



**WRITTEN COMMENTS ON 2023 HEALTH SERVICE AREA II
FIXED PET SCANNER COMPETITIVE REVIEW**

SUBMITTED BY NOVANT HEALTH FORSYTH MEDICAL CENTER

OCTOBER 31, 2023

Three applicants submitted CON applications in response to the need identified in the 2023 SMFP for one additional fixed PET scanner in Health Service Area (HSA) II. The applicants include:

- CON Project ID G-012432-23: Novant Health Forsyth Medical Center
- CON Project ID G-012425-23: Cone Health
- CON Project ID G-012433-23: Piedmont Cardiovascular, P.A.

Novant Health Forsyth Medical Center (NHFMC or Novant) 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 NHFMC may develop additional opinions, as appropriate upon further review and analysis. Nothing in these comments is intended to amend any statement in the NHFMC application; to the extent the Agency deems any comment an amendment to the NHFMC application, NHFMC 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

Three CON applications have been submitted to develop a fixed PET scanner in Health Service Area II. Based on the 2023 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 NHFMC demonstrates conformity to all Statutory and Regulatory Review Criteria.

Conformity of Applicants

Applicant	Project I.D.	Conforming with All Applicable Statutory & Regulatory Review Criteria
NHFMC	G-012432-23	Yes
Cone Health	G-012425-23	No
Piedmont Cardiovascular	G-012433-23	No

The NHFMC application is based upon reasonable and supported volume projections and reasonable projections of cost and revenues. As discussed separately in this document, the competing applications contain errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the **NHFMC** 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 2023 SMFP need determination in HSA II 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	Type of Facility	Proposed Scope of Services		
		Oncological PET	Neurologic PET	Cardiac PET
NHFMC	Hospital Based Outpatient Department	X	X	X
Cone Health	Hospital Based Outpatient Department	X	X	X
Piedmont Cardiovascular	Diagnostic Center			X

NHFMC is an existing provider of fixed PET services and proposes to develop a second, hospital-based fixed PET scanner. Cone Health proposes to develop one fixed PET scanner at Moses Cone Hospital (MCH)

located within the Cone Health Heart and Vascular Center. Both NHFMC and MCH propose to offer oncological, neurological, and cardiac PET scans. Piedmont Cardiovascular proposes to develop a fixed PET scanner in a diagnostic center and will offer only cardiac PET scans. Therefore, regarding scope of services, the proposal by Piedmont Cardiovascular is a less effective alternative. The proposals by NHFMC and Cone Health applications are equally effective alternatives.

Historical Utilization

In previous competitive reviews, the Agency has assessed historical utilization among the competing applicants. The following summarizes FY2022 utilization data for Novant Health and Cone Health from the Proposed 2024 SMFP.

Facility	Planning Inventory	FFY2022 Procedures	Facility Utilization Rate
Alamance Regional Medical Center	1	809	26.97%
Cone Health	1	1,991	66.37%
Novant Health Forsyth Medical Center	1	2,500	83.33%

Source: Proposed 2024 SMFP

The need determination in Health Service Area II was generated based on the utilization of NHFMC’s fixed PET scanner, which is by far the most highly utilized fixed PET scanner in HSA II. NHFMC acknowledges that a provider that generates the need determination for additional capacity is not entitled to receive a certificate of need for the respective incremental capacity. However, based solely on a comparison of historical fixed PET utilization, **NHFMC** is the **most effective** alternative.

Geographic Accessibility

The 2023 SMFP identifies the need for one fixed PET scanner in HSA II. The following table summarizes the locations of existing and approved fixed PET scanners in HSA II as reported by the 2023 SMFP and other publicly available information.

Facility	Inventory	Location City/County
Alamance Regional Medical Center	1	Burlington/Alamance Co.
Cone Health	1	Greensboro/Guilford Co.
High Point Regional Health	1	High Point, Guilford Co.
Atrium Health Wake Forest Baptist	2	Winston-Salem, Forsyth Co.
Novant Health Forsyth Medical Center	1	Winston-Salem, Forsyth Co.

