



**WRITTEN COMMENTS ON 2024 HEALTH SERVICE AREA III
FIXED PET SCANNER COMPETITIVE REVIEW**

SUBMITTED BY NOVANT HEALTH PRESBYTERIAN MEDICAL CENTER

OCTOBER 31, 2024

Two applicants submitted CON applications in response to the need identified in the 2024 SMFP for one additional fixed PET scanner in Health Service Area (HSA) III. The applicants include:

- CON Project ID F-012557-24: Novant Health Presbyterian Medical Center (NHPMC)
- CON Project ID F-012550-24: Atrium Health Pineville (AHP)

NHPMC submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the competing applications, including their ability to conform with applicable statutory and regulatory review criteria. These comments also discuss the comparative analysis of the applicable and most significant issues concerning this competitive batch review. Other non-conformities may exist in the competing applications and NHPMC may develop additional opinions, as appropriate upon further review and analysis. Nothing in these comments is intended to amend any statement in the NHPMC application; to the extent the Agency deems any comment an amendment to the NHPMC application, NHPMC respectfully asks the Agency to disregard the comment.

COMPARATIVE ANALYSIS OF THE COMPETING FIXED PET SCANNER APPLICATIONS

The following factors have been utilized in prior competitive CON reviews regardless of the type of services or equipment proposed:

- Conformity with Statutory & Regulatory Review Criteria
- Competition (Access to a New or Alternate Provider)
- Scope of Services
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Historical Utilization
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Projected Average Net Revenue
- Projected Average Total Operating Cost

The following pages summarize the competing applications relative to the identified comparative factors.

Conformity to CON Review Criteria

Two CON applications have been submitted to develop a fixed PET scanner in Health Service Area III. Based on the 2024 SMFP’s need determination, only one fixed PET scanner can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by NHPMC demonstrates conformity to all Statutory and Regulatory Review Criteria.

Conformity of Applicants

Applicant	Project I.D.	Conforming with All Applicable Statutory & Regulatory Review Criteria
Novant Health Presbyterian Medical Center	F-012557-24	Yes
Atrium Health Pineville	F-012550-24	No

The NHPMC application is based upon reasonable and supported volume projections and reasonable projections of cost and revenues. As discussed separately in this document, the AHP application contains errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the **NHPMC** application is the **most effective** alternative regarding conformity with applicable review Criteria.

Scope of Services

Regarding scope of services, the competing applications are each responsive to the 2024 SMFP need determination in HSA III for one fixed PET scanner. The following table compares the scope of services offered by each applicant. Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor.

Scope of Services

Facility	Proposed Scope of Services		
	Oncological PET	Neurologic PET	Cardiac PET
Novant Health Presbyterian Medical Center	X	X	X
Atrium Health Pineville	X	X	X

Source: CON applications

NHPMC is an existing provider of fixed PET services and proposes to develop a second, hospital-based fixed PET scanner. Atrium Health proposes to develop one fixed PET scanner at the Pineville Medical Plaza located on the AHP campus. Both NHPMC and AHP propose to offer oncological, neurological, and cardiac PET scans. However, as described in the application specific comments, AHP did not adequately demonstrate that it will be able to perform cardiac PET procedures because it did not account for the cost

of a rubidium generator. Therefore, the NHPMC application is a **more effective alternative** regarding scope of services.

Historical Utilization

In previous competitive reviews, the Agency has assessed historical utilization among the competing applicants. NHPMC is part of Novant Health, which operates one (1) fixed PET scanner in HSA III located at NHPMC. AHP is part of Atrium Health, which operates four (4) fixed PET scanners in HSA III. The following summarizes FY2023 utilization data for Novant Health and Atrium Health from the Proposed 2025 SMFP.

Health System	PET Scanner Planning Inventory	FFY2023 Procedures	PET Utilization Rate*
Atrium Health	4	8,056	67.1%
Novant Health	1	2,275	75.8%

*Based on a fixed PET scanner capacity of 3,000 procedures per unit

Source: Proposed 2025 SMFP, Table 15F-1: Utilization of Existing Dedicated Fixed PET Scanners

Novant Health’s fixed PET scanner was utilized at 75.8 percent capacity during FFY2023. Atrium Health’s fixed PET scanners were utilized at 67.1 percent capacity during FFY2023. Therefore, based on a comparison of historical fixed PET utilization, **NHPMC** is the **most effective** alternative regarding this factor.

