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

SUBMITTED BY WR IMAGING, LLC & WAKE RADIOLOGY DIAGNOSTIC IMAGING, INC.

MARCH 31, 2025

Seven applicants submitted CON applications in response to the need identified in the 2025 SMFP for two additional fixed PET scanners in Health Service Area (HSA) IV. The applicants include:

- J-12593-25 Durham Diagnostic Imaging-Independence Park
- J-12610-25 Duke University Hospital
- J-12595-25 University of North Carolina Medical Center
- J-12598-25 Raleigh PET Imaging
- J-12602-25 Wake Radiology UNC REX Healthcare-Garner
- J-12607-25 Duke Cary Hospital
- J-12611-25 WakeMed Raleigh Medial Park

WR Imaging, LLC ("WR Imaging") and Wake Radiology Diagnostic Imaging, Inc. ("WRDI") (collectively, "the Applicants") submit these comments pursuant to N.C. Gen. Stat. § 131E-185(a1)(1) to address representations made in competing applications, including their ability to comply with applicable statutory and regulatory review criteria.

Additionally, these comments provide a comparative analysis of the most significant issues relevant to this competitive batch review. No comments are included here on Project J-12595-25 but, for completeness, that application is included in the comparative analysis discussion below. The Applicants acknowledge that other non-conformities or issues may exist in any or all of the competing applications and reserve the right to identify additional concerns upon further review and analysis.

These comments are not intended to amend any statement in Project ID J-12602-25. Should the Agency interpret any comment as an amendment, the Applicants respectfully request that it be disregarded.

COMPARATIVE ANALYSIS OF THE COMPETING FIXED PET SCANNER APPLICATIONS

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

- Conformity with Statutory & Regulatory Review Criteria
- Competition (Access to a New or Alternate Provider)
- Scope of Services
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents

- Historical Utilization
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Projected Average Net Revenue Per Procedure/Case/Patient
- Projected Average Total Operating Cost Per Procedure/Case/Patient

In 2020 (1.7.2020), the Agency issued a Comparative Analysis Factors (Suggested) memorandum which stated that "Other factors not listed … may be appropriate depending on the specifics of the review." "Patient Access to Lower Cost PET Procedures" was included in the Agency Findings for the 2021 HSA I PET Scanner Review (pp. 58-59). As this 2025 HSA IV Fixed PET Scanner Review includes both hospital based and free-standing proposals, it is appropriate to assess this comparative in this review.

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

Conformity To CON Review Criteria

Seven CON applications have been submitted to develop a fixed PET scanner in Health Service Area IV. Based on the 2025 SMFP's need determination, only two fixed PET scanners can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the applications submitted by WR Imaging and UNC demonstrate conformity to all Statutory and Regulatory Review Criteria.

Conformity of Applicants

Applicant	Project I.D.	Conforming with All Applicable Statutory & Regulatory Review Criteria
WR Imaging	J-12602-25	**Yes**
Durham Diagnostic Imaging	J-12593-25	No
Duke University Hospital	J-12610-25	No
UNC Medical Center	J-12595-25	**Yes**
Raleigh PET Imaging	J-12598-25	No
Duke Cary Hospital	J-12607-25	No
WakeMed Raleigh Medical Park	J-12611-25	No

The WR Imaging and UNC applications are based upon reasonable and supported volume projections and reasonable projections of cost and revenues. As discussed separately in this document, the competing applications contain errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the **WR Imaging and UNC** applications are the **most effective** alternatives regarding conformity with applicable review Criteria.

Scope of Services

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

Scope of Services

Facility	Proposed Scope of Services		
	Oncological PET	Neurologic PET	Cardiac PET
WR Imaging	X	X	X
Durham Diagnostic Imaging	X	X	X
Duke University Hospital	X	X	X
UNC Medical Center	X	X	X
Raleigh PET Imaging	X	X	X
Duke Cary Hospital	X	X	X
WakeMed Raleigh Medical Park	X	X	X

Source: CON applications

All applicants propose to offer oncological, neurological and cardiac PET services. Therefore, all applications are **equally effective** regarding scope of services.

Historical Utilization

In previous competitive reviews, the Agency has assessed historical utilization among the competing applicants. The following summarizes FY2023 utilization data for providers in HSA IV from the Proposed 2025 SMFP.

Provider	PET Scanner Inventory	FFY2023 Procedures	PET Utilization Rate*
Duke Raleigh Hospital	1	2,002	66.7%
UNC Rex Hospital	2	4,772	79.5%
Wake PET Services	1	1,660	55.3%
Duke University	3	7,442	82.7%
UNC Hospital	2	5,375	89.6%

*Based on a fixed PET scanner capacity of 3,000 procedures per unit
Source: Proposed 2025 SMFP, Table 15F-1: Utilization of Existing Dedicated Fixed PET Scanners

The following applicants do not currently operate a fixed PET scanner, WR Imaging, Durham Diagnostic Imaging, Raleigh PET Imaging, and Duke Cary Hospital. Duke University Hospital and UNC Medical Center currently provide PET scanner services. Wake PET Service is majority owned (51%) by WakeMed Raleigh. *See* the above table for utilization rates. However, based on the lack of historical utilization data for all applicants, the finding of this competitive factor is inconclusive.

Geographic Accessibility

The 2025 SMFP identifies the need for two fixed PET scanners in HSA IV. HSA IV is a multi-county service area that includes Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, Warren counties. The following table summarizes the locations of existing and approved fixed PET scanners in HSA IV as reported by the 2025 SMFP and other publicly available information.

Facility	Existing + Proposed Fixed PET Scanners	Location
WR Imaging	1 Proposed	Garner/Wake County
Durham Diagnostic Imaging	1 Proposed	Durham/Durham County
Duke University Hospital	3 Existing + 1 Proposed	Durham/Durham County
UNC Medical Center	2 Existing + 1 Proposed	Chapel Hill/Orange County
Raleigh PET Imaging	1 Proposed	Raleigh/Wake County
Duke Cary Hospital	1 Proposed	Cary/Wake County
WakeMed Raleigh Medical Park	1 Proposed	Raleigh/Wake County
Wake PET Services	1 Existing	Cary/Wake County
REX Hospital	1 Existing	Raleigh/Wake County

WR Imaging is the only applicant that proposes locating a fixed PET scanner in a new geographic location within the service area, i.e., Garner (Wake County).

Currently, the fixed PET scanners within HSA IV are concentrated in the central and western portions of the service area, leaving the eastern region underserved. WR Imaging – Garner is an established, full-service outpatient imaging center at 300 Health Park Road in Garner. The proposal to add a fixed PET scanner at this location directly addresses the existing disparity by expanding access eastward. The proposed site is strategically located near the intersection of I-40 and Hwy 70 to serve patients from multiple surrounding communities, reducing travel burdens and improving timely access to essential diagnostic services.

The eastern portions of Wake County and the western areas of Johnston County are experiencing exponential growth. As these communities expand, so does the demand for accessible healthcare services, including advanced diagnostic imaging. Without additional PET service locations, the growing population in these areas will face increasing barriers to timely and convenient care. Establishing a fixed PET scanner in Garner proactively addresses this demand and ensures that infrastructure keeps pace with regional population trends.

By establishing a fixed PET scanner in Garner, residents throughout the service area will gain an additional access point for PET imaging. The proposed fixed PET scanner at **WR Imaging** is the **most effective** alternative regarding geographic access.

Access By Service Area Residents

The 2025 SMFP defines the service area for a fixed PET scanner as "the HSA [Health Service Area] in which it is located (Table 15F-1)." Thus, the service area for this review is HSA IV. The counties in HSA IV include: Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, Warren counties. Facilities may also serve residents of counties not included in the defined service area. Generally, regarding this comparative factor, the application projecting to serve the largest number or percentage of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional fixed PET scanners in the service area where they live.

	WR Imaging	Durham Diagnostic Imaging	Duke University Hospital	UNC Medical Center	Raleigh PET Imaging	Duke Cary Hospital	WakeMed Raleigh Medical Park
PET Patients from HSA IV	2,761	2,675	4,818	2,863	2,378	1,723	1,855
Total PET Patients	2,761	2,875	9,519	5,890	2,646	2,150	2,222
HSA IV % of Total Patients	**100.0%**	**93.0%**	**50.6%**	**48.6%**	**89.9%**	**80.1%**	**83.5%**

Source: CON Applications, Section C.3

The WR Imaging application projects to serve the largest percentage of patients from HSA IV.

As demonstrated in the previous table, Duke University Hospital anticipates serving a significantly higher volume of patients from HSA IV during the third project year. However, directly comparing the absolute number of HSA IV patients served among applicants would be inappropriate. Duke University Hospital, with three existing and one proposed fixed PET scanner (a total of four), has a vastly different capacity than the other applicants. In contrast, WR Imaging, operating with a single fixed PET scanner, will naturally serve fewer patients due to its limited capacity. Duke's ability to treat a larger number of patients is primarily a function of its scale, not necessarily a measure of greater efficiency or effectiveness. This disparity in capacity makes any direct numerical comparison misleading and inherently biased against new competitors.

To ensure a fair and accurate evaluation, the Agency should instead consider the percentage of HSA IV patients served by each applicant. This metric provides a more meaningful measure of how effectively each provider meets the needs of the service area. For instance, WR Imaging, despite its smaller size, could serve a higher percentage of the service area population relative to its capacity, demonstrating efficiency and responsiveness to community needs. Meanwhile, Duke University Hospital's higher patient volume reflects its greater resources, but this does not necessarily indicate superior service in addressing local healthcare demands.

By prioritizing the percentage of patients served rather than absolute numbers, the Agency can conduct a more balanced assessment of each applicant's contribution to healthcare access in the region. This approach ensures that evaluations are based on effectiveness rather than sheer capacity. Given this framework, **WR Imaging** presents the **most effective** alternative for improving access to care in the service area.

Competition (Patient Access to a New or Alternate Provider)

According to the Federal Trade Commission, competition in health care markets benefits consumers because it helps contain costs, improve quality, and encourage innovation. The introduction of a new provider in the service area would be the most effective alternative because increased patient choice encourages all providers in the service area to improve quality or lower costs to compete for patients.

WR Imaging is the ideal choice for operating a fixed PET scanner due to their broad diagnostic expertise, neutrality, and ability to serve patients from various specialties. Radiologists accept referrals from all specialties, ensuring that PET imaging services are available to a wider patient population. This neutrality prevents bias, as radiologists do not have financial or practice-driven incentives when interpreting PET scans. Their extensive training in advanced imaging techniques ensures accurate and clinically relevant results, crucial for guiding treatment decisions.

Wake Radiology is a physician-owned, physician-led, locally owned practice. This sets it apart from other specialty practices that may have interest in developing a fixed PET scanner. For example, some specialty practices that were once "local" have recently sold to private equity firms, others are owned by out of state investors. This shift in ownership often prioritizes financial returns over patient care, potentially leading to higher patient costs, reduced local control, and decisions driven by investor interests rather than community needs. In contrast, WR Imaging remains deeply rooted in the region, with decisions made by physicians who live and work in the community. This ensures a steadfast commitment to patient-centered care, quality imaging services, and long-term investment in the well-being of local residents.

In conclusion, radiologists offer the greatest accessibility, expertise, and neutrality in managing fixed PET scanners, making them the best choice for developing freestanding PET services.

Thus, regarding competition for fixed PET services in the service area, the application submitted by **WR Imaging** is the **most effective alternative** in this review.

Patient Access to Lower Cost PET Procedures

Dedicated fixed PET scanners can be located either in a free-standing diagnostic center or a hospital. The following table summarizes the locations of the existing and approved fixed PET scanners in HSA IV.

