services	1st Full FY	2nd Full FY	3rd Full FY
	CY2029	CY2030	CY2031
Total Procedures (Form C.2b)	1,064	1,723	2,481
Total Gross Revenues (Charges)	\$12,416,889	\$20,713,164	\$30,721,747
Total Net Revenue	\$1,649,954	\$2,751,981	\$4,081,511
Average Net Revenue per Procedure	\$1,551	\$1,597	\$1,645
Total Operating Expenses (Costs)	\$1,598,944	\$1,827,823	\$2,100,619
Average Operating Expense per Procedure	\$1,503	\$1,061	\$847
Net Income	\$51,011	\$924,158	\$1,980,892

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 131. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant used the January – December 2024 gross charges for outpatient PET services at Novant Health to project gross patient revenue.
- The projected financial statements assume 3.0 percent annual inflation.
- The applicant adjusted for case mix differences between Novant Health’s historical PET scans and Mission Hospital’s.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in its existing HOPD in Asheville, Buncombe County for no more than two fixed PET scanners in HSA I.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 150, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contract(s)	\$1,893,000
Architect/Engineering Fees	\$193,600
Medical Equipment	\$2,432,802
Non Medical Equipment	\$61,100
Furniture	\$28,000
Consultant Fees	\$42,400
Other (Contingency, sales tax)	\$300,000
Total	\$4,950,902

In Exhibits F-1.1 and F-1.2, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit F-1.1, the applicant provides a letter from the project architect stating that construction costs are based on her review and the assistance of a specialty general contractor.
- In Exhibit F-1.2, the applicant provides the vendor quotation for medical equipment.

In Section F, pages 99-100, the applicant states there will be no start-up costs or initial operating expenses because the proposed project involves placing the proposed PET scanner at a fully functioning, existing HOPD at which revenues will exceed expenses from day one of the new project because of ongoing, existing operations there.

Availability of Funds

In Section F, page 98, the applicant states that the capital cost will be funded with the accumulated reserves of MH Mission Hospital, LLLP. In Exhibit F-2.1, the applicant provides a letter dated August 7, 2025, signed by the Chief Financial Officer of the National Group of Mission affiliate HCA Healthcare, Inc. documenting the commitment of HCA to fund the capital cost for the proposed project through an intercompany loan. The North Carolina Division, which includes Mission Hospital, is part of HCA’s National Group. In Exhibit F-2.2, the applicant provides a copy of the audited financial statements for HCA Healthcare, Inc. as of December 31, 2024, and 2023. For the year ending December 31, 2024, HCA Healthcare, Inc. had sufficient accumulated reserves to fund the capital needs of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate HCA Healthcare, Inc. official confirming the availability of the funding proposed for the capital needs of the proposed project and the commitment to use those funds to develop the proposed project.
- The applicant provides documentation of sufficient accumulated reserves to fund the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, page 155, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Mission 5 Vanderbilt Park PET Services	1st Full FY CY2028	2nd Full FY CY2029	3rd Full FY CY2030
Total Procedures (Form C.2b)	1,713	1,961	2,120
Total Gross Revenues (Charges)	\$33,300,766	\$41,171,644	\$48,070,676
Total Net Revenue	\$5,147,558	\$6,022,864	\$6,650,032
Average Net Revenue per Procedure	\$3,005	\$3,071	\$3,137
Total Operating Expenses (Costs)	\$4,033,230	\$4,557,430	\$4,889,300
Average Operating Expense per Procedure	\$2,354	\$2,324	\$2,306
Net Income	\$1,114,327	\$1,465,434	\$1,760,732

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 156-158 and 163-166. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant calculated the average PET Charge per Procedure by taking historic PET gross revenue for CY2024 and multiplying by volumes in Form C.2b.
- The Patient Services Payor Mix was calculated as a percentage of Gross Revenue for CY2024 and assumed to be held constant in Years 1-3 of the project.

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

In response to comments provided by the other applicants in this review, the applicant states on page 118, that it will be renovating existing space at an HOPD and in its response to comments, states that there is an existing lease which is the reason that rental cost is not included in its operating costs. In addition, the applicant states on pages 99-100 and in its response to comments that support services are already in place and thus, are not reflected in the proposed project's operational costs. Therefore, the Agency concludes that the proposed project's financial feasibility is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire a fixed PET scanner at AdventHealth Asheville pursuant to the 2025 SMFP need determination which is a change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds).

Capital and Working Capital Costs

In Section Q, Form F.1a, page 136, the applicant projects the total capital cost of the project, as shown in the table below.

	Previously Approved Capital Cost	Capital Cost for this Project	New Total Capital Cost
	Project ID#s B-12233-22 and B-12526-24	Project ID# B-12688-25	
Purchase Price of Land	\$22,865,218	\$0	\$22,865,218
Site Preparation	\$14,565,750	\$0	\$14,565,750
Construction/Renovation Contracts	\$245,634,000	\$2,161,708	\$247,795,708
Architect / Engineering Fees	\$11,025,000	\$21,800	\$11,046,800
Medical Equipment	\$24,973,000	2,896,121	\$27,869,121
Non-Medical Equipment	\$9,180,000	\$183,714	\$9,363,714
Furniture	\$5,333,700	\$58,829	\$5,392,529
Consultant Fees	\$75,000	\$12,154	\$87,154
Other (CON Filing Fees)	\$50,000	\$0	\$50,000
Contingency	\$29,627,000	\$216,170	\$29,843,170
Total Capital Cost	\$363,328,668	\$5,550,496	\$368,879,164

In Section Q, page 141, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit K.5-3, the architect certifies that the construction costs are based on his review and comparison of the project to recent similar installations.
- Medical equipment cost is based on the vendor quotation.
- Furniture cost estimate for PET-related spaces is based on the applicant’s experience

In Section F, page 91, the applicant states that the previously approved working capital for AdventHealth Asheville has been determined to be sufficient to support the incorporation of the proposed fixed PET services.

Availability of Funds

In Section F, pages 89-90, the applicant states that the capital cost will be funded with the accumulated reserves of Adventist Health System Sunbelt Healthcare Corporation. In Exhibit F.2, the applicant provides a letter dated July 30, 2025, signed by the Chief Financial Officer for the Southeastern Region of AdventHealth, documenting the commitment of Adventist Health System Sunbelt Healthcare Corporation to fund the capital cost for the proposed project through existing accumulated reserves. In Exhibit F.2, the applicant provides a copy of the audited financial statements for AdventHealth as of December 31, 2024, and 2023. For the year ending December 31, 2024, AdventHealth had sufficient accumulated reserves to fund the capital cost of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate Adventist Health System Sunbelt Healthcare Corporation official confirming the availability of the funding proposed for the capital needs of the proposed project and the commitment to use those funds to develop the proposed project.
- The applicant provides documentation of sufficient accumulated reserves to fund the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, page 137, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

AdventHealth Asheville PET Services	1st Full FY CY2029	2nd Full FY CY2030	3rd Full FY CY2031
Total Procedures (Form C.2b)	880	1,447	2,091
Total Gross Revenues (Charges)	\$20,826,092	\$34,591,617	\$50,505,156
Total Net Revenue	\$2,395,001	\$3,978,036	\$5,808,093
Average Net Revenue per Procedure	\$2,722	\$2,749	\$2,778
Total Operating Expenses (Costs)	\$2,118,248	\$2,934,378	\$3,810,974
Average Operating Expense per Procedure	\$2,407	\$2,028	\$1,823
Net Income	\$276,753	\$1,043,658	\$1,997,119

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 141-142.

However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. Projected revenues and expenses are based at least in part on projected utilization. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

UNC Health Pardee
 Novant Health
 Mission Hospital

NC
 AdventHealth

On page 363, the 2025 SMFP defines the service area for a fixed PET scanner “*the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” Thus, the service area for each proposal is HSA I. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing dedicated fixed PET scanners in HSA I, and the number of procedures for each PET scanner in 2022-2023 as found in Table 15F-1 on page 365 of the 2025 SMFP:

Facility	Planning Inventory	Procedures 2022-2023
AdventHealth Hendersonville*	1	
Catawba Valley Medical Center / Frye Regional Medical Center	1	1,649
Messino Cancer Center	1	192
Mission Hospital	1	2,862
HSA I Totals	4	4,703

*CON issued for new PET March 5, 2024. CON Project ID: B-12331-23

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner to be located on the main campus of UNC Health Pardee.

