Comments on
Competing Applications for Two Additional Fixed PET Scanners in HSA IV

March 31, 2025

Competitive Comments on Health Service Area IV
Fixed PET Scanner Applications

submitted by

UNC Hospitals

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), UNC Hospitals hereby submits the following comments related to the competing applications filed by Raleigh Imaging (WakeMed), Duke University Health System (DUHS), Durham Diagnostic Imaging (Novant), and Associated Urologists of North Carolina (AUNC) to add a dedicated fixed PET scanner in response to the need identified in the *2025 State Medical Facilities Plan* (*SMFP*) for two dedicated fixed PET scanners for Health Service Area (HSA) IV. UNC Hospitals' 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, UNC Hospitals has organized its discussion by applicant and 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 the applications submitted. UNC Hospitals' comments include issue-specific comments on the following applications as well as a comparative analysis related to all submitted PET applications:

- Raleigh PET, LLC, add one fixed PET scanner, Project ID # J-12611-25
- Durham Diagnostic Imaging, add one fixed PET scanner, Project ID # J-12598-25
- Associated Urologists of North Carolina, add one fixed PET scanner, Project ID # J-12598-25
- Duke University Hospital, add one fixed PET scanner, Project ID # J-12610-25
- Duke Cary Hospital, add one fixed PET scanner, Project ID # J-12607-25
- WR Imaging, add one fixed PET scanner, Project ID # J-12602-25[2]

As detailed above, given the number of proposed additional fixed PET scanners, all the applications submitted cannot be approved as proposed. UNC Hospitals' detailed comments include application-specific comments related to each competing application and a comparative analysis relative to its application. The comments below include substantial issues that UNC Hospitals believes render most of the competing applications non-conforming with applicable statutory criteria and regulatory review criteria. However, as presented at the end of these comments, even if one or more of these applications is found conforming, the UNC Hospitals application is comparatively superior to the other applications filed and represents the most effective alternative for expanding access to fixed PET services in HSA IV.

UNC Hospitals has a longstanding demonstrated commitment to developing projects that increase geographic and financial accessibility to healthcare services for residents of North Carolina, provide cost-effective and efficient patient care services, and incorporate the research and medical education missions of UNC Health. As detailed in its application, UNC Hospitals believes that the most appropriate way to

[1] UNC Hospitals is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its application filed on February 15, 2025 (Project ID # J-12576-25).

[2] UNC Hospitals is not commenting on the WR Imaging PET application, nor does it contend that the application by WR Imaging is non-conforming with any review criteria or performance standards. The WR Imaging application is, however, included in the Comparative Factors discussion, along with the remaining competing applications.

meet the need for additional fixed PET resources identified in the *2025 SMFP* is to develop one additional fixed PET unit at UNC Hospitals in Chapel Hill. The UNC Hospitals application is the result of prudent healthcare planning to provide greater access to advanced imaging services in Health Service Area IV that will serve the growing need for PET imaging that supports a multitude of clinical specialties.

GENERAL COMMENTS ON RALEIGH PET

It should be noted that the PET scanner owned and operated by WakeMed, d/b/a Wake PET Services, has had the lowest utilization rate of any PET scanner in HSA IV. The WakeMed PET operated at only 55 percent of capacity in FFY 2023, as shown in the following table from the WakeMed application:

Table 1: HSA IV PET Scanner Utilization in FY 2022 per SMFP Table 15F

Facility	Planning Inventory	2022-2023 Procedures	Facility Utilization Rate FY 2023	Facility Utilization Rate Rounded	2022-2023 procedures per Scanner	Inventory located in Facilities at or Over 80% Capacity
Duke Raleigh Hospital	1	2,002	66.73%	67.00%	2,002	0
Duke University Hospital	3	7,442	82.69%	83.00%	2,481	3
UNC Rex Hospital	2	4,772	79.53%	80.00%	2,386	2
University of North Carolina Hospitals	2	5,375	89.58%	90.00%	2,688	2
Wake PET Services	1	1,660	55.33%	55.00%	1,660	0
HSA IV Totals	**9**	**21,251**			**2,361**	**7**

Source: Table 15F, 2025 SMFP, expanded

Source: WakeMed application, p. 42.

The WakeMed PET scanner performed fewer PET scans than any other facility in HSA IV in FFY 2023. The WakeMed PET scanner was approved in November 2005 and has had nearly 20 years of operation in the service area, yet still had not exceeded the need threshold in the *2025 SMFP*, nearly two decades later. WakeMed's existing PET scanner volume is also lower than Duke Raleigh's, which performed 20 percent more PET scans than the WakeMed PET unit in FFY 2023, with 2,002 PET scans compared to WakeMed's 1,660, despite the fact that the Duke Raleigh PET unit received its CON in August 2018.[3] In contrast to WakeMed's existing scanner, UNC Hospitals and UNC Rex Hospital, which first started operating PET services in 2002 and 2003, respectively, have both generated needs for additional PET scanners since their original start of service, based on their strong utilization growth.

WakeMed appears to have experienced relatively recent growth, as demonstrated in the following table from its CON application that was part of its need discussion. WakeMed points to a significant increase in PET scans in FY 2024. However, the most recently reported utilization is still below the utilization capacity threshold for a need determination in the *SMFP* and does not provide evidence of a long term trend. Even if WakeMed exceeded the threshold recently, its historical volume trend does not indicate a pressing need for an additional scanner at this time.

[3] Project ID # J-11384-17.

Table 2: PET Scan History, 210 PET Imaging (Wake PET Services), FY20-FY24

Metric	FY20	FY21	FY22	FY23	FY24
a. Total PET Scans	626	209	1,200	1,660	2,264
b. SMFP Annual Capacity	3,000	3,000	3,000	3,000	3,000
c. Percent Utilization	20.9%	7.0%	40.0%	55.3%	75.5%

Notes:

a. *2021 – 2025 Equipment and Inventory Forms*
b. *C15-F, PET Methodology Assumption #2, p363*
c. *a / b*

Source: WakeMed application, p. 42.

ISSUE-SPECIFIC COMMENTS ON RALEIGH PET

Raleigh PET, LLC's (WakeMed's) application to develop a new freestanding facility with PET imaging services should not be approved. The WakeMed application contains multiple errors, omissions, and unsupported assumptions in its methodology. Please note that relative to each issue, UNC Hospitals has identified the statutory review criteria and specific regulatory criteria and standards creating the non-conformity. The following issues result in areas of non-conformity for the WakeMed application:

1. <u>The methodology utilized by WakeMed results in volume projections that are significantly overstated and unsupported; it provides no reasonable justification for its growth rate in PET procedures.</u>

   WakeMed uses aggressive assumptions for its PET use rate that result in overstated market volume. Rather than basing its market growth projections on the specific historical utilization rates for the counties comprising HSA IV, WakeMed instead applies the relatively higher FY 2023 statewide use rate of 7.14 procedures per 1,000 population. The overall use rate for the 11 counties in the service area was 6.40 in FY 2023, 12 percent lower than the statewide average. This difference has a significant impact on the projected total number of PET procedures for the WakeMed project by artificially inflating the expected number of PET procedures in the service area. The demographics and population growth in HSA IV vary significantly from county to county, and thus, the use rates also vary considerably. WakeMed should have applied county-specific use rates to the projected populations of each county to avoid unreasonable assumptions about growth in PET procedures but instead applies a statewide rate merely because it is higher and allows it to project higher utilization. WakeMed provides no justification for its application of a statewide use rate to the service area, nor is this assumption reasonable or adequately supported.

   WakeMed magnifies this overstated growth when it applies the statewide use rate of 7.14 and then further inflates this rate by an additional 25 percent, for a projected use rate of 8.93 procedures per 1,000 population. The magnified rate is then applied in the first three project years (FY 2028-FY 2030).[4] WakeMed uses this rate to project growth for all 11 HSA IV counties from FY 2024 through FY 2030. WakeMed states that this higher adjustment reflects "advancements in PET software and hardware as well as new radioisotopes approved by the FDA."[5] While it may be true there will be future advancements in radiopharmaceuticals and that additional tracers may be approved for use in PET imaging, there is no analytical basis for WakeMed's higher adjustment. Not only is it unreasonable to apply this arbitrary growth factor to the historical use rate based on the presumption that new radiotracers will expand the clinical applications of PET scans, but the indiscriminate application of the statewide rate to all counties in the HSA is not reflective of PET use rates within the service area. The following table shows the FY 2023 PET use rates for the counties in the service area:

FY 2020 – FY 2023 PET Use Rates by HSA IV County

County	*FY20*	*FY21*	*FY22*	*FY23*
Chatham	4.20	4.32	5.44	7.66
Durham	3.21	3.26	4.59	5.63
Franklin	4.56	4.19	4.44	6.42
Granville	4.14	4.46	4.70	6.04

[4] Raleigh PET application, p.120.

[5] Raleigh PET application, p. 117.

Johnston	3.61	3.60	3.76	4.66
Lee	3.93	3.42	8.36	9.57
Orange	4.99	5.76	7.05	10.06
Person	10.44	4.30	7.27	8.11
Vance	4.56	3.31	4.89	7.74
Wake	3.94	4.19	4.61	6.06
Warren	4.24	3.60	4.39	12.65
HSA IV Total	**4.03**	**4.06**	**4.86**	**6.40**
NC Total	*4.95*	*5.09*	*5.83*	*7.14*

Source: Raleigh PET application, Exhibit C.4.

The overall PET use rate for HSA IV was 6.40 in FY 2023, 28 percent lower than the base use rate of 8.93 that WakeMed uses. Even the overall rate for the service area is misleading, since four counties including Wake County, by far the largest in terms of population and representing nearly half of HSA IV's residents, have use rates that are still lower than the 6.40 rate for the entire service area. Within the service area, six counties have use rates that are greater than the statewide average of 7.14: Chatham, Lee, Orange, Person, Vance, and Warren. These counties all have relatively low populations and are not representative of the entire service area. In FY 2024, these counties represented less than 16 percent of the HSA IV total population (400,535 ÷ 2,590,701 = 15.5%).[6] WakeMed is assuming that the HSA IV use rate will be same as the statewide rate using a disproportionately low percentage of the service area's population.

Furthermore, there is a large variance in the use rates at the county level within HSA IV: in FY 2023, Warren County had a 12.65 PET use rate while Johnston County had only a 4.66 use rate. WakeMed itself points out the disparity between use rates, noting that "there is a three-fold variation in county use rates within the proposed service area"[7] and assumes "the reported high use rates are not sustainable."[8] Wake County, the service area's largest in terms of population, had a use rate of 6.06 in FY 2023. This was just 68 percent of the rate WakeMed has chosen (6.06 ÷ 8.93 = 67.9%).

Despite these documented utilization variations within the region, and despite the fact that WakeMed has chosen to include FY 2020 as its base year, a year when COVID-related access restrictions severely depressed ambulatory care utilization for elective procedures including PET scans, WakeMed still uses this high use rate to calculate need in all eleven counties in the service area. WakeMed projects future utilization based on an adjusted statewide average, assuming the use rate will increase to 8.93 per 1,000 residents by FY 2027 (a 25 percent increase from the FY 2023 statewide average of 7.14, as noted in Step 6 on page 120). This approach ignores the persistent regional variations in PET utilization that WakeMed's own data demonstrates. WakeMed provides no substantial evidence to support the assumption that HSA IV or Wake County utilization rates would suddenly converge with or exceed state averages, especially at the accelerated growth rate they project. This results in an unsupported estimation of the total PET procedures for HSA IV in the proposed project years.

6 NC OSBM population projection data; see WakeMed application, p. 117.

7 Raleigh PET application, p. 117.

8 Ibid.

Because WakeMed then estimates its PET utilization based on its market share of service area PET procedures, WakeMed's volumes are also overstated. WakeMed assumes its service area market share at the Raleigh PET facility will be 4.8 percent in the first project year, increasing to 8.0 percent in the third year (FY 2030). This calculation results in a total of 2,039 patients from the service area in FY 2030, as shown in the table below:

Table 8: Raleigh PET LLC Estimated Market Share of All PSA PET Patients Served, FY2028-FY2030

Metric	FY28	FY29	FY30
a. Raleigh PET Patients from PSA	1,178	1,504	2,039
b. Total PET Patients from PSA	24,751	25,133	25,524
c. Market Share	4.8%	6.0%	8.0%

Calculation: PSA total from Step 8, Table 7 divided by the PSA total from Step 7, Table 5

a. From Step 8, Table 7, PSA Total

b. From Step 7, Table 5, PSA Total

c. a/b

Source: Raleigh PET application, p. 124.

The reduction of WakeMed's total projected volume would be substantial if a more appropriate use rate is applied. For example, if WakeMed had chosen the FY 2023 Wake County rate of 6.06, and then grown this base rate by 25 percent, the service area would have a total of 19,704 PET procedures in FY 2030, not 23,221. This represents a difference in total market PET procedures of approximately 15 percent. Using the HSA IV-adjusted base rate would reduce its total PSA volume in FY 2030 by approximately 10 percent, to around 1,837 procedures. Using county-specific adjusted rates would decrease projections by approximately 15 percent, to around 1,727 procedures.