Provider	Hospital Based or Free-standing
Duke Raleigh Hospital	Hospital
UNC Rex Hospital	Hospital
Wake PET Services	Free-standing
Duke University	Hospital
UNC Hospital	Hospital

Source: Proposed 2025 SMFP; 2025 License Renewal Applications for Duke University Hospital, Duke Raleigh Hospital UNC Rex Hospital, and UNC Hospital; 2025 Registration & Inventory Report for Wake PET Services

Of the nine existing and approved fixed PET scanners in HSA IV, only one is located in a free-standing diagnostic center, i.e., Wake PET Services.

Freestanding imaging facilities, such as the one proposed by WR Imaging, provide significant benefits to patients. These facilities typically operate with a lower cost structure, offering more affordable services compared to hospital-based imaging centers. For example, the cost of a PET scan is often substantially higher at hospital-licensed facilities but considerably more affordable at freestanding diagnostic centers. The table below highlights the locations of the proposed fixed PET scanners included in this review.

Facility	Hospital Based or Free-standing
WR Imaging	Free-standing
Durham Diagnostic Imaging	Free-standing
Duke University Hospital	Hospital
UNC Medical Center	Hospital
Raleigh PET Imaging	Free-standing
Duke Cary Hospital	Hospital
WakeMed Raleigh Medical Park	Hospital

Source: CON applications

Regarding this comparative factor, the applications by **WR Imaging**, Durham Diagnostic Imaging, and Raleigh PET Imaging are **more effective** alternatives and the applications by Duke University Hospital, UNC Medical Center, Duke Cary Hospital, and WakeMed Raleigh Medical Park are less effective.

Access By Underserved Groups

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

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

For access by underserved groups, applications are compared concerning two underserved groups: Medicare patients, and Medicaid patients.[1] Access by each group is treated as a separate factor. The Agency may use one or more of the following metrics to compare the applications:

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

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

Projected Medicare Access

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for WR Imaging and other applicants.

Projected Medicare Access – 3rd Full FY

Applicant	Number of Medicare Patients	Medicare Patients as a % of Total Patients	Projected Medicare as % of Gross Revenue
WR Imaging	1,739	**63.0%**	**63.0%**
Durham Diagnostic Imaging	1,233	42.9%	42.9%
Duke University Hospital	5,331	56.0%	56.1%
UNC Medical Center	3,245	55.1%	55.1%
WakeMed Raleigh Medical Park	1,058	47.6%	47.6%
Duke Cary Hospital	1,266	58.9%	58.9%
Raleigh PET Imaging	1,746	66.0%	29.1%

Source: CON applications

As shown in the above table, WR Imaging projects the **highest** percentage of Medicare Gross Revenue as a percentage of Total Gross Revenue and the **second highest** Medicare Patients as a percentage of Total Patients. Therefore, WR Imaging is the **most effective** alternative regarding Medicare Access.

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

As previously described, Duke University Hospital has a vastly different capacity than the other applicants. Duke's ability to treat a larger number of Medicare patients is a function of its scale. This disparity in capacity makes any direct numerical comparison misleading and inherently biased against new competitors.

Projected Medicaid Access

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion.

Projected Medicaid Access – 3rd Full FY

Applicant	Number of Medicaid Patients	Medicaid Patient as a % of Total Patients	Projected Medicaid as % of Gross Revenue
WR Imaging	193	**7.0%**	**7.0%**
Durham Diagnostic Imaging	158	5.5%	5.5%
Duke University Hospital	371	3.9%	3.9%
UNC Medical Center	477	8.1%	8.1%
WakeMed Raleigh Medical Park	164	7.4%	7.4%
Duke Cary Hospital	75	3.5%	3.5%
Raleigh PET (AUNC)	56	2.1%	2.1%

Source: CON applications, Form C, Section L, and Form F.2

As shown in the above table, WR Imaging proposes to provide one of the highest percentages of Medicaid Patients as a percentage of Total patients and one of the highest percentages of Medicaid Gross Revenue as a percentage of Total Gross Revenue. Therefore, regarding Medicaid access, WR Imaging is an effective alternative regarding Medicaid access.

As previously described, Duke University Hospital has a vastly different capacity than the other applicants. Duke's ability to treat a larger number of Medicaid patients is a function of its scale. This disparity in capacity makes any direct numerical comparison misleading and inherently biased against new competitors.

Projected Average Net Revenue per Fixed PET Procedure

The following table compares WR Imaging and other applications on projected average net revenue per fixed PET procedure in the third year of operation, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per PET Procedure – 3rd Full FY

Applicant	Total Number of PET Scans	Total Net Revenue	Average Net Revenue/ PET Scan
WR Imaging	2,761	$4,034,179	**$1,461**
Durham Diagnostic Imaging	2,875	$7,624,175	$2,652
Duke University Hospital	9,519	$26,293,577	$2,762
UNC Medical Center	5,890	$18,828,320	$3,197
WakeMed Raleigh Medical Park	2,222	$10,864,390	$4,889
Duke Cary Hospital	2,150	$8,635,601	$4,017
Raleigh PET Imaging	2,646	$16,671,122	$6,300

Source: CON applications

As shown in the previous table, WR Imaging projects the lowest average net revenue per PET scan procedure in the third full fiscal year following project completion. Therefore, the **WR Imaging** application is the **most effective** alternative.

Projected Average Operating Expense per PET Procedure

The following table compares the projected average operating expense per PET procedure in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense is the more effective alternative concerning this comparative factor to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

Projected Average Operating Expense per PET Procedure – 3rd Full FY

Applicant	Total Number of PET Scans	Total Operating Expenses	Average OpEx/ PET Scan
WR Imaging	2,761	$2,545,335	**$922**
Durham Diagnostic Imaging	2,875	$7,523,723	$2,617
Duke University Hospital	9,519	$27,416,693	$2,880
UNC Medical Center	5,890	$14,914,596	$2,532
WakeMed Raleigh Medical Park	2,222	$8,430,460	$3,794
Duke Cary Hospital	2,150	$5,720,308	$2,661
Raleigh PET Imaging	2,646	$14,767,800	$5,581

Source: CON applications

As shown in the previous table, WR Imaging projects the lowest average operating expense per PET scan procedure in the third full fiscal year following project completion. Therefore, the **WR Imaging** application is the **most effective** alternative.

Summary

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

Comparative Factor	WR Imaging	Durham Diagnostic Imaging	Duke University Hospital	UNC Medical Center	WakeMed Raleigh Medical Park	Duke Cary Hospital	Raleigh PET
Conformity with Review Criteria	**More Effective**	Less Effective	Less Effective	**More Effective**	Less Effective	Less Effective	Less Effective
Scope of Services	Equally effective	Equally effective	Equally effective	Equally effective	Equally effective	Equally effective	Equally effective
Historical Utilization	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Geographic Accessibility	**Most effective**	Less Effective	Less Effective	Less Effective	Less Effective	Less Effective	Less Effective
Competition	**More Effective**	**More Effective**	Less Effective	Less Effective	Less Effective	Less Effective	**More Effective**
Access by Service Area Residents	**More Effective**	**More Effective**	Less Effective	Less Effective	Less Effective	Less Effective	Less Effective
Patient Access to Lower Cost PET Procedures	**More Effective**	**More Effective**	Less Effective	Less Effective	Less Effective	Less Effective	**More Effective**
Access by Medicaid	Less Effective	Less Effective	Less Effective	**More Effective**	Less Effective	Less Effective	**More Effective**
Access by Medicare	**More Effective**	Less Effective	Less Effective	Less Effective	Less Effective	Less Effective	Less Effective
Projected Average Net Revenue per Procedure	**More Effective**	**More Effective**	Less Effective	Less Effective	Less Effective	Less Effective	Less Effective
Projected Average OpEx Per Procedure	**More Effective**	Less Effective	Less Effective	**More Effective**	Less Effective	Less Effective	Less Effective

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

- Conformity with Review Criteria
- Geographic Access
- Competition
- Access by Service Area Residents
- Patient Access to Lower Cost PET Procedures
- Access by Medicare Patients
- Projected Average Net Revenue per Procedure
- Projected Average Operating Expense per Procedure

Conclusion

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

WR Imaging is fully conforming to all statutory and regulatory review criteria. The WR Imaging application should be approved for one of the two need determined fixed PET scanners because it is overall comparatively more effective than the competing proposals.

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

COMMENTS SPECIFIC TO DURHAM DIAGNOSTIC IMAGING, PROJECT ID J-012593-25

Please note that the DDI application mistakenly states on page 59 that: "nine existing PET/CT scanners are collectively owned by three entities: Duke Health, UNC Healthcare and Wake Radiology." This statement is in error. Wake Radiology does not own any PET/CT scanners in Health Service Area IV, either on its own or through WR Imaging, its joint venture entity with Rex. WR Imaging will be a new market entrant for PET in Health Service Area IV. WR Imaging is a joint venture entity which includes Rex Hospital, Inc. (UNC Rex Healthcare) which, of course, is an experienced, existing PET provider offering one PET scanner and approval for a second PET scanner at UNC REX Hospital. However, it is simply not correct to say that Wake Radiology owns any of the nine existing PET/CT scanner now in operation in Health Service Area IV. Wake Radiology has not held any ownership interest in any entity owing a PET/CT scanner in Health Service Area IV for the last five years. This mistake is reflected again in the graphic on page 88 and the chart on page 89 of the DDI application.

Comments Regarding Criterion (3)

DDI does not adequately demonstrate that the patients projected to be served have a need for the proposed project, as its projected utilization is based on unreasonable and inadequately supported assumptions.

DDI's Form C.2 Utilization – Assumptions and Methodology outlines Steps 1 through 4, which provide historical and projected utilization data for HSA IV and assumptions about its proposed PET scanner. However, this information fails to substantiate DDI's ability to serve any portion of the HSA IV market.

- **Lack of Market Connection**: While Steps 1 and 2 provide historical and projected utilization data for HSA IV, DDI does not establish its capacity to attract or serve patients within this market. Step 3 discusses the maximum capacity of the proposed fixed PET scanner, and Step 4 presents projected utilization. However, DDI offers no direct evidence linking its projections to the specific needs of the population it intends to serve.

- **Unsubstantiated Assumptions**: In Step 4, DDI claims that "In Project Year 1, DDI reasonably anticipates providing 1 procedure per hour of operation, equating to 8 procedures per day (2,000 annual procedures)." This assumption is unsupported, relying solely on Novant Health's historical experience in other counties. However, the utilization of Novant Health's PET services in Forsyth, Mecklenburg, and New Hanover counties does not necessarily translate to HSA IV, where Novant Health has limited presence and no inpatient facilities. DDI fails to provide any quantitative justification, such as demographic, referral, or market data, to substantiate the assumed rate of 1 procedure per hour.

- **Limited Support from Referring Physicians**: The application includes letters of support from only four practices or clinics, which is insufficient to validate its projected utilization. A stronger demonstration of referring physician support would be necessary to reasonably predict the patient volume DDI anticipates.

- **Inadequate Comparison to HSA IV Providers**: In Step 7, DDI argues that its projected utilization is reasonable because it is below the overall average number of PET scans per provider in HSA IV.

