

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 27, 2024

Findings Date: February 27, 2024

Project Analyst: Tanya M. Saporito

Co-Signer: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: F-12550-24
Facility: Atrium Health Pineville
FID #: 110878
County: Mecklenburg
Applicant(s): The Charlotte-Mecklenburg Hospital Authority
Project: Acquire no more than one fixed PET Scanner pursuant to the 2024 SMFP need determination

Project ID #: F-12557-24
Facility: Novant Health Presbyterian Medical Center
FID #: 943501
County: Mecklenburg
Applicants: Novant Health, Inc.
The Presbyterian Hospital
Project: Acquire no more than one fixed PET Scanner pursuant to the 2024 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 – Both Applications

Need Determination

The 2024 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed PET/CT scanners in North Carolina by service area. Application of the need methodology in the 2024 SMFP identified a need for one additional fixed PET/CT scanner in Health Service Area (HSA) III. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) proposing to develop a total of two new fixed PET/CT scanners in HSA III. However, pursuant to the need determination, only one fixed PET/CT scanner may be approved in this review.

Policies

There are two policies in the 2024 SMFP that are applicable to both applications: *Policy GEN-3* and *Policy GEN-4* in Chapter 4 of the 2024 SMFP.

Policy GEN-3

Policy GEN-3 on page 29 of the 2024 SMFP states:

“A certificate of need applicant applying to develop or offer 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 promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Policy GEN-4

Policy GEN-4 on page 30 of the 2024 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 of 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."

Project ID #F-12550-24 The Charlotte-Mecklenburg Hospital Authority (hereinafter referred to as "the applicant" or "CMHA") operates Atrium Health Pineville, an acute care hospital in Charlotte that provides acute, emergency and imaging services. The applicant proposes to acquire one fixed PET scanner to be located in Pineville Medical Plaza I (PMP I), a medical office building on the Atrium Health Pineville campus. Following project completion, the applicant would be licensed for one fixed PET scanner.

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

Policy GEN-3. In Section B, pages 27-31 the applicant explains why it believes its application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$4 million but less than \$5 million. In Section B, pages 32-33 the applicant explains why it believes its application is conforming to Policy GEN-4.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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- 3 and Policy GEN-4 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of PET services in the HSA III service area;
 - The applicant adequately documents how the project will promote equitable access to PET services in the HSA III service area;
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Project ID #F-12557-24 Novant Health, Inc. and The Presbyterian Hospital (hereinafter collectively referred to as “the applicant”) proposes to acquire no more than one fixed PET scanner to be developed along with the existing fixed PET scanner in the radiology department at Novant Health Presbyterian Medical Center (NHPMC) pursuant to the need determination in the 2024 SMFP, for a total of two fixed PET scanners.

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

Policy GEN-3. In Section B, pages 28-29 the applicant explains why it believes its application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is more than \$5 million. In Section B, pages 29-30 the applicant explains why it believes its application is conforming to Policy GEN-4.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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- 3 and Policy GEN-4 based on the following:

- The applicant adequately documents how the project will promote safety and quality in the delivery of PET services in the HSA III service area;
 - The applicant adequately documents how the project will promote equitable access to PET services in the HSA III service area;
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation
- (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 – Both Applications

Project ID #F-12550-24 The Charlotte-Mecklenburg Hospital Authority proposes to acquire one fixed PET scanner to be located in Pineville Medical Plaza I (PMP I), a medical office building on the Atrium Health Pineville campus. Following project completion, the applicant would be licensed for a total of five fixed PET scanners in the HSA III fixed PET scanner service area: two at Carolinas Medical Center in Mecklenburg County; one at Atrium Health Cabarrus in Cabarrus County, one at Atrium Health Union in Union County and one (proposed) at Atrium Health Pineville.

In Section C, page 34 the applicant describes the project as follows:

“The proposed fixed PET scanner will be the first at Atrium Health Pineville. It will serve oncology patients as well as patients from a range of other specialties, including neurology and cardiology.

...

The proposed fixed PET scanner will be developed at Pineville Medical Plaza I (PMP I), an existing medical office building (MOB) on Atrium Health Pineville's main campus that is connected to the hospital via a hallway. PMP I has vacated space on the first floor that was previously occupied by radiation oncology. ... a portion of this vacated space at PMP I is temporarily being used for storage and office space and would require minimal upfit to accommodate the proposed fixed PET scanner and associated support spaces.”

Patient Origin

On page 362, the 2024 SMFP defines the service area for fixed PET scanners as follows: “A fixed PET scanner’s **service area** is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Mecklenburg County which, according to Appendix A on page 367 of the 2024 SMFP is in HSA III. Thus, the service area for this proposal is HSA III. Facilities may also serve residents of counties not included in their service area.

The applicant does not currently offer fixed PET services at Atrium Health Pineville but provides historical patient origin for the entire facility for the last full fiscal year (FY), calendar year (CY) 2023, as shown in the following table:

Atrium Health Pineville Historical Patient Origin CY 2023

County	# Patients	% of Total
Mecklenburg	84,813	50.4%
York, SC	45,176	26.8%
Lancaster, SC	12,753	7.6%
Union	10,793	6.4%
Gaston	3,705	2.2%
Chester, SC	1,893	1.1%
Other*	9,178	5.5%
Total	168,311	100.0%

Source: Application Section C, page 37

*The applicant states “other” includes Cabarrus, Lincoln, Stanly, Anson, Iredell, Chesterfield (SC), Catawba, Richland (SC), Rowan counties, other NC counties and other states.

In Section C, page 38 the applicant states projected patient origin for PET/CT services is not expected to change as a result of this project. On page 40 the applicant provides projected patient origin for the first three full operating years following project completion, CYs 2027-2029 for fixed PET/CT services at Atrium Health Pineville, as shown in the following table:

Atrium Health Pineville Projected Patient Origin for PET Services, CYs 2027-2029

County	PY 1 (CY 2027)		PY 2 (CY 2028)		PY 3 (CY 2029)	
	# Pts	% of Total	# Pts	% of Total	# Pts	% of Total
Mecklenburg	621	37.6%	885	37.6%	946	37.6%
York, SC	541	32.8%	771	32.8%	824	32.8%
Union	227	13.7%	323	13.7%	346	13.7%
Lancaster, SC	195	11.8%	278	11.8%	297	11.8%
Chester, SC	46	2.8%	66	2.8%	71	2.8%
Anson	21	1.3%	31	1.3%	33	1.3%
Total	1,652	100.0%	2,354	100.0%	2,517	100.0%

In Section C, pages 38-39 the applicant provides the assumptions and methodology used to project patient origin for the proposed fixed PET/CT scanner.

The applicant's assumptions are reasonable and adequately supported because they are based on historical patient origin for all of Atrium Health Pineville.

Analysis of Need

In Section C.4, pages 42-53, the applicant explains why it believes the population projected to utilize the proposed fixed PET/CT services needs the proposed services, as summarized below:

- There is a need determination in the 2024 SMFP for one additional fixed PET scanner in the HSA III service area, and the applicant proposes to locate the proposed fixed PET scanner at Atrium Health Pineville, which is in HSA III (page 42).
- Expansion of clinical applications of PET imaging – The applicant states PET imaging is an imaging method that uses small amounts of radioactive materials to diagnose, stage and treat a variety of diseases, including but not limited to cancers, cardiac disease, GI disease, neurological and endocrine disorders. Because they use the radioactive materials (“radiopharmaceuticals” or “radiotracers”) to pinpoint diseases, PET scans are critical in the early detection and treatment of those diseases and disorders (pages 43-48).
- Need for additional PET capacity in Mecklenburg County – The applicant states that, although the need determination for additional fixed PET services includes all of HSA III, Mecklenburg County would be the most effective location for the proposed fixed PET scanner. The applicant states the North Carolina Office of State Budget and Management (NC OSBM) data shows that Mecklenburg County is the most populous of all the counties that comprise HSA III, and is projected to have the largest population per fixed PET scanner by 2029 (pages 48-50).
- Need for additional PET capacity for CMHA patients – The applicant states it currently operates four PET scanners in different counties within HSA III, and utilization increased by 13.8% from CY 2021-2024 (annualized). The applicant states CMC's PET utilization is what generated the need for the fixed PET scanner in the 2024 SMFP and providing additional PET capacity for patients who choose a CMHA facility is the most effective way to meet that need. The applicant states its patients who need a PET scan must wait an average of three weeks for a scan. These wait times are more than a delay to diagnostic imaging for its patients; excessive wait times could result in delays to a patient's treatment plan and recovery (pages 50-51).
- Need for PET imaging services at Atrium Health Pineville – The applicant states a number of its patients travel from the Southern Charlotte Region, which includes southern Mecklenburg County, adjacent areas in northern South Carolina, and adjacent counties southeast of Mecklenburg County. Most of these patients are geographically closer to Atrium Health Pineville than CMC. Excessive travel times

are burdensome for patients whose diagnosis and treatment are impacted by the excessive travel. The applicant provides patient letters in Exhibit I.2, some of which indicate the adverse impact of travel when dealing with difficult diagnoses like cancer or Alzheimer's disease.

The applicant states the proposed PET scanner at Atrium Health Pineville will not only provide a more convenient option for PET imaging services for its patients, but will also free up capacity at CMC, which will positively impact overall patient satisfaction, safety, and quality of care. In addition, the applicant states CMC does not have existing space in which to develop an additional fixed PET scanner without significant renovation. Atrium Health Pineville has vacated space that was previously occupied by radiation oncology and thus would require minimal upfit to accommodate the proposed fixed PET scanner (pages 51-53).

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

- There is a need determination in the 2024 SMFP for one additional PET scanner in HSA III, which includes Mecklenburg County.
- The applicant is the only provider of fixed PET services in the service area and its utilization generated the need in the 2024 SMFP.
- The applicant relies on its own internal historical utilization of its existing PET scanners in other counties within HSA III to illustrate the increasing demand for PET services in the service area.
- The applicant uses its historical patient origin data to project the population to be served, the projected growth of that population, and the need the identified population has for the proposed PET services.
- The applicant provides reasonable and clearly identified information to support the need for a fixed PET scanner at Atrium Health Pineville.