Either of these more appropriate methodologies would result in Raleigh PET failing to meet the minimum performance standard of 2,080 scans by the third project year, rendering the application non-conforming with 10A NCAC 14C .3703. Using WakeMed's market share assumption of 8.0 percent, the Raleigh PET facility would have 1,420 PET procedures from the service area if the use rate for Wake County were applied. This recalculation is shown in the following table:

Recalculation of Service Area PET Procedures by HSA IV County

County	*FY 2030 Pop.*	*FY23 County Use Rate*	*FY23 NC Use Rate*	*Wake County Use Rate*	*PET Visits with NC Use Rate^*	*PET Visits using Wake County Rate^*	*Raleigh PET Visits @ 8.0% Mkt Share of Wake County Rate*
Chatham	90,115	7.66	7.14		804	683	55
Durham	365,528	5.63	7.14		3,263	2,769	222
Franklin	95,631	6.42	7.14		854	724	58
Granville	66,816	6.04	7.14		596	506	40
Johnston	287,852	4.66	7.14		2,570	2,180	174
Lee	72,503	9.57	7.14		647	549	44
Orange	160,411	10.06	7.14		1,432	1,215	97

Person	39,466	8.11	7.14		352	299	24
Vance	40,046	7.74	7.14		357	303	24
Wake	1,363,836	6.06	7.14	6.06	12,175	10,331	826
Warren	18,992	12.65	7.14		170	144	12
HSA IV Total	**2,601,196**	**6.40**	**7.14**		**23,221***	**19,704***	**1,420**

^ Visits calculated using the FY 2023 actual use rate, then applying WakeMed's 25 percent use rate inflation assumption.
*Estimated PET Procedures by County in Table 5 of WakeMed's methodology on page 121 includes two counties outside of HSA IV, Harnett and Nash. The totals in the table exclude this utilization.

WakeMed assumes that 8.2 percent of patients at Raleigh PET will inmigrate from counties outside of the service area. WakeMed also includes two counties, Harnett and Nash, in its service area that are not part of HSA IV. Adding in the volume for these two counties to calculate the total service area, as well as the resulting 8.2 percent inmigration from other counties, results in the following utilization projections:

Raleigh PET Total Utilization Including Inmigration, Recalculated

County	*FY 2030 Pop.*	*Wake County FY23 Use Rate*	*PET Visits using Wake County Rate^*	*Raleigh PET Visits @ 8.0% Mkt Share, FY30*
HSA IV Counties	2,601,196	6.06	19,704*	1,420
Harnett	158,600	6.06	1,201	96
Nash	99,266	6.06	753	60
Raleigh PET PSA	2,859,233	6.06	21,659	1,733
Inmigration Percentage (8.2%)*				155
Raleigh PET Total Utilization				**1,888**

^ Visits calculated using the FY 2023 actual use rate, then applying WakeMed's 25 percent use rate inflation assumption.
*See Step 9 of WakeMed's methodology on page 125 of the Raleigh PET application.

Of note, this analysis remains generous in applying a higher use rate to several counties with much lower use rates from which WakeMed projects significant volume, such as Durham and Johnston. These calculations also retain WakeMed's specious assumption that use rates will grow an additional 25 percent due to technological factors. Nonetheless, with these corrections to the WakeMed methodology, the project will not achieve the required performance standard of 2,080 PET scans by the third project year. WakeMed has overstated volumes that are not supported by its assumptions and therefore has not demonstrated a need for the proposed project.

Based on this analysis, WakeMed has overstated its projected volumes and is non-conforming with Criteria 1, 3, 4, 5, 6, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703.

2. <u>WakeMed applies inconsistent market share assumptions based on its statements regarding the need for additional PET resources.</u>

WakeMed's market share projections contain internal inconsistencies that further undermine the reliability of its utilization forecasts. On page 41, it claims that eight of the nine existing fixed PET scanners in HSA IV are performing or will perform enough PET procedures to trigger the need for an

additional PET scanner in the *SMFP*: "That translates to a deficit of not two, but as many as seven PET scanners." This statement suggests HSA IV requires up to a total of 16 PET scanners (nine existing plus seven additional). Moreover, it clearly shows that even WakeMed acknowledges that among existing providers in the service area, WakeMed and Duke Raleigh are the only two sites that are not close to showing need for another PET scanner under the *SMFP* methodology. WakeMed also includes a table based on the *2025 SMFP* need methodology to demonstrate that seven existing fixed PET scanners are above the 80% capacity threshold that triggers a need for additional assets:

Table 1: HSA IV PET Scanner Utilization in FY 2022 per SMFP Table 15F

Facility	Planning Inventory	2022-2023 Procedures	Facility Utilization Rate FY 2023	Facility Utilization Rate Rounded	2022-2023 procedures per Scanner	Inventory located in Facilities at or Over 80% Capacity
Duke Raleigh Hospital	1	2,002	66.73%	67.00%	2,002	0
Duke University Hospital	3	7,442	82.69%	83.00%	2,481	3
UNC Rex Hospital	2	4,772	79.53%	80.00%	2,386	2
University of North Carolina Hospitals	2	5,375	89.58%	90.00%	2,688	2
Wake PET Services	1	1,660	55.33%	55.00%	1,660	0
HSA IV Totals	**9**	**21,251**			**2,361**	**7**

Source: Table 15F, 2025 SMFP, expanded

Raleigh PET application, p. 42.

However, when justifying its market share projections on page 124, WakeMed contradicts this claim, stating its projected 8.0 percent market share assumption for the Raleigh PET facility is reasonable because the PET unit it proposes to operate will represent "9 percent of the total HSA IV [fixed] PET scanners" (one out of 11 scanners after both need determination scanners are operational). A 9.0 percent share of fixed PET assets in HSA IV assumes Raleigh PET will have an equal share of the nine existing and two approved fixed PET scanners.

If WakeMed genuinely believes HSA IV requires up to seven additional scanners and also believes it will have an equal share of the fixed PET inventory, then its projected market share should be approximately 6.25 percent (1 out of 16 scanners), not 8.0 percent. This adjustment would reflect the additional PET scanners awarded based on the *SMFP* need methodology WakeMed references and would further reduce its projected volume below the performance standard threshold. With this lower market share and by using a more reasonable use rate to project the total number of PET procedures in the WakeMed service area, the total utilization for WakeMed is far short of the performance standard required for fixed PET scanners. Indeed, the recalculation of WakeMed's utilization in the third project year with this lower market share assumption results in the WakeMed facility performing just 1,534 PET procedures in FY 2030, the third project year. This would represent 74 percent of the required performance standard of 2,080 PET procedures.

Raleigh PET Total Utilization Including Inmigration, Recalculated

County	*FY 2030 Pop.*	*Wake County FY23 Use Rate*	*PET Visits using Wake County Rate^*	*Raleigh PET Visits @ 6.5% Mkt Share, FY30*
HSA IV Counties	2,601,196	6.06	19,704*	1,281
Harnett	158,600	6.06	1,201	78
Nash	99,266	6.06	753	49
Raleigh PET PSA	2,859,233	6.06	21,659	1,408
Inmigration Percentage (8.2%)*				126
Raleigh PET Total Utilization				**1,534**

^ Visits calculated using the FY 2023 actual use rate, then applying WakeMed's 25 percent use rate inflation assumption.

*See Step 9 of WakeMed's methodology on page 125 of the Raleigh PET application.

This lower utilization also calls into question the financial feasibility of the WakeMed project and its justification for the project.

Accordingly, WakeMed's application is non-conforming with Criteria 3, 4, 5, 12, and 18a, and should not be approved.

3. WakeMed overstates gross charges at the Raleigh PET facility.

The WakeMed application contains significant contradictions between its claims about cost savings created at freestanding PET facilities and its own financial projections. On page 45, WakeMed emphasizes the importance of lower-cost freestanding outpatient PET services, citing an article that states "the target fair price for a PET scan is $2,000" and that "going to an outpatient facility instead of a hospital can save you thousands of dollars — $2,250 versus $7,275." This cost advantage is presented as a key benefit for establishing its facility and is cited as a key need argument.

However, WakeMed's own financial projections directly contradict these claims. Its Form F.2b reveals that in Project Year 3, the projected average charge is $13,036 per scan with net revenue of $4,889 per scan. This projected net revenue is significantly higher than the "target fair price" ($2,000) cited by a source utilized in its own application.

Raleigh PET Gross and Net Revenue, PY1 – PY3

	FY 2028 (PY1)	*FY 2029 (PY2)*	*FY 2030 (PY3)*
Gross Revenue	$15,777,859	$20,744,322	$28,966,871
Total Net Revenue	$5,917,684	$7,780,419	$10,864,390
PET Procedures	1,284	1,639	2,222
Gross Revenue per Procedure	$12,288	$12,657	$13,036
Net Revenue per Procedure	$4,609	$4,747	$4,889

Source: Raleigh PET application, Form C.2a and Form F.2b.

This discrepancy presents two problematic conclusions:

1. Either WakeMed's financial projections are unreasonable and substantially overstate its expected revenues, rendering its financial feasibility analysis unreliable; or
2. WakeMed does not actually intend to deliver the cost savings it claims as a key benefit of its proposed facility.

In either case, this inconsistency between WakeMed's statements about cost advantages and its own financial projections raises serious concerns about the accuracy and reliability of its application. If a central benefit of the proposed project is to provide a lower-cost alternative to hospital-based PET services, yet its own projections show charges significantly higher than hospital rates, the application fails to demonstrate how it will actually achieve this stated goal.

The WakeMed application is therefore non-conforming with Criteria 3, 4, 5, 6, and 18a.

4. WakeMed fails to consider less costly or more effective alternatives for meeting its stated need.

WakeMed claims that it has a need for an additional PET scanner at WakeMed Raleigh Hospital, despite the underutilized capacity at its existing fixed PET facility. WakeMed states that its cancer program has a large base of patients and its current fixed PET scanner "cannot meet the long-term needs of all WakeMed cancer patients."[9] WakeMed also states that it cannot offer cardiac PET imaging to its patients and therefore has a "care deficit."[10]

However, in its response in Section E.1 on page 61 of its application, WakeMed states that there are no alternatives to its proposed project that will meet this need. WakeMed appears to believe that only a freestanding fixed PET scanner will improve access and promote cost-effective care. However, this claim is undermined by the ample capacity to perform additional PET procedures at its existing location. The WakeMed PET facility has the lowest utilization of any PET scanner in the service area, with additional capacity to accept patients. Despite WakeMed's statements about its large pool of patients needing PET imaging, these patients do not appear to be choosing the WakeMed facility for these diagnostic services.

One option that WakeMed does not discuss is contracting for a mobile PET unit on the WakeMed campus. This would give WakeMed the flexibility to match demand with the appropriate level of resources, which would not be possible with a full-time fixed PET unit. Because WakeMed's existing scanner is operating with available capacity now, the introduction of a second scanner will only serve to further decrease volume as patients are shifted to the proposed PET scanner at the WakeMed campus. Conversely, operating a mobile unit on a part-time basis would allow WakeMed to scale its days of operation to align with referral volume and cases that would benefit from having PET imaging performed at the hospital campus. WakeMed could bill for mobile PET services at freestanding rates, thereby offering a lower cost option to patients and payors. Because the medical office building that the proposed PET scanner would be located at is still under construction, it would be relatively easy to design the facility to include a pad site that would accommodate a mobile PET unit. Yet WakeMed does not appear to have considered this possibility, which would be more cost effective.

[9] WakeMed application, p. 45.

[10] Ibid.

For these reasons, WakeMed has not demonstrated that its project is the most effective alternative, or that there is a need to acquire a second fixed PET scanner given its modest historical utilization. The WakeMed application therefore is non-conforming with Criteria 1, 4, 6, 12, and 18a.

In summary, based on the issues detailed above, the WakeMed application is non-conforming with the review criteria established under N.C. GEN. STAT. § 131E-183, specifically Criteria 1, 3, 4, 5, 6, 12, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703. The WakeMed application should not be approved.

ISSUE-SPECIFIC COMMENTS ON ASSOCIATED UROLOGISTS OF NORTH CAROLINA

The application for the Raleigh PET Imaging facility by Associated Urologists of North Carolina (AUNC) should not be approved. The AUNC application contains multiple methodological errors, omissions, and inconsistencies, as well as incorrect financial pro forma assumptions. UNC Hospitals has identified the statutory review criteria and specific regulatory criteria and standards creating non-conformity. The following issues result in areas of non-conformity for the AUNC application:

1. AUNC's unreasonable utilization methodology results in overstated volume.

PSMA Scan Methodology

AUNC's projected prostate cancer (PSMA) PET scan volumes are significantly overstated due to the application of growth rates that far exceed historical data used to support the projections. AUNC's data shows a compound annual growth rate (CAGR) of 10.67 percent for PET scans in HSA IV between FFY 2019 and FFY 2023, based on *SMFP* figures. While AUNC acknowledges this growth rate in its utilization methodology and claims to apply it in its projections, its actual growth in projected PSMA PET scans reflects a much higher CAGR - more than double the supported historical rate. Specifically, AUNC projects an increase in projected PSMA PET scans from 828 in FY 2024 to 2,221 scans in FY 2029. This represents a five-year increase of 168.2 percent, or compound annual growth of 21.8 percent.

