Comments on
Novant Health Kernersville Medical Center's and High Point Regional Health's Fixed PET Scanner Certificate of Need Applications, Project IDs #G-12653-25 and #G-12657-25

July 31, 2025

Competitive Comments on Health Service Area II
Fixed PET Scanner Applications

submitted by

Cone Health

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Cone Health hereby submits the following comments related to the applications filed by Novant Health Kernersville Medical Center (Novant) and High Point Regional Health , an affiliate of Atrium Health Wake Forest Baptist (AHWFB), to add a dedicated fixed PET scanner in response to the need identified in the *2025 State Medical Facilities Plan* (*SMFP*) for one dedicated fixed PET scanner in Health Service Area (HSA) II. Novant proposes locating a fixed PET scanner at its Novant Kernersville campus, where it currently offers PET services via a mobile PET scanner. High Point Regional Health (HPR) proposes to acquire an additional PET scanner and locate it at a new health campus under development in northwest Greensboro, separate from the High Point Medical Center (HPMC) campus where one existing fixed PET scanner is located. The proposed scanner would be the second PET scanner on the High Point Medical Center license. Cone Health's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c).[1] In order to facilitate the Agency's ease in reviewing these comments, Cone Health has organized its discussion by issue, specifically noting the general Certificate of Need (CON) statutory review criteria and regulations creating the non-conformity of each issue, as they relate to Novant Health's application, Project ID # G-12653-25, and the HPR application, Project ID # G-12657-25. Cone Health's comments include issue-specific comments on the Novant and HPR applications as well as a comparative analysis related to its application:

- Cone Health, acquire one fixed PET scanner, Project ID # G-012650-25

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

[1] Cone Health is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its application filed on June 15, 2025 (Project ID # G-12650-25).

GENERAL COMMENTS ON HIGH POINT REGIONAL HEALTH

It should be noted that the existing PET scanner in High Point that is owned and operated by HPR, d/b/a High Point Medical Center, has had the lowest utilization rate of any PET scanner in HSA II. The HPMC scanner operated at only 19 percent of capacity in Federal Fiscal Year (FFY) 2023, as shown in the following table from the *2025 SMFP*:

Table 1: HSA II PET Scanner Utilization in FFY 2023

Facility	Planning Inventory	FFY 2023 Procedures	Facility Utilization Rate	Procedures Per Scanner	Inventory Located in Facilities ≥ 80% Capacity
Alamance Regional	1	702	23.4%	702	0
North Carolina Baptist Hospital	2	4,248	70.8%	2,124	0
Cone Health	1	2,750	91.7%	2,750	1
High Point Medical Center	1	583	19.4%	583	0
Novant Forsyth*	2	2,907	48.5%	1,454	0
HSA II Total	**7**	**11,190**			**1**

Source: *2025 SMFP*, Table 15F-1, expanded

* The second PET scanner at Novant Forsyth was approved pursuant to Project ID # G-012432-23 and began operation in May 2025.

The HPMC scanner performed fewer PET procedures than any other facility in HSA II in FFY 2023. The PET scanner at the High Point campus was approved in 2004 and has had nearly 20 years of operation yet still had not exceeded the need threshold in the *2025 SMFP*, nearly two decades later. Furthermore, according to volumes reported on the 2025 License Renewal Application (LRA), although PET volume at High Point Medical Center increased in the most recent year, HPMC's existing PET scanner volume is still well under the capacity threshold for a fixed PET scanner. High Point Medical Center reported 1,401 procedures on its existing PET scanner in FFY 2024, or 46.7 percent of the maximum capacity (1,401 ÷ 3,000 = 46.7%).

The HPR application contends that demand for PET procedures has been growing, and it anticipates a significant increase in PET procedures at HPMC that will require another scanner. However, the most recently reported fixed PET utilization for HPMC is still below the utilization capacity threshold for a need determination in the *SMFP* and does not provide evidence of a long term trend. Fixed PET procedures at HPMC increased to 1,401 in FFY 2024, representing a compound annual growth rate (CAGR) of 9.0 percent from FFY 2020 to FFY 2024. Assuming this growth rate remains constant, HPMC's existing PET scanner will not exceed 80 percent of capacity until 2031, six years in the future.

Table 2: High Point Medical Center Fixed PET Historical Utilization

	FFY 2020	FFY 2021	FFY 2022	FFY 2023	FFY 2024	CAGR
Total PET Procedures	991	1,013	1,223	583	1,401	9.0%
SMFP Annual Capacity	3,000	3,000	3,000	3,000	3,000	
Percent Utilization	33.0%	33.8%	40.8%	19.4%	46.7%	

Source: 2021-2025 LRA applications.

ISSUE-SPECIFIC COMMENTS – HIGH POINT REGIONAL HEALTH

1. <u>HPR's PET volume projections are overstated and unreasonable.</u>

HPR presents a methodology for projecting PET utilization at both High Point Medical Center and its system affiliate North Carolina Baptist Hospital that does not adequately demonstrate the reasonableness of its volume projections. The fundamental flaw lies in the organization's use of inconsistent and inflated baseline data that creates artificial growth trajectories, making performance standards appear achievable through the manipulation of historical volumes rather than through demonstrated market demand.

The most glaring issue with HPR's application is the considerable variance between PET procedure volumes reported in the CON application versus those reported in the organization's Hospital License Renewal Applications (LRAs) for the same facilities and time periods. The following tables show the reported PET procedure volume in Federal Fiscal Year (FFY) 2024 for both AHWFB hospitals, according to 2025 LRA reports submitted by AHWFB.

Positron Emission Tomography (PET)

		Number of Procedures*		
SCAN TYPE	Number of Units	Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	1	7	1394	1401
Mobile PET Scanner	0	0	0	0
PET pursuant to Policy AC-3	0	0	0	0
Other PET Scanners used for Human Research only	0	0	0	0

Source: High Point Medical Center 2025 LRA.

Positron Emission Tomography (PET)

		Number of Procedures*		
SCAN TYPE	Number of Units	Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	2	68	4269	4337
Mobile PET Scanner	0	0	0	0
PET pursuant to Policy AC-3	1	0	27	27
Other PET Scanners used for Human Research only	0	0	0	0

Source: North Carolina Baptist Hospital 2025 LRA.

This LRA data is significantly lower than the volumes that HPR uses as its baseline year in its Form C Methodology. On page 135 of its application, HPR shows the 2024 volume for HPMC at 1,913 procedures. This represents a variance of 512 procedures, or an inflation of 36.5 percent above the officially reported LRA figures. The historical PET volumes presented by HPR in the CON application are shown in the following table.

High Point Medical Center
Historical PET Utilization, CY2021 – CY2025

	CY2021	CY2022	CY2023	CY2024	Annualized CY2025	4-YR CAGR
Procedures	1,051	1,324	1,490	1,913	2,163	19.78%

Source: AHWFB internal data. CY2025 annualized based on historical utilization of 723 from January 1 – May 2, 2025.

Source: HPR application, p. 135.

Similarly, page 140 of HPR's application shows the PET volume for North Carolina Baptist Hospital as 5,140 procedures in 2024, 18.5 percent higher than the reported LRA volume. This represents a variance of 803 procedures, or an inflation of 18.5 percent above the figure reported in LRA data. Although there is a one quarter difference in the reporting periods for the fiscal year and calendar year, these variances are far higher than would be expected for a difference of three months. Moreover, HPR provides no explanation for these substantial discrepancies. The organization did not reconcile the data sources or provide any methodology for converting between Federal Fiscal Year and Calendar Year reporting that would support the high variances in PET procedures, raising fundamental questions about the reliability of its projections. The net effect is that HPR uses these inflated base year volumes as the starting point for its projections and therefore uses artificial means to meet the performance standard for its PET scanners. For instance, the additional 803 PET procedures at North Carolina Baptist Hospital represents 38 percent of the required performance standard of 2,080 procedures per year.[2] Without this mathematical adjustment, the historical data shows no viable path for HPR to achieve the required performance standard.