Projected Utilization

In Section Q, page 124 the applicant states the proposed PET scanner is projected to become operational in April 2026 and its operating year is a calendar year. Therefore, the first three full fiscal years of operation are CYs 2027-2029. In Section Q, Forms C.2b, the applicant provides projected utilization for its existing and the proposed fixed PET scanners, as shown in the following table:

ATRIUM HEALTH PINEVILLE	PARTIAL FY (04/01/2026- 12/31/2026)	1 ST FULL FY CY 2027	2 ND FULL FY CY 2028	3 RD FULL FY CY 2029
# PET Scanners	1	1	1	1
# Procedures	773	1,652	2,354	2,517

Source: Application Section Q, Form C.2b, page 117.

CAROLINAS MEDICAL CENTER	PARTIAL FY (04/01/2026-12/31/2026)	1 ST FULL FY CY 2027	2 ND FULL FY CY 2028	3 RD FULL FY CY 2029
# PET Scanners	2	2	2	2
# Procedures	5,672	5,238	5,010	5,356

Source: Application Section Q, Form C.2b, page 119.

ATRIUM HEALTH CABARRUS	PARTIAL FY (04/01/2026-12/31/2026)	1 ST FULL FY CY 2027	2 ND FULL FY CY 2028	3 RD FULL FY CY 2029
# PET Scanners	1	1	1	1
# Procedures	2,345	2,507	2,679	2,864

Source: Application Section Q, Form C.2b, page 121.

ATRIUM HEALTH UNION	PARTIAL FY (04/01/2026-12/31/2026)	1 ST FULL FY CY 2027	2 ND FULL FY CY 2028	3 RD FULL FY CY 2029
# PET Scanners	1	1	1	1
# Procedures	1,566	1,674	1,789	1,913

Source: Application Section Q, Form C.2b, page 123.

In Section Q, “*Form C Utilization – Assumptions and Methodology*”, pages 124-128, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

- Determine historical utilization of existing fixed PET scanners in the CMHA network – The applicant operates four PET scanners in HSA III: two at CMC and one each at Atrium Health Union and Atrium Health Cabarrus. Citing its internal utilization data from CY 2019-2024, the applicant determined that PET utilization in its existing facilities in HSA III increased by an average of 8.5% between CY 2019-2024 (annualized). The applicant states historical utilization is even greater when measured from CY 2021-2024 at 13.8%. The applicant states the PET scanner at Atrium Health Union has been recently utilized for CT simulator services until its dedicated CT simulator became operational in September 2024. Additionally, there has been a three week patient backlog at Atrium Health Cabarrus, which has impacted utilization.
- Project utilization of existing and proposed fixed PET scanners – To project utilization of its existing and proposed fixed PET scanners, the applicant assumes PET procedures will increase at a rate that is approximately one-half of the historical growth rate of the existing fixed PET scanners from CY 2021-2024, or 6.9%. The applicant states the growth rate is reasonable, given that it is lower than actual historical growth in each of the CMHA facilities and close to the 6.0% historical growth rate of all PET procedures in HSA III from federal fiscal year (FFY) 2019-2023. Citing the proposed 2025 SMFP

data, the applicant provides the following table to illustrate historical growth of PET procedures in HSA III:

Historical Fixed PET Procedures in HSA III, FFY 2019-2023

	FFY 2019	FFY 2020	FFY 2021	FFY 2022	FFY 2023	CAGR
HSA III Total	9,782	9,427	8,508	10,619	12,359	6.0%
State Total	44,657	41,330	45,264	55,147	64,215	9.5%

Source: Application Section Q, page 125.

On page 125, the applicant provides the following table to illustrate projected utilization of all of CMHA’s fixed PET scanners in HSA III, using the 6.9% growth rate:

CMHA HSA III Projected Fixed PET Procedures, CY 2024-2029

	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029	CAGR
CMC	5,640	6,029	6,445	6,889	7,365	7,873	6.9%
Atrium Health CI	2,052	2,194	2,345	2,507	2,679	2,864	6.9%
Atrium Health Union	1,370	1,465	1,566	1,674	1,789	1,913	6.9%
Total	9,062	9,687	10,356	11,070	11,833	12,650	6.9%

*Atrium Health Cabarrus Imaging.

- Project fixed PET utilization at Atrium Health Pineville – The applicant states the fixed PET scanner is proposed to be located in Pineville in the southern Charlotte region, which includes southern Mecklenburg County, adjacent areas in northern South Carolina and adjacent counties southeast of Mecklenburg County. The applicant states the patients who reside in this area are closer to Atrium Health Pineville. The applicant examined historical fixed PET procedures at CMHA facilities provided to those patients who reside in this region, and historical fixed PET procedures for those patients from the southern Charlotte region who received their procedures at CMC. Utilization increased as shown in the following tables from page 126:

Historical Fixed PET Procedures at CMHA Facilities from the Southern Charlotte Region

	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024*	CAGR 2019-24	CAGR 2021-24
Southern Charlotte Region	2,274	2,273	2,405	2,903	3,275	3,552	9.3%	13.9%

*Annualized based on January – May utilization.

Historical Fixed PET Procedures at CMC from the Southern Charlotte Region

	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024*	CAGR 2019-24	CAGR 2021-24
Southern Charlotte Region	1,771	1,739	1,912	2,225	2,314	2,254	4.9%	5.6%

*Annualized based on January – May utilization.

The applicant projects utilization at CMC from the southern Charlotte region will increase by 6.9% per year, as shown in the following table from page 127:

CMC Projected Fixed PET Procedures, CYs 2024-2029

	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029	CAGR 2024-29
Southern Charlotte Region	2,254	2,409	2,575	2,753	2,943	3,146	6.9%

The applicant assumes that 80% of the patients who reside in the southern Charlotte region and who currently travel to CMC for their PET services will shift their care to Atrium Health Pineville following project completion, which will reduce the demand and ease existing capacity constraints at CMC. The following table illustrates the ramp up of procedures at CMC using the 6.9% growth rate, and the 80% shift of procedures to Atrium Health Pineville in the first three project years:

Fixed PET Procedures Projected to Shift from CMC to Atrium Health Pineville

	CY 2024	CY 2025	CY 2026	PY 1 CY 2027	PY 2 CY 2028	PY 3 CY 2029
Southern Charlotte Region	2,254	2,409	2,575	2,753	2,943	3,146
Shift Percentage			80.0%	80.0%	80.0%	80.0%
Ramp Up			37.5%	75.0%	100.0%	100.0%
# Procedures to Shift			773	1,652	2,354	2,517

Source: Application page 127.

Projected PET Utilization Atrium Health Facilities

	CY 2024	CY 2025	CY 2026	PY 1 CY 2027	PY 2 CY 2028	PY 3 CY 2029
Atrium Health Pineville			773	1,652	2,354	2,517
CMC	5,640	6,029	5,672	5,238	5,010	5,356
Atrium Health Cabarrus Imaging	2,052	2,194	2,345	2,507	2,679	2,864
Atrium Health Union	1,370	1,465	1,566	1,674	1,789	1,913
HSA III Total	9,062	9,687	10,356	11,070	11,833	12,650
Fixed Scanners	4	4	5	5	5	5
Procedures Per Scanner	2,266	2,422	2,071	2,214	2,367	2,530

Projected utilization is reasonable and adequately supported based on the information in these findings, a review of the application and the exhibits and the following:

- The applicant makes reasonable and adequately supported assumptions regarding projected PET utilization based on documented population data, statewide PET use rates, and its historical PET utilization.
- The applicant provides reliable demographic and historical data to support the projected shift of PET procedures from its existing CMC facility to Atrium Health Pineville.

- The projected utilization of the applicant’s existing and proposed PET scanners meets the Performance Standards in 10A NCAC 14C .3703.

Access to Medically Underserved Groups

In Section C.6, page 60, the applicant states:

“Consistent with all CMHA facilities, Atrium Health Pineville provides services to all people in need of medical care and will continue to following the proposed project. ... As noted in CMHA’s Non-Discrimination Policy Statement, “[n]o individual shall be subject to discrimination or denied the benefits of the services, programs, or activities of Atrium Health on the basis of race, color, religion, national origin, age, sex, sexual orientation, gender identity, gender expression, disability or source of payment.” CMHA will continue to serve this population as dictated by the mission of CMHA, which is the foundation for every action taken. The mission is simple, but unique: To improve health, elevate hope, and advance healing – for all. This includes the medically underserved.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from Section C, page 61:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons*	
Racial and ethnic minorities	32.7%
Women	57.1%
Persons with Disabilities*	
Persons 65 and older	31.4%
Medicare beneficiaries	32.9%
Medicaid recipients	14.1%

*the applicant states it does not maintain data that includes the number of low income or disabled persons it serves and thus does not have a reasonable basis with which to estimate the percentage of low income or disabled persons it proposes to serve.

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 documents historical and projected access to Atrium Health Pineville, including PET services, for all residents of the service area, including underserved groups.
- The applicant projects its payor mix, which includes underserved groups, based on its historical experience.

Conclusion

The agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written comments
- Response 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 #F-12557-24 Novant Health, Inc. and The Presbyterian Hospital proposes to acquire no more than one fixed PET scanner to be developed along with the existing fixed PET scanner in the radiology department at Novant Health Presbyterian Medical Center (NHPMC) pursuant to the need determination in the 2024 SMFP, for a total of two fixed PET scanners.

Patient Origin

On page 362, the 2024 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s **service area** is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Mecklenburg County which, according to Appendix A on page 367 of the 2024 SMFP is in HSA III. Thus, the service area for this proposal is HSA III. Facilities may also serve residents of counties not included in their service area.

The following table, from Section C page 32 illustrates NHPMC’s historical patient origin for fixed PET services in the last full fiscal year of operation, CY 2023:

Novant Health Presbyterian Medical Center Historical Patient Origin

COUNTY	CY 2023	
	# OF PATIENTS	% OF TOTAL
Mecklenburg	1,140	58.7%
Union	199	8.3%
Gaston	161	6.7%
Iredell	107	4.5%
Cabarrus	58	2.4%
Lincoln	56	2.3%
Rowan	43	1.8%
Catawba	24	1.0%
Cleveland	14	0.6%
Stanly	12	0.5%
South Carolina	237	9.9%
Other*	82	3.4%
Total	2,403	100.0%

On page32 the applicant states “other” includes less than 1% from the remaining counties in North Carolina and other states.

