

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 26, 2025

Findings Date: October 3, 2025

Project Analyst: Ena Lightbourne

Co-Signer: Lisa Pittman

COMPETITIVE REVIEW

Project ID #:	F-12627-25
Facility:	Novant Health Huntersville Medical Center
FID #:	990440
County:	Mecklenburg
Applicants:	Novant Health, Inc.
Project:	The Presbyterian Hospital Novant Health Huntersville Medical Center Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

Project ID #:	F-12630-25
Facility:	Atrium Health Pineville
FID #:	110878
County:	Mecklenburg
Applicant:	The Charlotte-Mecklenburg Hospital Authority
Project:	Acquire no more than one fixed PET scanner pursuant to the 2025 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 2025 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed PET scanners in North Carolina by service area. Application of the need methodology in the 2025 SMFP identified a need for one additional fixed PET scanner in Health Service Area (HSA) 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 scanners in HSA III. However, pursuant to the need determination, only one fixed PET scanner may be approved in this review.

Policies

There are two policies in the 2025 SMFP that are applicable to both applications: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* and *Policy GEN-5: Access to Culturally Competent Healthcare* as stated in Chapter 4 of the 2025 SMFP.

Policy GEN-4 on page 30 of the 2025 SMFP states:

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

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy

efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

Policy GEN-5 on pages 30-31 of the 2025 SMFP states:

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

CON applications will include the following:

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

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

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

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

Item 4: *Provide support (e.g., best-practice methodologies, evidence-based studies with similar communities) that the strategies described in Items 2 – 3 are reasonable pathways for reducing health disparities, increasing*

health equity and improving the health outcomes to the medically underserved communities within the relevant service area.

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

In approving an application, Certificate of Need shall impose a condition requiring the applicant to implement the described strategies in a manner that is consistent with the applicant's representations in its CON application.

Project ID# F-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

Novant Health, Inc. and The Presbyterian Hospital Novant Health Huntersville (hereinafter referred to as "the applicant" or "Novant Health") propose to acquire one fixed PET/CT scanner to be located in a renovated space adjacent to the radiology department on the Novant Health Huntersville Medical Center ("NHHMC") campus. Following project completion, the facility would be licensed for one fixed PET/CT scanner. The facility currently offers mobile PET services.

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-4. The proposed capital expenditure for this project is greater than \$4 million but less than \$5 million. In Section B, page 26 the applicant explains why it believes its application is conforming to *Policy GEN-4*.

Policy GEN-5. In Section B, pages 27-33, the applicant explains why it believes its application is conforming to *Policy GEN-5*.

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- 4* and *Policy GEN-5* based on the following:

- The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.
- The applicant adequately describes the demographics of HSA III, which consists of eight counties, that include age, racial composition, disability, spoken language, and income and education levels.
- The applicant adequately describes its data-driven and evidence-based strategies for the purposes of health equities. These strategies include offering interpretation and translation services, spiritual services, diverse recruitment and training, ensuring access by utilizing mobile units, and tracking demographic and health data to identify gaps in care and improvements.
- The applicant adequately documents how Novant Health has successfully promoted health equities and improved health outcomes in the medically underserved communities.

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination The Charlotte-Mecklenburg Hospital Authority (hereinafter referred to as "the applicant" or "CMHA") proposes to acquire one fixed PET scanner to be located in an existing medical office building on the Atrium Health Pineville main hospital campus. Following project completion, the facility will 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-4. The proposed capital expenditure for this project is greater than \$4 million but less than \$5 million. In Section B, pages 27-28 the applicant explains why it believes its application is conforming to *Policy GEN-4*.

Policy GEN-5. In Section B, pages 29-34, the applicant explains why it believes its application is conforming to *Policy GEN-5*.

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- 4* and *Policy GEN-5* based on the following:
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.
 - The applicant adequately describes the demographics of HSA III. In Exhibit B.20, the applicant provides a chart that compares demographics by HSA III counties, which include but not limited to, age, race, education, household income, and language.
 - The applicant adequately demonstrates CMHA's effort to ensure equity in access to healthcare by describing its existing strategies, such as language access services, disability accommodations, screening and subsequent referrals for social barriers, its Hospital Violence Intervention Program, and Atrium Health Pineville's participation in Kids Eat Free.
 - The applicant documents CMHA's awards and accolades that reflect CMHA's efforts in improving access to healthcare.
- (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 – Novant Health

NC-CMHA

Project ID# F-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET/CT scanner to be located on the NHHMC campus. Following project completion, the applicant will be licensed for one fixed PET/CT scanner.

Patient Origin

On page 363, the 2025 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." The applicant proposes locating the fixed PET scanner in Mecklenburg County which, according to

Appendix A on page 369 of the 2025 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.

As of the date of this review, NHHMC does not offer fixed PET imaging services but provides mobile PET imaging services. The following tables illustrate historical projected patient origin.

NHHMC Historical Patient Origin Mobile PET services 01/01/2024-12/31/2024		
County	# of Patients	% of Total
Mecklenburg	440	40.2%
Iredell	336	30.7%
Lincoln	112	10.2%
Cabarrus	54	4.9%
Gaston	53	4.8%
Rowan	21	1.9%
Union	6	0.5%
Stanly	1	0.1%
Catawba	37	3.4%
Other NC Counties	22	2.0%
Other States	14	1.3%
Total	1,095	100.00%

Source: Section C, page 37

NHHMC Projected Patient Origin Fixed PET Services						
County	1 st Full FY		2 nd Full FY		3 rd Full FY	
	01/01/2027- 12/31/2027		01/01/2028- 12/31/2028		01/01/2029- 12/31/2029	
	CY 2027		CY 2028		CY 2029	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	686	43.6%	897	45.5%	1,192	47.6%
Iredell	427	27.1%	484	24.6%	556	22.2%
Lincoln	150	9.5%	183	9.3%	219	9.0%
Cabarrus	88	5.6%	129	6.5%	188	7.5%
Gaston	85	5.4%	112	5.7%	142	5.7%
Rowan	24	1.5%	25	1.3%	26	1.0%
Union	7	0.5%	7	0.4%	8	0.3%
Stanly	1	0.06%	1	0.05%	1	0.04%
Other-NC Counties and out of state	105	6.7%	132	6.7%	167	6.7%
Total	1,573	100.0%	1,970	100.0%	2,499	100.0%

Source: Section C, page 39

In Section C, page 39, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the CY 2024 historical patient origin of the facility's mobile PET imaging, anticipated market shares and demographic factors, as demonstrated in the applicant's projected utilization methodology.

Analysis of Need

In Section C, pages 41-54, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

High Demand for PET Services-North Carolina has seen a significant growth in PET volumes in recent years, according to the 2022-2025 SMFPs. More healthcare providers are adopting the usage of PET/CT scanners as diagnostic capabilities advance. The applicant states that the proposed PET scanner represents the most current technology and will have the capacity to perform up to three procedures per hour. The applicant states that this is an important factor considering anticipated growth in PET volume in HSA III. (pages 42-43)

Population Growth and Projected Aging in HSA III-The applicant states historical and projected population growth in the HSA III counties is driving the need to maintain PET capacity. Growth among the older population is significant, as this group tends to have

more complicated health issues and utilize healthcare services more than other age groups. (pages 43-45)

Prevalence Rates of Diseases in HSA III- Citing data from the North Carolina Office of State Budget and Management (NCOSBM) and health and science resources, the applicant states that the incidence of diseases such as cancer, cardiovascular and neurological are likely to increase as the population ages. The applicant demonstrates that PET scans play a vital role in detecting, staging, and/or treatment of these diseases further demonstrating the need for access to PET imaging services. The applicant states that the most recent increase in the statewide PET use rate supports continuing demand for PET services in the service area. (pages 45-52)

NHHMC mobile PET service-The applicant states that NHHMC's mobile PET/CT scanner is operating at full capacity. This has resulted in waitlists, backlogs and possible delays in treatment. The mobile PET/CT scanner operates two days of service per week and every other Saturday. The applicant states that the availability of a full-time fixed PET/CT scanner at NHHMC will increase accessibility and decrease wait times. (pages 52-53)

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

- There is a need determination in the 2025 SMFP for one additional PET scanner in HSA III.
- The applicant uses clearly cited, reasonable, and verifiable demographic, historical utilization, and health data to make assumptions regarding growth and aging of the service area population, statewide use rates, and the prevalence of diseases for which PET scans are needed.

Projected Utilization

In Section Q, Form D.2, the applicant provides historical and projected utilization, as illustrated in the following table.