North Carolina Baptist Hospital Fixed PET Scanners
Historical PET Utilization, CY2021 - CY2025

	CY2021	CY2022	CY2023	CY2024	Annualized CY2025	4-YR CAGR
Procedures	2,455	2,849	3,425	5,140	5,687	23.37%

Source: AHWFB internal data. CY 2025 annualized based on historical utilization of 1,901 from January 1 – May 2, 2025.

Source: AHWFB application, p. 140.

HPR further compounds its unreasonable baseline volumes by deriving growth rates from these artificially inflated figures. The organization claims that High Point Medical Center experienced a CAGR of 19.78 percent from CY 2021 through annualized CY 2025. Similarly, North Carolina Baptist Hospital allegedly experienced a CAGR of 23.37 percent during the same period.

However, this picture changes dramatically when the actual LRA data is analyzed to determine legitimate growth rates. Based on the officially reported LRA data, High Point Medical Center's actual growth rate would be a CAGR of 11.4 percent, while North Carolina Baptist Hospital's actual growth rate would be a 10.5 percent CAGR, both considerably lower than the growth rates chosen by HPR.

[2] As required in 10A NCAC 14C .3703, performance standards for fixed PET scanners.

Comparison of Historical PET Volume and Growth Rates

	High Point Medical Center			North Carolina Baptist Hospital		
Year	LRA*	Application	Variance	LRA*	Application	Variance
2021	1,013	1,051	38	3,216	2,455	(761)
2022	1,223	1,324	101	3,367	2,849	(518)
2023	583	1,490	907	4,248	3,425	(823)
2024	1,401	1,913	512	4,337	5,140	803
CAGR	11.4%	22.1%		10.5%	27.9%	

*Data in the LRA is for the Federal Fiscal Year period (October-September); the LRA submission is one year later. As an example, the FFY 2024 data of 1,401 PET procedures at High Point Medical Center is included in the 2025 LRA submitted.

While HPR ultimately revises these excessively inflated rates of growth claiming it does so in order to be conservative, these initial rates are so high that the selected growth rates remain higher than more reasonable alternatives HPR could have used. For instance, the population of Health Service Area II is projected to grow at a 0.8 percent CAGR from 2024 to 2029,[3] while the growth in total PET procedures in HSA II from FFY 2018 to FFY 2024 was 6.6 percent.[4] HPR uses a 10.9 percent CAGR for PET procedures at High Point Medical Center and claims this is conservative, despite this rate being higher than either of these service area-specific benchmarks. Reducing an artificially high growth rate by a certain percentage does not result in a conservative projection if the underlying historical data is unreliable to begin with. The claim that this somehow represents a cautious approach is therefore misleading and does not address the core data validity problems with the methodology.

The regulatory requirement that PET scanners must perform 2,080 or more procedures during the third full fiscal year of operation becomes artificially achievable when baseline volumes are inflated and unrealistic growth rates are applied. HPR projects that its combined PET operations will perform well above this threshold, but these projections are built upon the foundation of fundamentally unreliable data.

The HPR application contains unreasonable utilization methodology assumptions and overstated projections. Accordingly, the application is non-conforming with Criteria 3, 4, 5, 6, and 18a, as well as the performance standard in 10A NCAC 14C .3703, and should not be approved.

2. HPR makes unreasonable patient origin projections.

In HPR's projections for patient origin, there is a significant increase in the number of patients from Davidson and Randolph counties receiving PET procedures at a HPMC facility. On page 45 of the application in the projected patient origin table, HPR projects nearly 1,100 patients will originate from Davidson County and over 600 from Randolph County by Project Year 3. This represents 860 additional PET procedures from these two counties by the third project year, as demonstrated in the following table.

[3] According to OSBM projections (1,774,873 in 2024 to 1,849,090 in 2029).

[4] According to *2019* and *2025 SMFP* data for HSA II (9,480 PET procedures in 2019 and 13,934 in 2025).

High Point Medical Center PET Volume Projections by County

County	2024	2028 (PY1)	2029 (PY2)	2030 (PY3)	Numeric Change	Percent Change
Davidson	513	854	964	1,080	+567	+110.5%
Randolph	327	504	559	620	+293	+89.6%

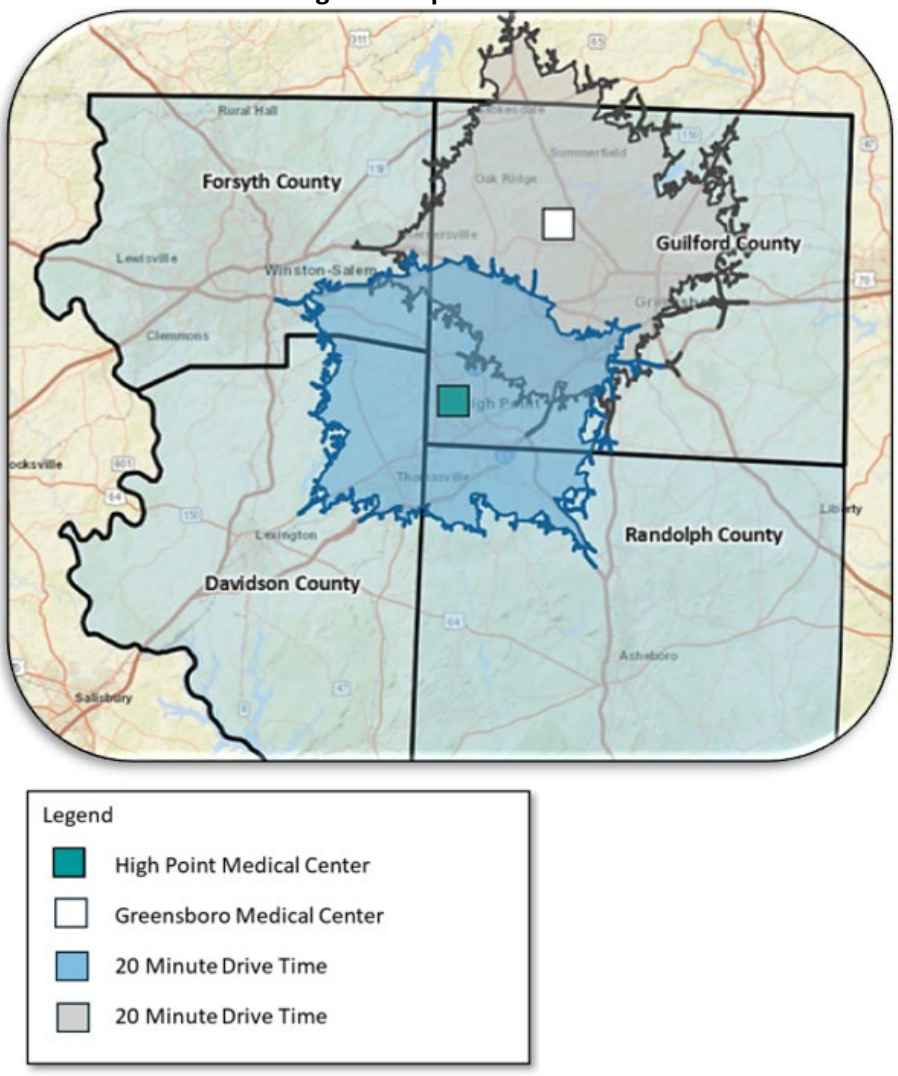
Source: HPR application, Section C.3.

