

Comments on Novant Health Huntersville Medical Center's and Novant Health, Inc.'s Fixed PET Scanner Certificate of Need Application, Project ID # F-012627-25

June 2, 2025

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 Novant Health Huntersville Medical Center and Novant Health, Inc. (collectively referred to herein as Novant Health) to add a dedicated fixed PET scanner to The Presbyterian Hospital Novant Health Huntersville Medical Center d/b/a Novant Health Huntersville Medical Center (NH Huntersville) in response to the need identified in the 2025 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 nonconformity of each issue, as they relate to Novant Health's application, Project ID # F-012627-25. CMHA's comments include issue-specific comments on the NH Huntersville application as well as a comparative analysis related to its application:

Atrium Health Pineville, add one fixed PET scanner, Project ID # F-012630-25

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 Huntersville application non-conforming with applicable statutory criteria and regulatory review criteria. However, as presented at the end of these comments, even if the NH Huntersville 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.

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 April 15, 2025 (Project ID # F-012630-25).

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. Additionally, Novant Health presents inconsistent historical data across applications, contradicts its own operational statements about equipment capacity, and proposes inadequate staffing levels significantly below those in its other similar facilities.

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 Huntersville. As a major cancer treatment facility with linear accelerator volume that triggered the need determination, which is discussed further below, Atrium Health Pineville offers an environment where PET services would complement its oncology and other growing tertiary care services, unlike NH Huntersville's community hospital setting. Furthermore, Atrium Health Pineville will likely continue to generate need determinations until approved due to the *SMFP* methodology's recognition that major cancer treatment facilities of this size should have dedicated fixed PET services.

2025 SMFP Need Determination for a Dedicated Fixed PET Scanner in HSA III

According to page 368 of the 2025 SMFP, the need for an additional fixed PET scanner in HSA III was generated pursuant to Part 2 of the Application of the Methodology. A need determination generated by Part 2 of the methodology is based on the following:

Step 5: Identify each major cancer treatment facility, program, or provider in the state, defined as providers that operate two linear accelerators that performed over 12,500 ESTV [Equivalent Simple Treatment Visit] procedures during the current reporting year (Table 15C-1).

Step 6: A service area has a need determination for one additional fixed PET scanner if a major cancer treatment facility, program, or provider identified in Step 5 is hospital-based (i.e., on a hospital's license) and does not own or operate a dedicated fixed PET scanner, except as provided in Step 7 for both parts of the methodology combined.

Step 7: The maximum need determination for a single HSA in any one year will be no more than two additional fixed PET scanners regardless of the numbers generated individually by each part of the methodology (Table 15F-1, Column F).

As described in the methodology above, a need determination derived through Part 2 differs fundamentally from other PET scanner need determinations in that it is exclusively predicated on linear accelerator volume at a major cancer treatment provider, rather than on existing PET scanner utilization. This methodology recognizes the fundamental relationship between high-volume cancer treatment programs and PET services.

Below is an excerpt of Table 15C-1 from the 2025 SMFP which includes every LINAC provider in the fixed PET scanner HSA III:

2025 SMFP Table 15C-1

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2022- 9/30/2023	Average Number of Procedures per Unit
Atrium Health Cleveland	6	Cleveland	1	7,097	7,097
CaroMont Regional Medical Center**	6	Gaston	3	22,929	7,643
North Carolina Radiation Therapy Management Services - Forest City	6	Rutherford	1	4,033	4,033
Atrium Health Carolinas Medical Center	7	Mecklenburg	3	18,929	6,310
Atrium Health Pineville	7	Mecklenburg	2	13.401	6.701
Atrium Health University City	7	Mecklenburg	1	8,714	8,714
Matthews Radiation Oncology Center	7	Mecklenburg	2	13,963	6,981
Novant Health Huntersville Medical Center	7	Mecklenburg	1	11,391	11,391
Novant Health Presbyterian Medical Center	7	Mecklenburg	2	6,356	3,178
Atrium Health Union	7	Union	1	8,996	8,996
Iredell Memorial Hospital	8	Iredell	2	5,217	2,609
Lake Norman Radiation Oncology	8	Iredell	1	4,654	4,654
Novant Health Rowan Medical Center-Cancer Institute	8	Rowan	1	7,805	7,805
Atrium Health Cabarrus	9	Cabarrus	3	13,967	4,656
Atrium Heatlh Stanly	9	Stanly	1	4,141	4,141
Atrium Health Wake Forest Baptist	10	Forsyth	4	25,124	6,281
Novant Health Forsyth Medical Center	10	Forsyth	5	25,810	5,162
Hugh Chatham Memorial Hospital****	10	Surry	1	0	0
Lexington Medical Center	11	Davidson	1	2,815	2,815

As shown in Table 15C-1 above, Atrium Health Pineville performed 13,401 ESTVs and exceeded the threshold of 12,500 ESTV procedures. Thus, the need for an additional PET scanner in HSA III is driven specifically by Atrium Health Pineville's linear accelerator volume.³

This background is important context for the issue-specific comments and comparative analysis to follow, which demonstrate that the Novant Health Huntersville application is non-conforming while the Atrium Health Pineville application is both fully conforming and represents the most effective alternative for meeting the identified need for a fixed PET scanner in HSA III.