Geographic Accessibility

The 2024 SMFP identifies the need for one fixed PET scanner in HSA III. HSA III is a multi-county service area that includes Cabarrus, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Stanly, and Union counties. The following table summarizes the locations of existing and approved fixed PET scanners in HSA III as reported by the 2024 SMFP and other publicly available information.

Facility	Planning Inventory	Location
Atrium Health Cabarrus	1	Concord/Cabarrus County
Atrium Health Union	1	Monroe/Union County
Carolinas Medical Center (Atrium)	2	Charlotte/Mecklenburg County
CaroMont Regional Medical Center	1	Gastonia/Gaston County
Iredell Memorial Hospital	1	Statesville/Iredell County
NH Presbyterian Medical Center	1	Charlotte/Mecklenburg County

Both NHPMC and Atrium health propose to develop a fixed PET scanner in Mecklenburg County, which already hosts three fixed PET scanners. Therefore, regarding geographic accessibility, the proposals by NHPMC and Atrium Healthcare **are equally effective** alternatives.

Atrium Health will likely argue that the AHP proposal will improve geographic access because AHP does not currently offer a fixed PET scanner. However, the AHP proposal will not enhance geographic access to fixed PET services for residents of the eight-county service area. Pineville, located near the South Carolina border, is not proximate to the other counties in HSA III. Additionally, projected patient origin shows that only 51.3% of AHP’s patients are expected to come from HSA III, while approximately 47% are anticipated to originate from South Carolina (as detailed in Section C.3). Consequently, AHP’s proposal would serve a significant portion of South Carolina patients, misaligning with the North Carolina need determination for an additional fixed PET scanner in HSA III. These facts make the AHP proposal comparatively less favorable than the NHPMC application.

Access By Service Area Residents

The 2024 SMFP defines the service area for a fixed PET scanner as “the HSA [Health Service Area] in which it is located (Table 15F-1).” Thus, the service area for this review is HSA III. The counties in HSA III include: Cabarrus, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Stanly, and Union counties. Facilities may also serve residents of counties not included in the defined service area. Generally, regarding this comparative factor, the application projecting to serve the largest number or percentage of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional fixed PET scanners in the service area where they live.

	Novant Health Presbyterian Medical Center	Atrium Health Pineville
PET Patients from HSA III	3,875	1,292
Total PET Patients	4,346	2,517
HSA III % of Total Patients	89.2%	51.3%

CON Applications Section C.3

The NHPMC application projects to serve both a larger percentage and number of patients from HSA III. Therefore, regarding this comparative factor, NHPMC is a **more effective** alternative than AHP.

Competition (Patient Access to a New or Alternate Provider)

According to the Federal Trade Commission, competition in health care markets benefits consumers because it helps contain costs, improve quality, and encourage innovation. The introduction of a new provider in the service area would be the most effective alternative because increased patient choice encourages all providers in the service area to improve quality or lower costs to compete for patients. Although AHP does not have a PET scanner currently, AHP is part of the much larger Atrium Health system which owns four PET scanners in Health Service Area III. Accordingly, neither applicant should be considered a new provider.

NHPMC is part of Novant Health, which operates one (1) fixed PET scanner in HSA III located at NHPMC. AHP is part of Atrium Health, which operates four (4) fixed PET scanners in HSA III. Atrium Health controls a significant majority (57%) of the fixed PET scanners in HSA III. The remaining providers of fixed PET each own just 14.2% of the fixed PET scanners in HSA III and are not even remotely close to Atrium Health's percentage. If AHP is approved in this review, Atrium Health's control of PET scanners in HSA III increases to 62.5%. Thus, regarding competition for fixed PET services in the service area, the application submitted by **NHPMC** is a **more effective alternative** than AHP.

Access By Underserved Groups

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

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

For access by underserved groups, the AHP and NHPMC applications are compared concerning two underserved groups: Medicare patients, and Medicaid patients.¹ Access by each group is treated as a separate factor. The Agency may use one or more of the following metrics to compare the applications:

- Total Medicare, or Medicaid procedures
- Medicare, or Medicaid procedures as a percentage of total procedures
- Total Medicare, or Medicaid dollars
- Medicare, or Medicaid dollars as a percentage of total gross or net revenues
- Medicare, or Medicaid cases per procedure

The above metrics the Agency uses are determined by whether the applications included in the review provide data that can be compared as presented above and whether such a comparison would be of value in evaluating the alternative factors.

