WRITTEN COMMENTS ON 2025 HEALTH SERVICE AREA II
FIXED PET SCANNER COMPETITIVE REVIEW

SUBMITTED BY NOVANT HEALTH KERNERSVILLE MEDICAL CENTER

JULY 31, 2025

INTRODUCTION

The 2025 State Medical Facilities Plan (SMFP) identified a need for one fixed PET/CT scanner in Health Service II (HSA II). In response to the need determination, three applicants have submitted Certificate of Need applications but only one applicant can be approved. Applications were submitted by the following providers:

Project ID No.	Applicant	Referred to As
G-12653-25	Novant Health Kernersville Medical Center	NHKMC
G-12657-25	Atrium Health High Point Regional Health System	Atrium Health
G-12650-25	Cone Health Moses Cone Hospital	Cone Health

Pursuant to N.C. Gen. Stat. § 131E-185(a)(1), Novant Health Kernersville Medical Center ("NHKMC") submits the following comments pertaining to the applications filed by Atrium Health and Cone Health to acquire a fixed PET/CT scanner in HSA II as identified in the 2025 SMFP. NHKMC provides a comparative analysis of the applications followed by comments on individual applications. Other non-conformities may exist in the Atrium Health and Cone Health applications and NHKMC may develop additional opinions, as appropriate upon further review and analysis. The Cone Health application is also non-conforming with Criterion (3) and other CON criteria and cannot be approved. NHKMC will discuss these issues in greater detail below, following its discussion of the comparative analysis. See page 122 of the Cone Health application.[1] Thus, the Cone Health application is also non-conforming with Criterion (3) and other CON criteria and cannot be approved. NHKMC will discuss these issues in greater detail below, following its discussion of the comparative analysis. Nothing in these comments is intended to amend any statement in the NHKMC application; to the extent the Agency deems any comment an amendment to the NHKMC application, NHKMC respectfully asks the Agency to disregard the comment.

[1]On July 29, 2025, Lisa Pittman, the Assistant Chief of the CON Section, testified at her deposition in 25 DHR 01148 that the Atrium Health Pineville application in the 2024 HSA PET scanner review should have been found nonconforming with the performance standard at 10A NCAC 14C.3703(a)(7) because its existing PET scanner at Atrium Health Union was only projected to perform 1,913 scans in PY 3. The same is true for Cone Health's scanner at ARMC, which is projected to perform only 1,868 scans in PY 3. See Attachment.

In this competitive review, only one applicant can be approved. An approved applicant must demonstrate not only that it is conforming to all applicable statutory and regulatory review criteria but also comparatively superior to the other applicants.

The only applicant that conforms to all statutory and regulatory review criteria is NHKMC. The Atrium Health application relies on a series of unreasonable and unsupported assumptions, as well as understated revenues and expenses. Accordingly, Atrium Health is non-conforming with multiple CON criteria, including Criterion (3), and cannot be approved. The Cone Health application not only suffers from unreasonable and unsupported assumptions but also fails to meet the performance standard in 10A NCAC 14C.3703(a)(7) of 2,080 scans per PET scanner in Project Year 3. Its existing PET scanner at Alamance Regional Medical Center (ARMC) is projected to reach only 1,868 scans in Project Year 3. *See* page 122 of the Cone Health application. Thus, the Cone Health application is also non-conforming with Criterion (3) and other CON criteria and cannot be approved. NHKMC will discuss these issues in greater detail below, following its discussion of the comparative analysis.

COMPARATIVE ANALYSIS OF THE COMPETING FIXED PET SCANNER APPLICATIONS

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

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

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

Conformity to CON Review Criteria

Three CON applications have been submitted to develop a fixed PET scanner in Health Service Area II. Based on the 2025 SMFP's need determination, only one fixed PET scanner can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by NHKMC demonstrates conformity to all statutory and regulatory review criteria.

Conformity of Applicants

Applicant	Project I.D.	Conforming with All Applicable Statutory & Regulatory Review Criteria
Novant Health Kernersville Medical Center	G-12653-25	**Yes**
Atrium Health High Point	G-12657-25	No
Cone Health MCH	G-12650-25	No

The NHKMC application is based upon reasonable and supported volume projections and reasonable projections of cost and revenues. As discussed separately in this document, the Atrium Health and Cone Health applications contain errors and flaws which result in one or more non-conformities with statutory and regulatory review criteria. NHKMC particularly emphasizes the fact that the Cone Health proposal does not meet the performance standard in 10A NCAC 14C.3703(a)(7) because its scanner at ARMC is projected to reach only 1,868 scans in Project Year 3. *See* page 122 of the Cone Health application. Therefore, the **NHKMC** application is the **most effective** alternative regarding conformity with applicable review Criteria.

Competition

Competition in the healthcare marketplace is a key factor in Certificate of Need reviews. In this review, all three applicants currently offer fixed PET services in HSA II. Atrium Health controls 3 fixed PET scanners or 42.8% of the existing seven fixed PET scanners in HSA II. Cone Health operates two fixed PET scanners, or 28.5% each of the available fixed PETs. Novant Health also operates two fixed PET scanners in HSA II, or 28.5% of the available fixed PET scanners. Atrium and Cone Health both operate the two underutilized fixed PET scanners in the service area. Cone Health's fixed PET scanner at Alamance Regional performed only 1,194 scans in FY 2023-24 as reported in the Draft 2026 SMFP. This represents a 39.8% utilization level at Alamance. At Atrium High Point Regional, the fixed PET scanner performed only 1,401 procedures during the same time period for a utilization rate of 46.7%. Novant Health's second fixed PET scanner was operational as of May 2025 and is already performing 10-12 procedures per day.

From a competitive point of view, Novant Health stands out from the other applicants by highly utilizing its existing fixed PET resources. Novant Health is the only applicant that has provided mobile PET services at the proposed location as further support for the demand for the proposed project. Novant Health is the only applicant that has clearly demonstrated the need for the proposed project and the positive impact on competition in the service area.

Competition among providers is meant to elevate patient experience through reduced prices, improved service and positive outcomes. The approval of either Atrium or Cone Health in this service area will not enhance competition and could result in ongoing underutilization of existing resources. The most effective way to enhance competition in HSA II is to introduce a new provider of fixed PET services at Novant Health Kernersville Medical Center. The approval of Novant's project would benefit residents

by offering a new location for fixed PET services at a facility that has a proven demand for PET services. Thus, the **NHKMC** application is the **most effective** alternative with respect to competition.

Scope of Services

Regarding scope of services, the competing applications are each responsive to the 2025 SMFP need determination in HSA II for one fixed PET scanner. The following table compares the scope of services offered by each applicant. Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor.

Scope of Services

Facility	Proposed Scope of Services		
	Oncological PET	Neurologic PET	Cardiac PET
Novant Health Kernersville Medical Center	X	X	X
Atrium Health	X	X	X
Cone Health	X	X	X

Source: CON applications

NHKMC is an existing provider of mobile PET services and proposes developing a hospital-based fixed PET scanner that will provide a wide range of access for HSA II residents. Atrium Health proposes to develop one fixed PET scanner at a new location in Greensboro. All three applicants propose to offer oncological, neurological, and cardiac PET scans. However, due to the unreasonably low pharmacy expenses discussed under Review Criterion (5), it is questionable whether Atrium Health will be able to provide the full range of services. At the opposite end of the spectrum, Cone Health intends to focus *primarily* on cardiac PET imaging but did not fully demonstrate the need for a full-time fixed PET scanner for the provision of cardiac PET imaging. In Novant Health's experience operating six fixed PET scanners across North Carolina, more than 90% of PET imaging is performed on oncology patients. Only the NHKMC application fully accounts for all relevant costs, including the costs for pharmaceuticals used in cardiac PET. Only the NHKMC proposes an appropriate and realistic mix of oncological, neurological and cardiac PET scans. Therefore, the NHKMC application is a **more effective alternative** regarding scope of services.

Historical Utilization

In other competitive reviews, the Agency has assessed historical utilization among the competing applicants. NHKMC is part of Novant Health, which operates two (2) fixed PET scanners in HSA II located at NHFMC in Winston-Salem. The second fixed PET scanner at NHFMC became operational in May 2025. Atrium Health High Point Regional Health System is part of Atrium Health, which operates three (3) of the seven existing fixed PET scanners in HSA II. The following summarizes FY2024 utilization data for Novant Health, Atrium Health and Cone Health from the proposed 2026 SMFP.