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³ As discussed in the Atrium Health Pineville application, CMHA acknowledges that a provider that generates the need for additional capacity is not entitled to that need; it must submit an approvable application and demonstrate that it has the most effective alternative.

ISSUE-SPECIFIC COMMENTS

1. <u>Novant Health's PET use rate methodology is flawed and double counts population growth resulting in overstated volume projections.</u>

Novant Health's methodology for projecting fixed PET scan volumes is fundamentally flawed in its PET use rate calculation. A comparison of Novant Health's PET use rate projections across its recently filed PET applications reveals material inconsistencies.

On September 16, 2024, Novant Health applied for an additional fixed PET scanner at Novant Health Presbyterian (Project ID # F-012557-24) pursuant to the need determination in HSA III. The following screenshot from page 118 of that application shows its projected PET procedure use rate.

North Carolina PET Procedure Use Rate (per 1,000 population)						
	2024	2025	2026	2027	2028	2029
PET Use Rate	7.34	7.62	7.92	8.22	8.54	8.87

Source: NH Presbyterian application, filed September 16, 2024, p. 118

Conversely, in Table 3 of Novant Health's methodology for its current application, it projects a PET procedure use rate of 9.34 for 2029, as shown in the table below.

Year	2024	2025	2026	2027	2028	2029
Estimated PET Use Rate	7.46	7.80	8.16	8.54	8.93	9.34

Source: NH Huntersville application, filed April 15, 2025, Section, Q p. 2

Novant Health's projected PET use rates have increased dramatically in just five months between applications. While Novant Health may claim it is the result of updated data to reflect the 2025 SMFP instead of the Proposed 2025 SMFP, this change alone would have minimal impact on the projections. The substantial increase is instead attributable to Novant Health's use of a 4.6 percent compound annual growth rate (CAGR) in the current application versus the 3.9 percent CAGR used in its previous application.

This methodological error stems from Novant Health's misapplication of growth rates. The CAGR of 4.6 percent is derived from the overall growth in statewide PET volume (FY2019-FY2023 CAGR of 9.2% \div 2 = 4.6%). However, this raw PET volume growth—not use rate growth—already incorporates population growth effects. By applying this growth rate to generate a higher use rate and then multiplying that higher use rate by projected population figures that reflect population growth, Novant Health is effectively double-counting population growth in its projections.

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 projects duplicative market share capture across multiple facilities.

Novant Health's application for NH Huntersville Medical Center includes a fundamental methodological flaw whereby Novant Health projects to capture PET market share for the same geographies multiple times across different facilities, essentially triple-counting market growth. This overlapping market share capture inflates projected volumes by counting the same potential patients from these geographies multiple times across different facilities, as evident when comparing Novant's various applications.

Incremental Market Share Capture by Geography in the 2024 and 2025 Novant Health PET Applications

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County	NH Presbyterian 2024 Application	NH Huntersville 2025 Application	Combined		
Cabarrus		+4.5%	+4.5%		
Gaston	+4.5%	+3.0%	+7.5%		
Iredell	+4.5%	+4.5%	+9.0%		
Lincoln		+6.0%	+6.0%		
Mecklenburg	+6.0%	+6.0%	+12.0%		
Union	+4.5%		+4.5%		

Source: NH Presbyterian application, filed September 16, 2024, p. 120; NH Huntersville application, filed April 15, 2025, Section Q, p. 6.

Both NH Presbyterian and NH Huntersville are located in Mecklenburg County and serve similar geographic areas. As shown in the table above, Novant Health projects market share increases for both facilities from the same patient pool in multiple counties in these recent applications. In its September 2024 application, NH Presbyterian was able to meet performance standards specifically based on its ability to capture 6.0 percent additional market share in Mecklenburg County. That same market share cannot now be captured again by NH Huntersville in its 2025 application, as it would already be included in volume projections of the previously approved facility. This represents a clear double-counting of market share capture, as both facilities are claiming to draw the same additional patients from Mecklenburg County. The same argument can be made for potential patients that reside in Gaston or Iredell counties.

This duplicative share increase becomes even more problematic when considering Novant Health's mobile PET scanner projections. For NH Matthews and NH Mint Hill (both located in Mecklenburg County), Novant Health projects volume will grow at 13.5 percent annually, a rate that substantially exceeds both population growth and the projected statewide PET use rate increases (4.6 percent annually). The only mathematical way to achieve such growth is through additional market share capture. Since these facilities are located in Mecklenburg County and primarily serve Mecklenburg County residents, Novant Health is effectively projecting a third instance of market share capture of the same patients.

The magnitude of this triple-counting becomes clear when examining the actual patient volumes involved. On page 6 of its methodology, Novant Health projects Mecklenburg County PET volume to reach 11,904 procedures in 2029. While a 6.0 percent market share capture might seem modest in percentage terms, it represents 714 additional procedures for NH Presbyterian and another 714 additional procedures for NH Huntersville, plus incremental volume for the mobile scanner serving

NH Matthews and NH Mint Hill. This level of market share capture across multiple facilities from the same patient population is not supported.

Furthermore, if these unsupported market share projections were removed, each of Novant Health's individual facilities would fail to meet the performance standard. For example, if NH Huntersville's duplicative 6.0 percent Mecklenburg County market share capture (714 procedures) were removed, NH Huntersville would project only 1,785 procedures in Year 3, falling well below the 2,080 performance standard.