However, this argument fails to account for significant variations in utilization among individual providers. For example, as evidenced by the historical data:

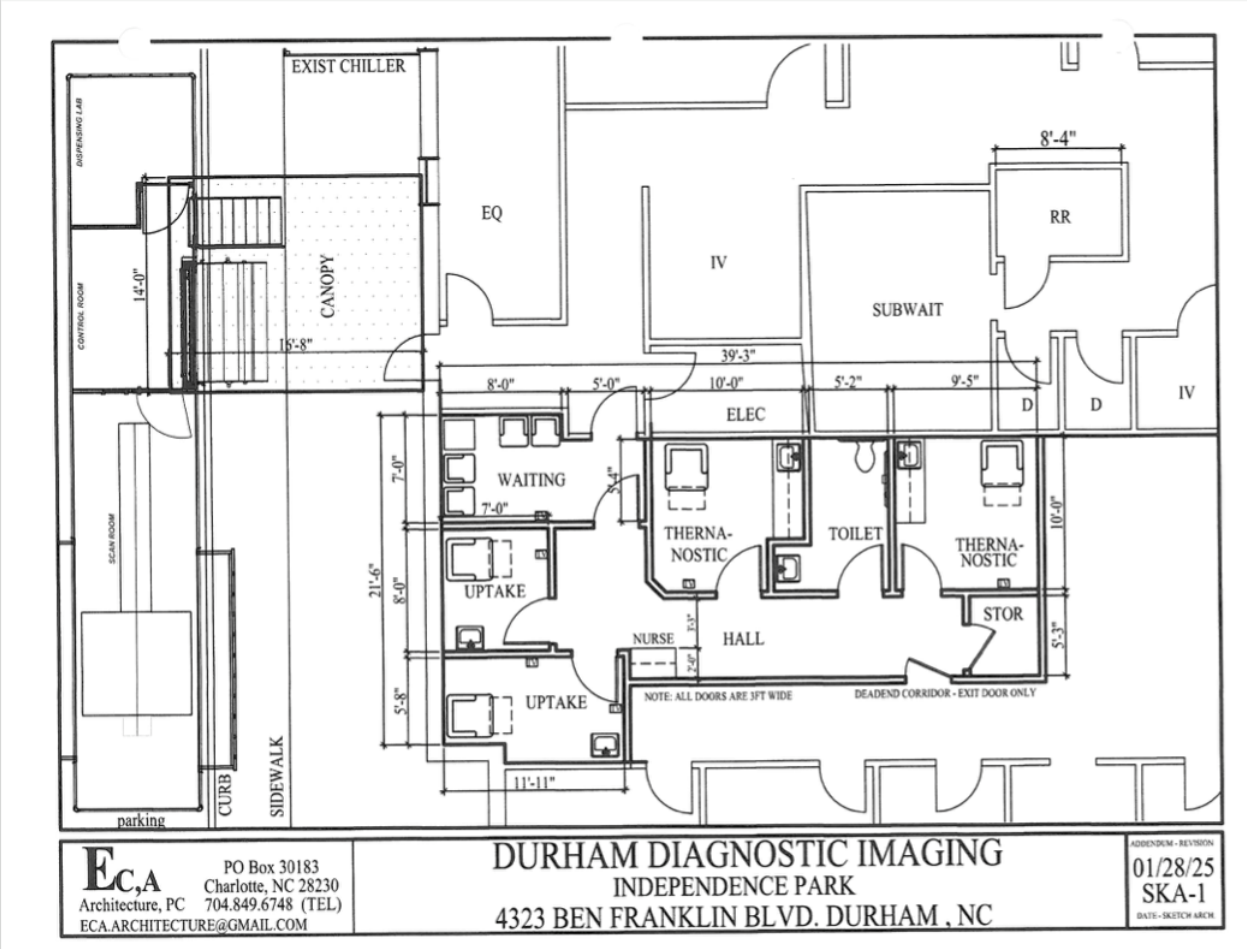
Fixed PET Utilization HSA IV

	Planning Inventory/Units	FFY21	FFY22	FFY23
Duke Raleigh	1	946	1,771	2,002
Duke University Hospital	3	5,405	6,623	7,442
REX Hospital	2	3,906	4,333	4,772
UNC Hospitals	2	3,952	4,320	5,375
Wake PET Services	**1**	**209**	**1,174**	**1,660**
HSA IV Totals	9	14,418	18,221	21,251
Average per Unit		**1,602**	**2,025**	**2,361**

Source: 2023 to 2025 SMFPs

While Wake PET Services is partially owned by WakeMed, a large, established health system in the service area, its utilization has historically been below the average for the service area. Novant Health, DDI's owner, does not currently operate any inpatient facilities in HSA IV and has a limited network of affiliated physicians. As such, it is unreasonable for DDI to assume that its projected utilization is reasonable just because it is below its projected average number of scans per unit in HSA IV.

- **Design Inconvenience for Patients**: DDI's proposed PET service design raises concerns about patient convenience. The PET/CT scanner will be housed in a modular unit attached to DDI's existing facility by a canopy, as indicated in the line drawings (Exhibit K.2).



Based on this design, DDI's proposed PET patients will have to exit its building and travel outside under a canopy to the modular unit where the proposed PET scanner will be housed. This design is similar to a mobile unit and is less convenient to patients than a fixed unit that is housed within a climate controlled building, which does not require patients to go outside for any period of time, and which minimizes the distance that patients have to travel to receive their scans.

DDI's application fails to provide a reasonable and adequately supported basis for its projected utilization, undermining its ability to demonstrate that it meets the needs of the patients it proposes to serve. Furthermore, its reliance on insufficient data, limited physician support, flawed comparative arguments, and a less convenient design collectively demonstrate nonconformance with Criterion (3).

Comments Regarding Criterion (5)

DDI does not adequately demonstrate the financial feasibility of the project based on reasonable projections of costs and charges. As shown below, DDI's financial projections include insufficient assumptions, unreasonable projections, understated expenses, and missing expenses. Additionally, the DDI application fails to identify any Start-Up costs for its proposed new PET/CT service.

In its assumptions for Form F.2a1 PET/CT Service (Project Years 1-3) section, DDI states that "Gross Patient Revenue is provided for Project Years 1-3 based on the total revenue anticipated for the proposed fixed

PET/CT service." DDI provides no other explanation for its proposed charges. As a proposed new provider of PET services, DDI fails to provide a reasonable basis or source for its revenue projections.

In its assumptions for Form F.3 for both its Total Facility and PET/CT Service, DDI includes an annual increase for inflation of Annual Salaries, Rental Expense, Utilities, and Property Taxes, but projects no annual inflation for any other expenses. It is unreasonable to assume that all other expenses including Medical Supplies and Other Supplies will remain unchanged on a per scan basis from FY 2024 to FY2029. As such, DDI has understated its expenses.

While DDI does not project an increase in expenses for annual inflation, some expense items increase on a per scan basis in 2027 for the Entire Facility without any explanation. DDI states that Housekeeping expenses "increase based on the cost multiplied by the total estimated scan volume per projected year for all service lines." Similarly, DDI states that Scheduling/Pre-Auth Fees "are projected on a cost per scan amount for all service lines" and that Banking Fees are "estimated as an overall per scan cost." However, as shown in the table below, each of these expense items increases on a per scan basis in 2027 without any basis.

DDI Expenses with Unexplained Increases per Case-Entire Facility

	2024	2025	2026	2027	2028	2029
Scans	27,153	27,697	28,250	30,692	31,664	32,725
Housekeeping	$37,743	$38,498	$39,267	$45,145	$47,482	$50,125
Housekeeping per Scan	$1.39	$1.39	**$1.39**	**$1.47**	$1.50	$1.53
Scheduling/Pre-Auth Fees	$507,761	$517,916	$528,275	$607,346	$638,793	$674,340
Scheduling/Pre-Auth Fees per Scan	$18.70	$18.70	**$18.70**	**$19.79**	$20.17	$20.61
Banking Fees	$52,948	$54,007	$55,087	$63,333	$66,612	$70,319
Banking Fees per Scan	$1.95	$1.95	**$1.95**	**$2.06**	$2.10	$2.15

Source: DDI Form C.2a and Form F.3b-Entire Facility

By contrast, these expense items for DDI's PET/CT service on a per scan basis are consistent with Entire Facility per scan costs from 2023 to 2026, as shown below.

DDI Expenses per Case-PET/CT

	2027	2028	2029
Scans	2,000	2,398	2,875
Housekeeping	$2,780	$3,333	$3,996
Housekeeping per Scan	**$1.39**	**$1.39**	**$1.39**
Scheduling/Pre-Auth Fees	$37,400	$44,843	$53,763
Scheduling/Pre-Auth Fees per Scan	**$18.70**	**$18.70**	**$18.70**
Banking Fees	$3,900	$4,676	$5,606
Banking Fees per Scan	**$1.95**	**$1.95**	**$1.95**

Source: DDI Form C.2a and Form F.3b-PET/CT

DDI provides no explanation for why it would be reasonable for Housekeeping Expenses for the facility to increase on a per scan basis in 2027, but not for PET/CT scans, and similarly for Scheduling/Pre-Auth Fees, and Banking Fees. As such, DDI's financial projections are unreasonable and unsupported.

For its PET/CT service, DDI states that "Medical and other supply expenses are based on Novant's experience providing fixed PET services in North Carolina on a per scan basis for PET/CT service. These expenses increase based on the cost multiplied by the total estimated scan volume per projected year as allotted to PET/CT service." As shown below, DDI projects $162.00 in Medical Supplies and $0.70 in Other Supplies per PET/CT scan and no Pharmacy expenses for the service. As such, DDI projects only $162.70per scan for Medical Supplies, Other Supplies, and Pharmacy combined.

DDI Medical Supplies, Other Supplies, and Pharmacy Expense per Scan

	FFY27	FFY28	FFY29
PET/CT Scans	2,000	2,398	2,875
Medical Supplies	$324,000	$388,476	$465,750
Medical Supplies per Scan	**$162.0**	**$162.0**	**$162.0**
Other Supplies	$1,480	$1,775	$2,128
Other Supplies per Scan	**$0.7**	**$0.7**	**$0.7**
Pharmacy Expense	**$0**	**$0**	**$0**
Medical, Other, Pharmacy Combined Expense per Scan	**$162.7**	**$162.7**	**$162.7**

Source: DDI Form C.2a and Form F.3b for PET/CT

In its recently approved CON application for an additional PET scanner at Novant Health Presbyterian Medical Center (Project ID # F-12557-24), Novant Health projected a combined Medical Supplies, Other Supplies, and Pharmacy expense ranging from $1,039 to $1,241 from historical FY2023 to projected FY2029, as shown below.

Novant Health Presbyterian Medical Center
Medical Supplies, Other Supplies, Pharmacy Expense per Scan

	2023	2024	2025	2026	2027	2028	2029
PET Scans	2,403	2,579	2,711	2,846	3,215	3,709	4,347
Medical Supplies	$8,401	$9,287	$10,055	$10,876	$12,651	$15,036	$18,147
Medical Supplies per Scan	**$3.5**	**$3.6**	**$3.7**	**$3.8**	**$3.9**	**$4.1**	**$4.2**
Other Supplies	$18,605	$20,567	$22,268	$24,087	$28,016	$33,300	$40,188
Other Supplies per Scan	**$7.7**	**$8.0**	**$8.2**	**$8.5**	**$8.7**	**$9.0**	**$9.2**
Pharmacy Expense	$2,470,699	$2,731,208	$2,957,128	$3,198,639	$3,720,455	$4,422,076	$5,336,778
Pharmacy Expense per Scan	**$1,028.2**	**$1,059.0**	**$1,090.8**	**$1,123.9**	**$1,157.2**	**$1,192.3**	**$1,227.7**
Medical, Other, Pharmacy Combined Expense per Scan	**$1,039.4**	**$1,070.6**	**$1,102.7**	**$1,136.2**	**$1,169.9**	**$1,205.3**	**$1,241.1**

Source: Novant Health Presbyterian Medical Center PET CON (Project ID # F-12557-24), Forms C.2a and Form F.3b for PET/CT

Clearly, DDI has failed to accurately base its projected Medical Supplies and Other Supplies expenses on Novant Health's experience and has failed to include Pharmacy expenses. As DDI notes in its application,

PET services use a variety of radioactive tracers. These tracers require higher Pharmacy expenses than other imaging services, like those currently provided by DDI. As shown above, Novant Health's experience indicates that DDI has understated these expenses by approximately $1,078 per case in 2029 ($1,078 = Novant combined expenses per case of $1,241.1 minus $162.7 projected by DDI). In total, DDI has understated these expenses by over $3.1 million in 2029 ($3.1 million = $1,078 per case of understated expenses x 2,875 projected cases). Based on Forms F.2b for the Entire Facility and for PET/CT services, if this understatement of expenses of $3.1 million were accounted for appropriately, neither DDI in total nor its proposed PET/CT service would have a positive net income, as net income for the facility and for the service, respectively, is less than $3.1 million.

