



Atrium Health

**Comments on
The Presbyterian Hospital's and
Novant Health, Inc.'s Fixed PET Scanner
Certificate of Need Application,
Project ID # F-012557-24**

October 31, 2024

**Competitive Comments on Health Service Area III
Fixed PET Scanner Applications**

submitted by

The Charlotte-Mecklenburg Hospital Authority

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), The Charlotte-Mecklenburg Hospital Authority¹ (CMHA) hereby submits the following comments related to the application filed by The Presbyterian Hospital and Novant Health, Inc. (collectively referred to herein as Novant Health) to add a dedicated fixed PET scanner to The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center (NH Presbyterian) in response to the need identified in the 2024 *State Medical Facilities Plan (SMFP)* for one dedicated fixed PET scanner for Health Service Area (HSA) III. CMHA's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards.*" See N.C. GEN. STAT. § 131E-185(a1)(1)(c).² In order to facilitate the Agency's ease in reviewing these comments, CMHA has organized its discussion by issue, specifically noting the general Certificate of Need (CON) statutory review criteria and regulations creating the non-conformity of each issue, as they relate to Novant Health's application, Project ID # F-012557-24. CMHA's comments include issue-specific comments on the NH Presbyterian application as well as a comparative analysis related to its application:

- Atrium Health Pineville, add one fixed PET scanner, Project ID # F-012550-24

As detailed above, given the number of proposed additional fixed PET scanners, both of the applications cannot be approved as proposed. The comments below include substantial issues that CMHA believes render Novant Health's NH Presbyterian application non-conforming with applicable statutory criteria and regulatory review criteria. However, as presented at the end of these comments, even if the NH Presbyterian application was conforming, the application filed by CMHA is comparatively superior to the application filed by Novant Health and represents the most effective alternative for expanding access to fixed PET services in HSA III.

¹ Advocate Aurora Health, Inc. ("AAH") and Atrium Health, Inc. ("Atrium Health") formed Advocate Health, Inc. ("Advocate Health"), a nonprofit corporation, to manage and oversee AAH, Atrium Health, and their respective subsidiaries and affiliates. As part of Atrium Health, The Charlotte-Mecklenburg Hospital Authority and Wake Forest University Baptist Medical Center are now part of the Advocate Health enterprise and are managed and overseen by Advocate Health.

² CMHA is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its application filed on September 16, 2024 (Project ID # F-012550-24).

GENERAL COMMENTS

As detailed in the issue-specific comments in the following section, Novant Health’s application does not conform to all of the Certificate of Need (CON) statutory review criteria and regulations. Most notably, Novant Health overstates its volume projections as its growth rates and market share assumptions are unreasonable and unsupported. When projected PET procedures are adjusted, NH Presbyterian does not meet the performance standards defined in 10A NCAC 14C .3703, as demonstrated in the issue-specific section below. As a result, Novant Health’s application is not approvable.

Even if Novant Health’s application were found conforming to all CON statutory review criteria and regulations, Atrium Health Pineville demonstrates a significantly greater need for a fixed PET scanner than NH Presbyterian.

ISSUE-SPECIFIC COMMENTS

1. The methodology utilized by Novant Health results in volume projections that are significantly overstated and unsupported; it provides no evidence that North Carolina’s growing PET use rate will result in additional PET volume at NH Presbyterian.

The underlying assumption of Novant Health’s methodology is that North Carolina’s growing PET use rate will result in additional PET volume at NH Presbyterian. However, PET utilization statewide is growing at a much faster rate than PET utilization has grown at NH Presbyterian. As demonstrated in the table below, prior to the COVID-19 pandemic, PET utilization across North Carolina grew at a compound annual growth rate (CAGR) of 6.9 percent, while PET utilization at NH Presbyterian grew at a CAGR of 2.2 percent.

North Carolina and NH Presbyterian Historical PET Growth FFY 2015-2019

	FFY15	FFY16	FFY17	FFY18	FFY19	CAGR
North Carolina	41,663	45,006	48,066	52,167	54,416	6.9%
NH Presbyterian	1,970	1,838	1,711	2,018	2,151	2.2%

Source: Application page 118. 2017-2021 SMFP.

In other words, the statewide growth rate was more than three times NH Presbyterian’s growth rate. Further, since FFY 2019, PET utilization in North Carolina has increased at a CAGR of 8.9 percent, while PET utilization at NH Presbyterian has increased at a CAGR of 1.4 percent. To put it another way, PET utilization in North Carolina is now growing at a rate that is more than six times faster than the rate at NH Presbyterian.

North Carolina and NH Presbyterian Historical PET Growth FFY 2019-2023

	FFY19	FFY20	FFY21	FFY22	FFY23	CAGR
North Carolina	54,416	50,572	54,837	63,698	76,584	8.9%
NH Presbyterian	2,151	2,039	2,001	2,085	2,275	1.4%

Source: Application page 118. 2021-Proposed 2025 SMFP.