Additionally, Novant Health's methodology fails to account for the competitive dynamics between its own facilities. When a health system adds multiple new fixed PET scanners in close geographical proximity, these scanners compete not only with other providers but also with each other for the same patient population. By projecting that each facility will independently capture substantial new market share without accounting for this internal competition, Novant Health's methodology systematically inflates its projected volumes.

This triple-counting of market share capture renders Novant Health's volume projections unsupported. When corrected for this methodological flaw, projected volumes would be substantially lower and likely insufficient to meet the performance standards.

As a result, 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. <u>Novant Health's projections for PET volume at NH Huntersville during interim years are contradictory</u> and unreasonable.

Novant Health's projections for PET scanner volume at NH Huntersville during the interim years (2025-2026) directly contradict its own operational statements, rendering these projections unreasonable and unsupported. On page 10 of its methodology, Novant Health states:

"During FY 2023-2024, the NHFMC mobile provided over 3,700 clinical hours of operation, equating to roughly 75-80 hours per week. This does not include time to move the mobile PET scanner and set up/disconnect service at each host site. From an operational perspective, there is no practical way to increase capacity on the mobile PET scanner" (emphasis added).

Based on this clear statement acknowledging the mobile scanner's operational constraints, Novant Health holds mobile volumes flat at NH Matthews, NH Mint Hill, and NH Kernersville for 2025 and 2026. However, inexplicably and in sharp contrast to this same data, Novant Health simultaneously projects NH Huntersville's mobile PET volume to increase from 1,101 procedures in 2024 to 1,169 in 2025 (a 6.2 percent increase) and further to 1,243 in 2026 (another 6.3 percent increase).

This internal contradiction cannot be reconciled. If "there is no practical way to increase capacity on the mobile PET scanner" as Novant Health states, then it is mathematically impossible for NH Huntersville to increase its mobile PET volume while other sites maintain their existing volumes. The mobile scanner has finite capacity that Novant Health states is already maximized. The only way NH Huntersville could perform more procedures would be if other sites performed fewer procedures, yet Novant Health projects no corresponding decrease at other sites.

Since Novant Health's interim year projections are overstated based on its own operational assertions, the subsequent project year volume projections must also be overstated as they build upon this flawed baseline. The projected volumes for years 2027-2029 rely on growth assumptions applied to an artificially inflated 2026 baseline, compounding the error throughout the projection period. This error chain renders the entire projection methodology unreasonable and unsupported by the data provided in the application.

This contradiction in Novant Health's own application demonstrates that its volume projections are unreasonable and methodologically unsound. Thus, Novant Health's application is non-conforming with Criteria 3, 4, 5, 6, and 18a.

4. <u>Novant Health fails to demonstrate conformity with performance standards as its volume projections</u> for NH Presbyterian are overstated and unreasonable.

The methodology utilized by Novant Health in its NH Huntersville application continues to rely on the same flawed assumptions for NH Presbyterian. Most critically, Novant Health persists in using statewide PET use rates to project local volume growth, despite clear evidence that NH Presbyterian's historical growth rates have consistently trailed statewide growth. From FFY 2015-2019, 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 just 2.2 percent, more than three times slower. This disparity has only widened since FFY 2019, with statewide PET growth at 8.9 percent CAGR compared to NH Presbyterian's mere 1.4 percent, now more than six times slower. These figures clearly demonstrate that statewide PET growth trends do not translate to proportional growth at NH Presbyterian, making Novant's continued use of this methodology fundamentally unsound.

Novant Health's PET market share projections remain equally problematic. The NH Huntersville application explicitly references and builds upon the NH Presbyterian projections, stating on page 9 that "NHHMC estimates no substantial changes in the projected volume for the NHPMC project as the projected operational dates are the same." 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 PET market share in both counties has declined every year since FFY 2019.**

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

	FFY19	FFY20	FFY21	FFY22	FFY23	CAGR	
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%		
	Unior	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 clear downward trend, Novant inexplicably continues to project market share increases of 6.0 percent in Mecklenburg County and 4.5 percent in Union County by project year 3, which artificially inflates projected procedures by approximately 840 cases.⁴

Particularly concerning is Novant Health's failure to provide updated historical volume data for NH Presbyterian in this new NH Huntersville application, despite the previous application only including data through July 2024. This omission is significant as it prevents any assessment of whether NH Presbyterian's actual volume has tracked with its previous projections, a critical piece of evidence given comments specific to overstated projections in the past application. Novant's reliance on outdated historical data further undermines the credibility of its projections and suggests an unwillingness to subject its methodology to verification.

When reasonable assumptions are applied, specifically, when the unsupported market share increases are removed, NH Presbyterian's projected procedures are well below the performance standard of 2,080 procedures.

As a result of continued use of NH Presbyterian's overstated volume projections, NH Huntersville cannot demonstrate conformity to the performance standards specified in 10A NCAC 14C .3703 and should be found non-conforming.

5. Novant Health's volume projections for its mobile PET scanner are unsupported.

Novant Health's latest application for a fixed PET scanner now at NH Huntersville presents yet another set of inconsistent historical volumes for its mobile PET scanner. Novant Health has filed three applications within 18 months that present dramatically different mobile PET volumes.