NHFMC proposes to develop a second fixed PET scanner in Forsyth County. Cone Health proposes to develop a second fixed PET scanner in Guilford County. Piedmont Cardiovascular proposes to develop a fixed PET scanner in Guilford County. Therefore, regarding geographic accessibility, the proposals by NHFMC, Cone Health, and Piedmont Cardiovascular are **equally effective** alternatives. However, the

Piedmont Cardiovascular application does not conform to the applicable statutory review criteria and cannot be approved.

Access By Service Area Residents

The 2023 SMFP defines the service area for a fixed PET scanner as “the HSA [Health Service Area] in which it is located (Table 17F-1).” Thus, the service area for this review is HSA II. The counties in HSA II include: Alamance, Caswell, Davidson, Davie, Forsyth, Guilford, Randolph, Rockingham, Stokes, Surry, and Yadkin. 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.

The competing applications each propose to provide access to PET services to patients from the counties in HSA II. However, Piedmont Cardiovascular failed to provide the assumptions and methodology used to project patient utilization and patient origin and cannot be approved. The NHFMC and Cone Health applications provide a percentage for the “other” category in their projected patient origin tables. However, because both applicants include counties in the “other” category that are not in HSA II, it is not possible to quantify which counties are included in “other” that may be part of the defined service area. Therefore, regarding this comparative factor, the results are **inconclusive**. This conclusion is consistent with the Agency’s analysis of this comparative factor in the 2023 Health Service Area I Fixed PET Review.

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.

Currently, Cone Health operates two fixed PET scanners in HSA II: one at Cone Health Wesley Long Hospital (WLH) in Guilford County, and one at Cone Health Alamance Regional Medical Center (ARMC) in Alamance County. NHFMC operates one fixed PET scanner. Piedmont Cardiovascular does not currently provide fixed PET services. However, the application submitted by Piedmont Cardiovascular does not conform to all statutory review criteria; therefore, it cannot be approved. Thus, regarding competition for fixed PET services in the service area, the application submitted by **NHFMC** is the **most effective alternative**.

Access By Underserved Groups

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

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

For access by underserved groups, applications are compared concerning three 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 NHFMC and Cone 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 be made for each factor related to access by underserved groups. The application submitted by Piedmont Cardiovascular did not include Form F.2 in its application; therefore, the proposal did not provide the required information regarding projected revenues by Medicare and Medicaid and cannot be approved. Thus, the following tables compare projected access by Medicare and Medicaid for NHFMC and Cone Health. The fact that Piedmont Cardiovascular failed to provide the required information does not mean the Agency should deem this factor inconclusive; it only means the comparison should be limited to NHFMC and Cone Health.

Projected Medicare Access

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for NHFMC and Cone Health. Piedmont Cardiovascular did not include Form F.2 in its application; therefore, the proposal did not provide the required information regarding projected revenues and cannot be approved. The fact that Piedmont Cardiovascular failed to provide Form F.2 does not mean the Agency should deem this factor inconclusive; it only means the comparison should be limited to NHFMC and Cone Health.

Projected Medicare Revenue – 3rd Full FY

	Medicare Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
NHFMC	\$46,848,799	\$64,596,533	72.5%
Cone	\$39,154,001	\$54,948,428	71.3%

Source: CON applications

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

As shown in the previous table, NHFMC proposes to provide the highest percentage of Medicare Gross Revenue as a percentage of Total Gross Revenue. Therefore, regarding Medicare access, **NHFMC** 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 NHFMC and Cone Health. Piedmont Cardiovascular did not include Form F.2 in its application; therefore, the proposal did not provide the required information regarding projected revenues and cannot be approved. The fact that Piedmont Cardiovascular failed to provide Form F.2 does not mean the Agency should deem this factor inconclusive; it only means the comparison should be limited to NHFMC and Cone Health.