The following table, from Section C page 34 illustrates NHPMC’s projected patient origin for fixed PET services in the first three full fiscal years of operation, CYs 2027-2029:

Novant Health Presbyterian Medical Center Projected Patient Origin

COUNTY	PY 1 CY 2027		PY 2 CY 2028		PY 3 CY 2029	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Cabarrus	74	2.3%	78	2.1%	82	1.9%
Gaston	217	6.7%	258	7.0%	314	7.2%
Iredell	156	4.9%	195	5.3%	248	5.7%
Lincoln	72	2.2%	76	2.0%	80	1.8%
Mecklenburg	1,936	60.2%	2,260	60.9%	2,671	61.5%
Rowan	52	1.6%	54	1.5%	57	1.3%
Stanly	14	0.4%	15	0.4%	16	0.4%
Union	280	8.7%	334	9.0%	407	9.4%
South Carolina	254	7.9%	254	6.9%	254	5.9%
Other	161	5.0%	185	5.0%	217	5.0%
Total	3,215	100.0%	3,709	100.0%	4,347	100.0%

On page34 the applicant states “other” includes less than 1% from the remaining counties in North Carolina and other states.

In Section C, page 34 the applicant states the projected patient origin is not expected to be significantly different from NHPMC’s historical patient origin.

The applicant's assumptions are reasonable and adequately supported because they are based on historical patient origin for existing fixed PET services at NHPMC.

Analysis of Need

In Section C, pages 37-57 the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- The 2024 SMFP identified a need in HSA III for one additional fixed PET scanner. The applicant states PET services are utilized to diagnose and treat many different types of diseases, including cancer and cardiac and neurological diseases. The applicant states demand for PET services at NHPMC continues to increase. The applicant states NHPMC is currently unable to offer cardiac PET procedures to its patients who need the service, despite having cardiologists on staff, due to demand for PET services (pages 37-43).
- The growing demand for PET services in North Carolina – The applicant cites data from the NCOSBM to illustrate the increase in PET utilization in the state as a whole from FY 2016-2023. The applicant states the North Carolina overall PET use rate per 1,000 increased 58% from FY 2016-2023. In addition, overall PET utilization increased by a CAGR of between 6.5% from FY 2016-2019, and by 7.7% from FY 2019-2023. The applicant states population growth and aging and disease incidence in North Carolina will continue to impact demand for PET services in the future (pages 43-44).
- Historical Utilization of Novant Health's fixed and mobile PET scanners – The applicant examined NHPMC's fixed PET utilization at NHPMC and mobile PET utilization at Novant Health Forsyth Medical Center (NHFMC). The applicant states fixed PET utilization increased by 13.6% from CY 2022-2023, and by 12.9% from CY 2023-2024. The applicant states the mobile PET utilization at NHRMC has increased as significantly as the fixed unit at NHPMC. The applicant states that demand for both mobile and fixed PET services continues to increase, creating scheduling constraints for its patients. The applicant states the existing and future PET services at NHPMC are supported by the hospital's service lines, including its Cancer Institute, Heart and Vascular Institute and its clinical research programs (pages 44-50).
- Projected population growth and aging in the service area – The applicant cites data from the NCOSBM to show the population in the counties that comprise HSA III (Cabarrus, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Stanly and Union) is projected to increase by a CAGR of 1.3% from 2024-2029. The projected growth in the 65 and over population during the same time is projected to increase by 3.7%. The older population cohort is the group more likely to utilize PET services to diagnose complications from cancer, cardiovascular disease and Alzheimer's disease (pages 50-53).
- The incidence of diseases for which PET scans are needed include cancer, cardiovascular disease and neurological diseases, all of which are prevalent in HSA III.

The applicant cites data from the NCOSBM to show the incidence of these diseases is likewise projected to increase during the same time as the population ages. The applicant states the population and demographic data support continuing demand for PET services in the area. The Novant Health network includes many physicians in many specialties that support the continued need for additional fixed PET services at NHPMC (pages 53-57).

Projected Utilization

In Section Q, “*Form C.2 Utilization Assumptions and Methodology*”, pages 117-124 the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

Step 1: Determine projected population growth in the counties that comprise HSA III by applying population growth data from the NCOSBM. The overall population in the eight counties that comprise HSA III is projected to increase by a CAGR of 1.6% from 2023-2029. See the tables that illustrate the data and projections in Section Q page 117.

Step 2: Using data from the NCOSBM, the applicant determined the statewide PET use rate per 1,000 increased from FY 2016-2023. The applicant states that, most recently (FY 2019-23), the statewide PET use rate increased by 7.7%. The applicant projects the statewide PET use rate will increase by one-half of the FY 2019-2023 rate, or by 3.9%. See the tables that illustrate the projections in Section Q page 118.

Step 3: The applicant applied the projected statewide PET use rate to the projected population growth in HSA III counties to project a PET procedure demand rate in the HAS III counties from 2024-2029. See the table that illustrates the calculations in Section Q page 119.

Step 4: Using its internal PET utilization data, the applicant estimated the Novant Health PET market share based on the CY2024 annualized PET procedures compared to the estimated demand by county from Step 3. Drawing on its own experience in providing PET services as well as the demographic data and population growth projections, the applicant projects that its market share in some counties within HSA III will remain consistent with the CY 2024 fixed PET market share, while the market share in other counties will increase during the three project years. See the tables that illustrate market share projections in Section Q pages 120-121.

Step 5: The applicant summarizes projected fixed PET procedures at NHPMC by applying the projected annual market share from Step 4 to projected PET demand from Step 3.

The applicant states that, based on historical utilization, it projects to provide 254 PET procedures in the third project year to patients who reside in South Carolina. The applicant also assumes, based on historical utilization, that immigration from other states and other counties in North Carolina will be 5% annually in each of the three project years. The following table, from Section Q page 122 summarizes Steps 1-5:

NHPMC Fixed PET Procedures

COUNTY	CY 2025	CY 2026	PY 1 (CY 2027)	PY 2 (CY 2028)	PY 3 (CY 2029)
Cabarrus	66	70	74	78	82
Gaston	181	188	217	258	314
Iredell	122	130	156	195	248
Lincoln	64	68	72	76	80
Mecklenburg	1,600	1,689	1,936	2,260	2,671
Rowan	48	50	52	54	57
Stanly	13	14	14	15	16
Union	227	241	280	334	407
SC	254	254	254	254	254
Inmigration 5.0%	135	142	161	185	217
Total	2,711	2,846	3,215	3,709	4,347

In Section Q, pages 123-124 the applicant projects utilization of its existing mobile PET scanner through each of the three project years, based on historical utilization.

Projected utilization is reasonable and adequately supported based on the information in these findings, a review of the application and the exhibits and the following:

- The applicant makes reasonable and adequately supported assumptions regarding projected PET utilization based on documented population data, statewide PET use rates, and its historical PET utilization.
- The projected utilization of the applicant’s existing and proposed PET scanners meets the Performance Standards in 10A NCAC 14C .3703.

Access to Medically Underserved Groups

In Section C.6, page 61, 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 NHPMC, as clinically appropriate.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from Section C, page 61:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	6.2%
Racial and ethnic minorities	40.9%
Women	59.0%
Persons with Disabilities*	
Persons 65 and older	26.9%
Medicare beneficiaries	27.6%
Medicaid recipients	19.4%

*the applicant states it does not maintain data that includes the number disabled persons it serves and thus does not have a reasonable basis with which to estimate the percentage of disabled persons it proposes to serve.

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 documents historical and projected access to NHPMC for all residents of the service area, including underserved groups.
- The applicant projects its payor mix, which includes underserved groups, based on its historical experience.

Conclusion

The agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written comments
- Response to Comments

Based on the review, the Agency concludes that the application is 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 with disabilities, and other underserved groups and the elderly to obtain needed health care.

NA – Both Applications

F-12550-24 The Charlotte-Mecklenburg Hospital Authority – The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

F-12557-24 Novant Health, Inc. and The Presbyterian Hospital – The applicant does not 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 – Both Applications

Project ID #F-12550-24 The Charlotte-Mecklenburg Hospital Authority proposes to acquire one fixed PET scanner to be located in Pineville Medical Plaza I (PMP I), a medical office building on the Atrium Health Pineville campus. Following project completion, the applicant would be licensed for one fixed PET scanner at Atrium Health Pineville.

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:

- Maintain the status quo – The applicant states current operation, under the status quo is not an effective alternative, because CMHA is “*seriously constrained*” in its ability to meet current patient demand for PET services. The applicant states patients wait three weeks on average for a PET scan, which ultimately delays diagnosis and treatment for patients facing significant health challenges. Delays are stressful to the patient and their family members, and adversely impact patients’ ultimate health. Therefore, the applicant states this is not an effective alternative to meet current and projected demand for PET services.
- Develop the proposed fixed PET scanner at CMC – The applicant considered locating the proposed fixed PET scanner at CMC because of its high utilization; however, the applicant states many patients who seek PET services at CMC are from the southern Charlotte region, which is closer to Atrium Health Pineville. The applicant states locating the proposed fixed PET scanner at Atrium Health Pineville will not only provide its current and future patients with a more convenient location for fixed PET services but will also relieve capacity and scheduling constraints. Thus, locating the fixed PET scanner at CMC is not a reasonable alternative.

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 credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional fixed PET scanner in Mecklenburg County.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

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

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

Project ID #F-12557-24 Novant Health, Inc. and The Presbyterian Hospital proposes to acquire no more than one fixed PET scanner to be developed along with the existing fixed PET scanner in the radiology department at Novant Health Presbyterian Medical Center (NHPMC) pursuant to the need determination in the 2024 SMFP, for a total of two fixed PET scanners.

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 states maintaining the status quo is not an effective alternative because it would ignore the need identified in the 2024 SMFP for a fixed PET scanner in the HSA III fixed PET scanner service area and would result in NHPMC extending hours of operation and its mobile PET service. Both scanners are operating in excess of capacity and NHPMC's patients are experiencing scheduling constraints and waiting for needed PET scans. Thus, this is not an effective alternative to meet the need for additional fixed PET services in the service area.
- Develop the proposed fixed PET scanner at another location – The applicant considered locating the proposed fixed PET scanner at another location in HSA III but determined that the proposed location is the most effective alternative to serve its existing and projected patients. Additionally, the applicant states developing the proposed fixed PET scanner at NHPMC is more cost effective than an alternate location because it will utilize existing facility space and support services. Thus, locating the fixed PET scanner at another location is not an effective alternative.

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 credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional fixed PET scanner in Mecklenburg County.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated 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 – Both Applications

Project ID #F-12550-24 The Charlotte-Mecklenburg Hospital Authority proposes to acquire one fixed PET scanner to be located in Pineville Medical Plaza I (PMP I), a medical office building on the Atrium Health Pineville campus. Following project completion, the applicant would be licensed for one fixed PET scanner at Atrium Health Pineville.