In its assumptions for Form F.3 for both its Total Facility and PET/CT Service, DDI states "**Billing-Revenue Cycle**-billing services are provided at a rate of 0.6% Net Patient Revenue per year." However, neither DDI's Total Facility nor its PET/CT Form F.3 show Billing-Revenue Cycle expenses or any similar expense. DDI has failed to include these expenses in its Financial Statements. As shown below, Billing-Revenue Cycle expenses are projected to be $251,706 for the entire facility and $39,500 for the PET/CT service in the third project year based on DDI's assumptions.

DDI Billing-Revenue Cycle Expenses

	2024	2025	2026	2027	2028	2029
Net Revenue-Entire Facility	$7,328,119	$20,937,483	$21,356,232	$33,752,700	$37,530,647	$41,950,927
Billing-Revenue Cycle as % of Net Revenue	0.60%	0.60%	0.60%	0.60%	0.60%	0.60%
Billing-Revenue Cycle Expenses-Entire Facility	**$43,969**	**$125,625**	**$128,137**	**$202,516**	**$225,184**	**$251,706**
Net Revenue-PET/CT				$4,579,686	$5,491,043	$6,583,298
Billing-Revenue Cycle as % of Net Revenue				0.60%	0.60%	0.60%
Billing-Revenue Cycle Expenses-PET/CT				**$27,478**	**$32,946**	**$39,500**

Source: DDI Forms F.2 and F.3 Assumptions

As such, DDI's projected expenses are understated, and its projected net income is overstated.

The DDI application fails to identify any Start-up Costs. For the purposes of a CON application, the term "start-up costs" means costs that are:

- not capital costs based on generally accepted accounting principles;
- necessary to offer the proposed new institutional health service; and
- incurred prior to offering the proposed new institutional health service.

In order to offer the proposed PET service, DDI plans to renovate 1,100 square feet of space in its existing DDI location that will be used to administratively support the new PET scanner which will be housed in a modular unit. It is unquestionable that DDI will need to incur some expenses before the first day it begins to offer its new PET service. WR Imaging is planning to add a PET service to an existing multi-modality imaging center just as DDI proposes to do. WR Imaging identified $25,000 in funds for start-up costs and documented the availability of these funds for its project.

Before "Day One" of offering the new PET service, Novant/DDI will undoubtedly need to:

- Turn on the lights in the newly-renovated space where it will provide administrative support to its new PET service – while this Utility expense may be a relatively minor expense item, it is necessary and is appropriately considered a project cost;
- Begin paying Rent for the space dedicated to the new PET service;
- Purchase Supplies to be ready to begin offering the PET service;
- Engage in Marketing or Advertising efforts to inform prospective patients and referral services of the new PET service;
- Hire Staff – specifically, DDI proposes to employ two (2) new PET/CT Technicians and a new "Technical Assistant" – the expenses associated with hiring new personnel are appropriately included in Start-up Cost projections. New personnel cannot be expected to train for any period without being compensated and paid Benefits for their working hours
- Train Staff – the new PET/CT technicians cannot be expected to begin working on "Day One" with no advance orientation or training, regardless of their education and prior experience.
- Pay any necessary fees or other miscellaneous expenses associated with beginning the offering of a new PET service.

The existing DDI facility does not now offer PET services – as such, it does not employ any individuals who work as PET Technicians – these individuals must be hired and trained before DDI begins offering the PET service. The DDI application specifically states: "DDI requires all clinical employees to complete orientation, as well as training specific to their position." Even if DDI has clinical staff that work, for example, as MRI technicians and those individuals who wish to begin working as PET technicians, they will need to be hired and trained to do so. Obviously, clinical staff cannot begin working without basic training on HIPAA, Medicare Compliance, and safety requirements. (DDI application, p. 92).

Novant documents that it "will commit … $3,656,229 for the development of the proposed [PET] project" (Exhibit F.2). This amount is only $2 more than the costs DDI forecasted for the PET/CT unit in the modular unit plus the necessary renovations to the existing DDI building ($3,656,227). Therefore, Novant has not documented any available funds to cover DDI's Start-up Costs.

The sum of $2 is insufficient to cover all the Start-up Costs described above. It is not reasonable to budget $0 or $2 to initiate a new PET service when such a budget does not allow funds to account for pre-opening utilities, rent, supplies, or funds to hire and train staff. The DDI financial forecasts fail to account for all costs associated with offering the new PET service.

Start-up costs, by definition, are costs that must be "incurred prior to offering" the service, and therefore, these costs are not reflected within the Year One operational budget which begins with costs from 10/01/2026 forward. Moreover, nothing in the Assumptions for Form F.3 suggest that these pre-opening expenses are included in the Year One Operating Expense Assumptions.

Based on the foregoing discussion, DDI's financial projections include insufficient assumptions, unreasonable projections, understated expenses, and missing expenses. Thus, DDI's project is not financially feasible and should be found non-conforming with Criterion (5).

Criterion (13)

DDI does not adequately demonstrate the extent to which medically underserved groups will be served by its proposed project and the extent to which these groups are expected to utilize its proposed PET/CT services.

On page 102 of its application, DDI provides the historical payor mix for its Entire Facility as shown in the excerpt below, indicating that Medicaid comprises 2.19% of patients.

Last Full FY before Submission of Application
10/01/2023 **to** 09/30/2024

<Durham Diagnostic Imaging – Entire Facility>	
Payor Source	**Percentage of Total Patients Served**
Self-Pay	1.6%
Charity Care	0.27%
Medicare *	42.92%
Medicaid *	2.19%
Insurance *	48.1%
Workers Compensation	2.62%
TRICARE	0.55%
Other (Commercial, Auto/Liability)	1.76%
Total	100.0%

* Including any managed care plans.

DDI has provided the payor mix for all services for the last full fiscal year. DDI does not currently offer fixed PET services.

In its assumptions for its projected payor mix, DDI states that it "projects an increase in Medicaid service with the approval of a full-time fixed PET scanner at its facility" (page 106). Additionally, DDI projects an increase in Charity Care from its historical experience. DDI concludes by stating "Projected payor sources for the Total Facility and the proposed PET/CT services are based on the historical experience of the applicant with adjustments made that reflect the changes anticipated in the proposed service area during the project years. As a result of the proposed project, the applicant anticipates higher percentages of charity care and Medicaid services" (emphasis added).

As shown below, DDI's response to Section L.3 indicates that Medicaid will comprise 5.5% of both its Entire Facility and PET/CT patients.

Projected Payor Mix during the 3rd Full FY
09/01/2028 to 09/30/2029

<Durham Diagnostic Imaging – Entire Facility>	
Payor Source	**Percentage of Total Patients Served**
Self-Pay	1.6%
Charity Care	1.0%
Medicare *	42.92%
Medicaid *	5.5%
Insurance *	44.1%
Workers Compensation	2.62%
TRICARE	0.55%
Other (Commercial, Auto/Liability)	1.76%
Total	100.0%

* Including any managed care plans.

<Durham Diagnostic Imaging – Fixed PET services>	
Payor Source	**Percentage of Total Patients Served**
Self-Pay	1.6%
Charity Care	1.0%
Medicare *	42.92%
Medicaid *	5.5%
Insurance *	44.1%
Workers Compensation	2.62%
TRICARE	0.55%
Other (Describe)	1.76%
Total	100.0%

* Including any managed care plans.

See page 105 of DDI application.

However, DDI's Form F.2 for its Entire Facility and PET/CT services does not reflect this projected increase in Medicaid patients. As shown below, DDI's financial statements indicate that Medicaid will comprise 2.19% of the total, consistent with 2024 experience and will not increase with the project.

DDI Medicaid as Percent of Total Revenue-Entire Facility

	2024	2025	2026	2027	2028	2029
Gross Revenue	$20,526,944	$20,937,483	$21,356,232	$33,752,700	$37,530,647	$41,950,927
Medicaid Revenue	$449,540	$458,531	$467,701	$739,184	$821,921	$918,725
Medicaid % of Total	**2.19%**	**2.19%**	**2.19%**	**2.19%**	**2.19%**	**2.19%**

Source: DDI Form F.2-Entire Facility

DDI Medicaid as Percent of Total Revenue-PET/CT

	2027	2028	2029
Gross Revenue	$12,828,251	$15,381,073	$18,440,611
Medicaid Revenue	$280,939	$336,846	$403,849
Medicaid % of Total	**2.19%**	**2.19%**	**2.19%**

Source: DDI Form F.2-PET/CT

As such, DDI has failed to demonstrate the extent to which Medicaid patients will utilize its projected services. As such, DDI should be found non-conforming with Criterion (13).

Impact on Other Review Criteria

Based on the previously described facts which render the DDI application non-conforming to Criteria (3), (5), (13), the application is also **non-conforming to Criteria (1), (4), (6), (18a) and 10A NCAC 14C .3703**.

COMMENTS SPECIFIC TO DUKE UNIVERSITY HOSPITAL APPLICATION, PROJECT ID J-012610-25

Comments Regarding Criterion (3)

Including DUHS and Duke Raleigh Hospital, the Duke Health system controls four of the nine fixed PET scanners in HSA IV (three at DUHS and one at Duke Raleigh). DUHS's application and Duke Cary Hospital's concurrent application, Duke Health seeks to develop two additional fixed PET scanners. If approved, Duke Health would control six of the 11 fixed PET scanners in HSA IV, further consolidating its market share.

All of Duke Health's fixed PET scanners are organized as hospital-based scanners, which are typically associated with higher costs and charges compared to freestanding services. Additionally, these scanners are or will be located within inpatient hospital settings, which present logistical challenges for patients, including navigating congested roads and parking facilities. In contrast, freestanding PET services generally offer more accessible and patient-friendly options.

The 2021 SMFP identified a need for one additional fixed PET scanner in HSA IV. DUHS was awarded that scanner, which remained undeveloped until it was temporarily put into service in the fall of 2024 via the use of a DUHS research scanner (see page 93 of DUHS application). DUHS's permanent fixed scanner is scheduled to be put into service in the summer of 2025, potentially during the review of these competitive applications. With the development of DUHS's permanent fixed scanner, DUHS will operate three fixed PET scanners.

DUHS claims that it requires additional PET capacity. However, its historical utilization data suggests otherwise. In 2022, DUHS performed 6,623 PET scans on two fixed PET scanners, equating to an average of 3,312 scans per scanner. In 2023, DUHS performed 7,443 PET scans on the same two scanners, or 3,722 scans per scanner. These figures indicate that DUHS has historically been able to accommodate substantial patient volumes with its existing resources.

DUHS PET Scans per Unit

	2022	2023
DUHS PET Scans	6,623	7,443
PET Scanners	2	2
PET Scans per Scanner	3,312	3,722
Scans Assuming 3 Scanner	**9,935**	**11,165**

Source: DUHS Application, pages 37-38

Based on these averages, DUHS's three PET scanners, once fully operational, could accommodate between 9,935 and 11,165 scans annually, assuming they are operated at historical levels of efficiency. In its application, DUHS projects 9,519 PET scans in its third project year (Form C.2a). This projection falls well within the capacity of DUHS's existing three scanners, demonstrating that its current infrastructure is sufficient to meet its projected utilization without the need for an additional scanner.

DUHS asserts that it is experiencing capacity constraints and scheduling backlogs. However, it provides no analysis or evidence to demonstrate that these constraints will persist after its third scanner is permanently installed in the summer of 2025. Historical utilization data strongly suggests that its existing

capacity will be sufficient to accommodate its projected demand. DUHS's failure to account for the impact of its third scanner undermines its claim of insufficient capacity.

Approving DUHS's application would further consolidate Duke Health's dominance in the HSA IV PET scanner market, giving it control of six out of 11 fixed PET scanners in the region. Such concentration raises concerns about limiting competition, increasing costs, and reducing patient choice. Furthermore, all Duke Health PET scanners are hospital-based, which generally results in higher charges and less convenient access compared to freestanding alternatives. Patients would likely face greater challenges navigating the associated hospital settings, including congested traffic and limited parking, as opposed to the more accessible design of freestanding facilities.