NHHMC						
Historical, Interim, and Projected Utilization						
	Last Full FY	Interim Full FY	Interim Full FY	1 st PY	2 nd PY	3 rd PY
	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029
# of PET Scanners	1 (Mobile)	1 (Mobile)	1 (Mobile)	1(Fixed)	1(Fixed)	1(Fixed)
# of Procedures	1,123	1,169	1,243	1,573	1,970	2,499

In Section Q, Form C.2 *Utilization-Assumptions and Methodology*, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

*Step 1: Health Service Area III's Population Projections-*The applicant cites data from NCOSBM, to illustrate projected population growth in the HSA III counties. The applicant

states that NHHMC's mobile PET service area is consistent with the counties in HSA III. According to the data, Mecklenburg County population is projected to grow by over 75,000 residents by 2029.

Step 2: Procedure Use Rate for North Carolina-The applicant calculates the historical statewide PET utilization rate using NCOSBM population data and the number of annual PET procedures performed statewide (fixed and mobile) from FY 2016-FY 2023. During FY 2016-2019, statewide PET procedures experienced a Compound Annual Growth Rate (CAGR) of 6.5 percent. During FY 2019-FY 2023, statewide PET procedures increased annually by 9.2 percent. FY 2022-FY 2023 experienced double-digit growth. The applicant states that factors such as population aging, disease incidence, and increasing clinical indications are driving the ongoing demand for PET procedures. The applicant projects that statewide PET uses rates will increase by 4.6 percent, half of the FY2019-FY 2023 CAGR.

North Carolina PET Procedure Use Rate						
Year	2024	2025	2026	2027	2028	2029
Estimate PET Use Rate	7.46	7.80	8.16	8.54	8.93	9.34

Section Q, Form C.2 Utilization-Assumptions and Methodology, page 2

Step 3: Projected PET Procedure Demand Based on PET Use Rate-The applicant projects the future demand for PET procedures in the HSA III using the estimated PET use rate from the previous table and applied it to the projected population of the HSA III counties (e.g. *Cabarrus 2024 projected population [246,620] / [1,000] x 2024 use rate [7.46] = [1,840]*). The applicant states that projections are reasonable and conservative considering the historical and projected growth for PET imaging services.

Projected PET Procedure Demand Based on PET Use Rate						
Estimate PET Use Rate	7.46	7.80	8.16	8.54	8.93	9.34
Year	2024	2025	2026	2027	2028	2029
HSA III Counties						
Cabarrus	1,840	1,953	2,078	2,216	2,365	2,526
Gaston	1,821	1,927	2,039	2,157	2,277	2,404
Iredell	1,537	1,637	1,744	1,857	1,975	2,099
Lincoln	725	775	827	881	937	996
Mecklenburg	8,803	9,348	9,933	10,557	11,210	11,904
Rowan	1,146	1,204	1,262	1,325	1,392	1,465
Stanly	487	512	538	565	594	624
Union	1,982	2,133	2,294	2,458	2,629	2,804
HSA III Totals	18,342	19,489	20,715	22,017	23,379	24,821

Section Q, Form C.2 Utilization-Assumptions and Methodology, page 3

Step 4: NHHMC's PET Market Share-The applicant estimates NHHMC's PET market share based on the FY 2024 PET procedures compared to the estimated demand based on the statewide PET use rate. The applicant states that market share estimates are supported

by population growth and aging, disease incidence, increased capacity and the PET's expanded capability.

NHHMC Estimated Fixed PET Market Share, FY 2024			
Counties	Column 1 PET Procedure Demand (Based on Statewide PET Use Rate-Step 3)	Column 2: Number of 2024 Mobile PET Patients at NHHMC	Column 3: 2024 Estimates County Market Share for NHHMC
Cabarrus	1,840	54	2.95%
Gaston	1,821	53	2.92%
Iredell	1,537	336	22.0%
Lincoln	725	112	15.5%
Mecklenburg	8,803	440	5.0%
Rowan	1,146	21	1.8%
Stanly	487	1	0.20%
Union	1,982	6	0.30%

Section Q, Form C.2 Utilization-Assumptions and Methodology, page 4

The applicant projects incremental market share increases ranging from 1.0% to 2.5% in five of the HSA III counties during the first three project years. The applicant does not project a market share increase for Rowan, Stanly, and Union counties.

NHHMC Incremental Fixed PET Market Share Increase			
Counties	2027	2028	2029
Cabarrus	1.0%	1.5%	2.0%
Gaston	1.0%	1.0%	1.0%
Iredell	1.0%	1.5%	2.0%
Lincoln	1.5%	2.0%	2.5%
Mecklenburg	1.5%	2.0%	2.0%
Rowan	No change	No change	No change
Stanly	No change	No change	No change
Union	No change	No change	No change

Section Q, Form C.2 Utilization-Assumptions and Methodology, page 6

NHHMC Projected Fixed PET Market Share-2025-2029					
Counties	Interim Year 2025	Interim Year 2026	Project Year 1 2027	Project Year 2 2028	Project Year 3 2029
Cabarrus	2.95%	2.95%	3.95%	5.45%	7.45%
Gaston	2.92%	2.92%	3.92%	4.92%	5.92%
Iredell	22.0%	22.0%	23.0%	24.5%	26.5%
Lincoln	15.5%	15.5%	17.0%	19.5%	22.0%
Mecklenburg	5.0%	5.0%	6.5%	8.0%	10.0%
Rowan	1.8%	1.8%	1.8%	1.8%	1.8%
Stanly	0.20%	0.20%	0.20%	0.20%	0.20%
Union	0.30%	0.30%	0.30%	0.30%	0.30%

Section Q, Form C.2 Utilization-Assumptions and Methodology, page 6

Step 5: NHHMC Fixed PET Procedures-The following table summarizes projected fixed PET procedures based on the projected annual market share (*Step 4*) applied to the projected PET demand (*Step 3*). The table includes the applicant's estimates for counties outside of HSA III and out of state. The applicant states that counties outside of HSA III and out of state represent 6.7 percent of NHHMC's PET patient origin. The applicant estimates that in-migration will remain consistent with the historical in-migration.

NHHMC Projected Volumes Years 1-3					
Counties	Interim Year CY 2025*	Interim Year CY 2026	Project Year 1 CY 2027	Project Year 2 CY 2028	Project Year 3 CY 2029
Cabarrus	58	61	88	129	188
Gaston	56	60	85	112	142
Iredell	360	384	427	484	556
Lincoln	120	128	150	183	219
Mecklenburg	467	497	686	897	1,191
Rowan	22	23	24	25	26
Stanly	1	1	1	1	1
Union	6	7	7	8	8
Subtotal HSA III Counties	1,091	1,160	1,468	1,838	2,332
Other NC Counties and Out of State	78	83	105	132	167
Total PET Procedures	1,169	1,243	1,573	1,970	2,499

Section Q, Form C.2 Utilization-Assumptions and Methodology, page 7

*Interim Volume performed on mobile PET.

Novant Health Presbyterian Medical Center

The applicant owns and operates one fixed PET scanner at Novant Health Presbyterian Medical Center. The facility was approved for a second fixed PET scanner (Project ID# F-12557-24) in 2024. The applicant projects utilization using the same market shares demonstrated in the 2024 approved application (F-12557-24). The applicant does not project a substantial change in volume but accounts for changes in population and PET use rates.

NHPMC Fixed PET Procedure volumes					
Counties	Interim Year 2025	Interim Year 2026	Project Year 1 2027	Project Year 2 2028	Project Year 3 2029
Cabarrus	66	71	75	80	86
Gaston	187	198	231	278	341
Iredell	123	131	158	197	252
Lincoln	64	69	73	78	83
Mecklenburg	1,617	1,718	1,985	2,332	2,774
Rowan	49	52	54	57	60
Stanly	14	15	15	16	17
Union	237	255	297	358	437
South Carolina	254	254	254	254	254
Other NC Counties and Out of State (5%)	137	145	165	192	226
Total PET Procedures	2,749	2,906	3,308	3,842	4,530

Section Q, Form C.2 Utilization-Assumptions and Methodology, page 9

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

- The applicant makes reasonable and adequately supported assumptions regarding projected PET utilization based on documented population data, statewide and service area PET use rates, and its historical mobile PET utilization.
- The projected utilization of the existing and proposed PET scanner meets the Performance Standards in 10A NCAC 14C .3700.

Access to Medically Underserved Groups

In Section C, page 60, the applicant states:

“As set forth in the pro formas, a significant proportion of NHHMC’s proposed services will be provided to Medicare, Medicaid, and uninsured patient. NHHMC’s services will continue to be accessible to persons with disabilities, as required by the Americans with Disabilities Act.”

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

Medically Underserved Groups	Estimated % of Total Patients in 3 rd Full FY
Low-income persons	0.60%
Racial and ethnic minorities	36.4%
Women	60.1%
Persons with disabilities*	
Persons 65 and older	26.9%
Medicare beneficiaries	27.6%
Medicaid recipients	19.4%

Source: Section C, page 60

*On page 60, the applicant states that Novant Health does not
Does not retain data that includes disabled persons and does
not have a reasonable basis to estimate percentages.

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 because NHHMC is an existing facility serving underserved groups.

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 for all the reasons described above.