Based on the analysis above, there is no evidence that North Carolina’s growing PET use rate has resulted in a similar increase in volume at Novant Health Presbyterian. Further, Novant Health provides no explanation for why it is reasonable to use the statewide use rate to project future

volume. Thus, it is unreasonable for Novant Health to assume that North Carolina’s growing PET use rate will directly impact volume at NH Presbyterian in the future. As a result, Novant Health’s methodology is unreasonable and unsupported.

Moreover, according to the 2024 SMFP³, “the facility has a deficit when its overall utilization of dedicated fixed PET scanners is at or above 80% of capacity during the current reporting year. For the purpose of need determination calculations, the annual capacity of a dedicated fixed PET scanner is 3,000 procedures; 80% capacity is 2,400 procedures.” Based on this definition, during the FFY 2015 to FFY 2023 period defined above, NH Presbyterian operated at less than 80 percent and had capacity to grow.

Based on this analysis, Novant Health has overstated its projected volumes and is non-conforming with Criteria 3, 4, 5, 6, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703.

2. Novant Health’s volume projections are overstated and unreasonable due to unsupported market share assumptions.

Novant Health projects its PET market share by county in Step 4 of its methodology. It assumes that its market share in Cabarrus, Lincoln, Rowan, and Stanly counties will remain consistent with its 2024 fixed PET market share but that its market share in Gaston, Iredell, Mecklenburg, and Union counties will increase.

The following table includes fixed PET procedure volume for all HSA III fixed PET providers from FFY 2019 through FFY 2023.

HSA III Fixed PET Procedures by Facility FFY 2019-2023

	<i>Units</i>	<i>FFY19</i>	<i>FFY20</i>	<i>FFY21</i>	<i>FFY22</i>	<i>FFY23</i>	<i>CAGR</i>
Atrium Health Cabarrus	1	1,105	1,135	1,068	1,189	1,417	6.4%
Atrium Health Union	1	595	589	585	680	953	12.5%
Carolinas Medical Center	2	4,497	4,287	4,455	5,119	5,686	6.0%
CaroMont Regional Medical Center	1	932	843	855	918	1,282	8.3%
Iredell Memorial Hospital	1	502	534	612	628	746	10.4%
Novant Health Presbyterian	1	2,151	2,039	2,001	2,085	2,275	1.4%
HSA III Total	7	9,782	9,427	9,576	10,619	12,359	6.0%
Novant Health Presbyterian’s Share of HSA III Fixed PET Volume		22.0%	21.6%	20.9%	19.6%	18.4%	

Source: 2021-Proposed 2025 SMFP.

As shown in the table above, NH Presbyterian’s CAGR was the lowest among all HSA III providers from FFY 2019 to FFY 2023. In fact, total fixed PET volume in HSA III grew at a CAGR that was four times faster than NH Presbyterian’s over the same time period. As a result, NH Presbyterian’s share of HSA III fixed PET volume has declined every year from FFY 2019 to FFY 2023. Based on this analysis, it is neither reasonable nor conservative for Novant Health to project a portion of its market share will

³ 2024 SMFP, P. 362.

remain static through the third project year “based on the historical demand for its fixed PET services.”⁴

The NC Division of Health Service Regulation (NCDHSR) patient origin reports indicate a similar trend in NH Presbyterian’s market share of patients residing in Mecklenburg and Union counties, the two counties where the majority of NH Presbyterian’s patients are projected to originate from. As shown below, NH Presbyterian’s Mecklenburg County market share declined from 24.8 percent in FFY 2019 to 17.8 percent in FFY 2023. Similarly, its Union County market share declined from 14.6 percent to 8.1 percent over the same time period. **Notably, NH Presbyterian’s market share in both counties has declined every year since FFY 2019.**

NH Presbyterian Mecklenburg and Union County Market Share FFY 2019-2023

	<i>FFY19</i>	<i>FFY20</i>	<i>FFY21</i>	<i>FFY22</i>	<i>FFY23</i>	<i>CAGR</i>
Mecklenburg County						
NH Presbyterian Patients	1,352	1,228	1,163	1,276	1,361	0.2%
Total County Patients	5,446	5,241	5,209	6,036	7,667	8.9%
Market Share	24.8%	23.4%	22.3%	21.1%	17.8%	
Union County						
NH Presbyterian Patients	207	186	197	177	157	-6.7%
Total County Patients	1,421	1,276	1,427	1,623	1,940	8.1%
Market Share	14.6%	14.6%	13.8%	10.9%	8.1%	

Source: 2020-2024 NCDHSR PET Procedures: Patient Origin by Facility and PET Procedures: Patient’s County of Residence reports.