Capital and Working Capital Costs

In Section Q, Form F.1a on page 129 the applicant projects the total capital cost of the project, as shown in the table below:

Construction/Renovation	\$1,178,000
Medical Equipment	\$2,068,000
Non-Medical Equipment	\$3,000
Miscellaneous Costs	\$1,062,000
Total	\$4,311,000

In Section F.3, page 77, the applicant states there are no start-up costs or initial operating expenses associated with the project because the project does not involve developing a new facility.

In Section Q, page 130 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:

- The applicant bases cost of construction, medical and other equipment acquisition and miscellaneous project costs on vendor quotations as well as the applicant's experience with similar projects.
- The applicant provides a letter signed by an architect in Exhibit F.2-1 that confirms the project construction costs.

Availability of Funds

In Section F, page 75 the applicant states that the capital cost will be funded with the accumulated reserves of CMHA. In Exhibit F.2-2 the applicant provides a September 16, 2024 letter signed by the Chief Financial Officer of CMHA that confirms the availability of sufficient accumulated reserves for the project costs and commits the funds to the project. Exhibit F.2-2 also provides the audited financial statements of CMHA for the year ending December 31, 2023 that shows the entire CMHA network had \$2.95 billion in total current assets.

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 CMHA official confirming the availability of the funding proposed for the capital and working capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of sufficient accumulated reserves to fund the capital and working capital needs of the project.

Financial Feasibility

In Section Q, page 131 the applicant provided pro forma financial statements for the proposed fixed PET scanner at Atrium Health Pineville for the first three fiscal years of operation following project completion. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full FYs, CYs 2027-2029 as shown in the following table:

	1 ST FULL FY (CY 2027)	2 ND FULL FY (CY 2028)	3 RD FULL FY (CY 2029)
Total Procedures (Form C)	1,652	2,354	2,517
Total Gross Revenues (Charges)	\$13,710,307	\$20,127,528	\$22,161,286
Total Net Revenue	\$3,549,663	\$5,211,112	\$5,737,661
Average Net Revenue per Procedure	\$2,149	\$2,214	\$2,280
Total Operating Expenses (Costs)	\$2,351,065	\$3,000,007	\$3,202,997
Average Operating Expense per Proc.	\$1,423	\$1,274	\$1,273
Net Income	\$1,198,598	\$2,211,105	\$2,534,664

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding 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 conforming to this criterion for the following reasons:

- 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.
- 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 #F-12557-24 Novant Health, Inc. and The Presbyterian Hospital proposes to acquire no more than one fixed PET scanner to be developed along with the existing fixed PET scanner in the radiology department at Novant Health Presbyterian Medical Center (NHPMC) pursuant to the need determination in the 2024 SMFP, for a total of two fixed PET scanners.

Capital and Working Capital Costs

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

Construction/Renovation	\$3,400,000
Medical Equipment	\$2,797,479
Non-Medical Equipment	\$54,133
Miscellaneous Costs	\$1,159,790
Total	\$7,411,402

In Section F.3, page 75, the applicant states there are no start-up costs or initial operating expenses associated with the project because NHPMC currently provides fixed PET services.

In Section Q, page 132 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:

- The applicant bases cost of construction, medical and other equipment acquisition and miscellaneous project costs on vendor quotations as well as the applicant’s experience with similar projects.
- The applicant provides a letter signed by an architect in Exhibit K.3-1 that confirms the project construction costs.

Availability of Funds

In Section F.2, page 73, the applicant states that the capital cost will be funded with the accumulated reserves of Novant Health, Inc.

In Exhibit F.2 the applicant provides a September 4, 2024 letter signed by the Senior vice President, Operational Finance and Revenue Cycle that documents the availability of sufficient funds to cover the capital cost of the project and commits the funds to the project if approved. The documentation shows total assets available for capital expenditures in the amount of \$4.6 billion as of December 31, 2023.

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 Novant Health official confirming the availability of sufficient funding proposed for the project capital needs and the commitment to use those funds to develop the proposed project.
- The applicant provides documentation of sufficient accumulated reserves/current assets to fund the project capital needs.

Financial Feasibility

In Section Q, Form F.2b the applicant provides pro forma financial statements for the first three full fiscal years of operation following project completion for fixed PET services at NHPMC. In Form F.2b, page 127 the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following project completion, as shown in the following table:

NHPMC Financial Feasibility, First Three Project Years

	1 ST FULL FISCAL YEAR (CY 2027)*	2 ND FULL FISCAL YEAR (CY 2028)	3 RD FULL FISCAL YEAR (CY 2029)
Total Procedures (Form C.1b)	3,215	3,709	4,347
Total Gross Revenues (Charges)	\$49,892,608	\$57,451,871	\$66,977,398
Total Net Revenue	\$10,275,113	\$11,831,902	\$13,793,633
Average Net Revenue per procedure	\$3,196	\$3,190	\$3,173
Total Operating Expenses (Costs)	\$5,440,036	\$6,234,199	\$7,194,631
Average Operating Expense per procedure	\$1,692	\$1,681	\$1,655
Net Income	\$4,835,077	\$5,597,703	\$6,599,002

*The applicant’s table on page 127, Form F.2b labels the first three project years as CYs 2026-2028; however, the remainder of the application, projections and tables indicate the first three project years are CYs 2027-2029. The project analyst concludes that the headings in the table on page 127 are a typographical error.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding 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 conforming to this criterion for the following reasons:

- 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.
 - 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.
- (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 – Both Applications

The 2024 SMFP includes a need determination for one fixed PET scanner in HSA III.

On page 362, the 2024 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s service area is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Mecklenburg County which, according to Appendix A on page 367 of the 2024 SMFP is in HSA III. Thus, the service area for this proposal is HSA III. Facilities may also serve residents of counties not included in their service area.

The applicant does not currently offer fixed PET services at Atrium Health Pineville

The following table identifies the existing dedicated fixed PET scanners in HSA III, and the number of procedures for each PET scanner in 2021-2022 as found in Table 15F-1 on page 364 of the 2024 SMFP:

Fixed PET Scanners HSA III

SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2021-2022
Atrium Health Cabarrus	1	1,189
Atrium Health Union	1	680
Carolinas Medical Center	2	5,119
CaroMont Regional Medical Center	1	918
Iredell Memorial Hospital	1	628
Novant Health Presbyterian Medical Center	1	2,085
Total HSA III fixed PET scanners / Procedures	7	10,619

Project ID #F-12550-24 The Charlotte-Mecklenburg Hospital Authority proposes to acquire one fixed PET scanner to be located in Pineville Medical Plaza I (PMP I), a medical office building on the Atrium Health Pineville campus. Following project completion, the applicant would be licensed for one fixed PET scanner at Atrium Health Pineville.

In Section G.2, page 85, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanners in the HSA III fixed PET scanner service area. The applicant states:

“CMC is the only facility in HSA III with any volume in excess of the planning threshold. Further, CMC is the only facility affiliated with CMHA in Mecklenburg County that provides fixed PET imaging services, and CMC has been facing a three-week patient backlog for more than half a year. ... a number of patients choosing CMC for PET imaging are from the Southern Charlotte Region, and most are geographically closer to Atrium Health Pineville than CMC. Thus, developing the proposed PET scanner at Atrium Health Pineville will provide a more convenient option for PET imaging services for these patients, while also freeing up capacity at CMC. Thus, the proposed project will not result in unnecessary duplication.”

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 2024 SMFP for the proposed fixed PET scanner in HSA III.
- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved PET services in HSA III.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing and approved fixed PET scanners in HSA III. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

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

Project ID #F-12557-24 Novant Health, Inc. and The Presbyterian Hospital proposes to acquire no more than one fixed PET scanner to be developed along with the existing fixed PET scanner in the radiology department at Novant Health Presbyterian Medical Center (NHPMC) pursuant to the need determination in the 2024 SMFP, for a total of two fixed PET scanners.

In Section G.2, pages 82-83, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET services. The applicant states:

“The proposed project will not result in unnecessary duplication of existing or approved facilities in Health Service Area III. The 2024 SMFP has identified a need for one additional fixed PET scanner in the multi-county service area because PET utilization in the service area is projected to exceed the capacity of the existing and approved providers. The proposed project is needed to expand access to NHPMC’s well-utilized PET services.”

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 2024 SMFP for one fixed PET scanner in HSA III.
- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved fixed PET services in the HSA III fixed PET scanner service area.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing and approved fixed PET scanners. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is 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 – Both Applications

Project ID #F-12550-24 The Charlotte-Mecklenburg Hospital Authority proposes to acquire one fixed PET scanner to be located in Pineville Medical Plaza I (PMP I), a medical office building on the Atrium Health Pineville campus. Following project completion, the applicant would be licensed for one fixed PET scanner at Atrium Health Pineville.

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

POSITION	1 ST FULL FY (CY 2027)	2 ND FULL FY (CY 2028)	3 RD FULL FY (CY 2029)
Nuclear Medicine Tech.	2.0	2.5	2.5
Registrar	1.0	1.0	1.0
Total	3.0	3.5	3.5

The assumptions and methodology used to project staffing are provided in Section Q, “*Form H Assumptions*” on page 136. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q.

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

- The applicant adequately documents the number of FTEs it projects will be needed to offer the services proposed in this application.
- The applicant’s projections for FTEs are based on its own experience with staffing patterns for PET services at CMHA facilities.
- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3b in Section Q.

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 reasons described above.

Project ID #F-12557-24 Novant Health, Inc. and The Presbyterian Hospital proposes to acquire no more than one fixed PET scanner to be developed along with the existing fixed PET scanner in the radiology department at Novant Health Presbyterian Medical Center (NHPMC) pursuant to the need determination in the 2024 SMFP, for a total of two fixed PET scanners.

On Form H in Section Q, page 130 the applicant projects full-time equivalent (FTE) staffing for the proposed fixed PET services, as illustrated in the following table:

POSITION	1 ST FULL FY (CY 2027)	2 ND FULL FY (CY 2028)	3 RD FULL FY (CY 2029)
Nuclear Medicine Tech.	6.5	6.5	6.5
Radiology Operations Asst.	0.5	0.5	0.5
Total	7.0	7.0	7.0

The assumptions and methodology used to project staffing are provided in Section H, page 84. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q.