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination The applicant proposes to acquire one fixed PET scanner to be located at Atrium Health Pineville. Following project completion, the facility will be licensed for one fixed PET scanner.

Patient Origin

On page 363, the 2025 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.”* The applicant proposes locating the fixed PET scanner in Mecklenburg County which, according to Appendix A on page 369 of the 2025 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.

As of the date of this review, Atrium Health Pineville does not offer fixed PET services. The following table illustrates projected patient origin.

Atrium Health Pineville Fixed PET Services Projected Patient Origin						
County	1 st Full FY		2 nd Full FY		3 rd Full FY	
	01/01/2027- 12/31/2027		01/01/2028- 12/31/2028		01/01/2029- 12/31/2029	
	CY 2027		CY 2028		CY 2029	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
28277	84	7.1%	135	7.1%	193	7.1%
29732-SC	81	6.8%	130	6.8%	185	6.8%
28210	73	6.1%	117	6.1%	166	6.1%
28226	73	6.1%	117	6.1%	166	6.1%
29707-SC	69	5.8%	110	5.8%	157	5.8%
29730-SC	66	5.5%	106	5.5%	151	5.5%
29708-SC	64	5.4%	103	5.4%	146	5.4%
29715-SC	63	5.3%	102	5.3%	145	5.3%
29720-SC	46	3.9%	74	3.9%	106	3.9%
28105	44	3.7%	71	3.7%	101	3.7%
28173	44	3.7%	70	3.7%	100	3.7%
28278	42	3.5%	67	3.5%	95	3.5%
29710-SC	39	3.3%	63	3.3%	89	3.3%
28270	37	3.1%	59	3.1%	85	3.1%
28104	36	3.0%	58	3.0%	83	3.0%
28273	36	3.0%	57	3.0%	81	3.0%
29745-SC	31	2.6%	50	2.6%	71	2.6%
28079	28	2.3%	45	2.3%	64	2.3%
Other from Service Area^	118	9.9%	189	9.9%	270	9.9%
Other^^	119	10.0%	191	10.0%	273	10.0%
Total	1,194	100.0%	1,914	100.0%	2,728	100.0%

Source: Section C, page 40

^Other from Service Area includes 28110, 29706, 28134, 28112, 29704, 28103, 28170, 29712, 29058, 29743, Other NC ZIP codes, and Other State ZIP Codes from the Southern Charlotte Region.

^^ Other is expected to be comprised largely of in-migration from zip codes in surrounding counties outside of the Service Area (Southern Charlotte Region), with some patients originating from ZIP codes throughout NC and other states.

In Section C, page 39, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states:

“...projected PET utilization for Atrium Health Pineville is based on shifts of PET procedures historically performed at CMC on patients who originate from the Southern Charlotte Region and who would be more conveniently served through the proposed project. Projected patient origin is based on the CY 2024 patient

origin of the volume proposed to shift from CMC as part of the proposed project and considers the in-migration..."

The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant provides the assumptions and methodology used to identify the patient population that would be more conveniently served at Atrium Health Pineville. The discussion regarding projected utilization found in this Section is incorporated herein by reference.
- The applicant relied on the CY 2024 patient origin of the patient population projected to be served.

Analysis of Need

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

The Expansion of Clinical Applications of PET Imaging-Although highly used in cancer diagnosis, staging, and treatment, due to technical advances, PET scanning can also be used for treatment of other diseases such as Alzheimer's, Parkinson's and Thoracic. As technology expands the use of PET scanners, the demand for PET services will continue to grow. (pages 43-48)

Need for Additional PET Capacity in Mecklenburg County-The applicant states that there is a need for additional PET capacity in Mecklenburg County. As the largest county in the HSA III service area, Mecklenburg County's older population is expected to grow 4.0 percent annually by 2030, according to NCOSBM. This would be the largest growth of the older population among all of the HSA III service area counties. The applicant states that this population typically utilizes healthcare services more frequently. (page 48-50)

The Need for PET Imaging Services at Atrium Health Pineville-The applicant states that Atrium Health Pineville generated the 2024 SMFP need for the fixed PET scanner based on the facility's LINAC utilization and the lack of an existing PET scanner to support it. The applicant states that CMHA is experiencing capacity constraints and will not be able to meet the demand for PET services as the population grows. The four CMHA PET scanners operating in the HSA III service area experienced an average 13.7 percent annual growth from CY 2021 to CY 2024. Additionally, CMC has experienced operational challenges such as a three-week wait for a PET scanner resulting in treatment delays.

Need for Additional PET Capacity for Patients Choosing CMHA-Atrium Health Pineville is located in the Southern Charlotte Region. Due to the population growth and the development in the region, the facility itself has expanded significantly. The applicant states that Atrium Health Pineville needs the fixed PET scanner to keep up with growing services and oncology, neurology, and cardiology needs. Additionally, the applicant has

determined that patients seeking PET services at CMC would be better served at Atrium Health Pineville because of the more convenient location.

However, the applicant does not adequately demonstrate that the need the projected population has for the proposed service is reasonable and adequately supported because the applicant does not adequately demonstrate that projected utilization of the applicant's existing and proposed PET scanners meets the performance standards promulgated in 10A NCAC 14C .3700. See the discussion regarding projected utilization below, which is incorporated herein by reference. Therefore, projected need, which is based in part on projected utilization, is also questionable.

Projected Utilization

In Section Q, pages 114-120, the applicant provides projected utilization, as illustrated in the following tables.

Atrium Health Pineville			
	1st Full FY	2nd Full FY	3rd Full FY
	CY 2027	CY 2028	CY 2029
# of PET Scanners	1	1	1
# of Procedures	1,194	1,914	2,728

Source: Section Q, page 114

Carolina Medical Center			
	1st Full FY	2nd Full FY	3rd Full FY
	CY 2027	CY 2028	CY 2029
# of PET Scanners	2	2	2
# of Procedures	5,584	5,393	5,150

Source: Section Q, page 116

Atrium Health Cabarrus			
	1st Full FY	2nd Full FY	3rd Full FY
	CY 2027	CY 2028	CY 2029
# of PET Scanners	1	1	1
# of Procedures	2,568	2,745	2,933

Source: Section Q, page 118

Atrium Health Union			
	1st Full FY	2nd Full FY	3rd Full FY
	CY 2027	CY 2028	CY 2029
# of PET Scanners	1	1	1
# of Procedures	1,820	1,945	2,079

Source: Section Q, page 120

In Section Q, pages 121-125, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

CMHA operates four PET scanners at three facilities in HSA III.

CMHA Fixed PET Scanners in HSA III		
Facility	County	Units
Carolina Medial Center (CMC)	Mecklenburg	2
Atrium Health Cabarrus Imaging*	Cabarrus	1
Atrium Health Union	Union	1

Source: Section Q, page 121; 2025 SMFP

*Licensed as part of Atrium Health Cabarrus

To project PET utilization, the applicant begins with the historical utilization of the existing PET scanners operated by CMHA in HSA III.

Historical Fixed PET Procedures at CMHA Facilities in HSA III								
	CY19	CY20	CY21	CY22	CY23	CY24	CY19-CY24 CAGR*	CY21-CY24 CAGR*
CMC	4,358	4,117	4,538	5,200	5,513	5,455	4.6%	6.3%
Atrium Health Cabarrus Imaging	1,092	1,123	1,052	1,182	1,617	2,104	14.0%	26.0%
Atrium Health Union	584	602	560	745	999	1,491	20.6%	38.6%
Total	6,034	5,842	6,150	7,127	8,129	9,050	8.4%	13.7%

Source: Section Q, page 121; CMHA internal data

*Compound annual growth rate

According to internal data, PET procedures at CMHA facilities experienced a CAGR of 8.4 percent from CY 2019 to CY 2024. This growth rate is significantly higher than NCOSBM projected Mecklenburg County population growth rate of 1.5 percent. From CY 2021 to CY 2024, PET procedures experienced a higher growth rate of 13.7 percent. The applicant states that this growth is partially due to the replacement PET scanner at Atrium Health Cabarrus Imaging that produced higher images in less time. Atrium Health Union's growth was limited during the same period because its PET scanner was used partially for CT simulator planning until the dedicated CT simulator became operational September 2024. As previously stated, CMC has experienced a three-week wait resulting in treatment delays. The applicant states that based on these factors and the historical growth, the applicant projects that PET procedures will grow annually at 6.9 percent, half of the historical CY 2021 – CY 2024 annual growth 13.7 percent.

Projected Fixed PET Procedures at CMHA Facilities in HSA III							
	CY24	CY25	CY26	CY27	CY28	CY29	CY24-CY29 CAGR
CMC	5,455	5,830	6,230	6,659	7,116	7,605	6.9%
Atrium Health Cabarrus Imaging	2,104	2,249	2,403	2,568	2,745	2,933	6.9%
Atrium Health Union	1,491	1,593	1,703	1,820	1,945	2,079	6.9%
Total	9,050	9,672	10,336	11,047	11,806	12,617	6.9%

Source: Section Q, page 122

The applicant states that the growth rate used to project utilization is reasonable considering the historical growth of PET utilization at CMHA facilities, statewide, and in HSA III, as illustrated in the table below.