This growth is unsupported by demographic data. According to OSBM population projections, the county population for Davidson is projected to grow at a CAGR of 0.85 percent from 2025 to 2030, while Randolph County has a CAGR of 0.52 percent during this period.[5] The relatively slow growth in these counties does not justify such aggressive increases in volume unless HPR assumes there will also be a large market share increase beyond its current portions of PET procedures from these two counties.

On page 136 in its Form C Methodology, HPR identifies nine ZIP codes in Randolph County with patients that currently receive PET services at North Carolina Baptist Hospital. HPR claims that these patients will shift to HPMC as the result of having access to a more "geographically proximate" PET facility. Notably, this list of ZIP codes does not include any that are located in Davidson County. HPR assumes that it will shift up to 75 percent of these Randolph County PET patients from NCBH to HPMC by the third year of operation for the proposed scanner in Greensboro. This assumption is not reasonable. First, any patients from these counties that choose to receive PET procedures at NCBH are doing so fully aware of the existence of HPMC's underutilized PET scanner in southwest Guilford County. The existing scanner in High Point is considerably closer for patients that live in Randolph and Davidson counties than the proposed scanner in Greensboro, which is actually northwest of Greensboro in the northern section of Guilford County. The accompanying map demonstrates that HPR patients in these two counties would be required to drive past HPR's existing PET scanner in High Point to access the proposed Greensboro scanner, adding in excess of 30 minutes additional driving time.

[5] HPR application, p. 55.

HPR Existing and Proposed Fixed PET Facilities



HPR does not explain why patients from these two counties south of High Point would choose to drive past the existing PET scanner at the High Point campus to receive PET services at the proposed site on Horse Pen Creek Road, which is farther from Randolph and Davidson counties and does not represent a different type of PET service or otherwise differentiate from the existing PET imaging available at the High Point campus. Patients from these counties that go to NCBH in Forsyth County are clearly doing so for reasons other than geographic proximity, and the proposed site will not provide clinical differentiation or services unavailable at the High Point campus that would justify this shift. The HPR application provides no explanation of market share growth or other factors that would explain this tremendous growth in patients from Davidson and Randolph counties, and why they will choose to lengthen the driving distance to a High Point Regional PET facility by a considerable amount of time.

If these incremental PET procedures from Davidson and Randolph are removed, High Point Medical Center's total PET volume in Project Year 3 would be reduced from 4,263 procedures to 3,403 procedures (4,263 – 860 = 3,403). This would result in HPMC being below the performance standard; the requirement for the proposed and existing scanner is 4,160 procedures (2,080 x 2 scanners = 4,160). HPR therefore does not meet the performance standard and cannot be found conforming.

The HPR application contains unreasonable assumptions for patient origin from Randolph and Davidson counties. Accordingly, the application is non-conforming with Criteria 3, 4, 5, 6, and 18a, as well as the performance standard in 10A NCAC 14C .3703, and should not be approved.

3. The HPR proposal is not the most effective alternative.

On page 136 of its application, HPR states that it is reasonable to assume that existing PET patients at NCBH in Winston-Salem will shift to the proposed HPMC scanner in Greensboro, "due to increased PET availability at HPMC." HPR shifts 75 percent of PET patients from select ZIP codes in Guilford, Randolph, and Rockingham counties that currently travel to North Carolina Baptist Hospital by the third project year. HPR states that this shift is reasonable because of the increase in capacity, convenience, and more timely access to fixed PET services."[6] However, this statement overlooks market factors that cast doubt on HPR's assumption.

First, the idea that patients in these select ZIP codes travel to Winston-Salem because there is a lack of capacity at HPMC is unsupported. The proposed *2026 SMFP* includes data from the 2025 LRA that was submitted by HPMC. The HPMC PET scanner reported 1,401 PET procedures in FFY 2024, or 67 percent of the performance standard and just 47 percent of the annual capacity of a fixed PET scanner according to the *SMFP* methodology.[7] Therefore, the idea that patients from Guilford County must travel to Winston-Salem because there is limited PET capacity in High Point is false. It is more likely that these patients in these select ZIP codes prefer to have their PET procedure performed at North Carolina Baptist Hospital for other reasons, such as the recommendation of their referring physician or proximity to other clinical services at the NCBH campus that High Point Medical Center does not provide, such as its comprehensive cancer center. Patients are choosing to travel to Winston-Salem despite the available capacity in High Point and the additional travel distance because the advantages outweigh the disadvantages. It is not reasonable for HPR to shift such a high percentage of patients from these ZIP codes to the proposed Greensboro facility.

Second, HPR appears to have identified the wrong facility as having the most pressing need for fixed PET capacity. Even if one assumes that HPR's assumptions for growth and the shift of patients from NCBH to High Point Medical Center are correct, there is still a giant disparity in the number of PET procedures per scanner at the Forsyth location versus the two High Point Medical Center scanners, as shown in the following table.

Average Volume per PET Scanner, Project Years 1-3

Location	2028 PY1	2029 PY2	2030 PY3
North Carolina Baptist Hospital	6,847	7,283	7,748
Average Procedures per Unit (2)	3,424	3,642	3,874
High Point Medical Center	3,324	3,789	4,263
Average Procedures per Unit (2)	1,662	1,895	2,132

Source: HPR application, Form C Assumptions, pp. 139-140.

[6] HPR application, p. 137.

[7] See *Proposed 2026 SMFP*, p. 352 (1,401 procedures ÷ 3,000 = 46.7%). https://info.ncdhhs.gov/dhsr/ncsmfp/2026/01_Proposed2026SMFP_v4.pdf?ver=1

In 2030, the third project year, the two PET scanners at NCBH are projected to average 3,874 procedures per year, or 129 percent of the maximum capacity. The two High Point Medical Center scanners, including the proposed Greensboro location, are projected to average 2,132 procedures per year. This is only 71 percent of the maximum capacity and is 40 percent lower than the utilization at NCBH. Furthermore, these figures include the unsupported shift of patients from NCBH to High Point Medical Center that was previously discussed. If a more reasonable assumption of a 25 percent shift of NCBH patients to the High Point Medical Center scanner from the selected ZIP codes is used, the total number of PET procedures at High Point Medical Center drops by approximately 200 procedures. Using this calculation, High Point Medical Center would have 3,838 total PET procedures in Project Year 3, or an average of 1,919 procedures per scanner. This would not meet the performance standard for the proposed project, and the HPR application would be non-conforming.

High Point Medical Center Revised PET Volume, Project Years 1-3

Location	2028 (PY1)	2029 (PY2)	2030 (PY3)
Organic Growth	2,948	3,269	3,625
Revised Shift from NCBH*	188	200	213
Total PET Procedures	3,136	3,469	3,838
Average Procedures per Unit (2)	1,568	1,735	1,919

*Assumes a 25 percent shift of the selected ZIP codes included in the table on page 137 of the AHWFB application.

Accordingly, the application is non-conforming with Criteria 3, 4, 5, 6, and 18a, as well as the performance standard in 10A NCAC 14C .3703, and should not be approved.

4. HPR understates the staffing expenses of its proposed PET service.

In its Form H staffing table, HPR shows an increase of 0.2 FTEs for scheduling and reception at the proposed facility in Greensboro. In Section H of the application, HPR states that HPMC has "existing management, registration, business office, and clinical staff."[8] HPR goes on to add that the FTE levels are "driven by the annual PET procedure projections."[9] HPR does not explain how it will operate a duplicate facility offering PET services with such limited staffing resources. Although the application does not specify the days and hours of operation, it presumably will operate for at least 40 hours per week. If the proposed facility uses a five day per week operating schedule, this will leave the equivalent of four days with no receptionist support. There is no mention in Section H or the Section F.3 assumptions of how HPMC will provide coverage to ensure patients are checked in and registered on these other days. HPR has therefore understated the required staffing for the proposed project, with a corresponding underestimated operating cost. If HPR intends to have its clinical staff at the proposed Greensboro PET facility perform front office responsibilities such as reception and check-in, this creates potential conflicts with the clinical care needs of patients and HPR's ability to complete the PET imaging procedures in a safe and timely manner.