In Section G, page 82, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET services in HSA I. The applicant states:

“The proposed fixed PET scanner will not result in unnecessary duplication of existing or approved health services in HSA I for several reasons. First, the 2025 SMFP specifically identified a need for one additional fixed PET scanner in HSA I, representing official acknowledgment that existing fixed PET capacity is insufficient to meet current demand across the twenty-six-county region. Second, Henderson County, despite being the third most populous county in HSA I, currently has no operational

fixed PET scanner. While AdventHealth was approved to develop a fixed PET scanner in July 2023, the most recent progress report from March 2025... states that development has been delayed to enable recovery following the impact of Hurricane Helene. In addition to filling this gap in services, the proposed project would result in the first fixed PET scanner at UNC Health Pardee, supporting the health system's extensive network of primary and specialty care that serves patients throughout the region.... the proposed project represents a strategic response to an identified need, fills a geographic and population-based service gap, and enhances the services of an established healthcare provider already operating robust cardiology, neurology, and oncology programs.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2025 SMFP for the proposed fixed PET scanner.
- The applicant provides information to explain why it believes the proposed fixed PET scanner will not unnecessarily duplicate existing or approved PET services in HSA I.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing or approved fixed PET scanners in HSA I.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in a MOB in Arden, Buncombe County.

In Section G, pages 84-85, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET services in HSA I. The applicant states:

“The proposed project will not result in unnecessary duplication of existing or approved facilities in HSA I. The 2025 SMFP has identified a need for one additional fixed PET scanner in the multi-county service area. The applicant shows, using reasonable and adequately supported assumptions, that by CY2031 (the third full project year) NH Asheville PET’s projected utilization for the proposed fixed PET

scanner will exceed 2,080 PET procedures. The service area's growing and aging population, the increasing PET use rate, and the expanding uses for PET scans are expected to increase the demand for PET/CT services in the area.

NH Asheville PET will acquire a state-of-the-art fixed PET/CT scanner for a new outpatient imaging center in Buncombe County. In the early stages of technological advancement, certain medical imaging tools are often hospital based. The majority of the fixed PET assets in HSA I are hospital based. The addition of a second provider offering fixed, non-hospital-based, outpatient PET scans in HSA I will improve access to services at a lower cost than the hospital-based fixed and mobile scanners and will also introduce a new provider in the area, which will increase competition....”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2025 SMFP for the proposed fixed PET scanner.
- The applicant provides information to explain why it believes the proposed fixed PET scanner will not unnecessarily duplicate existing or approved PET services in HSA I.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing or approved fixed PET scanners in HSA I.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in its existing HOPD in Asheville, Buncombe County for no more than two fixed PET scanners in HSA I.

In Section G, pages 107-108, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET services in HSA I. The applicant states:

“There are two other existing and operational providers of Fixed PET services in HSA I, Catawba Valley Medical Center/Frye Regional Medical Center and Messino Cancer Center. Catawba Valley Medical Center/Frye Regional PET in Hickory, North

Carolina is located over 70 miles from Mission Hospital PET scanner, with a drive time of more than an hour and fifteen minutes. It is also located outside of Mission's proposed service area. As such, there is minimal overlap in markets served between the two providers.

...

...Additionally, AdventHealth Hendersonville has been approved for a fixed PET scanner in Henderson County, which is expected to come online in 2026. However, this new PET unit is not expected to impact Mission's PET volumes since there is no medical staff and referral pattern relationship between Mission and AdventHealth.

...

Mission Hospital believes that the current and projected demand is sufficient to support all three fixed PET providers (two existing and one approved) in the service area without creating unnecessary duplication. Importantly, since there is currently no PET access in the region to serve cardiovascular patients, Mission Hospital's plan to introduce cardiac PET at Mission's cardiovascular diagnostic center is not duplicative. Rather, it will address a critical gap in services while expanding capacity for the growing volume of oncology PET scans."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2025 SMFP for the proposed fixed PET scanner.
- The applicant provides reasonable information to explain why it believes the proposed fixed PET scanner will not unnecessarily duplicate existing or approved PET services in HSA I.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing or approved fixed PET scanners in HSA I.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire a fixed PET scanner at AdventHealth Asheville pursuant to the 2025 SMFP need determination which is a change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds).

In Section G, pages 92-93, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET services in HSA I. The applicant states:

“The proposed project will not result in unnecessary duplication of existing or approved facilities in Health Service Area I. The 2025 SMFP has identified a need for one additional fixed PET scanner in HSA I PET utilization in the service area is projected to exceed the capacity of the existing and approved providers.

...

The proposed fixed PET scanner in Weaverville will complement, not duplicate, the fixed PET scanner that AdventHealth is currently developing in Hendersonville. While the two service areas may share some overlapping counties, the scanners will serve as discreet, strategically located points of access that improve geographic coverage and scheduling flexibility for residents across western North Carolina.”

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant does not adequately demonstrate that the proposed fixed PET scanner is needed in addition to the existing or approved fixed PET scanners in HSA I. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C – All Applications

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner to be located on the main campus of UNC Health Pardee.

In Section Q, Form H, page 126, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	1st Full FY	2nd Full FY	3rd Full FY
Registration	1.0	1.0	1.0
Radiology Front Desk Clerical	1.5	2.0	2.0
PET Technologist	2.5	3.0	3.0
Total	5.0	6.0	6.0

The assumptions and methodology used to project staffing are provided in Section Q, page 127. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, page 123. In Section H, pages 84-85, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant’s projections of the types of positions needed are based on UNC Health Pardee’s experience with staffing patterns for imaging services and knowledge about PET services.
- The applicant uses multiple methods to recruit or fill vacant or new positions.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in a MOB in Arden, Buncombe County.

In Section Q, Form H, page 135, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	1st Full FY	2nd Full FY	3rd Full FY
Nuclear Medicine Tech	1.25	1.25	2.25
Patient Access Specialist	1.25	1.25	1.25
Nuclear Med Supervisor	1.25	1.25	1.25
Total	3.75	3.75	3.75

The assumptions and methodology used to project staffing are provided in Section Q, page 136. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 87-89, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services because the applicant states that its staffing projections reflect the estimated FTE staff necessary to provide services during the project period and the projections are based on expected volume with minimum staffing requirements per discussions with its clinical operations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in its existing HOPD in Asheville, Buncombe County for no more than two fixed PET scanners in HSA I.

In Section Q, Form H, page 167, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current Staff	Projected Staff		
	As of 6/30/2025	1st Full FY	2nd Full FY	3rd Full FY
Radiology Technologists (Nuc Med)	2	3	3	3
RN	0	1	1	1
Total	2	4	4	4

The assumptions and methodology used to project staffing are provided in Section Q, page 168. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 110-113, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant has existing staff currently supporting all functional areas within the diagnostic center.
- The applicant’s projections of the types of positions needed are based on the applicant’s historical experience of operating its fixed PET scanner.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire a fixed PET scanner at AdventHealth Asheville pursuant to the 2025 SMFP need determination which is a change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds).

In Section Q, Form H, page 139, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected Staff		
	1st Full FY CY2029	2nd Full FY CY2030	3rd Full FY CY2031
Registered Nurse	1.0	1.0	1.0
PET Technologist	2.25	2.25	2.25
Total	4.25 [3.25]*	4.25 [3.25]*	4.25 [3.25]*

*Applicant's numbers appear to be a typographical error. Corrected numbers are shown in brackets.

