Comparative Analysis Submitted by

Associated Urologists of North Carolina, P.A. Raleigh PET Imaging

Project ID # J-12598-25

In Opposition to

J-12593-25 / Durham Diagnostic Imaging-Independence Park / Acquire a fixed PET scanner pursuant to the 2025 need determination.

J-12610-25 / Duke University Hospital / Acquire a fixed PET scanner pursuant to the 2025 need determination.

J-12595-25 / University of North Carolina Medical Center / Acquire a fixed PET scanner pursuant to the 2025 need determination.

J-12602-25 / Wake Radiology UNC REX Healthcare-Garner / Acquire a fixed PET scanner pursuant to the 2025 need determination.

J-12607-25 / Duke Cary Hospital / Acquire a fixed PET scanner pursuant to the 2025 need determination.

J-12611-25 / WakeMed Raleigh Medical Park / Acquire a fixed PET scanner pursuant to the 2025 need determination.

COMPARATIVE ANALYSIS

Scope of Services

Regarding scope of services, all seven applications were submitted in response to the need determination for two fixed PET scanners in HSA IV in the 2025 State Medical Facilities Plan (SMFP). The application proposing to provide the broadest scope of services with the proposed equipment is usually the more effective alternative regarding this comparative factor.

The following table compares the scope of services proposed to be offered by each applicant on the proposed fixed PET scanner:

Facility	Oncology	Cardiac	Neuro
Raleigh PET Imaging	Х	Х	Х
Duke Cary Hospital	X	X	Х
Duke University Hospital	X	X	Х
Durham Diagnostic Imaging	Х	Х	Х
WakeMed Raleigh Medical Park	Х	Х	Х
UNC Hospitals	Х	Х	Х
Wake Radiology UNC REX-Garner	Х	Х	Х

All applicants propose to provide PET services to oncology, cardiac and neurologic patients and are all equally effective alternatives.

Historical Utilization

The following table illustrates historical utilization of the existing fixed PET scanners in HSA IV as provided in the 2024 and 2025 SMFPs representing FY2022 and FY2023 reported utilization. However, this comparative factor does not consider the limited number of PET scanner need determinations in previous SMFPs. In fact, over the last 15 years only 10 fixed PET scanners have been need determined in the SMFP and all 10 fixed PET scanners were awarded to hospitals. Historical Utilization appears to be a comparative factor used to nullify the benefit of a new provider in the service area:

Facility	PET	2024	2025
Raleigh PET Imaging	0	0	0
Duke Cary Hospital	0	0	0
Duke University Hospital	3	6,623	7,442
Durham Diagnostic Imaging	0	0	0
WakeMed Raleigh Medical Park	0	0	0
UNC Hospitals	2	4,320	5,357
Wake Radiology UNC REX-Garner	0	0	0

Duke University Hospital and UNC Hospitals are current and historical providers of fixed PET services in HSA IV. It should be noted that these hospitals are owners of two other applicants in this review and WakeMed is an owner in Wake PET Services and also an owner in an applicant in this review. Only Raleigh PET Imaging and Durham Diagnostic Imaging are not owned by current providers of PET services in the service area. Historical utilization should not be a comparative factor in this review.

Geographic Accessibility (Location within the Service Area)

The 2025 SMFP identifies the need for two fixed PET scanners in HSA IV, which includes 11 counties. The following table illustrates the location of the existing and approved fixed PET scanners in HSA IV:

Facility	City	County
Duke Raleigh Hospital	Raleigh	Wake
Duke University Hospital	Durham	Durham
REX Hospital	Raleigh	Wake
UNC Hospitals	Chapel Hill	Orange
Wake PET Services	Raleigh	Wake

The following table illustrates the proposed location of the fixed PET scanners under review in HSA IV:

Facility	City	County
Raleigh PET Imaging	Raleigh	Wake
Duke Cary Hospital	Cary	Wake
Duke University Hospital	Durham	Durham
Durham Diagnostic Imaging	Durham	Durham
WakeMed Raleigh Medical Park	Raleigh	Wake
UNC Hospitals	Chapel Hill	Orange
Wake Radiology UNC REX-Garner	Garner	Wake

Source: 2023 SMFP

All seven applicants propose to locate PET scanners in Durham, Orange, and Wake counties, the same counties where the existing 9 PET scanners are located. None of the applicants propose to locate a PET scanner in one of the other 8 counties in HSA IV. As a result, there is no significant difference in the distance to an existing PET scanner each applicant is proposing to locate their proposed fixed PET scanner. Regarding this comparative factor, all the applications are equally effective alternatives.