Projected Medicaid Revenue – 3rd Full FY

	Medicaid Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
NHFMC	\$2,957,956	\$64,596,533	4.6%
Cone	\$2,006,646	\$54,948,428	3.7%

Source: CON applications

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

Projected Average Net Revenue per Fixed PET Procedure

The Piedmont Cardiovascular application failed to include Section Q and projected revenues and expenses; therefore, the application does not conform to applicable statutory review criteria and cannot be approved. Further, NHFMC respectfully submits the Agency should not deem a factor inconclusive simply because an applicant failed to submit required information in its application; rather, the comparison should be limited to those applicants that did provide the required information.

The following table compares NHFMC and Cone Health’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	
NHFMC	4,289	\$13,083,363	\$3,040
Cone Health	5,436	\$17,964,517	\$3,305

Source: CON applications

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

Projected Average Operating Expense per PET Procedure

The Piedmont Cardiovascular application failed to include Section Q and projected expenses; therefore, the application does not conform to applicable statutory review criteria and cannot be approved. Further, NHFMC respectfully submits the Agency should not deem a factor inconclusive simply because an applicant failed to submit required information in its application; rather, the comparison should be limited to those applicants that did provide the required information.

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	
NHFMC	4,289	\$6,822,152	\$1,591
Cone Health	5,436	\$7,768,234	\$1,429

Source: CON applications

As shown in the previous table, Cone Health projects the lowest average operating expense per PET scan procedure in the third full fiscal year following project completion. However, as discussed in the application-specific comments, Cone Health failed to adequately account for its projected radiopharmaceutical costs based on the projected fixed PET procedures by specialty; therefore, the Cone Health application cannot be the most effective alternative.

Summary

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

Comparative Factor	NHFCM	Cone Health	Piedmont Cardiovascular
Conformity with Statutory and Regulatory Review Criteria	Most Effective	Less Effective	Not approvable
Scope of Services	Equally Effective	Equally Effective	Not approvable
Historical Utilization	Most Effective	Less Effective	Not approvable
Geographic Accessibility (Location within the Service Area)	Equally Effective	Equally Effective	Not approvable
Access by Service Area Residents	Inconclusive	Inconclusive	Not approvable
Access by Medicaid	Most Effective	Less Effective	Not approvable
Access by Medicare	Most Effective	Less Effective	Not approvable
Competition (Access to a New or Alternate Provider)	Most Effective	Less Effective	Not approvable
Projected Average Net Revenue per PET Procedure	Most Effective	Less Effective	Not approvable
Projected Average Operating Expense per PET Procedure	Most Effective	Less Effective	Not approvable

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

- Conformity with Review Criteria
- Historical Utilization
- Competition
- Medicare Access
- Medicaid Access
- Projected Average Net Revenue per PET Procedure
- Projected Average Operating Expense per PET Procedure

Cone Health’s application fails to conform with all applicable statutory and regulatory review criteria; thus, it cannot be approved. In addition, Cone Health’s application fails to measure more favorably with respect to the aforementioned comparative factors.

Piedmont Cardiovascular’s application fails to conform with all applicable statutory and regulatory review criteria; thus, it cannot be approved.

Based on the previous analysis and discussion, the application submitted by **NHFCM** is comparatively superior and should be approved in this competitive review.

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

**COMMENTS SPECIFIC TO CONE HEALTH
PROJECT I.D. G-012425-23**

Criterion (3) *“The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”*

Regarding historical utilization, the following table summarizes FY2022 utilization data for Novant Health and Cone Health from the Proposed 2024 SMFP.

Facility	Planning Inventory	FFY2022 Procedures	Facility Utilization Rate
Alamance Regional Medical Center	1	809	26.97%
Cone Health	1	1,991	66.37%
Novant Health Forsyth Medical Center	1	2,500	83.33%

Source: Proposed 2024 SMFP

NHFMC’s fixed PET scanner is, by far, the most highly utilized fixed PET scanner in HSA II and demonstrates a robust need for additional fixed PET capacity. Cone Health fails to demonstrate a compelling need for a third fixed PET scanner.