In this competitive review, both Novant Health and Atrium Health propose to develop fixed PET scanners as part of a hospital outpatient department. Both applicants also propose to offer the same scope of PET scanner services, *i.e.*, oncology, neurology, and cardiac. Therefore, conclusive comparisons can presumably be made for each factor related to access by underserved groups. The following tables compare projected access by Medicare and Medicaid for NHPMC and AHP.

Projected Medicare Access

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for NHPMC and Atrium Health.

¹ Due to differences in definitions of charity care among applicants, comparisons of charity care are inconclusive.

Projected Medicare Revenue – 3rd Full FY

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

Source: CON applications

As shown in the previous table, AHP projects a higher percentage of Medicare Gross Revenue as a percentage of Total Gross Revenue. However, NHPMC projected to provide the highest Medicaid total gross revenue.

The AHP application on page 102 states the projected payor mix is “based on the payor mix associated with the PET procedures performed at CMC in CY 2023 that are expected to shift to Atrium Health Pineville as part of the proposed project.” However, as described in the application specific comments, the Atrium Health application fails to demonstrate that its assumed shift of PET patients from CMC to AHP is reasonable and supported. Therefore, AHP’s projected Medicare Revenue is not supported and NHPMC is the **most effective** alternative.

Projected Medicaid Access

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for NHPMC and AHP.

Projected Medicaid Revenue – 3rd Full FY

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

Source: CON applications

As shown in the previous table, NHPMC proposes to provide the highest total Medicaid gross revenue and the highest percentage of Medicaid Gross Revenue as a percentage of Total Gross Revenue. Therefore, regarding Medicaid access, **NHPMC** is the **most effective alternative**.

Projected Average Net Revenue per Fixed PET Procedure

The following table compares NHPMC and AHP’s projected average net revenue per fixed PET procedure in the third year of operation, based on the information provided in the applicants’ pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue is the more

effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per PET Procedure – 3rd Full FY

Applicant	Form C.2b	Form F.2b	Average Net Revenue per PET Procedure
	Fixed PET Procedures	Net Revenue	
Novant Health Presbyterian Medical Center	4,347	\$13,793,633	\$3,173
Atrium Health Pineville	2,517	\$5,737,661	\$2,280

Source: CON applications

As shown in the previous table, AHP projects a lower average net revenue per PET scan procedure in the third full fiscal year following project completion. However, as described in the application specific comments, the AHP application fails to demonstrate that its projected utilization, revenues, and expenses are based on reasonable and adequately supported assumptions. Therefore, the AHP application cannot be the most effective alternative.

Additionally, revenues for PET procedures are significantly influenced by the essential radiopharmaceutical charges required for each specific type of PET scan.² The costs of radiopharmaceuticals used in PET procedures—such as prostate-specific membrane antigen (PSMA),³ non-PSMA oncology, neurology, and cardiovascular imaging—can vary widely due to differences in production, availability, and regulatory requirements. These variances in radiopharmaceutical expenses directly impact revenue per PET procedure, as shown in the following table:

Radiopharmaceutical:	Cost per dose:	Used for:
Fludeoxyglucose F-18 (FDG)	\$115.00	Cancer
Pylarify	\$3857.82	Prostate Cancer (PSMA)
Illuccix	\$3530.95	Prostate Cancer (PSMA)
Cerianna	\$2851.09	Breast Cancer
Detectnet	\$4050.00	Neuroendocrine Cancer
Amyvid	\$3029.00	Alzheimer’s Disease

Source: Novant Health internal data

As shown on page 123 of NHPMC’s application, PSMA PET scans account for approximately 14 percent of PET procedures during the third year of the project. Therefore, providers performing a higher proportion of PET scans that require more costly radiopharmaceuticals will naturally see higher average net revenue per PET procedure, driven primarily by patient-specific diagnostic needs rather than operational

² A PET scan uses a radiotracer that is injected into the patient before the scan. The radiotracer is absorbed by cells and emits positrons, which collide with electrons to produce photons. The PET scanner captures the photons to create a 3D image of the body’s tissues. Cancerous cells absorb more of the radiotracer and appear brighter in the scan.