As such, the HPR application is non-conforming with Criteria 4, 5, 7, and 18a, as the application does not demonstrate the availability of resources, including sufficient staffing, for the proposed project.

8 HPR application, p. 97.

9 Ibid.

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

ISSUE-SPECIFIC COMMENTS – NOVANT KERNERSVILLE

Novant's PET use rate methodology is unreasonable.

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

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

North Carolina PET Procedure Use Rate (per 1,000 population)

	2024	2025	2026	2027	2028	2029
PET Use Rate	7.34	7.62	7.92	8.22	8.54	8.87

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

In April 2025, Novant included a similar projection of statewide PET use rates for 2024 through 2029. However, the PET procedure use rate for 2029 increases to 9.34 in the April 2025 application, as shown in the table below.

Table 3: North Carolina PET Procedure Use Rate

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

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

Then, in the instant application, Novant has *again* inflated its statewide PET utilization rates. In Section Q of the Kernersville application, Table 3 shows the growth in projected statewide PET use rates for 2024 through 2029. These statewide use rates are substantially higher than those used in Novant's Huntersville application filed just two months earlier. The following table shows Novant's projected PET use rates in the Kernersville application:

Table 3: North Carolina PET Procedure Use Rate

Year	2024	2025	2026	2027	2028	2029
Estimated PET Use Rate	7.50	7.99	8.51	9.06	9.65	10.28

Source: NH Kernersville application, filed June 15, 2025, Section Q, p. 2.

Novant's projected statewide PET use rates have increased dramatically in just nine months between the three applications. The dramatic increase in projected statewide use rates between applications filed within nine months demonstrates a lack of methodological rigor and consistency.

Novant's use of inconsistent and unreasonably high PET use rates renders its volume projections unreliable and overstated. The methodology fails to provide a reasonable basis for projecting future

PET demand in HSA II and results in artificial inflation of projected volumes. This methodological flaw undermines the fundamental assumptions underlying Novant's demonstration of need.

Based on this analysis, Novant has failed to adequately demonstrate need for the proposed fixed PET scanner and has overstated its projected volumes. The Novant application is non-conforming with Criteria 3, 4, 5, 6, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703.

1. Novant's market share projections are unreasonable and result in double-counting PET procedures at its Kernersville and Forsyth facilities.

Novant's methodology contains a fundamental flaw in its market share projections that results in the artificial inflation of projected volumes through double-counting of PET procedures. The application projects significant market share increases for Novant Kernersville without any corresponding decrease in market share for Novant's existing Forsyth Medical Center (NHFMC) facility, despite the geographic proximity and overlapping service areas of these facilities. In Table 7 on page 5 of the Form C Assumptions, Novant projects substantial market share increases for the proposed Kernersville facility across multiple counties:

Novant Health Kernersville Incremental Market Share Capture by HSA II County

County	2025 Baseline	2029 Projected	Share Increase
Davidson	1.12%	7.5%	+6.4%
Forsyth	9.4%	21.9%	+12.5%
Guilford	2.2%	13.2%	+11.0%
Rockingham	3.75%	14.0%	+10.3%

Source: NH Kernersville application, Form C Assumptions, p. 5.

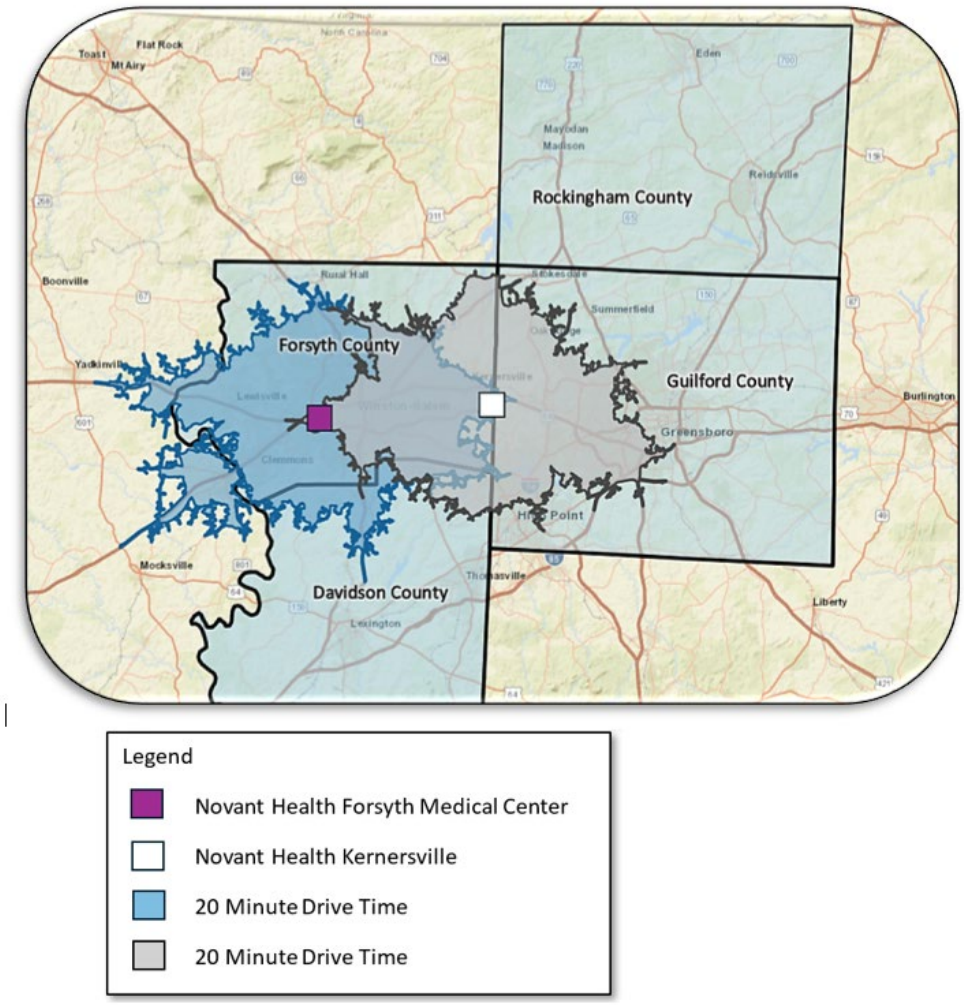
These projected increases are unreasonable given the existing competitive landscape and geographic relationships between facilities. Novant provides no analytical support for why these substantial market share gains would occur, particularly in counties with other existing PET providers. Novant Kernersville is located in eastern Forsyth County, west of Greensboro and east of NHFMC in Winston-Salem. Given this geographic positioning, Novant Kernersville would logically be more convenient for patients residing in eastern Forsyth County, northern Guilford County, and Rockingham County than the existing NHFMC facility. Yet in Davidson County, patients that live in the main population centers, Lexington and Thomasville, are both closer to existing fixed PET scanners in HSA II than to Kernersville, and there is no increase in access that would justify such a significant increase in market share. However, Novant's methodology completely fails to account for these geographic realities.

The following map provides a visual representation of the overlap between service areas for the NH Forsyth and proposed NH Kernersville PET scanners. Given the significant overlap in the drive time service area for both facilities and the Kernersville location's closer proximity to Rockingham, it is not reasonable for Novant's PET facility in Forsyth County to experience no impact on volume and patient origin once the proposed Kernersville facility begins service.

