

**COMMENTS ABOUT CERTIFICATE OF NEED APPLICATION FOR
NOVANT HEALTH FORSYTH MEDICAL CENTER
PROJECT ID# G-12432-23**

**Submitted by The Moses H. Cone Memorial Hospital
October 31, 2023**

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1) The Moses H. Cone Memorial Hospital, hereafter referred to as Cone Health, submits the following comments related to the application by Novant Health Forsyth Medical Center (NHFMC), which proposes to acquire “a second fixed PET scanner in Forsyth County pursuant to the need determination in the 2023 State Medical Facilities Plan.”¹

The comments herein relate to the representations made in the application and discussion regarding whether the material in the application complies with the relevant review criteria and standards. Cone Health contends that NHFMC’s application does not conform to the basic principles set forth in the State Medical Facilities Plan, and does not demonstrate conformity with all applicable review criteria and standards. Additionally, Cone Health’s application is more effective in comparison.

In particular:

- **Geographic Access** - NHFMC attempts to demonstrate need by using projected population growth, aging of the population, and disease incidence for its current and proposed PET service area; however, the need methodology fails to provide enhanced geographic access to patients in HSA II based on where the population is growing and aging most within HSA II. Policy GEN-3 of the 2023 NC State Medical Facilities Plan states “A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while **promoting equitable access and maximizing healthcare value for resources expended**.” (emphasis added). NHFMC’s proposed project does not promote equitable geographic access and is non-conforming with Policy GEN-3.
- **Service Line Utilization** – NHFMC states that expanded clinical applications of PET for cardiac and neurological conditions will impact demand for PET services. While Cone Health agrees with this assertion, the assumptions in the need methodology for NHFMC’s proposed project do not clearly demonstrate how cardiology and neurology volumes are expected to impact the projected PET volumes. Therefore, the assumptions and methodology are unreasonable, and the application is non-conforming with Criterion 3.
- **Adequate Alternatives** – NHFMC’s application fails to appropriately consider a less-costly, more effective alternative via Novant Health’s existing mobile PET scanner. That scanner was initially approved as a fixed PET scanner for HSA II, but later converted to a mobile scanner that primarily serves patients from HSA III, even though Novant’s fixed PET scanner in HSA III has available capacity. NHFMC’s application is, therefore, non-conforming with Criterion 4.
- **Maximizing Healthcare Value** – NHFMC’s application has the highest proposed project capital cost as well as operating cost per scan, failing to “**demonstrate how the project will maximize healthcare value for the resources expended**”. Therefore, NHFMC’s proposed project is non-conforming to Policy GEN-3.

¹ Novant Health Forsyth Medical Center CON Application for Project ID#: G-12432-23, p. 20

For these reasons, the application to develop a second fixed PET Scanner at Novant Health Forsyth Medical Center should be denied. By comparison, Cone Health’s application meets all relevant statutory criteria. Cone Health’s need methodology clearly outlines how its proposed project will meet the needs of all residents of the proposed service area and will enhance geographic and clinical access.

Geographic Access

Cone Health proposes to develop one fixed PET Scanner at a medical office building currently under development on the main campus of the Moses Cone Hospital², in Guilford County. Novant Health proposes to develop the fixed PET Scanner in Winston-Salem in the radiology department at Novant Health Forsyth Medical Center, in Forsyth County. There is a clear benefit to locating the new PET scanner in Guilford County, as is demonstrated in Section C of Cone Health’s application. Guilford County is the most populous county in HSA II, yet only has two fixed PET Scanners while Forsyth County, which has nearly 160,000 fewer residents, has three fixed PET Scanners. A quantitative analysis provided in Cone Health’s application demonstrates that the current ratio of population per fixed PET Scanner is 273,467 population per one fixed PET scanner in Guilford County, whereas there is 129,455 population per one fixed PET scanner in Forsyth County, or roughly twice as many residents per PET scanner in Guilford as compared to Forsyth.

Population per Fixed PET Scanners in HSA II

<i>County</i>	<i>Population (2023)</i>	<i>PET Scanners</i>	<i>Population per Scanner</i>
Guilford	546,934	2	273,467
Alamance	178,943	1	178,943
Forsyth	388,365	3	129,455

Source: 2023 SMFP, NC OSBM.