DUHS has not demonstrated a need for an additional PET scanner. Its historical utilization data shows that its existing capacity is sufficient to meet its projected demand once its third scanner is fully operational. Moreover, its application fails to address how its capacity constraints will change following the installation of its third unit. Given these factors, DUHS does not conform with Criterion (3).

Comments Regarding Criterion (4)

The DUHS application fails to demonstrate that its proposed project represents the most effective alternative, as it does not adequately address the elimination of PET research capacity or the benefits and need for a freestanding PET service.

As outlined on page 31 of its application, DUHS proposes to develop the new PET scanner by converting an existing research-only PET scanner to permanent clinical use. However, DUHS provides no substantive discussion of the implications of permanently eliminating this dedicated research scanner. Although DUHS acknowledges that it has received approval via a Material Compliance determination to temporarily use the research scanner for clinical purposes until its third permanent PET scanner is developed, it fails to address how the needs of PET research patients or researchers will be met once this transition is made permanent.

DUHS also neglects to consider alternative project designs that would allow it to meet clinical PET needs while preserving PET research capacity. For instance, developing a new fixed PET scanner without converting the research scanner would ensure that PET research capabilities remain intact, thereby supporting the ongoing needs of clinicians and research initiatives. The failure to adequately consider the implications of this elimination demonstrates a significant oversight in assessing the most effective alternative.

Regarding the potential development of a freestanding PET service, DUHS dismisses this alternative with a brief statement: "A freestanding location would not serve inpatients and would not provide the same range of services that will be available on the hospital campus." This response is insufficient and overlooks critical considerations related to patient accessibility, cost, and capacity.
DUHS fails to recognize that a significant portion of its PET patients are outpatients, who would benefit from the lower costs and improved convenience of a freestanding PET service. Hospital-based PET scanners typically incur higher charges due to facility fees and are located within complex medical campuses, where patients face challenges such as congested roads, limited parking, and lengthy navigation within the hospital setting.

Moreover, in HSA IV, there is only one freestanding PET service compared to eight hospital-based units. The development of an additional freestanding PET scanner would provide outpatients with greater access to affordable and convenient care while freeing up capacity at hospital-based units to focus on inpatient needs. This alternative would better address the region's needs while promoting a more balanced distribution of services across care settings. DUHS's failure to provide a robust evaluation of this alternative is a critical shortcoming in its application.

DUHS's application does not sufficiently address the permanent elimination of PET research capacity or the potential benefits of a freestanding PET service. Its dismissal of these considerations demonstrates that it has not adequately explored or presented the most effective alternative to meet patient and community needs. Based on the foregoing discussion, the DUHS application is non-conforming with Criterion (4).

Impact on Other Review Criteria

Based on the previously described facts which render the DUHS application non-conforming to Criteria (3) and (4), the application is also **non-conforming to Criteria (1), (5), (6), (18a), and 10A NCAC 14C .3703**.

COMMENTS SPECIFIC TO DUKE CARY HOSPITAL APPLICATION PROJECT ID J-012607-26

Comments Regarding Criterion (3)

Including DUHS and Duke Raleigh Hospital, the Duke Health system controls four of the nine fixed PET scanners in HSA IV (three at DUHS and one at Duke Raleigh). DUHS's application and Duke Cary Hospital's concurrent application, Duke Health seeks to develop two additional fixed PET scanners. If approved, Duke Health would control six of the 11 fixed PET scanners in HSA IV, further consolidating its market share.

All of Duke Health's fixed PET scanners are organized as hospital-based scanners, which are typically associated with higher costs and charges compared to freestanding services. Additionally, these scanners are or will be located within inpatient hospital settings, which present logistical challenges for patients, including navigating congested roads and parking facilities. In contrast, freestanding PET services generally offer more accessible and patient-friendly options.

The 2021 SMFP identified a need for one additional fixed PET scanner in HSA IV. DUHS was awarded that scanner, which remained undeveloped until it was temporarily put into service in the fall of 2024 via the use of a DUHS research scanner (see page 93 of DUHS application). DUHS's permanent fixed scanner is scheduled to be put into service in the summer of 2025, potentially during the review of these competitive applications. With the development of DUHS's permanent fixed scanner, DUHS will operate three fixed PET scanners.

DUHS claims that it requires additional PET capacity. However, its historical utilization data suggests otherwise. In 2022, DUHS performed 6,623 PET scans on two fixed PET scanners, equating to an average of 3,312 scans per scanner. In 2023, DUHS performed 7,443 PET scans on the same two scanners, or 3,722 scans per scanner. These figures indicate that DUHS has historically been able to accommodate substantial patient volumes with its existing resources.

DUHS PET Scans per Unit

	2022	2023
DUHS PET Scans	6,623	7,443
PET Scanners	2	2
PET Scans per Scanner	3,312	3,722
Scans Assuming 3 Scanner	**9,935**	**11,165**

Source: DUHS Application, pages 37-38

Based on these averages, DUHS's three PET scanners, once fully operational, could accommodate between 9,935 and 11,165 scans annually, assuming they are operated at historical levels of efficiency. In its application, DUHS projects 9,519 PET scans in its third project year (Form C.2a). This projection falls well within the capacity of DUHS's existing three scanners, demonstrating that its current infrastructure is sufficient to meet its projected utilization without the need for an additional scanner.

DUHS asserts that it is experiencing capacity constraints and scheduling backlogs. However, it provides no analysis or evidence to demonstrate that these constraints will persist after its third scanner is permanently installed in the summer of 2025. Historical utilization data strongly suggests that its existing

capacity will be sufficient to accommodate its projected demand. DUHS's failure to account for the impact of its third scanner undermines its claim of insufficient capacity.

Approving DUHS's application would further consolidate Duke Health's dominance in the HSA IV PET scanner market, giving it control of six out of 11 fixed PET scanners in the region. Such concentration raises concerns about limiting competition, increasing costs, and reducing patient choice. Furthermore, all Duke Health PET scanners are hospital-based, which generally results in higher charges and less convenient access compared to freestanding alternatives. Patients would likely face greater challenges navigating the associated hospital settings, including congested traffic and limited parking, as opposed to the more accessible design of freestanding facilities.

Further, Duke Cary Hospital does not mention any current or previous shifts of DUHS patients to Duke Raleigh given DUH's alleged PET capacity constraints. As shown above, in 2022 and 2023, DUHS provided 3,312 and 3,722 scans per unit, respectively. According to page 40 of Duke Cary Hospital's application, excerpted below, Duke Raleigh Hospital provided 1,771 and 2,022 PET scans in 2022 and 2023, respectively, on its one fixed PET scanner.

Historical DUHS PET Utilization

	2021	2022	2023	2024	3-year Growth
Duke University Hospital	5,405	6,623	7,443	8,211	52%
Duke Raleigh Hospital	1,448	1,771	2,002	2,473	71%
Total DUHS	6,853	8,394	9,445	10,684	56%

This disparity in utilization is evidence that patients have not shifted from Duke University Hospital to Duke Raleigh Hospital in response to DUHS's alleged PET capacity constraints.

On page 105, Duke Cary Hospital states that its project shift is reasonable because the "shift generates a total volume of additional Wake County patients at the DUHS Wake County locations that is less than the number of Wake County patients seen in each of the first three project years at Duke Raleigh Hospital's fixed PET scanner (note that FY 2021 was a partial year and FY 2024 was the third full project year)." However, this statement is disingenuous because it fails to note that Duke Raleigh Hospital utilized a mobile PET scanner prior to the development of its fixed PET scanner. As shown in the excerpt below from Table 9(M)2 of the 2019 SMFP, Duke Raleigh had a multi-year history of providing PET services via a mobile unit.

Table 9M(2): PET Scanner Sites Utilization of Existing Mobile Dedicated Scanners

Mobile Site	Mobile Provider	Number of Sites	Procedures			
			2013-2014	2014-2015	2015-2016	2016-2017
Caldwell Memorial Hospital	Alliance I	1	96	79	70	102
Carolinas HealthCare System Blue Ridge	Alliance I	2	228	241	257	280
Carolinas HealthCare System Cleveland	Alliance I	1	575	685	753	786
Carolinas HealthCare System Stanly	Alliance I	1	119	173	230	226
Columbus Regional Healthcare System	Alliance II	1	0	0	0	3
Carteret General Hospital	Alliance II	1	248	230	342	249
Cone Health	Alliance I	1	29	0	0	0
Duke Raleigh Hospital	Alliance II	1	493	675	951	1,092

As such, the utilization of Duke Raleigh's PET scanner in its first three project years is not comparable to the projected first three years of Duke Cary Hospital. Duke Raleigh Hospital had been providing PET services for many years whereas Duke Cary Hospital will be an entirely new provider of PET services with no prior history.

On page 105 of its application, Duke Cary Hospital states that the proposed shift from Duke University Hospital to Duke Raleigh and Duke Cary "is projected to ramp over time, culminating in third project year at 75% of the potential DUH Wake County volume." Duke Cary Hospital assumes that the proposed shift "will be evenly split between the two Wake County locations, [Duke Cary Hospital and Duke Raleigh]" (page 106). However, Duke Cary Hospital fails to demonstrate that Duke Cary Hospital would be clinically appropriate for patients shifted from Duke University Hospital or that Duke Cary Hospital would even be able to serve these Duke University Hospital patients.

PET imaging is a fundamental component of an integrated cancer care plan at a specific site of care. Duke Cary notes that on page 41 that "Cancer care is the most common application of PET scanner." PET imaging is used to stage and restage cancer treatment as well as for radiotherapy planning. Duke Cary Hospital does not demonstrate that it would be reasonable for patients undergoing cancer treatment at Duke University Hospital to stage or restage their cancer treatment at Duke Cary Hospital or to have radiotherapy/radiation therapy treatments that will be performed at Duke University Hospital will be able to use the proposed Duke Cary Hospital PET scanner.

Further, Duke Cary Hospital does not demonstrate that it will provide the scope of services that will allow it to serve the proposed shift of patients from Duke University Hospital. While Duke Cary notes on page 39 that PET scanning is also for patients with cardiac and neurological conditions, in addition to cancer, it fails to demonstrate that it plans or will be able to do so. For example, there is no mention in Duke Cary Hospital's application of a Rubidium generator which is necessary to provide certain cardiac PET services or that it can provide the necessary radiopharmaceuticals for the breadth of PET procedure types provided at Duke University Hospital.