It is also not reasonable for the Novant Kernersville facility to have a significant increase in patients from Davidson County. As shown on the map, the Kernersville PET will be no closer to patients in

Davidson than Novant's existing Forsyth PET facility or to fixed PET providers in southwest Guilford County. Novant does not provide acceptable evidence to support its market share assumptions.

Novant Existing and Proposed PET Facilities



In Table 12 on page 8 of the Form C Assumptions, Novant projects that NHFMC's market share will remain constant throughout all project years after the proposed Novant Kernersville PET begins operation:

Novant Health Forsyth County Market Share Capture in Project Years

County	2027 (PY1)	2028 (PY2)	2029 (PY3)
Forsyth	51.7%	51.7%	51.7%
Guilford	1.68%	1.68%	1.68%
Rockingham	4.3%	4.3%	4.3%

Source: NH Kernersville application, Form C Assumptions, p. 8.

This assumption made by Novant regarding market share is unreasonable for several reasons:

- Geographic Convenience: It is reasonable that patients from eastern Forsyth County, northern Guilford County, and Rockingham County would find the Kernersville location more accessible

than traveling a longer distance to Winston-Salem. However, this is not demonstrated in the market share capture rates of NHFMC.

- Natural Market Shift: Novant's Forsyth and Kernersville facilities have overlapping service areas. It is logical that when a health system offers the same service at a new facility, some volume will naturally shift from existing facilities to the new, more convenient location. Yet this is not indicated in utilization projected for NHFMC.
- Agency Precedent: The Agency regularly evaluates the impact and location of existing facilities utilization on proposed projects on other facilities operated by the same applicant as well as by competitors and expects reasonable projections of volume shifts between related facilities. For example, in the 2024 Wake Acute Care Bed findings the Agency found Novant non-conforming with Criterion 3 due to the applicant not providing a reasonable basis for assessing market share capture rates and thereby overstating utilization projections.

The combination of maintaining NHFMC's market share while adding substantial market share for Novant Kernersville, a facility that has an overlapping service area with NHFMC, results in an unreasonable combined Forsyth County projected market share of 73.6 percent (51.7 percent for NHFMC plus 21.9 percent for Novant Kernersville). This projection is particularly unreasonable, given that AHWFB operates two of the four existing fixed PET scanners in Forsyth County, providing substantial competition. Additionally, some Forsyth County patients may choose to receive PET imaging in other neighboring counties with convenient access. The projected 73.6 percent market share is excessive and unreasonable, especially in light of the competitive landscape with numerous other PET providers.

Novant's market share projections fail to account for the competitive realities in the affected counties:

- Forsyth County: North Carolina Baptist Hospital operates two existing PET scanners in Winston-Salem, providing direct competition to both Novant facilities.
- Guilford County: Cone Health currently operates one PET scanner in Greensboro, the largest city in Guilford County, which would compete directly with the proposed Kernersville facility. In addition, AHWFB operates a PET scanner in High Point.
- Davidson County: AHWFB's PET scanner is in High Point, in the southwest corner of Guilford County and with areas of the community that cross over into Davidson and Forsyth counties. Davidson County residents in communities such as Lexington and Thomasville are more likely to go to Winston-Salem or High Point for PET imaging, as these locations have existing PET providers and are more geographically accessible than Kernersville. Patients would need to drive past the High Point facility or bypass the Winston-Salem locations to reach Kernersville, making such travel patterns unlikely.

By projecting substantial market share increases for Novant Kernersville while maintaining constant market share for NHFMC with no adjustment to account for a new PET facility that will serve the Novant system's patients, Novant effectively double-counts PET procedures that would naturally shift between its facilities. This methodological error artificially inflates the total projected volume for Novant's PET services and overstates the demand for the proposed Kernersville facility. Novant's 73.6 percent market share in 2029 for all PET procedures in Forsyth County represents 3,112 of the 4,228 total procedures. This level of market dominance is unsupported by the competitive landscape and represents an unreasonable projection. Novant's current share of fixed PET patients from Forsyth

County is approximately 53 percent, according to DHSR data.[10] It is unreasonable for Novant to assume adding a PET scanner at Kernersville will result in a gain of 20 additional market share points.

Based on this analysis, Novant has failed to adequately demonstrate need for the proposed fixed PET scanner and is non-conforming with Criteria 3, 4, 5, 6, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703.

2. Novant has projected vastly different assumptions regarding PET capacity at NHKMC; it proposes additional mobile PET capacity that can accommodate its projected growth more effectively and in a less costly manner than the proposed fixed scanner.

On pages 59-60 of its application, Novant states "The current mobile schedule provides NHKMC with only **one day of service per week**. Considering the current capacity constraints on the mobile PET scanner, there are no available days for NHKMC to increase access for NHKMC's patients… The mobile capacity issues have been a primary factor in limiting the amount of PET procedures that NHKMC can perform annually." However, this statement contradicts the information that Novant included in its recently filed Huntersville PET application that is currently under review.[11] According to page 10 of the Form C Assumptions & Methodology in the Huntersville application, "(t)he current mobile schedule provides NHHMC **with two days of service per week and every other Saturday**." Novant then states that it will grow utilization at three facilities, including Kernersville as "(I)t also reflects the availability of two full days of weekly service and every other Saturday being available for use after NHHMC develops the fixed PET/CT scanner at its Huntersville location." In the Huntersville application, Novant is acknowledging the vacated mobile PET capacity that can be redirected to the Kernersville location, which would give Novant's Kernersville location an additional 2.5 days per week of PET service, thereby increasing capacity to up to 3.5 days per week. This operational capacity is more than sufficient to meet demand at Novant Kernersville, and the proposed fixed PET scanner is therefore not needed. Moreover, increasing the frequency of mobile PET days of operation at the Novant Kernersville campus would have minimal capital cost requirements compared to the proposed project, and would be a far less expensive alternative than the development of the proposed fixed PET scanner.

Based on this analysis, Novant has failed to adequately demonstrate need for the proposed fixed PET scanner and is non-conforming with Criteria 3, 4, 5, 6, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703.

3. Novant's projections for PET volume at NH Kernersville are inconsistent and unreasonable.

The Novant application contains volume projections for Novant Kernersville that are vastly different from the projections for that facility in the Novant Huntersville application that was filed on April 15, 2025. In the Huntersville application, Novant's methodology assumed that the Kernersville facility would have an additional 2.5 days per week of mobile PET service availability (see preceding quote above), and this would result in volume growth at a 13.5 percent CAGR. With this rate of growth,

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10 DHSR PET procedures patient origin reports, https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2024/32-Facility_PET-2024.pdf. NHFMC had 2,030 PET patients from Forsyth County in 2023, the most recent data reporting year. There were 3,854 total PET patients from Forsyth County (2,030 ÷ 3,854 = 52.7%).

11 See Project ID # F-12647-25. Novant Health has two applications under review at the same time, each projecting vastly different assumptions regarding PET capacity at NHKMC.

Novant Kernersville's PET volume increased to 943 procedures in CY 2029, as illustrated in Novant's Form C Methodology.

Table 15: NHFMC – Projected Mobile PET Procedure Volumes

Host Sites	Interim Yr – CY 2025*	Interim Yr- CY 2026*	PY 1- CY 2027	PY 2- CY 2028	PY 3- CY 2029
NHHMC	1169	1243	0	0	0
NH Matthews	674	674	765	868	985
NH Mint Hill	141	141	160	182	207
NH Kernersville	645	645	732	831	943
NH Rowan	---	---	156	156	156
Totals	2629	2703	**1813**	**2037**	**2291**

**Interim volume from Table 9 for NHHMC. Projected CY 2025 data for NHHMC is extremely conservative.*
Procedure volume for January 2025-March 2025 indicates an annualized total of 1,304 procedures for CY 2025.