Despite this consistent decline in market share, Novant Health projects a 6.0 percent increase in market share in Mecklenburg County and a 4.5 percent increase in market share in Union County by project year (PY) 3. The impact of these projected market share increases on Novant Health’s methodology can be calculated as follows:

⁴ NH Presbyterian application, p. 121.

Impact of NH Presbyterian 's Projected Market Share Increase in PY 3 (CY 2029)

	Mecklenburg	Union
NH Presbyterian's Market Share in 2024	17.3%	11.1%
NH Presbyterian's Projected Market Share Increase	6.0%	4.5%
NH Presbyterian's Projected Market Share in 2029	23.3%	15.6%
Projected PET Procedures in 2029 For the County (Per NH's Application)	11,453	2,618
Incremental PET Procedures in 2029 Due to Projected Market Share Increases*	687	118
Total Incremental PET Procedures in 2029	805	

Source: NH Presbyterian application, p. 119 - 121.

*NH Presbyterian's Projected Market Share Increase x Projected PET Procedures in 2029 (Per NH's Application)

As shown in the table above, Novant Health's projected market share gains in Mecklenburg and Union counties result in an additional 805 PET procedures in PY 3. Given that Novant Health's assumption to increase market share in these counties is unsupported and unreasonable, its projected volume should be recalculated without the projected increase as demonstrated in the table below:

NH Presbyterian's Adjusted PY 3 Volume

	CY 2029
Projected PET Procedures (Per NH's Application)	4,347
Incremental PET Procedures Due to Projected Market Share Increases in Mecklenburg and Union Counties	805
<i>Projected PET Procedures Minus Incremental PET Procedures</i>	3,542
Fixed PET Scanners	2
Procedures per PET Scanner	1,771
Performance Standard	2,080

Source: NH Presbyterian application, p. 122.

As demonstrated in the table above, NH Presbyterian would not meet the performance standard without the unsupported market share increases as it would only project 1,771 procedures per fixed PET scanner in PY 3, well below the performance standard.

Historical data suggests that NH Presbyterian's market share has been in decline, both in relation to other fixed PET providers located in HSA III and in Mecklenburg and Union counties, the two counties where the majority of NH Presbyterian's patients are projected to originate from. Ultimately, this data does not support Novant Health's assumption that its market share will remain flat in Cabarrus, Lincoln, Rowan, and Stanly counties or its assumption to increase market share in Mecklenburg, Union, Gaston, and Iredell counties. As a result, the NH Presbyterian volume projections are overstated and unreasonable.

Thus, Novant Health’s application is non-conforming with Criteria 3, 4, 5, 6, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703.

3. Novant Health’s volume projections for its mobile PET scanner are unsupported.

On September 15, 2023, Novant Health applied for an additional fixed PET scanner pursuant to the need determination in HSA II at Novant Health Forsyth Medical Center (Project ID # G-012432-23). Given that its mobile scanner serves both HSA II and HSA III, Novant Health was required to project mobile PET procedure volumes in its HSA II application and the current application.

The following screenshot from page 117 of Novant Health’s 2023 HSA II PET application shows the historical volume of its mobile scanner through annualized CY 2023.

Host Site Facility	CY2019	CY2020	CY2021	CY2022	CY2023*	CAGR
Novant Health Huntersville Medical Center	670	642	723	901	1,135	14.1%
Novant Health Kernersville Medical Center	357	364	428	438	711	18.8%
Novant Health Matthews Medical Center	372	534	566	692	939	26.1%
Novant Health Mint Hill Medical Center	236	79	132	194	391	13.4%
Novant Health Rowan Medical Center Julian Road	380	343	353	395	463	5.1%
NHFMC Mobile PET Scanner Total	2,015	1,962	2,202	2,620	3,639	15.9%

*Annualized based on seven months data (Jan-July)
Source: Novant Health internal data

As shown in the table above, Novant Health projected its mobile scanner would perform 3,639 PET procedures in CY 2023 based on seven months of data annualized. Novant Health went on to assume that mobile PET procedures would remain flat at 3,639 procedures through the third project year, or CY 2028.

The following screenshot from page 124 of Novant Health’s current CON application shows the historical volume of its mobile PET scanner through annualized CY 2024.