Access by Service Area Residents

On page 363, the 2025 SMFP defines the service area for fixed PET scanners as follows: "A fixed PET scanner's service area is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs." According to Appendix A, HSA IV is comprised of 11 counties, including Durham, Orange, and Wake counties. Two applicants propose locating a fixed PET scanner in Durham County, 1 applicant propose locating a PET scanner in Orange County, and 4 applicants propose locating a PET scanner in Wake County.

As a result, the service area for each proposal is HSA IV. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number 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 services in or in close proximity to the service area in which they live. 8 applicants proposes to serve counties located within HSA IV and outside of HSA IV.

The following bullet points discuss the patient origin tables on the next page:

- Raleigh PET Imaging proposes treating 2,378 patients from 11 of the 11 HSA IV counties.
- Duke Cary Hospital proposes treating 1,724 patients from 6 of the 11 HSA IV counties.
- Duke University Hospital proposes treating 4,818 patients from 8 of the 11 HSA IV counties. However, since Duke University Hospital already operates 3 PET scanners, it only proposes treating 1,206 patients (4,818 / 4) on the proposed PET scanner.
- Durham Diagnostic Imaging proposes treating 2,675 patients from 11 of the 11 HSA IV counties.
- WakeMed Raleigh Medical Park proposes treating 1,855 patients from 11 of the 11 HSA IV counties.
- UNC Hospitals proposes treating 2,863 patients from 6 of the 11 HSA IV counties. However, since UNC Hospitals already operates 2 PET scanners, it only proposes treating 954 patients (2,863/3) on the proposed PET scanner.
- Wake Rad UNC REX-Garner proposes treating 2,761 patients from 11 of the 11 HSA IV counties. However, REX Healthcare already operates 1 PET scanner, and the applicant makes the unreasonable assumption that 100% of its "referring" physicians do not refer to REX Healthcare. There is no discussion as to how many PET patients can assume to be cannibalized by the proposed PET scanner in Garner.

Each applicant provides the projected number of service area patients to be served in each of the fiscal years following project completion. The following tables compare the projected number of service area patients to be served by each applicant in the third project year following project completion:

County	Raleigh P	ET Imaging	Duke Car	y Hospital	Duke Unive	rsity Hospital
Chatham County	25	0.9%	0	0.0%	87	0.9%
Durham County	83	3.1%	33	1.5%	1,886	19.8%
Franklin County	104	3.9%	73	3.4%	115	1.2%
Granville County	15	0.6%	16	0.7%	369	3.9%
Johnston County	214	8.1%	79	3.7%	0	0.0%
Lee County	95	3.6%	0	0.0%	0	0.0%
Orange County	30	1.1%	0	0.0%	431	4.5%
Person County	11	0.4%	0	0.0%	292	3.1%
Vance County	16	0.6%	18	0.8%	213	2.2%
Wake County	1,774	67.0%	1,505	70.0%	1,425	15.0%
Warren County	11	0.4%	0	0.0%	0	0.0%
Total HSA IV	2,378	89.9%	1,724	80.2%	4,818	50.6%
Other HSAs	268	10.1%	426	19.8%	4,701	49.4%
Total	2,646	100.0%	2,150	100.0%	9,519	100.0%