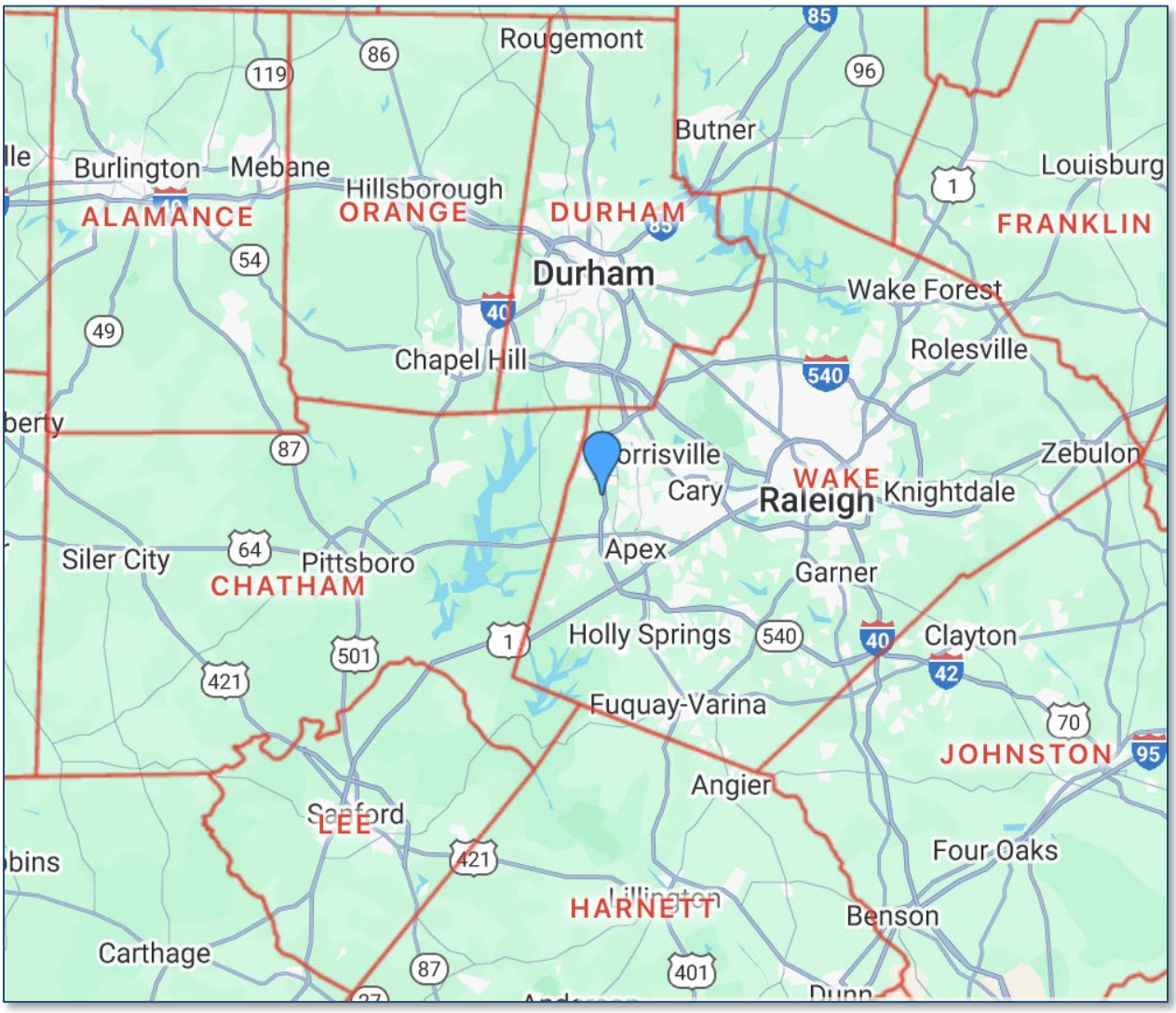
Finally, Duke Cary Hospital provides no evidence that Duke University Hospital has experience shifting patients in the manner proposed or that it has successfully done so in the past. As shown above, Duke Cary Hospital does not mention any current or previous shifts of Duke University Hospital patients to Duke Raleigh given DUHS's alleged PET capacity constraints.

In fact, a review of Duke Cary Hospital's PET and overall patient origin demonstrates that the proposed shift is unreasonable. On page 36, Duke Cary Hospital provides its projected patient origin, as excerpted below, which includes no identified patients from Chatham, Lee, or Orange counties.

PET Procedures	Duke Cary Hospital*					
	1st Full FY		2nd Full FY		3rd Full FY	
	7/1/2029 to 6/30/2030		7/1/2030 to 6/30/2031		7/1/2031 to 6/30/2032	
County or other geographic area such as ZIP code	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients	% of Total
Wake	1,052	63.4%	1,273	67.0%	1,505	70.0%
Johnston	74	4.5%	76	4.0%	79	3.7%
Franklin	69	4.1%	71	3.7%	73	3.4%
Cumberland	39	2.3%	40	2.1%	41	1.9%
Durham	31	1.9%	32	1.7%	33	1.5%
Harnett	28	1.7%	29	1.5%	30	1.4%
Nash	26	1.6%	27	1.4%	28	1.3%
Brunswick	26	1.6%	27	1.4%	28	1.3%
New Hanover	20	1.2%	21	1.1%	22	1.0%
Vance	17	1.0%	18	0.9%	18	0.9%
Wilson	17	1.0%	17	0.9%	18	0.8%
Granville	15	0.9%	15	0.8%	16	0.7%
Wayne	13	0.8%	13	0.7%	13	0.6%
Moore	11	0.7%	12	0.6%	12	0.6%
Halifax	11	0.7%	12	0.6%	12	0.6%
Other NC	162	9.7%	167	8.8%	172	8.0%
VA	19	1.1%	19	1.0%	20	0.9%
SC	13	0.8%	13	0.7%	13	0.6%
All Other	17	1.0%	18	0.9%	18	0.9%
Total	**1,660**	**100.0%**	**1,899**	**100.0%**	**2,150**	**100.0%**

* 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.

As shown in the map below, the proposed site (indicated by the blue marker) for the Duke Cary Hospital PET project, at 200 Duke Health Cary Place is in western Wake County and closer for residents of Chatham County, in particular, as well as Orange and Lee county residents than many other counties listed in its patient origin (e.g., Cumberland, Brunswick, New Hanover, and other counties distant from Wake County).



According to Google Maps, the proposed site is less than three miles on Green Level Road to the Chatham County boundary. It is unreasonable for Duke Cary to propose to serve patients from Cumberland, New Hanover, and Brunswick counties, among others, and to identify no patients that it will serve from Chatham, Lee, or Orange counties given the proximity of the proposed site to the latter counties.

In fact, the proposed patient origin for the Duke Health Cary Total Facility demonstrates the unreasonableness of the proposed patient origin for Duke Cary Hospital's PET service. As shown below, Duke Health Cary's Total Facility Patient Origin on page 37 identifies Chatham, Lee, and Orange counties as three of the five total specified counties in its projected patient origin in addition to Wake and Durham counties.

Entire Facility: Acute Care Beds, ORs, Procedure Rooms, Emergency Department + PET	Duke Cary Hospital					
	1st Full FY		2nd Full FY		3rd Full FY	
	07/01/2029 to 06/30/2030		07/01/2030 to 06/30/2031		07/01/2031 to 06/30/2032	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Wake	10,485	84%	14,318	85%	20,478	84%
Durham	942	8%	1,377	8%	2,175	9%
Chatham	200	2%	296	2%	544	2%
Lee	130	1%	198	1%	267	1%
Orange	83	1%	129	1%	178	1%
Other^	577	5%	594	4%	612	3%
Total	12,416	100%	16,912	100%	24,254	100%

^Other includes all other counties.

Given these factors, Duke Cary Hospital fails to demonstrate that its projected utilization is reasonable and fails to adequately identify the population to be served and should be found non-conforming with Criterion (3).

Comments Regarding Criterion (4)

The Duke Cary Hospital application fails to demonstrate that its proposed project provides the most effective alternative as it does not adequately address the benefits and need for a freestanding PET service.

Regarding the possibility of developing a freestanding PET service, Duke Cary Hospital states "A freestanding location would not serve inpatients and would not provide the same range of services that will be available on the hospital campus. It would also not provide the same coordination of care that will be available at the hospital campus that will offer medical and surgical oncology, ambulatory surgery, and inpatient services" (page 63). Duke Cary Hospital's statement does not address the number of outpatients it projects to provide with PET services, who would benefit from the lower cost and greater convenience of a freestanding PET service. There is only one existing freestanding PET service in HSA IV whereas there are eight hospital-based units. The development of a freestanding PET service would allow outpatients to avoid the congested roads and parking associated with a complex inpatient medical campus and create greater capacity for hospitals to treat inpatients. Duke Cary Hospital fails to adequately address this alternative.

Based on the foregoing discussion, the Duke Cary Hospital application is non-conforming with Criterion (4).

Impact on Other Review Criteria

Based on the previously described facts which render the Duke Cary application non-conforming to Criteria 3 and 4, the application is also **non-conforming to Criteria (1), (5), (6), (18a) and 10A NCAC 14C .3703**.

COMMENTS SPECIFIC TO WAKEMED RALEIGH MEDICAL PARK PROJECT ID J-012611-25

Please note that the WakeMed Raleigh application mistakenly states that, "Two academic health systems currently control eight of the nine PET scanners located in HSA IV" (p. 41). For clarity, two of the existing/approved PET scanners in HSA IV are located at UNC Health REX. REX Hospital is part of the UNC Health system, but it is UNC Hospitals on Manning Drive in Chapel Hill that is an Academic Medical Center Teaching Hospital (as designated in 1983) according to Appendix F to the 2025 State Medical Facilities Plan. REX Hospital is not an Academic Medical Center for CON purposes.

Comments Regarding Criterion (3)

Like Wake Radiology, WakeMed Raleigh notes that HSA IV only has one freestanding PET scanner among its nine fixed units. This existing freestanding PET service, Wake PET Services d/b/a 210 PET Imaging per WakeMed Raleigh, is majority owned (51%) by WakeMed Raleigh. WakeMed Raleigh, the sole owner of Raleigh PET, is the only provider in the HSA that *already* has ownership in a freestanding PET service. From this perspective, WakeMed Raleigh is the provider that least needs a CON to establish a freestanding PET service. As the discussion below demonstrates, WakeMed Raleigh's existing freestanding PET service has been historically underutilized and currently has excess capacity. As such, WakeMed Raleigh fails to demonstrate that it needs to develop a second freestanding PET service.

WakeMed Raleigh states that its project, Raleigh PET, "proposes replicating the 210 PET service program in east Raleigh" (page 42). As shown on page 42, excerpted below, 210 PET Imaging has operated at less than 60% of capacity in four of the last five years and below 80% of capacity for at least the last five years.

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

Notably, in the narrative just above the chart, Raleigh PET states that its "internal records for 210 PET Imaging demonstrate that it operated over 80 percent capacity in FY 2024." However, in the chart, Raleigh PET appropriately represents this utilization as reflecting 75.5% of capacity.

WakeMed Raleigh states that the increase in utilization at 210 PET Imaging represents real growth and is attributable to factors like state-of-the-art equipment and global billing. Yet, next it states that "WakeMed patients" are referred to Duke, REX, and UNC's PET scanners (p. 43). It is unclear why "WakeMed patients"

would be referred to Duke, REX, and UNC scanners if the 210 PET Imaging scanner is, as represented, an optimal choice for PET imaging.

Contrary to WakeMed Raleigh's arguments, 210 PET Imaging's historical utilization indicates that WakeMed Raleigh has unsuccessfully operated freestanding PET services in HSA IV. As noted above, 210 PET Imaging operated below 60% of capacity for four straight years and has only operated above 75% in the most recent year. WakeMed Raleigh does not adequately explain why its proposed project will differ from the low utilization experience of 210 PET Imaging - in fact, WakeMed Raleigh just does the opposite; it states it will *replicate* the 210 PET service program. It is unreasonable to assume that WakeMed Raleigh's proposed project will differ from the low utilization experience of 210 PET Imaging given that statement. Moreover, 210 PET Imaging currently has additional capacity for additional WakeMed Raleigh patients as is clear from the above utilization table.

Notably, WakeMed Raleigh argues that its proposed project will offer greater convenience to patients stating in Section C.4 that "An outpatient setting is also more convenient for patients" (page 45). While WakeMed Raleigh proposes a "freestanding" PET, it proposes to locate its PET unit directly across the street from the large WakeMed Raleigh campus on New Bern Avenue, meaning patients will be "going to the hospital" experientially when accessing the proposed PET scanner. Not only is the proposed PET in the immediate area of WakeMed's hospital, but it also appears the PET scanner will be located adjacent to Capital Surgery Center, suggesting patients will compete for parking with this bustling 7-OR surgery center which performs over 7,200 surgeries annually.

The applications in this review are filed in response to a need identified for HSA IV and the Performance Standard requires a projection of 2,080 scans by Year Three. While it is certainly permissible and perhaps expected that some patients will come from outside HSA IV and while there is no requirement that the Performance Standard volumes be met with HSA IV residents, it is nonetheless notable that WakeMed Raleigh forecasts that only 2,039 patients will originate from HSA IV in Year Three – this total is less than the Performance Standard goal of 2,080. In other words, without the 183 patients expected to come from outside the area for which the need determination was identified, WakeMed Raleigh's projections would fail to satisfy the Performance Standard.