Host Site Facility	CY2019	CY2020	CY2021	CY2022	CY2023	CY2024*
Novant Health Huntersville Medical Center	632	634	63	806	1,070	1,023
Novant Health Matthews Medical Center	513	387	549	632	573	744
Novant Health Mint Hill Medical Center	102	190	111	163	0	168
Novant Health Rowan Medical Center - Julian Road	338	348	4	354	0	0
Novant Health Kernersville Medical Center					729	549
Total	1,585	1,559	727	1,955	2,372	2,484

*Annualized based on seven months data (Jan-July)
Source: Novant Health internal data

Several items immediately stand out when comparing historical volumes across the two applications. First, based on the name and host site locations, the volumes provided were for the same mobile PET scanner and sites. Second, the mobile PET scanner’s historical volumes vary wildly, both in total and for each host site facility. Third, in the current application, Novant Health reports that 2,372 mobile

PET procedures were performed in CY 2023. In other words, actual mobile volume in CY 2023 (2,372 procedures) was nearly 35 percent less than what was projected (3,639 procedures) less than a year prior.

Given the large discrepancies associated with the historical volume on Novant Health’s mobile PET scanner, it is unclear if the volumes provided in this application are accurate, reasonable, or can represent the basis for future performance.

As a result, Novant Health’s application is non-conforming with the performance standards specified in 10A NCAC 14C .3703 as it cannot be determined if its mobile PET scanner will meet the volume requirement.

4. Novant Health’s patient origin tables for the entire NH Presbyterian facility are unreasonable.

Novant Health provides the total facility patient origin for NH Presbyterian on page 33 of its application. The patient origin table is as follows:

Facility	NHPMC *	
	Last Full CY 01/01/2023 to 12/31/2023	
County	Patients	% of Total
Mecklenburg	22,017	67.7%
Union	1,852	5.7%
Gaston	1,656	5.1%
Cabarrus	993	3.1%
Rowan	971	3.0%
Iredell	796	2.4%
Lincoln	375	1.2%
Stanly	254	0.8%
Catawba	172	0.5%
Cleveland	145	0.4%
South Carolina	2,024	6.2%
Other [^]	1,251	3.8%
Total	32,506	100.0%

[^]Other includes <1 percent patient origin from the remaining counties in North Carolina and other states.
 * This should match the name provided in Section A, Question 4.

According to page 44 of its application, NH Presbyterian is an 859-bed, tertiary level hospital, the second largest hospital in the Novant Health system. The screenshot below is from NH Presbyterian’s 2024 HLRA.

Novant Health Presbyterian Medical Center					
Primary Payer Source	Inpatient Days of Care (total should be the same as The Total General Acute Care Days in Beds by Service)	Emergency Visits on this campus. For multi-campus hospitals, the total for the cumulative record should match the number of ED visits in Services and Facilities, Item 3b, from the Services for Entire Facility tab.	Outpatient Visits (excluding Emergency Visits and Surgical Cases, including Imaging services)	Inpatient Surgical Cases (total should be same as Total Surgical Cases-Inpatient Cases in Surgical Cases by Speciality Area)	Ambulatory Surgical Cases (total should be same Total Surgical Cases-Ambulatory Cases in Surgical Cases by Speciality Area)
Self Pay	3336	3495	1582	121	101
Charity Care	3128	7622	3037	127	154
Medicare *	58091	13923	51847	2415	1986
Medicaid *	30068	23969	15251	973	911
Insurance *	48580	22505	70885	3371	5382
Other (Institutional, Other Govt, Tricare, Workers Comp)	3351	2291	3988	205	267
TOTAL	146554	73805	146590	7212	8801

As shown above, the facility had almost 150,000 inpatient days of care and nearly 75,000 ED visits, 150,000 outpatient visits, and 10,000 ambulatory surgery cases in FFY 2023. Based on this information, the number of patients served at NH Presbyterian far exceeded 32,506, the total patient count included in the patient origin table above.

Further, Novant Health filed another CON application for NH Presbyterian on October 15, 2024, which included vastly different numbers for the facility. The following screenshot is from page 32 of Novant Health's 2024 application to develop additional licensed acute care beds at NH Presbyterian (Project ID # F-012570-24).

Facility	Novant Health Presbyterian Medical Center	
	FY2023	
	01/01/2023 to 12/31/2023	
County	Number of Patients	% of Total
Mecklenburg	174,238	70.0%
Union	16,821	6.8%
Gaston	10,998	4.4%
York (SC)	8,564	3.4%
Cabarrus	7,550	3.0%
Iredell	5,525	2.2%
Rowan	3,995	1.6%
Lincoln	3,172	1.3%
Other*	18,041	7.2%
Total	248,904	100.0%

As shown above, Novant Health reports a total of 248,904 patients served at NH Presbyterian in CY 2023. This is more than seven times the number of patients included in the NH Presbyterian PET application, further highlighting the inconsistent and unreliable data provided. In addition to the volume difference, the patient origin percentage by county differs between the two applications.

Thus, Novant Health's application is non-conforming with Criteria 3 as it fails to provide reasonable patient origin for the entire facility.

In summary, based on the issues detailed above, the NH Presbyterian application is non-conforming with the review criteria established under N.C. GEN. STAT. § 131E-183, specifically Criteria 3, 4, 5, 6, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703. The NH Presbyterian application should not be approved.

