Durham Diagnostic Imaging, LLC's Comments in Opposition to Certificate of Need Applications for Two Fixed PET/CT Scanners in HSA IV March 1, 2025 Review Cycle

INTRODUCTION

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

Project ID No.	Applicant	Referred to As
J-12593-25	Durham Diagnostic Imaging, LLC & Novant Health, Inc. & Novant Health Norfolk, LLC / Durham Diagnostic Imaging Independence Park	DDI
J-12595-25	University of North Carolina Hospitals at Chapel Hill / University of North Carolina Medical Center	UNCMC
J-12598-25	Associated Urologists of North Carolina, P.A. & Associated Urologists of NC Properties I, LLC / Raleigh PET Imaging	Raleigh PET Imaging
J-12602-25	Wake Radiology Diagnostic Imaging, Inc & WR Imaging, LLC / Wake Radiology UNC REX Healthcare-Garner	Wake Radiology UNC REX
J-12607-25	Duke University Health System, Inc. / Duke Cary Hospital	Duke Cary Hospital
J-12610-25	Duke University Health System, Inc. / Duke University Hospital	Duke University Hospital
J-12611-25	Raleigh PET, LLC / WakeMed Raleigh Medical Park	WakeMed Raleigh

Nearly 95% of the 37 existing fixed PET scanners in North Carolina are operated by hospitals. In HSA IV, all nine fixed PET scanners are hospital-owned. However, the overwhelming majority of PET scans are performed on outpatients. Historically, PET imaging was provided solely by hospitals due to the complexities of the equipment and radiopharmaceuticals necessary for the procedures. Today, advances in technology and radiopharmaceuticals have set the stage for the next phase of PET imaging. This imaging service can be implemented in convenient and affordable outpatient facilities, like DDI, which has a proven record of excellence in imaging services. Outpatient settings benefit patients by reducing the stress that can be experienced with hospital visits and limiting exposure for patients, especially for those cancer patients who have compromised immune systems. The transition to outpatient settings is the future of PET imaging in North Carolina and will promote patient access, affordability and improve patient experience.

In HSA IV, the influx of new residents, aging of the population and the availability of an extensive range of healthcare providers and services create high demand for the proposed services. With nearly 2.35 million residents and growing, HSA IV residents require immediate access to fixed PET services.

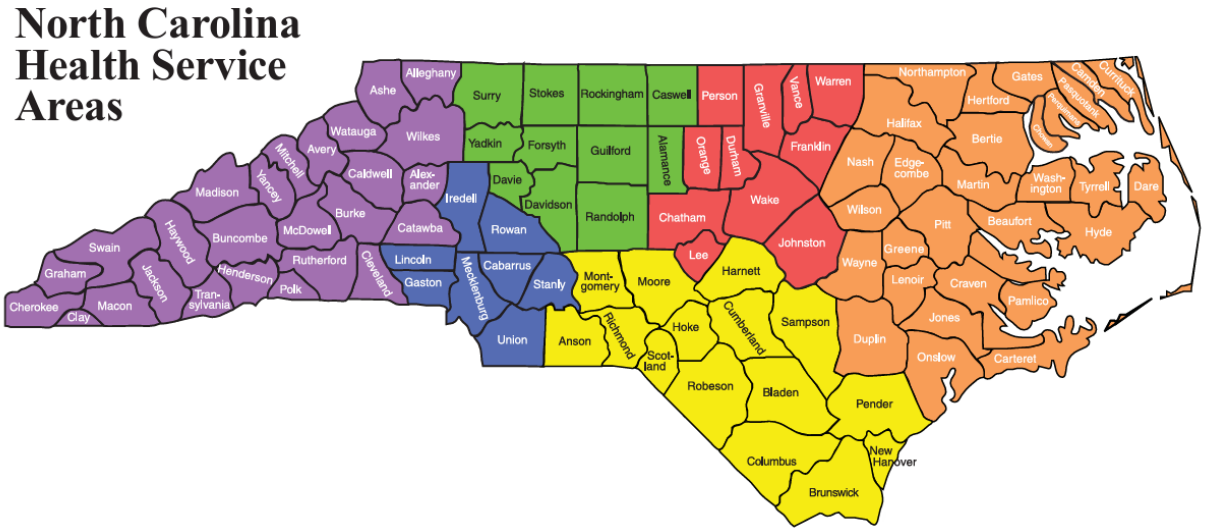
Unfortunately, the last two approved fixed PET scanners in HSA IV have not been developed as set forth in their respective CON applications. On May 1, 2019, UNC Rex Healthcare was awarded a second fixed PET scanner (Project ID No. J-11659-19) that remains undeveloped (Wake Radiology and UNC REX have submitted an application in this review for yet another fixed PET scanner). On November 23, 2021, Duke University Hospital was awarded a CON for a third fixed PET scanner (Project ID No. J-12803-21) that was to be operational by September 1, 2022. Duke requested approval to utilize a clinical research fixed PET scanner in the place of the third fixed scanner. In the March 1, 2025 review, Duke is requesting that the clinical research fixed PET scanner be converted to the third fixed PET scanner status permanently (Cost Overrun CON application Project ID No. J-12609-25). Duke University Hospital has also submitted another CON application to acquire a fourth fixed PET scanner at its campus in Durham.

These ongoing delays in the development of fixed PET services in HSA IV have had a negative impact on accessibility for service area patients and have created a strain on existing resources in the area. These issues underscore the need for a new provider of fixed PET services in HSA IV.

Pursuant to N.C. Gen. Stat. § 131E-185(a)(1), Durham Diagnostic Imaging ("DDI") submits the following comments pertaining to the applications filed by the other applicants to acquire a fixed PET/CT scanner in HSA IV as identified in the 2025 SMFP. DDI provides a comparative analysis of the applications followed by comments on individual applications.

Geographic Accessibility

Health Service Area IV, centrally located in North Carolina and home to the Research Triangle Park, is a destination for people in need of advanced medical care. Durham, Orange and Wake Counties are the current locations for the existing nine PET scanners in HSA IV.



The applicants propose locations in the following counties, Wake, Durham and Orange, all of which have existing fixed PET scanners.

Applicant	County
DDI	Durham
UNCMC	Orange
Raleigh PET Imaging	Wake
Wake Radiology UNC REX	Wake
Duke Cary Hospital	Wake
Duke University Hospital	Durham
WakeMed	Wake

Nine existing PET/CT scanners service the imaging needs of HSA IV residents. These nine existing PET/CT scanners are collectively owned by three entities, Duke Health, UNC Healthcare and WakeMed.