The assumptions and methodology used to project staffing are provided in Section Q, page 143. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, page 95, the applicant states that the proposed project does not change the staffing associated with the conditionally approved acute care services. The applicant states that modest incremental staff are needed to support the proposed fixed PET scanner.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant states that the proposed project does not change the staffing associated with the conditionally approved acute care services.
- The applicant states that modest incremental staff are needed to support the proposed fixed PET scanner.
- The applicant's projections for staffing are based on the applicant's experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner to be located on the main campus of UNC Health Pardee.

Ancillary and Support Services

In Section I, page 86, the applicant identifies the necessary ancillary and support services for the proposed services. On page 86, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides a statement that UNC Health Pardee, as an existing hospital, has all the ancillary and support services in place to support hospital operations as well as the proposed PET services.
- The applicant has provided a letter dated August 15, 2025, signed by the President and Chief Executive Officer at UNC Health Pardee, documenting the availability of the necessary ancillary and support services for the proposed PET services.

Coordination

In Section I, page 87, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has established relationships with local health care and social service providers as an existing health care facility in HSA I.
- In Exhibit I.2, the applicant has provided letters of support for the proposed project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in a MOB in Arden, Buncombe County.

Ancillary and Support Services

In Section I, page 91, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 91-92, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I-1.1 and Exhibit I-1.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- In Exhibit I-1.1, the applicant provides a letter signed by the SVP & President Acute Care Operations & Specialty Institutes at Novant Health that states the necessary ancillary and support services required to operate NH Asheville PET will be provided by facility staff or Novant Health corporate staff.
- In Exhibit I-1.2, the applicant provides a letter from the President of ARA Health Specialists, P.A., stating that ARA Health Specialists has agreed to provide radiologic interpretive services and Authorized User duties under the Radioactive Materials License for Novant Health's proposed PET scanner.

Coordination

In Section I, pages 92-96, the applicant describes its proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- In Exhibit C-4.1, the applicant provides letters of support from providers in the Asheville area.
- In Exhibit C-4.2, the applicant provides letters of support from community members in the Asheville area.
- The applicant states that it has partnered with local providers in Western North Carolina and that it is also committing to further develop access to care, including primary care in rural areas.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in its existing HOPD in Asheville, Buncombe County for no more than two fixed PET scanners in HSA I.

Ancillary and Support Services

In Section I, page 114, the applicant identifies the necessary ancillary and support services for the proposed services. On page 114, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.1 and I-1.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because the applicant has provided a letter in Exhibit I-1.1 dated August 5, 2025, signed by the VP of Cardiovascular and Neuroscience service lines at Mission Hospital, documenting the availability of the necessary ancillary and support services for the proposed PET services.

Coordination

In Section I, pages 115-116, the applicant describes its existing relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant, as an existing provider of diagnostic services in HSA I, has longstanding relationships with local health care and social service providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire a fixed PET scanner at AdventHealth Asheville pursuant to the 2025 SMFP need determination which is a change of scope for Project ID# B-12233-22

(Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds).

Ancillary and Support Services

In Section I, page 97, the applicant states that the proposed change of scope does not result in changes to the provision of necessary ancillary and support services. On page 97, the applicant states the proposed service will be integrated into the hospital's radiology department and supported by the full continuum of ancillary services available at the hospital.

Coordination

In Section I, page 97, the applicant states that the proposed change of scopes does not result in changes to coordination with existing health system. The applicant states that while the proposed change of scope will not materially change coordination with the existing health care system as represented in the previously approved project, AdventHealth remains committed to engaging stakeholders throughout the region to ensure its services are aligned with local needs and AdventHealth has proactively sought input from key community leaders and organizations. The applicant provides supporting documentation in Exhibit I.3. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA – All Applications

The applicants do not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicants do not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA – All Applications

The applicants are not HMOs. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C – All Applications

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner to be located on the main campus of UNC Health Pardee.

In Section K, page 90, the applicant states that the project involves renovating 1,300 square feet of existing space. Line drawings are provided in Exhibit C.1-2.

On pages 90-91, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that cost of the project is minimized by renovating existing space rather than constructing new space.
- The applicant states that the design of the proposed project takes into consideration the space, mechanical, and electrical needs for the future PET unit to avoid costly rework as well as optimize existing infrastructure and resources.

On page 91, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services because UNC Health Pardee has set aside excess revenues from previous years to enable it to pay for projects such as the proposed PET scanner, without necessitating an increase in costs or charges to pay for the project.

In Section B, page 26, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in a MOB in Arden, Buncombe County.

In Section K, page 99, the applicant states that the project involves renovating approximately 3,752 square feet of existing space. Line drawings are provided in Exhibit K-2.1.

On page 99, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal because the applicant states that it worked with experienced healthcare architects and the architect based the projected design and renovation cost on a review of the project and costs of similar projects, published construction costing data, and the architect's design experience. The applicant provided supporting documentation in Exhibit K-3.1.

On page 100, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that the project costs incurred by Novant Health will be spread over the projected utilization and across the larger health care system.
- The applicant states that the project will not increase the costs and charges to the public because reimbursement for health care services, including PET services, are established by Medicare, Medicaid and existing private payor contracts.

In Section K, page 100, and Section B, pages 26-28, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in its existing HOPD in Asheville, Buncombe County for no more than two fixed PET scanners in HSA I.

In Section K, page 118, the applicant states that the project involves renovating 3,536 square feet of existing space. Line drawings are provided in Exhibit K.-2.1.

On page 118, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal because interior renovation is significantly cheaper and faster than the construction of exterior additions. The applicant states that the proposed solution was thoroughly vetted against other candidate spaces to minimize the square footage of renovation.

On page 119, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services because the renovation costs will be controlled by competitively bidding the construction contract to ensure the best market price is obtained and renovating space in an existing leased space avoids the costs of property acquisition and land development.

On page 119 and Section B, page 31, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire a fixed PET scanner at AdventHealth Asheville pursuant to the 2025 SMFP need determination which is a change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds).

In Section K, page 102, the applicant states that the project involves renovating existing space. The applicant states it will upfit space in an outpatient building on the hospital campus for the proposed fixed PET scanner. In Exhibit K.5-3, the project architect states that the construction cost is for a suite of approximately 2,600 square feet. Line drawings are provided in Exhibit K.5-2.

On pages 102-103, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal because it worked with experienced healthcare architects to develop a cost-effective plan and the project will be co-located in an outpatient building with its oncology services, thereby providing convenient access for patients receiving other cancer services.

On page 103, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services because the charges or projected reimbursement for the proposed services are established by Medicare, Medicaid and/or existing private payor contracts.

On page 103 and Section B, page 27, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans. The applicant provides supporting documentation in Exhibit K.5-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C
 UNC Health Pardee
 Mission Hospital

NA
 Novant Health Asheville PET
 AdventHealth Asheville

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 94, the applicant provides the historical payor mix during 07/01/2023 to 06/30/2024, for UNC Health Pardee, as shown in the table below.

UNC Health Pardee Historical Payor Mix, SFY 2024^	
Payor Category	% of Total
Self-Pay	3.1%
Charity Care^^	--
Medicare	61.9%
Medicaid	8.8%
Insurance	12.3%
Workers Compensation	--
TRICARE	--
Other (Other Govt, Worker's Comp)^^^	13.9%
Total	100.0%

^SFY 2024 represents the last full year of comprehensive data available during application preparation. While SFY 2025 volume data was available and used for baseline projections, other required year-end financial and utilization data for the table above remained unavailable due to ongoing close-out processes.

^^UNC Health Pardee internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care.

^^^Workers Compensation, TRICARE and other payors are included in the Other payor category.

In Section L, page 95, the applicant provides the following comparison.

UNC Health Pardee	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area*
Female	60.8%	51.5%
Male	39.2%	48.5%
Unknown	--	--
64 and Younger	38.9%	72.6%
65 and Older	61.1	27.4%
American Indian	0.2%	0.8%
Asian	0.4%	1.3%
Black or African-American	3.0%	3.5%
Native Hawaiian or Pacific Islander	0.1%	0.3%
White or Caucasian	92.0%	91.9%
Other Race	3.4%	2.2%
Declined / Unavailable	1.0%	0.0%

*The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 103, the applicant states it is not an existing facility or provider of PET services and as such does not have any historical data. Therefore, Criterion (13a) is not applicable to this review.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 122, the applicant provides the historical payor mix during CY2024, for Mission Cancer Center PET, as shown in the table below.