On September 15, 2023, Novant Health applied for an additional fixed PET scanner at Novant Health Forsyth Medical Center (Project ID # G-012432-23) pursuant to the need determination in HSA II. 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.

NHFMC Mobile PET Utilization By Host Site						
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						

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This overstatement was calculated at 805 procedures in CMHA's 2024 Comments on NH Presbyterian's Fixed PET Scanner. It was increased here as market volumes in Mecklenburg and Union counties have increased per NH Huntersville's new use rates.

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.

As previously discussed, on September 16, 2024, Novant Health applied for an additional fixed PET scanner at Novant Health Presbyterian (Project ID # F-012557-24) pursuant to the need determination in HSA III. The following screenshot from page 124 of that application shows the historical volume of its mobile PET scanner through annualized CY 2024.

NHFMC Mobile PET Utilization By Host Site						
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						

Now, in its current application, Novant Health presents historical utilization of its mobile PET scanner on page 10 of its methodology as follows:

Year	NHFMC – Mobile PET Volume ALL SITES	% of 2600 Mobile PET Scanner Capacity	NHHMC Mobile PET Volume
FY 2023-24	2561	98.5%	1101
FY 2022-23	2733	105.1%	1116
FY 2021-22	2375	91.3%	808
FY 2020-21	1750	67.3%	663

A summary of the different historical volume projections for Novant Health's mobile is as follows:

	2023 Application	2024 Application	2025 Application
2021	2,202	727	1,750
2022	2,620	1,955	2,375
2023	3,639	2,372	2,733
2024	N/A	2,484	2,561

Several items immediately stand out when comparing historical volumes across the three applications. First, Novant Health switches its data source and projection year from internal data on a calendar year to LRA data on a federal fiscal year, distracting from continued use of unreliable data. Second, the mobile PET scanner's historical volumes vary significantly.

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.

6. <u>Novant Health's projected growth for its mobile PET scanner is unreasonable given planned fixed PET scanner expansion.</u>

Novant Health's projections for its mobile PET scanner in the NH Huntersville application fail to account for the significant impact of its planned fixed PET scanner expansion. The application projects mobile volume will grow at a compound annual growth rate (CAGR) of 13.5 percent at remaining mobile host sites after NH Huntersville converts to a fixed scanner. This growth rate is derived from the mobile unit's historical experience between FY 2021-2024, when Novant Health states it had limited fixed scanner capacity. However, this approach fundamentally ignores the operational reality of Novant Health's changing PET service landscape. Novant Health will be adding substantial new fixed PET capacity across its service areas in the coming years:

- One fixed PET scanner at NH Presbyterian (projected operational in 2027)
- One fixed PET scanner at NH Huntersville (projected operational in 2027)
- One fixed PET scanner at Forsyth Medical Center (projected operational in 2025)

This expansion represents a tripling of Novant's fixed PET capacity in HSA III (from one to three scanners) and a doubling in HSA II (from one to two scanners). It is unlikely that mobile volumes will continue to grow when multiple new fixed scanners have capacity. Novant Health's application projects that NH Matthews, NH Mint Hill, and NH Kernersville all will experience 13.5 percent annual growth in mobile PET volume through 2029, despite the fact that these facilities' patients will have access to newly available fixed scanners at Novant facilities within reasonable driving distance.

By failing to account for this fundamental operational reality, Novant's mobile PET projections are unreasonable and unsupported, rendering the application non-conforming with the performance standards specified in 10A NCAC 14C .3703.

7. <u>Novant Health's staffing projections for fixed PET services at NH Huntersville are inadequate and unreasonable.</u>

Novant Health's staffing projections for its proposed fixed PET scanner at NH Huntersville Medical Center are inadequate and unreasonable when compared with the operational data provided in its own application, as well as compared to staffing it has provided in other recently filed PET applications. Analysis of Novant Health's historical time allocation per procedure at this site reveals a significant discrepancy between projected staffing and the actual time required to perform the anticipated volume of procedures.

In its 2025 Registration and Inventory of Medical Equipment for its mobile PET scanner, Novant Health reports that it performed 1,101 procedures in 1,512 hours of operation at the NH Huntersville site. This equates to approximately 1.37 hours per procedure.

However, in Form H of its current application, Novant Health projects to operate its new fixed PET scanner with just 1.0 FTE nuclear medicine technologist and 0.2 FTE supervisor. Given the historical operational experience at the same site, it would logically require approximately 3,424 hours (2,499 procedures \times 1.37 hours per procedure) to perform the 2,499 procedures projected for Year 3. This equates to approximately 65.8 hours per week (3,424 hours \div 52 weeks), which is significantly more than a single full-time technologist could reasonably be expected to cover.

This staffing projection is also inconsistent when compared to relatively recent past Novant Health fixed PET CON applications. Novant Health's 2024 CON application for NH Presbyterian projected 6.5 FTE nuclear medicine technologists and 0.5 FTE radiology operations assistant for two scanners performing a combined 4,347 PET scans. On a per-scanner basis, this equates to 3.25 FTE technologists per scanner and 0.25 FTE support staff per scanner at NH Presbyterian. Additionally, in its 2023 CON application for NH Forsyth, Novant Health projected 7.0 FTE nuclear medicine technologists, 0.5 FTE supervisors, and 0.5 FTE radiology operations assistant for 4,289 scans. On a per-scanner basis, this equates to 3.75 FTE technologists and 0.25 FTE support staff per scanner. The staffing level in these other Novant Health applications is substantially higher than the 1.0 FTE technologist and 0.2 FTE supervisor projected for NH Huntersville. Typically, there are economies of scale when adding resources, which would suggest that staffing at a single-scanner facility like NH Huntersville should be proportionally higher than a two-scanner facility, not dramatically lower.