County	Total Number of Fixed PET Scanners	Total Fixed PET volume	Avg Volume/Fixed PET
Wake	4	8,434 procedures	2,109 procedures
Durham	3	7,442 procedures	2,481 procedures
Orange	2	5,375 procedures	2,689 procedures

Source: 2025 SMFP

Wake County

Wake County has the highest total fixed PET volume but also has the highest number of fixed PET scanners with four existing scanners located at Duke Raleigh Hospital, UNC Rex Healthcare and WakeMed. There are 3 different providers of fixed PET services in Wake County, which indicates diversity in the area of competition.

As discussed in the Wake Radiology UNC REX application, UNC Rex Healthcare was previously approved for a fixed PET/CT scanner in 2019, which remains undeveloped at this time. In 2023, Wake Radiology and UNC REX submitted a second CON application to relocate the approved but not operational scanner to a new site. Now, in this 2025 CON application, Wake Radiology UNC REX is seeking an additional fixed PET scanner indicating they will relinquish the 2023 CON approval and develop the 2019 Fixed PET as described in the original application. The proposed development schedule in the 2023 CON application indicated that project would have been operational by October 1, 2024. Wake Radiology previously operated a fixed PET scanner until 2020 when its partner, WakeMed, assumed control over that fixed PET scanner. Given these issues and the substantial delay in developing the 2019 fixed PET scanner in Wake County, it seems unreasonable to approve Wake Radiology UNC REX for yet another fixed PET scanner.

Durham County

Durham County has the second highest volume of PET procedures with three existing PET/CT scanners exclusively owned and operated by Duke Health. In this review, Duke University Hospital is proposing to acquire its fourth fixed PET scanner in Durham. In this March 1, 2025 review period, Duke simultaneously filed a cost overrun application for the development of its third approved, but not yet operational, fixed PET scanner. Duke University Hospital was originally approved for its third fixed PET scanner in 2021. Duke requested permission from the CON Section to utilize its clinical research PET scanner during development. As an alternative to the proposed project, Duke could replace its older PET scanners which may increase capacity.

DDI's project would be Durham County's only outpatient-based service option. This offers patients and payors choice, convenience and affordability. DDI is an established diagnostic center with a physician referral base of over 1,400 providers in the area. DDI has proposed an efficient design plan utilization a mobile cassette system, which improves the speed in which this project can be developed. The mobile cassette system is a fully built modular containment system for the PET scanner that has all necessary clinical spaces, including uptake rooms for patients. This fully built system will increase development efficiencies and bring this service online quickly for patients.

Orange County

UNC Healthcare operates two fixed PET scanners in Orange County. UNC Hospital is the only provider of fixed PET services in Orange County.

It is important to consider in this review that fixed PET scanners that are approved but not developed in a timely manner are not accessible for patients. In this service area, the Agency should consider the introduction of a new provider of fixed PET services to be an opportunity to enhance geographic accessibility for service area residents in need of this important imaging service.

In terms of geographic accessibility, the DDI application should be found a more effective alternative.

Access by Medicare Patients

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

Applicant	% Medicare Patients for PET Service – PY 3
DDI	42.92%
UNCMC	55.0%
Raleigh PET Imaging	29.4%
Wake Radiology UNC REX	63.0%

Duke Cary Hospital	58.9%
Duke University Hospital	56.0%
WakeMed	47.86%

Source: CON applications for each applicant, Section L.

Raleigh PET Imaging is the least effective alternative related to the provision of Medicare services.

Notably, Wake Radiology UNC REX fails to provide reasonable assumptions related to the level of service projected for Medicare patients. As shown on page 102 of the Wake Radiology UNC REX application, it currently provides **39.9%** of its existing diagnostic imaging services to Medicare recipients. Wake Radiology UNC REX estimates that its Medicare service will not only be significantly higher than its own historical experience. In fact, Wake Radiology UNC REX's projected Medicare percentage is substantially higher than every hospital, including UNC, in this review, which seems highly questionable. Wake Radiology UNC REX fails to offer any reasonable assumptions related to this astronomical increase in Medicare patients. Without reasonable assumptions to support this dramatic increase in Medicare patients, the Wake Radiology UNC REX application should be found non-conforming with Criteria 3, 5 and 13.

Access by Medicaid Patients

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

Applicant	**% Medicaid Patients for PET Service – PY 3**
DDI	5.5%
UNCMC	8.1%
Raleigh PET Imaging	2.1%
Wake Radiology UNC REX	7.0%
Duke Cary Hospital	3.5%
Duke University Hospital	3.9%
WakeMed	7.4%

Source: CON applications for each applicant, Section L

Raleigh PET Imaging is the least effective alternative for the provision of Medicaid services.

Competition

Competition in the healthcare marketplace is a key factor in Certificate of Need reviews. HSA IV's nine existing fixed PET scanners are owned and operated by UNC, Duke and WakeMed. Fixed PET scanners that were awarded in 2019 and 2021 to UNC Rex and Duke remain undeveloped. However, these providers are seeking approval for additional fixed PET scanners in this service area. Competition among providers is meant to elevate patient experience through reduced prices, improved service and positive outcomes. The approval of existing fixed PET providers in this service area will not enhance competition and could result in further service delays. The most effective way to enhance competition in HSA IV is to introduce a new provider of fixed PET services.

Applicant	**NEW PROVIDER or EXISTING PROVIDER?**
DDI	NEW PROVIDER
UNCMC	EXISTING
Raleigh PET Imaging	NEW PROVIDER
Wake Radiology UNC REX	EXISTING
Duke Cary Hospital	EXISTING
Duke University Hospital	EXISTING
WakeMed	EXISTING

DDI represents the most effective alternative as a new provider of fixed PET services in HSA IV. As an established diagnostic imaging provider, DDI has a substantial physician referral base that extends to a wide range of specialties. In contrast, Raleigh PET Imaging is a new provider but as a urology practice offers a limited scope of services. DDI's parent company, Novant Health, is an experienced fixed and mobile PET services provider that can guide DDI in the development of the proposed service. As shown in DDI's financial pro formas, DDI proposes effective average net revenue per scan and average operating expenses per scan that are reasonable and offer tangible benefits for service area residents. Furthermore, DDI will offer a global billing system that further reduces patient expenses. A global bill system provides the patient with one bill for both technical (actual procedure) and the professional component (radiologist's reading fees). DDI is committed to developing the project as quickly as possible to meet the high demand for PET services in HSA IV.