³ A PSMA PET scan, or prostate-specific membrane antigen positron emission tomography scan, is a nuclear imaging test that helps detect prostate cancer in the body. Pylarify (piflufolastat F 18) is a radioactive diagnostic agent used in PET scans to image prostate-specific membrane antigen positive lesions in men with prostate cancer.

efficiencies or pricing strategies. Consequently, comparing average net revenue per PET procedure across providers is not only inconclusive but can also be misleading, as it overlooks these crucial differences in radiopharmaceutical costs across PET imaging types.

Projected Average Operating Expense per PET Procedure

The following table compares the projected average operating expense per PET procedure in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense is the more effective alternative concerning this comparative factor to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

Projected Average Operating Expense per PET Procedure – 3rd Full FY

Applicant	Form C.1b	Form F.2b	Average Operating Expense per PET Procedure
	Fixed PET Procedures	Operating Expense	
Novant Health Presbyterian Medical Center	4,347	\$7,194,631	\$1,655
Atrium Health Pineville	2,517	\$3,202,997	\$1,273

Source: CON applications

As shown in the previous table, AHP projects a lower average operating expense per PET scan procedure in the third full fiscal year following project completion. However, as discussed in the application-specific comments, the AHP application fails to demonstrate that its projected utilization, revenues, and expenses are based on reasonable and adequately supported assumptions. Therefore, the AHP application cannot be the most effective alternative.

Separately, as previously described, expenses for PET procedures are significantly influenced by the costs of essential radiopharmaceuticals, which vary substantially across PET scan types, including PSMA, non-PSMA oncology, neurology, and cardiovascular scans. This variability is shown in the following table summarizing NHPMC’s costs for key radiopharmaceuticals:

Radiopharmaceutical:	Cost per dose:	Used for:
Fludeoxyglucose F-18 (FDG)	\$115.00	Cancer
Pylarify	\$3857.82	Prostate Cancer (PSMA)
Illuccix	\$3530.95	Prostate Cancer (PSMA)
Cerianna	\$2851.09	Breast Cancer
Detectnet	\$4050.00	Neuroendocrine Cancer
Amyvid	\$3029.00	Alzheimer’s Disease

Source: Novant Health internal data

As shown on page 123 of NHPMC’s application, PSMA PET scans account for approximately 14 percent of PET procedures during the third year of the project. Notable, AHP’s average pharmacy expense per PET procedure is approximately one-half of NHPMC’s average pharmacy expense per PET procedure, as shown in the following table.

	PET Procedures, YR 3	Pharm. Expense, YR 3	Avg. Pharm. Expense per Procedure, YR 3
Novant Health Presbyterian Medical Center	4,347	\$5,336,778	\$1,228
Atrium Health Pineville	2,517	\$1,627,294	\$647

According to Year 3 projections in Form C and Form F.3b, NHPMC’s pharmacy expense is 75% of its total expense per PET procedure. AHP’s Year 3 pharmacy expense is 50% of its total expense per PET procedure. This difference reflects the higher cost of NHPMC’s PET procedure mix, which includes more complex scans like cardiac PET that AHP’s proposal does not account for, as it lacks a rubidium generator. Therefore, NHPMC’s higher average operating expense likely stems from a difference in PET procedure mix. Consequently, comparing average expenses per PET procedure without considering procedural complexity and radiopharmaceutical costs is inconclusive and potentially misleading.

Summary

The table below summarizes the comparative factors and states which application is the most effective alternative.

Comparative Factor	NHPMC	AHP
Conformity with Review Criteria	More Effective	Less Effective
Scope of Services	Equally Effective	Equally Effective
Historical Utilization	More Effective	Less Effective
Geographic Accessibility	Equally Effective	Equally Effective
Competition	More Effective	Less Effective
Access by Service Area Residents	More Effective	Less Effective
Access by Medicaid	More Effective	Less Effective
Access by Medicare	More Effective	Less Effective
Projected Average Net Revenue per PET Procedure	Inconclusive	Inconclusive
Projected Average OpEx Per PET Procedure	Inconclusive	Inconclusive

For each of the comparative factors previously discussed, NHPMC’s application is determined to be the more effective alternative for the following factors:

- Conformity with Review Criteria
- Historical Utilization
- Competition
- Access by Service Area Residents
- Access by Medicaid Patients
- Access by Medicare Patients

AHP’s application fails to conform with all applicable statutory and regulatory review criteria; thus, it cannot be approved. In addition, Atrium Health’s application fails to measure more favorably with respect to the aforementioned comparative factors. Based on the previous analysis and discussion, the application submitted by **NHPMC** is comparatively superior and should be approved in this competitive review.