Source: Novant Huntersville application, Section Q, p. 10.

In the current Kernersville application, Novant is suddenly projecting that the Kernersville PET scanner will perform more than 2,200 procedures in 2029. There is no discussion of the previous methodology or how Novant has revised its methodology to more than double the number of procedures in Kernersville.

Additionally, NHFMC's second fixed PET scanner became operational on May 12, 2025 - just one month before Novant filed this Kernersville application, according to page 68 of the Kernersville application. This additional scanner doubled NHFMC's fixed PET capacity from approximately 2,400 to 4,800 procedures annually, yet Novant's projections completely ignore this fundamental change to its capacity and the competitive landscape. Despite this capacity doubling, Table 12 on page 8 of its methodology, the 2024 NHFMC market shares for all eleven counties in HSA II are held constant through 2029. Novant states that the projected increase in PET procedure volume at NHFMC is "based on its historical demand for PET services." The increases in fixed PET volume at NHFMC result only from projected population growth and Novant's aggressive assumptions about increases in PET use rates. This methodology is overly simplistic and does not demonstrate why the additional PET scanner will not have any impact on utilization patterns at NHFMC.

The doubling of capacity should enable NHFMC to increase volume and even capture additional market share. Moreover, NHFMC could now accommodate patients who previously might have chosen other providers due to wait times or scheduling constraints at the Winston-Salem facility. Most importantly, this additional capacity should reduce any pent-up demand that might justify the need for the proposed Kernersville scanner, since patients in overlapping service areas now have access to expanded capacity at the existing NHFMC location.

Novant systematically inflates mobile PET projections across multiple facilities to create the appearance of mobile capacity constraints, thereby artificially supporting the need for the proposed Kernersville fixed scanner, as evidenced by the key differences in the projected mobile PET volumes for the Kernersville application versus the 2025 Novant Huntersville application. In Table 15 of the Kernersville Form C Assumptions & Methodology section, Novant's PET utilization for locations in Matthews, Mint Hill, and Rowan show significant revisions from the Huntersville application that was filed just two months earlier.

Table 15: NHFMC – Projected Mobile PET Procedure Volumes

Host Sites	Interim Yr – CY 2025*	Interim Yr- CY 2026*	PY 1- CY 2027	PY 2- CY 2028	PY 3- CY 2029
NHHMC	1304	1304	0	0	0
NH Matthews	624	624	765	868	985 +312
NH Mint Hill	452	452	513	582 +260	956
NH Kernersville	503	503	0	0	0
NH Rowan	---	---	156	208	260
NH Presbyterian	---	---	1,224	864	---
Totals	2,883	2,883	**2,658**	**2,782**	**2,513**

Source: Novant Health Internal Data

Source: Novant Kernersville application, Form C Assumptions, p. 11.

Among the key changes in the Kernersville application is a 31.6 percent increase in mobile PET procedures at the Matthews location, which now shows 312 more procedures in the third project year. There is no support for this growth beyond Novant's explanation that "Matthews will be allocated additional mobile capacity" in 2029 and "perform 12 procedures per day of additional service."[12] Novant fails to clearly explain the source of additional mobile capacity allocated to Matthews in 2029, creating the potential for double-counting mobile PET procedures. In the Kernersville application, Novant projects that Matthews will receive "additional mobile capacity" and perform "12 procedures per day of additional service" starting in 2029, resulting in 312 additional procedures. However, Novant does not specify where this additional mobile capacity will come from or how it relates to the mobile capacity reallocations described in its Huntersville application filed just two months earlier. Without clear documentation of mobile capacity sources and timing, Novant may be counting the same mobile PET capacity multiple times across different applications resulting in unreasonably inflated projected volumes at various facilities.

In addition, the Huntersville application had the Mint Hill mobile PET performing 207 procedures in 2029, but in the Kernersville application this figure soars to 956 -- a 362 percent increase. Novant states that Mint Hill will be able to perform an additional 0.5 days of service per week beginning in 2028, enabling the site to perform an additional 10 procedures per day. However, since the original Huntersville growth projections were already based on additional days of service, this again constitutes double-counting of incremental utilization.

At Rowan Medical Center, Novant abandons its previous assumption of constant utilization (156 procedures annually across all three project years in the Huntersville application) and instead projects escalating volume from 156 procedures in 2027 to 260 procedures in 2029. Novant provides no explanation for why procedures per day would increase from six to ten, despite no increase in days of service, nor identifies any operational changes that occurred in the two months between applications that would justify this change in volume.

Finally, there is no basis for Novant to include mobile PET volume at Novant Presbyterian. While Novant claims that mobile PET capacity will be required "due to the delay caused by the appeal of its

[12] Novant Kernersville application, Form C Assumptions, p. 12.

approval for the new fixed PET scanner,"[13] any changes to the methodology for Presbyterian are unreasonable. At the time of filing its Huntersville application, Novant was aware that an appeal of its approved CON for fixed PET at Presbyterian was underway, yet it did not account for this in its Huntersville methodology. The appeal status and potential delay of service is not new information that arose in the two months that have elapsed since the Huntersville application was completed, and Novant's addition of mobile PET volume at Presbyterian in the Kernersville methodology contradicts the volume projections in its Huntersville application.

These contradictions in Novant's Huntersville and Kernersville applications demonstrate that its volume projections are unreasonable and methodologically unsound. Thus, Novant's application is non-conforming with Criteria 3, 4, 5, 6, and 18a.

4. Novant's staffing projections for fixed PET services at NH Kernersville are inadequate and unreasonable.

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

In its 2025 Registration and Inventory of Medical Equipment for its mobile PET scanner, Novant reports that it performed 645 procedures in 1,008 hours of operation at the NH Kernersville site. This equates to approximately 1.56 hours per procedure.

However, in Form H of its current application, Novant projects to operate its new fixed PET scanner with just 1.0 FTE nuclear medicine technologist and 0.2 FTE supervisor. Given the historical operational experience at the same site, it would logically require approximately 3,435 hours (2,202 procedures × 1.56 hours per procedure) to perform the 2,202 procedures projected for Year 3. This equates to approximately 66.1 hours per week (3,435 hours ÷ 52 weeks), which is significantly more than a single full-time technologist could reasonably be expected to cover.

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

[13] Ibid, p. 12.

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

For these reasons, the Novant Kernersville application is non-conforming with Criterion 7.

5. Novant's financial projections and assumptions are unreasonable.

The financial projections for the proposed fixed scanner at Kernersville are not reasonable for multiple reasons.

First, Novant shows an unsupported increase in gross revenue beginning in 2025, the first interim year of its projections. Gross revenue increases 23.35 percent from 2024 to $6,460,780 in 2025.[14] This considerable rise in revenue occurs two years before the proposed fixed scanner begins service, when any presumed adjustments to procedure type and mix of procedures would occur. Novant Kernersville's average gross revenue per procedure increases from $10,413 in 2024 ($5,237,622 / 503 procedures) to $12,844 per procedure ($6,460,779 / 503 procedures) in 2025. This revenue increase defies logical explanation, as the same 503 procedures are projected for both years, meaning Novant is essentially claiming it can charge 23 percent more per procedure without any operational improvements, service enhancements, or equipment changes until 2027. Furthermore, this calculation directly contradicts its stated assumption of a "3% annual inflation factor."[15]

Novant also omits operating costs in its interim year projections. Total operating costs in 2025 and 2026 are between $68,000 and $70,000. These abnormally low figures are not reasonable for a service generating over $1.4 million in net patient revenue. By comparison, Novant's Huntersville application had roughly $1.5 million in expenses during the interim period ($1,294 per mobile procedure in 2024). Given that the same mobile scanner will serve Novant's locations in Huntersville and Kernersville, one would expect a similar expense for Kernersville. Using the Huntersville amount per procedure would result in $650,882 in expenses in 2024 which would then be increased due to inflation in 2025 and 2026. Novant has understated its operating expenses in these years by a considerable amount.