Projected Average Net Revenue/Scan

The projected average net revenue per scan is a comparative factor typically used by the Agency. In this review, four of the seven applicants will "globally" bill for each PET procedure. A global billing system is a cost-effective measure that reduces the out-of-pocket expenses for patients. This means that patients utilizing facilities with a global bill system will receive only one bill for the PET procedure, which includes both the technical component (the actual scan) and the professional component for radiologist's interpretation of the scan. The hospitals will only bill the patient for the technical procedure and patients will receive a second bill for professional reading fees. For patients, receiving multiple bills for the same service is not only confusing and inconvenient, but may also increases costs

to the patients. There is no guarantee that separately billed radiologist fees will be the same or lower than the global bill system. This means that patients could potentially pay more out of pocket expenses when utilizing facilities that do not include the radiologists reading fees.

The following chart summarizes the applicants proposing a global billing system:

Applicant	GLOBAL BILLING
DDI	YES
UNCMC	NO
Raleigh PET Imaging	YES
Wake Radiology UNC REX	YES
Duke Cary Hospital	NO
Duke University Hospital	NO
WakeMed	YES

Source: CON applications for each applicant, Section F, Qs.4.c.

The Agency should consider global billing as a comparative factor and find applicants, such as DDI who offer global billing, to be more effective alternatives than applicants that do not offer global billing.

The following chart compares the average net revenue per scan for each applicant in Project Year 3. This information demonstrates that DDI can globally bill for the proposed service, offering a fully inclusive charge for the patient, and remain financially competitive.

Applicant	Project Year 3 - Net Revenue	Project Year 3 - # of PET Procedures	Project Year 3 Projected Average Net Revenue Per PET Procedure
DDI	$6,583,298	2,875	$2,289
UNCMC	$18,828,320	5,890	$3,196
Raleigh PET Imaging	$16,671,122	2,646	$6,300
Wake Radiology UNC REX	$4,034,179	2,761	$1,461
Duke Cary Hospital	$8,635,601	2,150	$4,016
Duke University Hospital	$33,642,562	9,519	$3,534
WakeMed	$10,864,390	2,222	$4,889

Source: Financial Pro Formas for each applicant.

As an applicant fully conforming with all statutory review criteria, DDI is the most effective alternative regarding net revenue per scan in this review.

Projected Average Operating Expense/Scan

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

Applicant	Project Year 3 – Operating Expenses	Project Year 3 - # of PET Procedures	Project Year 3 Projected Average Operating Expense Per PET Procedure
DDI	$4,199,934	2,875	$1,460
UNCMC	$14,014,596	5,890	$2,379
Raleigh PET Imaging	$14,767,800	2,646	$5,581
Wake Radiology UNC REX	$2,545,335	2,761	$922
Duke Cary Hospital	$5,720,308	2,150	$2,660
Duke University Hospital	$27,416,693	9,519	$2,880
WakeMed	$8,430,460	2,222	$3,794

Source: Financial Pro Formas for each applicant.

As an applicant fully conforming with all statutory review criteria, DDI is the most effective alternative regarding net revenue per scan in this review.

Wake Radiology UNC REX has failed to demonstrate that its proposed operating expenses account for all necessary expenses and should be found non-conforming with Criterion 5. There are numerous issues that raises questions about the validity of the financial pro formas for this project:

1. In Year 1, Wake Radiology allocates only one PET Technologist as staff for the proposed project, which is insufficient to provide appropriate coverage.
2. Wake Radiology UNC REX indicates that other staff "are included in central office overhead". The pro formas specifically request that all staff necessary for the provision of the service be identified in Form H of the pro formas. Without fully identifying the staff required for the proposed project, the application should be found non-conforming with Criteria 5 and 7.
3. The allocation of rent for space occupied by the fixed PET scanner at $30 per square foot seems unusually low.
4. The applicant's construction estimate does not include the cost of shielding which would be necessary based on the line drawing submitted with the application.

Conclusion

Durham Diagnostic Imaging's application meets all applicable review criteria and standards for the proposed fixed PET services. Based on the comparative analysis, DDI's application is the most effective alternative for the development of one of the two fixed PET scanners based on the following factors:

- DDI is the most effective alternative regarding geographic accessibility. Many of the applicants agree that a fixed PET scanner in an outpatient facility is needed in HSA IV. DDI will develop the proposed scanner quickly and at a lower capital cost, which in turn improves access in more timely fashion.

- DDI is an effective alternative for lowering prices for the patients by utilizing a global billing system for PET scans.

- DDI is the most effective alternative regarding average net revenue per procedure.

- DDI is the most effective alternative regarding average operating expense per procedure. DDI's operating expenses include the professional component which is extremely beneficial for patients. This means patients will not receive a separate bill from a radiology practice for the reading fee.

- DDI is the most effective alternative regarding the provision of service to the medically underserved populations, including Medicare and Medicaid patients. DDI utilizes its historical operating experience as an existing diagnostic imaging facility to accurately project service for each of these patient categories.

- DDI would enhance competition by introducing a new provider of fixed PET services in HSA IV and would offer these services as the first outpatient facility in Durham County. The approval of DDI's application will have a positive impact on competition.

The outcome of this PET scanner review is critical for Health Service Area IV. After years of approved fixed PET scanners being undeveloped, HSA IV is in desperate need of additional resources and new providers that will enhance competition in the service area. DDI has more than two decades of service to the community as a diagnostic imaging facility with a physician referral base of more than 1,400 providers representing a wide range of specialties. The approval of the DDI application will benefit the proposed service area by allowing a provider, with a proven track record of high-quality service and outreach to the medically underserved populations, the ability to offer additional fixed PET services for the community at reasonable costs and charges. The approval of DDI's application will provide the greatest good for the greatest number of service area residents and their referring physicians.

Individual Comments Regarding Applications

Wake Radiology UNC REX

The Wake Radiology UNC REX application is non-conforming with several review criteria and should be denied.

Criterion 3

Wake Radiology UNC REX fails to provide reasonable assumptions regarding its projected fixed PET market share for Chatham, Franklin, Granville, Person, Vance, Wake and Warren Counties. Wake Radiology UNC REX's existing diagnostic center serves a small service area as indicated by their historical patient origin:

Diagnostic Imaging Services	Wake Radiology UNC REX Healthcare – Garner *	
	Last Full FY 01/01/2024 to 12/31/2024	
County	Number of Patients	% of Total
Wake	14,189	55.7%
Johnston	7,929	31.1%
Harnett	1,323	5.2%
Sampson	738	2.9%
Wayne	282	1.1%
Other	1,021	4.0%
Total	25,482	100.0%

^Other includes <1 percent patient origin from the remaining counties in North Carolina and other states.