The following pages provide application-specific comments regarding the AHP application and its respective conformity to applicable statutory and regulatory review criteria.

**COMMENTS SPECIFIC TO ATRIUM HEALTH PINEVILLE APPLICATION
PROJECT I.D. F-012550-24**

The AHP application fails to conform with the statutory review criteria based on the following:

- 1. The Atrium Health Pineville application fails to demonstrate that its assumed growth rates are reasonable and supported.**

Atrium Health fails to demonstrate the reasonableness of the 6.9 percent growth rate used to project future Carolina Medical Center (CMC) PET total utilization and CMC PET utilization from the Southern Charlotte Region.

In its Form C Utilization on page 124, Atrium Health presents historical fixed PET procedure utilization at its facilities in HSA III as follows:

Historical Fixed PET Procedures at CMHA Facilities in HSA III

	CY19	CY20	CY21	CY22	CY23	Ann. CY24 [^]	CY19- CY24 CAGR*	CY21- CY24 CAGR*
CMC	4,358	4,117	4,538	5,200	5,513	5,640	5.3%	7.5%
Atrium Health Cabarrus Imaging	1,092	1,123	1,052	1,182	1,617	2,052	13.4%	24.9%
Atrium Health Union	584	602	560	745	999	1,370	18.6%	34.8%
Total	6,034	5,842	6,150	7,127	8,129	9,062	8.5%	13.8%

Source: CMHA internal data

*Compound annual growth rate

[^]CY 2024 procedures based on actual January – May utilization data annualized.

As shown above, CMC’s historical PET growth rate from CY 2019 to 2024 annualized was 5.3 percent annually. More significantly, CMC’s two most recent years of annual PET growth were 6.0 percent from CY 2022 to 2023 and 2.3 percent from CY 2023 to 2024. Despite this clear evidence that growth has slowed at CMC, Atrium Health assumes that PET procedures at CMC will grow 6.9 percent annually through CY 2029 (see page 125), well above its historical trend.

Atrium Health states that “CMC has been facing a three-week patient backlog for more than half a year despite additional capacity at Atrium Health Cabarrus Imaging. As a result, growth at CMC has been restricted” (page 125). Clearly, additional PET capacity at Atrium Health Cabarrus has not mitigated the slowing PET utilization growth at CMC. As such, Atrium Health’s own experience suggests that additional PET capacity at AHP as proposed will not reverse the slowing PET

utilization growth at CMC. Moreover, Atrium Health does not provide any evidence or support in its application that its proposed project to develop additional PET capacity at AHP will allow CMC to grow more rapidly than its historical utilization trend. In fact, Atrium Health assumes that CMC’s PET utilization will increase 6.9 percent annually from CY 2024 to 2025, before the development of the proposed PET unit at AHP in April 2026. This further demonstrates that the proposed additional PET capacity at AHP will not enable more PET growth at CMC.

Thus, despite the slowing PET growth at CMC and the lack of evidence that any factors would support a reversal in this trend including additional capacity at Atrium Health Cabarrus or the proposed project, Atrium Health unreasonably assumes that PET utilization at CMC will accelerate in future years.

In addition to its unreasonable growth assumption for CMC’s overall PET utilization, Atrium Health also fails to support its growth assumption for the subset of CMC PET procedures that originate from its self-defined “Southern Charlotte Region.” In its Form C Utilization on page 126, Atrium Health presents historical fixed PET utilization at CMC from the Southern Charlotte Region as follows:

**Historical Fixed PET Procedures at CMC
From the Southern Charlotte Region**

	CY19	CY20	CY21	CY22	CY23	Ann. CY24 [^]	CY19- CY24 CAGR	CY21- CY24 CAGR
Southern Charlotte Region	1,771	1,739	1,912	2,225	2,314	2,254	4.9%	5.6%

Source: CMHA internal data

[^]CY 2024 PET procedures based on actual January – May utilization data and annualized.