Payor Category	% of Total
Self-Pay	0.5%
Charity Care	1.0%
Medicare	65.5%
Medicaid	5.2%
Insurance	25.8%
Workers Compensation	0.0%
TRICARE	0.1%
Other (Other Fed, Non-Medicaid State)	1.9%
Total	100.0%

In Section L, page 123, the applicant provides the following comparison.

Mission Cancer Center PET	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area*
Female	43.5%	51.8%
Male	56.5%	48.2%
Unknown	0.0%	0.0%
64 and Younger	30.7%	79.0%
65 and Older	69.3%	21.0%
American Indian	0.7%	0.6%
Asian	0.2%	1.5%
Black or African-American	3.5%	6.2%
Native Hawaiian or Pacific Islander	0.1%	0.2%
White or Caucasian	86.8%	82.9%
Other Race	0.0%	2.3%
Declined / Unavailable	8.6%	N/A

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Note: Buncombe County, the location of the proposed service, is used to represent the service area; from Quickfacts referenced above.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

AdventHealth Asheville is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C
UNC Health Pardee
Mission Hospital

NA
Novant Health Asheville PET
AdventHealth Asheville

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 96, the applicant states it is not under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 97, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

Novant Health Asheville PET is not an existing facility. Therefore Criterion (13b) is not applicable review.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 124, the applicant states that Mission Hospital is not under a federal obligation to provide uncompensated care.

In Section L, page 126, the applicant states that during the 18 months immediately preceding the application deadline, Mission Hospital received a complaint from Disability Rights North Carolina on 2/24/2024, alleging a patient was subjected to abuse related to unlawful mechanical restraint. The North Carolina Department of Health and Human Services reviewed the patient's record during a hospital survey that concluded on May 23, 2024. The applicant states that no opportunities for improvement were identified and no additional actions are required.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

AdventHealth Asheville is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, pages 97-98, the applicant projects the following payor mix for the entire facility and the proposed PET services at UNC Health Pardee, during the third full fiscal year of operation following completion of the project, as shown in the tables below.

UNC Health Pardee Entire Facility Projected Payor Mix during the 3rd Full FY 07/01/2029 – 06/30/2030	
Payor Source	Percentage of Total Patients Served
Self-Pay	2.3%
Charity Care [^]	--
Medicare	61.9%
Medicaid	9.6%
Insurance	12.3%
Workers Compensation ^{^^}	--
TRICARE ^{^^}	--
Other (Other Govt, Worker’s Comp) ^{^^}	13.9%
Total	100.0%

[^]UNC Health Pardee internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care.

^{^^}Workers Compensation, TRICARE and other payors are included in the Other payor category.

UNC Health Pardee Fixed PET Services Projected Payor Mix during the 3rd Full FY 07/01/2029 – 06/30/2030	
Payor Source	Percentage of Total Patients Served
Self-Pay	0.8%
Charity Care [^]	--
Medicare	77.1%
Medicaid	4.8%
Insurance	9.0%
Workers Compensation ^{^^}	--
TRICARE ^{^^}	--
Other (Other Payors) ^{^^}	8.3%
Total	100.0%

[^]UNC Health Pardee internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care.

^{^^}Workers Compensation, TRICARE and other payors are included in the Other payor category.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.3% of total services will be provided to self-pay patients, 61.9% to

Medicare patients and 9.6% to Medicaid patients. Additionally, the applicant projects that 0.8% of PET services will be provided to self-pay patients, 77.1% to Medicare patients and 4.8% to Medicaid patients.

On page 97, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix for PET scanner services and the entire facility are based on SFY 2024 actual payor mix and the ongoing estimated effect of Medicaid expansion.
- The applicant projects a 25.0% shift of Self-Pay patients to Medicaid with the expansion of Medicaid coverage.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 106, the applicant projects the following payor mix for the proposed PET services during the third full fiscal year of operation following completion of the project, as shown in the tables below.

NH Asheville PET	
Projected Payor Mix during the 3rd Full FY, CY2031	
Payor Source	Percentage of Total Patients Served
Self-Pay	1.7%
Charity Care*	0.0%
Medicare	70.7%
Medicaid	5.8%
Insurance	19.8%
Workers Compensation	0.0%
TRICARE	0.0%
Other	2.0%
Total	100.0%

*The applicant states, on pages 106-107, that it will provide charity care and that it does so across payor classes.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.7% of PET services will be provided to self-pay patients, 70.7% to Medicare patients and 5.8% to Medicaid patients.

On pages 105-106, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant states that it relied on HIDI data because it is the best available data source for payor mix for PET/CT services in HSA I.
- The projected payor mix is based on calendar year 2024 data for outpatient PET/CT scans conducted on Mission Hospital’s fixed PET/CT scanner.
- The applicant states that Mission’s experience is a reasonable basis for projecting future payor mix, as it is a fixed PET/CT provider in Buncombe County.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

Project ID # B-12685-25 / Mission Hospital / Acquire one fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, pages 126-127, the applicant projects the following payor mix for proposed PET services at Mission 5 Vanderbilt Park Drive PET and the existing PET services at Mission Cancer Center, during the third full fiscal year of operation following completion of the project, as shown in the tables below.

Mission 5 Vanderbilt Park Drive PET Projected Payor Mix during the 3rd Full FY	
Payor Source	Percentage of Total Patients Served**
Self-Pay	0.5%
Charity Care	1.0%
Medicare	65.5%
Medicaid	5.2%
Insurance	25.8%
Workers Compensation	0.0%
TRICARE	0.1%
Other	1.9%
Total	100.0%

**Note that the payor mix of patients is slightly different than the payor mix of gross revenues

identified in Section Q.

Mission Cancer Center Fixed PET Scanner Projected Payor Mix during the 3rd Full FY	
Payor Source	Percentage of Total Patients Served**
Self-Pay	0.5%
Charity Care	1.0%
Medicare	65.5%
Medicaid	5.2%
Insurance	25.8%
Workers Compensation	0.0%
TRICARE	0.1%
Other	1.9%
Total	100.0%

**Note that the payor mix of patients is slightly different than the payor mix of gross revenues identified in Section Q.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.5% of PET services will be provided to self-pay patients, 65.5% to Medicare patients and 5.2% to Medicaid patients.

On page 127, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix for the facility payor mix is based on Mission Cancer Center’s historical facility payor mix for CY2024.
- The applicant assumes the payor mix for the new PET scanner at Mission 5 Vanderbilt Park Drive will be the same as the payor mix projected at Mission Cancer Center PET, in part because both cancer patients and cardiac patients are heavily weighted toward Medicare.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 110, the applicant projects the following payor mix for the proposed PET services during the third full fiscal year of operation following completion of the project, as shown in the tables below.

AdventHealth Asheville	
Projected Fixed PET Payor Mix during the 3rd Full FY	
Payor Source	Percentage of Total Patients Served
Self-Pay	1.9%
Charity Care	-
Medicare	77.5%
Medicaid	6.0%
Insurance	14.2%
Workers Compensation	-
TRICARE	-
Other	0.3%
Total	100.0%

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.9% of PET services will be provided to self-pay patients, 77.5% to Medicare patients and 6.0% to Medicaid patients.

On page 110, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the CY2024 payor mix for mobile PET services at AdventHealth Hendersonville.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 99, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 109, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 128, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section Q, pages 130-131, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

UNC Health Pardee
Mission Hospital
AdventHealth

CA

Novant Health

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner to be located on the main campus of UNC Health Pardee.

In Section M, page 100, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes because the applicant states it has formal Clinical Affiliation Training Agreements with local community colleges, including AB Tech, Blue Ridge Community College, and South College of Asheville.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in a MOB in Arden, Buncombe County.