Historical Fixed PET Procedures in HSA III and North Carolina						
	FFY19	FFY20	FFY21	FFY22	FFY23	FFY19-FFY23 CAGR
HSA III Total	9,782	9,427	8,508	10,619	12,359	6.0%
HSA III Total Excluding Novant	7,631	7,388	6,507	8,534	10,084	7.2%
North Carolina Total	44,657	41,330	45,264	55,147	64,215	9.5%

Source: Section Q, page 122; 2021-2025 SMFP

To project fixed PET procedures at Atrium Health Pineville, the applicant analyzed the historical fixed PET procedures that originated from the Southern Charlotte Region. The applicant assumes that patients who choose Atrium Health Pineville for PET services will originate from Southern Charlotte Region. The following table illustrates the historical fixed PET procedures at CMHA facilities in HSA III originating from the Southern Charlotte Region.

Historical Fixed PET Procedures at CMHA Facilities in HSA III From the Southern Charlotte Region								
	CY19	CY20	CY21	CY22	CY23	CY24	CY19-CY24 CAGR*	CY21-CY24 CAGR
Southern Charlotte Region	2,274	2,273	2,405	2,903	3,257	3,597	9.6%	14.4%

Source: Section Q, page 123; CMHA internal data

The applicant states that patients from the Southern Charlotte Region are choosing CMC for PET imaging although they are geographically closer to Atrium Health Pineville. However, these patients are choosing at a lower rate of growth due to their existing capacity constraints. The applicant exams the historical fixed PET procedures at CMC originating from the Southern Charlotte Region.

Historical Fixed PET Procedures at CMC From the Southern Charlotte Region								
	CY19	CY20	CY21	CY22	CY23	CY24	CY19-CY24 CAGR*	CY21-CY24 CAGR
Southern Charlotte Region	1,771	1,739	1,912	2,225	2,314	2,201	4.4%	4.8%

Source: Section Q, page 123; CMHA internal data

The applicant projects the fixed PET procedures at CMC from the Southern Charlotte Region prior to the projected shift of patients to Atrium Health Pineville, using the annual growth rate of 6.9 percent.

Projected Fixed PET Procedures at CMC From the Southern Charlotte Region Before shift							
	CY24	CY25	CY26	CY27	CY28	CY29	CY24-CY29 CAGR
Southern Charlotte Region	2,201	2,352	2,514	2,687	2,871	3,069	6.9%

Source: Section Q, page 123

The applicant projects that 80 percent of patients originating from the Southern Charlotte Region (SCR) and choosing CMC for PET imaging, will shift to Atrium Health Pineville as a more convenient option. The applicant states that this percentage is reasonable because it will increase patient satisfaction, safety, and quality of care in the region while alleviating capacity constraints at CMC.

Projected Fixed PET Procedures to Shift from CMC to Atrium Health Pineville						
				PY1	PY2	PY3
	CY24	CY25	CY26	CY27	CY28	CY29
Southern Charlotte Region	2,201	2,352	2,514	2,687	2,871	3,069
Shift Percentage				80.0%	80.0%	80.0%
Ramp Up				50.0%	75.0%	100.0%
Total Procedures to Shift from CMC to Atrium Health Pineville				1,075	1,723	2,455

Source: Section Q, page 124

The applicant assumes that 10 percent of Atrium Health Pineville PET patients will originate from ZIP codes outside of the applicant's defined service area (SCR), including HSA III, that are not CMC patients and do not reside in the Southern Charlotte Region. The applicant states that these assumptions are reasonable and conservative considering the actual patient origin data from Atrium Health Cabarrus and Atrium Health Union. Both facilities operate one PET scanner in HSA III and attract over 10 percent of patients outside their respective service areas. The applicant projects fixed PET procedures at Atrium Health Pineville, including procedures from in-migration. The applicant projects that Atrium Health Pineville will perform 2,728 procedures by the third operating year, 90.9 percent of the 2025 capacity for a fixed PET scanner.

Total Projected Fixed PET Procedures at Atrium Health Pineville			
	PY1	PY2	PY3
	CY27	CY28	CY29
Total procedures to Shift from CMC to Atrium Health Pineville	1,075	1,723	2,455
Total Procedures from In-Migration	119	191	273
Total Procedures	1,194	1,914	2,728

Source: Section Q, page 125

The following table illustrates the projected fixed PET procedures at CMHA facilities in HSA III after the shift. The applicant projects to perform an average of 2,578 PET procedures per PET scanner by the third operating year. However, the Performance Standard of 2,080 procedures per PET scanner, promulgated in 10A NCAC 14C .3700, means each scanner. The applicant does not meet this standard, as shown below.

Projected Fixed PET Procedures at CMHA Facilities in HSA III After Shift						
				PY1	PY2	PY3
	CY24	CY25	CY26	CY27	CY28	CY29
Atrium Health Pineville				1,194	1,914	2,728
CMC	5,455	5,830	6,230	5,584	5,393	5,150
Atrium Health Cabarrus Imaging	2,104	2,249	2,403	2,568	2,745	2,933
Atrium Health Union	1,491	1,593	1,703	1,820	1,945	2,079
HSA III Total	9,050	9,672	10,336	11,166	11,997	12,890
Fixed Scanners	4	4	4	5	5	5
Procedures Per Scanner	2,263	2,418	2,584	2,233	2,399	2,578

Source: Section Q, page 125

Projected utilization is not reasonable and adequately supported. Although the applicant makes reasonable and adequately supported assumptions regarding projected PET utilization based on documented population data, statewide and service area PET use rates, and its historical PET utilization, the applicant does not adequately demonstrate that projected utilization of the applicant's existing and proposed PET scanners meets the performance standards promulgated in 10A NCAC 14C .3700.

Access to Medically Underserved Groups

In Section C, 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. Please see Exhibit C.6 for CMHA’s Non-Discrimination policies. ...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 healing – for all. This includes the medically underserved.

...

Patients lacking coverage receive financial counseling to determine eligibility for financial assistance. Patients who do not qualify for financial assistance will be able to establish an installment payment plan. Patients will receive the appropriate medical screening examination and any necessary stabilizing treatment for emergency medical conditions, regardless of ability to pay, in compliance with Federal EMTALA regulations."

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

Medically Underserved Groups	Estimated % of Total Patients in 3 rd Full FY
Low-income persons*	
Racial and ethnic minorities	32.6%
Women	56.8%
Persons with disabilities*	
Persons 65 and older	31.9%
Medicare beneficiaries	32.9%
Medicaid recipients	14.4%

Source: Section C, page 61

*The applicant does not maintain data on low-income or disabled persons.

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

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

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

NA – Both Applications

Neither applicant proposes 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 – Novant Health

NC-CMHA

Project ID# F-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET/CT scanner to be located on the NHHMC campus. Following project completion, the applicant will be licensed for one fixed PET/CT scanner.

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 that this alternative was rejected due to the 2025 SMFP need determination for one fixed PET scanner in HSA III. Maintaining the status quo would not meet the growing demand for PET services in the service area.
- Utilize Mobile PET Services-The applicant states that the existing mobile PET scanner located at NHHMC is operating at full capacity and has a four-to-five-week waiting list. Additionally, its patients and their referring physicians require access to a full time PET scanner. Therefore, this alternative was dismissed.

- Develop a Fixed Scanner at Another Location-The applicant dismissed this alternative based on the need to expand capacity in the large 8-county service area and the high utilization of mobile PET services at NHHMC.

On page 72, the applicant states that its proposal is the most effective alternative because it will meet the growing demand for PET services in HSA III and it would be the first fixed PET/CT scanner in northern Mecklenburg County.

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
- Responses to comments

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination CMHA proposes to acquire one fixed PET scanner to be located at Atrium Health Pineville. Following project completion, the facility will be licensed for one fixed PET scanner.

In Section E, pages 72-73, 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 Status Quo-The applicant states that maintaining the status quo is not a practical alternative. CMHA has issues meeting patient demand for PET services that has grown due to population growth and technical advances. Carolina Medical Center is the only facility affiliated with CMHA in Mecklenburg County that provides PET imaging and currently has a three-week patient backlog. This can result in delaying a patient treatment plan.

Develop the Proposed Fixed PET Scanner at CMC-The applicant states that this alternative is less effective because it would require significant renovation since CMC does not have existing space available.

On pages 72-73, the applicant states that its proposal is the most effective alternative because Atrium Health Pineville generated the need for the PET scanner in the service area and the proposed project will free up capacity at CMC while enhancing access to services for patients who reside closer to Atrium Health Pineville.