As shown above, CMC’s historical PET growth rate for Southern Charlotte Region patients from CY 2019 to 2024 annualized was 4.9 percent annually. More significantly, CMC’s two most recent years of annual PET growth for these patients were 4.0 percent from CY 2022 to 2023 and negative 2.6 percent from CY 2023 to CY 2024. Despite this clear evidence that growth for Southern Charlotte Region patients has slowed and declined in the most recent year at CMC, Atrium Health assumes that Southern Charlotte Region PET procedures at CMC will grow 6.9 percent annually through CY 2029 (see page 126), well above its historical trend. Like its unreasonable assumption for overall CMC PET growth, Atrium Health unreasonably assumes that Southern Charlotte Region PET utilization at CMC will accelerate in future years despite the slowing and most recent decline in growth for these patients at CMC and the lack of evidence that any factors would support a reversal in this trend including additional capacity at Atrium Health Cabarrus or the proposed project.

Based on the discussion above, the AHP application fails to demonstrate that its utilization is based on reasonable and supported assumptions. As such, the Atrium Health application is **non-conforming with Criteria (1), (3), (4), (5), (6), (8), and (18(a)) and 10A NCAC 14C .3703.**

2. The Atrium Health Pineville application fails to demonstrate that its assumed shift of PET patients from CMC to Atrium Health Pineville is reasonable and supported.

Atrium Health fails to demonstrate the reasonableness of its assumed shift of 80 percent of patients traveling to CMC from the Southern Charlotte Region for PET services to AHP following the development of the proposed project.

In its Form C Utilization on page 127, Atrium Health states that it “reasonably assumes that 80 percent of patients traveling to CMC from the Southern Charlotte Region for PET imaging services will shift to Atrium Health Pineville following the proposed project.” Atrium Health provides only one factor to support this shift, *i.e.*, that AHP would provide a more convenient option for these patients. Atrium Health provides limited support for this increased convenience, only noting that most of its projected patient population is geographically closer to AHP than CMC and that CMC has capacity constraints. However, Atrium Health fails to demonstrate that AHP would be a more clinically appropriate than CMC or that AHP would even be able to serve these CMC patients.

PET imaging is a fundamental component of an integrated cancer care plan at a specific site of care. As Atrium Health notes on page 43 of its application, PET imaging is used to stage and restage cancer treatment as well as for radiotherapy planning. Atrium Health does not demonstrate that it would be reasonable for patients undergoing cancer treatment at CMC to stage or restage their cancer treatment at AHP or to have radiotherapy/radiation therapy treatment that will be performed at CMC, planned using the proposed AHP PET scanner.

Further, Atrium Health does not demonstrate that AHP will provide the scope of services that will allow it to serve the proposed shift of patients from CMC. While Atrium Health states that AHP will serve oncology patients, as well as patients from other specialties such as neurology and cardiology, it fails to demonstrate that it will be able to do so. For example, there is no mention in Atrium Health’s application of a Rubidium generator which is necessary to provide cardiac PET services or that it can provide the necessary radiopharmaceuticals for the proposed PET procedure types.

Finally, Atrium Health provides no evidence that it has experience shifting patients in the manner proposed or that it has successfully done so in the past. It is not clear that the defined service area patients would prefer Atrium Health Pineville instead of CMC or would shift as assumed by Atrium Health.

In fact, a comparison of projected patient origin for the proposed PET scanner to overall patient origin for AHP indicates that the assumed shift is unreasonable. On page 38, Atrium Health states for the proposed PET services, “[p]rojected patient origin is based on CY 2023 patient origin of the volume proposed to shift from CMC as part of the proposed project” and the resulting patient origin is shown on page 40, as excerpted below.

b. **Service Component(s)** – Complete the following table for each service component included in this proposal for the facility or campus identified in Section A, Question 4.

<PET>	<Atrium Health Pineville> *					
	1 st Full FY		2 nd Full FY		3 rd Full FY	
	01/01/2027 to 12/31/2027		01/01/2028 to 12/31/2028		01/01/2029 to 12/31/2029	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Mecklenburg	621	37.6%	885	37.6%	946	37.6%
York, SC	541	32.8%	771	32.8%	824	32.8%
Union	227	13.7%	323	13.7%	346	13.7%
Lancaster, SC	195	11.8%	278	11.8%	297	11.8%
Chester, SC	46	2.8%	66	2.8%	71	2.8%
Anson	21	1.3%	31	1.3%	33	1.3%
Total	1,652	100.0%	2,354	100.0%	2,517	100.0%

* This should match the name provided in Section A, Question 4.