Source: Cone Health CON Application for Project ID#: G-12425-23, p.50

There are several other reasons why Guilford County is a more accessible location for the proposed PET scanner, as is demonstrated in both Cone Health and NHFMC’s applications. In Section C of both applications, data are provided that demonstrate that Guilford County population is projected to grow at a faster rate and a larger absolute number than Forsyth County. Additionally, amongst HSA II counties, Guilford County has the second highest CAGR for its population age 65 and older, who are most likely to need PET services. Age-adjusted incidence rates for cancer and heart disease, and Alzheimer’s/dementia prevalence rates are higher in Guilford than Forsyth County, again demonstrating that projected need is greater in Guilford County. For brevity, Cone Health is not providing those details in this document, but relevant supporting data are provided on pages 48 – 53 of Cone Health’s application for CON Project ID # G- and are similarly corroborated by NHFMC on pages 48 – 49. Novant’s own service area analysis on these pages demonstrates greater population growth and aging in Guilford County as compared to Forsyth County.

Additionally, as the data show in the table below, the population aged 65+ proposed to be served by Cone Health’s project is larger than Novant Health’s proposed project. Cone Health’s proposal to

² Cone Health CON Application for Project ID # G-12425-23, p. 24

develop one fixed PET scanner in Guilford County provides the greatest geographic access to the patient populations which utilize PET services.

Table 1: Access for Patients Aged 65 and Older in HSA II based on Applicant Proposed Service Area

Applicant	Total Population Aged 65+ to be Served 2023	Total Projected Population Aged 65+ to be Served in 2028
Cone Health's Proposed Service Area	248,596	279,605
Novant Health's Proposed Service Area	237,643	267,544
Difference	10,953	12,061

Source:

Cone Health CON Application for Project ID # G-12425-23, p. 51

Novant Health Forsyth Medical Center CON Application for Project ID#: G-12432-23, p. 48 (Wilkes County is not part of HSA II and was removed from the above calculations)

Service Line Utilization

Currently, the most common use of PET scanners is to provide information that can help detect and monitor cancer in oncology patients, yet both applicants also propose to expand the utilization of PET scans to both cardiology and neurology patients. However, NHFMC is vague and fails to clearly demonstrate in its methodology how the volume of cardiology or neurology scans will increase. In its methodology, demonstrated below, NHFMC uses the North Carolina PET use rate and applies it to each county it intends to serve to indicate procedure demand.

Step 3: Projected PET Procedure Demand Based on PET Use Rate

The following table projects future PET scan procedure demand based on the statewide PET use rate applied to the projected population of the respective counties.

Projected PET Procedure Demand Based on PET Use Rate

County	2023	2024	2025	2026	2027	2028
Davidson	1,094	1,163	1,236	1,313	1,395	1,482
Davie	278	296	316	336	358	381
Forsyth	2,444	2,593	2,752	2,922	3,103	3,296
Guilford	3,442	3,649	3,872	4,111	4,367	4,640
Stokes	284	301	318	335	354	373
Surry	449	472	498	524	552	581
Wilkes	413	434	457	481	506	533
Yadkin	233	246	259	273	287	303
Total	8,637	9,154	9,707	10,295	10,922	11,589

Formula: (Step 1 Population ÷ 1000) x Step 2 PET Use Rate

Source: Novant Health Forsyth Medical Center CON Application for Project ID#: G-12432-23, p. 113

As there are few current sites utilizing PET scans for cardiology patients in North Carolina, this use rate fails to include those patients, indicating the misapplication of oncology scan utilization to cardiology and neurology patients. With an incomplete methodology, NHFMC’s volumes are unsupported and non-conforming with Criterion 3.

However, Cone Health clearly accounts for its proposed growth in PET scans by providing each service line separately in its methodology as demonstrated below.

**Table 11: MCH Projected Incremental PET Scans
FY 2025 - 2028**

	FY25*	FY26 (PY1)	FY27 (PY2)	FY28 (PY3)
Incremental PET Scans from Myocardial SPECT Procedures	1,792	1,648	1,516	1,394
Incremental Scans for Patients with Alzheimer’s Disease	976	988	1,001	1,013
Total Incremental Potential PET Scans	2,768	2,636	2,517	2,408
Ramp-Up	25%	50%	75%	100%
Total Incremental Projected PET Scans with Ramp-Up	346	1,318	1,887	2,408

* FY 2025 is a partial project year, representing April 1, 2025 through September 30, 2025. The totals shown have been annualized.

Source: Cone Health CON Application for Project ID#: G-12425-23, p.129

In addition, Novant Health Forsyth Medical Center focuses its cardiac PET program as a form of intervention instead of a method of prevention. It notes, “...If the tissue is viable, patients may benefit from a percutaneous coronary intervention such as angioplasty and stenting, coronary artery bypass surgery, or another procedure. PET scans can also be used to evaluate the effectiveness of treatments for cardiovascular conditions, such as bypass surgery or angioplasty.”³ However, Cone Health’s focus on utilizing the fixed PET scanner for prevention underscores its commitment to value-based care and preventing unnecessary procedures or hospital admissions. While NHFMC states that it intends to treat patients from all 3 service lines it fails to clearly demonstrate how those patients impact its projected volumes. Cone Health’s application is superior because it clearly states not only how each of the 3 service lines will impact its projected volumes, but how it is actively working to create competitive low-cost preventative services.