ARMC PET Procedures

Cone Health projects FY2023 fixed PET scanner utilization at ARMC based on only three months of mobile PET scans and ignores ten months of utilization on ARMC’s fixed PET scanner. Cone Health provides the following historical fixed PET scanner utilization in Section Q, page 1.

Cone Health Historical Fixed PET Scans, 2019 – 2023

Facility	FY19	FY20	FY21	FY22	FY23*
Alamance Regional Medical Center	845	692	744	809	652

Source: Section Q, page 1

*FY 2023 is annualized using data from October 2022 through July 2023²

Cone Health states it has utilized a temporary mobile PET scanner at ARMC beginning in April 2023. The mobile PET procedure volume is summarized in the following table.

²² Cone Health states a mobile PET scanner was in use at ARMC beginning April 2023; thus, it is unclear whether ARMC’s fixed PET scanner was operational during May 2023 – July 2023.

Table 2: ARMC Mobile PET Scans by Month, 2023

<i>Month</i>	<i>Scans</i>
May	73
June	72
July	63
Total	208
Annualized ARMC PET Scans	832

Source: Section Q, page 2

Cone Health ignored the 10 months of historical utilization on ARMC’s fixed PET scanner and substituted FY2023 PET procedure volume with only three months of annualized mobile PET procedures. Cone Health’s assumption is not reasonable because it is not supported by ARMC’s historical fixed PET procedure volume. For example, it is unclear why “unanticipated installation delays to replace the existing fixed PET scanner” at ARMC would so significantly impact historical procedure volumes that Cone Health would completely ignore 10 months of fixed PET procedure volume, *which occurred before the fixed PET scanner was in the process of being replaced*. Cone Health did not describe incidents of downtime or days the fixed PET was not available. Cone Health simply refers to delays in replacing the equipment. There is no logical relationship between historical volume and issues with the installation of the replacement machine. Furthermore, procedure volume often fluctuates during the year based on seasonality. Indeed, ARMC’s May 2023 utilization is 15 percent higher compared to July 2023 mobile PET procedures. Thus, the May-June volume may be artificially high due to seasonality. Cone Health could have combined its fixed PET procedure volume with its mobile PET procedure volume to annualize FY2023 utilization. Instead, Cone Health arbitrarily chose to rely on only three months of mobile volume. Cone Health failed to demonstrate that the limited cohort of mobile PET procedures is a reasonable proxy for projecting FY2023 utilization at ARMC.

Novant Health would note that even with Cone Health’s projection based on only three months of mobile PET data, ARMC’s annualized FY2023 procedures are lower compared to its FY2019 utilization and overall, Cone Health’s fixed PET scanner utilization remains well below the SMFP threshold of 80 percent.

Cone Health Historical PET Scans, 2019 – 2023

<i>Facility</i>	<i>FY19</i>	<i>FY20</i>	<i>FY21</i>	<i>FY22</i>	<i>FY23*</i>
Wesley Long Hospital	1,992	1,816	1,818	2,005	2,665
Alamance Regional Medical Center	845	692	744	809	832
Cone Health Total	2,837	2,508	2,562	2,814	3,497
Fixed PET Scanner Inventory	2	2	2	2	2
Fixed PET Utilization Rate	59.1%	52.3%	53.4%	58.6%	72.9%

Source: Section Q, page 1-2

Cone Health projects PET utilization by applying a 4.0 percent growth rate to the sum of WLH and ARMC’s FY2023 PET procedures. This assumption is not reasonable because it assumes ARMC will experience a 4.0 percent growth rate, despite having experienced a negative CAGR from FY2019-FY2023.