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

- The applicant adequately documents the number of FTEs it projects will be needed to offer the services proposed in this application, building on the previously-approved FTE complement for its fixed PET services at NHPMC.
- The applicant's projections for FTEs are based on its own historical experience in providing fixed PET services, and the projected staffing increases are a result of the fixed PET bed capacity proposed in this application.
- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3b in Section Q.

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 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.

C – Both Applications

Project ID #F-12550-24 The Charlotte-Mecklenburg Hospital Authority proposes to acquire one fixed PET scanner to be located in Pineville Medical Plaza I (PMP I), a medical office building on the Atrium Health Pineville campus. Following project completion, the applicant would be licensed for one fixed PET scanner at Atrium Health Pineville.

In Section I.1, page 91, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will be made available. Atrium Health Pineville is an existing hospital that currently provides the necessary ancillary and support services. The applicant states those same services will continue to be made available upon project completion. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I.2, page 92, the applicant describes its existing and proposed relationships with other local health care and social service providers. Atrium Health Pineville is an existing facility that currently has established relationships with local health care and social service providers, and those same relationships will continue following project completion. 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 stated above.

Project ID #F-12557-24 Novant Health, Inc. and The Presbyterian Hospital proposes to acquire no more than one fixed PET scanner to be developed along with the existing fixed PET scanner in the radiology department at Novant Health Presbyterian Medical Center (NHPMC) pursuant to the need determination in the 2024 SMFP, for a total of two fixed PET scanners.

In Section I.1, page 88, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will continue to be made available. NHPMC is an existing hospital that currently provides fixed PET services and necessary ancillary and support services, and those same services will continue to be made available upon project completion. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I.2, page 89, the applicant describes its existing and proposed relationships with other local health care and social service providers. NHPMC is an existing hospital that currently has established relationships with local health care and social service providers, and those same relationships will continue following project completion. 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 stated 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 – Both Applications

Project ID #F-12550-24 The Charlotte Mecklenburg Hospital Authority – Acquire one fixed PET scanner – The applicant does 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 applicant does 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.

Project ID #F-12557-24 The Presbyterian Hospital and Novant Health, Inc. - Acquire one fixed PET scanner – The applicant does 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 applicant does 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 – Both Applications

Project ID #F-12550-24 The Charlotte Mecklenburg Hospital Authority – Acquire one fixed PET scanner – The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

Project ID #F-12557-24 The Presbyterian Hospital and Novant Health, Inc. - Acquire one fixed PET scanner – The applicant is not an HMO. 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 – Both Applications

Project ID #F-12550-24 The Charlotte-Mecklenburg Hospital Authority proposes to acquire one fixed PET scanner to be located in Pineville Medical Plaza I (PMP I), a medical

office building on the Atrium Health Pineville campus. Following project completion, the applicant would be licensed for one fixed PET scanner at Atrium Health Pineville.

In Section K, page 95 the applicant states the project involves renovating 6,703 square feet of existing space in an existing medical office building on the Atrium Health Pineville campus. Line drawings are provided in Exhibit C.1.

On pages 95-96, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information in the application and exhibits and on the following:

- The applicant states the proposed fixed PET scanner will be developed in a medical office building on the main campus that is connected to the hospital via a hallway. There are minimal renovation costs associated with the project.
- The applicant states there is space in the medical office building that was previously used for radiation oncology, is currently used for storage and would require minimal upfit, thereby minimizing costs.

On page 96 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 information in the application and exhibits and on the following:

- The applicant states that the proposed renovation and upfit costs are necessary to accommodate the proposed fixed PET scanner.
- The applicant states the costs will ensure additional access to essential fixed PET services in the service area.
- The applicant states it has sufficient revenues set aside for project development without the need to increase costs or charges to the public.

In Section B.21, pages 32-33, the applicant identifies any applicable energy saving features that will be incorporated into the renovation and upfit plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

Project ID #F-12557-24 Novant Health, Inc. and The Presbyterian Hospital proposes to acquire no more than one fixed PET scanner to be developed along with the existing fixed PET scanner in the radiology department at Novant Health Presbyterian Medical Center (NHPMC) pursuant to the need determination in the 2024 SMFP, for a total of two fixed PET scanners.

In Section K, page 93 the applicant states that the project involves renovating 1,500 square feet of existing space to accommodate the proposed fixed PET scanner. Line drawings are provided in Exhibit K.2.

On pages 93-94 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information in the application and exhibits and on the following:

- 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 proposes to locate the fixed PET scanner in the NHPMC radiology department where the existing fixed PET scanner is located, thereby containing costs.

On page 93, 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 information in the application and exhibits and on the following:

- The applicant states that it has extensive experience developing and operating PET services and has confirmed that the size and scope associated with the proposed project renovation at NHPMC are consistent with the need the population has for the proposed fixed PET scanner.
- The applicant states the costs incurred to develop and operate this project are necessary and appropriate to promote competition and enhance access for service area patients.
- The applicant states the project will not increase charges or reimbursement for fixed PET services.

In Section K, page 94 the applicant describes the applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated 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 – Both Applications

Project ID # F-12550-24 / CMHA / Acquire one fixed PET scanner

In Section L, page 99, the applicant provides historical payor mix for CY 2023 for Atrium Health Pineville, as shown in the following table:

Atrium Health Pineville Total Historical Payor Mix, CY 2023

Payor Category	Percentage of Total Patients Served
Self-Pay	8.3%
Medicare*	32.9%
Medicaid*	14.1%
Insurance*	41.6%
Other (Includes other government plans)	3.1%
Total	100.0%

*Including any managed care plans.

On page 99 the applicant states CMHA internal data does not include charity care as a payor source for patients. The applicant states “Workers’ Compensation, TRICARE and other payors” are included in the “other” category.

In Section L, page 100, the applicant provides the following comparison.

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	57.1%	51.7%
Male	42.8%	48.3%
Unknown	0.1%	0.0%
64 and Younger	68.6%	87.8%
65 and Older	31.4%	12.3%
American Indian	0.6%	1.0%
Asian	2.8%	6.7%
Black or African American	26.8%	32.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	62.7%	56.6%
Other Race	2.3%	2.7%
Declined / Unavailable	4.7%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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 # F-12557-24 / The Presbyterian Hospital and Novant Health, Inc. / Acquire one fixed PET scanner

In Section L, page 96, the applicant provides historical payor mix for the last full operating year, CY 2023 for the facility, as shown in the following table:

NHPMC Historical Payor Mix, CY 2023

Payor Category	Percentage of Total Patients Served
Charity Care	4.0%
Medicare*	27.6%
Medicaid*	19.4%
Insurance*	43.7%
Other (other govt, institutional, workers comp)	5.3%
Total	100.0%

*Including any managed care plans.

In Section L, page 97, the applicant provides the following comparison.

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	59.0%	51.7%
Male	41.0%	48.3%
Unknown	0.0%	
64 and Younger	73.1%	87.7%
65 and Older	26.9%	12.3%
American Indian	0.4%	1.0%
Asian	2.7%	6.7%
Black or African American	31.6%	32.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	45.5%	43.9%
Other Race	6.5%	2.7%
Declined / Unavailable	13.2%	

The Agency reviewed the:

- Application
- Exhibits to the application

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.

- (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 – Both Applications

Project ID # F-12550-24 / CMHA / Acquire one fixed PET scanner

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 101, the applicant states:

“Atrium Health Pineville has no obligation to provide a specific uncompensated care amount, community service, or access by minorities or persons with disabilities. However, ... Atrium Health Pineville provides and will continue to provide services to all persons in need of medical care,

regardless of race, color, religion, national origin, age, sex, sexual orientation, gender identity, gender expression, disability, or source of payment....”

On page 102, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against Atrium Health Pineville.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

Project ID # F-12557-24 / The Presbyterian Hospital and Novant Health, Inc. / Acquire one fixed PET scanner

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 98, the applicant states it has no such obligation.

On page 98, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against NHPMC or any Novant Health facilities in the last five years.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

C – Both Applications

Project ID # F-12550-24 / CMHA / Acquire one fixed PET scanner

In Section L, page 102, the applicant states:

“Projected payor mix for the entire facility during the third full fiscal year of the project is based on the entire facility’s CY 2023 payor mix. Projected payor mix for the PET service component during the third full fiscal year of the project is based on the payor mix associated with the PET procedures performed at CMC in CY 2023 that are expected to shift to Atrium Health Pineville as part of the proposed project. With the expansion of Medicaid coverage in North Carolina, payor mix for the proposed services are expected to shift in the coming years. Based on what is known to date, it is expected that the increase in percentage of Medicaid patients will come primarily from those that are currently classified as Self-Pay. As both Medicaid and Self-Pay are considered underserved, CMHA demonstrates that patients from both categories will continue to have access to the proposed services....”

In Section L, page 102, the applicant projects the following payor mix for the proposed total facility and for PET services, respectively, during the third full FY of operation (CY 2029) following project completion, as shown in the tables below:

Atrium Health Pineville Total Facility Projected Payor Mix, CY 2029

Payor Category	Percentage of Total Patients Served
Self-Pay	8.3%
Medicare*	32.9%
Medicaid*	14.1%
Insurance*	41.6%
Other (Includes other government plans)	3.1%
Total	100.0%

*Including any managed care plans.

On page 102 the applicant states CMHA internal data does not include charity care as a payor source for patients. The applicant states “Workers’ Compensation, TRICARE and other payors” are included in the “other” category.

Atrium Health Pineville PET Services Projected Payor Mix, CY 2029

Payor Category	Percentage of Total Patients Served
Self-Pay	1.6%
Medicare*	58.9%
Medicaid*	3.2%
Insurance*	34.0%
Other (Includes other government plans)	2.4%
Total	100.0%

*Including any managed care plans.

On page 99 the applicant states CMHA internal data does not include charity care as a payor source for patients. The applicant states “Workers’ Compensation, TRICARE and other payors” are included in the “other” category.

As shown in the tables above, during the third full fiscal year of operation, the applicant projects that 8.3% of total facility services will be provided to self-pay patients, 32.9% to Medicare patients and 14.1% to Medicaid patients. Additionally, the applicant projects that 1.6% of PET services will be provided to self-pay patients, 58.9% to Medicare patients and 3.2% to Medicaid patients.