The proposed staffing levels at NH Huntersville are inadequate to safely and effectively operate the scanner at the projected volume levels. This staffing plan would require the single nuclear medicine technologist to work excessive hours, potentially compromising patient safety and quality of care, or would result in the scanner being unutilized for significant periods due to insufficient staffing. Either outcome would render the application non-conforming with Criterion 7, which requires the applicant to demonstrate that it can adequately staff the proposed service.

Thus, Novant Health's application is non-conforming with Criteria 7.

In summary, based on the issues detailed above, the NH Huntersville application is non-conforming with the review criteria established under N.C. GEN. STAT. § 131E-183, specifically Criteria 3, 4, 5, 6, 7, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703. The NH Huntersville application should not be approved.

COMPARATIVE ANALYSIS

The NH Huntersville application (Project ID # F-012627-25) and the Atrium Health Pineville application (Project ID # F-012630-25) each propose to develop a fixed PET scanner in response to the 2025 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.

Given the need determination is based on linear accelerator volume at a major cancer treatment facility, the comparative analysis that follows incorporates linear accelerator volume where appropriate, as will be discussed more below.

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 Huntersville application does not adequately demonstrate that its proposal is conforming to all applicable statutory review criteria as discussed previously. Specifically, the NH Huntersville application is non-conforming with Criteria 3, 4, 5, 6, 7, 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 Huntersville application.

Scope of Services

Both applications were submitted in response to the need determination for one fixed PET scanner in HSA III in the 2025 SMFP. Generally, the application proposing the broadest scope of services with the proposed equipment is the more effective alternative regarding this comparative factor. Both applicants propose to provide PET services to oncology, cardiac, and neurology patients (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 service; additionally, prostate-specific membrane antigen, or PSMA, scans are a subset of oncology scans and should not be considered a separate category). However, the use of this type of comparison is less meaningful in a fixed PET need determination based on the linear accelerator volume of a major cancer treatment facility.

As previously discussed, the need determination for an additional fixed PET scanner in HSA III was generated by Atrium Health Pineville's linear accelerator volume in the 2025 SMFP and will likely continue to generate future need determinations until approved, reflecting the SMFP methodology's inherent recognition that high-volume cancer treatment facilities require dedicated fixed PET services. As such, scope of services should consider two additional factors. First, according to the SMFP need determination, Atrium Health Pineville has a need for a fixed PET scanner based on its cancer treatment program while Novant Health Huntersville does not. Additionally, Atrium Health Pineville is a 268-bed tertiary care facility. Novant Health Huntersville is a 135-bed community hospital. In other competitive reviews, the Agency has found that tertiary care providers have a higher scope of service than a community hospital. Thus, with regard to scope of services, the Atrium Health Pineville application is more effective than the NH Huntersville application.

Geographic Accessibility

The 2025 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 Huntersville, an existing mobile PET provider. CMHA proposes to locate a fixed PET scanner at Atrium Health Pineville, a growing tertiary and major cancer treatment provider without existing fixed PET services.

Atrium Health Pineville represents an entirely new access point for PET services in southern Mecklenburg County, an area currently without any PET services, while NH Huntersville offers mobile PET services at its proposed facility today. The Atrium Health Pineville location would substantially reduce travel times for patients residing in the southern portion of the county, southern Union County, and adjacent areas, delivering immediate access benefits to an entirely new population rather than merely converting an existing mobile service to fixed service at a location that already has some form of PET access. 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.

Furthermore, Atrium Health Pineville, as a growing tertiary care facility, offers significant clinical advantages over community hospitals for fixed PET scanner placement. As a tertiary provider, Atrium Health Pineville delivers advanced medical treatment through its established cancer institute, cardiovascular services, and other specialty programs that frequently require PET imaging for diagnosis and treatment planning. This addition of PET services within a comprehensive tertiary care environment would provide superior clinical value compared to placement at NH Huntersville, a community hospital.

As outlined above, the Atrium Health Pineville application is more effective than the NH Huntersville application in regard to geographic accessibility.

Historical Utilization

The table below represents Table 15F-1 from the 2025 SMFP for HSA III. Generally, regarding this comparative factor, an existing provider with higher historical utilization rates is the more effective

alternative based on an assumption that that provider has a greater need for the proposed fixed PET scanner in order to serve its projected patients.

Utilization of Existing Dedicated Fixed PET Scanners

	Planning Inventory	2025 SMFP	Facility Deficit
Atrium Health Cabarrus*	1	1,417	-
Atrium Health Union*	1	953	-
Carolinas Medical Center*	2	5,686	1
CaroMont Regional Medical Center	1	1,282	-
Iredell Memorial Hospital	1	746	-
Novant Health Presbyterian	2**	2,275	-
HSA III Totals	8**	12,359	1

Source: 2025 SMFP. *CMHA Facility. **Novant Health Presbyterian was approved for a second fixed scanner in the 2024 HSA III PET Review.