Cone Health states that it believes the growth rate is reasonable and conservative because it is less than the system’s FY19-FY23 CAGR of 5.7 percent. However, the respective CAGR was calculated based on 10

months annualized fixed PET procedures at WLH and only three months of mobile PET volume at ARMC. Thus, the 5.7 percent CAGR is unreliable and does not support a 4.0 percent projected growth rate.

Projected Cardiac PET Procedures

Cone Health states that it “has prioritized scheduling many patients who could receive a myocardial SPECT scan to instead receive a cardiovascular PET scan, so that those patients may benefit from the numerous clinical and quality advantages that PET imaging offers to those with cardiovascular conditions.”³ The applicant provided historical data to show the number of myocardial SPECT scans decrease from FY2019-FY2023; however, the applicant failed to provide any data regarding the actual number of cardiac PET scans performed at its facilities during the same time period. Without any data regarding the number of cardiac PET scans performed by Cone Health, there is no evidence to support a correlation between declining myocardial SPECT procedures and an assumed increase in cardiac PET procedure demand. Therefore, Cone Health’s projections of myocardial SPECT procedures and its assumed projected shift to cardiac PET procedures are not supported.

Furthermore, the historical myocardial SPECT procedures provided in Section Q, Table 7 reflect the total number of myocardial SPECT scans performed across all Cone Health imaging facilities – MCH, Wesley Long Hospital, and ARMC – from FY 2019 through FY 2023, annualized.

Table 7: Cone Health Historical Myocardial SPECT Scans FY 2019 – 2023

	<i>FY19</i>	<i>FY20</i>	<i>FY21</i>	<i>FY22</i>	<i>FY23*</i>
Total Myocardial SPECT Scans	4,933	4,078	4,359	4,139	3,530

Source: Cone Health internal data.

* FY 2023 is annualized using data from October 2022 through July 2023.

Cone Health projects the following cardiac PET scans during the first three project years.

**Table 8: Cone Health Projected PET Scans to Shift from Myocardial SPECT Scans
FY 2023 - 2028**

	<i>FY23</i>	<i>FY24</i>	<i>FY25</i>	<i>FY26 (PY1)</i>	<i>FY27 (PY2)</i>	<i>FY28 (PY3)</i>
Myocardial SPECT Scans	3,530	3,247	2,987	2,747	2,527	2,324
Shift % to PET Scans	60%	60%	60%	60%	60%	60%
Potential PET Scans	2,118	1,948	1,792	1,648	1,516	1,394

Source: Section Q, page 5

As previously described, the projected “potential PET scans” include patients that originated from ARMC located in Alamance County; however, Cone Health assumes the volume of cardiac PET scans will be distributed equally between WLH and MCH. Cone Health does not project any of the potential cardiac PET

³ Section Q, page 4

scans will be realized at ARMC even though ARMC will have a new, replacement fixed PET scanner with cardiac PET capabilities. Furthermore, the applicant failed to demonstrate why it is reasonable to assume that myocardial SPECT patients that have historically been served at ARMC in Alamance County will instead be served at WLH or MCH in Guilford County upon completion of the proposed project. Consequently, Cone Health’s projections of cardiac PET procedures are not supported.

Projected PET Scans for Alzheimer’s Disease

Cone Health anticipates that 33 percent of the expected Alzheimer's patient population will receive a PET scan. Nevertheless, the applicant has not substantiated this assumption with any supporting rationale. The projection is purely speculative and lacks any foundation. The assumption results in approximately 1,000 incremental projected PET scans solely for Alzheimer's patients. The applicant failed to provide any documentation to support such volume of PET services by Alzheimer's patients.

Total Projected Fixed PET Utilization

Cone Health’s assumptions and methodology result in the following fixed PET utilization.