In Section M, page 110, the applicant states that Novant Health has established clinical education agreements with area health education programs in North Carolina and will work to extend appropriate agreements to apply to the proposed PET scanner. The applicant provides a list of its clinical education programs in Exhibit M-1.1. including area colleges and universities. The Agency notes that if the applicant is conditionally approved for the PET scanner, it will need to provide documentation that an effort has been made to accommodate the clinical needs of health professional training programs in the area at its Novant Health Asheville PET facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in its existing HOPD in Asheville, Buncombe County for no more than two fixed PET scanners in HSA I.

In Section M, page 129, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes because the applicant has medical residency and medical school programs and Mission Hospital's parent health system, Mission Health, has existing relationships with

many health professional training programs. The applicant provides a list of Mission Health's existing clinical education agreements in Exhibit M-1.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire a fixed PET scanner at AdventHealth Asheville pursuant to the 2025 SMFP need determination which is a change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds).

In Section M, page 111, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes because the applicant has existing relationships and established agreements with health professional training programs in the area including Lenoir-Rhyne University, Mars Hill University and Asheville-Buncombe Technical Community College. The applicant states it will work to extend these agreements to AdventHealth Asheville upon completion of the project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.

- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C
 UNC Health Pardee
 Novant Health
 Mission Hospital

NC
 AdventHealth

On page 363, the 2025 SMFP defines the service area for a fixed PET scanner “the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” Thus, the service area for each proposal is HSA I. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved dedicated fixed PET scanners in HSA I, and the number of procedures for each PET scanner in 2022-2023 as found in Table 15F-1 on page 365 of the 2025 SMFP:

Facility	Planning Inventory	Procedures 2022-2023
AdventHealth Hendersonville*	1	0
Catawba Valley Medical Center / Frye Regional Medical Center	1	1,649
Messino Cancer Center	1	192
Mission Hospital	1	2,862
HSA I Totals	4	4,703

*CON issued for new PET March 5, 2024. CON Project ID: B-12331-23.

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner to be located on the main campus of UNC Health Pardee.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 101, the applicant states:

“The proposed project will enhance competition in the service area (HSA I) for fixed PET services by promoting value, safety, quality, and increased access. ... the proposed fixed PET scanner may be the first operational fixed PET scanner in Henderson

County, addressing the ongoing gap in service availability resulting from the approved but delayed development of a fixed unit at AdventHealth.... As a regional referral center with extensive primary and specialty care, including robust oncology, cardiology, and neurology programs, UNC Health Pardee's fixed PET scanner will support comprehensive, coordinated care within the health system. This improved access and full range of service capabilities will foster competition by providing patients throughout the region with another option for high quality PET imaging, one collocated with relevant services and operated by a well-established and growing healthcare system."

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 101-102, the applicant states:

"The proposed project is indicative of UNC Health Pardee's commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended, while also ensuring that it develops the services and capacity to meet the needs of the population it serves.... the proposed project will utilize existing space, avoiding new construction and thus representing the most value-conscious alternative for the development of PET imaging services. Additionally, replacing mobile PET services with a fixed scanner eliminates costs related to current operational inefficiencies....."

Further, UNC Health Pardee, through its relationship with the larger UNC Health Care System, benefits from significant cost saving measures through the consolidation of support functions and large economies of scale...."

See also Sections E, F, K and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 102, the applicant states:

"UNC Health Pardee believes that the proposed project will promote safety and quality in the delivery of healthcare services by expanding access to the high-quality services it provides. UNC Health Pardee is dedicated to providing the highest quality care and is continually recognized locally and nationally for its commitment to delivering efficient, quality care. Each year, UNC Health Pardee is recognized by many of the top accrediting and ranking organizations in the industry...."

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 104, the applicant states:

"...consistent with all UNC Health facilities, UNC Health Pardee provides services to all people in need of medical care and will continue to do so following the proposed project. As stated in UNC Health's Notice of Nondiscrimination, 'UNC Health and its affiliated Network Entities comply with applicable Federal civil rights laws and do not

discriminate, exclude, or treat people less favorably based on race, color, national origin, age, disability, or sex.”

See also Sections L, B and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination for one fixed PET scanner in the HSA I.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 111, the applicant states:

“The PET/CT scanner proposed by NH Asheville PET will be only the second non-hospital-based PET scanner in the HSA. ... the shift in fixed PET scans between FY 23 and FY 24 indicates that patients chose non-hospital-based PET/CT services when that alternative became available in the region. In its first full year of opening its non-

hospital-based PET/CT, Messino Cancer Centers was operating at the highest capacity of any fixed PET/CT scanner in HSA I (70% utilization in FY 2024, as compared to Mission Hospital's 63% and Catawba Valley Medical Center's 59%). The addition of this proposed non-hospital-based PET/CT scanner will offer residents a second option that improves access to care, which will increase competition in the area."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 111, the applicant states:

"NH Asheville PET's proposed non-hospital based, outpatient site of care will provide a lower-cost alternative than hospital-based PET/CT scanners for many residents with commercial insurers. The only non-hospital option for PET/CT scans in HSA I is Messino Cancer Centers.... Messino Cancer Centers' PET/CT scanner performed over 2,000 scans in its first full year of operations (FY 2024), indicating that patients are choosing non-hospital-based sites of care, when available."

See also Sections C, F and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 112, the applicant states:

"Novant Health provides high-quality care at its existing PET/CT sites and will continue to do so at NH Asheville PET, which will be accredited by the American College of Radiology. Novant Health delivers value and quality in outcomes through its value-based care delivery model. This approach encourages wellness and preventive care and manages existing conditions to slow or reverse the progression of disease, all while lowering the overall cost of care. The key to value-based care is a coordinated effort with physicians, nurses, pharmacists, dieticians, social workers, referral coordinators, and others working together to give patients the customized care they want and need. Ultimately, this type of care provides high-quality, safe, and more-affordable care with better outcomes, and is centered on patients' unique needs."

See also Sections C, E and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 113, the applicant states:

"...Novant Health will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved."

See also Sections L, B and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination to be located in its existing HOPD in Asheville, Buncombe County for no more than two fixed PET scanners in HSA I.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 132, the applicant states:

“The proposed project will positively impact competition in the service area by expanding access to PET services for cancer patients and introducing cardiac PET imaging, an advanced diagnostic tool not currently available in western North Carolina.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 133, the applicant states:

“The project is cost effective for cardiac patients who will, upon approval and implementation of this project, have improved access to PET scans, supporting more efficient care and helping reduce overall healthcare costs. Additional potential cost savings are expected from the enhanced diagnostic capabilities of PET/CT scans for patients with several types of cardiovascular conditions....the availability of high-quality PET/CT for these patients can reduce reliance on multiple, less effective,

imaging modalities such as SPECT. Thus, minimizing redundant testing, expediting appropriate care, and lowering downstream costs.”

See also Sections F and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 134, the applicant states:

“Mission Hospital will provide the same quality oversight for the new PET scanner at 5 Vanderbilt Park Drive as it provides for its existing PET scanner at Mission Hospital’s Mission Cancer Center. All radiologic technologists working for Mission Hospital are credentialed by their professional governing body. All modalities (CT, US, Mammo, MRI and Nuclear Medicine) eligible for accreditation by American College of Radiology (ACR) are accredited....The staff at 5 Vanderbilt Park Drive will be subject to the same oversight by the Radiation Safety Committee and the Policies and Procedures Committee that currently governs the existing PET scanner.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 135, the applicant states:

“The additional PET scanner will provide Mission Hospital the flexibility to meet current and future demands for comprehensive cancer services and cardiovascular services in the region. It will also ensure that residents of the health service area have timely access to high quality, affordable diagnostic imaging. More specifically... Mission Hospital proposes to continue to serve medically underserved, including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons ages 65 and older, Medicare beneficiaries, and Medicaid recipients.”