County	Durham Diagi	nostic Imaging		aleigh Medical ark	UNC H	lospitals
Chatham County	12	0.4%	16	0.7%	367	6.2%
Durham County	1,593	55.4%	65	2.9%	315	5.3%
Franklin County	23	0.8%	68	3.1%	0	0.0%
Granville County	224	7.8%	24	1.1%	0	0.0%
Johnston County	3	0.1%	283	12.7%	161	2.7%
Lee County	3	0.1%	26	1.2%	216	3.7%
Orange County	201	7.0%	14	0.6%	853	14.5%
Person County	469	16.3%	4	0.2%	0	0.0%
Vance County	37	1.3%	14	0.6%	0	0.0%
Wake County	101	3.5%	1,339	60.3%	951	16.1%
Warren County	9	0.3%	2	0.1%	0	0.0%
Total HSA IV	2,675	93.0%	1,855	83.5%	2,863	48.6%
Other HSAs	200	7.0%	367	16.5%	3,027	51.4%
Total	2,875	100.0%	2,222	100.0%	5,890	100.0%

County	Wake Rad UNC REX-Garner			
Chatham County	44	1.6%		
Durham County	70	2.5%		
Franklin County	135	4.9%		
Granville County	32	1.2%		
Johnston County	415	15.0%		
Lee County	36	1.3%		
Orange County	31	1.1%		
Person County	20	0.7%		
Vance County	20	0.7%		
Wake County	1,949	70.6%		
Warren County	9	0.3%		
Total HSA IV	2,761	100.0%		
Other HSAs	0	0.0%		
Total	2,761	100.0%		

Raleigh PET Imaging and Durham Diagnostic Imaging are the most effective alternatives in relation to Access by Service Area Residents.

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 with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is evaluated as a separate factor.

Projected Access by Medicare Recipients

For each applicant in this review, the following table compares the total number of Medicare patients as a percentage of total patients in the third full fiscal year of operations. Generally, the application proposing the highest number of Medicare patients as a percentage of total patients is the more effective alternative with regard to this comparative factor.

Facility	Total	Medicare	%
Raleigh PET Imaging	2,646	778	29.4%
Duke Cary Hospital	2,150	1,266	58.9%
Duke University Hospital	9,519	5,331	56.0%
Durham Diagnostic Imaging	2,875	1,234	42.9%
WakeMed Raleigh Medical Park	2,222	1,058	47.6%
UNC Hospitals	5,890	3,245	55.1%
Wake Radiology UNC REX-Garner	2,761	1,102	39.9%

Facility	HSA IV Total	Medicare	%
Raleigh PET Imaging	2,378	699	29.4%
Duke Cary Hospital	1,724	1,015	58.9%
Duke University Hospital	4,818	2,698	56.0%
Durham Diagnostic Imaging	2,675	1,148	42.9%
WakeMed Raleigh Medical Park	1,855	883	47.6%
UNC Hospitals	2,863	1,578	55.1%
Wake Radiology UNC REX-Garner	2,761	1,102	39.9%

Duke Cary Hospital, Duke University Hospital, and UNC Hospitals have the highest percentage of Medicare patients, but Duke University Hospital, UNC Hospitals, and Durham Diagnostic Center have the highest number of Medicare patients from HSA IV. They also have the three highest percentages of proposed PET patients residing outside of HSA IV. There is no way to actually identify if more Medicare patients are originating from outside of HSA IV.

Additionally, the high number of Medicare patients can also indicate that the facilities are not treating patients earlier in their disease progression. A facility like Raleigh PET Imaging that is aligned with Associated Urologists of North Carolina physicians treat many more patients earlier in their disease progression prior to their 65 birthdays, when they become eligible for Medicare.

The Agency will need to determine if patients under 65 years old and not on Medicare are less worthy of recognition, if their illness/disease, etc. is being treated prior to reaching Medicare age.

Projected Access by Medicaid Recipients

For each applicant in this review, the following table compares the total number of Medicaid patients as a percentage of total patients in the third full fiscal year of operations. Generally, the application proposing the highest number of Medicaid patients as a percentage of total patients is the more effective alternative with regard to this comparative factor.