Health System	PET Scanner Planning Inventory	FFY2024 Procedures	PET Scans/Unit	PET Utilization Rate*
Novant Health	1 existing^	3,238	3,238	108%
Atrium Health	3 existing	5,738	1,913	63.7%
Cone Health	2 existing	4,958	2,479[2]	82.6%

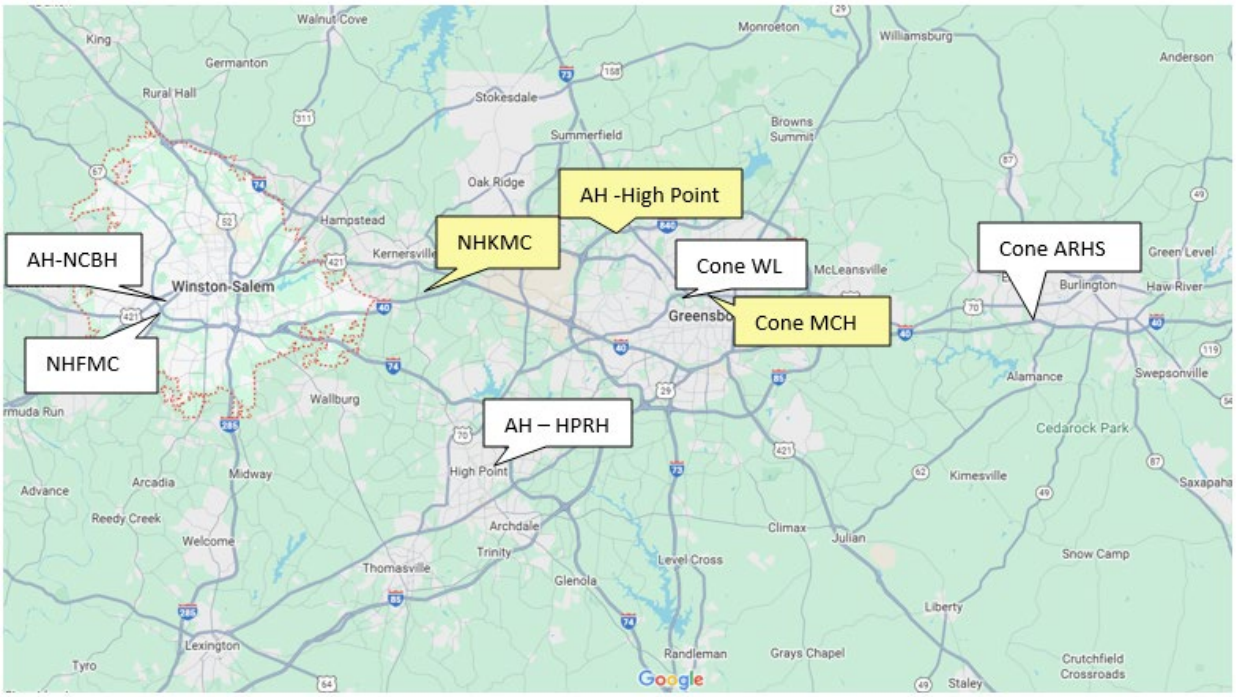
*Based on a fixed PET scanner capacity of 3,000 procedures per unit.
Source: Proposed 2026 SMFP, Table 15F-1: Utilization of Existing Dedicated Fixed PET Scanners
^ Novant Health was approved for a new fixed PET in 2023. The second fixed PET scanner was operational as of May 2025, after the FFY 2024 reporting period.

Novant Health's single fixed PET scanner was utilized at 108% capacity during FFY2024. NHFMC's second fixed PET scanner is in operation and is performing a minimum of 10- PET scans per day. See NHKMC, Section Q page 9. Atrium Health's fixed PET scanners were utilized at 63.7% capacity during FFY2024. Cone Health's fixed PET scanners in Greensboro and Burlington are operating at a total of 82.6% utilization. In addition, NHKMC is the only applicant that currently offers PET services at the proposed location for the new fixed PET scanner. As a mobile host site, NHKMC performed 645 PET scans during FFY 2024. Therefore, based on a comparison of historical fixed PET utilization, **NHKMC** is the **most effective** alternative regarding this factor.

Geographic Accessibility

Health Service Area II, centrally located in North Carolina, is a destination for people in need of advanced medical care. Forsyth, Guilford, and Alamance Counties are the current locations for the existing seven fixed PET scanners in HSA II. The proposed locations for the new fixed PET scanner in HSA II are highlighted in yellow in the following map.

[2] On page 122of the Cone Health application, Cone expressly states that the PET scanner at ARMC will only reach 1,868 scans in Project Year 3. Accordingly, the Cone Health application does not meet the performance standard in 10A NCAC 14C.3703(a)(7).



In HSA II, existing fixed PET scanners are located in Burlington, High Point, Greensboro and Winston-Salem. In Alamance County, Cone Health operates a fixed PET scanner at ARMC. In Guilford County, Cone Health currently operates one fixed PET scanner in Greensboro. Cone Health proposes a new fixed PET scanner at Moses Cone Hospital less than one mile from the existing fixed PET at Wesley Long. Atrium Health High Point Regional Hospital operates one fixed PET scanner in Guilford County. Atrium proposes a fixed PET scanner in a newly developed site in northern Greensboro. Atrium is proposing to develop the fixed PET scanner at an approved but not operational acute care facility in Greensboro. In addition to not having any track record of providing any services, let alone PET, the complexity of adding a fixed PET scanner to an undeveloped hospital may encounter delays. In Forsyth County, Atrium Health Wake Forest Baptist Hospital currently operates two fixed PET scanners. Novant Health Forsyth Medical Center operates two fixed PET scanners. Novant Heath Kernersville Medical Center proposes a new fixed PET scanner at the hospital campus on the border of Forsyth and Guilford Counties. There is no fixed PET scanner in Kernersville at the present time. The three proposed locations for the new fixed PET scanners are within a twenty-mile radius of one another.

Both Cone and Atrium Health argue that Guilford County needs an additional fixed PET scanner primarily based on the number of residents. While Guilford County is larger than Forsyth County by resident count, the number of physicians in Forsyth County greatly outnumber the availability of Guilford County physicians. Furthermore, the overall growth in the number of physicians is higher in Forsyth County than in Guilford County.

Total Number of Physicians – All Specialties			
County	**2022**	**2023**	**2024**
Forsyth	**2178**	**2238**	**2347**
Percent Change	**---**	**2.75%**	**4.87%**
Guilford	1414	1471	1475
Percent Change	---	4.0%	0.27%

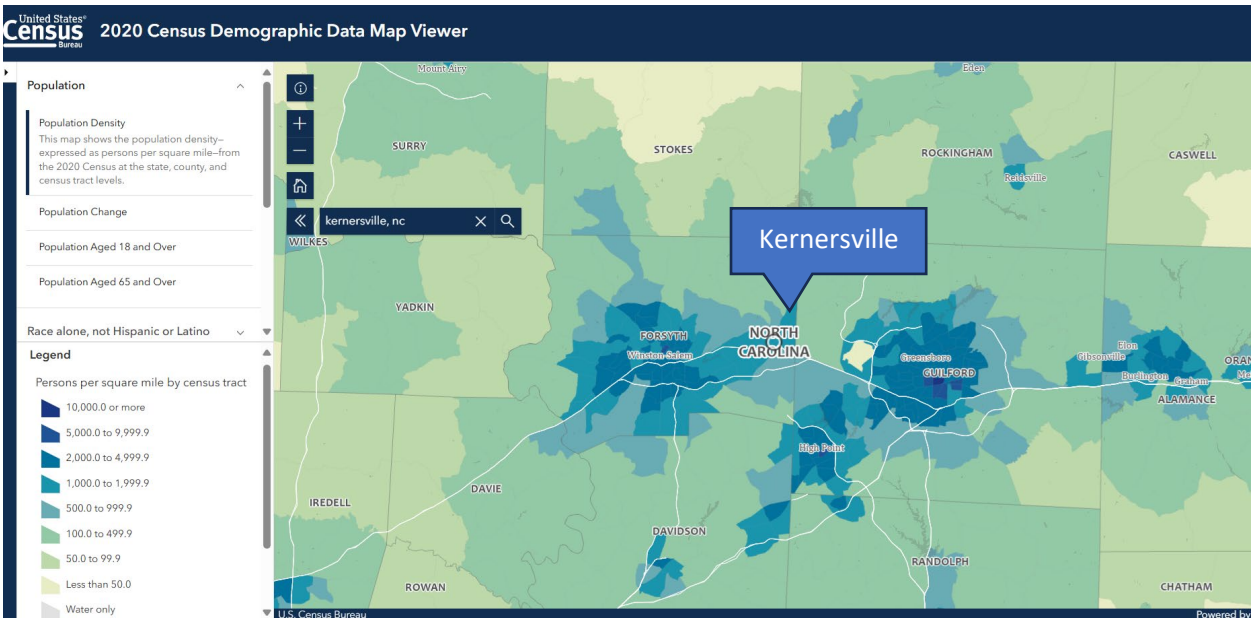
Source: Cecil B Sheps Center, UNC https://nchealthworkforce.unc.edu/downloaddata/

Cone Health, on page 56 of its CON application makes the following statement:

> Moreover, PET imaging requires robust referral networks from multiple specialties. Guilford County, anchored by Greensboro, hosts the largest concentration of specialty physicians in HSA II outside of Winston-Salem, including comprehensive cardiology, oncology, and neurology practices that generate the majority of PET referrals.

Novant would agree with Cone Health that PET imaging requires robust referral networks. Not only does Forsyth County have significantly higher numbers of physicians, Forsyth County continues to experience growth in the number of physicians. The same cannot be said for Guilford County.

Considering the substantial network of physicians in Forsyth County, it makes sense that residents of HSA II seek specialized healthcare services, like PET imaging, in Forsyth County. NHKMC is the only applicant proposing a location in Kernersville, which is mostly located in Forsyth County and a small portion in Guilford County[3]. Population data indicates that Kernersville is one of the fastest growing municipalities in the area. According to the OBSM, Kernersville's population increased by 5.1% while Winston-Salem grew by 2.3% and Greensboro increased by 1.2%.



[3] https://toknc.com/finance/tax-info/ (Guilford County also collects taxes in Kernersville).

The higher population growth rate is reflective of Kernersville's convenient location between Winston-Salem and Greensboro, while offering more affordable living. As the map above shows, the number of residents choosing to live and work in the Kernersville area continues to increase. From Kernersville, Winston-Salem is approximately 10 miles away and Greensboro is less than 15 miles. NHKMC's convenient location right off of Interstate 40 between both cities creates an opportunity for Novant to enhance accessibility for both Forsyth and Guilford County patients. Unlike Atrium Health and Cone that do not have historical operating experience at each proposed location for PET services, NHKMC has offered mobile PET services which are in high demand. This provides reasonable assurance that NHKMC will operate a successful fixed PET program. Further, NHKMC has provided over 140 letters of support from local healthcare providers for its proposed project. This level of support is definitive statement in favor of the Novant project to bring fixed PET services to Kernersville for HSA II residents.