Raleigh PET Imaging
Project PET Scans
FY2027-FY2029

	FY2024	FY2025	FY2026	FY2027	FY2028	FY2029
PSMA PET Referrals / AUNC Physician	59.1	82.2	91.0	100.7	111.5	123.4
Bone Scan Referrals / AUNC Physician	23.1					
5-Year CAGR			10.67%			
# of AUNC Physicians	14	18	18	18	18	18
New Physician Referral %		25.0%	50.0%	75.0%	100.0%	
Projected PSMA PET Scans	**828**	**1,234**	**1,456**	**1,712**	**2,007**	**2,221**
% of Referrals Accepted to RPI				94.3%	94.3%	94.3%
Projected RPI PSMA PET Scans				**1,615**	**1,892**	**2,094**

Source: AUNC application, Form C Methodology p. 1.

This unreasonable growth projection is the result of a flawed methodology that:

1. Adds bone scan referrals to PSMA referrals, then
2. Applies the 10.67 percent annual HSA IV growth rate for to the referral base of PSMA scans and bone scans, and then
3. Further compounds this growth by projecting an increase from 14 to 18 physicians.

The historical growth rate for HSA IV already accounts for the increasing provider pool of referring physicians as a contributing factor in the service area's rapid increase of PET procedures. Adding growth from AUNC's new providers in addition to the historical growth is plainly double-counting new PET procedures. In comparison, the compound average growth rate for the Wake County population, where the majority of AUNC's physician practices are located and from which it can expect to get the

vast majority of its patient referrals[11], is only 1.87 percent, as shown in the AUNC application. The population growth rate is certainly a more appropriate growth rate than AUNC's overstated and flawed methodology. In addition, AUNC claims that all bone scan referrals that are currently sent out by AUNC providers will be converted to PET scans when it begins operating its own PET imaging facility. There is no clinical basis provided for this conversion from one modality to another, nor is any trend data included to support further growth in converted bone scan procedures, as AUNC has assumed. The inclusion of these bone scans to the base of PSMA PET scan referrals is therefore unsupported, and the inclusion of these procedures in AUNC's projections is unreasonable.

If a more reasonable and data-supported estimate of average referrals per AUNC physician for PSMA PET scans is calculated for existing and new providers, while excluding bone scan referrals and not double-counting new physicians at AUNC practices, the resulting number of PSMA PET scans is much lower. These recalculated projections are shown in the following table:

AUNC Restated PSMA PET Referrals, PY1 - PY3

	FY 2024	*FY 2025*	*FY 2026*	*FY 2027 (PY1)*	*FY 2028 (PY2)*	*FY 2029 (PY3)*
PSMA Average Referrals/MD^	59.1	60.2	61.3	62.5	63.6	64.8
# of Existing Physicians	14	14	14	14	14	14
Existing Physician PSMA Referrals	**828**	**843**	**859**	**875**	**892**	**908**
# of New AUNC Physicians	--	4	4	4	4	4
Referral Ramp-Up	--	25%	50%	75%	100%	100%
Referrals/MD – New AUNC Physicians	--	15.1	30.7	46.9	63.6	64.8
New Physician PSMA Referrals	**--**	**60**	**123**	**188**	**254**	**259**
Total PSMA PET Referrals	**828**	**903**	**982**	**1,063**	**1,146**	**1,167**
PET Referral Acceptance %				94.3%	94.3%	94.3%
Projected AUNC PSMA PET Scans	**828**	**903**	**983**	**1,002**	**1,081**	**1,100**

^ Increases by 1.9% annually, based on Wake County projected population growth from 2025-2029.

With these corrections to the flaws in AUNC's methodology, the resulting volume would be only 1,100 PSMA PET scans in FY 2029 – a difference of 1,121 fewer PSMA scans compared to what AUNC projects. This reduction would have a significant impact on Project Year 3 volumes and financial feasibility, as shown in the summary table on a subsequent page below.

Renal Scan Methodology

Similarly, AUNC makes the same growth compounding error while using unsupported data for its calculation of renal PET scans. On page 143 of its application, AUNC describes its methodology for projecting renal PET scans performed at its proposed facility. In the steps that are described, AUNC calculates the historical growth rate in MRI/CT scans, which it claims is 5.7 percent. The statistical source for the figures AUNC uses to support its modeling assumptions are unclear. AUNC states that there were 210,871 MRI/CT scans in Wake County in FY 2019 and 277,837 scans in FY 2013. Of note,

[11] AUNC has a total of four Wake County practices: two are in Cary, one in Raleigh, and one in Wake Forest. AUNC also operates practices in Johnston County (Clayton) and Harnett County (Dunn). Practically speaking, it is unlikely these counties will represent a significant volume of PET patients at the proposed AUNC facility.

the application repeatedly uses "2013" and may instead be intending to refer to "2023"; however, the repeated use of 2013 (in the table in Step 2, in the fourth bullet in Step 3.1) further confound its methodology. In any case, the source of "Wake County MRI/CT scans" is not provided. Volume for CT scans is not provided in the SMFP or any DHSR patient origin reports, and the figures used by AUNC also do not match those found in the *2021* and *2025 SMFP* tables; the *SMFPs* list these volumes as 108,970 and 134,520 unadjusted scans, respectively. It is also unclear whether the application is intending to refer to scans performed in Wake County or scans performed on Wake County residents. Given the lack of detail regarding its assumptions, the AUNC methodology is not reasonably supported.

Next, AUNC adds in the incremental growth in MRI/CT referrals from four new physicians at the AUNC practice. Just as it did with the projected growth in PSMA PET scan referrals, AUNC double-counts the growth drivers by:

1. Applying a 2.5 percent annual growth rate to the referral base rate of 168.8 MRI/CT referrals to future years, and then
2. Including additional growth by projecting an increase from 14 to 18 physicians.

The historical Wake County growth rate would have already incorporated the increasing provider pool of physicians that referred patients for MRI/CT scans, resulting in AUNC overstating the potential growth in referrals. AUNC's actual potential base of MRI/CT scans can be calculated by holding the historical rate of 168.8 referrals per physician in FY 2024 constant and then accounting for the new physicians in its calculation. [12]

AUNC Restated Renal PET Referrals, PY1 - PY3

	FY 2024	*FY 2025*	*FY 2026*	*FY 2027 (PY1)*	*FY 2028 (PY2)*	*FY 2029 (PY3)*
MRI/CT Average Referral Rate/MD	168.8	168.8	168.8	168.8	168.8	168.8
Existing Physicians	14	14	14	14	14	14
Referrals – AUNC Existing Physicians	2,363	2,363	2,363	2,363	2,363	2,363
New Physicians	0	4	4	4	4	4
Referral Ramp-Up	--	25%	50%	75%	100%	100%
Referrals – AUNC New Physicians	--	169	338	506	675	675
Total AUNC MRI/CT Referrals	**2,363**	**2,532**	**2,701**	**2,869**	**3,038**	**3,038**
MRI to PET Referral Conversion %	25%	25%	25%	25%	25%	25%
PET Referrals	**591**	**633**	**675**	**717**	**760**	**760**
PET Referral Acceptance %	50%	50%	50%	50%	50%	50%
AUNC Renal PET Scans	**296**	**317**	**338**	**359**	**380**	**380**

[12] AUNC application, p. 140. AUNC assumes the four new physicians will have lower MRI referrals than the AUNC physician average in the first four years, with the percentages increasing from 25% in the first year to 100% by the fourth year at the practice. Note that Step 2 in the Form C Utilization Methodology and Assumptions description on page 144 erroneously shows new physician ramp-up at 25% each year from FY 2025 to FY 2029, although the calculations for the number of referrals are correct.

These revisions result in renal PET scan utilization at AUNC of 359, 380, and 380 scans for project years 1 through 3, respectively. The recalculated figures are lower than the projections of 386, 419, and 430 that AUNC shows in its methodology summary on page 140 of its application and further lower the total number of PET scans performed each year at the proposed facility.

The following table summarizes the restated PET volumes for PSMA and renal procedures at the AUNC facility. The total number of PET scans at AUNC is 1,602 in FY 2029, the third project year. This is substantially lower than the required performance standard of 2,080 PET scans by the third project year. With these more reasonable assumptions, AUNC cannot demonstrate that it meets the required volume threshold or that there is a need for its project.

AUNC Restated PET Scan Utilization, PY1 - PY3

	FY 2027 (PY1)	*FY 2028 (PY2)*	*FY 2029 (PY3)*
Restated PSMA PET Scans	1,002	1,081	1,100
Restated Renal PET Scans	359	380	380
Cardiac/Ortho/Neuro PET Scans	122	122	122
AUNC Total PET Scans	**1,483**	**1,583**	**1,602**

As such, the AUNC application is non-conforming with Criteria 1, 3, 4, 5, 6, and 18a, as well as the performance standard at 10A NCAC 14C .3703, and should not be approved.

2. AUNC does not provide reasonable evidence it will perform non-urologic PET procedures.

AUNC's projected utilization includes more than 100 procedures per year that are not related to urology, nephrology, or prostate cancer.

PET Scans	FY2027	FY2028	FY2029
PSMA	1,615	1,892	2,094
Renal	386	419	430
Cardiac-Ortho-Neuro	122	122	122
Total	**2,123**	**2,434**	**2,646**

Source: AUNC application, Form C Assumptions and Methodology, p. 1.

AUNC also asserts on page 4 of its Form C Assumptions and Methodology that "several physicians from other medical specialties have stated their willingness to refer PET scans (Cardiac, Orthopedic, Neurologic) to Raleigh PET Imaging" and references physician support letters attached in the Form C Assumptions. However, none of the letters that were included with the AUNC application are from cardiologists. The specialties represented in the AUNC application are orthopedics, neurology, and pulmonology. There is no evidence to support that AUNC will receive referrals for cardiac PET scans; therefore, the utilization projections for 122 scans in this category are without any basis and are overstated.

Similarly, AUNC does not provide documentation that it will have the facilities and resources necessary to perform cardiac PET scans. In Section C.1, AUNC describes the process for performing

cardiac PET, including the injection of radiotracers such as Rubidium-82 or 18F-FDG.[13] While stating the need for Rubidium to do cardiology scans, there is no discussion of having an onsite generator or a vendor contract to provide this tracer. Further, the line drawings in Exhibit C.1 of the AUNC application provide no evidence that a Rubidium generator is included in the proposed project. Without this documentation, it is unclear how AUNC will perform cardiac PET scans, and this volume is unsupported.

Furthermore, the AUNC facility is primarily designed and operated as a urology specialty practice. Although PET scanning can be used for diagnosing cancers in other anatomical sites, the AUNC facility does not have complementary programs and services for cancer care, and the facility is poorly equipped to serve these patients. Cancer patients and their referring doctors consistently demonstrate a strong preference for comprehensive cancer treatment centers where they can receive integrated care including diagnostics, treatment planning, therapy, and supportive services under one roof. This preference is not merely a matter of convenience but reflects the superior clinical outcomes associated with coordinated, multidisciplinary care. The proposed PET scanner at AUNC will not be part of this type of comprehensive continuum of care for patients with non-urological cancers. It is more realistic that virtually all patients referred to AUNC for PET imaging will be referred by AUNC physicians and will thus entirely consist of urological patients. Without established referral relationships beyond urology, complementary treatment services for non-urological cancers, or specialized oncological expertise with other anatomical sites, it is unreasonable to expect that AUNC will attract significant numbers of non-urological patients. AUNC has not included a satisfactory explanation for why its PET imaging facility will offer clinical care advantages to patients over more comprehensive cancer care facilities. Therefore, the projected volume of PET scans for non-urological patients at AUNC is unsupported.

Accordingly, the AUNC application is non-conforming with Criteria 3, 4, 5, 6, 12, and 18a, and should not be approved.

3. <u>AUNC understates its net revenue and operating expenses.</u>

AUNC does not include revenue or operating costs for the radiotracers needed to perform PSMA and renal PET procedures. AUNC states in its Form F.2 and Form F.3 assumptions that the reimbursement for these supplies "is essentially a 'passthrough' from the Payor to the radiotracer manufacturer"[14] and therefore does not include this item in its calculation of revenue and expenses and argues these costs should not be used for comparative purposes. While excluding the cost for these supplies will result in AUNC having relatively lower and thus more favorable revenue per procedure and average operating cost per procedure figures in a review of Comparative Factors, it is inappropriate to exclude these radiotracers from the revenue and expense calculations. These supplies are actual costs that the patient/payor will incur when performing PSMA and renal PET procedures, and as such should be part of the financial calculations, in addition to any comparison of the AUNC application with competing projects in the review.