COMPARATIVE ANALYSIS

The NH Presbyterian application (Project ID # F-012557-24) and the Atrium Health Pineville application (Project ID # F-012550-24) each propose to develop a fixed PET scanner in response to the 2024 SMFP need determination for HSA III. Given that two applicants propose to meet the need for the fixed PET scanner in HSA III, only one can be approved as proposed. To determine the comparative factors that are applicable in this review, CMHA examined recent Agency findings for competitive fixed PET scanner reviews. Based on that examination and the facts and circumstances of the competing applications in this review, CMHA considered the following comparative factors:

- Conformity with Review Criteria
- Scope of Services
- Geographic Accessibility
- Historical Utilization
- Competition – Access to a New Provider
- Access by Service Area Residents
- Access by Underserved Groups
 - Projected Medicare and
 - Projected Medicaid
- Average Net Revenue per Procedure
- Average Operating Expense per Procedure

CMHA believes that the factors presented above and discussed in turn below should be used by the Agency in reviewing the competing applications.

Conformity with Applicable Statutory and Regulatory Review Criteria

The Atrium Health Pineville application adequately demonstrates that its fixed PET scanner proposal is conforming to all applicable statutory and regulatory review criteria. In contrast, the NH Presbyterian application does not adequately demonstrate that its proposal is conforming to all applicable statutory review criteria as discussed previously. Specifically, the NH Presbyterian application is non-conforming with Criteria 3, 4, 5, 6, and 18a and fails to meet the performance standards specified in 10A NCAC 14C .3703. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, with regard to conformity, the Atrium Health Pineville application is more effective than the NH Presbyterian application.

Scope of Services

Both applications were submitted in response to the need determination for one fixed PET scanner in HSA III in the 2024 SMFP. Generally, the application proposing to provide the broadest scope of services with the proposed equipment is the more effective alternative regarding this comparative factor.

The following table compares the scope of services proposed by each applicant:

Proposed Scope of Service

	<i>Oncology</i>	<i>Cardiac</i>	<i>Neurology</i>
Atrium Health Pineville	X	X	X
NH Presbyterian	X	X	X

Both applicants propose to provide PET services to oncology, cardiac, and neurology patients. Therefore, regarding scope of services, both applications are equally effective.

In Section C, Novant Health states, “In addition to oncology, PET scans are also used in neurology and cardiology.”⁵ Novant Health then goes on to discuss these three categories in detail. Notably, it discusses brain scans at length as a subset of its neurology service type. On page 123 of its application, Novant Health separates brain as a separate procedure type for informational purposes. It should be noted that brain scans are a subset of neurology PET procedure types and should not be considered a separate category regarding scope of services. On page 34 of its application, CMHA states that it will serve oncology patients as well as patients from a range of other specialties, including neurology and cardiology. It then references Section C.4 for a discussion of the various applications of PET imaging that will be available at Atrium Health Pineville, including those specific to the brain. Section C.4 specifically cites the evaluation of brain abnormalities⁶ and the diagnosis of Alzheimer’s Disease, Dementia, and Parkinson’s Disease as a few examples.⁷ The two applicants are equal regarding scope of services.

Geographic Accessibility

The 2024 SMFP identifies a need for one fixed PET scanner in HSA III. Both applicants in this review propose to locate a fixed PET scanner in Mecklenburg County. Novant Health proposes to locate a fixed PET scanner at NH Presbyterian, an existing PET provider with one fixed PET scanner. Additionally, NH Presbyterian is located just 1.3 miles from Carolinas Medical Center (CMC), an existing PET provider with two fixed PET scanners. CMHA proposes to locate a fixed PET scanner at Atrium Health Pineville, a growing tertiary provider without existing fixed PET services. Atrium Health Pineville is located approximately 9 miles, or a 24-minute drive, from CMC, the nearest fixed PET scanner, and 10 miles, or a 30-minute drive, from Novant Health Presbyterian. The Atrium Health Pineville application will expand and improve access by developing fixed PET services in a new area within HSA III. The patient support letters included with Atrium Health Pineville’s application describe the challenges that cancer patients in the Southern Charlotte Region currently face without an existing fixed PET scanner nearby. Thus, Atrium Health Pineville is the more effective alternative in this competitive review.

Moreover, in 2021, Novant Health was part of a competitive review for a fixed PET need determination in HSA V. The following excerpt is from page 15 of its Comments in Opposition to Wilmington Health, PLLC from that review:

⁵ NH Presbyterian application, p. 39.
⁶ Atrium Health Pineville application, p. 43.
⁷ Atrium Health Pineville application, p. 46-47.