See also Sections L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire a fixed PET scanner at AdventHealth Asheville pursuant to the 2025 SMFP need determination which is a change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 113, the applicant states:

“The addition of a fixed PET scanner at AdventHealth Asheville... will further enhance competition in HSA I by:

- *Increasing access to fixed PET services in a region where demand continues to grow, particularly due to population aging and the rising prevalence of cancer and neurological conditions.*
- *Expanding patient choice by offering an alternative access point for PET imaging in a convenient, community-based hospital setting.*
- *Supporting cost-effective care delivery by integrating PET services within the existing radiology department, reducing the need for patients to travel long distances for advanced diagnostic imaging.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 113, the applicant states:

“This project will support the cost-effective delivery of healthcare in HSA I. The addition of a fixed PET scanner does not affect the cost to patients or payors, as reimbursement rates for PET services are determined by Medicare, Medicaid, and commercial insurers. The project leverages existing infrastructure within AdventHealth Asheville’s radiology department, promoting operational efficiency.”

See also Sections F and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 113, the applicant states:

“The PET services will be delivered by qualified, licensed clinical and technical personnel, all of whom will meet continuing education and credentialing requirements. AdventHealth Asheville will uphold the same high standards of safety and quality that are reflected systemwide.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 114, the applicant states:

“This project does not diminish access for medically underserved populations. On the contrary, it enhances local access to advanced diagnostic services, especially for patients in rural and mountainous areas of HSA I. AdventHealth Asheville will provide PET services to all patients without regard to income, race/ethnicity, gender, age, disability, or ability to pay. The AdventHealth financial assistance policy will apply to PET services, ensuring that cost is not a barrier to care.”

See also Sections L and C of the application and any exhibits.

However, the applicant does not adequately describe the expected effects of the proposed services on competition in the service area and does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant does not adequately demonstrate that:

- 1) The proposal is cost effective because the applicant does not adequately demonstrate: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable. The discussions regarding analysis of need, alternatives, financial feasibility, and duplication of services found in Criteria (3), (4), (5) and (6), respectively, are included herein by reference. A project that cannot demonstrate it is the least costly or most effective alternative cannot demonstrate how any enhanced competition will have a positive impact on the cost-effectiveness of the proposal.
- 2) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix. The applicant’s payor mix is questionable based on the proposal’s projected patient origin. The discussion regarding access to the proposed services by medically underserved groups found in Criterion (3) is included herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C – All Applications

Project ID # B-12675-25 / Margaret R. Pardee Memorial Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner to be located on the main campus of UNC Health Pardee.

In Section Q, Form O, page 128, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity that provide PET services. The applicant identifies one of this type of facility located in North Carolina. However, since UNC Health manages UNC Health Pardee and other facilities, there are a total of four facilities that provide PET services.

In Section O, page 107, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care had not occurred in its facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care did not occur at the facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of its facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID # B-12684-25 / Novant Health Asheville PET / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET scanner pursuant to the 2025 need determination for one fixed PET scanner in the HSA I.

In Section Q, Form O, the applicant identifies the diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a

total of 14 of this type of facility located in North Carolina. In addition, the applicant owns or operates five fixed PET scanners at three hospitals in the state.

In Section O, page 107, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care had not occurred in any of the diagnostic facilities it identified in Form O. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care did not occur in any of the applicant's hospitals that provide PET services. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of its facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID # B-12685-25 / Mission Hospital / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section Q, Form O, page 169, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of six of this type of facility located in North Carolina.

In Section O, page 137, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care had not occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care did not occur in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the two facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID # B-12688-25 / AdventHealth Asheville / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

In Section Q, Form O, page 140, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three of this type of facility located in North Carolina.

In Section O, page 117, the applicant states that during the 18 months immediately preceding the submittal of the application, a finding of immediate jeopardy occurred on July 25, 2024, at one of these facilities, St. Luke's Hospital, prior to AdventHealth assuming management of the facility in October 2024. The facility was back in compliance as of November 1, 2024. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care did not occur in any of the other facilities. After reviewing and considering information provided by the applicant and by the Acute and

Home Care Licensure and Certification Section and considering the quality of care provided at all three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C – All Applications

The Criteria and Standards for Positron Emission Tomography Scanners, promulgated in 10A NCAC 14C .3700, are applicable to this review.

SECTION .3700 CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER

10A NCAC 14C .3703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a fixed PET scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

(1) identify the existing fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed fixed PET scanner service area;

-NA- UNC Health Pardee. Neither the applicant nor any related entities own or operate an existing fixed PET scanner in the proposed fixed PET scanner service area.

-NA- Novant Health Asheville PET. Neither the applicant nor any related entities own or operate an existing fixed PET scanner in the proposed fixed PET scanner service area.

-C-Mission Hospital. The applicant or a related entity owns and operates one fixed PET scanner in the proposed fixed PET scanner service area. One fixed PET scanner is located on the hospital's main campus at Mission Cancer Center.

-NA- AdventHealth Asheville. The applicant or related entity does not own and operate an existing fixed PET scanner in the proposed fixed PET scanner service area.

(2) identify the approved fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed fixed PET scanner service area;

-NA- UNC Health Pardee. Neither the applicant nor any related entity owns nor operates an approved fixed PET scanner in the proposed fixed PET scanner service area.

-NA- Novant Health Asheville PET. Neither the applicant nor any related entity owns nor operates an approved fixed PET scanner in the proposed fixed PET scanner service area.

-NA-Mission Hospital. Neither the applicant nor any related entity owns nor operates an approved fixed PET scanner in the proposed fixed PET scanner service area.

-C-AdventHealth Asheville. AdventHealth Hendersonville is approved to develop a fixed PET scanner at its existing hospital in Henderson County. The project is under development and expected to become operational in 2026.

- (3) *identify the existing mobile PET scanners owned or operated by the applicant or a related entity that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period;*

-NA- UNC Health Pardee. Neither the applicant nor any related entity owns nor operates a mobile PET scanner in the proposed fixed PET scanner service area.

-NA- Novant Health Asheville PET. Neither the applicant nor any related entity owns nor operates a mobile PET scanner in the proposed fixed PET scanner service area.

-NA- Mission Hospital. Neither the applicant nor any related entity owns nor operates a mobile PET scanner in the proposed fixed PET scanner service area.

-NA- AdventHealth Asheville. Neither the applicant nor any related entity owns nor operates a mobile PET scanner in the proposed fixed PET scanner service area.

- (4) *identify the approved mobile PET scanners owned or operated by the applicant or a related entity that will provide services at host sites located in the proposed fixed PET scanner service area;*

-NA- UNC Health Pardee. Neither the applicant nor any related entity owns nor operates an approved mobile PET scanner in the proposed fixed PET scanner service area.

-NA- Novant Health Asheville PET. Neither the applicant nor any related entity owns nor operates an approved mobile PET scanner in the proposed fixed PET scanner service area.

-NA- Mission Hospital. Neither the applicant nor any related entity owns nor operates an approved mobile PET scanner in the proposed fixed PET scanner service area.

-NA- AdventHealth Asheville. Neither the applicant nor any related entity owns nor operates an approved mobile PET scanner in the proposed fixed PET scanner service area.

- (5) *provide projected utilization of the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner during each of the first three full fiscal years of operation following completion of the project;*

-C- UNC Health Pardee. In Section Q, Form C.2b, page 111, the applicant provides projected utilization of the proposed fixed PET scanner to be located in HSA I during each of the first three full fiscal years of operation following completion of the project.

-C- Novant Health Asheville PET. In Section Q, Form C.2b, page 121, the applicant provides projected utilization for the proposed fixed PET scanner to be located in HSA I during each of the first three full fiscal years of operation following completion of the project.

-C-Mission Hospital. In Section C, page 88, and Section Q, pages 141-142, the applicant provides projected utilization of its existing fixed PET scanner and the proposed fixed PET scanner located or proposed to be located in HSA I during each of the first three full fiscal years of operation following completion of the project.

-C- AdventHealth Asheville. In Section Q, Form C.2b, pages 120-121, the applicant provides projected utilization for the proposed and approved fixed PET scanners to be located in HSA I during each of the first three full fiscal years of operation following completion of the project.

- (6) *provide the assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph; and*

-C- UNC Health Pardee. In Section Q, *Form C Utilization-Assumptions and Methodology*, pages 112-117, the applicant provides assumptions and methodology used to project utilization of the proposed fixed PET scanner.