Kernersville is called the "Heart of the Triad" for a reason.[4] It is centrally located between the three major cities of the Triad: Greensboro, High Point and Winston-Salem. NHKMC attracts patients from all three cities, and other municipalities in the area. The growth of NHKMC since its opening in 2011[5] is indicative of how strongly the Triad has embraced NHKMC as a health care hub – it offers first class, highly sophisticated care but without some of the downsides associated with larger medical centers such as complicated parking and way finding. NHKMC is at the stage of its life cycle where it should have a full-time fixed PET scanner to meet the growing needs of the population who count on NHKMC for their health care needs.

The NHKMC application also proposes fixed PET services at a location in HSA II that does not have fixed PET services. Atrium Health and Cone, by contrast, are simply proposing to add more PET resources to Greensboro, which is already well served by fixed PET services. In terms of geographic accessibility, the NHKMC application is the most effective alternative.

Access by Service Area Residents

The 2025 SMFP defines the service area for a fixed PET scanner as "the HSA [Health Service Area] in which it is located (Table 15F-1)." Thus, the service area for this review is HSA II. The counties in HSA II include: Alamance, Caswell, Davidson, Davie, Forsyth, Guilford, Randolph, Rockingham, Stokes, Surry and Yadkin Counties.

Applicant	Total Patient Origin – HSA II Counties	Patient Origin – Other Counties
NHKMC	95%	5%
Atrium Health	96%	4%
Cone Health	92%	8%

Source: Section C, Question 3 for each application.

[4] https://toknc.com/.

[5] Examples of growth at NHKMC since 2011 include the opening of two medical office buildings (2013 and 2017); radiation oncology as of 2011 with a linear accelerator replaced in 2021; establishing the metabolic and bariatric surgery program (2014); opening NH Kernersville Outpatient Surgery Center (2018); adding robotic surgery and tele-ICU capabilities (2020); adding a Heart and Vascular Institute procedural lab (2023); and adding comprehensive maternity services (2024)

Regarding access by service area residents, Cone Health is the less effective alternative, and NHKMC and Atrium Health are equally effective alternatives. However, since Atrium Health's application is not approvable, the Agency should find that NHKMC's proposal is the most effective alternative.

Access By Underserved Groups

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

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

For access by underserved groups, the applications are compared concerning two underserved groups: Medicare patients, and Medicaid patients.[6] Access by each group is treated as a separate factor. The Agency may use one or more of the following metrics to compare the applications:

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

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

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

Access by Medicare Patients

The applicants with existing PET services utilized their historical data to project the percentage of Medicare patients for each proposed project. The following chart provides the Medicare percentage in Project Year 3 for each applicant.

Applicant	% Medicare Patients for PET Service – PY 3
NHKMC	68.2%
AH	65.3%

[6] Due to differences in definitions of charity care among applicants, comparisons of charity care are inconclusive.

Cone	68.5%

Source: CON applications for each applicant, Section L.

NHKMC and Cone Health are the most effective alternatives related to the provision of Medicare services. Atrium Health is the less effective alternative related to Medicare services. However, the Cone Health application is not approvable, so the Agency should conclude that the NHKMC application is the most effective alternative with respect to this comparative factor.

Access by Medicaid Patients

The applicants with existing PET services utilized their historical data to project the percentage of Medicaid patients for each proposed project. The following chart provides the Medicaid percentage in Project Year 3 for each applicant.

Applicant	% Medicaid Patients for PET Service – PY 3
NHKMC	3.8%
AH	7.6%
Cone	5.5%

Source: CON applications for each applicant, Section L

As shown in the previous table, Atrium Health projects a higher percentage of Medicaid gross revenue per PET scan procedure in the third full fiscal year following project completion. However, as will be described in the application specific comments, the Atrium Health application fails to demonstrate that its projected utilization, revenues, and expenses are based on reasonable and adequately supported assumptions. Therefore, the Atrium Health application cannot be the most effective alternative. Similarly, the Cone Health application is not approvable, so the Agency should conclude that the NHKMC application is the most effective alternative with respect to this comparative factor.

Projected Average Net Revenue/Scan

The projected average net revenue per scan is a comparative factor typically used by the Agency. The following chart compares the average net revenue per scan for each applicant in Project Year 3.

Applicant	Project Year 3 - Net Revenue	Project Year 3 - # of PET Procedures	Project Year 3 Projected Average Net Revenue Per PET Procedure
NHKMC	$6,511,593	2,202	$2,957
Atrium Health	$7,067,670	4,263	$1,658
Cone Health	$22,625,469	5,682	$3,982

Source: Financial Pro Formas for each applicant.

Atrium Health is non-conforming with all applicable statutory review criteria and therefore cannot be considered the most effective alternative. As an applicant fully conforming with all statutory review criteria, NHKMC is the most effective alternative regarding net revenue per scan in this review.

Projected Average Operating Expense/Scan

The following table presents the projected average operating expense per scan for the third year of operation for the applicants based on the information provided in Form C and Form F.3 of each application.

Applicant	Project Year 3 – Operating Expenses	Project Year 3 - # of PET Procedures	Project Year 3 Projected Average Operating Expense Per PET Procedure
NHKMC	$2,982,491	2,202	$1,354
Atrium Health	$4,830,905	4,263	$1,133
Cone Health	$13,303,650	5,682	$2,341

Source: Financial Pro Formas for each applicant.

As an applicant fully conforming with all statutory review criteria, NHKMC is the most effective alternative regarding operating expense per scan in this review.

As will be detailed in the application specific comments, Atrium Health has failed to demonstrate that its proposed operating expenses account for all necessary expenses and should be found non-conforming with Criterion (5).

As shown in the previous table, Atrium Health projects a lower average operating expense per PET scan procedure in the third full fiscal year following project completion than either Cone Health or NHKMC. However, as discussed in the application-specific comments, the Atrium Health application fails to demonstrate that its projected utilization, revenues, and expenses are based on reasonable and adequately supported assumptions standing alone.

NHKMC has accurately accounted for all necessary operating expenses in its financial proformas allowing it to provide a wide range of PET imaging services for oncology, cardiology and neurology patients. In PY 3, NHKMC estimates that its pharmacy expense alone will be $1,843,150 or $837 per scan. In contrast, Atrium Health has an estimated pharmacy expense of $1,651,924 in PY 3, which equates to $387 per scan. This is unreasonably low.

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

Radiopharmaceutical:	Cost per dose:	Used for:
Fludeoxyglucose F-18 (FDG)	$115.00	Cancer
Pylarify	$3917.01	Prostate Cancer (PSMA)
Illuccix	$3525	Prostate Cancer (PSMA)
Cerianna	$4891.51	Breast Cancer
Detectnet	$4050.00	Neuroendocrine Cancer
Amyvid	$3029.00	Alzheimer's Disease

Source: Novant Health internal data

Notably, Atrium Health's average pharmacy expense per PET procedure is significantly lower than both NHKMC's average pharmacy expense per PET procedure and Cone Health's expense, as shown in the following table. This casts further doubt on the reasonableness of Atrium Health's average pharmacy expense per procedure.

	PET Procedures, YR 3	Pharm. Expense, YR 3	Avg. Pharm. Expense per Procedure, YR 3
Novant Health Kernersville Medical Center	2,202	$1,843,150	$837
Atrium Health	4,263	$1,651,924	$387
Cone Health	5,682	$8,066,226	$1,419

This difference reflects the higher cost of NHKMC's PET procedure mix, which includes more complex scans like cardiac PET that Atrium Health's proposal does not take into account in the financial pro formas although Atrium Health indicates it will perform these types of procedures. Therefore, NHKMC's higher average operating expense likely stems from a difference in PET procedure mix. Consequently, comparing average expenses per PET procedure without considering procedural complexity and radiopharmaceutical costs is inconclusive and potentially misleading. Accordingly, the Agency should find NHKMC's application as the most reasonable alternative regarding this factor based on its use of supported procedure mix and corresponding operating expenses.

Summary

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

- Conformity with Review Criteria
- Historical Utilization
- Competition
- Geographic Accessibility
- Access by Service Area Residents
- Access by Medicare Patients
- Projected Net Revenue per Procedure
- Projected Operating Expense per Procedure

The applications submitted by Atrium Health and Cone Health fail to conform with all applicable statutory and regulatory review criteria; thus, they cannot be approved. Based on the previous analysis and discussion, the application submitted by **NHKMC** is comparatively superior and should be approved in this competitive review.

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed PET scanners that can be approved by the Healthcare Planning and Certificate of Need Section. The applicants collectively propose to develop three fixed PET scanners in Health Service Area II. Based on the 2025 SMFP's need determination, only one fixed PET scanner can be approved.

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

Individual Comments Regarding Applications

Atrium Health High Point Regional Health System

The Atrium Health application is non-conforming with several review criteria and should be denied.

Criterion (3)

Atrium Health fails to provide reasonable assumptions regarding its projected fixed PET volume for the existing fixed PET scanner at High Point Regional Health and the proposed fixed PET at its new location in Greensboro. Atrium Health's existing fixed PET at HPRHS is the lowest performing PET scanner in HSA II operating at 19% capacity with a reported 583 scans in the 2025 SMFP. By CY 2030, Atrium Health projects that both the existing and proposed fixed PET scanners will perform a total of 4,263 scans for an increase of 631%. This is patently unreasonable.

Using its own "organic" projections, High Point would not generate sufficient demand for two fixed PET scanners to comply with the performance requirements of 2,080 scans per scanner (4,160 scans for two units). As shown on page 138 of the Atrium application, the projected volume utilizing a healthy 10.88% growth rate would fall short of the performance standard in Project Year 3.