* This should match the name provided in Section A, Question 4.

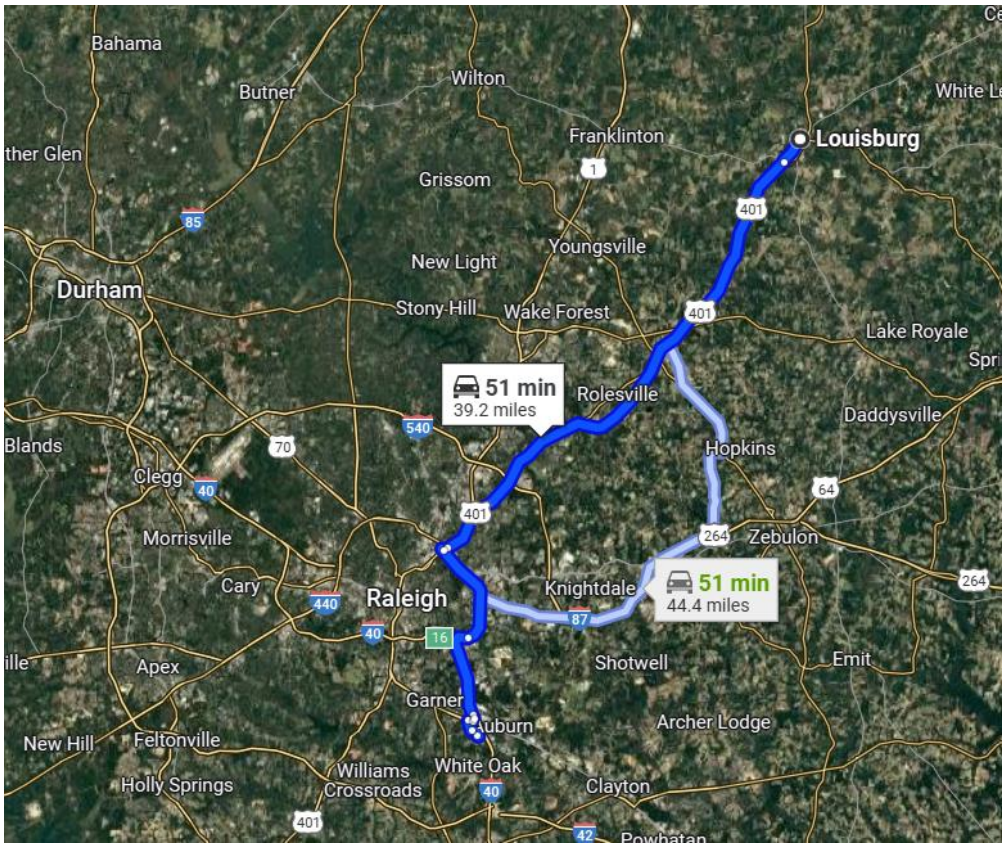
On page 122 of the application, Wake Radiology UNC REX provides market share percentages for distant counties that are unsupported by reasonable assumptions or historical operating experience as an existing diagnostic center. Wake Radiology UNC REX projects that these market shares will increase significantly each year. For example, Wake Radiology UNC REX projects substantial market share from Johnston County but does not address the mobile PET service available at UNC Health Johnston.

Fixed PET Market Share

County	2027	2028	2029
Chatham	2.5%	5.0%	5.0%
Durham	2.0%	2.0%	2.0%
Franklin	5.0%	10.0%	15.0%
Granville	2.5%	5.0%	5.0%
Johnston	5.0%	10.0%	15.0%
Lee	2.5%	5.0%	5.0%
Orange	2.0%	2.0%	2.0%
Person	2.5%	5.0%	5.0%
Vance	2.5%	5.0%	5.0%
Wake	5.0%	10.0%	15.0%
Warren	2.5%	5.0%	5.0%

Wake Radiology UNC REX's existing diagnostic center does not provide more than 1% service to residents from Chatham, Durham, Franklin, Granville, Lee, Orange, Person, Vance or Warren Counties. These counties will total more than 22.5% of the projected patient origin for the proposed project in Project Year 1.

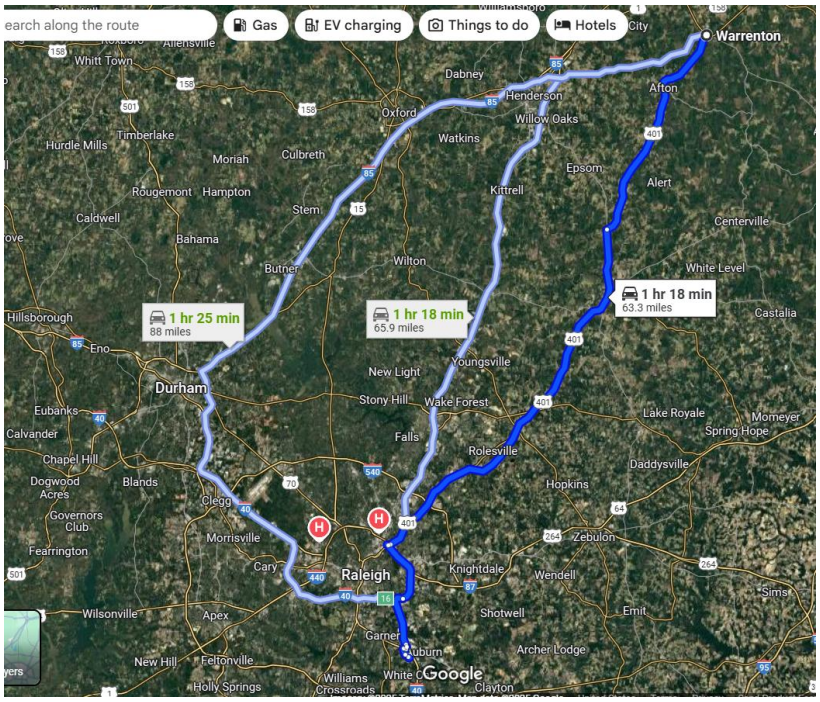
Wake Radiology UNC REX fails to consider the geography of the service area and typical travel patterns in its market share percentage assumptions. For example, the applicant states "Although Franklin County is north of Wake County, residents of Louisburg can likely reach the proposed outpatient PET site in Garner as quickly if not more quickly than the existing hospital-based PET sites in Raleigh, Durham, or Chapel Hill". This statement is unsupported. The distance from Louisburg to the applicant's facility in Garner is nearly an hour's drive. Two existing providers of fixed PET services, UNC REX Healthcare at Lake Boone Trail and Duke Raleigh Hospital would both be closer for residents of Franklin County. The trip from Louisburg to Garner in light direction would take nearly an hour one way.