**Wesley Long Hospital and Moses Cone Hospital Projected PET Scans
 FY 2025 - 2028**

Procedure Type	PET Scans	% of Total
Growth of Scans at WLH	3,027	55.7%
Incremental Cardiac PET Scans	1,394	25.7%
Incremental Alzheimer's / Neurology Scans	1,013	18.6%
Total PET Procedures	5,434	100.0%

Source: Section Q, pages 6-7

Cone Health projects that over 44 percent of projected PET procedures at WLH and MCH will be the result of incremental volume from cardiac and Alzheimer’s patients. The projected utilization relies heavily on unsupported shifts of cardiac and neurology patients that are expected to receive PET imaging in the future despite no quantifiable evidence of any cardiac or neurology PET procedures having been performed at MCH in the past.

Impact on Other Review Criteria

Based on the previously described facts for which the Cone Health application does not conform to Criterion (3), the application is also **non-conforming to Criteria (1), (4), (5), (6), and (18a) and 10A NCAC 14C .3703.**

Additionally, NHFMC highlights the following issues for the Agency’s consideration:

Criterion (5)

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 patients per year.⁴ While, Cone Health states its currently has a Rubidium generator, it does not appear that Cone Health has adjusted its expenses to account for the significant increase in cardiac PET studies as proposed in its application.

Due to the higher cost of providing myocardial PET perfusion studies, payors typically reimburse the procedures at a higher rate compared to other PET studies, e.g., oncology-related PET procedures. The following table compares Medicare reimbursement rates for several PET procedures by type.

Procedure Type	CPT Code	Description	Medicare Pays
Cardiac	78431	Myocardial imaging, PET, perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired CT transmission scan	\$2,270
Cardiac	78432	Myocardial imaging, PET, combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability)	\$1,554
Cardiac	78433	Myocardial imaging, PET, combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	\$1,641
Oncology	78815	PET with concurrently acquired CT for attenuation correction and anatomical localization imaging; skull base to mid-thigh	\$1,282
Neurology	78608	Brain imaging, PET; metabolic evaluation	\$1,246
Oncology	78814	PET with concurrently acquired CT for attenuation correction and anatomical localization imaging; limited area (e.g., chest, head/neck)	\$1,273

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.istage.jst.go.jp/article/anc/5/1/5_19-00105/.pdf

Oncology	78815	PET with concurrently acquired CT for attenuation correction and anatomical localization imaging; skull base to mid-thigh	\$1,282
Oncology	78816	PET with concurrently acquired CT for attenuation correction and anatomical localization imaging; whole body	\$1,282

Source: <https://www.medicare.gov/procedure-price-lookup/>

Cone Health projects 1,394 incremental cardiac PET procedures during the third project year, which will comprise over 25 percent of its total PET procedures. See comments regarding Criterion (3).

Cone Health’s projected medical supply expenses do not account for the increased costs that will be incurred due to the shift in procedure mix to include substantially more cardiac PET procedures as a percentage of total PET procedures. As shown in the following table, Cone Health’s average medical supply expense per procedure increases by an inflation rate of 4 percent.

Cone Health Average Medical Supply Expense Per PET Procedure							
	FFY2022	FFY2023	FFY2024	FFY2025	FFY2026	FFY2027	FFY2028
Medical Supplies Cost	\$888,007	\$1,227,624	\$1,240,471	\$1,513,860	\$2,133,738	\$2,585,931	\$3,045,831
PET Procedures	2,005	2,665	2,590	3,039	4,118	4,798	5,436
Average Medical Supply Cost per PET Procedure	\$443	\$461	\$479	\$498	\$518	\$539	\$560
Annual Change		4.0%	4.0%	4.0%	4.0%	4.0%	4.0%

Source: Form C, Form F.3

If Cone Health expects to realize a significant shift in procedure mix to include cardiac PET scans comprising over 25 percent of total procedures, the average medical supply cost should accordingly increase beyond the expected overall inflation rate. Instead, it is evident from the previous analysis that Cone Health failed to account for increased medical supply costs due to the projected increase of Rubidium-82 for myocardial perfusion PET procedures. Thus, the application should be found non-conforming to Criterion (5). Additionally, the application should not be deemed the most effective alternative regarding average operating expense per PET procedure.