-C- Novant Health Asheville PET. In Section Q, *Form C.2 Assumptions and Methodology*, pages 122-127, the applicant provides assumptions and methodology used to project utilization for the proposed fixed PET scanner.

-C- Mission Hospital. In Section Q, *Assumptions to Form C Historical and Projected Utilization*, pages 144-149, the applicant provides the assumptions and methodology used to project utilization of the existing fixed PET scanner and the proposed fixed PET scanner.

-C- AdventHealth Asheville. In Section Q, *Form C.2 Utilization – Assumptions and Methodology*, pages 122-135, the applicant provides the assumptions and methodology used to project utilization of the approved fixed PET scanner and the proposed fixed PET scanner.

- (7) *project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.*

-C- UNC Health Pardee. In Section Q, Table 9, page 117, the applicant projects that the proposed fixed PET scanner to be located in HSA I will perform more than 2,080 procedures during the third full fiscal year of operation following completion of the project. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

-C- Novant Health Asheville PET. In Section Q, page 126, the applicant projects that the proposed fixed PET scanner to be located in HSA I will perform more than 2,080 procedures during the third full fiscal year of operation following project completion. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

-C-Mission Hospital. In Section C, page 88, and Section Q, pages 141-142, the applicant projects that the existing and proposed fixed PET scanner located or to be located in HSA I will perform more than 2,080 procedures per PET scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

-NC-AdventHealth Asheville. In Section Q, pages 120-121, the applicant projects that the approved and proposed fixed PET scanners to be located in HSA I will perform more than 2,080 procedures per PET scanner during the third full fiscal year of operation following project completion. However, the applicant does not adequately demonstrate that the projected utilization of its proposed PET scanner is reasonable and adequately supported. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

(b) An applicant proposing to acquire a mobile PET scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing mobile PET scanners owned or operated by the applicant or a related entity that provided services at host sites located in the proposed mobile PET scanner service area during the 12 months before the application deadline for the review period;*
- (2) identify the approved mobile PET scanners owned or operated by the applicant or a related entity that will provide services at host sites located in the proposed mobile PET scanner service area during the first three full fiscal years following completion of the project;*
- (3) identify the existing fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed mobile PET scanner service area;*
- (4) identify the approved fixed PET scanners owned and operated by the applicant or a related entity and located in the proposed mobile PET scanner service area;*
- (5) identify the existing and proposed host sites for each mobile PET scanner identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile PET scanner;*

- (6) *provide projected utilization of the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile PET scanner during each of the first three full fiscal years of operation following completion of the project;*
- (7) *provide the assumptions and methodology used to project the utilization required by Subparagraph (6) of this Paragraph; and*
- (8) *project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.*

-NA-UNC Health Pardee. The applicant does not propose to acquire a mobile PET scanner.

-NA-Novant Health Asheville PET. The applicant does not propose to acquire a mobile PET scanner.

-NA- Mission Hospital. The applicant does not propose to acquire a mobile PET scanner.

-NA- AdventHealth Asheville. The applicant does not propose to acquire a mobile PET scanner.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2025 SMFP, no more than one fixed PET scanner may be approved for HSA I in this review. Because the four applications in this review collectively propose to develop four additional fixed PET scanners, all the applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review.

- Project I.D. #B-12675-25 / **Margaret R. Pardee Memorial Hospital** / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination
- Project I.D. #B-12684-25 / **Novant Health Asheville PET** / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination
- Project I.D. #B-12685-25 / **Mission Hospital** / Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination
- Project I.D. #B-12688-25 / **AdventHealth Asheville** / Change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds) to acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

Conformity with Statutory and Regulatory Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

UNC Health Pardee, Novant Health, and Mission Hospital are conforming to all applicable statutory and regulatory review criteria. The application submitted by **AdventHealth** is not conforming to all applicable statutory and regulatory review criteria and therefore, cannot be approved. Therefore, regarding this comparative factor, **UNC Health Pardee, Novant Health, and Mission Hospital** are more effective alternatives.

Scope of Services

The following table compares the scope of services proposed to be offered by each applicant on the proposed fixed PET scanner.

Facility	Proposed Scope of Proposed PET Services		
	Oncological PET	Cardiac PET	Neurological PET
UNC Health Pardee	X	X	X
Novant Health	X	X	X
Mission	X	X	X
AdventHealth	X	X	X

Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor. All the applicants propose to provide PET services to oncology, cardiac and

neurology patients. Therefore, regarding scope of services, **UNC Health Pardee**, **Novant Health**, and **Mission Hospital** are equally effective alternatives. The application submitted by **AdventHealth** is not approvable, therefore it cannot be an effective alternative.

Geographic Accessibility (Location within the Service Area)

The following table illustrates where in the service area the existing fixed PET scanners are located.

Facility	City	County
AdventHealth Hendersonville*	Hendersonville	Henderson
Catawba Valley Medical Center / Frye Regional Medical Center	Hickory	Catawba
Messino Cancer Centers	Asheville	Buncombe
Mission Hospital	Asheville	Buncombe

*Approved for a PET scanner but not in operation yet.

The following table illustrates where in the service area each applicant proposes to develop its proposal.

Applicant	Facility	City	County
UNC Health Pardee	Margaret R. Pardee Memorial Hospital	Hendersonville	Henderson
Novant Health	Novant Health Asheville PET	Arden	Buncombe
Mission	Mission Hospital	Asheville	Buncombe
AdventHealth	AdventHealth Asheville	Weaverville*	Buncombe

*AdventHealth’s change of scope application, Project ID# B-12526-24, approved by the Agency on November 21, 2024, proposed to change the location of the hospital from Candler to Weaverville. The decision is under appeal.

Novant Health, **Mission Hospital** and **AdventHealth** propose to locate their fixed PET scanner in Buncombe County. **UNC Health Pardee** proposes to locate its fixed PET scanner in Henderson County.

Generally, the application proposing to locate the fixed PET scanner in an area that does not have fixed PET services would be the most effective alternative. **UNC Health Pardee** and **Mission Hospital** propose to locate their fixed PET scanner in Hendersonville and Asheville, respectively, where fixed PET services are currently located. **Novant Health** proposes to locate its fixed PET scanner in Arden in Buncombe County. **AdventHealth** proposes to locate its fixed PET scanner in Weaverville in Buncombe County. Therefore, regarding this comparative factor, the applications submitted by **Novant Health** and **AdventHealth** are equally effective alternatives because they propose to locate the fixed PET scanner in areas which do not have a fixed PET scanner. However, **AdventHealth** is not approvable, therefore it cannot be an effective alternative. Therefore, **Novant Health** is the most effective alternative. **UNC Health Pardee** and **Mission Hospital** are less effective alternatives.

Access by Service Area Residents

The 2025 SMFP defines the service area for a fixed PET scanner as “the HSA in which it is located (Table 17F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” HSA I is comprised of 26 counties, including Henderson and Buncombe counties. **UNC Health Pardee** proposes to locate its fixed PET scanner in Henderson County. **Novant Health**, **Mission Hospital** and

AdventHealth propose to locate their fixed PET scanner in Buncombe County. Thus, the service area for this review is HSA I. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional fixed PET services in the service area where they live.

Each applicant provides the projected number of service area patients by county to be served in the initial three full project years following project completion.

UNC Health Pardee and **AdventHealth** provide percentages for the “Other” category in their projected patient origin tables. However, because the applicants include counties in the Other category that are in HSA I, it is not possible to quantify the number of patients projected to be served solely in HSA I counties. Therefore, the result of this analysis is inconclusive.

Access by Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”

For access by underserved groups, applications are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

Projected Medicaid

The following table compares projected access by Medicaid patients for PET services in the third full fiscal year following project completion for each facility.

Projected Percentage of Medicaid Patients , 3rd Full FY			
Applicant	Medicaid Gross Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
UNC Health Pardee	\$1,441,905	\$30,167,403	4.8%
Novant Health	\$1,781,861	\$30,721,747	5.8%
Mission	\$2,689,269	\$48,070,676	5.6%
AdventHealth	\$3,038,924	\$50,505,156	6.0%

Source: Form F.2b for each applicant.