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

- The applicant did not demonstrate in the application as submitted that it was conforming with the Criteria and Standards for PET Scanners promulgated in 10A NCAC 14C .3700. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference. A proposal that cannot meet the required performance standards cannot be the most effective alternative.
- Because the applicant did not demonstrate the need to develop the proposed project, the applicant cannot demonstrate that it needs to acquire a fixed PET scanner. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference. A project that is unnecessarily duplicative cannot be the most effective alternative.
- Because the applicant did not demonstrate the need to acquire a PET scanner, it cannot demonstrate that any enhanced competition in the service area includes a positive impact on the cost-effectiveness of the proposed services. An applicant that did not demonstrate the need for a proposed project cannot demonstrate the cost-effectiveness of the proposed project. The discussion regarding demonstrating 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, found in Criterion (18a), is incorporated herein by reference. A project that cannot show a positive impact on the cost-effectiveness of the proposed services as the result of any enhanced competition cannot be the most effective alternative.
- The application is not conforming to all statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

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

- (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-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET/CT scanner to be located on the NHHMC campus. Following project completion, the applicant will be licensed for one fixed PET/CT scanner.

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.

Capital Costs	
Construction/Renovation Contracts	\$3,940,000
Architect/Engineering Fees	\$400,000
Medical Equipment	\$2,946,853
Consultant Fees	\$42,000
Project Contingency	\$100,000
Total	\$7,428,853

On Form F.1a, 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 that are based on the architect's cost estimates and the medical equipment quote. The applicant provides supporting documentation in Exhibits K and F.

In Section F, page 75, the applicant states there will be no start-up costs or initial operating expenses because NHHMC is an existing facility.

Availability of Funds

In Section F, page 73, the applicant states that the capital cost will be funded by Novant Health's accumulative reserves.

In Exhibit F, the applicant provides a letter dated April 7, 2025, from the Executive Vice president and Chief Financial Officer of Novant Health Inc., documenting its commitment to fund the project through Novant Health's accumulated reserves. Exhibit F includes Novant Health's 2023 and 2024 Consolidated Financial Statements documenting sufficient cash and cash equivalents and assets available to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

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

NHHMC	1 st Project Year	2 nd Project Year	3 rd Project Year
	CY2027	CY2028	CY2029
Total procedures	1,573	1,970	2,499
Total Gross Revenues (Charges)	\$21,715,819	\$28,326,897	\$37,385,256
Total Net Revenue	\$4,579,446	\$5,973,594	\$7,883,826
Average Net Revenue per Treatment	\$2,911	\$3,032	\$3,155
Total Operating Expenses (Costs)	\$3,022,834	\$3,641,951	\$4,482,264
Average Operating Expense per Treatment	\$1,922	\$1,849	\$1,794
Net Income	\$1,556,612	\$2,331,643	\$3,401,562

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:

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

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination CMHA proposes to acquire one fixed PET scanner to be located at Atrium Health Pineville. Following project completion, the facility will be licensed for one fixed PET scanner.

Capital and Working Capital Costs

In Section Q, page 126, the applicant projects the total capital cost of the project, as shown in the table below.

Capital Costs	
Construction/Renovation Contracts	\$1,354,700
Architect/Engineering Fees	\$271,400
Medical Equipment	\$2,389,000
Non-Medical Equipment	\$3,000
Furniture	\$82,000
Consultant Fees (CON and Legal Fees)	\$90,000
Other (IS, Security, Internal Allocation)	\$732,550
Total	\$4,922,650

On page 127, 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 that are based on CMHA and the architect's experience with similar projects and cost estimates.

In Section F, page 76, the applicant states there will be no start-up costs or initial operating expenses because the applicant is not proposing to develop a new facility.

Availability of Funds

In Section F, page 74, the applicant states that the capital cost will be funded by CMHA's accumulative reserves.

In Exhibit F.2-1, the applicant provides a letter dated April 15, 2025, from the Chief Financial Officer of CMHA, documenting its commitment to fund the project through CMHA's accumulated reserves. Exhibit F.2-2 includes CMHA's December 2023 Financial Statements documenting sufficient cash, cash equivalents and assets available to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

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

Atrium Health Pineville	1 st Project Year	2 nd Project Year	3 rd Project Year
	CY2027	CY2028	CY2029
Total procedures	1,194	1,914	2,728
Total Gross Revenues (Charges)	\$10,122,371	\$16,713,698	\$24,530,721
Total Net Revenue	\$2,523,344	\$4,166,456	\$6,115,114
Average Net Revenue per Treatment	\$2,113	\$2,177	\$2,242
Total Operating Expenses (Costs)	\$1,848,792	\$2,308,499	\$2,779,983
Average Operating Expense per Treatment	\$1,548	\$1,206	\$1,019
Net Income	\$674,552	\$1,857,957	\$3,335,131

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:

- 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 – Novant Health

NC-CMHA

The 2025 SMFP includes a need determination for one fixed PET scanner in HSA III.

On page 363, the 2025 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.”* The applicants propose locating the fixed PET scanner in Mecklenburg County which, according to Appendix A on page 369 of the 2025 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 fixed PET scanners in HSA III, and the number of procedures for each PET scanner in 2022-2023 as found in Table 15F-1 on page 365 of the 2025 SMFP:

Fixed PET Scanners in HSA III		
Site/Provider	# of Scanners	Total PET Procedures
Atrium Health Cabarrus	1	1,417
Atrium Health Union	1	953
Carolinas Medical Center	2	5,686
CaroMont Regional Medical Center	1	1,282
Iredell Memorial Hospital	1	746
Novant Health Presbyterian Medical Center	1	2,275
Total HSA III fixed PET scanners / Procedures	7	12,359

Project ID# F-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET/CT scanner to be located on the NHHMC campus. Following project completion, the applicant will be licensed for one fixed PET/CT scanner.

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

“NHHMC’s proposed project will not result in a duplication of existing services. The 2025 SMFP contains a need determination for additional fixed PET scanner due to high demand in the service area. NHHMC will acquire a state-of-the-art fixed PET/CT scanner at its existing facility to offer full-time fixed PET services for its patients. If approved, this will be NHHMC’s first fixed PET/CT scanner. The proposed fixed PET scanner at NHHMC will be the first one available in northern Mecklenburg County, which increases access and decreases travel time for patients.”

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

- There is a need determination in the 2025 SMFP for the proposed fixed PET scanner.
- The applicant adequately explains why 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 or approved PET scanners in HSA III. The discussion regarding the 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 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-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination CMHA proposes to acquire one fixed PET scanner to be located at Atrium Health Pineville. Following project completion, the facility will be licensed for one fixed PET scanner.

In Section G, page 83, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET imaging services in HSA III. The applicant states:

“...Atrium Health Pineville alone generated the need identified in the 2025 SMFP based on its significant linear accelerator utilization and lack of an existing PET scanner to support it. Further, CMHA’s flagship facility, CMC, is the only provider in HSA III with PET volume in excess of the planning threshold. Moreover, CMC is the only CMHA-affiliated facility in Mecklenburg County that currently provides fixed PET imaging services...”

However, the applicant did not adequately demonstrate the need it has for the proposed imaging services because the applicant does not adequately demonstrate that projected utilization of the applicant’s existing and proposed PET scanners meets the performance standards promulgated in 10A NCAC 14C .3700. The discussion regarding analysis of need including projected utilization found in Criteria (3) is incorporated herein by reference. Because the applicant did not demonstrate the need for the PET scanner, it cannot demonstrate that it is needed in addition to existing and approved PET scanners in the service area.

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 not conforming to this criterion for all the reasons described above.

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

Project ID# F-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET/CT scanner to be located on the NHHMC campus. Following project completion, the applicant will be licensed for one fixed PET/CT scanner.

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

Position	Projected FTE Staff		
	CY2027	CY2028	CY2029
Nuclear Medicine Tech	1.0	1.0	1.0
Supervisor	0.2	0.2	0.2
Total	1.2	1.2	1.2

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

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

- NHHMC is an established provider in the service area with a history of recruiting and retaining clinical and non-clinical staff.
- Novant Health has existing relationships with universities and colleges and uses scholarship programs to recruit staff.
- All clinical staff are required to complete orientation and training in their specific field and maintain appropriate licensure and certification.

Conclusion

The Agency reviewed the:

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

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

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination CMHA proposes to acquire one fixed PET scanner to be located at Atrium Health Pineville. Following project completion, the facility will be licensed for one fixed PET scanner.

In Section Q, page 131, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff		
	CY2027	CY2028	CY2029
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. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 85-87, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- CMHA has an established human resource department to recruit appropriate staff through media outlets, advertising on social network sites and participate in school career fairs and professional job fairs.
- CMHA adequately demonstrates its efforts to address hard-to-fill positions and the effectiveness of its existing initiatives.
- The applicant has relationships with Cabarrus College of Health Sciences and Carolinas College of Health Sciences, which are in the Cabarrus and Mecklenburg counties, respectively.