High Point Medical Center
Projected Organic Growth PET Scanner Utilization, CY2026 - CY2030

	CY2026	CY2027	CY2028	CY2029	CY2030	5-YR CAGR
Organic Growth	2,398	2,659	2,948	3,269	3,625	10.88%

Totals may not foot due to rounding.

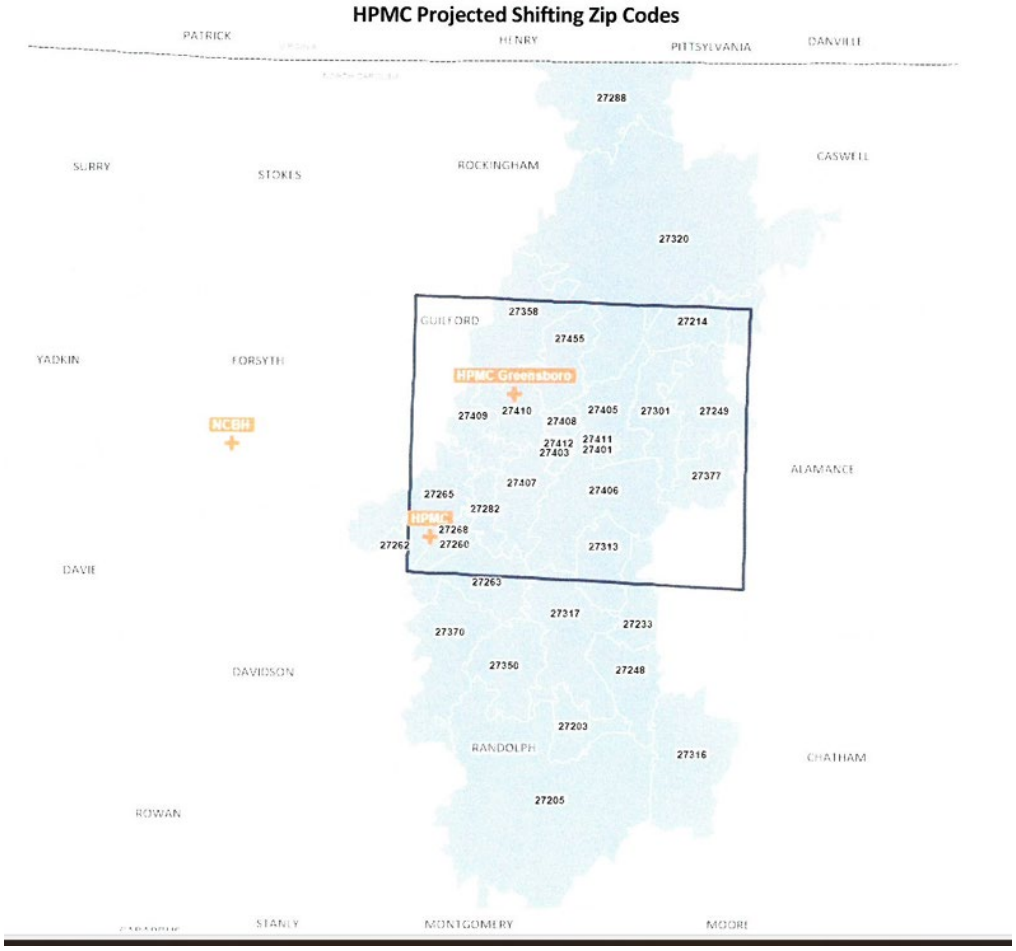
In order to meet the performance standards, Atrium Health relies on shifting patient volumes from Wake Forest Baptist Medical Center in Winston-Salem in order to achieve these lofty projections. Based on data from the draft 2026 SMFP for FY 2023-24, the fixed PET scanners at Wake Forest Baptist are operating at 72% utilization. Atrium provides elaborate zip code and patient origin data to outline the proposed "shift" to High Point. Atrium fails to explain why patients that currently seek specialized care at Wake Forest Baptist Medical Center would suddenly shift their care to High Point. This option is currently available to these patients as High Point has an underutilized fixed PET scanner and this shift has not occurred.

Atrium cites the following reasons for the patient shift:

- Capacity increase from the availability of an additional HPMC fixed PET scanner,
- convenient Greensboro location,
- reduced travel burden for local patients seeking PET services,
- more timely access to fixed PET services, and
- proximity to referring physicians located in Greensboro and Guilford County

Atrium provides the following map from page 136:

HPMC reasonably projects that, due to increased PET availability at HPMC, some NCBH PET patients will shift from obtaining a PET scan in Winston-Salem to utilizing the HPMC PET service through the initial three project years. Specifically, HPMC projects that some patients from geographically proximate zip codes in Guilford, Randolph and Rockingham counties will shift to HPMC. Please see the following zip code map which portrays these zip codes.



Atrium's logic does not add up. Atrium identifies patients from the zip codes identified above and lists as reasons they would shift away from Wake Forest Baptist Hospital to High Point Regional. The fixed PET scanner at High Point is operating at 46% utilization, which means it has plenty of capacity available at this time. Atrium also cites reduced travel burden and proximity to physicians in Guilford County. However, all of these patients identified are traveling to Wake Forest Baptist Hospital while High Point Regional located just south of Greensboro has struggled to perform more than 2,080 scans. A review of the fixed PET volume since 2013 clearly shows that High Point Regional has a chronically underutilized fixed PET scanner.

Time Period	High Point Regional – Fixed PET Volume
FY 2013-14	592
FY 2014-15	639
FY 2015-16	649
FY 2016-17	815
FY 2017-18	885
FY 2018-19	946
FY 2019-20	991
FY 2020-21	1,013
FY 2021-22	1,223
FY 2022-23	583
FY 2023-24	1,401

Source: 2019-Draft 2026 SMFPs.

Historical data for High Point Regional's fixed PET services indicate low use from service area residents as far back as 2013. Atrium fails to provide reasonable support and documentation that service area residents will significantly shift their utilization patterns and select services at High Point as well as the proposed location in north Guilford County. Atrium Health provides limited support for this increased convenience, only noting that most of its projected patient population is geographically closer to the proposed location. Convenience is *a* factor but obviously not the *only* factor to be considered when determining the reasonableness of proposed patient shifts. Clinical appropriateness must also be considered. A provider's location may be more convenient for a patient in the sense that it is closer to where the patient lives or works, but the provider's location may not be a clinically appropriate site for that patient. For example, does the provider's location have experience performing PET scans specific to the patient's diagnosis? Is the patient's clinical care team located at that site or at some other location? These and other factors can impact the clinical appropriateness of a location. Atrium Health fails to demonstrate that Atrium Health Greensboro would be a more clinically appropriate than Atrium Health High Point or that Atrium Health Greensboro would even be able to serve these patients. It should be noted that Atrium Health Greensboro is a yet to be opened hospital with no track record and no cancer program. Even though the PET scanner is proposed to be operational in July 2027, the hospital will not open until 2029. There is absolutely no way the Agency can be confident that Atrium Health's projections are reasonable.

Further, Atrium Health does not demonstrate that it will provide the scope of services that will allow it to serve the proposed shift of patients from Atrium Health High Point. While Atrium Health states that the proposed location in Greensboro will serve oncology patients, as well as patients from other specialties

such as neurology and cardiology, it fails to demonstrate that it will be able to do so. For example, there is no mention in Atrium Health's application that it can provide the necessary radiopharmaceuticals for the proposed PET procedure types.

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

Atrium Health has failed to demonstrate the need the population has for the proposed service and should be found non-conforming with Criterion (3).

Criterion (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.

Atrium Health has failed to demonstrate that the least costly or most effective alternative has been proposed for this project. Atrium Health relies heavily on shifting patients from Atrium Health Wake Forest Baptist in order to meet the required scan volume for Project Year 3. This represents unnecessary duplication of existing resources. Further, Atrium Health has underutilized fixed PET scanners at Atrium Health Wake Forest and Atrium Health High Point that could be more effectively utilized. Atrium Health's proposal will not effectively serve HSA II residents and should be found nonconforming with Criterion (4).

Criterion (5)

Financial 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 upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

It is unclear whether Atrium Health has accurately accounted for all necessary operating expenses for the proposed project.

Net Revenue Per Procedure

It is unclear whether Atrium Health has accurately accounted for net revenue for the proposed project. As discussed in the Comparative Analysis, Atrium Health's projected net revenue per procedure is considerably lower than the other applicants. See the chart below:

Applicant	Project Year 3 - Net Revenue	Project Year 3 - # of PET Procedures	Project Year 3 Projected Average Net Revenue Per PET Procedure
NHKMC	$6,511,593	2,202	$2,957
Atrium Health	$7,067,670	4,263	$1,658
Cone Health	$22,625,469	5,682	$3,982

The projected net revenue for the Atrium Health project is more consistent with an applicant proposing nearly 100% Medicare service. But that is not what Atrium Health is proposing. For example, some of the most common PET CT scans are:

CPT Codes for PET Scans	*2025 Medicare Reimbursement Rates*
78814 – (PET CT) Tumor imaging limited	2025 CMS $1,421.44
78815 – (PET CT) Tumor imaging skull to mid-thigh	2025 CMS $1,424.38
78816 – (PET CT) Tumor imaging whole body	2025 CMS $1,427.58

This means that Atrium Health is utilizing one of the lowest reimbursement rates for the entirety of its scan volume As discussed below, Atrium Health projected that more than 22.4% of scans would be performed on insurance patients. Based on its projected scan volume for Project Year 3, this would impact the revenue for over 955 scans. In reality, commercial insurance reimbursement rates are higher than those of Medicare. This means that Atrium Health understated its actual net revenue for the proposed project.