Geographic Accessibility

The 2021 SMFP identified a need for one PET scanner in HSA V. The Wilmington and Brunswick areas of HSA V are already well covered for PET services. Wilmington Health proposes to locate its proposed PET scanner just a half mile from the existing PET scanner operated by NHRMC. NHRMC, on the other hand, proposes to improve geographic access by locating its proposed PET scanner on its Scotts Hill campus in northern New Hanover County. Doing so will reduce travel time for patients residing in northern New Hanover County, as well as Pender, Onslow, and surrounding counties. This is particularly important for cancer patients in need of PET services because cancer patients will make multiple trips over the course of many weeks to receive diagnostic and treatment services. Bringing PET services closer to where they live will help to alleviate the travel burden on cancer patients.

As it relates to geographic accessibility, NHRMC is the more effective applicant.

As shown above, Novant Health argued that a new location in another part of the county would improve geographic access. Based on Novant Health’s own logic, and given that the facts of this review are similar, Atrium Health Pineville is the more effective alternative.

Historical Utilization

The table below represents Table 15F-1 from the 2024 SMFP and the Proposed 2025 SMFP for HSA III:

Utilization of Existing Dedicated Fixed PET Scanners

	<i>Planning Inventory</i>	<i>2024 SMFP</i>	<i>Facility Deficit</i>	<i>2025 SMFP</i>
Atrium Health Cabarrus*	1	1,189	-	1,417
Atrium Health Union*	1	680	-	953
Carolinas Medical Center*	2	5,119	1	5,686
CaroMont Regional Medical Center	1	918	-	1,282
Iredell Memorial Hospital	1	628	-	746
Novant Health Presbyterian	1	2,085	-	2,275
HSA III Totals	7	10,619	1	12,359

Source: 2024 SMFP and 2025 Proposed SMFP. *CMHA Facility.

CMHA and Novant Health are both existing providers of fixed PET services within HSA III. CMHA performed 6,988 fixed PET procedures in FFY 2022 and 8,056 in FFY 2023 compared to just 2,085 and 2,275 performed by Novant Health, respectively.

Additionally, in this competitive review, CMC and NH Presbyterian are the most relevant facilities. In CMHA’s current application, 100 percent of the fixed PET volume at Atrium Health Pineville is projected to shift from CMC. The need determination in the 2024 SMFP for an additional fixed PET scanner in HSA III was generated exclusively by CMC, and, according to the Proposed 2025 SMFP, CMC had the highest PET utilization rate in the state in FFY 2023 at 94.77 percent. In contrast, NH Presbyterian had a utilization rate of 75.83 percent in the Proposed 2025 SMFP. That utilization rate is below the need threshold and nearly 20 percent below CMC’s utilization rate. Therefore, regarding historical utilization, Atrium Health Pineville is the more effective alternative.

Competition

Generally, the application proposing to increase competition in the service area is the more effective alternative regarding this comparative factor. The introduction of a new provider in the service area would be the most effective alternative. However, neither applicant in this competitive review represents a new provider.

Novant Health is an existing provider and proposes to develop its project in Mecklenburg County. It currently operates a fixed PET scanner at NH Presbyterian and its mobile PET scanner at Novant Health Huntersville Medical Center, Novant Health Matthews Medical Center, and Novant Health Mint Hill Medical Center⁸ in Mecklenburg County. In addition, it provides mobile PET services at Novant Health Rowan in HSA III.

CMHA is an existing provider and proposes to develop its project in Mecklenburg County. It currently operates two fixed PET scanners at CMC in Mecklenburg County. In addition, it provides fixed PET services at Atrium Health Cabarrus Imaging and Atrium Health Union and mobile PET services at Atrium Health Lincoln and Atrium Health Stanly within HSA III.

Both Novant Health and CMHA propose to locate its project in Mecklenburg County. Currently, Novant Health operates PET services at four locations (one fixed and three mobile) within Mecklenburg County while CHMA only operates PET services at one location within Mecklenburg County.

As outlined above, both Novant Health and CMHA are existing providers of both fixed and mobile PET services. As such, the applicants are equally effective.

Access by Service Area Residents

CMHA discusses patient origin assumptions and the *2024 SMFP* PET need on pages 38-40 of its application. That narrative has been duplicated here for convenience:

According to page 364 of the *2024 SMFP*, the need for an additional fixed PET scanner in HSA III was based on CMC's facility utilization of 85.32 percent. This need for an additional fixed PET scanner is driven not only by the residents of the HSA, but also by the population centers that surround HSA III in both North and South Carolina. According to patient origin data submitted in CMC's 2023 license renewal application (LRA), less than 65 percent of patients served by CMC originate from within the HSA. As shown in the table below, out of state patients comprise over 26 percent of PET patients at CMC.

⁸ NH Presbyterian application, p. 124 for 2024.