** Home health agencies should report the number of unduplicated clients.

The following page of AHP’s application provides total projected AHP patient origin, excerpted below, which is “based on the CY 2023 patient origin for the entire facility” (page 38).

Entire Facility or Campus	<Atrium Health Pineville> *					
	1 st Full FY		2 nd Full FY		3 rd Full FY	
	01/01/2027 to 12/31/2027		01/01/2028 to 12/31/2028		01/01/2029 to 12/31/2029	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Mecklenburg	90,495	50.4%	91,974	50.4%	93,478	50.4%
York, SC	48,203	26.8%	48,991	26.8%	49,791	26.8%
Lancaster, SC	13,607	7.6%	13,830	7.6%	14,056	7.6%
Union	11,516	6.4%	11,704	6.4%	11,896	6.4%
Gaston	3,953	2.2%	4,018	2.2%	4,084	2.2%
Chester, SC	2,020	1.1%	2,053	1.1%	2,086	1.1%
Other^	9,794	5.5%	9,953	5.5%	10,115	5.5%
Total	179,588	100.0%	182,523	100.0%	185,506	100.0%

* This should match the name provided in Section A, Question 4.

** Home health agencies should report the number of unduplicated clients.

^ Other includes Cabarrus, Cleveland, Lincoln, Stanly, Anson, Iredell, Chesterfield (SC), Catawba, Richland (SC), Rowan, Other NC counties, and Other States.

As shown above, Mecklenburg County residents are expected to comprise less than 38 percent of AHP’s projected PET patients compared to more than 50 percent of its total patients. Projected PET patients are projected to be much more heavily comprised of York (SC) and Union County patients. Of particular note, Union County patients are expected to represent 13.7 percent of PET patients compared to 6.4 percent of total patients or more than double. As noted in the Atrium Health application, Atrium Health Union operates a PET scanner with available capacity (see page

51). Despite this available capacity in Union County, a substantial number of Union County patients seek PET services at CMC (as the projected PET patient origin represents the composition of PET patients currently served at CMC). This dynamic directly contradicts Atrium Health's assumption that CMC PET patients from this area will shift to AHP because it will be a more convenient option. These Union County patients already have a more convenient option for PET services in their home county with available capacity and yet they travel to CMC for services. This evidence suggests that convenience is not the determinative factor for a patient's location of service, but rather other factors determine where a patient is served such as clinical appropriateness (e.g., is the patient being treated with an integrated care plan at CMC and thus not appropriate for PET services elsewhere) or availability of scope of services (e.g., does the location of care offer the type of PET scan such as cardiology or neurology that the patient needs). As such, Atrium Health fails to demonstrate that its assumed shift will occur due to convenience.

Given these factors, Atrium Health fails to demonstrate that its assumed shift of 80 percent of CMC PET patients from the Southern Charlotte Region is reasonable and supported. Therefore, the Atrium Health application fails to demonstrate that its utilization is based on reasonable and supported assumptions. As such, the Atrium Health application is **non-conforming with Criteria (1), (3), (4), (5), (6), (8), and (18(a) and 10A NCAC 14C .3703.**

3. The Atrium Health Pineville application fails to demonstrate that that all necessary ancillary and support services will be provided, and that projected revenues and expenses are supported.

Atrium Health fails to provide information in the application to demonstrate that it will provide ancillary and support services that are essential to serve the PET procedure types proposed by AHP. Further, Atrium Health's projected financial results are not supported given the absence of information about these ancillary and support services.

Atrium Health states on page 35 that AHP proposes to serve "oncology patients as well as patients from a range of other specialties, including neurology and cardiology." The radiopharmaceuticals used with cardiac PET procedures are a significant component of the cost in offering fixed PET services. Rubidium-82 is a radiotracer that is most often used in cardiac PET scans for the assessment of blood flow to the heart muscle. Rubidium-82 is more costly compared to other PET radiotracers due to its extremely short half-life, which is approximately 76 seconds. Rubidium-82 is produced by the decay of radioactive Strontium-82. To use Rubidium-82 in a medical setting, it is typically produced and delivered using a generator system. Because Strontium-82 is also radioactive, the generator must be replaced every four to six weeks to maintain the desired daily yield of Rubidium-82 needed for studies. Therefore, hospitals typically enter into leasing agreements with vendors that provide the generators. A recent article in the Annals of Nuclear Cardiology estimates a generator supply contract expense of \$400,000 per year for a site imaging 2,000 cardiac PET patients per year.⁴