Accordingly, the AUNC application is non-conforming with Criterion 5, and should not be approved.

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13 AUNC application, p. 50.

14 AUNC application, pp. 158, 164.

In summary, based on the issues detailed above, the AUNC application is non-conforming with the review criteria established under N.C. GEN. STAT. § 131E-183, specifically Criteria 1, 3, 4, 5, 6, 12, 13(c), and 18a, as well as the performance standards specified in 10A NCAC 14C .3703. The AUNC application should not be approved.

ISSUE-SPECIFIC COMMENTS ON DURHAM DIAGNOSTIC IMAGING

The application by Durham Diagnostic Imaging (DDI, Novant) should not be approved. The Novant application contains multiple methodological errors and inconsistencies, as well as incorrect financial pro forma assumptions. UNC Hospitals has identified the statutory review criteria and specific regulatory criteria and standards that are non-conforming. The following issues result in areas of non-conformity for the Novant application:

1. Novant's utilization methodology is unreasonable and its projections are overstated.

   In its "Form C.2 Utilization - Assumptions and Methodology,"[15] Novant presents a methodology for projecting PET utilization that does not adequately demonstrate the need for the proposed service or the reasonableness of its volume projections. As shown below, there are numerous critical flaws in Novant's approach and assumptions.

   The methodology for the DDI PET service appears to be based on an estimate of available capacity rather than demonstrated patient need or market demand. In Step 3 of its methodology (page 3), Novant calculates its equipment capacity at 4,000 procedures annually based on operational assumptions.

   Estimated Capacity for Fixed PET/CT Scanner at DDI:

Proposed Operational Schedule	5 days per week x 50 weeks = 250 operational days annually
Estimated Annual Capacity	250 operational days x 8 hours per day x 2 procedure appointments per hour = 4,000 procedures annually

   Source: DDI application, Utilization Projections & Assumptions, p. 2.

   However, this estimate of maximum capacity is not based on historical data for Novant PET facilities nor any industry benchmarking data. Further, this capacity definition does not align with the capacity presented in the *2025 SMFP*. Novant states that it operates fixed PET scanners in Mecklenburg, Forsyth, and New Hanover counties,[16] yet fails to include any calculation of throughput for these locations as a basis for its projections at the DDI facility. The presumed maximum capacity of 4,000 procedures is therefore not based on historical data specific to Novant that was available to the applicant.

   The lack of a reasonable basis for its assumed capacity is a fundamental issue for the projected utilization because of how Novant projects its volume. Specifically, in Steps 4 through 7, Novant works backwards to develop utilization projections that would fill its assumed capacity, rather than demonstrating why patients actually need the number of PET scans projected at the facility. Novant justifies its projected utilization of 2,000 PET scans in the first project year (FY 2027) based solely on the fact that 2,000 procedures would represent one-half of its estimated maximum capacity of 4,000

[15] DDI application, pp. 122-127.

[16] DDI application, Utilization Projections & Assumptions, p. 3.

procedures per year. It does not provide any justification for why this percentage is appropriate, nor does it use market utilization data specific to existing PET service providers to determine this volume.

Similarly, Novant assumes that for the sole reason it operates PET services in other markets, it will automatically attain the same utilization volume for its startup PET scanner in HSA IV as its existing fixed PET units in Mecklenburg, Forsyth, and New Hanover counties.[17] Novant makes no mention of the physician practices that it also operates in these counties, and the correlation between employed specialty physician practices such as oncologists and cardiologists with referral patterns for imaging services such as PET imaging. In fact, Novant fails to demonstrate that it has any specialty physician groups in HSA IV that will reasonably refer patients for PET procedures to the proposed DDI facility. Novant's projection of 2,000 procedures in the first year of operation represents 9.4 percent of the total procedures performed by HSA IV PET facilities in FFY 2023 (2,000 ÷ 21,251 = 9.41%). This is an overstated projection for several reasons. The proposed Novant PET scanner will be a new market entrant with no existing referral base or familiarity with referring physicians. Novant operates primary care practices in Wake Forest and Sports Medicine practices in Cary and North Raleigh. These practices alone cannot reasonably be expected to refer 2,000 patients per year, as PET imaging is not recognized as a preferred modality for musculoskeletal injuries and a primary care practice located nearly 30 miles from the proposed PET facility can expect a significant percentage of patients will opt to have PET scans performed at a location that requires less travel. In any case, Novant makes no mention of specific physician practices that will refer patients to its proposed PET service.

The other PET facilities in the service area include UNC Hospitals and Duke Health, two academic medical centers that draw significant numbers of patients from outside the HSA. In contrast, it is unlikely that Novant's facility will receive many, if any, referrals from outside the HSA, and, in fact, inmigration from outside the HSA is not part of its utilization projections. Given the number of existing PET providers in HSA IV and the prominent role some of those facilities have as medical care destinations for patients from all parts of North Carolina, it is not realistic for Novant to immediately capture such a high share of the PET procedures performed in the HSA.

Next, to project PET utilization in project years 2 and 3, Novant applies the compound annual growth rate for PET procedures performed at existing HSA IV facilities from 2020 to 2023. The CAGR in the service area was 19.9 percent over this period, as shown in the following table:

Year	Statewide - Number of PET Procedures	% Change	HSA IV- Number of PET Procedures	% Change
2020	50572	----	12325	----
2021	54837	8.4%	14418	17.0%
2022	65356	19.1%	18221	26.3%
2023	77351	18.3%	21251	16.6%
FIXED PET	**NC CAGR**	**15.2%**	**HSA IV CAGR**	**19.9%**

Source: 2022-2025 SMFPs

Source: DDI application, Utilization & Projections, p. 1.

Novant then applies this CAGR to its estimate of PET procedures that will be performed at the DDI facility in the first year of operation to calculate total PET procedures in Project Years 2 through 3.

[17] DDI application, Utilization Projections & Assumptions, pp. 3-4.

This results in annual volumes of 2,398 procedures and 2,875 procedures, respectively, in FY 2028 and FY 2029:

Timeframe	*Estimated PET Volume/Project Year*	*% Change*
Project Year 1 10/1/2026-9/30/2027	2000	----
Project Year 2 10/1/2027-9/30/2028	2398	19.9%
Project Year 3 10/1/2028-9/30/2029	2875	19.9%

Source: DDI application, Utilization & Projections, p. 4.

Applying this CAGR as the growth assumption for the DDI facility is unrealistic and unsupported for numerous reasons. First, the choice of 2020 as a base year artificially increases the historical growth because 2020 coincided with the COVID-19 pandemic, and many ambulatory facilities and elective procedures were canceled when these facilities were closed or available only for emergent health care needs. The effect of using 2020 as a starting point artificially inflates the growth rate compared to using a baseline year prior to the pandemic. Indeed, if one uses the FFY 2019 utilization from the *2021 SMFP*, there were 12,798 PET procedures performed in HSA IV,[18] which would result in a CAGR of just 13.5 percent for the period from 2019 to 2023.

Second, Novant does not provide a sufficient explanation for why utilization at the DDI facility will grow at the same historical rate as existing PET providers in the service area. The other PET facilities in HSA IV are existing providers with established referral patterns and provider relationships. Although DDI is an existing imaging facility, it has no prior history of providing PET services. Without an accompanying discussion of why DDI will grow at the same rate as these other providers, this growth rate is not reasonable. While Novant mentions general factors such as population growth, aging demographics, and disease prevalence rates that could affect utilization in its need discussion in Section C, it does not provide specific, quantitative evidence connecting these factors to its volume projections. The applicant has not adequately demonstrated why patients would choose this facility over existing providers or how these factors translate directly into specific utilization projections.

Third, while Novant projects that PET utilization at its own facility will grow at the HSA IV historical CAGR of 19.9 percent, it assumes that the total market volume in the HSA will grow at less than half this rate. In Step 2 of its Utilization Projections & Assumptions, Novant chooses to apply the lower statewide historical PET procedure CAGR of 15.2 percent to the PET volume in HSA IV, and then further reduces this growth assumption by half, for a growth rate of 7.6 percent from FY 2023 to FY 2029, with a resulting total market PET utilization of 32,290 procedures in FY 2029:

[18] *2021 SMFP*, Table 1F-1: Utilization of Existing Dedicated Fixed PET Scanners, https://info.ncdhhs.gov/dhsr/ncsmfp/2021/2021-F-SMFP-assembled-num-bookmarks.pdf

Projected Fixed PET Volume – HSA IV		FY 22-2023#	FY 23-2024	FY 24-2025	FY 25-2026	FY 26-2027	FY 27-2028	FY 28-2029
Growth Rate	7.6%	21251	22866	24604	26474	28486	30651	32980
No. of Existing PET Units		9	9	9	9	11*	11*	11*
Average Volume/Unit		2361	2541	2734	2942	**2590**	**2787**	**2998**

NC CAGR of 15.2%/2=7.6% growth rate #Data from the 2025 SMFP is based on FY 2022-23 data reported by providers.

Source: DDI application, Utilization Projections & Assumptions, p. 2.

It is not reasonable for Novant to project the utilization of its proposed PET scanner to grow at 2.6 times the overall growth in the service area (19.9% ÷ 7.6% = 2.62). As discussed earlier, DDI is not an established provider of PET imaging, nor does Novant have an established physician practice network to refer patients. To achieve this growth rate, Novant would need to capture market share from other existing PET providers in HSA IV. Novant has given no explanation for how it would accomplish these outrageous market share increases. As noted previously, Novant unrealistically assumes that it will achieve its projected utilization simply by obtaining a PET scanner with capacity to serve patients. Without demonstrating the process for how it will attain these patients, this assumption is unsupported and unreasonable.

Although Novant states that it "reviewed historical data for fixed PET/CT scanners in North Carolina and HSA IV" to develop its utilization projections, the projections for the DDI facility are not consistent even with Novant's other facilities that provide PET services. In Step 4 on page 3 of its methodology, DDI notes that "Novant Health operates fixed PET scanners in Forsyth County (2 Fixed Units – 1 existing and 1 approved), Mecklenburg County (1 Fixed Unit) and New Hanover County (2 Fixed Units – 1 existing and 1 approved)." However, according to the *2025 SMFP*, these four existing units performed a total of 9,312 procedures in FFY 2023, which equates to just 2,328 procedures per scanner on average. This historical performance casts doubt on DDI's assertion that its new scanner will perform 2,000 procedures in Year 1, 2,398 procedures in Year 2, and 2,875 procedures in Year 3. Given that DDI's projections for its new facility exceed the average performance of Novant Health's four well-established PET scanners, and those same locations have had years to develop referral patterns and community awareness, DDI's utilization projections are unreasonable and inadequately supported.

The county-specific volume projections for DDI further demonstrate the unreasonableness of its methodology. According to its patient origin table in Section C.3, DDI projects 469 scans from Person County in Project Year 3:

<Fixed PET Services>	<Durham Diagnostic Imaging> *					
	1st Full FY		2nd Full FY		3rd Full FY	
	mm/dd/yyyy to mm/dd/yyyy		mm/dd/yyyy to mm/dd/yyyy		mm/dd/yyyy to mm/dd/yyyy	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Durham County	1108	55.4%	1328	55.4%	1593	55.4%
Person County	326	16.3%	391	16.3%	469	16.3%
Granville County	156	7.8%	187	7.8%	224	7.8%
Orange County	140	7.0%	168	7.0%	201	7.0%
Wake County	70	3.5%	84	3.5%	101	3.5%
Vance County	26	1.3%	31	1.3%	37	1.3%
Franklin County	16	0.8%	19	0.8%	23	0.8%
Chatham County	8	0.4%	10	0.4%	12	0.4%
Warren County	6	0.3%	7	0.3%	9	0.3%
Lee County	2	0.1%	2	0.1%	3	0.1%
Johnston County	2	0.1%	2	0.1%	3	0.1%
Alamance County	64	3.2%	77	3.2%	92	3.2%
Caswell County	12	0.6%	14	0.6%	17	0.6%
Other – NC and out of state	64	3.2%	77	3.2%	92	3.2%
Total	**2000**	**100%**	**2398**	**100%**	**2875**	**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.

Source: DDI application, p. 47.

However, according to Division of Health Service Regulation data, there were only 318 total PET scans for all Person County residents in 2023, across all statewide PET facilities.[19] This means DDI is projecting to capture 147 percent of the entire existing Person County PET scan volume, which is mathematically impossible without extraordinary population growth or disease prevalence and clinical practice changes that DDI fails to document or justify. This significant overestimation calls into question the validity of all of DDI's county-level projections and, by extension, its total volume projections.