In April 2023, WakeMed filed a CON Application describing how it has provided oncology services for years but has no LINAC to provide radiation therapy services. WakeMed acknowledged that radiation therapy has become a standard modality in cancer care and treatment. WakeMed stated that it needed a LINAC to be able to provide this standard modality in its "cancer care program."

In September 2023, the Agency approved WakeMed to locate a LINAC in its WakeMed Raleigh Medical Park (RMP) building. However, in February 2025, just after the CON applications were filed in this PET Review, Administrative Law Judge Byrne reversed the Agency decision to award WakeMed a CON for its proposed LINAC project. The Judge ruled that the Agency erred in denying Duke's CON application for the LINAC.

Duke proposed to acquire a LINAC and CT simulator and develop a new radiation oncology facility, Duke Radiation Oncology Garner (Duke Garner), to be licensed under Duke Raleigh Hospital. Unless an appellate Court overturns Judge Byrne's decision, WakeMed will not hold CON approval to develop a LINAC in the RMP building where it has proposed to locate the PET scanner proposed in the CON application at issue in this Review. In other words, WakeMed will not be offering LINAC services which it has described as a standard modality for patients seeking cancer care and treatment. Absent a Court reversing Judge Byrne,

the RMP building will not be home to a LINAC service as originally forecasted. (The Raleigh PET scanner is slated to be housed in RMP2).

The support letter signed by several different physicians with "WakeMed Cancer Care," recites as follows:

> *WakeMed's cancer care program has made remarkable strides since its inception. Following the successful CON application for a linear accelerator in 2023, the addition of a PET/CT scanner in the same facility represents the next critical step in achieving our vision of a fully integrated, patient-center cancer treatment center.*
>
> ***
>
> *… [the] availability [of PET/CT imaging] is crucial for patients undergoing radiation therapy, such as those who will benefit from our new linear accelerator …*
>
> *Locating the PET/CT scanner within the same facility as the linear accelerator would enable seamless care coordination …*

The "successful CON application" and the "new linear accelerator" referred to by these doctors is the CON approval that Judge Byrne has now reversed. As such, the PET project proposed in this review will not be a next "step" after the LINAC, as the landscape now stands. This change impacts the reasonableness of the assumptions used to demonstrate conformity with Criterion (3). Instead (unless overturned by an appellate Court), it appears Duke will be CON approved to develop a new cancer treatment center to be known as Duke Radiation Oncology in Garner, the same city where WR Imaging proposes to develop its proposed PET scanner project per this Review.

Based on the factors discussed above, WakeMed Raleigh should be found non-conforming with Criterion (3).

Comments Regarding Criterion (5)

WakeMed Raleigh fails to reasonably demonstrate the availability of funds for capital and operating needs for the proposed project.

On page 65 of the application, WakeMed Raleigh states that total working capital for the project is $1,593,996. However, on the following page, WakeMed Raleigh provides the source for only $823,362 of the $1.5 million in working capital the project requires. WakeMed Raleigh does not provide a source for the remaining $770,634 in working capital required which is equivalent to the start-up costs for the proposed project. As such, WakeMed Raleigh fails to demonstrate the availability of funds for its working capital.

Further, WakeMed Raleigh's application provides directly conflicting information regarding its proposed mode of project funding. In its response to Section F.2, WakeMed Raleigh states that it will fund the project with Accumulated Reserves. However, in its Assumptions for Form F.1a, WakeMed Raleigh states that it will incur "Financing Costs" and the supporting information in Exhibit F.1 states that this consists of a "Bond Issance (sic) Expense @ 1.5%" and "Capitalized Interest at 4.5%." On Form F.1a, WakeMed Raleigh projects that it will incur a total of $241,049 in "Financing Costs" equivalent to $60,262 + $180,787 as shown on the Project Cost Estimate.

As such, WakeMed Raleigh provides contradictory information as to its proposal for project funding. In one place, the application states the funding will come from WakeMed Raleigh accumulated reserves and in another place, it states that certain costs will be incurred with over $240,000 in "Financing Costs," made up of over $60,000 for a Bond Issuance Expense and over $180,000 for a Capitalized Interest amount. WakeMed Raleigh's "Financing Costs" indicate that the project will be financed via a bond. If WakeMed Raleigh intends to finance the project with a Bond – as it reflects on Form F.1a and on the Project Cost Estimate -- to demonstrate conformity with Criterion 5, it must provide financing documentation – e.g., a letter from the entity proposing to provide the financing. This is true regardless of WakeMed's financial position.

Form F.1a appears to identify that the purpose of the loan is for Capital Costs and appears to refer to two different percentages that may be interest rates, but the application does not state anything to reflect:

- Name of the Proposed Borrower
- Proposed Term (Period of the Loan)
- Amortization Schedule

Moreover, the application does not identify the prospective lending institution nor provide a statement from that lender that it would consider financing the project capital costs of over $4 million dollars (or any amount for that matter). Further, WakeMed Raleigh fails to include interest expense associated with this bond financing in its financial statements.

Based on the factors discussed above, WakeMed Raleigh should be found non-conforming with Criterion (5).

Comments Regarding Criterion (20)

Criterion (20) seeks information on the applicant or any related entity which provides "the same service components" included in the CON Application – here, the service component is PET. In Section O, the applicant states WakeMed "does not directly provide PET scans." While the applicant describes that WakeMed "is a joint venture owner (51%) of 210 PET Imaging," the application refers the reader to Form O which lists only WakeMed and WakeMed Cary hospitals, neither of which provide the service component of PET. As WakeMed Raleigh states throughout the application, WakeMed partially owns Wake PET Services, LLC. Yet, curiously, in response to Question O.2, the application does not provide any description of the methods used by Wake PET Services, LLC to ensure and maintain the quality of care at its existing PET service. The applicant does not provide any specific or even sample policies or procedures that will govern Raleigh PET. The Quality documentation included with the application is "generic" to WakeMed generally and does not appear to address any aspects of the functioning of an imaging center. This is notable because WakeMed already runs a freestanding PET imaging center, 210 PET Imaging.

Considering this application seeks a PET CON, it is notable that, beyond a few limited mentions (e.g., of speedy interpretation experience), the applicant provides no substantive description of WakeMed's existing PET service in terms of its provision of quality care. There is no publicly available information which details the methods used by Wake PET Services to address the quality of care offered at 210 PET Imaging in Cary. Moreover, in response to Question O.3, the application does not document that Wake PET Services, LLC is currently licensed, certified, or accredited. Admittedly, a web search does show ACR

accreditation for Wake PET Services, LLC. However, that web search did not immediately show any ACR survey results for Wake PET Services over the last 18 months nor any further details.

The next question, Question O.4, is regarding the quality care history of the applicant and any related entities. Again, this question is intended to relate to the applicant's facilities providing the relevant service component, PET. No information is provided on the quality care record of Wake PET Services, LLC, which is a joint venture in which WakeMed holds a 51% interest. An identical letter provided at Exhibit O.3 (and O.4) attests that "all WakeMed facilities" have provided quality care during the most recent 18-month period and are licensed, certified, and/or Joint Commission accredited, as relevant. Considering Wake PET Services is not listed on Form O or mentioned by name in the letter in Exhibit O.3, it is unclear whether this statement about "WakeMed facilities" encompasses Wake PET Services or not. Importantly, the internet does not appear to offer sufficient information to independently document whether Wake PET Services, LLC provided quality care during the 18 months immediately preceding the submission of the CON application at issue. Unlike for instance, home health agencies and nursing homes which can be researched on Medicare.Gov and compared to other similar facilities, it is unclear what could be said to be publicly available from a reliable source to provide any details about WakeMed's provision of PET services in Cary.

The information in Section O fails to respond to the questions as posed and results in a lack of information to show conformity with Criterion (20).

Impact on Other Review Criteria

Based on the previously described facts which render the WakeMed application non-conforming to Criteria (3), (5), and (20), the application is also **non-conforming to Criteria (1), (4), (6), (18a), and 10A NCAC 14C .3703**.

COMMENTS SPECIFIC TO RALEIGH PET IMAGING APPLICATION PROJECT ID J-012598-25

Comments Regarding Criterion (3)

The AUNC Utilization Methodology and Assumptions section which presents its projections is not reasonable and adequately supported. The Methodology incorporates several key logic flaws and unsupported assertions.

AUNC begins with the premise that its fourteen doctors referred a total of 828 PSMA PET scans and referred another 324 bone scans which AUNC surmises will "all" become PET scan referrals beginning in FY 2025. AUNC provides no information on whether or why it is reasonable to assume that once AUNC develops its proposed PET scanner, all bone scans (not previously performed using PET equipment) will now "become" PET scans. In an article published in 2021 in the National Library of Medicine, researchers compared the use of bone scans, PET scans, and MRI scans as to their sensitivity, specificity, and predictive values for assessing certain patient conditions and found no difference between the different imaging modalities (https://pmc.ncbi.nlm.nih.gov/articles/PMC8277296/). While the AUNC assumption that all bone scans will "become" PET scans in the future *may* be appropriate, the AUNC application as filed provides nothing to indicate that this assumption is reasonable and supportable.

AUNC than assumes that these PSMA PET and bone scans referrals will "increase annually by the 5-year CAGR of 10.67%" which is equivalent to the HSA IV PET Scan 5-Year CAGR. This assumption is not reasonably supported. AUNC provides no evidence that the referrals from its physician group for PSMA PET scans will grow consistent with overall PET scan trends. PSMA PET Scans "are primarily used for diagnosing, staging, and monitoring prostate cancer" (page 43). However, HSA IV's overall utilization is comprised of many more types of PET scans. AUNC specifically discusses three other types of PET scans in its application: Renal-Specific PET, Cardiac PET, and Neurological PET (see pages 46-52). AUNC also projects to provide Ortho PET scans per its Utilization Methodology. AUNC provides no demonstration that AUNC historical referral trends have been consistent with overall PET scan trends. In fact, AUNC assumes a much lower growth rate for its Renal PET scans referrals. As such, AUNC's assumed 10.67% growth rate is not adequately supported.

The unreasonableness of this growth rate is evident when reviewing the projected increase in referrals over time. By the third project year, AUNC expects every one of its doctors to have increased from ordering an annual average of 82 PSMA + Bone scans (FY25) to ordering over 123 scans each year (FY29) – this equates to over a 50% increase in the average number of scans ordered per MD per year. Because AUNC provides no further explanation or justification in its application, this 50%+ increase in scan referral activity among the AUNC doctors cannot be found reasonable nor adequately supported.

AUNC uses an average-scan-per-physician statistic in its methodology. Yet, it is highly unlikely that the fourteen AUNC physicians refer PSMA PET scans at the same rates. It is more likely that some AUNC physicians refer PSMA PET scans less frequently than others. A PSMA PET scan is a Prostate-Specific Membrane Antigen PET scan, used for prostate cancer imaging for men. The prostate is a gland found only in men that plays a role in men's reproductive and urinary systems. For instance, the AUNC website says: "Dr. Jalkut diagnoses and treats all types of urologic problems, but specializes in urologic cancer, laparoscopic and robotic surgery, as well as female and reconstructive urology." Clearly, a portion of Dr. Jalkut's practice involves the care of patients (females) for whom PSMA PET scans are not ordered. Dr. Kaspar practices general urology but specializes in female urology and incontinence. Like Dr. Jalkut, Dr.

Kaspar's practice may involve some PSMA PET scan referrals but, according to the website, his practice involves a specialization in female urology and incontinence.