If Atrium Health utilized the lower reimbursement rate for all services, this means the total net revenue for the project is understated. If the overall net revenue for the project is understated, it lowers the average net revenue per scan for this applicant (a comparative review factor utilized by the Agency in comparative reviews). As a result, this applicant "appears" to be an effective alternative related to net revenue per scan due to the understated net revenues. But the reality is that Atrium Health has materially understated both its revenue and expenses in order to make itself look better in the comparative analysis. The Agency should see this tactic for what it is, and Atrium Health should be found non-conforming with Criterion (5).

Operating Expense per Procedure

Atrium Health has failed to demonstrate that its proposed operating expenses account for all necessary expenses and should be found non-conforming with Criterion (5).

The Atrium Health application fails to demonstrate that its projected utilization, revenues, and expenses are based on reasonable and adequately supported assumptions standing alone.

NHKMC has accurately accounted for all necessary operating expenses in its financial proformas allowing it to provide a wide range of PET imaging services for oncology, cardiology and neurology patients. In PY 3, NHKMC estimates that its pharmacy expense alone will be $1,843,150 or $837 per scan. In contrast, Atrium Health has an estimated pharmacy expense of $1,651,924 in PY 3, which equates to $387 per scan. This is unreasonably low.

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

Radiopharmaceutical:	Cost per dose:	Used for:
Fludeoxyglucose F-18 (FDG)	$115.00	Cancer
Pylarify	$3917.01	Prostate Cancer (PSMA)
Illuccix	$3525	Prostate Cancer (PSMA)
Cerianna	$4891.51	Breast Cancer
Detectnet	$4050.00	Neuroendocrine Cancer
Amyvid	$3029.00	Alzheimer's Disease

Source: Novant Health internal data

Notably, Atrium Health's average pharmacy expense per PET procedure is significantly lower than both NHKMC's average pharmacy expense per PET procedure and Cone Health's expense, as shown in the following table. This casts further doubt on the reasonableness of Atrium Health's average pharmacy expense per procedure.

	PET Procedures, YR 3	Pharm. Expense, YR 3	Avg. Pharm. Expense per Procedure, YR 3
Novant Health Kernersville Medical Center	2,202	$1,843,150	$837
Atrium Health	4,263	$1,651,924	$387
Cone Health	5,682	$8,066,226	$1,419

Atrium Health has failed to adequately account for all necessary operating expenses for the proposed project and should be found nonconforming with Criterion (5).

Criterion (6)

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

Atrium Health currently owns and operates three fixed PET scanners in HSA II. Atrium Health's existing fixed PET scanner at High Point Regional in Guilford County is underutilized. Data from the proposed 2026 SMFP indicates that fixed PET services at Atrium Health Wake Forest Baptist are operating at 72.28% and Atrium Health High Point at 46.7%.

II	2025 Need Determination		1	1	0	0.00%	-1	
	Alamance Regional Medical Center	1	0	1	1,194	39.80%	0	
	Atrium Health Wake Forest Baptist	2	0	2	4,337	72.28%	0	
	Atrium Health Wake Forest Baptist - High Point Medical Center	1	0	1	1,401	46.70%	0	
	Cone Health	1	0	1	3,764	125.47%	1	
	Novant Health Forsyth Medical Center	1	1	2	3,238	53.97%	0	
	HSA II Total	**6**	**2**	**8**	**13,934**		**0**	**0**

As discussed in Criterion (3), Atrium Health relies on numerous unreasonable and duplicative measures to project sufficient patient scan volume for its project. Atrium Health relies on shifting patients from

Wake Forest Baptist to justify the projected scan volume without supporting information that indicates such dramatic shifts would occur.

For these reasons in addition to any other reasons the Agency may discern, the Atrium Health application should be found non-conforming with Criterion (6).

Criterion 18(a)

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 Atrium Health proposal will not enhance competition or have a positive impact on cost effectiveness, quality or access to the services proposed. Atrium Health relies heavily on utilization of its proposed service by shifting patients to the new location from Wake Forest Baptist in Forsyth County. Atrium Health has failed to demonstrate that its proposed project is based on reasonably supported financial assumptions. Atrium Health continues to own and operate the majority of the existing fixed PET scanners in HSA II (3/7 or 43%). Approval of the Atrium Health application would increase Atrium Health's control to 50% (4/8). The approval of the Atrium Health application will not have a positive impact on competition in the service area.

The Atrium Health application should be found nonconforming with Criterion 18(a).

10A NCAC 14C.3703(a)(7)

> (7) project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.

As discussed under Criterion (3), Atrium Health relies heavily on patient shifting from NCBH. Atrium Health fails to demonstrate that patients will shift from Wake Forest Baptist in Forsyth County to Atrium Health Greensboro for fixed PET services. With a difference of just 51 scans between its Year 3 projections and the performance standard (2,131-2,080=51), the smallest variations in these assumptions will have a significant impact on the projected volume for the project.

Cone Health

The Cone Health application is non-conforming with several review criteria and should be denied.

Criterion (3)

Cone Health is non-conforming with the performance standard at 10A NCAC 14C.3707(a)(7). The rule requires that each PET scanner the applicant owns in the health service area as well as the proposed PET scanner, be projected to provide at least 2,080 PET scans in Project Year 3. As show on Table 8, page 122 of the Cone Health application, the PET scanner at ARMC falls well below this standard:

Table 8: Projected PET Scans at Cone Health Facilities in HSA II

				PY1	PY2	PY3
Facility	*CY24^*	*CY25*	*CY26^^*	*CY27*	*CY28*	*CY29*
Moses Cone Hospital License*	919	3,776	4,182	4,632	5,130	5,682
ARMC	336	1,371	1,481	1,600	1,729	1,868
HSA II Total	**1,255**	**5,147**	**5,664**	**6,232**	**6,859**	**7,550**
Fixed Scanners	2	2	3	3	3	3
Procedures Per Scanner	**628**	**2,574**	**1,888**	**2,077**	**2,286**	**2,517**

^October 1, 2024, to December 31, 2024
^^Proposed PET scanner operational October 1, 2026
*Includes Wesley Long Hospital and Moses Cone Hospital

An application that fails to meet the performance standard is necessarily non-conforming with Criterion (3) because it does not demonstrate the need the population has for the services proposed.

In addition, Cone Health fails to provide reasonable assumptions regarding its projected fixed PET volume for the existing fixed PET scanners at Wesley Long Hospital and ARMC, and the proposed fixed PET at Moses Cone Hospital in Greensboro. Based on data from the 2025 SMFP, Wesley Long performed 2,750 scans on its existing fixed PET scanner and Alamance Regional performed 702 scans on its fixed PET scanner. In total, Cone Health averaged only 1,726 scans per fixed PET scanner. By PY 3 (CY 2029), Cone anticipates performing 7,550 scans or an increase of 119%. This enormous increase is patently unreasonable.

Cone Health indicates that it has done everything possible from an operational standpoint to alleviate the backlog for PET scans at its facilities. Cone Health states the following on page 53:

> Furthermore, the high utilization of the PET scanner at Wesley Long Hospital has increased access challenges for patients. The PET scanner at Wesley Long is operating beyond its functional capacity and has created a three-month waiting period for patients to schedule a PET scan. This wait time existed prior to 2023 when Cone Health submitted an application for a PET scanner in HSA II, Project ID # G-012425-23. To mitigate these capacity concerns, service hours for PET have been extended significantly to allow for additional access. Hours at Wesley Long Hospital have been extended to 7:00 AM to 5:00 PM, Monday through Friday, and the PET service hours at ARMC have been extended to 8:00 AM to 5:00 PM, Monday through Friday. Despite these operational adjustments, significant wait times still persist and cannot be alleviated without an additional PET scanner.

It appears that Cone Health has "extended" its hours on Monday-Friday 7:00am-5:00pm. Assuming that Cone Health was not previously utilizing its fixed PET scanners during normal business hours, this could have been a major factor in delays for patients.

Cone Health's narrative regarding the need for the proposed project relies heavily on cardiac PET imaging. In Novant Health's experience operating four fixed and one mobile PET scanners across North Carolina, most PET scans are performed on oncology patients. Besides mentioning one clinical study and the creation of a new cardiac center at Alamance Regional, Cone Health does not correlate the need for a fixed PET scanner at MCH to serve cardiac patients. Assuming there is a demand for cardiac PET imaging at Alamance Regional Hospital, its fixed PET scanner has ample capacity to address the demand (which Cone Health does not specifically quantify in its application).

> Cone Health has worked diligently to mitigate these capacity constraints to provide high-quality access to imaging and expand the use of PET as a superior alternative to SPECT imaging for cardiac patients and cardiac catheterization. Despite operational adjustments including extended service hours, Wesley Long continues to experience a three-month patient backlog, demonstrating that demand has exceeded the scanner's ability to provide timely access.
>
> As previously stated, the proposed PET scanner will not perform cardiovascular PET scans exclusively. As the fixed PET scanner at Wesley Long Hospital continues to experience high volumes, the proposed PET scanner can both provide ready access to PET services for cardiac patients at MCH, while also decanting some of the oncological and neurological PET volume at Wesley Long, thereby reducing wait times for all patients in need of this expanding diagnostic and treatment tool.

Despite Cone Health's assertions regarding capacity constraints, there seem to be reasonable concerns about the operational efficiencies of the facilities. By PY 3 (CY 2029), the projected fixed PET utilization at Alamance Regional will be 1,868 scans or 62% capacity. See Cone Health application, page 123.