Based on this omission of operating expenses and unexplained increase in revenue, the financial projections are unreasonable and unsupported. Thus, Novant's application is non-conforming with Criteria 4, 5, and 18a.

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

COMPARATIVE ANALYSIS

[14] Novant Kernersville application, Form F.2a.

[15] Ibid, Form F.2 Revenue Assumptions.

The Novant Kernersville application (Project ID # G-12653-25) and the High Point Regional Health application (Project ID # G-12657-25), along with Cone Health (Project ID # G-12650-25), each propose to develop a fixed PET scanner in response to the *2025 SMFP* need determination for HSA II. Given that three applicants propose to meet the need for the fixed PET scanner in HSA II, only one can be approved as proposed. To determine the comparative factors that are applicable in this review, Cone Health examined recent Agency findings for competitive fixed PET scanner reviews. Based on that examination and the facts and circumstances of the competing applications in this review, Cone Health considered the following comparative factors:

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

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

Conformity with Applicable Statutory and Regulatory Review Criteria

The Cone Health application adequately demonstrates that its fixed PET scanner proposal is conforming to all applicable statutory and regulatory review criteria. In contrast, neither the Novant Kernersville application nor the AHWFB application adequately demonstrates that its proposal is conforming to all applicable statutory review criteria as discussed previously. Specifically, the Novant Kernersville application is non-conforming with Criteria 3, 4, 5, 6, 7, and 18a and fails to meet the performance standards specified in 10A NCAC 14C .3703, while the HPR application is non-conforming with Criteria 3,4,5,6,7, and 18a, and fails to meet the performance standards specified in 10A NCAC 14C .3703. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, with regard to conformity, the Cone Health application is more effective than the Novant Kernersville and HPR applications.

Scope of Services

Generally, the application that proposes to provide the broadest scope of services with the proposed equipment is the more effective alternative regarding this comparative factor.

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

Proposed Scope of Service

Applicant	*Inpatient Access*	*Hospital Category*	*Oncology*	*Cardiac*	*Neurology*
Cone Health	X	Tertiary	X	X	X
Novant Kernersville	X	Community	X	X	X
High Point Medical Center*	X	Community	X	X	X

*Note: High Point Medical Center's ambulatory facility will be on the same campus as the approved Greensboro Medical Center acute care facility on Horse Pen Creek Road that is projected to open in January 2029, project year 2 for the HPR fixed PET application.

As shown above, all three applicants propose to provide PET services for oncology, cardiology, and neurology, as described in their respective applications. The applications are therefore equally effective for the types of clinical applications the proposed PET scanner will perform. All three applicants also propose locating the PET scanner at an inpatient facility, and as such have similar abilities to deliver PET services to either admitted or ambulatory patients.

While all three applicants are hospitals that can offer inpatient-based as well as ambulatory hospital based care, only Moses Cone Hospital is a tertiary facility that can therefore offer a higher level of inpatient care than Novant Kernersville, a 63-bed community hospital, or the planned High Point Medical Center campus in Greensboro. That facility will have 36 acute care beds when it opens in 2029. In addition to ancillary and support services available at an acute care facility, Moses Cone Hospital is a Level 2 Trauma center and is a Joint Commission Certified Comprehensive Stroke Center, the top designation possible. Moses Cone Hospital can therefore provide comprehensive clinical care beyond inpatient and outpatient PET imaging services.

Geographic Accessibility

The *2025 SMFP* identifies a need for one fixed PET scanner in HSA II. Cone Health and AHWFB both propose to locate an additional PET scanner in Guilford County at a campus separate from the site of their existing PET scanners. Novant proposes locating a fixed PET scanner at its Kernersville facility in eastern Forsyth County, close to the border with Guilford County, where it currently operates a mobile PET scanner. Cone Health and the HPMC campus in Greensboro both represent an entirely new access point for PET services in Guilford County, an area relatively underrepresented for PET services, while Novant Kernersville offers PET services at its Forsyth County campus today. The following table shows the difference in fixed PET scanners per population for Forsyth and Guilford counties. Guilford has 2.8 times the average population per PET scanner compared to Forsyth County, underscoring the relative scarcity of PET imaging in Guilford County.

HSA II Fixed PET Scanners per Population, 2025

County	*PET Scanners*	*2025 Population*	*Population per Scanner*
Alamance	1	185,255	185,255
Forsyth	4	398,434	99,609
Guilford	2	560,760	280,380

Source: *2025 SMFP*; OSBM county population projections.

As outlined above, the Cone Health and HPR proposals both represent new sites of care for fixed PET services and are in a county that is relatively underserved for fixed PET resources. Therefore, Cone Health and HPR are more effective options for this factor, and the Novant application is less effective. However, the HPR application is non-conforming with multiple review criteria and therefore cannot be approved.

Historical Utilization

The table below represents Table 15F-1 from the *2025 SMFP* for HSA II. Generally, regarding this comparative factor, an existing provider with higher historical utilization rates is the more effective alternative based on an assumption that that provider has a greater need for the proposed fixed PET scanner in order to serve its projected patients.

Utilization of Existing Dedicated Fixed PET Scanners

	Planning Inventory	*2025 SMFP*	*Facility Deficit*
Alamance Regional Medical Center*	1	1,194	-
High Point Medical Center	1	1,401	-
Novant Forsyth Medical Center	2**	3,238	-
North Carolina Baptist Hospital	2	4,337	-
Moses H. Cone Memorial Hospital*	1	3,784	1
HSA II Total	**7**		**1**

Source: *2025 SMFP*.

*Cone Health facility. Moses H. Cone Memorial Hospital has two acute care campuses; Moses Cone Hospital and Wesley Long Hospital, the location of its fixed PET scanner.

**Novant Health Forsyth began operation of its second fixed PET scanner on May 12, 2025.

Cone Health's Moses H. Cone Memorial Hospital, NH Forsyth Medical Center, and High Point Medical Center are all existing providers of fixed PET services within HSA II. Cone Health performed 3,784 PET procedures in FFY 2023 compared to just 3,238 performed by NHFMC and 1,401 by High Point Medical Center. On a per scanner basis, Cone Health performed 3,784 per fixed scanner, the most of any of the three applicants. While Novant had the second-highest number of PET scans per unit in FFY 2024, when the approved second scanner that began operation in May 2025 is added to Novant's inventory it would equate to 1,619 PET scans per unit, indicating that Novant has significant capacity for future growth. The High Point Medical Center PET scanner performed 1,401 procedures in FFY 2023 according to *SMFP* data.

As previously discussed, the need determination for an additional fixed PET scanner in HSA II was generated by Moses H. Cone Memorial Hospital. The Moses Cone facility was the only one in the HSA to have a deficit, based on the *SMFP* methodology. Moses H. Cone Memorial Hospital performed more fixed PET procedures than NHFMC or High Point Medical Center. Thus, with regard to historical utilization, the Cone Health application is more effective and the Novant and AHWFB applications are less effective.

Competition

Generally, the application proposing to increase competition in the service area is the more effective alternative regarding this comparative factor. The introduction of a new provider in the service area would be the most effective alternative. However, none of the applicants in this competitive review represents a new provider.

Novant is an existing provider and proposes to develop its project in Forsyth County. It currently operates fixed PET services at its Winston-Salem campus and has a mobile PET scanner at its Kernersville facility. In the 2023 HSA III PET review, Novant was awarded a second fixed PET scanner at NHFMC that began operation in May 2025.