On page 102, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for Atrium Health Pineville and contemplates the impact of Medicaid expansion in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

Project ID # F-12557-24 / The Presbyterian Hospital and Novant Health, Inc. / Acquire one fixed PET scanner

In Section L, page 99, the applicant projects the following payor mix for the proposed total facility and for PET services, respectively, during the third full FY of operation (CY 2029) following project completion. The applicant indicates on page 99 that the third year of operation is CY 2028; however, the project analyst determined this is a

typographical error, since the remainder of the application confirms the three operating years are CYs 2027-2029. The following tables illustrate projected payor mix during the third FY of operation, CY 2029:

NHPMC Total Facility Projected Payor Mix, CY 2029

Payor Category	Percentage of Total Patients Served
Charity Care	4.0%
Medicare*	27.6%
Medicaid*	19.4%
Insurance*	43.7%
Other (other govt, institutional, workers comp)	5.3%
Total	100.0%

*Including any managed care plans.

NHPMC Fixed PET Projected Payor Mix, CY 2029

Payor Category	Percentage of Total Patients Served
Charity Care	1.9%
Medicare*	56.7%
Medicaid*	4.1%
Insurance*	34.2%
Other (other govt, institutional, workers comp)	3.1%
Total	100.0%

*Including any managed care plans.

As shown in the tables above, during the third full fiscal year of operation, the applicant projects that 4.0% of total facility services will be provided to charity care patients, 27.6% to Medicare patients and 19.4% to Medicaid patients. Additionally, the applicant projects that 1.9% of fixed PET services will be provided to charity care patients, 56.7% to Medicare patients and 4.1% to Medicaid patients.

On page 98, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for NHPMC fixed PET services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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.

C – Both Applications

Project ID # F-12550-24 / CMHA / Acquire one fixed PET scanner

In Section L.5, page 104, 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

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

Project ID # F-12557-24 / The Presbyterian Hospital and Novant Health, Inc. / Acquire one fixed PET scanner

In Section L.5, page 102 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

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 – Both Applications

Both Applications. In Section M, the applicants describe the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provide supporting documentation in the referenced exhibits.

The Agency reviewed the:

- Applications
- Exhibits to the applications

Based on that review, the Agency concludes that both of the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, both of the applications are conforming to this criterion.

(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 – Both Applications

The 2024 SMFP includes a need determination for one fixed PET scanner in HSA III.

On page 362, the 2024 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s service area is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Mecklenburg County which, according to Appendix A on page 367 of the 2024 SMFP is in HSA III. Thus, the service area for this proposal is HSA III. 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 III, and the number of procedures for each PET scanner in 2021-2022 as found in Table 15F-1 on page 364 of the 2024 SMFP:

Fixed PET Scanners HSA III

SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2021-2022
Atrium Health Cabarrus	1	1,189
Atrium Health Union	1	680
Carolinas Medical Center	2	5,119
CaroMont Regional Medical Center	1	918
Iredell Memorial Hospital	1	628
Novant Health Presbyterian Medical Center	1	2,085
Total HSA III fixed PET scanners / Procedures	7	10,619

Project ID #F-12550-24 The Charlotte-Mecklenburg Hospital Authority proposes to acquire one fixed PET scanner to be located in Pineville Medical Plaza I (PMP I), a medical office building on the Atrium Health Pineville campus. Following project completion, the applicant would be licensed for one fixed PET scanner at Atrium Health Pineville.

Regarding the expected effects of the proposal on competition, cost-effectiveness, quality, and access by medically underserved groups in the service area, in Section N, page 108, the applicant states:

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and particularly access to PET imaging services. Notably, as discussed in Section C.4, the proposed PET scanner at Atrium Health Pineville will provide a more convenient option for PET imaging services for the growing number of patients from the Southern Charlotte Region that are seeking care at CMC today, while also freeing up capacity at CMC – thus increasing overall patient satisfaction, safety, and quality of care, promoting competition in the region.”

Regarding the expected effects of the proposal on cost effectiveness in the service area, in Section B, page 31, the applicant states:

“Atrium Health Pineville, as a part of the larger CMHA system, benefits from significant cost savings measures through the consolidation of multiple services and large economies of scale. The proposed project will enable Atrium Health Pineville to provide its patients with the best care possible, while also being responsive in a healthcare environment that emphasizes cost containment and efficient utilization of existing resources.”

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

Regarding the expected effects of the proposal on quality in the service area, in Section B, page 27, the applicant states:

“CMHA 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, CMHA facilities are recognized by many of the top accrediting and ranking organizations in the industry.”

See the remainder of Section B, pages 27-28 and Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section B, page 28, the applicant states:

“The proposed project is designed to expand and improve access to all patients, including the medically underserved, particularly geographic and timely access to PET services ... CMHA has long-promoted economic access to its services as it historically has provided services to all persons in need of medical care, regardless of race, color, religion, national origin, age, sex, sexual orientation, gender identity, gender expression, disability or source of payment as demonstrated in CMHA’s Non-Discrimination policies provided in Exhibit B.20-4. The proposed project will continue to serve this population.... ”

See also Sections B, L and Q 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 will 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
- Information publicly available during the review and used by the Agency

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

Project ID #F-12557-24 Novant Health, Inc. and The Presbyterian Hospital proposes to acquire no more than one fixed PET scanner to be developed along with the existing fixed PET scanner in the radiology department at Novant Health Presbyterian Medical Center (NHPMC) pursuant to the need determination in the 2024 SMFP, for a total of two fixed PET scanners.

Regarding the expected effects of the proposal on competition, cost-effectiveness, quality, and access by medically underserved groups in the service area, in Section N, page 105 the applicant states:

“... additional fixed PET capacity is needed at NHPMC to alleviate capacity constraints and accommodate the increasing demand for PET procedures. The proposed project will promote cost-effectiveness, quality, and access to services and therefore will promote competition in the service area because it will allow Novant Health to expand access services to fixed PET services, to better meet the needs of its existing patient population, and to reduce scheduling delays, and improve patient satisfaction.”

Regarding the expected effects of the proposal on cost effectiveness in the service area, in Section N, page 105 the applicant states:

“This project will not increase the cost to patients or payors for the fixed PET services provided by NHPMC because reimbursement rates are set by the federal government and commercial insurers. The nominal capital expenditure for this project is necessary to ensure that NHPMC will have the capacity to continue to provide high-quality services that are accessible to patients. Locating the additional fixed PET scanner within the NHPMC facility will facilitate economies of scale of existing facility space and support services, which is efficient and cost effective.”

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

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 106 the applicant states:

“Novant Health is collaborating with payors and partners to identify payment models that match Novant Health’s value-based care delivery. Getting the right care in the right setting at the right price is the future of healthcare. It is what makes healthcare affordable and more sustainable. It is Novant Health’s approach to delivering remarkable healthcare so that people can get better and stay healthy.”

See also the remainder of Section N, Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 106 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. Novant Health’s financial assistance policy will apply to the proposed services.”

See also Sections B, L and Q 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 will 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
- Information publicly available during the review and used by the Agency

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 – Both Applications

Project ID #F-12550-24 The Charlotte-Mecklenburg Hospital Authority proposes to acquire one fixed PET scanner to be located in Pineville Medical Plaza I (PMP I), a medical office building on the Atrium Health Pineville campus. Following project completion, the applicant would be licensed for one fixed PET scanner at Atrium Health Pineville.

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

In Section O.4, page 113, the applicant states that, during the 18 months immediately preceding the submittal of the application, it is not aware of any deficiencies in quality of care at its acute care hospitals. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all of the applicant's 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 #F-12557-24 Novant Health, Inc. and The Presbyterian Hospital proposes to acquire no more than one fixed PET scanner to be developed along with the existing fixed PET scanner in the radiology department at Novant Health Presbyterian Medical Center (NHPMC) pursuant to the need determination in the 2024 SMFP, for a total of two fixed PET scanners.

In Section Q, Form O, the applicant identifies 18 hospitals located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.4, page 111 the applicant states that, during the 18 months immediately preceding the submittal of the application, there was a finding of *Immediate Jeopardy* on May 1, 2024 at Novant Health Pender Memorial Hospital's skilled nursing facility. The applicant states the facility was back in compliance as of May 6, 2024. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all of the applicant's 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 – Both 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;*
- C- CHMA.** The applicant states CMHA or a related entity currently owns or operates four fixed PET scanners in the fixed PET scanner service area: two at Carolinas Medical Center in Mecklenburg County, one at Atrium Health Cabarrus Imaging in Cabarrus County, and one at Atrium Health Union in Union County.
- C- Novant Health, Inc. and The Presbyterian Hospital.** The applicant states NHPMC owns and operates one fixed PET scanner in HSA III.
- (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- CMHA.** Neither the applicant nor any related entity has been approved to own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.
- NA- Novant Health, Inc. and The Presbyterian Hospital.** Neither the applicant nor any related entity has been approved to own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina..
- (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- CMHA.** Neither the applicant nor any related entity owns or operates any mobile PET scanners 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. The applicant contracts with Akumin (formerly Alliance Imaging) for mobile PET services at two locations in HSA III.
- C- Novant Health, Inc. and The Presbyterian Hospital.** In Section C, page 63 the applicant states NHPMC owns and operates one mobile PET scanner that serves four host sites located in HSA III, the fixed PET scanner service area. The applicant provides a table that identifies the four host sites on page 63.

- (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- CMHA.** Neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that will provide services at host sites located in the proposed fixed PET scanner service area.
- NA- Novant Health, Inc. and The Presbyterian Hospital.** Neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that will provide services at host sites located 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- CMHA.** In Section Q, Forms C.2b, the applicant provides projected utilization of its existing fixed PET scanners and the proposed fixed PET scanner located or proposed to be located in HSA III in each of the first three full fiscal years of operation.
- C- Novant Health, Inc. and The Presbyterian Hospital.** In Section Q, Forms C.2b, the applicant provides projected utilization of its existing fixed PET scanners, the proposed fixed PET scanner and the mobile PET scanner located or proposed to be located in HSA III in each of the first three full fiscal years of operation.
- (6) *provide assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph; and*
- C- CMHA.** In Section Q, “*Form C Assumptions and Methodology*” the applicant provides the assumptions and methodology used to project utilization of its existing and proposed fixed PET scanners located in HSA III.
- C- Novant Health, Inc. and The Presbyterian Hospital.** In Section Q, “*Form C.2 Utilization Assumptions and Methodology*” the applicant provides the assumptions and methodology used to project utilization of its existing and proposed fixed and mobile PET scanners located in HSA III.
- (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- CMHA.** In Section Q, “*Form C Assumptions and Methodology*” the applicant projects that the existing and proposed fixed PET scanners located or to be located in HSA III shall 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 found in Criterion (3) is incorporated herein by reference.