Table 8: Projected PET Scans at Cone Health Facilities in HSA II

				PY1	*PY2*	*PY3*
Facility	***CY24^***	***CY25***	***CY26^^***	***CY27***	***CY28***	***CY29***
Moses Cone Hospital License*	919	3,776	4,182	4,632	5,130	5,682
ARMC	336	1,371	1,481	1,600	1,729	1,868
HSA II Total	**1,255**	**5,147**	**5,664**	**6,232**	**6,859**	**7,550**
Fixed Scanners	2	2	3	3	3	3
Procedures Per Scanner	**628**	**2,574**	**1,888**	**2,077**	**2,286**	**2,517**

^October 1, 2024, to December 31, 2024
^^Proposed PET scanner operational October 1, 2026
*Includes Wesley Long Hospital and Moses Cone Hospital

By Cone's admission, ARMC does not meet the performance standard in 10A NAC 14C.3703(a)(7). Each PET scanner must achieve 2,080 scans by Project Year 3, and ARMC falls well below that mandatory standard. The projected patient origin for the proposed fixed PET scanner is based on Wesley Long's existing PET imaging patient origin.

< PET Services >	<Moses Cone Hospital^^> *					
	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2027 to 12/31/2027		01/01/2028 to 12/31/2028		01/01/2029 to 12/31/2029	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Guilford	3,227	69.7%	3,574	69.7%	3,959	69.7%
Rockingham	442	9.5%	490	9.5%	543	9.5%
Randolph	339	8.6%	442	8.6%	489	8.6%
Forsyth	124	2.7%	138	2.7%	152	2.7%
Alamance	71	1.5%	79	1.5%	87	1.5%
Other^	368	8.0%	408	8.0%	452	8.0%
Total	**4,632**	**100%**	**5,130**	**100%**	**5,682**	**100%**

* This should match the name provided in Section A, Question 4, and includes mobile health services

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

^ Other includes: Alleghany, Carteret, Caswell, Chatham, Davidson, Montgomery, Stokes, Surry, Wake, Wilkes, Other NC Counties and Other States

^^Includes both the Moses Cone and Wesley Long Campuses (i.e., the two PET scanners to be licensed under the Moses Cone Hospital license).

Despite underutilization of the fixed PET scanner at ARMC, Cone Health projects that proposed fixed scanner at MCH will provide a portion of service to Alamance County residents accounting for 87 patients or 1.5% of the patient population. Other patients account for 8.0% or 452 patients in Project Year 3. Many of the counties identified as "other" would need to drive past the fixed PET scanner in Alamance County to reach MCH as shown in the following map.

Cone Health has failed to demonstrate the need the population has for the proposed service at MCH and should be found non-conforming with Criterion (3).

Cone Health also claims that this scanner will be used primarily for cardiac imaging. While PET can be used for cardiac imaging, PET is used primarily for oncology imaging. The need in the SMFP was for a general use PET scanner. Cone Health did not provide any information in the application that the population proposed to be served needs a PET scanner that will be used primarily for cardiac imaging.

For these reasons, in addition to any other reasons the Agency may discern, the Cone Health application should be found non-conforming with Criterion (3).

Criterion (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.

Cone Health has failed to demonstrate that the least costly or most effective alternative has been proposed for this project. Cone Health has failed to identify the need for the proposed service at MCH and relies heavily on shifting patients from Wesley Long in order to meet the required scan volume for Project Year 3. This represents unnecessary duplication of existing resources. Further, Cone Health has a severely underutilized fixed PET scanner at ARMC that could be more effectively utilized. Cone Health's proposal will not effectively serve HSA II residents and should be found nonconforming with Criterion (4).

Criterion (5)

Financial 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 upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

Cone Health fails to demonstrate the need for the proposed project based on the projections provided in the application. See discussion above under Criterion (3). As a result, the financial projections for the proposed project are not based on reasonable assumptions and the Cone Health application should also be found nonconforming with Criterion (5).

Criterion (6)

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

Cone Health currently owns and operates two fixed PET scanners in HSA II and contracts for mobile PET service in Rockingham County. Cone Health's existing fixed PET scanner at ARMC is significantly underutilized. Data from the proposed 2026 SMFP indicates that fixed PET services at Alamance is 39.8% while Wesley Long is operating at 125.47%.

II	2025 Need Determination		1	1	0	0.00%	-1	
	Alamance Regional Medical Center	1	0	1	1,194	39.80%	0	
	Atrium Health Wake Forest Baptist	2	0	2	4,337	72.28%	0	
	Atrium Health Wake Forest Baptist - High Point Medical Center	1	0	1	1,401	46.70%	0	
	Cone Health	1	0	1	3,764	125.47%	1	
	Novant Health Forsyth Medical Center	1	1	2	3,238	53.97%	0	
	HSA II Total	**6**	**2**	**8**	**13,934**		**0**	**0**

As discussed in Criterion (3), Cone Health relies on numerous unreasonable and duplicative measures such as shifting patients from Wesley Long to justify the projected scan volume. Cone Health does not provide supporting information that indicates such dramatic shifts would occur. On page 36, Cone Health also indicates that the proposed fixed PET will primarily serve cardiac patients. However, PET imaging is primarily used for oncology patients. If indeed this proposed PET scanner will focus primarily

on cardiac imaging, then Cone Health should have provided detailed information demonstrating the need the population has for cardiac PET. Cone Health did not do so.

For these reasons in addition to any other reasons the Agency may discern, the Cone Health application should be found non-conforming with Criterion (6).

Criterion 18(a)

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 Cone Health proposal will not enhance competition or have a positive impact on cost effectiveness, quality or access to the services proposed. Cone Health relies heavily on utilization of its proposed service for cardiac patients. Based on Novant Health's extensive operational experience for PET services across North Carolina, cardiac PET imaging is a very small percentage of overall service. Oncology patients have a significant demand for PET imaging services. Cone Health operates an underutilized fixed PET scanner at ARMC in Burlington (39.8% utilization). The approval of the Cone Health application will not have a positive impact on competition in the service area.

The Cone Health application should be found nonconforming with Criterion 18(a).

10A NCAC 14C.3703(a)(7)

> (7) project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.

By Cone's admission, ARMC does not meet the performance standard in 10A NAC 14C.3703(a)(7). Each PET scanner must achieve 2,080 scans by Project Year 3, and ARMC falls well below that mandatory standard. See page 123 of the Cone Health application. As a result, the Cone Health application is nonconforming with the required performance standards for fixed PET scanners and is unapprovable.

Table 8: Projected PET Scans at Cone Health Facilities in HSA II

				PY1	PY2	PY3
Facility	***CY24^***	***CY25***	***CY26^^***	***CY27***	***CY28***	***CY29***
Moses Cone Hospital License*	919	3,776	4,182	4,632	5,130	5,682
ARMC	336	1,371	1,481	1,600	1,729	1,868
HSA II Total	**1,255**	**5,147**	**5,664**	**6,232**	**6,859**	**7,550**
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^October 1, 2024, to December 31, 2024
^^Proposed PET scanner operational October 1, 2026
*Includes Wesley Long Hospital and Moses Cone Hospital

Summary

The outcome of this PET scanner review is critical for Health Service Area II. The approval of the NHKMC application will benefit the proposed service area by allowing a provider, with a proven track record of high-quality service and outreach to the medically underserved populations, the ability to offer additional fixed PET services for the community at reasonable costs and charges in a new location in Kernersville. The approval of NHKMC's application will provide the greatest good for the greatest number of service area residents and their referring physicians.

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

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

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

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

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

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed PET scanners that can be approved by the Healthcare Planning and Certificate of Need Section. The applicants collectively propose to develop three fixed PET scanners in Health Service Area II. Based on the 2025 SMFP's need determination, only one fixed PET scanner can be approved.

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

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Case: CHARLOTTE-MECKLENBURG V NCDHHS
Date: 7.29.25
Witness: LISA PITTMAN

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Court Reporter's Name: ANDREA L. KINGSLEY
Firm Name: VERITEXT LEGAL SOLUTIONS

EXAMINATION BY

BY MS. GUNTER:

Q. Good afternoon, Ms. Pittman, it's Denise Gunter. It's good to see you. Sorry I'm looking at you a little funky here because my monitors are set up weird, but I am looking at you even though it looks like I'm off to the side.

Ms. Pittman, you said that you reviewed something on the order of 700 applications over the course of 15 years at the agency; is that right?

A. Yes.

Q. Would you agree based on that experience that every review is unique?

A. Absolutely.

Q. And given the uniqueness of each review can it be difficult to draw comparisons from one review to another?

A. It is particularly when all you're looking at is just an old piece of it if you look at the whole thing it might be easier to compare but even that there's so many nuances and differences it's just hard.

Q. Is it fair to say that just because the agency may have decided for example the HSA 1 PET

25 scanner review in a certain way it might not make

1 the same decision with respect HSA 3 PET scanner
2 review a couple years later?
3 MR. SHACKELFORD: I object to the
4 leading.
5 A. Correct.
6 Q. I'm sorry, what was your answer?
7 A. My answer is correct.
8 Q. Was anybody in this review applying for
9 beds or ORs or an MRI scanner?
10 A. Not in the same review.
11 Q. You were asked some questions about the
12 number of hours that you spent on this review. Is
13 there any required number of hours that a cosigner
14 is required to spend on a review?
15 A. Too many but no there's not a numerical
16 goal.
17 Q. Similarly for project analysts, is there
18 a required number of hours that a project analyst is
19 supposed to spend on a review?
20 A. No.
21 Q. You said earlier today that there aren't
22 many things in the CON world that are absolutes. Do
23 you recall saying that?
24 A. I do.