As shown in the table above, **AdventHealth** projects the highest percentage of Medicaid revenue during the third full fiscal year following project completion. Generally, the application projecting to provide the highest percentage of Medicaid revenue is the more effective alternative for this comparative factor. Therefore, regarding projected access for Medicaid patients, the application submitted by **AdventHealth** is a more effective alternative. However, the application submitted by **AdventHealth**

is not approvable, therefore, it cannot be an effective alternative. **Novant Health** projects the next highest percentage of Medicaid revenue and is therefore the more effective alternative. **UNC Health Pardee** and **Mission Hospital** are less effective alternatives.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for each facility.

Projected Percentage of Medicare Patients , 3rd Full FY			
Applicant	Medicare Gross Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
UNC Health Pardee	\$23,263, 226	\$30,167,403	77.1%
Novant Health	\$21,720,275	\$30,721,747	70.7%
Mission	\$34,064,069	\$48,070,676	70.9%
AdventHealth	\$39,163,032	\$50,505,156	77.5%

Source: Form F.2b for each applicant.

As shown in the table above, **AdventHealth** projects the highest percentage of Medicare revenue during the third full fiscal year following project completion. Generally, the application projecting the highest percentage of Medicare revenue is the more effective alternative for this comparative factor. Therefore, regarding projected access for Medicare patients, the application submitted by **AdventHealth** is a more effective alternative. However, the application submitted by **AdventHealth** is not approvable. **UNC Health Pardee** projects the next highest percentage of Medicare revenue and is therefore the more effective alternative.

Competition (Access to a New or Alternate Provider)

The following table from page 365 of the 2025 SMFP illustrates the existing and approved providers of PET services located in the service area.

Facility	Planning Inventory	Procedures 2022-2023
AdventHealth Hendersonville*	1	
Catawba Valley Medical Center / Frye Regional Medical Center	1	1,649
Messino Cancer Center	1	192
Mission Hospital	1	2,862
HSA I Totals	4	4,703

*CON issued for new PET March 5, 2024. CON Project ID: B-12331-23

Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer fixed PET scanners than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

AdventHealth currently has one approved fixed PET scanner in Henderson County. **Mission Hospital** current owns and operates one fixed PET scanner in Buncombe County. **UNC Health Pardee** and **Novant Health** do not own or operate an existing or approved fixed PET scanner in the service area. **UNC Health Pardee** and **Novant Health** would be new providers of fixed PET services in HSA I. Therefore, **UNC Health Pardee** and **Novant Health** are more effective alternatives and **AdventHealth** and **Mission Hospital** are less effective alternatives. However, **AdventHealth** is not approvable and therefore, cannot be an effective alternative.

Projected Average Net Revenue per PET Procedure

The following table compares projected average net revenue per PET procedure in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average net revenue per procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

Average Net Revenue per PET Procedure 3rd Full FY			
Applicant	Total # of Procedures	Net Revenue	Average Net Revenue per PET Procedure
UNC Health Pardee	2,696	\$7,095,040	\$2,632
Novant Health	2,481	\$4,081,511	\$1,645
Mission	2,120	\$6,650,032	\$3,137
AdventHealth	2,091	\$5,808,093	\$2,778

Source: Section Q, Form C.2b and F.2b for each application.

As shown in the table above, **Novant Health** projects the lowest average net revenue per PET procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **Novant Health** is a more effective alternative and the applications submitted by **UNC Health Pardee**, **Mission Hospital** and **AdventHealth** are less effective alternatives. However, **AdventHealth** is not approvable and therefore, cannot be an effective alternative.

Projected Average Operating Expense per PET Procedure

The following table compares projected average operating expense per PET procedure in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average operating expense per procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Average Operating Expense per PET Procedure 3rd Full FY			
Applicant	Total # of PET Procedures	Operating Expenses	Average Operating Expense per PET Procedure
UNC Health Pardee	2,696	\$4,397,223	\$1,631
Novant Health	2,481	\$2,100,619	\$847
Mission	2,120	\$4,889,300	\$2,306
AdventHealth	2,091	\$3,810,974	\$1,823

Source: Section Q, Form C.2a and F.2b for each application.

As shown in the table above, **Novant Health** projects the lowest average operating expense per PET procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **Novant Health** is a more effective alternative and the applications submitted by **UNC Health Pardee**, **Mission Hospital** and **AdventHealth** are less effective alternatives. However, **AdventHealth** is not approvable and therefore, cannot be an effective alternative.

Summary

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor based on the comparative analysis results. The comparative factors are listed in the same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance.

Comparative Factor	UNC Health Pardee	Novant Health	Mission	AdventHealth*
Conformity with Statutory and Regulatory Review Criteria	Equally Effective	Equally Effective	Equally Effective	Not Conforming
Scope of Services	Equally Effective	Equally Effective	Equally Effective	Not Approvable
Geographic Accessibility (Location within the Service Area)	Less Effective	More Effective	Less Effective	Not Approvable
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Medicaid Patients	Less Effective	More Effective	Less Effective	Not Approvable
Access by Medicare Patients	More Effective	Less Effective	Less Effective	Not Approvable
Competition (Access to a New or Alternate Provider)	More Effective	More Effective	Less Effective	Not Approvable
Projected Average Net Revenue per Procedure	Less Effective	More Effective	Less Effective	Less Effective
Projected Average Operating Expense per Procedure	Less Effective	More Effective	Less Effective	Less Effective

*Had AdventHealth been conforming to all statutory and regulatory criteria, it would have been more effective for the following comparative factors: Geographic Accessibility (tied with Novant Health), Access by Medicaid Patients, and Access by Medicare Patients.

The application submitted by **Novant Health** was determined to be a more effective alternative regarding the following five factors:

- Geographic Accessibility (Location within the Service Area)
- Access by Medicaid Patients
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per PET Procedure
- Projected Average Operating Expense per PET Procedure

The application submitted by **UNC Health Pardee** was determined to be a more effective alternative regarding the following two factors:

- Access by Medicare Patients
- Competition (Access to a New or Alternate Provider)

The application submitted by **Mission Hospital** was not determined to be more effective regarding any of the comparative factors.

DECISION

UNC Health Pardee, Novant Health, and Mission Hospital's applications are individually conforming to the need determination in the 2025 SMFP for the development of one fixed PET scanner in HSA I as well as individually conforming to all applicable statutory and regulatory review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the 2025 SMFP is the determinative limit on the number of fixed PET scanners that can be approved by the Healthcare Planning and Certificate of Need Section. The application submitted by **AdventHealth** is not conforming to all applicable statutory and regulatory review criteria and therefore cannot be approved.

Based upon the independent review of each application and the Comparative Analysis, the following application is approved as submitted:

- **Project I.D. #B-12684-25 /Novant Health Asheville PET/ Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination**

And the following applications are denied:

- **Project I.D. #B-12675-25/Margaret R. Pardee Memorial Hospital/ Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination**
- **Project I.D. #B-12685-25/Mission Hospital/ Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination**
- **Project I.D. #B-12688-25/AdventHealth Asheville/Change of scope for Project ID# B-12233-22 (Develop a new 67-bed acute care hospital) and Project ID# B-12526-24 (Add 26 acute care beds) to acquire a fixed PET scanner pursuant to the 2025 SMFP need determination**

Project I.D. #B-12684-25/Novant Health Asheville PET is approved subject to the following conditions.

1. **Novant Health Long Shoals Imaging, LLC and Novant Health, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **Prior to issuance of the Certificate of Need, the certificate holder shall provide the Agency with documentation that an effort has been made to accommodate the clinical needs of health professional training programs in the area at Novant Health Asheville PET.**
3. **The certificate holder shall acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP, to be located at Novant Health Asheville PET in Arden, Buncombe County.**
4. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form**

provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.

- b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on September 1, 2026.
5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
 6. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
 7. The certificate holder shall develop and implement strategies to provide culturally competent services to members of its defined medically underserved community that are consistent with representations made in the certificate of need application.
 8. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.