There is no mention in Atrium Health's application of a Rubidium generator which is necessary to provide cardiac PET services or that it can provide the necessary radiopharmaceuticals for the proposed PET procedure types. Without these essential ancillary and support services, AHP cannot serve the scope of patients it proposes to serve. There is no discussion of the expense for

⁴Klein, Ran, PhD, Rb is the Best Flow Tracer for High-Volume Sites. Annals of Nuclear Cardiology, Vol. 5 No.1 53-62, July 20, 2019 https://www.ijstage.ist.go.jp/article/anc/5/1/5_19-00105/.pdf

a Rubidium generator in the projected financial statements or that projected expenses adequately accounted for the radiopharmaceuticals necessary to provide the proposed services. On page 134, Atrium Health states that “Medical Supplies, Other Supplies (includes Dietary), Pharmacy, and Other Expenses are based on the CY 2023 per procedure experience at [CMC Morehead Medical Plaza or MMP].” However, there is no evidence in the application as submitted that MMP provides the same range of services that is proposed at AHP. Further, the average medical supply expense per procedure in Project Year 3 is only \$13.34, which is insufficient to cover the expense of a Rubidium generator [see Form F.3b ($\$33,569 \div 2,517$ PET procedures)]. As such, it is impossible to determine if the projected financial results are reasonable or include the expenses necessary to provide the services as proposed.

Atrium Health also fails to demonstrate that projected equipment maintenance expenses are reasonable. On page 132, Atrium Health shows its projected Equipment Maintenance expense for its nine month Partial Fiscal Year from April 1, 2026 to December 31, 2026 as well as its first three full Fiscal Years as shown at the bottom of the excerpt below.

Form F.3b Projected Operating Costs upon Project Completion Atrium Health Pineville PET	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	F: 04/01/2026 T: 12/31/2026	F: 01/01/2027 T: 12/31/2027	F: 01/01/2028 T: 12/31/2028	F: 01/01/2029 T: 12/31/2029
Salaries (from Form H Staffing) ^a	\$173,170	\$237,821	\$294,266	\$303,094
Taxes and Benefits ^b	\$39,292	\$53,961	\$66,769	\$68,772
Medical Supplies ^c	\$9,431	\$20,768	\$30,488	\$33,569
Other Supplies ^c	\$1,901	\$4,186	\$6,145	\$6,766
Pharmacy (2) ^c	\$457,176	\$1,006,742	\$1,477,956	\$1,627,294
Dietary (2) incl. in Other Supplies	\$0	\$0	\$0	\$0
Equipment Maintenance (2) ^d	\$118,822	\$122,387	\$126,058	\$129,840

As shown, Atrium Health projects \$118,822 for Equipment Maintenance in the nine month Partial Fiscal Year, or \$13,202.44 per month. Assuming 3.0 percent inflation annually, Atrium Health’s Equipment Maintenance expense in its First full Fiscal Year will be \$163,182.21 or \$40,795.21 more than projected by Atrium Health in Form F.3b. Atrium Health’s understatement of Equipment Maintenance expenses for each year is shown below.

	Partial FY	1 st Full FY	2 nd Full FY	3 rd Full FY
Equipment Maintenance Expense assuming \$13,202 per month in CY 2026 and 3.0 annual inflation	\$118,822	\$163,182	\$168,078	\$173,120
Equipment Maintenance Expense shown by Atrium Health on F.3b	\$118,822	\$122,387	\$126,058	\$129,840
Understatement	\$0	\$40,795	\$42,020	\$43,280

Given these factors, Atrium Health fails to demonstrate that all necessary ancillary and support services will be provided and that projected revenues and expenses are reasonable and supported. Therefore, the Atrium Health application is **non-conforming with Criteria (5) and (8)**. Additionally, the application should not be deemed the most effective alternative regarding average operating expense per PET procedure.

Conclusion

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed PET scanners that can be approved by the Healthcare Planning and Certificate of Need Section. The applicants collectively propose to develop two fixed PET scanners in Health Service Area III. Based on the 2024 SMFP's need determination, only one fixed PET scanner can be approved.

NHPMC is the only application fully conforming to all statutory and regulatory review criteria. Furthermore, NHPMC is comparatively superior to the Atrium Health proposal. Thus, the application submitted by NHPMC is the most effective alternative and should be approved as submitted.