CMHA and Novant Health are both existing providers of fixed PET services within HSA III. CMHA performed 8,056 in FFY 2023 compared to just 2,275 performed by Novant Health. On a per scanner basis, CMHA performed 2,014 per fixed scanner while Novant Health only performed 1,138 when considering it now has two fixed scanners approved at NH Presbyterian. However, the use of this type of comparison is less meaningful in a fixed PET need determination based on the linear accelerator volume of a major cancer treatment facility.

As previously discussed, the need determination for an additional fixed PET scanner in HSA III was generated by Atrium Health Pineville's linear accelerator volume. In FFY 2023, according to table 15C-1, Atrium Health Pineville performed 13,401 ESTVs on its linear accelerator and exceeded the fixed PET Step 2 threshold of 12,500 ESTV procedures. Novant Health Presbyterian performed only 11,391 ESTVs.

Regardless of the approach, CMHA performed more fixed PET procedures than Novant Health, and Atrium Health Pineville performed more ESTVs than Novant Health Huntersville. Thus, with regard to historical utilization, the Atrium Health Pineville application is more effective than the NH Huntersville application.

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 Center in Mecklenburg County. In addition, it provides mobile PET services at Novant Health Rowan in HSA III. Novant Health was awarded a second fixed PET scanner at Novant Health Presbyterian in the 2024 HSA III PET review.

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 the PET scanners in Mecklenburg County. Currently, Novant Health operates PET services at four locations (one fixed and three mobile) within Mecklenburg County while CHMA operates PET services at only one location within Mecklenburg County.

As outlined above, CMHA and Novant Health are two existing, mature, and well-established PET service providers in HSA III. As such, neither CMHA nor Novant Health would qualify as a "new or alternative provider" under the Agency's historical reasoning of the "Competition (Patient Access to a New or Alternative Provider)" comparative factor in competitive reviews over the last decade. Specifically, the Agency has stated in numerous competitive reviews over the last several years that an applicant proposing to increase access to a "new provider" is a more effective alternative with regard to "Competition/Patient Access to a New or Alternative Provider." In the 2022 MRI review for the Pitt, Greene, Hyde and Tyrrell multicounty service area, the Agency declared the two well-established applicants – OrthoEast (with one existing mobile MRI scanner) and Greenville MRI (with two existing fixed MRI scanners) – as equally effective in regard to this comparative factor. The Agency specifically noted that both applicants are equally effective despite the fact that OrthoEast does not yet own a fixed MRI scanner:

"Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. 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. Although OrthoEast does not own a fixed MRI scanner, both applicants are existing providers of MRI services in the service area of Pitt, Green[sic], Hyde and Tyrrell Counties; therefore, neither of the applicants would qualify as a new or alternative provider in the service area. Thus, with regard to this comparative factor, the proposals are equally effective." See Findings, p. 61

Likewise, both CMHA and Novant Health provide PET services in the HSA III service area. Neither system qualifies as a new or alternative provider of PET services in Mecklenburg County.

In addition, Novant Health has a history of arguing that existing service providers are equal regarding this comparative factor regardless of the number of service component resources. In its comments in opposition to Wilmington Health and EmergeOrtho in the 2023 New Hanover MRI competitive review, Novant Health stated, "NH New Hanover, Wilmington Health, and EmergeOrtho all provide fixed MRI scanner services in New Hanover County. As discussed above, both Wilmington Health and EmergeOrtho already offer fixed MRI services at freestanding sites in New Hanover County, so their applications to offer 'freestanding fixed MRI services' do not propose anything new or different. Accordingly, this factor does not favor any applicant in this review." According to Novant Health, all three applicants in this review were equal despite differences in MRI inventory; upon submission, Novant Health was operating five fixed MRI scanners in the county while EmergeOrtho and Wilmington Health were operating one fixed MRI

Comments Submitted by Novant Health New Hanover Regional Medical Center, LLC and Novant Health, Inc. In Opposition to Wilmington Health, PLLC and EmergeOrtho, P.A. dated May 31, 2023. P. 41-42.

scanner each. Similarly, in its comments in opposition to OrthoCarolina in the 2022 Mecklenburg MRI competitive review, Novant Health stated, "...both NH Matthews and OrthoCarolina are existing providers of fixed and mobile MRI services in Mecklenburg County . . . As neither applicant is a new fixed MRI provider, both applicants are equally effective with respect to competition." In that review, Novant Health once again stated the applicants were equal despite differences in MRI inventory; upon submission, Novant Health owned nine fixed MRI scanners in the county while OrthoCarolina only owned two. By Novant Health's own reasoning, since both CMHA and Novant Health are established providers of PET services in Mecklenburg County, they are equally effective in terms of competition.