As such, the Novant application is non-conforming with Criteria 3, 4, 5, 6, and 18a, as well as the performance standard for PET Scanners (10A NCAC 14C .3703).

2. Novant fails to demonstrate the reasonableness of its projected payor mix.

The Novant application projects the payor mix for its proposed PET scanner based on the "historical payor mix [for] DDI as of the last full year of operation."[20] DDI's existing imaging services do not include PET scans, but do include MRI, CT, X-Ray, Ultrasound, and Mammography. This methodology is fundamentally flawed and does not adequately support the projected payor mix expected for PET patients.

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19 DHSR 2024 PET Patient Origin Report, https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2024/33-PatientOrigin_PET-2024.pdf

20 DDI application, Form F.2 Assumptions, p. 1.

PET scanning is a highly specialized nuclear imaging technique predominantly used for oncology, neurology, and cardiology applications, while conventional imaging modalities serve broader diagnostic purposes with different clinical applications, such as musculoskeletal injuries and conditions for MRI and CT. The patient population requiring PET scans typically has different clinical characteristics, insurance coverage, and access patterns compared to patients that routinely use diagnostic imaging services.

Novant's application fails to acknowledge these fundamental differences or provide evidence that its current payor mix from general imaging services would reasonably translate to PET services. The applicant does not provide data from comparable PET providers, including Novant's other PET facilities in North Carolina. Nor does Novant reference any industry standards for PET services, or address how its projected payor mix aligns with the known payor distribution for cancer care services, which constitute the majority of PET scan indications.

Novant's reliance on the existing payor mix for its other imaging modalities without providing a sufficient discussion of why these payor assumptions would apply to a distinctly different service like PET scanning undermines the credibility of its financial projections and access projections.

As such, the Novant application is non-conforming with Criteria 5 and 13(c), as it fails to adequately demonstrate the reasonableness of its payor mix projections or the financial feasibility of the project based on those projections.

3. Novant has omitted necessary expenses and does not demonstrate financial feasibility.

In its financial projections, Novant has significantly understated the operational expenses for its proposed PET scanner by omitting critical pharmacy costs associated with PET services. The application states that "medical and other supply expenses are estimated based on Novant's experience providing fixed PET services in North Carolina on a per scan basis for PET/CT service,"[21] projecting only $163 per scan for medical supplies, as calculated in the following table:

DDI Medical Supply Expense per PET Procedure, PY1 - PY3

	FY 2027 (PY1)	*FY 2028 (PY2)*	*FY 2029 (PY3)*
Medical Supply Expense	$324,000	$388,476	$465,750
Other Supply Expense	$1,480	$1,775	$2,128
Pharmacy Expense	$0	$0	$0
PET Scans	2,000	2,398	2,875
Total Supply Expense per Scan	$163	$163	$163

Source: DDI application, Forms C.2a and F.3b.

This projection is unreasonably low and inconsistent with Novant Health's own documented experience with PET scanner operations. In its most recent CON application for Novant Health Presbyterian Medical Center (NHPMC), the facility reported pharmacy expenses of $2,470,699 for 2,403 PET scans in 2023, which equates to approximately $1,028 per scan for pharmaceutical costs alone.[22] In its cost projections for FY 2027 through FY 2029 (the same years as the projections in the

21 DDI application, Form F.3 Assumptions, p. 5.

22 See Project ID # F-12557-24, Form F.3a.

DDI application), NHPMC projected total supply costs of $1,170 in the first project year, increasing to $1,241 in project year 3, as summarized in the following table:

NHPMC Supply Expense per PET Procedure, PY1 - PY3

	FY 2027 (PY1)	*FY 2028 (PY2)*	*FY 2029 (PY3)*
Medical Supply Expense	$12,651	$15,036	$18,147
Other Supply Expense	$28,016	$33,300	$40,188
Pharmacy Expense	$3,720,455	$4,422,076	$5,336,778
PET Scans	3,215	3,709	4,347
Total Supply Expense per Scan	$1,170	$1,205	$1,241

Source: NHPMC application, Forms C.2a and F.3b.

The DDI application clearly understates medical supply expenses by a considerable amount. Using the 2023 pharmacy expense rate from the 2024 NHPMC CON application (without accounting for inflation) would increase DDI's project expenses by over $2.4 million in Project Year 3, as shown below in Form F.3a from the NHPMC CON application. This substantial additional expense would render the DDI project financially infeasible as proposed.

Form F.3a Historical & Interim Operating Costs

Form F.3a Historical and Interim Operating Costs NHPMC Fixed PET Scanner	Last Full FY F: 01/01/2023 T: 12/31/2023	Interim Full FY F: 01/01/2024 T: 12/31/2024	Interim Full FY F: 01/01/2025 T: 12/31/2025	Interim Full FY F: 01/01/2026 T: 12/31/2026
Salaries (from Form H Staffing)	$304,950	$314,099	$323,522	$333,227
Taxes and Benefits	$92,130	$94,893	$97,740	$100,672
Independent Contractors (1)	$6,470	$7,153	$7,744	$8,377
Medical Supplies	$8,401	$9,287	$10,055	$10,876
Other Supplies	$18,605	$20,567	$22,268	$24,087
Pharmacy (2)	$2,470,699	$2,731,208	$2,957,128	$3,198,639
Equipment Maintenance (2)	$92,915	$95,714	$98,594	$25,539
Total Expenses	$2,994,171	$3,272,920	$3,517,052	$3,701,418

Source: Project ID # F-12557-24.

Form C.2 Medical Equipment Utilization

Form C.2a Historical and Interim Medical Equipment Utilization NHPMC	Last Full FY F: 01/01/2023 T: 12/31/2023	Interim Full FY F: 01/01/2024 T: 12/31/2024	Interim Full FY F: 01/01/2025 T: 12/31/2025	Interim Full FY F: 01/01/2026 T: 12/31/2026
PET Scanner (fixed) # of Units	1	1	1	1
# of Procedures	2,403	2,579	2,711	2,846

Source: Project ID # F-12557-24.

This omission represents a critical flaw in Novant's financial projections and demonstrates that the DDI application does not adequately account for all necessary operational costs associated with providing PET services. The application therefore fails to provide reasonable projections of the costs that will be incurred by the applicant in providing the proposed services.

As such, the Novant application is non-conforming with Criteria 1, 5, 13(c), and 18a, as it fails to adequately demonstrate the immediate and long-term financial feasibility of the proposal, and that the project is cost-effective and meets the needs of underserved populations.

4. Novant's revenue assumptions are unsupported and unreasonable.

The financial projections for the proposed PET scanner at the DDI facility contain vague and insufficient detail regarding its expected revenue. In its assumptions, Novant states simply that gross revenue is "based on the total revenue anticipated for the proposed fixed PET/CT service,"[23] without providing any substantive methodology or supporting data.

This cursory explanation fails to provide the level of detail required to evaluate the reasonableness of the projected revenue. Novant does not specify what charges or fee schedules were used, how these charges compare to industry standards, or what assumptions were made regarding reimbursement rates from different payors.

Furthermore, Novant assumes that its contractual adjustments for PET services at DDI will be similar to the facility's other imaging services, stating these payor adjustments "will approximate its historical experience for the entire facility."[24] This is an unreasonable assumption, as PET scanning is fundamentally different from conventional imaging in terms of reimbursement structures and payor policies. Just as with payor mix, contractual adjustment rates for specialized nuclear medicine services like PET may not be reliably projected based on general diagnostic imaging services.

The vague revenue assumptions, combined with unsupported contractual adjustment projections and the previously discussed underestimation of expenses, prevent a thorough assessment of the project's financial feasibility.

As such, the Novant application is non-conforming with Criterion 5, as it fails to adequately demonstrate the reasonableness of its financial assumptions and the financial feasibility of the proposal.

5. Novant fails to demonstrate the DDI facility is properly designed to assure safety and quality.

Novant implies that the DDI PET service will perform cardiac PET procedures, based on its description of the application of PET imaging for performing non-invasive heart and vascular testing to identify diseases and performance deficiencies. However, the Novant application does not include any letters of support from cardiology physicians to demonstrate there is support for cardiac PET scans at DDI or

[23] DDI application, Form F.2a.1 PET Service Assumptions, p.2.

[24] Ibid.

a willingness to send patients to the facility.[25] One of the key radiotracers necessary for performing cardiac myocardial perfusion imaging PET scans is Rubidium-82, which has a short half-life and should ideally be produced in an on-site generator facility. The DDI facility shows no evidence of a rubidium generator included in its floor plan in Exhibit K.2. Moreover, although Novant explains that new radiotracers such as Flurpiridaz F-18 will supplant Rb-82 due to its longer lifespan and ability to have more flexibility in scheduling and completing cardiac PET scans, the floor plan diagram also shows no evidence of a "hot room" to be used for storing radiotracers and preparing the doses for patient uptake. The architectural renderings of the DDI PET facility include two uptake rooms and two "theranostic" rooms, without explanation of what the specific purpose is for these rooms. If Novant intends to purchase radiotracers like Flurpiridaz F-18 and immediately bring them from the courier delivery to the uptake room, this could compromise the radiation safety and controlled delivery of radiopharmaceuticals. The line drawings do not demonstrate that the facilities have a secure and shielded area for storing and preparing radioactive supplies.

Accordingly, the Novant application is non-conforming with Criteria 1, 4, 8, 12, and 18a, as the facility design is not reasonable, nor does it provide evidence that quality care will be provided.

6. Novant overstates the operational efficiency of its proposed PET service.

Novant states that it has "conservatively assume[d] that 2 procedures per hour can be performed" on its proposed PET scanner.[26] Novant explains that it has received assurances from its equipment vendor that a PET scan procedure can be completed in 10 minutes. Novant therefore allows a total of 20 additional minutes for the remaining steps in the patient's visit, including registration, rooming and changing, staff preparation, dosing, and administering of the radiopharmaceutical, and wait time for the uptake of the radiotracer before performing the PET scan. Given the number of steps in this process and the coordination required to prepare the patient for their scan, it is not realistic to achieve this operational throughput. Using these assumptions, Novant estimates the maximum capacity for its proposed scanner is 4,000 PET scans per year.[27] This is 33 percent higher than the maximum capacity standard of 3,000 PET procedures listed in the *SMFP.*[28] Novant does not elaborate on how its facility can achieve such rapid throughput. Adding to this dubious assumption, the DDI facility line drawing in Exhibit K.2 does not appear to have a hot lab for storing and preparing radiopharmaceuticals. Without having a dedicated area to have radioactive materials delivered and stored so that patients may be dosed appropriately and safely, it is even more unlikely that Novant will be able to perform PET procedures with the level of coordination necessary to reach this level of throughput.

If Novant has used these productivity assumptions to build its staffing model, then the staffing requirements for the proposed project are understated. In its Form H Staffing Assumptions, Novant states that the DDI facility will add 2.0 FTE PET /CT Technicians and a 1.0 FTE Tech Assistant to staff the proposed project.[29] Additional clinical staff will be needed to achieve the throughput rate of two

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25 The support letters included in Exhibit C of the DDI application are from Internal Medicine and Urology providers.

26 DDI application, Utilization Projections & Assumptions, p. 2.

27 DDI application, Utilization Projections & Assumptions, p. 3.

28 *2025 SMFP* PET Scanner Methodology, p. 363. https://info.ncdhhs.gov/dhsr/ncsmfp/2025/2025SMFP_eversion_FINAL.pdf

29 DDI application, p. 164.

patients per hour that Novant has estimated, adding to the project's operating costs in its first three years. Novant has not budgeted for any additional administrative or customer service staff; if the existing staff at the DDI facility will be expected to perform patient registration and other administrative processes, this further reduces the reasonableness of Novant's excessively optimistic productivity assumptions.

As such, the Novant application is non-conforming with Criteria 4, 5, 6, 7, and 18a, as the facility's operating model and impact on competition are not supported.

In summary, based on the issues detailed above, the Novant application is non-conforming with the review criteria established under N.C. GEN. STAT. § 131E-183, specifically Criteria 1, 3, 4, 5, 6, 7, 8, 12, 13(c), and 18a, as well as the performance standards specified in 10A NCAC 14C .3703. The Novant application should not be approved.