Facility	Total	Medicaid	%
Raleigh PET Imaging	2,646	56	2.1%
Duke Cary Hospital	2,150	75	3.5%
Duke University Hospital	9,519	371	3.9%
Durham Diagnostic Imaging	2,875	158	5.5%
WakeMed Raleigh Medical Park	2,222	164	7.4%
UNC Hospitals	5,890	477	8.1%
Wake Radiology UNC REX-Garner	2,761	141	5.1%

Facility	HSA IV Total	Medicaid	%
Raleigh PET Imaging	2,646	50	2.1%
Duke Cary Hospital	2,150	60	3.5%
Duke University Hospital	9,519	188	3.9%
Durham Diagnostic Imaging	2,875	147	5.5%
WakeMed Raleigh Medical Park	2,222	137	7.4%
UNC Hospitals	5,890	232	8.1%
Wake Radiology UNC REX-Garner	2,761	141	5.1%

UNC Hospitals and WakeMed Raleigh Medical Park have the highest percentage of Medicaid patients, but UNC Hospitals and Duke University Hospital have the highest number of Medicaid patients from HSA IV. They also have the three highest percentages of proposed PET patients residing outside of HSA IV. There is no way to actually identify if more Medicaid patients originating from outside of HSA IV. This comparative factor is inconclusive.

<u>Competition (Access to a New or Alternate Provider)</u>

The application proposing to increase competition in the service area is the more effective alternative regarding this comparative factor. The introduction of a new provider in the service area would be the more effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. Although 5 of the 7 applicants do not currently provide PET services in HSA IV, 3 of the 5 applicants are owned by a related entity that does provide PET services in HSA IV. Only Raleigh PET Imaging and Durham Diagnostic Imaging are truly new providers of fixed PET imaging services in HSA IV.

Facility	Applicant	Owner
Raleigh PET Imaging	Yes	Yes
Duke Cary Hospital	Yes	No
Duke University Hospital	No	No
Durham Diagnostic Imaging	Yes	Yes
WakeMed Raleigh Medical Park	Yes	No
UNC Hospitals	No	No
Wake Radiology UNC REX-Garner	Yes	No

Regarding this comparative factor, the applications submitted by Raleigh PET Imaging and Durham Diagnostic Imaging are more effective alternatives.

Projected Average Net Revenue per PET Scan

The following table compares projected average net revenue per PET scan in the third full fiscal year following project completion for each project, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, the application proposing the lowest average net revenue per PET scan is the more effective alternative regarding this comparative factor, assuming the average net revenue per procedure could ultimately result in a lower cost to the patient or third-party payor.

Facility	Total	Net Rev	NR/Scan
Raleigh PET Imaging *	2,646	\$4,257,614	\$1,609
Raleigh PET Imaging	2,646	\$16,671,122	\$6,300
Duke Cary Hospital	2,150	\$8,635,601	\$4,017
Duke University Hospital	9,519	\$33,642,562	\$3,534
Durham Diagnostic Imaging	2,875	\$6,583,298	\$2,290
WakeMed Raleigh Medical Park	2,222	\$10,864,390	\$4,889
UNC Hospitals	5,890	\$18,828,320	\$3,197
Wake Radiology UNC REX-Garner	2,761	\$4,034,179	\$1,461

^{*} Excluding reimbursement for the radiotracer.

It should be noted that the currently utilized PSMA radiotracer and the soon-to-be FDA approved renal radiotracer respectively have and will have a separate A- CPT Code for reimbursement of the radiotracer. This is different from other PET scans including cardiac and neurologic. This A-CPT Code reimbursement is essentially a "passthrough" from the Payor to the radiotracer manufacturer. Raleigh PET Imaging will not generate any net income from the reimbursement for the PSMA / Renal radiotracer. As a result, including this expense in any revenue per PET scan comparison would NOT be comparing apples to apples.

If taken into consideration that the reimbursement of the PSMA radiotracer and the soon-to-be FDA approved renal radiotracer are out of the control of Raleigh PET Imaging, then Raleigh PET Imaging and Wake Radiology UNC REX-Garner are more effective alternatives with regard to this comparative factor. If the fact the reimbursement of the PSMA radiotracer and the soon-to-be FDA approved renal radiotracer is not taken into consideration, then this comparative factor is inconclusive.