-C- Novant Health, Inc. and The Presbyterian Hospital. In Section Q, “*Form C Utilization Assumptions and Methodology*” the applicant projects that the existing and proposed fixed PET scanners located or to be located in HSA III shall 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 found 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- CMHA. The applicant does not propose to acquire a mobile PET scanner.

-NA- Novant Health, Inc. and The Presbyterian Hospital. The applicant does not propose to acquire a mobile PET scanner

COMPARATIVE ANALYSIS FOR FIXED PET SCANNER

Pursuant to G.S. 131E-183(a)(1) and the 2024 State Medical Facilities Plan, no more than one fixed PET scanner may be approved for the HSA III fixed PET scanner service area in this review. Because the applications in this review collectively propose to develop two additional fixed PET scanners in the HSA III fixed PET scanner service area, both applications cannot be approved for the total number of fixed PET scanners proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable 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 the Fixed PET Scanner Comparative Analysis.

- Project ID #F-12550-24 / **Atrium Health Pineville** / Acquire one fixed PET scanner pursuant to the need determination in the 2024 SMFP.
- Project ID #F-12557-24 / **Novant Health Presbyterian Hospital** / Acquire one fixed PET scanner pursuant to the need determination in the 2024 SMFP.

Conformity with Review Criteria

An application that is not conforming or not conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

Each application as submitted is conforming to all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with all applicable statutory and regulatory review criteria, the applications as submitted are individually approvable and equally effective.

Scope of Services

Regarding scope of services, both applications were submitted in response to the need determination in the 2024 State Medical Facilities Plan (SMFP) for one fixed PET scanner in Health Service Area (HSA) III. Generally, the application proposing to provide the broadest scope of services with the proposed equipment is the more effective alternative regarding this comparative factor.

The following table compares the scope of services proposed to be offered by each applicant on its proposed fixed PET scanner, based on information contained within each application:

Facility	Proposed Scope of Proposed Scope of PET Services		
	Oncological PET	Cardiac PET	Neurologic PET
Atrium Health	X	X	X
Novant Health	X	X	X

Each of the applicants proposes to provide fixed PET services to oncology, cardiac and neurologic patients. Therefore, regarding scope of services, the applications are equally effective.

Geographic Accessibility (Location within the Service Area)

The 2024 SMFP identifies the need for one fixed PET scanner in HSA III, which includes eight counties. The following table illustrates the location of the existing fixed PET scanners in HSA III:

Existing Fixed PET Scanners in HSA III

FACILITY	CITY	COUNTY
Atrium Health Cabarrus	Concord	Cabarrus
Atrium Health Union	Matthews	Union
Carolinas Medical Center	Monroe	Union
CaroMont Regional Medical Center	Mount Holly	Gaston
Iredell Memorial Hospital	Statesville	Iredell
Novant Health Presbyterian Medical Center	Charlotte	Mecklenburg

Source: 2024 SMFP, Table 15F-1, page 364

Atrium Health Pineville proposes to locate its fixed PET scanner at the hospital at 10628 Park Road in the town of Pineville in in the southern portion of Mecklenburg County, approximately 11 miles south of Charlotte and 30 minutes driving time from the existing fixed PET scanner located at Novant Health Presbyterian Medical Center. **Novant Health Presbyterian Medical Center** proposes to locate its fixed PET scanner in a medical office building connected to the main hospital at 200 Hawthorne Lane in Charlotte, in Mecklenburg County, on the same campus as the existing fixed PET scanner. It is reasonable to conclude that a proposed fixed PET scanner to be located in an area not currently served by an existing fixed PET scanner would be available to provide fixed PET services to a greater number of HSA III residents residing in an area not currently served by existing fixed PET services.

Therefore, regarding this comparative factor, the proposal submitted by **Atrium Health Pineville** is the more effective alternative, since it proposes to locate its proposed PET scanner in an area that could serve more patients residing in the southern portion of Mecklenburg County and HSA III who may not be able to travel to the existing fixed PET scanner in Charlotte. The application submitted by **Novant Health Presbyterian Medical Center** would be less effective because it proposes to locate the fixed PET scanner in Charlotte, which is currently served by both fixed and mobile PET services.

Access by Service Area Residents

On page 364, the 2024 SMFP defines the service area for fixed PET scanners as follows: “A fixed PET scanner’s service area is the HSA in which it is located (Table 17F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” According to Appendix A on page 367, HSA III is comprised of eight counties, including Mecklenburg County. Thus, the service area for each proposal is HSA III. **Atrium Health Pineville** and **Novant Health Presbyterian Medical Center** each propose to locate its fixed PET scanner, if approved, in Mecklenburg County which is in HSA III. 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 that service area.

Each applicant provides the projected number of service area patients by county to be served in each of the three fiscal years following project completion. On page 40 of its application, **Atrium Health Pineville** proposes to offer fixed PET services to patients in two of the eight counties that comprise HSA III. Although Atrium Health Pineville may serve patients who reside outside of HSA III on its proposed fixed PET scanner, the applicant specifically names the counties in North Carolina and in South Carolina from which its projected fixed PET patients will reside. The applicant does not include an “*other*” category. On page 34 of its application, **Novant Health** states it proposes to offer fixed PET services in each of the eight counties that comprise HSA III, and does include a category defined as “*other*.” However, on page 34 of its application, the applicant states “...*the ‘other’ category does not include any patients from the defined service area, i.e., HSA III.*” Therefore, each applicant provided information from which the Project Analyst can discern projected provision of fixed PET services to those patients residing in HSA III counties. This analysis will therefore focus only on service to residents of counties within HSA III as identified by each applicant in Section C of the application.

Novant Health Presbyterian Medical Center has been providing fixed PET services in Charlotte, which is in Mecklenburg County. Therefore, in order for the Project Analyst to conduct an equitable comparison of the projected numbers of service area patients to be served by each applicant, the historical (CY 2023) service area patients served by NHPMC’s existing fixed PET scanner was subtracted from Novant’s project year projections, resulting in the assumption that each applicant will add patients in the first project year from a base of zero. The Project Analyst prepared the following table to illustrate the projected number of service area patients to be served by each applicant in each applicant’s three project years following project completion for the proposed fixed PET services:

HSA III COUNTIES	NOVANT HEALTH PRESBYTERIAN MEDICAL CENTER			ATRIUM HEALTH PINEVILLE		
	PY 1 CY 2027	PY 2 CY 2028	PY 3 CY 2029	PY 1 CY 2027	PY 2 CY 2-28	PY 3 CY 2029
Cabarrus	16	62	66			
Gaston	56	202	258			
Iredell	49	146	199			
Lincoln	16	60	64			
Mecklenburg	526	1,734	2,145	621	885	946
Rowan	9	45	48			
Stanly	2	13	14			
Union	81	253	326	227	323	346
Total SA Patients	755	2,515	3,120	848	1,208	1,292

Source: F-12550-24: Application page 40; F-12557-24: Application pages 32 and 34

In Section C, pages 38-39 of its application, CMHA suggests that the Agency avoid a comparison of “Access by Service Area Residents” based on the Agency’s decisions in prior competitive

reviews of acute care beds and operating rooms in Mecklenburg County from 2019-2023. However, this review can be distinguished as follows:

- The reviews cited by the applicant involved acute care beds and/or operating rooms in the single county service area of Mecklenburg County.¹ This review is for a specific piece of equipment, a fixed PET scanner, in the multicounty service area of HSA III.
- The Agency's decision not to utilize *Access by Service Area Residents* in each of the reviews cited by the applicant assumed that the hospitals and hospital systems applying for acute care beds and/or operating rooms in the single county service area for which there was a need determination could draw patients from outside of the single county service area, because acute care and surgical services can draw patients from many counties, depending on the services offered by those hospitals. Hospitals, including those involved in the reviews cited by the Applicant, provide differing levels of acute and trauma care and surgical services which necessarily draw patients from outside of a service area, and which rendered an analysis of access by single county service area residents controvertible in that instance.

A fixed PET scanner's service area is defined on page 362 of the 2024 SMFP as "... *the HSA in which it is located.*" The 2024 SMFP identified a need determination for a fixed PET scanner in HSA III, which consists of eight counties including Mecklenburg County. It is reasonable in this review to analyze each applicant's projected patient origin for fixed PET services in HSA III and the number of patients residing in HSA III who would potentially derive a benefit from additional fixed PET services located in HSA III. Moreover, each applicant in this review either specifically excluded those counties outside of HSA III (**Novant Health**) or did not include an "*other*" category in its projections after specifically identifying those counties in HSA III that it projected to serve (**Atrium**).

- Acute care beds and operating rooms are health services that are available to patients for a multitude of reasons, wherein the reason for treatment, length of stay, treatment regimen and care vary greatly. By contrast, PET scans are specific diagnostic and treatment monitoring procedures.

Therefore, access by service area residents is an appropriate comparative factor in this review since the need determination in this review is for a fixed PET scanner to be located within HSA III. Applicants can and do serve patients from outside their defined service area; however, that does not bar the Agency from comparatively analyzing an applicant's projected service to service area residents as in this instance.

The Agency will only consider, for purposes of this comparative factor, those projected patients to be served residing within HSA III as represented by each of the applicants. As shown in the table above, **Atrium Health Pineville** projects to serve fewer residents from counties within the HSA III

¹ An acute care bed service area is defined on page 31 of the 2024 SMFP as "... *the single or multicounty grouping shown in Figure 5.1*". Mecklenburg County is identified in Figure 5.1 of the 2024 SMFP as a single county acute care bed service area. An operating room service area is defined on page 47 of the 2024 SMFP as "... *the single or multicounty grouping shown in Figure 6.1*". Mecklenburg County is identified in Figure 6.1 in the 2024 SMFP as a single county operating room service area.

fixed PET scanner service area than **Novant Health Presbyterian Medical Center**. Therefore, regarding this comparative factor, the application submitted by **Novant Health Presbyterian Medical Center** is the more effective alternative, since it proposes to provide fixed PET services to a greater number of patients residing in the HSA III fixed PET scanner service area.

Competition (Patient Access to a New or Alternate Provider)

Generally, the application proposing to increase patient access to a new provider of fixed PET services in the service area is the more effective alternative based on the assumption that introduction of a new provider would increase patient choice and competition and thus would encourage all providers in the service area to improve quality and/or lower costs in order to compete for patients.