ISSUE-SPECIFIC COMMENTS ON DUKE CARY HOSPITAL APPLICATION

The Duke Cary Hospital (Duke Cary) application should not be approved. The Duke Cary application contains multiple methodological errors and inconsistencies, as well as incorrect financial pro forma assumptions. UNC Hospitals has identified the statutory review criteria and specific regulatory criteria and standards that are non-conforming. The following issues result in areas of non-conformity for the Duke Cary application:

1. <u>The Duke Cary application does not adequately explain why the project is the most effective alternative.</u>

   In Section E of its application Duke Cary states that the current utilization of its four PET scanners would exceed the performance standards described in 10A NCAC 14C .3703 for five PET scanners, and its current inventory "is not sufficient to sustain current utilization, let alone future increased demand."[30] DUHS also observes that locating a second PET scanner at Duke Raleigh Hospital (Duke Raleigh), the location of one existing PET scanner, would have the effect of increasing capacity in Wake County.[31] Yet Duke Cary proposes to locate the additional PET scanner that it claims is necessary to provide immediate relief for DUHS's highly utilized scanners at the future Duke Cary Hospital that will take years to complete, rather than a location where the PET scanner can be operationalized more quickly. The following table shows the differences in start dates for the seven proposed projects in the review:

Proposed PET Scanner Start of Operation

CON Applicant	*Start Date*
Duke University Hospital	October 2025
UNC Hospitals	July 2026
Raleigh PET Imaging (AUNC)	July 2026
WR Imaging	October 2026
Durham Diagnostic Imaging (Novant)	October 2026
Raleigh PET (WakeMed)	October 2027
Duke Cary Hospital	July 2029

Source: CON applications, Section P.

Because Duke Cary claims that it does not have adequate capacity to accommodate continued utilization growth, it is unusual that the timeframe for developing its proposed PET scanner has such a long development schedule. While UNC Hospitals is aware that projects such as acute care hospitals have longer design and development phases than less complex service components and extended construction timelines, it believes that if there are immediate capacity issues then Duke Cary has not selected the most effective alternative. DUHS could meet the demand for PET services in Wake County by either locating its proposed PET scanner at Duke Raleigh Hospital, at one of DUHS's outpatient cancer centers in Wake County, or even on the Duke Cary campus as an outpatient facility. Any one of these locations would address the alleged capacity challenges DUHS's existing PET scanners are experiencing and would increase access to PET services in Wake County as proposed in the application. Locating the proposed PET scanner at Duke Cary Hospital will not increase available

[30] Duke Cary application, p. 62.

[31] Ibid.

resources for PET services in Wake County for nearly four years, creating even longer delays in scheduling PET procedures for DUHS patients as demand continues to grow.

Accordingly, the Duke Cary application is non-conforming with Criteria 3, 4, 6, and 12, and should not be approved.

2. DUHS uses an unreasonable methodology for allocating volume to its Wake County PET facilities.

DUHS uses an unsupported methodology to shift PET volume from Duke University Hospital (DUH) to the two Wake County facilities, Duke Raleigh and the proposed PET at Duke Cary Hospital. As noted in its Form C Methodology, DUHS has identified Wake County PET cases that currently go to Duke University Hospital and assumes that ultimately 75 percent of these cases will shift to a DUHS location in Wake County.[32]

In Step 3 of its methodology, DUHS adds the projected utilization at Duke Raleigh and the calculation of Wake County patients at Duke University Hospital that will potentially shift to calculate the total amount of available PET procedures that will be served at a Wake County facility. In 2030, this volume is estimated at 3,320 procedures, increasing to 4,300 procedures in 2032. DUHS then evenly divides the volume of procedures between Duke Raleigh and Duke Cary, so that both facilities have equal volume in project years 1-3. These steps are summarized in the following table:

DUHS Methodology Summary for Wake County Facilities

	2030	*2031*	*2032*	*CAGR*
Duke Raleigh Pre-Shift	2,953	3,041	3,133	3.0%
DUH Wake County Patients Shifted	367	756	1,168	78.4%
Total Wake County Facilities	3,320	3,797	4,300	13.8%
Duke Cary Hospital (50%)	1,660	1,899	2,150	13.8%
Duke Raleigh Hospital (50%)	1,660	1,899	2,150	
Patients Diverted from Raleigh to Cary*	1,293	1,142	983	-12.8%

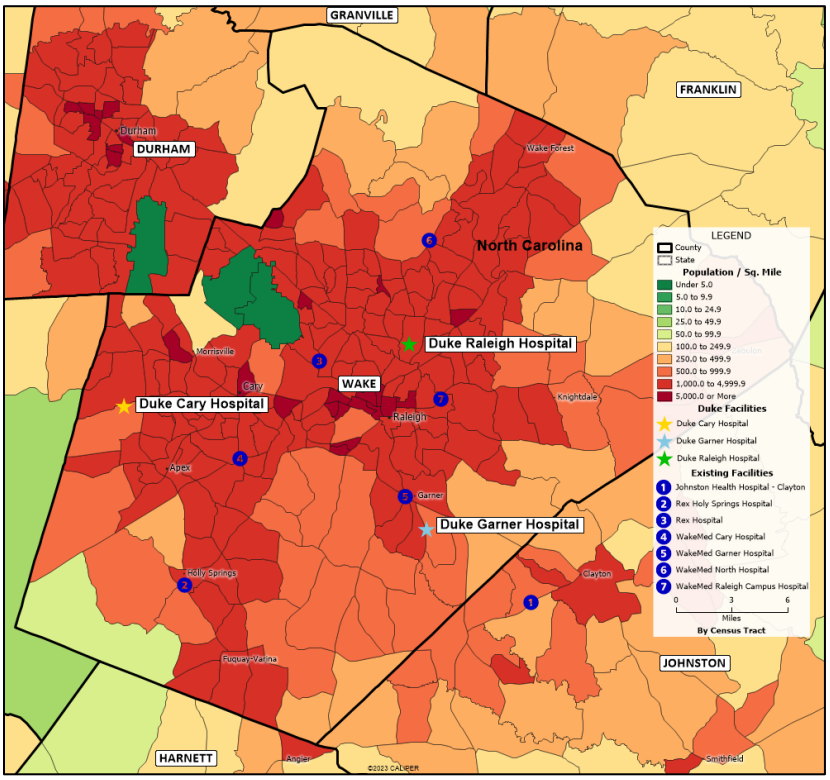
Source: Duke Cary application, p. 106 and p.107

* Duke Raleigh pre-shift – Duke Raleigh utilization after 50-50 split

DUHS does not explain why it is reasonable to divide PET utilization equally at Duke Raleigh, a facility that has offered PET services since 2021, and the proposed Duke Cary Hospital. Growing the base volume at Duke Raleigh before any shift to other facilities would result in 3,133 total PET procedures at Duke Raleigh in 2032. The addition of the proposed PET scanner at Duke Cary would remove nearly 1,300 PET procedures from Duke Raleigh in the first project year. It is not reasonable that a new facility with no operational history will immediately experience volume comparable to a more established facility like Duke Raleigh. Furthermore, Duke Raleigh is more centrally located in Wake County and closer to more populated communities within the county. DUH assumes it will shift 11.2 percent of Wake County PET procedures from the Durham County location to a site in Wake County but has included no ZIP code-level analysis to indicate where in Wake County these patients originate from. It is unreasonable to assume that patients from northern and eastern Wake County will drive past Duke Raleigh to receive their PET scan in Cary. DUHS notes that "while a second scanner at Duke

[32] Duke Cary application, pp. 104-106.

Raleigh Hospital would also increase capacity in Wake County, it may be less convenient for the growing population in the western part of the county and surrounding areas" (p. 63). This may be true, but the need for PET services in central Wake County is relatively higher than in Cary, due to the greater population. Indeed, DUHS's own population density map shows that there are more high-density census tracts near Duke Raleigh than the Duke Cary site:



Source: Duke Cary application, p. 43.

The map also shows the location of the Duke Cary Hospital near the border of Wake County—much less central than the existing facility in Raleigh. Without any supporting data to demonstrate that it is reasonable that one-half of the volume for Duke's Wake County facilities will shift to the Cary facility, the projected utilization is unreasonable and unsupported.

Furthermore, the projected shift of patients from DUH to a Duke PET scanner in Wake County is unreasonably aggressive, given the assumptions about patients shifting from DUH in Duke's 2017 fixed PET application for Duke Raleigh Hospital.[33] In that application, DUHS included a shift of patients from DUH to the proposed Duke Raleigh fixed PET unit, based on an estimation of Wake County patients that currently received outpatient PET services at DUH. DUHS estimated this shift at 25 percent of all Wake County patients in the first project year, increasing to 30 percent in project years 2 and 3. The shift is assumed to remain constant at 30 percent in future years.

[33] Project ID # J-11384-17.

Percent of Outpatient PET Volumes projected to shift from DUH to DRaH

HSA IV Counties	Project Year 1	Project Year 2	Project Year 3	Project Year 4
Chatham County, NC	**30%**	**35%**	**40%**	**40%**
Durham County, NC	*0%*	*0%*	*0%*	*0%*
Franklin County, NC	**30%**	**35%**	**40%**	**40%**
Granville County, NC	*0%*	*0%*	*0%*	*0%*
Johnston County, NC	**30%**	**35%**	**40%**	**40%**
Lee County, NC	**30%**	**35%**	**40%**	**40%**
Orange County, NC	*0%*	*0%*	*0%*	*0%*
Person County, NC	*0%*	*0%*	*0%*	*0%*
Vance County, NC	*0%*	*0%*	*0%*	*0%*
Wake County, NC	**20%**	**25%**	**30%**	**30%**
Warren County, NC	*0%*	*0%*	*0%*	*0%*

Source: Duke Raleigh PET application (Project ID # J-11384-17), p. 86.

Note: Project Year 1 represents a partial year in the application, and the first three full fiscal years are Project Years 2-4.

By this methodology, 30 percent of Wake County patients that previously received PET scans at DUH have already been shifted to Duke Raleigh since the start of service for that fixed PET unit. Now, DUHS is saying that Wake County patients will again shift to a DUHS PET scanner in Wake County, this time divided evenly between Duke Raleigh and the proposed Duke Cary Hospital PET scanner:

Projected Shift from Duke University Hospital to Wake County Scanners

	2024	2025	2026	2027	2028	2029	2030	2031	2032
DUH "Shiftable" Volumes Equal to Percentage Attributed to Wake Patients (15% of total volume)	1229	1,266	1,304	1,343	1,383	1,425	1,467	1,512	1,557
Anticipated Shift of Identified "Shiftable" Volume from Duke University Hospital to Wake County locations (%)							25%	50%	75%
DUH Volume Shifting to Wake County locations							367	756	1,168
Percentage of total DUH volume shifted to Wake County							3.7%	7.5%	11.2%

Source: Duke Cary application, p. 106.

DUHS assumes that another 75 percent of Wake County patients will be shifted to a DUHS PET scanner in Wake County, in addition to the 30 percent of Wake County outpatients that were already shifted. DUHS does not explain why it is reasonable for such a high percentage of Wake County patients to suddenly shift from DUH, since the Duke Raleigh PET scanner has been operating since FY 2021. The *2025 SMFP* shows that the Duke Raleigh PET scanner operated at just 66.7 percent of capacity,[34] indicating there is sufficient capacity at Duke Raleigh to accommodate Wake County patients that

[34] *2025 SMFP*, Table 15F-1, p. 365.

would prefer to have their PET procedure performed in Wake County rather than at DUH. Conversely, DUHS argues that the DUH PET scanners operate at near capacity now. If DUH is experiencing the high overall demand for PET services it alleges, it is reasonable to assume that Wake County patients would already have been shifted to Duke Raleigh if they wished to receive their PET scan at a more convenient and accessible Duke facility. It is therefore unreasonable to assume that another 1,168 Wake County patients will shift from DUH, even if a second location in Wake County is available via the proposed project.

Accordingly, DUHS fails to demonstrate need for the project, and the application is non-conforming with Criteria 1, 3, 4, 5, 6, and 18a.

3. DUHS fails to demonstrate the new PET service will not impact Duke Cary Hospital's previously approved service component projections.

In Section C.8, DUHS claims that the introduction of PET service at the Duke Cary Hospital will have no effect on its original patient origin and utilization projections for other clinical services offered at Duke Cary Hospital, nor have any impact on the utilization of services that were originally proposed in its 2021 CON application.[35] DUHS assumes the proposed PET scanner at Duke Cary will perform 70 percent of scans on Wake County patients, as shown in the patient origin table on page 36 of the 2025 Duke Cary application. The total Duke Cary facility, including all services, expects that 84 percent of its patients will be from Wake County. This is consistent with the total facility patient origin in the 2021 Duke Cary Hospital application, which assumed 86 percent of patients will originate from Wake County.[36]

PET patients are expected to account for 2,150 of the Duke Cary Hospital facility total in FY 2032, the third project year. This is nearly nine percent of the facility total (2,150 ÷ 24,254 = 8.9%). Despite the significant difference in the percentage of Wake County patients for the PET service compared to the facility total, and the likelihood that patients referred to Duke Cary Hospital for PET services will also receive complementary hospital-licensed services, Duke Cary projects only a two percent difference in the percentage of patients from Wake County. It is unrealistic that the addition of PET services at Duke Cary will have no impact on the other clinical services or that the variance in patient origin will not decrease the overall percentage of Wake County patients that receive care at Duke Cary Hospital.

Accordingly, DUHS fails to reasonably identify the population that will be served, and the application is non-conforming with Criteria 3, 13(c), and 18a.