Total Patient Origin for CMC PET

NC County/State of Origin	2023 Percent of Total
HSA III	
Mecklenburg	43.7%
Gaston	6.6%
Union	5.8%
Cabarrus	2.8%
Lincoln	2.3%
Iredell	1.9%
Rowan	0.9%
Stanly	0.7%
Total HSA III	64.7%
Other NC	8.8%
Out of State	26.5%
Total	100.0%

Source: CMC’s 2023 LRA

Simply put, without the demand for PET services originating from outside of the HSA, there would not be a need for an additional PET scanner located in HSA III.

Based on this analysis, CMHA believes that the Agency should evaluate its review of patient origin similar to its analysis of acute care beds in Mecklenburg County. Specifically, in the Agency Findings for the 2019 Mecklenburg County Acute Care Bed and OR Review, the Agency’s comparative analyses included a comparative factor, Access by Service Area Residents, but did not draw any conclusions about the factor. Pages 235 and 236 of the Agency Findings for the 2019 Mecklenburg County Acute Care Bed and OR Review state, *“Atrium is correct that the Acute Care Bed Need Determination in the 2019 SMFP is based on the total number of acute care days at each hospital and not based on anything related to Mecklenburg County-specific acute care days. Further, Mecklenburg County is a large urban county with over one million residents, two large health systems plus other smaller healthcare groups, and is on the border of North Carolina and South Carolina... the Agency believes that in this specific instance attempting to compare the applicants based on the projected acute care bed access of Mecklenburg County residents has little value [emphasis added].”* Subsequently, the Agency maintained this position in its Findings for the 2020 Mecklenburg County Acute Care Bed and OR Review and the 2021, 2022, and 2023 Mecklenburg County Acute Care Bed Reviews in which it did not evaluate this comparative factor. CMHA agrees with the Agency’s findings regarding this factor in the 2019 and subsequent Acute Care Bed and OR reviews. Further, CMHA believes that this comparative factor, if applied, would be inappropriate for a review of the proposed project. The need for additional fixed PET capacity in HSA III and, specifically, the need determination in the 2024 SMFP, is a result of the utilization of all patients seeking PET services at CMC. Given HSA III residents comprise less than 65 percent of CMC’s PET utilization, there would be no need determination for an additional fixed PET scanner in HSA III without the demand for PET services

originating from outside the service area.⁹ As affirmed by the Agency in similar reviews, under these circumstances, it is not appropriate to determine the comparative effectiveness of an applicant based on service to HSA III residents when the need as identified for the proposed additional fixed PET capacity is not based solely on HSA III patients. (Other methodologies in the *SMFP*, such as nursing facility beds, are based only on the population residing in the county; a factor for Service to Residents of the Service Area may be more appropriate in such a review, but that is not the case with PET.)

Access by Underserved Groups

Projected Medicare

The following table illustrates each applicant’s percentage of fixed PET utilization to be provided to Medicare patients as stated in Section L.3 of the respective applications.

Medicare Percentage of Fixed PET Utilization

	<i>% of Medicare</i>
Atrium Health Pineville	58.9%
NH Presbyterian	56.7%

Source: Section L.3.

As shown in the table above, Atrium Health Pineville projects to serve the higher percentage of Medicare patients. Thus, regarding access by Medicare recipients, Atrium Health Pineville is the more effective alternative.

Regarding this competitive review, a comparison of Medicare as a percentage of patients is the most appropriate as it reflects the proportion of an applicant’s access dedicated to underserved patients regardless of its overall capacity, volume, or charge structure. Thus, this method allows an equitable comparison by eliminating factors that may inadvertently skew the comparison.

A comparison of the raw number of Medicare patients is inappropriate for this competitive review. This method would arbitrarily and inequitably benefit the applicant with more fixed PET scanners at its proposed location as it has a higher capacity to perform more procedures (volume of two scanners vs volume of one scanner). To utilize a Medicare patient comparison, a patient per PET scanner analysis would be required. As shown below, Atrium Health Pineville projects to serve more Medicare patients per PET scanner than NH Presbyterian.

Medicare Patients Per PET Scanner

	<i>PY 3 Volume</i>	<i>% of Medicare</i>	<i>Medicare Patients</i>	<i>Medicare Patients / PET Scanner</i>
Atrium Health Pineville	2,517	58.9%	1,483	1,483
NH Presbyterian	4,347	56.7%	2,463	1,231

Source: Form C.2b, Form F.2b, Section L.3.

⁹ 3,312 PET procedures performed at CMC originating from HSA III ÷ 5,119 total PET procedures performed at CMC = 64.7 percent. If just these 3,312 PET procedures originating from HSA III were considered, CMC’s PET utilization rate would be 55.2 percent (3,312 ÷ CMC’s total capacity of 6,000) and there would be no need in the 2024 *SMFP* for an additional PET scanner in HSA III.