<u>Projected Average Operating Expense per PET Scan</u>

The following table compares projected average operating expense per PET scan in the third full fiscal year following project completion, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, the application proposing the lowest average operating expense per PET scan is the more effective alternative regarding this comparative factor, assuming the average net revenue per scan could ultimately result in a lower cost to the patient or third-party payor.

Facility	Total	Ор Ехр	OE/Scan
Raleigh PET Imaging*	2,646	\$2,354,293	\$890
Raleigh PET Imaging	2,646	\$14,767,800	\$5,581
Duke Cary Hospital	2,150	\$5,720,308	\$2,661
Duke University Hospital	9,519	\$27,416,693	\$2,880
Durham Diagnostic Imaging	2,875	\$4,199,934	\$1,461
WakeMed Raleigh Medical Park	2,222	\$8,430,460	\$3,794
UNC Hospitals	5,890	\$14,014,596	\$2,379
Wake Radiology UNC REX-Garner	2,761	\$2,545,335	\$922

^{*} Excluding cost of the radiotracer.

If taken into consideration that the cost of the PSMA radiotracer and the soon-to-be FDA approved renal radiotracer are out of the control of Raleigh PET Imaging, then Raleigh PET Imaging and Wake Radiology UNC REX-Garner are more effective alternatives with regard to this comparative factor. If the fact the cost of the PSMA radiotracer and the soon-to-be FDA approved renal radiotracer is not taken into consideration, then this comparative factor is inconclusive.

SUMMARY

The following table lists the comparative factors and indicates whether each application was more effective, less effective, equally effective or inconclusive for each factor.

	Raleigh PET Imaging	Duke Cary Hospital	Duke University Hospital	Durham Diagnostic Imaging	Raleigh PET Imaging	UNC Hospitals	Wake Radiology UNC REX- Garner
Scope of Services	Equally	Equally	Equally	Equally	Equally	Equally	Equally
Historical Utilization	Inappropriate Comparative Factor						
Geographic Accessibility	Equally	Equally	Equally	Equally	Equally	Equally	Equally
Access by Service Area Residents	More	Less	Less	More	Less	Less	Less
Access by Medicare Recipients	Inconclusive						
Access by Medicaid Recipients	Inconclusive						
Competition (Access to a New Provider)	More	Less	Less	More	Less	Less	Less
Projected Average Net Revenue per PET Scan	More	Less	Less	More	Less	Less	Less
Projected Average Operating Expense per PET Scan	More	Less	Less	More	Less	Less	Less

As shown in the table above, Raleigh PET Imaging believes the applications submitted by Raleigh PET Imaging and Durham Diagnostic Imaging are the more effective alternatives regarding the following factors and should be approved:

- Access by Service Area Recipients
- Competition (Access to a New Provider)
- Projected Average Net Revenue per PET Scan
- Projected Average Operating Expense per PET Scan

If the reimbursement and costs of the radiotracers are not taken into consideration, then the two comparative factors; Projected Average Net Revenue per PET Scan and Projected Average Operating Expense per PET Scan would be **Inconclusive**.

	Raleigh PET Imaging	Duke Cary Hospital	Duke University Hospital	Durham Diagnostic Imaging	Raleigh PET Imaging	UNC Hospitals	Wake Radiology UNC REX- Garner
Scope of Services	Equally	Equally	Equally	Equally	Equally	Equally	Equally
Historical Utilization	Inappropriate Comparative Factor						
Geographic Accessibility	Equally	Equally	Equally	Equally	Equally	Equally	Equally
Access by Service Area Residents	More	Less	Less	More	Less	Less	Less
Access by Medicare Recipients	Inconclusive						
Access by Medicaid Recipients	Inconclusive						
Competition (Access to a New Provider)	More	Less	Less	More	Less	Less	Less
Projected Average Net Revenue per PET Scan*	Inconclusive						
Projected Average Operating Expense per PET Scan*	Inconclusive						

As a result, Raleigh PET Imaging still believes the applications submitted by Raleigh PET Imaging and Durham Diagnostic Imaging are still the more effective alternatives regarding the following factors and should be approved:

- Access by Service Area Recipients
- Competition (Access to a New Provider)