Criterion (18a)

Currently, Cone Health operates two fixed PET scanners in HSA II: one at Cone Health Wesley Long Hospital in Guilford County, and one at ARMC in Alamance County. In addition, Cone Health’s two fixed PET scanners in HSA II were underutilized based on publicly available information reported in the Proposed 2024 SMFP.

Facility	Planning Inventory	FFY2022 Procedures	Facility Utilization Rate
Alamance Regional Medical Center	1	809	26.97%
Cone Health	1	1,991	66.37%

Source: Proposed 2024 SMFP

Regarding competition, Cone Health’s proposal will not positively impact competition. This is because their proposed project would result in Cone Health gaining control of three fixed PET scanners, which would make them the predominant provider in the service area, with the highest number of fixed PET scanners. Furthermore, Cone Health’s existing fixed PET scanners are far from being utilized at practical capacity; thus, indicating no immediate necessity to further strengthen their control over this essential capacity.

**COMMENTS SPECIFIC TO PIEDMONT CARDIOVASCULAR, PA
PROJECT I.D. G-012433-23**

Piedmont Cardiovascular failed to submit a complete and approvable application. Specifically, Piedmont Cardiovascular's application did not include Section Q, which includes projected utilization, revenues, and expenses and related assumptions. The application also failed to provide responses to multiple application sections resulting in a failure to provide adequate information to demonstrate conformity to multiple statutory review criteria and administrative rules. These are fatal errors which render Piedmont Cardiovascular's application unapprovable.

Without utilization projections, the application fails to demonstrate conformity to Criterion (3) because it cannot demonstrate the need the population has for the services proposed.

Without utilization projections, the application fails to demonstrate conformity to 10 NCAC 14C .3703 because it cannot demonstrate the proposed PET scanner will be utilized more than the minimum performance standard of 2,080 PET procedures during the third project year.

Based on the previously described facts for which the Piedmont Cardiovascular application does not conform to Criterion (3), the application is also non-conforming to Criteria (1), (4), (5), (6), and (18a) and 10A NCAC 14C .3703.

NHFMC also notes the following nonconformities:

Piedmont Cardiovascular failed to provide information regarding available alternatives to is proposed project and an explanation of how those respective alternatives would be more costly or less effective than the selected alternative. Therefore, the application does not conform to Criterion (4).

Without Form F.2 and F. 3 and projections of revenues and expenses, the application fails to demonstrate conformity to Criterion (5) because it cannot demonstrate reasonable projections of the costs of and charges.

Without an equipment quotation, the application fails to demonstrate conformity to Criterion (5) because it cannot demonstrate capital costs are based on reasonable and supported assumptions.

Without Form F.1 and capital cost projections, the application fails to demonstrate conformity to Criterion (12) because it cannot demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative.

Without Form F.2 and F.3 and projections of revenues by payor source, the application fails to demonstrate conformity to Criteria (3) and (13) because it cannot demonstrate access by medically underserved patients. Additionally, the payor mix projections provided in Section L.3 total more than 100 percent; thus, the applicant's payor mix projections in Section L.3 are unreliable.

Without Form F.2 and F. 3 and projections of revenues and expenses, the application cannot be included in a comparative analysis regarding the following factors: average net revenue per procedure, average operating expense per procedure, access by Medicare patients, and access by Medicaid patients.

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 three fixed PET scanners in Health Service Area II. Based on the 2023 SMFP's need determination, only one fixed PET scanner can be approved.

NHFMC is the only application fully conforming to all statutory and regulatory review criteria. Furthermore, NHFMC is comparatively superior to the Cone Health and Piedmont Cardiovascular proposals. Thus, the application submitted by NHFMC is the most effective alternative and should be approved as submitted.