Adequate Alternatives

Cone Health’s application is also the most effective, as it acknowledges three alternatives to its proposed plan to locate one fixed PET scanner at Moses Cone Hospital in a medical office building. Those options are:

1. Maintain the status quo.
2. Develop a fixed PET scanner at a different location.
3. Contract with a mobile provider as Cone Health does not own a mobile unit.

³ Novant Health Forsyth Medical Center CON Application for Project ID#: G-12432-23, p. 50

Written Comments from The Moses H. Cone Memorial Hospital re:
2023 Novant Health Forsyth Medical Center Fixed PET Scanner Health Service Area II CON Application
CON Project ID# G-12432-23

In its application, NHFMC discussed maintaining the status quo or developing a fixed PET scanner at a location other than Novant Health Forsyth Medical Center, yet it failed to acknowledge that there is a more cost-effective option; it could redeploy its mobile PET scanner back to HSA II where it was initially determined necessary. On page 43 of its application, NHFMC acknowledged that it received CON approval in 2004 for its first fixed PET scanner. Subsequently, in 2008 (CON Project I.D. G-8129-08), it received approval for a second fixed PET scanner. NHFMC then made the choice to develop one fixed PET scanner and convert the second fixed PET scanner, using Policy TE-1, to a mobile PET scanner in 2015 (CON Project I.D. G-11051-15). The table below shows the current utilization of the NHFMC mobile PET scanner.

NHFMC Mobile PET Host Site Facility	County	HSA	CY2022 PET Scans
Novant Health Huntersville Medical Center	Mecklenburg	III	901
Novant Health Kernersville Medical Center	Forsyth	II	438
Novant Health Matthews Medical Center	Mecklenburg	III	692
Novant Health Mint Hill Medical Center	Mecklenburg	III	194
Novant Health Rowan Medical Center Julian Road	Rowan	III	395
NHFMC Mobile PET Scans			2,620

Source: Novant Health Forsyth Medical Center CON Application for Project ID#: G-12432-23, p. 59

This table illustrates that the mobile PET scanner is currently performing 16.7% of its scans in CY2022 in HSA II for which it was initially determined necessary. Based on data from the proposed 2024 State Medical Facilities Plan, Novant Health owns and operates a fixed mobile PET scanner in HSA III, which is operating at less than 70% capacity. A more cost-effective alternative could be to increase utilization on its fixed PET scanner in HSA III and re-deploy capacity from the mobile PET scanner to HSA II. The Proposed 2024 State Medical Facilities Plan also indicates a need determination for a fixed PET Scanner in HSA III which could also lead to available capacity on Novant’s mobile PET scanner to serve sites in HSA II.

Table 15F-1: Utilization of Existing Dedicated Fixed PET Scanners

A	B	C	D	E	F	G
HSA	Facility	Planning Inventory	2021-2022 Procedures	Facility Utilization Rate	Facility Deficit	Need Determination
III	Atrium Health Cabarrus	1	1,189	39.63%	0	
	Atrium Health Union	1	680	22.67%	0	
	Atrium Health Carolinas Medical Center	2	5,119	85.32%	1	
	CaroMont Regional Medical Center	1	918	30.60%	0	
	Iredell Memorial Hospital	1	628	20.93%	0	
	Novant Health Presbyterian Medical Center	1	2,085	69.50%	0	
	HSA III Totals					

Source: Proposed 2024 State Medical Facilities Plan page 365

Maximizing Healthcare Value

Cone Health’s proposed project cost is approximately one-third the project cost of NHFMC’s proposed project cost, as illustrated below.

Table 3: Proposed Project Cost

	Proposed Project Cost
Cone Health	\$2,272,362
Novant Health Forsyth Medical Center	\$6,075,180
Proposed Project Cost Difference	\$3,802,818

Source:

Cone Health CON Application for Project ID # G-12425-23, p. 76

Novant Health Forsyth Medical Center CON Application for Project ID#: G-12432-23, p. 69

In addition to having an overall higher project cost, NHFMC’s proposed project has a higher operating cost per scan. As illustrated below, Cone Health’s proposed project has a higher total operating cost, but a lower operating cost per scan.