4. DUHS fails to provide the information needed for a Change of Scope application.

Although DUHS states in Section C.8a that this application represents a Change of Scope to its approved CON application from 2021 (Project ID # J-12029-21), DUHS largely does not complete the required responses for a Change of Scope project in the CON Section Q forms. Examples include the exclusion of Form F.5b, showing the difference in capital cost for the new project compared to the previous project. DUHS includes only the capital cost estimate for the proposed PET scanner in Form F.1a, rather than completing the required Form F.1b to compare the project's total capital cost versus the previously approved amount in the 2021 application. Similarly, DUHS only includes the revenue

[35] Duke Cary application, p. 56.

[36] Duke Cary Hospital 2021 application (Project ID # J-12029-21), p. 37.

and operating cost projections for the PET service at Duke Cary Hospital in Forms F.2b and F.3b and does not provide total facility financial projections that can be compared to the 2021 Duke Cary application. Without providing financial revenue and operating costs projections for the total facility, it is not possible to evaluate the new costs in the Change of Scope application.

DUHS also does not include a response to the CON application question F.5b, which requires the applicant to supply the new working capital estimates compared to the previously approved total.[37] DUHS instead provides the incremental working capital for only the proposed PET service in its response to Question F.3.b, on page 66 of its application. Again, the omission of the total facility working capital costs make it impossible to compare the instant application with the previously approved Duke Cary Hospital application. DUHS also does not submit Form C.4b in its Duke Cary application, which shows the projected volume for ambulatory and ancillary services at the facility. It follows that the introduction of the PET service at Duke Cary would have some measurable impact on other services at the campus, such as laboratory and pharmacy visits. DUHS has unreasonably isolated the proposed PET service from the other clinical services at Duke Cary Hospital. This has an effect on the utilization and financial projections that are provided.

DUHS does not include the required information for a Change of Scope application and the total facility utilization projections for the proposed project. The Duke Cary Hospital application is therefore non-conforming with Criteria, 3, 4, 5, 12, and 13(c), and should not be approved.

In summary, based on the issues detailed above, the Novant application is non-conforming with the review criteria established under N.C. GEN. STAT. § 131E-183, specifically Criteria 1, 3, 4, 5, 6, 12, 13(c), and 18a, as well as the performance standards specified in 10A NCAC 14C .3703. The Novant application should not be approved.

[37] Duke Cary application, p. 72.

ISSUE-SPECIFIC COMMENTS ON DUKE UNIVERSITY HOSPITAL APPLICATION

1. <u>DUHS fails to properly account for the elimination of Its research PET scanner.</u>

   In its Form F.1a Assumptions on page 95, DUHS explains that it is temporarily using a research scanner that has been converted to clinical use as one of its three fixed PET scanners. DUHS intends to permanently use the research scanner for clinical PET procedures if the proposed application is approved, as evidenced by its response to Question C.1:

   > Given the significant growth in utilization since the third scanner was approved, DUH now proposes that it would implement a fourth clinical scanner by continuing to use the existing research scanner for clinical procedures after completion of the installation of the permanent third PET scanner. Because the equipment is already owned and in use, this project would not require any construction or capital expenditure. DUHS has allocated a budget of $500,000 as a contingency for any potential unanticipated project costs that may arise during the first project year such as acquisition of replacement parts.
   > *Source: Duke University Hospital application, p. 32.*

   DUHS fails to explain why the research capabilities of the existing scanner are no longer needed. DUHS offers no detail on its existing resources and ability to perform research-related PET scans, nor how these scans are performed now while it has a temporary exemption for the research scanner. If the scanner that DUHS proposes to convert to full-time clinical use will also perform some percentage of research procedures, DUHS has failed to demonstrate that it can accommodate the projected clinical scans along with the existing research scans. If DUHS will no longer offer research scans, it has not properly responded to the questions in Section D of the CON application. Section D requires the applicant to state whether there will be a reduction or elimination of services, and to demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements…"[38] DUHS states in its response to Question D.2.a that there will not be a reduction in service, and provides no explanation of how its patient population will be able to continue receiving research-based PET scans once the proposed project is operational and the research scanner becomes permanently converted to clinical use.

   For this reason, the Duke University Hospital application is non-conforming with Criterion 3a.

2. <u>DUHS' projected utilization fails to demonstrate the need for another PET scanner.</u>

   The DUHS application states that it can meet the performance standards for five PET scanners across the system without projecting future growth. While that may be the case, it has nonetheless not yet implemented its third PET scanner at DUH, for which it was approved in 2021. The application does not disclose how many clinical scans were performed on its research scanner and to what extent it is still being used for research scans. As such, it has effectively performed PET scans on two units at DUH and one at DRH. As shown on page 39, DUH performed 10,684 scans in FY 2024, which translates to 3,561 scans per scanner. Clearly, DUHS could obtain more capacity immediately through the implementation of its third approved PET scanner at DUH. This is demonstrated by the historical volume on Form C.2.a, where DUHS shows 8,457 scans on three scanners in FY 2025, or 2,819 per scanner. The projected scans on Form C.2.a show 9,519 scans in the third fiscal year, or 2,380 scans per scanner. For Duke Raleigh, the application projects 2,867 scans on its single scanner in FY 2029,

[38] See N.C.G.S 131E-183(a)(3a).

indicating that it will be able to accommodate year-over-year growth for several years. As such, it appears that DUHS is capable of performing more than the performance standard minimum number of scans, while still accommodating growth. Given these factors, DUHS has not demonstrated that it needs another PET scanner in order to achieve its projected utilization.

For this reason, the Duke University Hospital application is non-conforming with Criteria 1, 3, 4, 5, 6, and 18a and the performance standards at 10A NCAC 14C .3703.

In summary, based on the issues detailed above, the Duke University Hospital application is non-conforming with the review criteria established under N.C. GEN. STAT. § 131E-183, specifically Criteria 1, 3, 3a, 4, 5, 6, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703. The DUHS application should not be approved.

COMPARATIVE ANALYSIS

The UNC Medical Center (UNC Hospitals) project (Project ID # J-012595-25), the Raleigh PET (WakeMed) project (Project ID # J-012611), the Duke University Hospital project (Project ID # J-12610-25), the Duke Cary Hospital project (Project ID # J-012607-25), the Durham Diagnostic Imaging (Novant) project (Project ID # J-012593-25), the Associated Urologists of North Carolina (AUNC, Raleigh PET Imaging) project (Project ID # J-12598-25), and the WR Imaging project (Project ID # J-012602-25) each propose to develop a fixed PET scanner in response to the *2025 SMFP* need determination for two additional fixed PET scanners in HSA IV. Given that seven applications propose to meet the need for two total fixed PET scanners, not all applications can be approved. To determine the comparative factors that are applicable in this review, UNC Hospitals 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, UNC Hospitals considered the following comparative factors:

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

UNC Hospitals 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

As discussed in the application specific comments above, the WakeMed application, Duke University Hospital application, Duke Cary Hospital application, Durham Diagnostic Imaging application, and the AUNC application are all non-conforming with multiple statutory and regulatory review criteria. In contrast, the UNC Hospitals application conforms with all applicable statutory and regulatory review criteria. Therefore, regarding conformity with statutory and regulatory review criteria, the UNC Hospitals application is the most effective alternative.

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

	Inpatient Access	*Oncology*	*Cardiac*	*Neurology*
UNC Hospitals	X	X	X	X
Raleigh PET		X	X	X
Duke University Hospital	X	X	X	X
Duke Cary Hospital	?	X		
Durham Diagnostic Imaging		X	X	X
AUNC		X		X
WR Imaging		X	X	X

As shown above, all seven applicants propose to provide PET services for oncology, as described in their respective applications. Six applicants, with the exception of Duke Cary, include discussion of serving cardiac and neurology patients. However, as discussed earlier in the issue-specific comments, the AUNC application does not provide sufficient evidence that it will get referrals from cardiology specialists or that there is provider interest in this type of PET procedure. It is also probable that the types of cancers the AUNC facility performs PET scans on will be limited to urological cancers for patients referred by AUNC physicians. In addition, there is insufficient information in the Duke Cary application to determine whether these additional clinical uses will be offered. Duke Cary's methodology includes a shift of patients from Duke University Hospital but does not provide detail on the specific procedures or types of patients that will shift. Therefore, it is assumed that the PET service at Duke Cary will be limited to cancer-related procedures as this discussion was included in its application. While it is possible that Duke Cary could perform inpatient scans, as a smaller community hospital, it is unlikely to have a significant inpatient population in need of PET scans. Duke Cary is thus the least effective in terms of the range of procedures available.

Four of the applicants – Durham Diagnostic Imaging, AUNC, WR Imaging, and Raleigh PET – propose to develop their PET scanners in freestanding facilities. As these facilities do not have inpatient services, it stands that they will be limited in the comprehensive scope of care able to be delivered to their patients. As such, these applications are less effective regarding the scope of services comparative factor.

Given this, the remaining applicants – UNC Hospitals and Duke University Hospital – are both quaternary care hospitals and can therefore offer the highest levels of inpatient care in addition to ancillary and support services available at an acute care facility. Both UNC Hospitals and Duke University Hospital are Level I Trauma Centers and academic medical centers, and as such can provide comprehensive clinical care beyond inpatient and outpatient PET imaging services. Given this broad range of services, the UNC Hospitals and Duke University Hospital applications are most effective, and the DDI, AUNC, WR Imaging, and Raleigh PET applications are less effective options regarding scope of services.

Historical Utilization

Generally, the applicant that has historically provided the most PET scans per PET unit is the more effective alternative regarding this comparative factor.

Not all applicants for the *2025 SMFP* need determination for two fixed PET scanners in HSA IV currently provide fixed PET services. Specifically, Duke Cary Hospital, Durham Diagnostic Imaging, and AUNC do not have any existing fixed PET scanners.

The four remaining applicants, UNC Hospitals, Duke University Hospital, WakeMed, and WR Imaging (through UNC Health Rex Hospital, a joint venture member), are all existing PET imaging providers. According to FY 2023 volumes as detailed in Table 15F-1 of the *2025 SMFP*, the volumes for these four providers in HSA IV are as follows:

Utilization of Existing Dedicated Fixed PET Scanners
HSA IV

	Planning Inventory	***2025 SMFP***	***Facility Utilization Rate***	***Facility Deficit***	***Utilization per Unit***
University of North Carolina Hospitals	1^	5,375	179.17%	2	5,375
Duke University Hospital	3	7,442	82.69%	1	2,481
Rex Hospital	2	4,772	79.53%	-	2,386
WakeMed*	1	1,660	55.33%	-	1,660

Source: *2025 SMFP.*
* WakeMed partially owns Wake PET Services, which is the facility listed in the *2025 SMFP*.
^ See discussion below regarding the correct inventory for UNC Hospitals.

As shown in the table above, UNC Hospitals is one of two facilities that generated the need for an additional fixed PET scanner in HSA IV. Additionally, no other applicant has a utilization rate for its fixed PET scanners as high as UNC Hospitals, with a utilization rate of nearly 90 percent. UNC Hospitals also has the highest utilization per unit of PET equipment, with 2,688 scans performed per PET scanner in FY 2023 (5,375 ÷ 2 = 2,688).

Of note, while the *2025 SMFP* lists UNC Hospitals as having two fixed PET scanners in the planning inventory, this total is not accurate, as discussed in UNC Hospitals' application. One of these two PET scanners was obtained through an AC-3 CON application, and as such should not be included in the planning inventory.[39] Given this, the usage of UNC Hospitals' one need determination-acquired PET unit is even *higher* than the *2025 SMFP* utilization rate. Even with this error, UNC Hospitals *still* displays the greatest need for an additional fixed PET scanner per the historical utilization listed in the *2025 SMFP.* Given this, UNC Hospitals is the most effective alternative for the historical utilization comparative factor.

Geographic Accessibility

The *2025 SMFP* identifies a need for two fixed PET scanners in HSA IV. HSA IV comprises eleven counties, not all of which currently have a PET scanner in-county, and not all of which have the same number of existing PET scanners. As such, UNC Hospitals believes the applicant that proposes to develop a PET scanner in the least served county by number of PET scanners is the most effective alternative regarding this comparative factor.

[39] See Project ID # J-012595-25, pp. 23-24 for additional detail.

The seven applicants propose to develop PET scanners in Durham, Orange, and Wake counties, all of which have existing PET scanners. Specifically, these three counties have the following number of PET scanners, as listed in the *2025 SMFP*:

Existing PET Scanners in HSA IV by County

County	*Number of Existing PET Scanners*
Durham	3
Orange	1^
Wake	4

Source: *2025 SMFP*.

^ See previous discussion regarding the error in the 2025 SMFP inventory for UNC Hospitals.