Additionally, a comparison of raw Medicare charges is inappropriate for this competitive review when looking at access for Medicare patients as this method would arbitrarily and inequitably benefit the applicant with more PET scanners or a higher charge structure. Disconcertingly, NH Presbyterian would benefit from its higher charge structure which is counter to the goal of reducing healthcare costs. As shown below, NH Presbyterian projects to charge Medicare PET patients 75 percent more than Atrium Health Pineville. Simply charging more does not translate to better access for the underserved. Despite Atrium Health Pineville serving proportionally more Medicare patients, NH Presbyterian arbitrarily has higher Medicare gross charges because it has more PET scanners and a significantly higher charge structure.

Gross Medicare Charges Per PET Procedure

	<i>% of Medicare</i>	<i>PY 3 Medicare Procedures</i>	<i>PY 3 Medicare Gross Charges</i>	<i>Medicare Gross Charge Per Procedure</i>
Atrium Health Pineville	58.9%	1,483	\$13,043,938	\$8,795
NH Presbyterian	56.7%	2,463	\$37,949,198	\$15,408

Source: Form C.2b, Form F.2b, Section L.3.

Projected Medicaid

The following table illustrates each applicant’s percentage of fixed PET utilization to be provided to Medicaid patients as stated in Section L.3 of the respective applications.

Medicaid Percentage of Fixed PET Utilization

	<i>% of Medicaid</i>
Atrium Health Pineville	3.2%
NH Presbyterian	4.1%

Source: Section L.3.

As shown in the table above, NH Presbyterian projects to serve the higher percentage of Medicaid patients. However, as previously discussed, the NH Presbyterian application does not adequately demonstrate that its proposal is conforming to all applicable statutory review criteria. Therefore, Atrium Health Pineville is the more effective alternative.

For the same reasons as outlined in the Medicare discussion above, a comparison of Medicaid patients or Medicaid charges is inappropriate for this competitive review. Utilizing these methods would arbitrarily and inequitably benefit the applicant with more fixed PET scanners at its proposed location as it has a higher capacity to perform more procedures. In addition, a charge method would benefit an applicant with a higher charge structure.

Average Net Revenue per Procedure

The following table shows average net revenue per PET procedure in the third full fiscal year of operation.

	Total Net Revenue	# of Procedures	Total Net Revenue per Procedure
Atrium Health Pineville	\$5,737,661	2,517	\$2,280
NH Presbyterian	\$13,793,633	4,347	\$3,173

Source: Forms C.2b and F.2b.

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

On October 31, 2023, Novant Health submitted written comments for the 2023 HSA II fixed pet scanner competitive review. In its comparative factors included in those comments, Novant Health included this same comparative factor and calculated it the same way. Novant Health concluded that the project with the lowest average net revenue per PET scan procedure in the third full fiscal year was the most effective alternative. This is consistent with CMHA’s conclusion for this comparative factor in this competitive review.

Average Operating Expense per Procedure

The following table calculates average operating expense per PET procedure in the third full fiscal year of operation.

	Total Operating Costs	# of Procedures	Total Operating Costs per Procedure
Atrium Health Pineville	\$3,202,997	2,517	\$1,272
NH Presbyterian	\$7,194,631	4,347	\$1,655

Source: Forms C.2b and F.2b.

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

Summary of Comparative Analysis

The following table summarizes the comparative analysis for fixed PET services in HSA III.

Comparative Factor	Atrium Health Pineville	NH Presbyterian
Conformity with Review Criteria	Yes	No
Scope of Services	Equally Effective	Equally Effective, But Not Approvable
Geographic Accessibility	More Effective	Less Effective

Comparative Factor	Atrium Health Pineville	NH Presbyterian
Historical Utilization	More Effective	Less Effective
Competition – Access to a New Provider	Equally Effective	Equally Effective, But Not Approvable
Access by Service Area Residents	Inconclusive	Inconclusive
Projected Medicare	More Effective	Less Effective
Projected Medicaid	More Effective	Less Effective
Average Net Revenue per Procedure	More Effective	Less Effective
Average Operating Expense per Procedure	More Effective	Less Effective

SUMMARY

In summary, Novant Health is not conforming to all applicable statutory review criteria nor does it demonstrate that it will meet the performance standards in Project Year 3 and thus its application is not approvable. Even if Novant Health’s application were approvable, CMHA believes that its application is the most effective alternative for the fixed PET scanner needed in HSA III. Atrium Health Pineville is fully conforming to all applicable statutory and regulatory review criteria and is comparatively superior on the relevant factors in this review. As such, the proposal by CMHA should be approved.

Please note that in no way does CMHA intend for these comments to change or amend its application as filed on September 16, 2024. If the Agency considers any statements to be amending CMHA’s applications, those comments should not be considered.