25 Q. Would you agree though that a rule such

1 as a rule found in the administrative code that
2 contains a performance standard for a CON
3 application, that might be one of the rare examples
4 of an absolute in the CON world?
5 MR. SHACKELFORD: Object to
6 leading.
7 A. Whatever the current rule is is the
8 rule.
9 Q. And the rule has to be followed;
10 correct?
11 MR. SHACKELFORD: Objection.
12 A. They are to be followed.
13 Q. I'm sorry, I didn't get that last word.
14 A. They are to be followed.
15 Q. You had mentioned the older version of
16 the PET scanner performance standard and I ask
17 Ms. Happ to please put that up on the screen and
18 we'll mark it as the next exhibit.
19 (Exhibit ^ ^ , ^ ^ Description,
20 marked for identification, as of this date.)
21 Q. I took this from the 2021 SMFP
22 Ms. Pittman this was the last year I could find the
23 older version of the rule. If we could go to the
24 next page. Just for housekeeping purposes, what

25 exhibit number are we on? Or we are on 10?

1 THE REPORTER: 11.

2 (Exhibit ^ ^ , ^ ^ Description,

3 marked for identification, as of this date.)

4 Q. Let's mark this as 11. Let me give you

5 a minute Ms. Pittman to orient yourself to the rule

6 and I will be asking you specifically about subpart

7 3 of the rule under 3703 A 3. Let me just give you

8 a moment to read that.

9 MR. SHACKELFORD: Ms. Gunter, when

10 you have an opportunity will you please send

11 us an email copy of this exhibit?

12 MS. GUNTER: Sure.

13 A. Yep, there's that word average.

14 Q. Do you see in subpart 1 of the rule that

15 requires the proposed dedicated PET scanner to be

16 used in an annual rate of at least 2080 PET

17 procedures by the end of the third year. Do you see

18 that?

19 MR. SHACKELFORD: Object to form.

20 A. I do.

21 Q. And then you see in subpart 2 of the

22 rule that word average comes up with regard to past

23 performance; is that right?

24 MR. SHACKELFORD: Object to form.

A. Correct.

Q. And in subpart 3 do you see where it says it's existing an approved dedicated PET scanner shall perform an average of at least 2080 PET procedures per PET scanner during the third year following completion of the project?

A. Correct.

Q. Let's go to the agency findings in this case, specifically Bates 792.

A. Okay.

Q. Where is that word average in subpart 7 of the rule?

A. It is not there.

Q. All right. I believe you had pointed out the word per, P-E-R, in that rule. Do you see that?

MR. SHACKELFORD: Object to form.

A. Yes.

Q. I believe you testified that means each; is that right?

MR. SHACKELFORD: Object to form.

A. In this scenario it does. In the former one it had the average per each. This doesn't have the average part.

Q. Let me go ahead and mark another

exhibit. We're now on Exhibit 12.

(Exhibit ^ ^ , ^ ^ Description, marked for identification, as of this date.)

Q. I would like to show you a page from Black's Law Dictionary. Do you see one of the definitions of the word "per" is -- I'm looking at part number 2, it says for each, for every and they give an example of 55 miles per hour. Do you see that?

MR. SHACKELFORD: Object to form.

A. I do.

Q. Would that be consistent with what your understanding of the word per means in subpart 7 of the rule we were just looking at?

MR. SHACKELFORD: Object to form.

A. Yes.

Q. Let me show you another definition. If we could put up Exhibit 13. This comes from Dictionary.com and do you see definition number 1 of per is for each or for every?

A. Yes.

Q. And they give two -- they use the word twice in a sentence membership costs 10 dollars per year. Would that mean each year?

MR. SHACKELFORD: Object to form.

25 A. Yes.

1 Q. And then they give another example this
2 clot is 2 dollars per yard. Would that mean each
3 yard?
4 MR. SHACKELFORD: Object to form.
5 A. Yes.
6 Q. You were asked multiple questions -- we
7 can that he exhibit down.
8 You were asked multiple questions,
9 Ms. Pittman, about the comparative analysis. Do you
10 have any reason to think that Ms. Saporito when she
11 was doing the analysis was being harder on Atrium
12 than she was on Novant?
13 MR. SHACKELFORD: Object to form.
14 A. No.
15 Q. To the best of your knowledge and
16 belief, was the agency biased in any way for or
17 against either of the applicants in this review?
18 A. No. In my 15 years I've never heard of
19 any staff person giving a coo-too about who won any
20 competitive review. We just want to do the review,
21 make the decision and whoever wins wins. We don't
22 have a dog in this show.
23 Q. You were asked some questions about
24 Criterion 20 and I would like to go to the Novant

25 application, specifically page 113. That's the

1 Bates page.

2 A. Yes. 113?

3 Q. Yes.

4 A. Okay.

5 Q. I would like to direct your attention

6 please to question 6 which is nursing facilities and

7 just read the question and the answers under parts A

8 and B to yourself and let me know when you're done.

9 A. Okay.

10 Q. Does it appear to you on page 113 of

11 this PET scanner application that Novant was self

12 disclosing an immediate jeopardy situation that had

13 occurred at one of its hospitals?

14 MR. SHACKELFORD: Object to form.

15 A. Yes.

16 Q. That was information that the agency

17 could use to assess the applicant's conformance with

18 Criterion 20; is that correct?

19 MR. SHACKELFORD: Object to form.

20 A. Correct.

21 Q. And the applicant reported that the

22 finding of immediate jeopardy had been removed and

23 was validated on May 6, 2024; is that right?

24 MR. SHACKELFORD: Object to form.

25 A. Yes.

1 Q. You would agree based on your 15 years
2 with CON that Novant files a number of CON
3 applications every year?
4 MR. SHACKELFORD: Object to form.
5 A. True.
6 Q. Society annual on annual basis has many
7 opportunities to review Novant's quality of care is
8 that correct?
9 MR. SHACKELFORD: Object to form.
10 A. True.
11 Q. Were you aware that just a month before
12 filing this PET scanner application in September of
13 2024 Novant had filed a CON application proposing to
14 build a new hospital in Knightdale North Carolina?
15 MR. SHACKELFORD: Object to form.
16 Q. I'm sorry, your answer was what?
17 A. Yes.
18 Q. Novant would have had to undergo a
19 Criterion 20 analysis in that review too wouldn't
20 it?
21 MR. SHACKELFORD: Object to form.
22 A. Yes.
23 Q. I would like to go back to the Novant
24 application and look at a few different pages.

25 Follow up on some questions you were asked. The

1 first page I would like to direct you to is page 26.
2 Again, that's the Bates page of the Novant
3 application.
4 A. Okay.
5 Q. Do you see there that Novant reports
6 that it has one fixed PET scanner at Presbyterian
7 Medical Center and that it was proposing to add a
8 second PET scanner at Presbyterian Medical Center?
9 A. Yes.
10 Q. Now I would like to go to page 33.
11 Again, that's Bates page 33.
12 A. Okay.
13 Q. Under scope of the project on page 33,
14 do you see where Novant stated NHPMC proposes to
15 develop a second fixed PET scanner located in its
16 hospital in Mecklenburg county. The proposed fix
17 PET scanner will be situated near NHPMCs existing
18 PET scanner within the hospital's radiology
19 department. Do you see that?
20 A. Yes.
21 Q. So what Novant was proposing was to
22 collocate these two PET scanners in other words have
23 both PET scanners in the radiology department of
24 Presbyterian hospital?

A. Correct.

Q. I would now like to go to page 36. Again, that's Bates 36.

A. Okay.

Q. Do you see there the patient origin table for the two PET scanners that Novant proposes for Novant Presbyterian Medical Center?

A. Yes.

Q. Would you expect that both PET scanners would be used to serve patients from each of the counties and other geographic areas listed on page 36 of this application?

MR. SHACKELFORD: Object to form.

A. Yes.

Q. So in other words it wouldn't be reasonable would it for Novant to allocate a scanner say to only patients from Mecklenburg county?

MR. SHACKELFORD: Object to form.

A. No. I think they would balance them basically by who's coming in.

Q. I would like to direct your attention to Bates page 85 of this application.

A. Okay.

Q. And do you see the second paragraph there that states the represent to section C

question 12, performance standards demonstrates that

by calendar year 2029 the third full project year NHPMC's projected utilization for the existing and proposed fixed PET scanners in NHFMC'S existing mobile PET scanner will exceed 2,000 PET procedures per unit?

A. Yes.

Q. Let's go to page 124 of this application.

A. Okay.

Q. Do you see in project year 3 where Novant projects 4347 PET procedures for the two PET scanners in project year 3?

A. Yes.

Q. Do you have a calculator handy?

A. I could use my phone.

Q. Okay. If you divide 4347 by 2, what do you get?

A. 2173.5.

Q. It wouldn't be reasonable would it to think that for example Novant was going to use one of the PET scanners 4,000 procedures in project year 3 and the second PET scanner would only do 347 scans in project year 3 would that be?

MR. SHACKELFORD: Object to form.

A. That would be crazy.

Q. Why would it be crazy?

A. My understanding of equipment in general and I assume would apply to PETs as well is that if you have two you want to balance their use so you don't just wear one out and it's kind of ridiculous one sitting around not being used.

Q. I realize you're not in the business of buying PET scanners for hospitals but is it your general understanding that these PET scanners cost millions of dollars?

MR. SHACKELFORD: Object to form.

A. Oh yes.

Q. Would it make sense then for Novant to spend several million dollars on a PET scanner and just let it sit idle?

MR. SHACKELFORD: Objection.

A. I hope not.

Q. Let go now to the Atrium application. Specifically I would like to go to page 133. Again, that's Bates page references.