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 for all the reasons described above.

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

C – Both Applications

Project ID# F-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET/CT scanner to be located on the NHHMC campus. Following project completion, the applicant will be licensed for one fixed PET/CT scanner.

Ancillary and Support Services

In Section I, page 87, the applicant identifies the necessary ancillary and support services for the proposed services. On page 87, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available. The applicant states that NHHMC currently provides mobile PET services and ancillary and supports services will be available to support the proposed project.

Coordination

In Section I, page 88, the applicant describes its existing and proposed relationships with other local health care and social service providers. NHHMC 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 described above.

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination CMHA proposes to acquire one fixed PET scanner to be located at Atrium Health Pineville. Following project completion, the facility will be licensed for one fixed PET scanner.

Ancillary and Support Services

In Section I, page 88, the applicant identifies the necessary ancillary and support services for the proposed services. On page 88, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- Atrium Health Pineville is an existing facility with ancillary and support services in place that will be extended to the proposed fixed PET scanner.
- In supporting documentation, the applicant provides a letter from the Vice President and Facility Executive of Atrium Health Pineville attesting to the availability of ancillary and support services.

Coordination

In Section I, page 89, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on Atrium Health Pineville's existing relationships and support from other providers, including physicians.

Conclusion

The Agency reviewed the:

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

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA-Both Applications

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. Therefore, Criterion (9) is not applicable to this review.

- (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

Neither applicant is 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-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET/CT scanner to be located on the NHHMC campus. Following project completion, the applicant will be licensed for one fixed PET/CT scanner.

In Section K, page 91, the applicant states that the project involves renovating approximately 1,100 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 91, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant states that NHHMC has worked with experienced architects to develop the most cost-effective plan to develop the project. The applicant provides supporting documentation in a cost estimate certified by the project architect.

On page 92, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that the proposed renovation and upfit costs are necessary to accommodate the proposed fixed PET scanner and ensure that the need for fixed PET/CT services in the service area are met.
- The applicant states that cost and charges will not increase to the public because reimbursement rates are established by payment sources.

On page 92, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

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

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

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination CMHA proposes to acquire one fixed PET scanner to be located at Atrium Health Pineville. Following project completion, the facility will be licensed for one fixed PET scanner.

In Section K, page 92, the applicant states that the project involves renovating 6,703 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

On pages 92-93, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal because the applicant states that the PET scanner will be developed in a vacant space that was previously occupied by radiation oncology which will require minimal upfitting.

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 following:

- The applicant states the cost of the project is necessary to develop the PET scanner and provide necessary PET imaging services.
- The applicant states that CMHA sets aside excess revenues to develop projects without increasing costs or charges.

In Section B, pages 27-28, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

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

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

(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-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 95, the applicant provides the historical payor mix during CY 2024 for the proposed services, as shown in the table below.

NHHMC Historical Payor Mix CY 2024	
Payor Source	% of Total
Self-Pay	2.7%
Charity Care	2.0%
Medicare*	37.4%
Medicaid*	11.0%
Insurance*	43.8%
Worker's Comp.	0.4%
TRICARE	1.2%
Other (Commercial, Auto/Liability)	1.6%
Total	100.0%

Including any managed care plans.

In Section L, page 96, the applicant provides the following comparison

	Percentage of Total Patients Served	Percentage of the Population of the Service Area *
Female	60.1%	51.7%
Male	39.8%	48.3%
Unknown	0.1%	0.0%
64 and Younger	63.6%	87.7%
65 and Older	36.4%	12.3%
American Indian	0.4%	1.0%
Asian	1.3%	6.7%
Black or African American	25.1%	32.8%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	61.9%	43.9%
Other Race	7.1%	2.7%
Declined / Unavailable	4.1%	-

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

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 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-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

Section L, page 96, the applicant provides the historical payor mix during CY 2024 for the proposed services, as shown in the table below.

Atrium Health Pineville Historical Payor Mix CY 2024	
Payor Source	% of Total
Self-Pay	7.1%
Medicare*	32.9%
Medicaid*	14.4%
Insurance*	42.4%
Other (Other Payor)	3.1%
Total	100.0%

Including any managed care plans.

*CMHA internal data does not include Charity Care as a payor source. Patients in any category can and do receive Charity Care. Workers Compensation, TRICARE, and other payors included in the Other Payor category.

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

	Percentage of Total Patients Served	Percentage of the Population of the Service Area *
Female	56.8%	51.7%
Male	43.0%	48.3%
Unknown	0.2%	0.0%
64 and Younger	68.1%	87.7%
65 and Older	31.9%	12.3%
American Indian	0.6%	1.0%
Asian	2.8%	6.7%
Black or African American	26.6%	32.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	63.1%	56.6%
Other Race	2.4%	2.8%
Declined / Unavailable	4.3%	0.0%

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

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 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-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 97, the applicant indicates that the facility does not have said obligation.

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

The Agency reviewed the:

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

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

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 98, 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, as stated earlier, 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 as demonstrated in CMHA’s Non-Discrimination policies provided in previously referenced Exhibit C.6.”

In Section L, page 99, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments

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

- (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-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 98, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the tables below.

NHHMC Entire Facility Projected Payor Mix CY 2029	
Payor Source	% of Total
Self-Pay	2.7%
Charity Care	2.0%
Medicare*	37.4%
Medicaid*	11.0%
Insurance*	43.8%
Worker's Comp.	0.4%
TRICARE	1.2%
Other (Commercial, Auto/Liability)	1.6%
Total	100.0%

Including any managed care plans.

NHHMC Fixed PET Services Projected Payor Mix CY 2029	
Payor Source	% of Total
Self-Pay	0.3%
Charity Care	0.3%
Medicare*	66.4%
Medicaid*	2.8%
Insurance*	27.1%
Worker's Comp.	0.9%
TRICARE	0.3%
Other (Commercial, Auto/Liability)	1.9%
Total	100.0%

Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.3% of total services will be provided to self-pay patients, 0.3% to charity care patients, 66.4% to Medicare patients and 2.8% to Medicaid patients.

On page 98, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the facility's historical payor mix for existing mobile PET imaging services.

The Agency reviewed the:

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

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

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 99, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the tables below.

Atrium Health Pineville Projected Payor Mix CY 2029	
Payor Source	% of Total
Self-Pay	7.1%
Medicare*	32.9%
Medicaid*	14.4%
Insurance*	42.4%
Other (Other Payor)	3.1%
Total	100.0%

*Including any managed care plans.
CMHA internal data does not include Charity Care as a payor source. Patients in any category can and do receive Charity Care. Workers Compensation, TRICARE, and other payors included in the Other Payor category.

Atrium Health Pineville PET Service Component Projected Payor Mix CY 2029	
Payor Source	% of Total
Self-Pay	0.9%
Medicare*	60.8%
Medicaid*	3.3%
Insurance*	32.7%
Other (Other Payor)	2.4%
Total	100.0%

*Including any managed care plans.
CMHA internal data does not include Charity Care as a payor source. Patients in any category can and do receive Charity Care. Workers Compensation, TRICARE, and other payors included in the Other Payor category.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.9% of total services will be provided to self-pay patients, 60.8% to Medicare patients and 3.3% to Medicaid patients.

On page 99, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported. The applicant projects payor mix for the PET service component based on the CY 2024 historical payor mix of PET services at CMC that are projected to shift to Atrium Health Pineville upon project completion. The applicant accounts for the possible shift in payor mix categories due to Medicaid Expansion.

The Agency reviewed the:

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

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

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

C – Both Applications

Project ID# F-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, 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
- Written comments
- Responses to comments

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

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

In Section L, page 101, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

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

C – Both Applications

Project ID# F-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET/CT scanner to be located on the NHHMC campus. Following project completion, the applicant will be licensed for one fixed PET/CT scanner.

In Section M, page 103, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on Novant Health's existing agreements with clinical education programs. The applicant states that Novant Health and NHHMC will continue to work with interested health professional programs.

Conclusion

The Agency reviewed the:

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

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

Project ID# F-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination CMHA proposes to acquire one fixed PET scanner to be located at Atrium Health Pineville. Following project completion, the facility will be licensed for one fixed PET scanner.

In Section M, page 102, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant adequately describes CMHA's collaborations with educational institutions to provide access for health professional training programs.
- In supporting documentation, the applicant provides a list of CMHA's existing clinical education affiliation agreements with colleges and universities.

Conclusion

The Agency reviewed the:

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

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

(15) Repealed effective July 1, 1987.

(16) Repealed effective July 1, 1987.

(17) Repealed effective July 1, 1987.

(18) Repealed effective July 1, 1987.

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

C – Novant Health

NC-CMHA

The 2025 SMFP includes a need determination for one fixed PET scanner in HSA III.