Source: Google Maps. Directions from Louisburg to 300 Health Park Drive, Garner, NC (the applicant's identified address for the proposed project)

Wake Radiology UNC REX estimates that by Project Year 3 it will secure 5% market share of Warren, Vance and Granville Counties. Patients from Warren and Vance Counties would have to pass nearly every hospital offering fixed PET services in HSA IV to reach Wake Radiology UNC REX's site in Garner. For patients from Warren County, the one way trip to Wake Radiology UNC REX in Garner would be more than an hour and take these patients past nearly every fixed PET scanner in HSA IV. The applicant fails to explain why this would be a reasonable assumption for its project.

Distance from Warrenton, NC to Wake Radiology UNC REX Garner's facility:



Patients from Granville County would also bypass the majority of fixed PET scanners in HSA IV to reach Wake Radiology UNC REX's facility. As the following map shows, it would also take Granville County residents more than an hour one-way to reach the proposed facility while passing UNC, Duke, WakeMed and UNC Rex Healthcare in Raleigh.

Distance from Oxford, NC to Wake Radiology UNC REX Garner's facility:

The projected patient origin for the Wake Radiology UNC REX's project indicates a significant number of patients coming from counties that the facility does not typically see. In all, Wake Radiology UNC REX projects more than 199 patients in Year 1, 330 patients in Year 2, and 403 patients in Year 3 from those nine counties that it rarely serves. Wake Radiology UNC REX fails to provide reasonable assumptions for the proposed patient origin for this project.

b. **Service Component(s)** – Complete the following table for each service component included in this proposal for the facility or campus identified in Section A, Question 4.

Fixed PET Scanner	Wake Radiology UNC REX Healthcare – Garner *					
	1st Full FY		2nd Full FY		3rd Full FY	
	10/01/2026 to 09/30/2027		10/01/2027 to 09/30/2028		10/01/2028 to 09/30/2029	
County	Patients	% of Total	Patients	% of Total	Patients	% of Total
Chatham	19	2.2%	41	2.3%	44	1.6%
Durham	62	7.0%	66	3.7%	70	2.5%
Franklin	39	4.4%	83	4.6%	135	4.9%
Granville	14	1.6%	30	1.7%	32	1.2%
Johnston	119	13.5%	257	14.3%	415	15.0%
Lee	16	1.8%	34	1.9%	36	1.3%
Orange	28	3.1%	29	1.6%	31	1.1%
Person	9	1.0%	19	1.0%	20	0.7%
Vance	9	1.0%	19	1.1%	20	0.7%
Wake	564	64.0%	1,211	67.4%	1,949	70.6%
Warren	4	0.5%	9	0.5%	9	0.3%
Total	**882**	**100.0%**	**1,798**	**100.0%**	**2,761**	**100.0%**

^Other includes <1 percent patient origin from each of the remaining counties in North Carolina and other states.

* This should match the name provided in Section A, Question 4.

Wake County

The substantial increase in market share percentages for Wake County is a key factor in the projections for this project. Wake Radiology UNC REX estimates that the number of Wake County residents utilizing its service will increase by 115% in Year 2, and 61% in Year 3. Wake Radiology UNC REX current percentage of Wake County patients is 55.7% based on the facility's historical patient origin. Wake Radiology UNC REX does not provide any reasonable assumptions related to the increase to 70.6% for Wake County residents.

The facility will not propose any fixed PET service for residents of Harnett, Sampson, or Wayne Counties although these areas currently account for 9.2% of its historical patient population. In this 2025 CON application, Wake Radiology UNC REX proposes to serve exclusively residents of HSA IV. This is considerably different than the patient origin submitted in the noncompetitive 2023 CON application. See below:

b. **Service Component(s)** – Complete the following table for each service component included in this proposal for the facility or campus identified in Section A, Question 4.

PET	Wake Radiology UNC REX PET-CT Imaging Center*					
	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2025 to 12/31/2025		01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027	
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	1,807	67.3%	1,844	67.3%	1,881	67.3%
Johnston	185	6.9%	189	6.9%	193	6.9%
Franklin	105	3.9%	108	3.9%	110	3.9%
Sampson	104	3.9%	106	3.9%	108	3.9%
Harnett	99	3.7%	101	3.7%	103	3.7%
Nash	61	2.3%	63	2.3%	64	2.3%
Wayne	48	1.8%	49	1.8%	50	1.8%
Durham	37	1.4%	38	1.4%	38	1.4%
Other^	237	8.8%	242	8.8%	247	8.8%
Total	**2,684**	**100.0%**	**2,739**	**100.0%**	**2,794**	**100.0%**

* This should match the name provided in Section A, Question 4.

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

^ Other includes Alamance, Beaufort, Bladen, Brunswick, Buncombe, Burke, Cabarrus, Carteret, Catawba, Chatham, Chowan, Columbus, Craven, Cumberland, Currituck, Duplin, Edgecombe, Granville, Greene, Guilford, Halifax, Hertford, Hyde, Jones, Lee, Lenoir, Martin, Mecklenburg, Moore, New Hanover, Northampton, Onslow, Orange, Pamlico, Pender, Person, Pitt, Randolph, Richmond, Robeson, Rockingham, Rowan, Rutherford, Stanly, Vance, Warren, Washington, Wilkes, and Wilson counties in North Carolina as well as other states.

In the 2023 CON application to relocate a previously approved fixed PET scanner (in a non-competitive review), Wake Radiology UNC REX indicated that it would provide fixed PET services to a number of counties outside of HSA IV consistent with its historical operating experience.

In the 2025 CON application, Wake Radiology UNC REX has completely altered the patient origin for the project exclusively for HSA IV counties which is inconsistent with its historical operating experience as an existing diagnostic center. Wake Radiology UNC REX essentially eliminates any non-HSA IV counties from the projected patient origin for the proposed fixed PET scanner in Garner.