As noted above, the *2025 SMFP*'s listing of two fixed PET scanners at UNC Hospitals is incorrect, as one of these two PET scanners was in fact obtained through an AC-3 CON application, and as such should not be included in the planning inventory. Regardless of this error, Orange County still has the fewest number of fixed PET scanners out of all counties that currently have fixed PET scanners in HSA IV. Additionally, UNC Hospitals is the only applicant that proposes to develop a fixed PET scanner in Orange County. Given that UNC Hospitals' application proposes to develop a fixed PET scanner in the county with relatively fewer assets than any of the other applications, and a county where the existing assets have the highest utilization, it follows that the UNC Hospitals application is the more effective alternative regarding this comparative factor, and all other applicants are least effective.

Access by Service Area Residents

Generally, the application proposing to serve the largest number of service area residents is the more effective alternative regarding this comparative factor. The service area for the two fixed PET scanners identified in the *2025 SMFP* is HSA IV. As such, the application that proposes to serve the largest number of patients from HSA IV is the more effective alternative for this comparative factor.

There are eleven total counties in HSA IV: Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, and Warren counties. The projected patient origins for these eleven counties in Project Year 3 for each application are shown in the table below.

PET Patients Proposed to be Served in HSA IV – Project Year 3

County	*UNC Hospitals*	*Raleigh PET*	*Duke University Hospital*	*Duke Cary Hospital*	*Durham Diagnostic Imaging*	*AUNC*	*WR Imaging*
Chatham	367	16	87	N/A	12	25	44
Durham	315	65	1,886	33	1,593	83	70
Franklin	N/A	68	115	73	23	104	135
Granville	N/A	24	369	16	224	15	32
Johnston	161	283	N/A	79	3	214	415
Lee	216	26	N/A	N/A	3	95	36
Orange	853	14	431	N/A	201	30	31
Person	N/A	4	292	N/A	469	11	20
Vance	N/A	14	213	18	37	16	20
Wake	951	1,339	1,425	1,505	101	1,774	1,949
Warren	N/A	2	N/A	N/A	9	11	9
HSA IV	**2,863**	**1,855**	**4,818**	**1,724**	**2,675**	**2,378**	**2,761**
"Other"	2,099	183	1,985	172	92	154	N/A

Source: Section C.3 for each application. PET services only.

As shown above, multiple applicants do not project total volume in the third full project year for all counties in HSA IV. Rather, these counties are included in an "Other" projection of patients, which often includes a projection of patients from counties *not* exclusive to HSA IV. As such, there is no way to accurately assess the total patients projected to be served from HSA IV for all applications – particularly, for UNC Hospitals' application, Duke University Hospital's application, and Duke Cary Hospital's application. Given this, the Access by Service Area Residents comparative factor is inconclusive.

Competition – Access to a New or Alternate Provider

Generally, the applicant that proposes to be a new provider of services in the proposed service area is the more effective alternative regarding this comparative factor.

As listed in Table 15F-1 of the *2025 SMFP*, there are five existing providers of fixed PET services in HSA IV: Duke Raleigh Hospital, Duke University Hospital, WR Imaging, University of North Carolina Hospitals, and WakeMed. Five of the seven applications proposing to meet the need for two additional fixed PET scanners in the *2025 SMFP* are existing providers in HSA IV: UNC Hospitals (University of North Carolina Hospitals), Duke University Hospital and Duke Cary Hospital, WR Imaging (through its joint venture member, UNC Health Rex Hospital), and WakeMed (Wake PET Services).

Given this, the two remaining applicants – Novant Health (DDI) and AUNC – are not existing providers of fixed PET services in HSA IV and might be considered to be more effective for this factor. However, as discussed at length above, both of these applications are not conforming with multiple statutory and regulatory review criteria, and as such cannot be approved.

The five remaining applications are for existing providers of PET services in HSA IV, so these applications are equally effective. However, as discussed in the issue-specific comments, the Duke University Hospital,

Duke Cary Hospital, and WakeMed applications are non-conforming with multiple statutory and regulatory review criteria and performance standard requirements.

Access by Underserved Groups

Projected Total Medicare Patients

The following table shows each applicant's projected total of fixed PET Medicare patients in the third project year.

Projected Medicare Patients for PET Services – PY3

Applicant	*Medicare Patients*
UNC Hospitals	3,245
Raleigh PET	1,058
Duke University Hospital	5,331
Duke Cary Hospital	1,266
Durham Diagnostic Imaging	1,234
AUNC	778
WR Imaging	1,739

Source: Section L.3 for each application

As shown in the table above, Duke University Hospital projects to serve the highest number of Medicare patients. As such, regarding this comparative factor, Duke University Hospital might be considered the most effective alternative. However, the Duke application is non-conforming with multiple statutory and regulatory criteria and cannot be approved. The UNC Hospitals application has the next-highest number of Medicare patients in the third project year. UNC Hospitals is thus more effective for this factor.

Projected Medicare as a Percent of Gross Revenue

The following table shows each applicant's projected percentage of fixed PET utilization to be provided to Medicare patients by Project Year Three.

Medicare Percentage of Gross Revenue – PY3

Applicant	*Medicare % of Gross Revenue*
UNC Hospitals	55.1%
Raleigh PET	47.6%
Duke University Hospital	56.1%
Duke Cary Hospital	58.9%
Durham Diagnostic Imaging	42.9%
AUNC	29.1%
WR Imaging	63.0%

Source: Section L.3 for each application.

As shown in the table above, WR Imaging projects to the highest percentage of Medicare revenue. As such, regarding this comparative factor, WR Imaging is the most effective alternative. UNC Hospitals, Duke

University Hospital, and Duke Cary Hospital all project Medicare gross revenue as approximately 55 to 59 percent of total gross revenue, making these three applicants appear more effective for the factor. However, both the Duke University Hospital and Duke Cary Hospital applications are non-conforming with multiple statutory and regulatory review criteria and cannot be approved.

Projected Total Medicaid Patients

The following table shows each applicant's projected total of fixed PET Medicaid patients by Project Year 3.

Projected Medicaid Patients for PET Services – PY3

Applicant	*Medicaid Patients*
UNC Hospitals	477
Raleigh PET	164
Duke University Hospital	371
Duke Cary Hospital	75
Durham Diagnostic Imaging	158
AUNC	56
WR Imaging	193

Source: Section L.3 for each application

As shown in the table above, UNC Hospitals projects to serve the highest number of Medicaid patients. As such, regarding this comparative factor, UNC Hospitals is the most effective alternative. Duke University Hospital has the next highest count of Medicaid patients and might be considered to be more effective for this factor. However, the Duke University Hospital application is non-conforming with multiple statutory and regulatory review criteria and cannot be approved.

Projected Medicaid as a Percent of Gross Revenue

The following table shows each applicant's projected Medicaid gross revenue as a percentage of gross revenue by Project Year 3.

Medicaid Percentage of Gross Revenue – PY3

Applicant	*Medicaid % of Gross Revenue*
UNC Hospitals	8.1%
Raleigh PET	7.4%
Duke University Hospital	3.8%
Duke Cary Hospital	3.5%
Durham Diagnostic Imaging	2.2%
AUNC	2.1%
WR Imaging	7.0%

Source: Section L.3 for each application.

As shown in the table above, UNC Hospitals projects the highest percentage of gross revenue for Medicaid patients. As such, regarding this comparative factor, UNC Hospitals is the most effective alternative.

Raleigh PET and WR Imaging have the next-highest percentages of Medicaid gross revenue and are more effective for this factor. However, the Raleigh PET application is non-conforming with multiple statutory and regulatory review criteria and cannot be approved.

Average Net Revenue per Procedure

Generally, the application that proposes the lowest average net revenue per procedure is the more effective alternative regarding this comparative factor. 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

Applicant	*Total Net Revenue*	*# of Procedures*	*Average Net Revenue per Procedure*
UNC Hospitals	$18,828,320	5,890	$3,197
Raleigh PET	$10,864,390	2,222	$4,889
Duke University Hospital	$33,642,562	9,519	$3,534
Duke Cary Hospital	$8,635,601	2,150	$4,017
Durham Diagnostic Imaging	$6,583,298	2,875	$2,290
AUNC	$16,671,122	2,646	$6,300
WR Imaging	$4,034,179	2,761	$1,461

Source: Forms C.2b and F.2b for each application.

As shown in the table above, WR Imaging projects the lowest average net revenue per PET procedure in the third full fiscal year following project completion. However, the seven applications propose developing fixed PET services at distinct types of facilities, including Level I trauma centers and academic medical centers, smaller community hospitals, and freestanding diagnostic imaging centers. This range of facility types will likely also affect the patient characteristics and mix of clinical applications for each proposed PET facility. The type of facility then likely affects the charges and revenue received by the applicant, including net revenues. Of note, the Agency has affirmed this conclusion regarding differing types of applicants for PET services before, most recently in its 2021 findings for the *2021 SMFP* need determination for one fixed PET scanner in HSA I.[40] Given this determination, the average net revenue per procedure comparative factor is inconclusive.

Average Operating Expense per Procedure

Generally, the application that proposes the lowest average operating expense per procedure is the more effective alternative regarding this comparative factor. The following table calculates average operating expense per PET procedure in the third full fiscal year of operation.

[40] See "Required State Agency Findings – 2021 HSA I PET Scanner Review," September 13, 2021, p. 63. Accessed at https://info.ncdhhs.gov/dhsr/coneed/decisions/2021/sept/findings/2021%20HSA%201%20PET%20Review%20Findings.pdf.

Average Operating Expense per PET Procedure – PY3

Applicant	*Total Operating Expenses*	*# of Procedures*	*Average Operating Expense per Procedure*
UNC Hospitals	$14,014,596	5,890	$2,379
Raleigh PET	$8,430,460	2,222	$3,794
Duke University Hospital	$27,416,693	9,519	$2,880
Duke Cary Hospital	$5,720,308	2,150	$2,661
Durham Diagnostic Imaging	$4,199,934	2,875	$1,461
AUNC	$14,767,800	2,646	$5,581
WR Imaging	$2,545,335	2,761	$922

Source: Forms C.2b and F.2b for each application.

As shown in the table above, WR Imaging projects the lowest average operating expense per PET procedure in the third full fiscal year following project completion. However, the seven applications propose developing fixed PET services at a variety of distinct types of facilities, including Level I trauma centers and academic medical centers, smaller community hospitals, and freestanding diagnostic imaging centers. The type of facility likely affects the total expenses incurred by each applicant. Of note, the Agency has affirmed this conclusion regarding differing types of applicants proposing PET services before, most recently in its findings for the *2021 SMFP* need determination for one fixed PET scanner in HSA I.[41] Given this determination, the average operating expense per procedure comparative factor is inconclusive.

Summary of Comparative Analysis

The following table summarizes the comparative analysis for fixed PET services in HSA IV.

[41] Ibid.

Comparative Factor	*UNC Hospitals*	*Raleigh PET*	*Duke University Hospital*	*Duke Cary Hospital*	*Durham Diagnostic Imaging*	*AUNC*	*WR Imaging*
Conformity with Review Criteria	**Yes**	No	No	No	No	No	
Scope of Services	**More Effective**	Less Effective	More Effective, But Not Approvable	Less Effective	Less Effective	Less Effective	Less Effective
Historical Utilization	**Most Effective**	Less Effective	More Effective, But Not Approvable	Not Applicable	Not Applicable	Not Applicable	Less Effective
Geographic Accessibility	**More Effective**	Less Effective	Less Effective	Less Effective	Less Effective	Less Effective	Less Effective
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Competition – Access to a New Provider	Less Effective	Less Effective	Less Effective	Less Effective	More Effective, But Not Approvable	More Effective, But Not Approvable	Less Effective
Projected Total Medicare Patients	**More Effective**	Less Effective	Most Effective, But Not Approvable	Less Effective	Less Effective	Less Effective	Less Effective
Projected Medicare as a Percentage of Gross Revenue	**More Effective**	Less Effective	More Effective, But Not Approvable	More Effective, But Not Approvable	Less Effective	Less Effective	**Most Effective**
Projected Total Medicaid Patients	**Most Effective**	Less Effective	More Effective, But Not Approvable	Less Effective	Less Effective	Less Effective	Less Effective
Projected Medicaid as a Percentage of Gross Revenue	**Most Effective**	More Effective, But Not Approvable	Less Effective	Less Effective	Less Effective	Less Effective	More Effective
Average Net Revenue per Procedure	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Average Operating Expense per Procedure	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive

SUMMARY

In summary, UNC Hospitals believes its application is the most effective alternative to meet the need for a fixed PET scanner in HSA IV. UNC Hospitals' application is conforming to all applicable statutory and regulatory review criteria and is comparatively superior in terms of the relevant factors in this review. As such, the UNC Hospitals application should be approved. The Raleigh PET, Duke University Hospital, Duke Cary Hospital, and AUNC applications do not conform with multiple statutory and review criteria and thus are not approvable.

Please note that in no way does UNC Hospitals intend for these comments to change or amend its application filed on February 15, 2025. If the Agency considers any of these comments to be amending the UNC Hospitals application, those responses should not be considered.