A. 133?

Q. Yes.

A. All right.

Q. Do you see there the PET procedures that

25 Atrium proposes to perform at the CMHA facilities in

1 Health Service Area 3 through project year 3?
2 A. Yes.
3 MR. SHACKELFORD: Object to form.
4 Q. Do you see that Atrium Health Pineville
5 they project 2517 scans in project year 3?
6 A. Correct.
7 Q. And then at CMC they propose 5 thousand
8 356 scans in project year 3?
9 A. Correct.
10 Q. What do you get if you divide 5356 by 2?
11 A. 2678.
12 Q. And similar to the question I asked you
13 for Novant, would it be reasonable to think that at
14 CMC they would use one scanner to the opportunity of
15 5 thousand scans a year and then the second scanner
16 used only for 356 scans in year 3?
17 MR. SHACKELFORD: Object to form.
18 A. No.
19 Q. Would that be crazy for the same reasons
20 you said it would be crazy for Novant to have such
21 an unbalanced usage of two scanners?
22 MR. SHACKELFORD: Object to form.
23 A. Both situations would be crazy.
24 Q. Continuing on the list of Atrium PET

25 scanners, do you see in project year 3 they project

1 that Cabarrus imaging will be used for 2864 PET
2 procedures?
3 A. Yes.
4 Q. Then we come to union and do you see
5 where they report they will use the union scanner
6 for 1913 scans in project year 3?
7 A. Yes.
8 Q. That's an express statement by Atrium
9 Health about the usage of that scanner; correct?
10 MR. SHACKELFORD: Object to form.
11 A. Correct.
12 Q. And Atrium wrote Atrium's application;
13 is that fair to say? The agency didn't write it for
14 them?
15 MR. SHACKELFORD: Object to form.
16 A. No, we did not. I assume Atrium wrote
17 their on application.
18 Q. So looking at this page, would you agree
19 that Atrium Health Pineville should have been found
20 nonconforming with the performance standard?
21 MR. SHACKELFORD: Object to form.
22 A. Yes.
23 Q. Why?
24 A. Because each of the five scanners does

25 not each expect toe have 2080 procedures in the

1 third year.

2 Q. You would agree that 1 thousand 913 is

3 less than 2080?

4 MR. SHACKELFORD: Object to form.

5 A. Correct.

6 Q. We didn't have to do any math to get to

7 that 1,913; did we?

8 A. No.

9 MR. SHACKELFORD: Object to form.

10 Q. I want to ask you about Exhibit 9 which

11 is the comparative factors with the words suggested

12 next to it. Do you have that exhibit?

13 A. I think so.

14 Q. This document comparative factor

15 (suggested), is this a rule?

16 A. No.

17 Q. Is this Exhibit 9 part of the CON

18 statute?

19 A. No.

20 Q. Is this Exhibit 9 part of the state

21 medical facilities plan?

22 A. No.

23 Q. What happens if a project analysts

24 deviates from this suggested list of comparative

25 factor? Do they get fired?

1 A. No.
2 MR. SHACKELFORD: Object to form.
3 Q. Would it be fair to say this is simply
4 guidance that a project analyst can refer to?
5 MR. SHACKELFORD: Object to form.
6 A. Yes. Guidance.
7 Q. You were asked a lot of questions about
8 historical utilization. Does Atrium Health
9 Pineville have a PET scanner?
10 A. No.
11 Q. So then it would be fair to say it has
12 no historical utilization when it comes to PET
13 scans; correct?
14 MR. SHACKELFORD: Object to form.
15 A. Correct.
16 Q. You were asked several questions about
17 Medicare. You're not an expert in reimbursement
18 matters for healthcare providers; are you?
19 MR. SHACKELFORD: Object to form.
20 A. No.
21 Q. But over the course of 15 years and 700
22 CON applications you've developed some familiarity
23 without healthcare providers get paid; right?
24 MR. SHACKELFORD: Object to form.

25 A. Correct.

1 Q. Is it your understanding that Medicare
2 pays pursuant to its own fee schedule?
3 MR. SHACKELFORD: Object to form.
4 A. Yes, it does.
5 Q. So for example if Denise Gunter decided
6 to open up a PET scanner tomorrow I would not be
7 able to send Medicare a bill for $5,000 per scan;
8 could I? I guess I could but they wouldn't pay it;
9 would they?
10 MR. SHACKELFORD: Object to form.
11 A. No successfully.
12 Q. So in other words the provider does not
13 tell Medicare what Medicare will pay; is that right?
14 A. Very true.
15 MR. SHACKELFORD: Object to form.
16 Q. Medicare tells the provider what
17 Medicare is going to pay?
18 A. Correct.
19 Q. So the whole series of questions that
20 you were asked about Presbyterian charging Medicare
21 more is the premise its of that question even
22 accurate?
23 MR. SHACKELFORD: Object to form.
24 A. No.

Q. If we could go back to our agency file please, page 164 which had been referred to a few times.

A. Okay.

Q. Looking at -- this is table 15 F 1 utilization of existing dedicated fixed PET scanners and I would like to direct your attention to the PET scanners in HSA 3. Do you see that?

A. I do.

Q. Would it be fair to say that as of the time this page of the SMFP was published, Atrium Health consisting of Atrium Health Cabarrus, Atrium Health union and Carolinas Medical Center had four PET scanners?

MR. SHACKELFORD: Object to form.

A. Yes, correct.

Q. How many did Novant Health Presbyterian Medical Center have?

A. One.

Q. Thank you, Ms. Pittman, I don't have any other questions.

MR. HUNTER: No questions from respondent. Thank you.

MR. SHACKELFORD: I just have a couple follow up.

25 FURTHER EXAMINATION

1 BY MR. SHACKELFORD:

2 Q. Ms. Pittman, Ms. Gunter showed you a

3 copy of the prior performance standard as it

4 appeared in the 2021 SMFP. Do you recall her

5 showing you that?

6 A. Yes.

7 Q. In this review did the agency follow the

8 current performance standard when reviewing Novant's

9 application?

10 A. No.

11 Q. Ms. Gunter asked you a number of

12 questions in connection with the reasonableness of

13 the breakdown service area patients among

14 Presbyterian's existing and proposed PET scanners in

15 this review. Do you recall those questions?

16 A. I think so.

17 Q. She was making a point, wasn't she, that

18 it would be ludicrous to assume that the proposed

19 patients originating from the service area would

20 materially differ from the existing and newly

21 proposed scanners at Presbyterian; correct?

22 A. Correct.

23 Q. So she insinuated that the proper way to

24 do that was to divide by 2 and ascribe to each

25 scanner the number of service area patients that it

1 projects to serve on each of those two scanners;
2 correct?
3 A. She didn't exactly say that.
4 Q. Okay. What did you understand her to be
5 saying?
6 A. Essentially about the third project year
7 in particular I think we both agreed that probably
8 those scanners would be more even in what they are
9 scanning number of procedure wise. That's having
10 something totally different for the two scanners.
11 Q. So in connection with that one question
12 Ms. Gunter took you to Exhibit 2, the Novant
13 application to Bates page 124. Could you get that
14 back there for me please.
15 A. Okay.
16 Q. Ms. Gunter noted that in project year 3
17 Novant projected the total of 4,347 scans; correct?
18 A. Correct.
19 Q. She had you divide that number by 2
20 didn't she?
21 A. Yes.
22 Q. Isn't dividing by 2 by definition
23 calculating an average?
24 A. Yes.

25 Q. And then at the end of her questioning

1 Ms. Gunter asked you some questions about Medicare
2 tells a provider what it's going to pay, a provider
3 is not at liberty to dictate to Medicare how much
4 Medicare is going to pay. Do you recall that
5 questions?
6 A. Yes.
7 Q. That's the whole point, isn't it, the
8 agency conducted a comparative analysis in which
9 under Medicare and Medicaid it analyzed the
10 applicants on the basis what they are charging
11 Medicare and Medicaid; didn't it?
12 A. That's part of it.
13 Q. Yes, ma'am. So if we look in the agency
14 file at page 800, projected Medicare as a percent of
15 gross revenue, let me know when you get there.
16 A. Okay.
17 Q. Do you recall me asking you questions
18 earlier today to the effect that if Atrium projected
19 to triple its charges for Medicare patients then it
20 would have fared better under this comparative
21 factor. Do you recall those questions?
22 A. I do.
23 Q. I agree with Ms. Gunter, it's quite
24 ludicrous to conduct a comparative factor on the

basis of what a provider is charging Medicare as opposed to what Medicare is actually paying so I believe she and I agree with that. Do you agree with that?

MS. GUNTER: Object to form. I don't think we agree about anything but go ahead.

A. I'm going to say with what the agency does at this point.

Q. And here the agency on the basis of what the applicants projected to charge Medicare patients determined that the applicants were equal under projected Medicare as a percent of gross revenue in part because Novant projected to charge those poor under served Medicare patients more than Atrium does?

MS. GUNTER: Object to form.

MR. HUNTER: Object to form.

Q. Correct?

A. Will you repeat your question?

Q. Sure. Here the agency on the basis of what the applicants projected to charge Medicare patients determined that the applicants were equal under the comparative factor projected Medicare as a percent of gross revenue in part because Novant

25 projected to charge those poor Medicare patients

more than Atrium?

MS. GUNTER: Object to form.

MR. HUNTER: Object to form.

A. Total gross revenue is part of this analysis, yes.

Q. Subject to follow up, no further questions.

MS. GUNTER: Nothing else for me.

MR. HUNTER: Nothing from respondent.

Q. Thank you, Ms. Pittman, for your time?

THE COURT REPORTER: Would you like a copy of the transcript, Mr. Shackelford?

MR. SHACKELFORD: Yes please.

THE COURT REPORTER: Would you like a copy of the transcript, Mr. Hunter?

MR. HUNTER: Yes, PDF only and we will read and sign.

THE COURT REPORTER: Ms. Gunter, would you like a copy of the transcript?

MS. GUNTER: Yes please.