High Point Medical Center is an existing fixed PET provider in Guilford County and proposes to develop a second fixed PET scanner at its Greensboro campus. If approved, the proposed PET scanner would be High Point Medical Center's second fixed PET unit and the fourth in HSA II for AHWFB.

Cone Health is an existing provider in Guilford County and proposes developing its project at the Moses H. Cone Memorial Hospital campus in Guilford County. It currently operates one fixed PET scanner at a different hospital campus, Wesley Long Hospital in Greensboro.

Cone Health, HPR, and Novant are all existing, mature, and well-established PET service providers in HSA II. As such, none of the applicants would qualify as a "new or alternative provider" under the Agency's historical reasoning of the "Competition (Patient Access to a New or Alternative Provider)" comparative factor in competitive reviews over the last decade. For these reasons, all three applications are equally effective in terms of competition.

Access by Service Area Residents

In most previous PET Findings, the Agency has regularly found this comparative factor to be inconclusive. For the 2023 HSA II review, the analyst concluded that the Access by Service Area Residents factor was inconclusive because two applicants, Novant and Cone Health, included an "Other" category in their patient origin projections that made it impossible to calculate the total number of patients from within the service area. Consistent with these findings, the Agency should find this comparative factor to be inconclusive for this competitive review. Both HPR and Cone Health include an "Other" category in their patient origin projections that includes undefined numbers of patients from counties in HSA II, preventing the calculation of accurate totals.[16] In addition, both Cone Health and High Point Medical Center show patient origin projections for the entire facility license, meaning that the patient origin tables include the applicants' existing PET scanners as well as the proposed scanner. Without this facility-specific breakout of patient origin, it is not possible to compare the applicants' effectiveness on this factor for the proposed projects.

Access by Underserved Groups

Projected Medicare

In the 2023 HSA II PET Review, the Agency conducted its analysis of Medicare and Medicaid factors using similar measures. For Medicare patients, the Agency compared the total number of Medicare patients as a percentage of total patients in the third full fiscal year of operations. Generally, the application proposing the highest number of Medicare patients as a percentage of total patients is the more effective alternative with regard to this comparative factor. The Agency performed the same analysis for Medicaid.

Medicare Patients as a Percent of Total PET Patients, PY3

[16] See the responses to C.3 in the respective applications.

	Cone Health	Novant Kernersville	High Point Medical Center
Total PET Patients	5,682	2,202	4,263
% of Medicare Patients	68.5%	68.2%	65.3%
Medicare Patients	3,892	1,502	2,784

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

As shown in the table above, Cone Health has the highest percentage of Medicare patients, with this payor class accounting for 68.5 percent of the total. Cone Health is therefore the most effective applicant using this measure.

Projected Medicaid

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

Medicaid Patients as a Percent of Total PET Patients, PY3

	Cone Health	Novant Kernersville	High Point Medical Center
Total PET Patients	5,682	2,202	4,263
% of Medicaid Patients	5.5%	3.8%	7.6%
Medicaid Patients	313	84	324

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

As shown in the table above, High Point Medical Center projects that 7.6 percent of all PET patients will be Medicaid patients in Project Year 3. However, the High Point application states that "the PET service payor mix through the initial three project years [is] based on HPMC's most recent historical CY2024 PET service payor mix."[17] High Point Medical Center does not differentiate the payor mix for its existing facility in High Point compared to its proposed facility on Horse Pen Creek Road northwest of Greensboro. There is a wide disparity in income and economic levels for the ZIP code where the existing HPMC facility operates compared to the Summerfield ZIP code near where High Point Medical Center is developing its new campus. For example, the percentage of uninsured residents is more than twice as high in the High Point ZIP code, while the percentage of persons in poverty is 90 percent lower in Summerfield than in High Point. The two communities therefore have vastly different characteristics that make it unreasonable for High Point Medical Center to apply the same payor mix to both facilities.

Demographic Comparison of High Point Medical Center Home ZIP Codes

	HPMC High Point	HPMC Greensboro
ZIP Code	27262	27358
Percent Uninsured	13.5%	5.6%
% of Population in Labor Force	61.8%	64.9%
Income Per Capita	$34,492	$67,127

[17] See High Point Medical Center application, p. 117.

	HPMC High Point	*HPMC Greensboro*
Median Value of Owner-Occupied Housing Units	$212,400	$490,100
Persons in Poverty (%)	14.7%	7.7%

Source: U.S. Census Quickfacts.

Based on this information, the Medicaid payor mix percentage shown in the HPR application is inconclusive and cannot be compared with the other applications. Of the two remaining applications, Cone Health has a higher percentage of Medicaid patients and is therefore more effective.

Average Net Revenue per Procedure

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

Average Net Revenue per PET Procedure, PY3

	Total Net Revenue	*# of Procedures*	*Total Net Revenue per Procedure*
Cone Health	$22,625,469	5,682	$3,982
Novant Kernersville	$6,511,593	2,202	$2,957
High Point Medical Center	$7,067,670	4,263	$1,658

Source: Form C.2, Form F.2b.

As shown in the table above, High Point Medical Center has the lowest average net revenue per PET procedure in the third full fiscal year following project completion, while Cone Health has the highest. Therefore, the application submitted by High Point Medical Center would be more effective regarding this comparative factor. However, as discussed earlier, volume assumptions in both the AHWFB and Novant applications are flawed and result in overstated utilization projections. These calculations are therefore inconclusive due to the direct effect of PET volume on this factor. This factor also does not account for the specific types of PET scans being performed; differences in anatomical location and use of various radiotracers specific to each type of scan prevent accurate comparisons of revenue per unit. Furthermore, the AHWFB and Novant applications are non-conforming with multiple review criteria and therefore cannot be approved. Cone Health, therefore, is the more effective applicant.

Average Operating Expense per Procedure

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

Average Operating Expense per PET Procedure, PY3

	Total Operating Costs	*# of Procedures*	*Total Operating Costs per Procedure*
Cone Health	$13,303,650	5,682	$2,341
Novant Kernersville	$2,982,491	2,202	$1,354

	Total Operating Costs	*# of Procedures*	*Total Operating Costs per Procedure*
High Point Medical Center	4,830,905	4,263	$1,133

Source: Form C.2, Form F.2b.

As shown in the table above, High Point Medical Center projects the lowest average operating cost per PET procedure in the third full fiscal year following project completion. The application submitted by High Point Medical Center would be the more effective alternative regarding this comparative factor. However, as discussed earlier, volume assumptions in both the AHWFB and Novant applications are flawed and result in overstated utilization projections. These calculations are therefore inconclusive due to the direct effect of PET volume on this factor. This factor also does not account for the specific types of PET scans being performed; differences in anatomical location and use of various radiotracers specific to each type of scan prevent accurate comparisons of operating costs per unit. Furthermore, the HPR and Novant applications are both non-conforming with multiple review criteria and therefore cannot be approved. Cone Health, therefore, is the more effective applicant.

SUMMARY

In summary, the Novant Kernersville and AHWFB fixed PET applications are not conforming to all applicable statutory review criteria, nor do they demonstrate they meet the performance standards in Project Year 3. The Novant and AHWFB applications are therefore not approvable. Even if these applications were approvable, Cone Health believes that its application is the most effective alternative for the fixed PET scanner need determination in HSA II. The Cone Health fixed PET application is fully conforming with all applicable statutory and regulatory review criteria and is comparatively superior on many relevant factors in this review. The need determination for an additional fixed PET scanner in HSA II was generated by Moses H. Cone Memorial Hospital. Additionally, the Moses Cone facility was the only one in the HSA to have a deficit, based on the *SMFP* methodology. As such, the application submitted by Cone Health should be approved.

Please note that in no way does Cone Health intend for these comments to change or amend its application that was filed on June 15, 2025. If the Agency considers any statements to be amending the Cone Health application, those comments should not be considered.