In previous reviews, the Agency has utilized a comparative factor of access by service area residents, which may explain the significantly altered patient origin for Wake Radiology UNC REX's proposed project. However, it seems that Wake Radiology UNC REX has failed to adequately explain and support its assumptions related to the population it intends to serve and should be found non-conforming with Criterion 3.

Criterion 5

It is unclear whether Wake Radiology UNC REX has accurately accounted for all necessary operating expenses for the proposed project.

Staffing Expenses

Wake Radiology UNC REX includes only one technologist in Project Year 1, and two technologists in Project Years 2 and 3 as the only identified staff for the project in Form H of the financial pro formas. Wake Radiology UNC REX states in its pro formas assumptions the following:

> Notwithstanding the above, the applicants have accounted for all operational costs associated with operating the proposed PET service in its Pro Forma. In other words, even though an additional staff person is not listed on Form H for check-in assistance, the costs of services which support the PET operation – including the pre-existing check-in services – are included within the project's operational costs, specifically within the line item labeled Central Office Overhead. This line item accounts for various existing services (including check-in services) which will be furnished by the applicants to allow for the operation of the PET service proposed in this application.

Without this staffing information clearly set forth in Form H of the pro formas, there is no way to determine if Wake Radiology UNC REX has accounted for all necessary staff – whether they provide incremental service or full-time service for the operation of the proposed service. This is an important issue when average operating expenses per scan are utilized as a comparative factor in a competitive review.

Central Office Overhead

Wake Radiology UNC REX states that a multitude of operating expenses are lumped into the "Central Office Overhead" category, including any "additional staff person".

> **Central Office Overhead**
> Central Office Overhead is based on the CY 2024 experience of Wake Radiology as a percentage of net revenue and is applied to projected net revenue. Central Office Overhead expense includes but is not limited to accounting, billing, human resources, information technology, WRS management fees, scheduling, and all other costs necessary to provide patient services based on the applicants' experience.

Based on Wake Radiology UNC REX's statements, Central Office Overhead includes the following expense items:

1. Support staff salaries
2. Support staff taxes and benefits
3. Accounting
4. Billing
5. Human Resources
6. Information technology
7. WRS management fees
8. Scheduling
9. "All other costs necessary to provide patient services"
10. Insurance (as stated on Form F.3b)
11. Property and other taxes (as stated on Form F.3b)

As shown in the applicant's Form F.3b Projected Operating costs, the following amounts are allocated for the expense of Central Office Overhead.

Expense Line Item	Project Year 1 10/1/2026-9/30/2027	Project Year 2 10/1/2027-9/30/2028	Project Year 3 10/1/2028-9/30/2029
Central Office Overhead	$121,488	$254,990	$403,418

Form F.3b Projected Operating Costs upon Project Completion

Form F.3b Operating Costs Fixed PET Service	1st Full FY FFY2027 From (10/01/2026) To (09/30/2027)	2nd Full FY FFY2028 From (10/01/2027) To (09/30/2028)	3rd Full FY FFY2029 From (10/01/2028) To (09/30/2029)
Salaries (from Form H Staffing)	$106,549	$219,491	$226,076
Taxes and Benefits	$31,965	$65,847	$67,823
Medical Supplies	$10,587	$22,004	$34,475
Pharmacy (2) (Radiopharmaceuticals)	$202,468	$420,834	$659,335
Rental Expense	$33,900	$34,832	$35,790
Housekeeping/Laundry (2)	$2,556	$2,607	$2,659
Equipment Maintenance		$259,704	$259,704
Utilities	$8,707	$8,881	$9,059
Insurance (incl. in Central Office Overhead)			
Professional Fees	$122,540	$254,701	$399,049
Central Office Overhead	$121,488	$254,990	$403,418
Property and Other Taxes (incl. in Central Office Overhead)			
Depreciation - Buildings	$19,433	$19,433	$19,433
Depreciation - Equipment	$423,915	$423,915	$423,915
Other (Accreditations, Physicist)	$4,600	$4,600	$4,600
Total Expenses	**$1,088,707**	**$1,991,840**	**$2,545,335**

In Year 3 of the 2023 Application (CY 2027), Wake Radiology UNC REX estimated it would perform 2,794 PET scans, which is similar to the 2,761 scans projected for PY 3 in the 2025 Application. The Central Office Overhead is estimated to be $372,809, which does not include unaccounted for administrative staff as they included those positions separately in the 2023 application.

Form F.3b Projected Operating Costs upon Project Completion Wake Radiology UNC REX PET-CT Imaging Center	Partial FY F: 10/01/2024 T: 12/31/2024	1st Full FY F: 01/01/2025 T: 12/31/2025	2nd Full FY F: 01/01/2026 T: 12/31/2026	3rd Full FY F: 01/01/2027 T: 12/31/2027
Salaries (from Form H Staffing)[a]	$62,957	$259,384	$267,165	$275,180
Taxes and Benefits[b]	$24,008	$98,913	$101,880	$104,937
Medical Supplies[c]	$134,543	$559,916	$588,362	$618,253
Other Supplies[c]	$6,892	$28,683	$30,140	$31,672
Housekeeping / Laundry (2) (incl. in Rental Expense)	$0	$0	$0	$0
Equipment Maintenance (2)[d]	$0	$61,943	$253,346	$260,946
Building & Grounds Maintenance (2) (incl. in Rental Expense)	$0	$0	$0	$0
Central Office Overhead[e]	$66,297	$275,903	$289,920	$304,649
Professional Fees[f]	$81,130	$337,631	$354,784	$372,809
Utilities (incl. in Rental Expense)	$0	$0	$0	$0
Insurance (incl. in Central Office Overhead)	$0	$0	$0	$0
Interest Expense[g]	$53,036	$188,160	$148,167	$105,918
Rental Expense[h]	$23,140	$95,338	$98,198	$101,144
Property and Other Taxes (except Income) (incl. in Central Office Overhead)	$0	$0	$0	$0
Depreciation - Buildings[i]	$15,619	$62,474	$62,474	$62,474
Depreciation - Equipment[j]	$95,690	$382,758	$382,758	$382,758
Total Expenses	$563,313	$2,351,104	$2,577,196	$2,620,740

F: = From

T: = To

In the 2023 CON application, Wake Radiology UNC REX projected 2,794 scans would require $372,809 in Central Office Overhead expense, which did not include support staffing (Project Year 3 – CY 2027). In comparison, Wake Radiology UNC REX currently projects that 2,761 scans in Project Year 3 will require a Central Office Overhead expense of only $403,418 in FFY 2029, which includes support staff salaries, taxes and benefits necessary for the operation of the project. Wake Radiology UNC REX appears to have understated its Central Office Overhead expenses, which lowers its average operating expense per scan.