Table 4: Average Operating Cost per scan

Applicant	Operating Cost	Number of Scans	Average Operating Cost per Scan
Cone Health	\$7,768,234	5,435	\$1,429.30
Novant Health Forsyth Medical Center	\$6,822,152	4,289	\$1,590.62

Source:

Cone Health CON Application for Project ID # G-12425-23, p. 133

Novant Health Forsyth Medical Center CON Application for Project ID#: G-12432-23, p. 123

Thus, Cone Health’s proposed project is the most cost-effective alternative.

Summary

In summary, Novant Health Forsyth Medical Center has failed to demonstrate conformity with all applicable review criteria and standards and basic principles set forth in the NC SMFP. For these reasons, the application to develop one fixed PET scanner at Cone Health is superior, and the application to develop one fixed PET scanner at Novant Health Forsyth Medical Center should be denied.

**COMMENTS ABOUT CERTIFICATE OF NEED APPLICATION FOR PIEDMONT CARDIOVASCULAR, P.A.
PROJECT ID# G-12433-23**

**Submitted by The Moses H. Cone Memorial Hospital
October 31, 2023**

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1) The Moses H. Cone Memorial Hospital, hereafter referred to as Cone Health, submits the following comments related to the application by Piedmont Cardiovascular, P.A., which proposes to “establish Cardiac only PET/CT services in office setting to the community.”¹

The comments herein relate to the representations made in the application and discussion regarding whether the material in the application complies with the relevant review criteria and standards. Cone Health contends that the application does not conform to the basic principles set forth in the State Medical Facilities Plan and does not demonstrate conformity with applicable review criteria and standards. In particular, the applicant is non-conforming to the following criterion:

1. **Criterion (3) G.S. 131E(a)(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 person, racial and ethnic minorities, women, ... person [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.”

Although the Applicant provides qualitative reasons the proposed project is needed, there is no quantitative data provided that identifies the population to be served by the proposed project. Where patient data are provided, it is unclear if the number of patients refers to the total number seen in the practice or those projected to receive PET scans on the proposed equipment. On page 41 of its application, the Applicant provides one historical year of data and two projected years of data; however, a methodology for projecting future volumes, with associated assumptions, does not appear to be included in the application.

In addition, under Criterion (3), the Applicant does not provide an adequate response to the applicable Performance Standards found at 10A NCAC 14C .3703. The Applicant states that .3703 (5) is not applicable because they do not own or operate any existing or approved fixed or mobile PET scanners in the service area. However, .3703 (5) also asks for projected utilization for “the proposed fixed PET scanner” which is the subject of the application.

2. **Criterion (4) G.S. 131E-183(a)(4)** “Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.”

The Applicant acknowledges that the alternative to its proposed project is for patients to experience wait times or travel to other sites for care but does not provide documentation to demonstrate that the proposed alternative is the least costly or most effective.

¹ Piedmont Cardiovascular CON Application for Project ID#: G-12433-23, p. 20

- 3. Criterion (5) G.S. 131E-183 (a)(5)** “Financing and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based on reasonable projections of the costs of and charges for providing health services by the person proposing the service.”

The Applicant fails to provide Form F.1A Capital Cost and documentation regarding sources of financing for working capital nor does it provide documentation of its “turn-key” lease for the PET scanner resulting in the limited capital outlay². Additionally, the Applicant does not provide evidence that its vendor has approval to operate a PET scanner in North Carolina.

- 4. Criterion (7) G.S. 131E-183(a)(7)** “The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.”

The Applicant fails to provide a completed Form H Staffing.

- 5. Criterion (12) G.S. 131E-183(a)(12)** “Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.”

The Application notes that approximately 2,000 square feet are to be renovated for its project. A line drawing of the existing space is included in Exhibit 7, but that drawing does not indicate the construction area for the PET/CT scanner, shield, hot lab, or dedicated bathroom. The Applicant states that the proposed location is shelled and ready for construction but does not provide supporting documentation to demonstrate what construction is needed and reasonability of capital costs for that renovation.

- 6. Criterion (18a) G.S. 131E(a)(18a)** “The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”

The Applicant notes that its proposed project will not have any positive impact on cost-effectiveness, quality, and access by medically underserved groups, and does not demonstrate that PET services is a service on which competition will not have a favorable impact.

² Piedmont Cardiovascular CON Application for Project ID#: G-12433-23, p. 61

7. **Criterion (5) G.S. 131E-183 (a)(5)** “Financing and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based on reasonable projections of the costs of and charges for providing health services by the person proposing the service.”

The Applicant fails to provide documentation regarding sources of financing. Additionally, no financial documents are provided to demonstrate the operating financial feasibility of the proposal, based on reasonable projections of the costs of and charges for providing PET scanning services.

For these reasons, the application by Piedmont Cardiology to develop one fixed PET scanner in Greensboro, NC should be denied.