On page 363, the 2025 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."* The applicants propose locating the fixed PET scanner in Mecklenburg County which, according to Appendix A on page 369 of the 2025 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 2022-2023 as found in Table 15F-1 on page 365 of the 2025 SMFP:

Fixed PET Scanners in HSA III		
Site/Provider	Planning Inventory	2022-2023
Atrium Health Cabarrus	1	1,417
Atrium Health Union	1	953
Carolinas Medical Center	2	5,686
CaroMont Regional Medical Center	1	1,282
Iredell Memorial Hospital	1	746
Novant Health Presbyterian Medical Center	1	2,275
Total HSA III fixed PET scanners / Procedures	7	12,359

Project ID# F-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET/CT scanner to be located on the NHHMC campus. Following project completion, the applicant will be licensed for one fixed PET/CT scanner.

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

“The proposed project, which will be NHHMC’s first fixed PET/CT scanner, 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 to services to fixed PET services, to better meet the needs of its existing population, and to reduce scheduling delay, and improve patient satisfaction.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 106, the applicant states:

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

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

Regarding the impact of the proposal on quality, in Section N, pages 106 and 108, the applicant states:

“Novant Health has a value-based strategy team that was launched to accelerate strategies for assuming risk and shifting further toward value-based care and payment modes to demonstrate greater value for patients served.

...

Novant health is committed to delivering high-quality care at all of its facilities. Novant Health has quality-related policies and procedures that are applicable to NHHMC.

...

NHHMC also participates in the Clinical Improvement Plan, the Infection Prevention Plan, and the Risk Management Plan...”

See also 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 109, 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 Section L and B of the application and any exhibits.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination CMHA proposes to acquire one fixed PET scanner to be located at Atrium Health Pineville. Following project completion, the facility will be licensed for one fixed PET scanner.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 104, the applicant states:

“...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. Additionally, the proposed project will add the only PET scanner in the Southern Charlotte Region, and this expanded geographic access will increase competition for PET imaging services throughout the region, as patients gain more options closer to home.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 104, the applicant states:

“...the proposed PET scanner at Atrium Health Pineville will provide a more convenient option for south Charlotte residents who are already accessing PET imaging services at Carolinas Medical Center (CMC), which is highly utilized. In addition, 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.

Further, 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.”

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

Regarding the impact of the proposal on quality, in Section N, pages 105-106, 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.

...

CMHA’s commitment to providing quality care is further demonstrated by its Quality, Patient Safety, and Infection Prevention Plan, Utilization Management Plan, and Risk Management Plan included in Exhibits N.2-1 through N.2-3. As CMHA continues to expand its services, these plans will ensure that quality care is provided to all patients.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 106, the applicant states:

“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 C.6. The proposed project will continue to serve this population as dictated by the mission of CMHA, which is the foundation for every action taken.”

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

However, the applicant does not adequately demonstrate how any enhanced competition in the service area will have a positive impact on the cost-effectiveness of the proposed services. The applicant did not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner or that the project is the least costly or most effective alternative. The discussions regarding projected utilization and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference. A project that cannot demonstrate the need for the services proposed and that cannot demonstrate it is the least costly or most effective alternative cannot demonstrate how any enhanced competition will have a positive impact on the cost-effectiveness of the proposal.

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 not 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-12627-25 / Novant Health Huntersville Medical Center / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination

The applicant proposes to acquire one fixed PET/CT scanner to be located on the NHHMC campus. Following project completion, the applicant will be licensed for one fixed PET/CT scanner.

In Section Q, Form O, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 14 of this type of facility located in North Carolina.

In Section O, page 112, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care had not occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care had not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 14 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-12630-25 / Atrium Health Pineville / Acquire no more than one fixed PET scanner pursuant to the 2025 SMFP need determination CMHA proposes to acquire one fixed PET scanner to be located at Atrium Health Pineville. Following project completion, the facility will be licensed for one fixed PET scanner.

In Section O, page 133, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of five of this type of facility located in North Carolina.

In Section O, page 111, the applicant states that, during the 18 months immediately preceding the submittal of the application, situations related to immediate jeopardy had not occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care had not occurred in any of these facilities. After reviewing and considering the information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all five 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- Novant Health, Inc. and The Presbyterian Hospital Novant Health Huntersville Medical Center. The applicant states Novant Health Presbyterian Medical Center owns and operates one fixed PET scanner in HSA III.

-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.

(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;*

-C- Novant Health, Inc. and The Presbyterian Hospital Novant Health Huntersville Medical Center. The applicant was approved for a second PET/CT scanner at Novant Health Presbyterian Medical Center, Project ID# F-12557-24), however it is under appeal.

-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.

(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;*

-C- Novant Health, Inc. and The Presbyterian Hospital Novant Health Huntersville Medical Center. In Section C, pages 62-63, the applicant states Novant Health Forsyth Medical Center owns and operates one mobile PET scanner that serves three host sites located in Mecklenburg County in the HSA III fixed PET scanner service area. The three host sites are Novant Health Huntersville Medical Center, Novant Health Matthews Medical Center, and Novant Health Mint Hill Medical Center.

-NA- CMHA. In Section C, page, the applicant states that neither the applicant nor any related entity owns or operates any mobile PET scanners that will provide mobile PET 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.

(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- Novant Health, Inc. and The Presbyterian Hospital Novant Health Huntersville Medical Center. 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- **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.

- (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- **Novant Health, Inc. and The Presbyterian Hospital Novant Health Huntersville Medical Center.** In Section C, page, 63 and Section Q, Form D.2, the applicant provides projected utilization of the proposed fixed, its existing 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.

- 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.

- (6) *provide assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph; and*

- C- **Novant Health, Inc. and The Presbyterian Hospital Novant Health Huntersville Medical Center.** 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.

- C- **CMHA.** In Section Q, pages 121-125, the applicant provides the assumptions and methodology used to project utilization of its existing and proposed fixed 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- **Novant Health, Inc. and The Presbyterian Hospital Novant Health Huntersville Medical Center.** 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.

-NC- CMHA. In Section Q, page 125, 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. However, the applicant does not adequately demonstrate that each 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, as required by this Rule. The applicant projects that Atrium Health Union will perform 2,079 procedures on its one existing PET scanner. 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- Novant Health, Inc. and The Presbyterian Hospital Novant Health Huntersville Medical Center. The applicant does not propose to acquire a mobile PET scanner.

-NA- CMHA. The applicant does not propose to acquire a mobile PET scanner.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2025 SMFP, no more than one fixed PET scanner may be approved for HSA III in this review. Because both applications in this review collectively propose to develop two fixed PET scanners, all the applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review.

- Project ID# F- 12627-25 / **Novant Health Huntersville Medical Center** / Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.
- Project ID #F-12630-25 / **Atrium Health Pineville** / Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

Conformity with Statutory and Regulatory Review Criteria

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

The application submitted by **Novant Health** is conforming to all applicable statutory and regulatory review criteria. However, the application submitted by **CMHA** is not conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, the application submitted by **Novant Health** is a more effective alternative.

Scope of Services

Regarding scope of services, both applications were submitted in response to the need determination in the 2025 State Medical Facilities Plan (SMFP) for one fixed PET scanner in Health Service Area (HSA) III. Generally, the application offering a greater scope of services is the more effective alternative for this comparative factor. The following table compares the scope of services proposed to be offered by each applicant.

Proposed Services			
Facility	Oncology	Cardiology	Neurology
NHHMC	X	X	X
Atrium Health Pineville	X	X	X

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

Geographic Accessibility (Location within the Service Area)

The 2025 SMFP identifies the need for one fixed PET scanner in HSA III, which includes eight

counties. The following table illustrates where in the service area the existing fixed PET scanners are located.

Fixed PET Scanners in HSA III		
Site/Provider	City	County
Atrium Health Cabarrus	Concord	Cabarrus
Atrium Health Union	Monroe	Union
Carolinas Medical Center	Charlotte	Mecklenburg
CaroMont Regional Medical Center	Gastonia	Gaston
Iredell Memorial Hospital	Statesville	Iredell
Novant Health Presbyterian Medical Center	Charlotte	Mecklenburg

Source: 2025 SMFP, Table 15F-1, page 363

The following table illustrates where in the service area each applicant proposes to develop its proposal.

Facility	City	County
NHHMC	Huntersville	Mecklenburg
Atrium Health Pineville	Pineville	Mecklenburg

Novant Health proposes to locate the fixed PET scanner in a renovated space adjacent to the radiology department on the main hospital campus of NHHMC. NHHMC is located at 10030 Gilead Road in the city of Huntersville and currently provides mobile PET services. **CMHA** proposes to locate its fixed PET scanner at the Atrium Health Pineville hospital at 10628 Park Road in the town of Pineville in the southern portion of Mecklenburg County, approximately 30-minute driving from the existing fixed PET scanner located at Novant Health Presbyterian Medical Center. Atrium Health Pineville does not currently provide PET services. **CMHA** proposes to serve patients in the southern portion of Mecklenburg County where residents would need to travel a distance to access PET services. **Novant Health** proposes to locate the fixed PET scanner at a facility currently offering mobile PET services. However, the proposed location is in the center of HSA III, allowing the applicant to reach residents from more counties in HSA III. It will be the first fixed PET scanner in the northern portion of Mecklenburg County. Therefore, regarding this comparative factor, the proposal submitted by **Novant Health** and **CMHA** are equally effective alternatives.