Lower Salaries, Taxes and Benefits

Further comparison indicates that Wake Radiology UNC REX has lowered salaries and taxes and benefits in the 2025 CON application for a fixed PET scanner. In Form H for the 2023 CON Application, Wake Radiology UNC REX indicates that PET Technologists would make $109,768 during CY 2027 (1/1/2027-12/31/2027). The applicant utilized 3.0% annual salary increases based on their experience.

Form H from the 2023 Wake Radiology UNC REX CON application:

Form H Staffing Include employees, contract employees and temporary employees but not independent contractors[a]	Projected Staff								
	1st Full FY			2nd Full FY			3rd Full FY		
	# of FTEs[b]	Average Annual Salary per 1 FTE[c]	Total Salary *	# of FTEs[b]	Average Annual Salary per 1 FTE[c]	Total Salary *	# of FTEs[b]	Average Annual Salary per 1 FTE[c]	Total Salary *
	B	C	D=B*C	E	F	G=E*F	H	I	J=H*I
PET Technologist	2.0	$103,466	$206,933	2.0	$106,570	$213,141	2.0	$109,768	$219,535
Front Desk Reception	1.0	$52,451	$52,451	1.0	$54,024	$54,024	1.0	$55,645	$55,645
Total	**3.0**		**$259,384**	**3.0**		**$267,165**	**3.0**		**$275,180**

* Exclusive of taxes and benefits

State the percentage of total salary projected for taxes and benefits: 38.1%

Applicants may delete rows for position types not applicable to the type of facility identified in response to Section A, Question 4.

Applicants may add rows for position types not listed.

In Form H for the 2025 CON Application, Wake Radiology UNC REX indicates that PET Technologists would make $106,549 during FY 2027 (10/1/2026-9/30/2027).

Form H Staffing

Form H Staffing Include employees, contract employees and temporary employees but not independent contractors	Projected Staff								
	1st Full FY			2nd Full FY			3rd Full FY		
	# of FTEs	Average Annual Salary per 1 FTE**	Total Salary *	# of FTEs	Average Annual Salary per 1 FTE**	Total Salary *	I	Average Annual Salary per 1 FTE**	Total Salary *
	E	F	G=E*F	H	I	J=H*I	K	L	M=K*L
PET Technologist	1.00	$106,549	$106,549	2.00	$109,745	$219,491	2.00	$113,038	$226,076
Total	**1.00**		**$106,549**	**2.00**		**$219,491**	**2.00**		**$226,076**

Not only did salaries shrink from the 2023 Application to the 2025 Application, taxes and benefits were inexplicably reduced from 38.1% (as noted above) to 30% in the 2025 Application. See the 2025 Form F.3b above, there is $226,076 in salaries and $67,823 listed for taxes and benefits ($67,823/$226,076=30.0%).

In an article titled *Radiology Technologists are in High Demand And Short Supply* from the Radiological Society of North America (RSNA) dated October 24, 2024, it states:

> *Health care organizations are using temporary staffing and other strategies aimed at finding and retaining employees*
>
> *A recent survey from the American Society of Radiologic Technologists (ASRT) found a radiology technologist vacancy rate of 18.1%, a dramatic increase from 6.2% only three years ago.*

With an ongoing shortage of imaging technologists, it is not reasonable to reduce salaries and/or taxes and benefits for these positions. Wake Radiology UNC REX appears to have understated its salaries and taxes and benefits expenses, which lowers its average operating expense per scan.

By understating salaries, taxes and benefits and failing to fully identify all necessary staff, Wake Radiology UNC REX has not demonstrated that its proposed project is based on reasonable assumptions and should be found non-conforming with Criterion (5).

Net Revenue Per Procedure

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

Applicant	Project Year 3 - Net Revenue	Project Year 3 - # of PET Procedures	Project Year 3 Projected Average Net Revenue Per PET Procedure
DDI	$6,583,298	2,875	$2,289
UNCMC	$18,828,320	5,890	$3,196
Raleigh PET Imaging	$16,671,122	2,646	$6,300
Wake Radiology UNC REX	$4,034,179	2,761	$1,461
Duke Cary Hospital	$8,635,601	2,150	$4,016
Duke University Hospital	$33,642,562	9,519	$3,534
WakeMed	$10,864,390	2,222	$4,889

The projected net revenue for the Wake Radiology UNC REX project is more consistent with an applicant proposing nearly 100% Medicare service. For example, some of the most common PET CT scans are:

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

This means that Wake Radiology UNC REX is utilizing one of the lowest reimbursement rates for the entirety of its scan volume As discussed below, Wake Radiology UNC REX projected that more than 25% of scans would be performed on insurance patients. Based on its projected scan volume for Project Year 3, this would impact the revenue for over 700 scans.

In the Wake Radiology UNC REX the projected payor source for the proposed service is as follows:

Projected Payor Mix during the 3rd Full FY
10/01/2028 to 09/30/2029

Wake Radiology UNC REX Healthcare – Garner (Diagnostic Center – All Modalities)	
Payor Source	**Percentage of Total Patients Served**
Self-Pay	1.0%
Charity Care^	
Medicare *	41.8%
Medicaid *	5.2%
Insurance *	50.0%
Workers Compensation	0.5%
TRICARE	1.1%
Other (other govt and institutional)	0.4%
Total	100.0%

* Including any managed care plans.
^ WR Imaging internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care. Please see Form F.2 for charity care projections.

Wake Radiology UNC REX Healthcare – Garner (Fixed PET Service)	
Payor Source	**Percentage of Total Patients Served**
Self-Pay	3.5%
Charity Care ^	
Medicare *	63.0%
Medicaid *	7.0%
Insurance *	25.5%
Workers Compensation	
TRICARE	1.0%
Other (**describe**)	
Total	100.0%

* Including any managed care plans.
^ WR Imaging internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care. Please see Form F.2 for charity care projections.