To reach the numbers in AUNC's projections – as noted above – each doctor will have to increase their average number of annual PSMA PET referrals by over 50% (going from 82 per year in FY25 to over 123 in FY29). If, as one would expect, only certain doctors are referring most of the PSMA scans, then this increase, by individual referring physician, will need to be even higher than 50%. By definition, the physicians who make these types of referrals do so based on their patient caseload. The website does not suggest any of the AUNC doctors are part-time physicians. Presumably, these doctors already treat a full roster of patients.

In its CON application, AUNC does not provide any historical data to show the number of men served by AUNC doctors and whether that number has remained constant over any prior term of years. In fact, the AUNC CON application describes how its new physicians can be expected to take about four years to "fully develop" their practices. This suggests that the fourteen MDs already on staff (or at least those who have been with the practice for at least four years) have fully developed practices or, in other words, a constant patient caseload. If the subset of AUNC doctors who treat men (the patients with a potential need for a PSMA PET scan) have treated about the same number of men each year over the last several years, it is illogical to assume that these same physicians will begin to treat significantly more men and begin to order significantly more PSMA PET scans in the years ahead.

In a different segment of its methodology, AUNC assumes not only growth in Renal PET scans but assumes that Renal PET scans will take the place of about one-fourth of what are now Renal MRI/CT scans. (Methodology, p. 5). AUNC does not present any data to show any historical growth in AUNC Renal MRT/CT patient volume or that it would be reasonable to assume that Renal MRI/CT volumes will grow consistently with overall MRI/CT volumes. Additionally, the AUNC projections are not reasonable and adequately supported because AUNC cites no scientific journal or article in support of the premise that about 25% of current Renal MRI/CT referrals will "become" PET scans. AUNC states that its 25% conversion projection is something the AUNC physicians "assume … based on their experience." Of course, the AUNC physicians do not have historical experience with this dynamic as it is a forecast of something new and different anticipated to occur in years ahead. The burden rests with the applicant to demonstrate that its projections are reasonable and adequately supported.

In the Health Service Area V PET scanner review, decided by the Agency in 2022, the Analyst reviewed an article cited by the applicant as support for an assumption used in its projections and determined, after review, that the applicant's assumption was "not supported" (HSA V PET Scanner Findings, page 28). The Project Analyst cannot be expected to accept as reasonable a premise in a methodology without a clear supporting source. If AUNC had attached or cited to a source that explained that, in the future, about one-fourth of Renal MRI/CT referrals can be expected to be supplanted with Renal PET scans, the Analyst could have evaluated and potentially accepted such evidence. Lacking such in its application as filed, the applicant's premise is not reasonable and adequately supported.

In addition, the AUNC application contains information which makes it clear that Zirconium-89 is "an investigational radiotracer" and a "promising advancement" but "[o]ngoing research and clinical trials are essential to further validate its clinical utility…" (pp. 46-47). The AUNC methodology (p. 4) specifically relies on a referenced future FDA approval as part of its forecasted volume (and financial) projections. While all can agree that PET technology is continuing to advance, the Agency should not assume

projections are reasonable and adequately supported when the applicant itself sets forth projections which are premised on future (needed) governmental approvals which have not yet been issued.

Based on the foregoing discussion, the AUNC application should be found non-conforming with Criterion (3).

Comments Regarding Criterion (3a)

The AUNC application fails to demonstrate that the needs of its existing CT patients will be adequately met following the development of the proposed project.

In response to Section C.1, AUNC states that "The proposed project will include renovation of 1,375 square feet within the existing medical practice of AUNC" (page 34). On page 37, AUNC provides a photograph of its existing CT Scanner Room. AUNC states "To be conservative, AUNC intentionally received a full-price quote to acquire a new Siemens PET/CT scanner from Siemens Healthineers. However, that quoted price may decrease if AUNC trades-in the existing Siemens CT scanner or upgrades the existing Siemens CT scanner with the required PET scanner components. A large percentage of the renovation quote is for additional lead shielding of the existing CT scanner room" (page 37). Later, on page 3 of its Utilization Methodology and Assumptions, AUNC states that "Raleigh PET Imaging uses the percentage of AUNC patients referred for CT scans that remain at AUNC for the CT scan."

Based on these mentions of AUNC's existing CT service, it is clear that AUNC currently provides CT services using equipment and space that will be renovated in order to provide the proposed PET/CT scanner. However, AUNC does not provide any demonstration that the needs of its existing CT patients will be adequately met following the development of the project. While the proposed PET/CT scanner can provide CT scans, AUNC does not demonstrate how many CT patients it will serve or that its proposed PET/CT scanner will have the capacity to provide CT scans given AUNC's projected PET utilization. AUNC's Form C.2b does not project any CT volumes. AUNC's Financial Statements do not include any revenue from CT patients, which indicates that it does not expect to continue providing CT services. If AUNC eliminates its CT service, it has not demonstrated how CT patient needs will continue to be met.

Based on the foregoing discussion, the AUNC application should be found non-conforming with Criterion (3a).

Comments Regarding Criterion (5)

AUNC does not adequately demonstrate the financial feasibility of the project based on reasonable projections of costs and charges. As shown below, AUNC's financial projections include miscalculations of total gross charges, which may impact projections for other amounts as well as overstated Medicare charges. Further, AUNC does not adequately demonstrate the availability of funds and the reasonableness of its initial operating period.

The Gross Revenue section of Form F.2b for Raleigh PET Imaging is excerpted below.

Form F.2b Projected Revenues and Net Income upon Project Completion Raleigh PET Imaging	1st Full FY F: 07/01/2026 T: 06/30/2027	2nd Full FY F: 07/01/2027 T: 06/30/2028	3rd Full FY F: 07/01/2028 T: 06/30/2029
Patient Services Gross Revenue			
Self Pay *	$53,015	$60,767	$66,073
Insurance *	$3,499,001	$4,010,644	$4,360,820
Medicare *	$1,558,646	$1,786,560	$1,942,547
Medicaid *	$111,332	$127,611	$138,753
Other (Governmental)	$79,523	$91,151	$99,110
Total Patient Services Gross Revenue	**$5,354,532**	**$6,137,501**	**$6,673,376**

In each of the three project years, Raleigh PET Imaging's Total Gross Revenue is miscalculated. As shown in the table below, Raleigh PET Imaging's Total Gross Revenue in Form F.2b is not equal to the gross revenue amounts by payor.

Overstatement of Raleigh PET Imaging Total Gross Revenue

	FY27	FY28	FY29
Self-Pay	$53,015	$60,767	$66,073
Insurance	$3,499,001	$4,010,644	$4,360,820
Medicare	$1,558,646	$1,786,560	$1,942,547
Medicaid	$111,332	$127,611	$138,753
Other (Governmental)	$79,523	$91,151	$99,110
Calculated Total for Total Patient Services Gross Revenue	$5,301,517	$6,076,733	$6,607,303
Form F.2b Total for Total Patient Services Gross Revenue	$5,354,532	$6,137,501	$6,673,376
Miscalculation	**$53,015**	**$60,768**	**$66,073**

Source: AUNC Raleigh PET Imaging Form F.2b

It is not clear based on the information provided whether the Form F.2b gross revenue total is correct and AUNC has understated one or more of the payor's gross revenue components or if the calculated total is correct. Because AUNC uses gross revenue as a basis for other elements of its financial results, this miscalculation impacts several other areas. As noted on its Form F.2 Revenue Assumptions, "Charity Care is estimated to be 4.9% and Bad Debt to be 1.1% of total patient services gross revenue." Further, AUNC states that "Contractual adjustments are estimated to be 30.2% of total patient services gross revenue." The uncertainty of the accuracy of Raleigh PET Imaging's Gross Revenue results in uncertainty regarding Raleigh PET Imaging's Charity Care, Bad Debt, and Contractual amounts. Because these amounts impact Net Revenue and Net Income, there is uncertainty regarding the those figures as well.

In addition to this Gross Revenue miscalculation, AUNC overstates its Medicare charges specifically. On page 94, AUNC states that "Raleigh PET Imaging will globally bill PET scans, which includes the radiologist's interpretive service, for non-Medicare patients. As a result, Raleigh PET Imaging will reimburse ProScan

Imaging $150.00 per non-Medicare patient PET scan for interpretive services. Please note that ProScan Imaging will directly bill Medicare patients for all Medicare patient PET scan interpretive services." Based on this statement, it is clear that ProScan will bill Medicare patients for the radiologist's interpretive services and not Raleigh PET Imaging. For non-Medicare patients, Raleigh PET Imaging will bill globally and reimburse ProScan Imaging for interpretive services. As such, Raleigh PET Imaging's charge to Medicare patients should be lower than its charge to non-Medicare patients because it will not bill Medicare for interpretative services, ProScan will instead. However, Raleigh PET Imaging's Medicare and non-Medicare charges are identical. As shown on its Form F.2b Assumptions and Calculations worksheet excerpted below, Raleigh PET Imaging projects to bill Medicare the same amount as other payors. This is simply unreasonable.

Form F.2b Assumptions and Calculations

PET Scan Revenue

	1st Full FY	% of Total	Scans	x	Projected Avg Charge	=	Gross Revenue
1	Self Pay	1.0%	21	x	$2,497	=	$53,015
2	Insurance **	66.0%	1,401	x	$2,497	=	$3,499,001
3	Medicare **	29.4%	624	x	$2,497	=	$1,558,646
4	Medicaid **	2.1%	45	x	$2,497	=	$111,332
5	Other (Governmental)	1.5%	32	x	$2,497	=	$79,523
	Total	**100.0%**	**2,123**		**$2,497**		**$5,301,517**

	2nd Full FY	% of Total	Scans	x	Projected Avg Charge	=	Gross Revenue
1	Self Pay	1.0%	24	x	$2,497	=	$60,767
2	Insurance **	66.0%	1,606	x	$2,497	=	$4,010,644
3	Medicare **	29.4%	715	x	$2,497	=	$1,786,560
4	Medicaid **	2.1%	51	x	$2,497	=	$127,611
5	Other (Governmental)	1.5%	37	x	$2,497	=	$91,151
	Total	**100.0%**	**2,434**		**$2,497**		**$6,076,734**

	3rd Full FY	% of Total	Scans	x	Projected Avg Charge	=	Gross Revenue
1	Self Pay	1.0%	26	x	$2,497	=	$66,073
2	Insurance **	66.0%	1,746	x	$2,497	=	$4,360,820
3	Medicare **	29.4%	778	x	$2,497	=	$1,942,547
4	Medicaid **	2.1%	56	x	$2,497	=	$138,753
5	Other (Governmental)	1.5%	40	x	$2,497	=	$99,110
	Total	**100.0%**	**2,646**		**$2,497**		**$6,607,303**

As a result, Raleigh PET Imaging's projected gross revenue, net revenue, and net income are unreasonable and not supported.

In its response to Section F.2 and F.3, AUNC states that more than $2.3 million in capital costs and working capital will be funded through a loan from Solaris Health. However, the documentation included in Exhibit F.2 does not indicate that the funds set to come from Solaris Health "are reasonably likely to be available when needed." Instead, the documentation plainly states that it reflects a comment on Solaris Health's present funds with no indication of whether those funds will remain available in the future. Solaris Health operates across multiple States with various ongoing and planned obligations. The CON Application Form

asks for attestation that funds will be available "when needed" and the application as filed includes no such representation.

Additionally, AUNC presents conflicting assumptions for its initial operating period on p. 89, once representing the period as 3 months and later estimating the period as 2 months. The reasonableness of the projection depends on the duration of the period and given the conflicting information, the Analyst cannot determine if the projection is reasonable.

Based on the factors discussed above, AUNC should be found non-confirming with Criterion (5).

Impact on Other Review Criteria

Based on the previously described facts which render the AUNC application non-conforming to Criteria (3), (3a), and (5), the application is also **non-conforming to Criteria (1), (6), (18a), and 10A NCAC 14C .3703**.

Conclusion

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

The WR Imaging application is fully conforming to all statutory and regulatory review criteria. Furthermore, WR Imaging is comparatively superior to the competing proposals. Thus, the application submitted by WR Imaging is the most effective alternative and should be approved as submitted.