Access by Service Area Residents

In the past five years, there have been six competitive reviews of fixed PET services. Four of the six sets of findings determined that Access by Service Area Residents was inconclusive:

- In the 2023 HSA II PET Scanner review, this comparative factor was found inconclusive due to the other category within the patient origin tables. "The Project Analyst is unable to discern, from the information provided by Cone Health and Novant Health, how many patients are included in "other" that may be part of the defined service area. . . Therefore, regarding this comparative factor, the results are inconclusive." ⁷
- In the 2023 HSA I PET Scanner review, this comparative factor was found inconclusive due to the other category within the patient origin tables. "Each of the applicants identifies a category ("other") that includes residents from other counties and other states. The Project Analyst is unable to discern, from the information provided by each applicant, which counties are included in "other" that may be part of the defined service area. Therefore, regarding this comparative factor, the results are inconclusive." 8
- In the 2021 HSA IV Fixed PET Scanner review, this comparative factor was inconclusive based on UNC's defined service area. "UNC provides the projected number of patients to be served by county on page 46 of its application. However, UNC states its service area is the entire state, "by mission." Therefore, a comparison of the applications regarding this comparative factor is inconclusive." 9
- In the 2021 HSA I PET Scanner Review, once again, this comparative factor was inconclusive due to an other category. "Because both applicants include counties in the "other" category that are not in HSA I, it is not possible to quantify the number of patients projected to be served solely in HSA I counties. Therefore, the result of this analysis is inconclusive." ¹⁰

Based on these PET findings, the Agency has regularly found this comparative factor to be inconclusive. Consistent with these previous findings, the Agency should find this comparative factor to be inconclusive in this competitive review. Novant Health and CMHA took dramatically different approaches to calculating patient origin. Novant Health utilized a service area based on county level data while CMHA utilized zip code level data. The different methodologies utilized by the applicants make a comparison impossible, especially considering the two "other" categories within CMHA's patient origin tables.

⁸ 2023 HSA I1 Fixed PET Scanner review p. 67

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⁶ Comments Submitted by Presbyterian Medical Care Corp. and Novant Health, Inc. In Opposition to OrthoCarolina, P.A. dated December 1, 2022. P. 24.

⁷ 2023 HSA II PET Scanner Review p. 87

⁹ 2021 HSA IV Fixed PET Scanner review p. 57

¹⁰ 2021 HSA I Fixed PET Scanner review p. 67

Additionally, CMHA believes that the Agency should evaluate its review of access by service area residents similar to its analysis of other services when the need is being generated in part from patients from outside of the service area.

As previously discussed, the need for an additional PET scanner in HSA III is driven specifically by Atrium Health Pineville's need based on its linear accelerator volume. 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 Atrium Health Pineville's 2024 license renewal application (LRA), less than 66 percent of linear accelerator patients served by Atrium Health Pineville originate from within the HSA. As shown in the table below, out of state patients comprise almost 33 percent of linear accelerator patients at Atrium Health Pineville.

Total Patient Origin for Atrium Health Pineville LINAC

NC County/State of Origin	2023 Percent of Total
HSA III	
Mecklenburg	55.4%
Union	9.0%
Gaston	0.9%
Cabarrus	0.3%
Iredell	0.1%
Lincoln	0.0%
Rowan	0.0%
Stanly	0.0%
Total HSA III	65.7%
Other NC	1.4%
Out of State	32.9%
Total	100.0%

Source: Atrium Health Pineville 2024 LRA

Simply put, without the demand for linear accelerator services originating from outside of the HSA, <u>there</u> would not be a need for an additional PET scanner located in HSA III in the <u>2025 SMFP</u>.

According to the NC DHSR PET procedure patient origin reports, existing PET providers within the service area also draw a substantial portion of patients from outside HSA III. For providers within the service area, approximately 76 percent of patients originate from within the HSA. As shown in the table below, out of state patients comprise 15 percent of patients.

Total Patient Origin for HSA III PET Providers

NC County/State of Origin	2023 Patients	2023 Percent of Total
HSA III		
Mecklenburg	4,280	34.6%
Union	1,438	11.6%
Gaston	1,065	8.6%
Cabarrus	1,016	8.2%
Iredell	818	6.6%
Lincoln	330	2.7%
Rowan	264	2.1%
Stanly	211	1.7%
Total HSA III	9,422	76.2%
Other NC	1,083	8.8%
Out of State	1,854	15.0%
Total	12,359	100.0%

Source: NC DHSR Patient Origin Reports (utilizing 2023 data)

Based on this analysis, CMHA believes that the Agency should evaluate its review of access by service area residents 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, 2023, and 2024 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 2025 SMFP, is a result of the utilization of all patients seeking linear accelerator services at Atrium Health Pineville. Given HSA III residents comprise less than 66 percent of Atrium Health Pineville's linear accelerator utilization, there would be no need determination for an additional fixed PET scanner in HSA III without the demand originating from outside the service area. 11 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

ESTVs at Atrium Health Pineville of 13,401 x HSA III patient origin of 65.7% = 8,804 ESTVs from HSA III. If just these 8,804 ESTV procedures originating from HSA III were considered, there would be no need in the 2025 SMFP for an additional PET scanner in HSA III.

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

In the 2024 HSA III PET Review, the Agency conducted its analysis of Medicare and Medicaid factors using three distinct measures. For Medicare patients, the Agency examined the projected number of Medicare patients, the percentage of gross revenue projected to be provided to Medicare patients, and the dollar amount of gross revenue for Medicare patients. The projected number of Medicare patients in the third year was included as one comparative factor and the two gross charge metrics were included as a second comparative factor. The Agency performed the same analysis for Medicaid. With this approach, the Agency double counted Medicare and Medicaid as comparative factors as it included each twice. This was the only PET review in the past five years that counted Medicare and Medicaid as two comparative factors each.

In the current competitive review, Novant Health's charge structure is significantly higher than CMHA's.