Although Wake Radiology UNC REX projects a substantially higher rate of Medicare service than any hospital in this review as well as its own historical operating experience[1] (which seems questionable), the applicant will provide additional services to non-Medicare patients. For example, Wake Radiology UNC REX assumes that 25.5% of the proposed service will be insurance patients. In reality, commercial insurance reimbursement rates are higher than those of Medicare. This means that Wake Radiology UNC REX may have understated its actual net revenue for the proposed project. As indicated by the applicant's financial pro forma assumptions, contractual adjustments were based on Medicare and Medicaid despite the fact that more than 25% of service would be utilized by commercial insurance patients.

> **Deduction from Gross Patient Revenue**
> Contractual adjustments are the difference between gross and net revenue. Contractual adjustments are based on FY2025 reimbursement rates for Medicare and Medicaid (including inflation) and Wake Radiology's collective experience operating a freestanding fixed PET scanner (Wake PET Services) and other diagnostic imaging services.

If Wake Radiology UNC REX utilized the lower reimbursement rate for all services, this means the total net revenue for the project is understated. If the overall net revenue for the project is understated, it lowers the average net revenue per scan for this applicant (a comparative review factor utilized by the Agency in comparative reviews). As a result, this applicant "appears" to be an effective alternative related to net revenue per scan due to the understated net revenues. Wake Radiology UNC should be found non-conforming with Criterion (5).

[1] On page 102, Wake Radiology UNC REX indicates on page 102 that its current service to Medicare patients is 39.9% for the past year.

Criterion 6

On May 1, 2019, UNC Rex Healthcare received CON approval for a second fixed PET scanner at its facility in Raleigh (Project ID No. J-11659-19). Four years later, Wake Radiology and UNC Rex Healthcare submit a joint CON application to relocate the 2019 fixed PET scanner (Project ID No. J-12402-23). This project was approved by the Agency on September 28, 2023. Wake Radiology and UNC Rex indicated in the 2023 application that the project would finally be operational by October 1, 2024. This has not happened.

Now in this 2025 CON review for a fixed PET scanner, Wake Radiology UNC REX is requesting yet another fixed PET scanner while the 2019 fixed PET remains undeveloped. This proposal is clearly a duplication of existing and approved services. The failure to develop the original 2019 project in a timely manner has strained existing resources and limited access for service area residents to this important diagnostic tool. The award of another fixed PET scanner to these applicants runs the risk of having two undeveloped fixed PET scanners in HSA that desperately needs more fixed PET resources. The Wake Radiology UNC REX application represents a duplication of existing and approved services and should be found non-conforming with Criterion 6.

Criterion 7

The application submitted by Wake Radiology UNC REX should be found non-conforming with Criterion 7, which states *"The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided."*

Wake Radiology UNC REX failed to demonstrate the following related to staffing for the proposed project:

- The applicant proposes only one technologist as staff for the proposed project in Year 1.
- The applicant fails to fully identify all health manpower and management personnel for the provision of the service.
- The applicant fails to show evidence of the availability of resources (operating expenses) for all staffing expenses and taxes and benefits for support and administrative staff.
- The applicant has inexplicably reduced both salaries and taxes and benefits for professional staff, which is currently under a national wide shortage of personnel.

The application submitted by Wake Radiology UNC REX should be found non-conforming with Criteria 3, 5, 6 and 7.

Raleigh PET Imaging (Associated Urologists)

Criterion 3

The applicant failed to adequately demonstrate need for the proposed project. As a basis for the applicant's projections, Raleigh PET Imaging states that Associated Urologists referred 823 PET scans during FY 2024. From that point on, Raleigh PET Imaging utilizes a convoluted system of acceptance rates, ne doctors, bone scan referrals that become PET scans in FY 2025, conversions, etc. to arrive at the projected 2,640 PET scans in Year 3.

Criterion 5

The applicant failed to account for all revenues associated with the proposed project. See the pro forma assumption below, from the Raleigh PET Imaging Application, Section Q.

> **RESPONSE:** 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 for all Medicare patient PET scan interpretive services.

Raleigh PET Imaging indicates that it will provide approximately 29% of its proposed service to Medicare patients.

WakeMed Raleigh

Criterion 5

The applicant failed to account for all expenses associated with the proposed project. See Form F.3b from the WakeMed application, Section Q:

Form F.3b Projected Operating Costs upon Project Completion	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	F: mm/dd/yyyy	F: 10/01/2027	F: 10/01/2028	F: 10/01/2029
Raleigh PET LLC	T: mm/dd/yyyy	T: 09/30/2028	T: 09/30/2029	T: 09/30/2030
Salaries (from Form H Staffing)	$0	$466,015	$479,995	$494,395
Taxes and Benefits	$0	$96,046	$98,927	$101,895
Pharmacy	$0	$3,043,123	$4,001,019	$5,586,926
Dietary	$0	$536	$704	$984
Laundry	$0	$736	$967	$1,350
Supplies- All Other	$0	$9,230	$12,136	$16,946
Equipment Maintenance	$0	$36	$47	$66
Building & Grounds Maintenance	$0	$3,922	$5,157	$7,201
Utilities	$0	$13,928	$14,346	$14,776
Rental Expense	$0	$50,648	$52,167	$53,732
Purchased Services- All Other	$0	$8,811	$11,585	$16,176
Professional Fees	$0	$558,440	$734,223	$1,025,251
Management Fees	$0	$0	$0	$0
Other Expenses	$0	$3,839	$5,047	$7,048
Insurance	$0	$1,946	$2,558	$3,572
Depreciation	$0	$234,501	$469,001	$469,001
Corporate Allocation	$0	$366,550	$466,565	$631,140
Total Expenses	$0	$4,858,304	$6,354,444	$8,430,460

F: = From
T: = To

The applicant identifies the equipment maintenance for the proposed project as $36 in Project Year 1, $47 in Project Year 2, and $66 in Project Year 3. Typically, equipment maintenance is included in Year 1 by the manufacturer then costs anywhere from $200,000 to $400,000 annually. It appears that WakeMed has failed to include the total equipment maintenance expenses in its pro formas and should be found non-conforming with Criterion (5).

Management Expenses

The applicant states on page 23, that it will have a management services agreement with WakeMed for the proposed project.

> Raleigh PET will have a management services arrangement with WakeMed. WakeMed has provided acute care hospital services in Wake County since 1961. Exhibit A.6 provides additional information about the WakeMed System.

As shown in Form F.3b for the applicant above, the amount of annual expense identified for the management fees is $0 each project year. This is unreasonable; the management services cannot be provided for "free". It appears that the applicant failed to include all relevant expenses for the proposed project in its financial pro formas and should be found non-conforming with Criterion (5).