Access by Service Area Residents

On page 363, the 2025 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.” The applicants propose locating the fixed PET scanner in Mecklenburg County which, according to Appendix A on page 369 of the 2025 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.

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 PET imaging

services in the service area where they live. On page 39 of the application, **Novant Health** proposes to offer fixed PET services to patients in all HSA III counties. In its projected patient origin, the applicant includes an “other” category that includes other NC counties and out of state residents. **CMHA** identifies patient origin by ZIP codes which include ZIP codes in the state of South Carolina. On page 40 of the application, **CMHA** proposes to offer fixed PET services to patients in two of the HSA III counties. The applicant identifies “other” as residents included in service area by ZIP codes, including other NC ZIP codes, and other State Zip codes from the Southern Charlotte Region. The Project Analyst is unable to calculate the total number of PET patients originating from HSA III projected to be served by Atrium Health Pineville in order to to conduct an equitable comparison of the projected numbers of service area patients to be served by each applicant. Therefore, regarding projected service to residents of the service area, the result of this analysis is inconclusive.

Access by Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”

For access by underserved groups, applications are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

Projected Access by Medicaid Patients

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for each facility.

Projected Number of Medicaid patients for PET Services in Project Year 3	
	# of Medicaid Patients
NHHMC	70
CMHA	90

Source: Sections C.3 and L.3 of the applications.

As shown in the table above, **CMHA** projects to serve a larger number of Medicaid patients. Generally, the application projecting to serve a larger number of Medicaid patients is the more effective alternative for this comparative factor. Therefore, regarding projected access for Medicaid patients, the application submitted by **CMHA** is a more effective alternative.

Projected Access by Medicare Patients

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for each facility.

Projected Medicare patients for PET Services in Project Year 3	
	# of Medicare Patients
NHHMC	1,659
CMHA	1,659

Source: Sections C.3 and L.3 of the applications.

As shown in the table above, **Novant Health** and **CMHA** projects to serve the same number of Medicare patients. Generally, the application projecting to serve a larger number of Medicare patients is the more effective alternative for this comparative factor. Therefore, regarding projected access for Medicare patients, the applications submitted by **Novant Health** and **CMHA** are equally effective alternatives.

Projected Medicaid as 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 patients as percentage of Gross Revenue in Project Year 3			
	Medicaid Revenue	Total Gross Revenue	Medicaid % of Gross Revenue
NHHMC	\$1,058,395	\$37,385,256	2.8%
CMHA	\$802,824	\$24,530,721	3.3%

Source: Sections L.3 and Forms F.2b of the applications.

As shown in the table above, **CMHA** projects to serve a larger percentage of gross Medicare patients as a percentage of Gross Revenue. Generally, the application projecting to serve a larger percentage of Medicare patients is the more effective alternative for this comparative factor. Therefore, regarding projected access for Medicare patients, the application submitted by **CMHA** is a more effective alternative.

Projected Medicare as 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 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 Medicare patients is the more effective alternative regarding this comparative factor, assuming that provision of services to Medicare recipients can indicate an applicant's provision of care to medically underserved groups.

Projected Medicare patients as percentage of Gross Revenue in Project Year 3			
	Medicare Revenue	Total Gross Revenue	Medicare % of Gross Revenue
NHHMC	\$24,821,078	\$37,385,256	66.4%
Atrium Health Pineville	\$14,919,138	\$24,530,721	60.8%

Source: Sections L.3 and Forms F.2b of the applications.

As shown in the table above, **Novant Health** projects to serve a larger percentage of gross Medicare patients as a percentage of Gross Revenue. Generally, the application projecting to serve a larger percentage of Medicare patients is the more effective alternative for this comparative factor. Therefore, regarding projected access for Medicare patients, the application submitted by **Novant Health** is a more effective alternative.

Competition (Access to a New or Alternate Provider)

The following table illustrates the existing and approved providers located in the service area. Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer fixed PET scanners than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

The following table identifies the existing dedicated fixed PET scanners in HSA III, as found in Table 15F-1 on page 365 of the 2025 SMFP:

Fixed PET Scanners in HSA III	
Site/Provider	# of Scanners
Atrium Health Cabarrus	1
Atrium Health Union	1
Carolinas Medical Center	2
CaroMont Regional Medical Center	1
Iredell Memorial Hospital	1
Novant Health Presbyterian Medical Center	1
Total HSA III fixed PET scanners / Procedures	7

The **Atrium Health System** currently owns and operates four fixed PET scanners 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.

Novant Health proposed to locate the fixed PET scanner at NHHMC, which currently offers mobile PET imaging services. By adding fixed PET imaging services at NHHMC, patients in HSA III and the northern portion Mecklenburg County would have an alternate choice for the first fixed PET scanner in the north portion of Mecklenburg County. 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.

Projected Average Net Revenue per PET Procedure

The following table compares projected average net revenue per PET procedure in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average net revenue per PET procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

Average Net Revenue per Patient Day, Surgical Case or Procedure 3 rd Full FY			
Applicant	Total # of Patient PET Procedures	Net Revenue	Average Net Revenue per Patient PET Procedure
NHHMC	2,499	\$7,883,826	\$3,155
CMHA	2,728	\$6,115,114	\$2,242

Source: Section Q, Forms C.2b and F.2b of the applications

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

Projected Average Operating Expense per PET Procedure

The following table compares projected average operating expense per PET procedure in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average operating expense PET procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Average Operating Expense per PET Procedure 3 rd Full FY			
Applicant	Total # of PET Procedures	Operating Expenses	Average Net Revenue per Patient Day, Surgical Case or Procedure
NHHMC	2,499	\$4,482,264	\$1,794
CMHA	2,728	\$2,779,983	\$1,019

Source: Section Q, Forms C.2b and F.2b of the applications

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

Summary

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the

same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance.

Comparative Factor	NHHMC	Atrium Health Pineville
Conformity with Statutory and Regulatory Review Criteria	More Effective	Less Effective
Scope of Services	Equally Effective	Equally Effective
Geographic Accessibility (Location within the Service Area)	Equally Effective	Equally Effective
Access by Service Area Residents	Inconclusive	Inconclusive
Access by Medicaid Patients	Less Effective	More Effective
Access by Medicare Patients	Equally Effective	Equally Effective
Projected Medicaid as Percent of Gross Revenue	Less Effective	More Effective
Projected Medicare as Percent of Gross Revenue	More Effective	Less Effective
Competition (Access to a New or Alternate Provider)	More Effective	Less Effective
Projected Average Net Revenue per PET Procedure	Less Effective	More Effective
Projected Average Operating Expense per PET Procedure	Less Effective	More Effective

As shown in the table above, **NHHMC** was determined to be a more effective alternative for the following three factors:

- Conformity with Statutory and Regulatory Review Criteria
- Projected Medicare as Percent of Gross Revenue
- Competition (Access to a New or Alternate Provider)

As shown in the table above, **CMHA** was determined to be a more effective alternative for the following four factors:

- Access by Medicaid Patients
- Projected Medicaid as Percent of Gross Revenue
- Projected Average Net Revenue per PET Procedure
- Projected Average Operating Expense per PET Procedure

However, **CMHA** is not conforming with all applicable statutory and regulatory review criteria, therefore, it is not approvable.

DECISION

Each application is individually conforming to the need determination in the 2025 SMFP for one additional fixed PET scanner in HSA III as well as individually conforming to all review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed PET scanners that can be approved by the Healthcare Planning and Certificate of Need Section.

However, the application submitted by **CMHA** is not approvable and therefore cannot be considered an effective alternative. Consequently, the application submitted by **CMHA**, Project ID # F-12630-25, is denied.

Based upon the independent review of each application and the Comparative Analysis, the following application is approved as submitted:

- **Project ID# F- 12627-25 / Novant Health Huntersville Medical Center / Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.**

And the following application is denied:

- **Project ID# F-12630-25/Atrium Health Pineville/ Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.**

Project ID# F-12627-25 is approved subject to the following conditions.

1. **The Novant Health, Inc. and The Presbyterian Hospital Novant Health Huntersville 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 2025 SMFP.**
3. **Upon completion of the project, Novant Health Huntersville Medical Center shall be licensed for no more than one fixed PET scanner.**
4. **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.**
5. **The certificate holder shall develop and implement strategies to provide culturally competent services to members of its defined medically underserved community that are consistent with representations made in the certificate of need application.**
6. **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 June 1, 2026.
7. 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.
8. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.