Gross Charges Per PET Procedure

	PY 3 Procedures	PY 3 Gross Charges	PY 3 Charge Per Procedure
Atrium Health Pineville	2,728	\$24,530,721	\$8,992
NH Huntersville	2,499	\$37,385,256	\$14,960

Source: Form C.2b (AH Pineville), Form D.2 (NH Huntersville), Form F.2b.

As shown in the table above, NH Huntersville projects to charge patients \$14,960 per PET procedure, while Atrium Health Pineville projects to charge \$8,992 per procedure. This represents a 66.4 percent higher charge per procedure at NH Huntersville. A comparison of raw Medicare or Medicaid charges is fundamentally inappropriate for this analysis as such a method would arbitrarily and inequitably benefit the applicant with a higher charge structure. The premise that simply charging more translates to better access for underserved populations is unsupported and contrary to established healthcare planning objectives.

According to the North Carolina Certificate of Need Statutes § 131E-175. Findings of fact:

(2) That the increasing cost of health care services offered through health service facilities threatens the health and welfare of the citizens of this State in that citizens need assurance of economical and readily available health care.

NH Huntersville's application would paradoxically benefit from its substantially higher charge structure if a comparison of raw Medicare or Medicaid charges were applied in this review. This outcome directly contradicts the statutory goal of reducing healthcare costs, as approving the NH Huntersville application would measurably increase the cost of PET scanner services.

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

	% of Medicare
Atrium Health Pineville	60.8%
NH Huntersville	66.4%

Source: Section L.3.

As shown in the table above, NH Huntersville projects to serve the higher percentage of Medicare patients. However, as outlined in the issue specific comments above, the NH Huntersville application is non-conforming with review criteria and cannot be approved. Additionally, NH Huntersville proposes a charge structure that would increase the cost of healthcare services which is counter to the goal of reducing healthcare costs. Therefore, Atrium Health Pineville is more effective regarding this comparative factor.

If the Agency were to use the projected number of Medicare patients' calculation in the 2025 review, the following table compares each applicant's total number of Medicare patients projected to utilize its fixed PET service in project year 3.

PY 3 Medicare Patients

	PY 3 Procedures	% of Medicare	PY 3 Medicare Patients
Atrium Health Pineville	2,728	60.8%	1,659
NH Huntersville	2,499	66.4%	1,659

Source: Form C.2b (AH Pineville), Form D.2 (NH Huntersville), Section L.3.

As shown in the table above, both applicants propose to serve 1,659 Medicare patients in PY 3. Despite NH Huntersville having a higher percentage of Medicare patients, both applicants project to serve the same number of patients.

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

	% of Medicaid	
Atrium Health Pineville	3.3%	
NH Huntersville	2.8%	

Source: Section L.3.

As shown in the table above, Atrium Health Pineville projects to serve the higher percentage of Medicaid patients.

The following table compares each applicant's projected number of Medicaid patients projected to utilize its fixed PET service in project year 3.

PY 3 Medicaid Patients

	PY 3 Procedures	% of Medicaid	PY 3 Medicaid Patients
Atrium Health Pineville	2,728	3.3%	90
NH Huntersville	2,499	2.8%	70

Source: Form C.2b (AH Pineville), Form D.2 (NH Huntersville), Section L.3.

As shown in the table above, Atrium Health Pineville projects to serve a higher number of Medicaid patients in project year 3.

Regardless of whether the Agency chooses to compare the applicants based on a percentage of Medicaid patients or the number of patients projected to be served, Atrium Health Pineville is the more effective alternative.

Average Net Revenue per Procedure

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

Average Net Revenue per Procedure

	Total Net Revenue	# of Procedures	Total Net Revenue per Procedure
Atrium Health Pineville	\$6,115,114	2,728	\$2,242
NH Huntersville	\$7,883,826	2,499	\$3,154

Source: Form C.2b (AH Pineville), Form D.2 (NH Huntersville), Form 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.

The Agency has consistently utilized this comparative factor in fixed PET reviews. The only exception was the 2021 HSA I review. In that competitive review, the Agency stated "differences in the types of facilities and the types of PET procedures proposed by each of the facilities may impact the averages shown in the table above, thus, the result of this analysis is inconclusive." In that competitive review, Mission Hospital was an existing hospital-based facility that proposed to offer oncological, neurologic, and cardiac PET. Conversely, AOP was a physician's practice office that provides only outpatient oncology services. In that instance, the Agency determined it could not compare a hospital to a physician office and two providers that offered different scopes of service. Neither of those fact patterns are true here; thus, this comparative factor should be utilized consistent with other recent fixed PET reviews.

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	\$2,779,983	2,728	\$1,019
NH Huntersville	\$4,482,264	2,499	\$1,794

Source: Form C.2b (AH Pineville), Form D.2 (NH Huntersville), Form 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.

Similar to the average net revenue per procedure comparative factor, the Agency has consistently utilized this comparative factor in recent fixed PET reviews with the exception of the 2021 HSA I review noted above. Again, the fact patterns in this competitive review do not match the fact patterns in that review; thus, this comparative factor should be utilized consistent with other recent fixed PET reviews.

SUMMARY

In summary, the Novant Health Huntersville fixed PET application 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 the 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. The Atrium Health Pineville fixed PET application 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 April 15, 2025. If the Agency considers any statements to be amending CMHA's applications, those comments should not be considered.