Similarly, the expansion of an existing provider that currently controls fewer fixed PET scanners in the service area would likewise be the more effective alternative based on the same assumption – that expansion of an existing provider of fewer services would increase patient choice and competition and thus would encourage all providers in the service area to improve quality and/or lower costs in order to compete for patients.

As of the date of this decision, there are seven existing and approved fixed PET scanners in HSA III allocated between four providers, as shown in the following table, from Table 15F-1, page 364 of the 2024 SMFP:

Existing Fixed PET Scanners, HSA III

PROVIDER (HOSPITAL SYSTEM)	# OF FIXED PET SCANNERS
Atrium Health Cabarrus (Atrium)	1
Atrium Health Union (Atrium)	1
Carolinas Medical Center (Atrium)	2
CaroMont Regional Medical Center (CaroMont Health)	1
Iredell Memorial Hospital (Iredell Health System)	1
Novant Health Presbyterian Medical Center (Novant)	1
HSA III Total Fixed PET Scanners	7

The Atrium Health System currently owns and operates four fixed PET scanners, two of which are in Mecklenburg County in HSA III. Novant Health currently owns and operates one fixed PET scanner in Mecklenburg County in HSA III. Therefore, neither applicant would represent a new provider of fixed PET services in HSA III or in Mecklenburg County.

The Atrium Health System’s existing fixed PET scanners in HSA III represent 57.1% of the total fixed PET scanners in HSA III. Novant Health’s existing fixed PET scanner in HSA III represents 14.3% of the total fixed PET scanners in HSA III. By expanding fixed PET services currently offered at Novant Health Presbyterian Medical Center, patients in HSA III and Mecklenburg County would have an additional alternate choice for fixed PET services. Therefore, with regard to the expansion of an existing provider of fixed PET services within Mecklenburg County, the application submitted by **Novant Health** is the more effective alternative.

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 handicapped persons, 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 evaluated as a separate factor.

Projected Access by Medicare Recipients

The following table compares the total number of Medicare patients projected to utilize PET services in the third full fiscal year of operation for each application in this review. Generally, the application proposing the highest number of Medicare patients is the more effective alternative with regard to this comparative factor, assuming that provision of services to a greater number of Medicare recipients can indicate an applicant’s provision of care to medically underserved groups.

	# OF MEDICARE PTS
Atrium Health Pineville	1,483
Novant Health Presbyterian Medical Center	2,465

Source: Section L.3 and Form F.2b for each application.

As shown in the table above, **Novant Health** projects to serve the highest number of Medicare patients in the third full fiscal year of operation. Therefore, regarding this comparative factor, the application submitted by **Novant Health** is the more effective alternative in this review.

Projected Access by Medicaid Recipients

The following table compares the total number of Medicaid patients projected to utilize PET services in the third full fiscal year of operation for each application in this review. Generally, the application proposing the highest number of Medicaid patients is the more effective alternative with regard to this comparative factor, assuming that provision of services to a greater number of Medicaid recipients can indicate an applicant’s provision of care to medically underserved groups.

	# OF MEDICAID PTS
Atrium Health Pineville	81
Novant Health Presbyterian Medical Center	178

Source: Section L .3 and Form F.3b for each application.

As shown in the table above, **Novant Health** projects to serve the highest number of Medicaid patients in the third full fiscal year of operation. Therefore, with regard to this comparative factor, the application submitted by **Novant Health** is the more effective alternative.

Projected Medicare as a Percent of Gross Revenue

The following table shows each applicant’s percentage of gross revenue and dollar amount projected to be provided to Medicare patients for fixed PET services in each applicant’s third full operating year following project completion, based on the information provided in each application’s pro forma financial statements in Section Q for fixed PET services. Generally, the application proposing to provide a higher percentage and/or dollar amount of gross revenue to Medicare patients is the more effective alternative regarding this comparative factor, assuming a higher percentage of gross revenue of services to Medicare recipients can indicate an applicant’s provision of care to medically underserved groups.

Projected Medicare as % of Gross Revenue, Project Year 3			
	Medicare Revenue	Total Gross Revenue	Medicare % of Gross Revenue
Atrium Health Pineville	\$13,043,938	\$22,161,286	58.9%
Novant Health Presbyterian Medical Center	\$37,949,198	\$66,977,398	56.7%

Source: Section Q, Forms F.2.b for each application.

As shown in the table above, **Atrium Health Pineville** projects the highest percentage of gross revenue for fixed PET services that will be provided to Medicare patients in the third year of operation. **Novant Health Presbyterian Medical Center** projects the highest dollar amount of service to Medicare patients. Therefore, regarding this comparative factor, both applications are equally effective.

Projected Medicaid as a Percent of Gross Revenue

The following table shows each applicant’s percentage of gross revenue and dollar amount projected to be provided to Medicaid patients for fixed PET services in each applicant’s third full year of operation following project completion, based on the information provided in each applicant’s pro forma financial statements in Section Q for fixed PET services. Generally, the application proposing to provide a higher percentage and/or dollar amount of gross revenue to Medicaid patients is the more effective alternative regarding this comparative factor, assuming that provision of services to Medicaid recipients can indicate an applicant’s provision of care to medically underserved groups.

Projected Medicaid as % of Gross Revenue, PY 3			
	Medicaid Revenue	Total Gross Revenue	Medicaid % of Gross Revenue
Atrium Health Pineville	\$699,124	\$22,161,286	3.2%
Novant Health Presbyterian Medical Center	\$2,732,913	\$66,977,398	4.1%

Source: Section Q, Forms F.2.b for each application.

As shown in the table above, **Novant Health Presbyterian Medical Center** projects the highest percentage of gross revenue for PET services and the highest dollar amount that will be provided to Medicaid patients in the third year of operation. Therefore, regarding this comparative factor, the application submitted by **Novant Health Presbyterian Medical Center** is the more effective alternative.

Projected Average Net Revenue per PET Procedure

The following table compares projected average net revenue per PET procedure in the third full operating year following project completion for each project, based on the information provided in each application’s pro forma financial statements in Section Q. Generally, the application proposing the lowest average net revenue per procedure is the more effective alternative regarding this comparative factor, assuming the average net revenue per procedure could ultimately result in a lower cost to the patient or third-party payor.

AVERAGE NET REVENUE PER PET PROCEDURE PROJECT YEAR 3			
	TOTAL # OF PROCEDURES	TOTAL NET REVENUE	AVERAGE NET REVENUE /PET PROCEDURE
Atrium Health Pineville	2,517	\$5,737,661	\$2,280
Novant Health Presbyterian Medical Center	4,347	\$13,793,633	\$3,173

Source: Section Q, Forms C.2b and F.2.b for each application.

As shown in the table above, **Atrium Health Pineville** projects the lowest average net revenue per PET procedure in the third full fiscal year following project completion. Therefore, the application submitted by **Atrium Health Pineville** is the more effective alternative regarding this comparative factor.

Projected Average Operating Expense per PET Procedure

The following table compares projected average operating expense (cost) per PET procedure in the third full operating year following project completion for each facility, based on the information provided in each application’s pro forma financial statements in Section Q. Generally, regarding this factor, the application proposing the lowest average operating expense (cost) per procedure is the more effective alternative, assuming a lower average operating cost per procedure may indicate a lower cost to the patient or third-party payor and/or a more cost-effective service.

AVERAGE OPERATING COST PER PET PROCEDURE PROJECT YEAR 3			
	TOTAL # OF PROCEDURES	TOTAL OPERATING COST	AVERAGE OPERATING COST PET PROCEDURE
Atrium Health Pineville	2,517	\$3,202,997	\$1,273
Novant Health Presbyterian Medical Center	4,347	\$7,194,631	\$1,655

Source: Section Q, Forms C.2b and F.2.b for each application.

As shown in the table above, **Atrium Health Pineville** projects the lowest average operating cost per PET procedure in the third full fiscal year following project completion. Therefore, the application submitted by **Atrium Health Pineville** is the more effective alternative regarding this comparative factor.

SUMMARY

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis, which does not indicate and should not be construed to indicate an order of importance:

COMPARATIVE FACTOR	ATRIUM HEALTH PINEVILLE	NOVANT HEALTH PMC
Conformity with Statutory and Regulatory Review Criteria	Yes	Yes
Scope of Services	Equally Effective	Equally Effective
Geographic Accessibility (Location within the Service Area)	More Effective	Less Effective
Access by Service Area Residents	Less Effective	More Effective
Competition (Patient Access to a New or Alternate Provider)	Less Effective	More Effective
Projected Number of Medicare PET Patients PY 3	Less Effective	More Effective
Projected Number of Medicaid PET Patients PY 3	Less Effective	More Effective
Projected Medicare as % of Gross Revenue	Equally Effective	Equally Effective
Projected Medicaid as % of Gross Revenue	Less Effective	More Effective
Projected Average Net Revenue per PET Procedure, 3 rd PY	More Effective	Less Effective
Projected Average Operating Cost per PET Procedure, 3 rd PY	More Effective	Less Effective

As shown in the table above, the application submitted by **Novant Health Presbyterian Medical Center** was determined to be a more effective alternative regarding the following factors:

- Access by service area residents
- Competition (Patient access to new or alternate provider)
- Projected number of Medicare patients, PY 3
- Projected number of Medicaid patients, PY 3
- Projected Medicaid as a percent of gross revenue, PY 3

The application submitted by **Atrium Health** was determined to be a more effective alternative regarding the following factors:

- Geographic accessibility
- Projected average net revenue per PET procedure, PY 3
- Projected average operating costs per PET procedure, PY 3

DECISION

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **Novant Health Presbyterian Medical Center** is the more effective alternative proposed in this review for the development of one fixed PET scanner in HSA III pursuant to the need determination in the 2024 SMFP.

While each application is approvable standing alone, the approval of two applications would result in the approval of more fixed PET scanners than is determined to be needed, and therefore, the applications submitted by **Atrium Health** is denied.

Novant Health Presbyterian Medical Center proposes to acquire one fixed PET scanner pursuant to the need determination in the 2024 SMFP and the application is approved subject to the following conditions:

1. **Novant Health, Inc. and Novant Health Presbyterian Medical Center (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall acquire no more than one fixed PET scanner pursuant to the need determination in the 2024 SMFP,**
3. **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.**
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 July 1, 2025.**
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 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.