

Comments on Competing Applications for One Additional Linear Accelerator in Service Area 20

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Competitive Comments on Service Area 20 Linear Accelerator Applications

Submitted by

UNC Health Rex Cancer Care of Wakefield (UNC Health Rex)

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Rex Hospital, Inc.¹ d/b/a UNC Health Rex Hospital (UNC Health Rex) hereby submits the following comments related to competing applications filed to acquire and develop one linear accelerator in Service Area 20, which includes Wake and Franklin counties, based on the need identified in the 2023 State Medical Facilities Plan (SMFP). UNC Health Rex's comments include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards." See N.C. GEN. STAT. § 131E-185(a1)(1)(c).² In order to facilitate the Agency's ease in reviewing these comments, UNC Health Rex has organized its discussion by issue, specifically noting the general Certificate of Need (CON) statutory review criteria and regulations creating the non-conformity relative to each issue, as they relate to competing applications. UNC Health Rex's comments relate to the following applications proposing to acquire and develop a linear accelerator in Service Area 20:

- Duke University Health System, Inc. (DUHS), Project ID # J-012379-23
- WakeMed, Project ID # J-012376-23

UNC Health Rex also applied to acquire and develop a linear accelerator in Service Area 20 (Project ID # J-012371-23). Given that all three applicants propose to meet the need for additional linear accelerator services in Service Area 20, only one can be approved. The comments below include substantial issues that UNC Health Rex believes render the competing applications filed by DUHS and WakeMed nonconforming with applicable statutory and regulatory review criteria.

¹ Please note that Rex Healthcare, Inc. is the parent company of Rex Hospital, Inc. Also note that the University of North Carolina Health Care System (UNC Health) is the sole member and parent of Rex Healthcare, Inc.

² UNC Health Rex is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its application filed on April 17, 2023 (Project ID # J-012371-23).

DUKE UNIVERSITY HEALTH SYSTEM, INC., PROJECT ID # J-012379-23

Issue-Specific Comments

1. DUHS fails to demonstrate the reasonableness of its proposed Garner service area.

In Step 1 of its "Assumptions – Form C" in Section Q, DUHS calculates the compound annual growth rate (CAGR) of both the Garner and Green Level "Catchment Area Populations," defined previously in its methodology, at 1.3 and 2.1 percent, respectively.³ It also provides a calculation of the CAGR for the Wake County population, which it lists as 1.4 percent.

Notably, the growth rate of the Garner service area is *lower* than that of Wake County overall, and 0.8 percent lower than that of the Green Level service area. In other words, the population growth in the proposed service area is not in line with the population growth of Wake County overall, meaning that other areas of the county – such as Green Level, where DUHS has already filed and been approved for a CON for a linear accelerator (Project ID # J-012000-20) – would be better served by a linear accelerator.

Even if one were to attest that the difference between Garner's population growth rate and Wake County's growth rate is marginal, it should be noted that DUHS provides a different population growth rate for Wake County elsewhere in its application, in Section C.4. This compound annual growth rate, taken via data from the North Carolina Office of State Budget and Management (NC OSBM), is 2.0 percent, a rate much more in line with the growth rate of Green Level than that of Garner.⁴ Because of this issue, particularly when considering the others discussed below, DUHS has failed to demonstrate that its proposed project is needed at the location it proposes.

As such, DUHS's application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3).

2. <u>DUHS's projected patient shifts are unreasonable and not adequately supported.</u>

In Step 3 of its "Assumptions – Form C" in Section Q, DUHS explains that it "projects that a significant percentage of procedures from the zip codes closest to the new facilities (Duke Radiation Oncology Garner and Duke Cancer Center Green Level Radiation Oncology) will choose to go to a new facility rather than another DUHS site, based on convenience and access."⁵ It then projects the shift rate, by ZIP code, of procedure volumes to Duke Radiation Oncology Garner, the facility at which the proposed project will be located. DUHS projects between 30 and 50 percent of patients from certain ZIP codes will shift to Duke Radiation Oncology Garner for radiation treatments by project year three (PY3), as shown in the excerpted table below.

³ CON Project ID # J-012379-23, p. 93.

⁴ Ibid, p. 38.

⁵ Ibid, p. 95.

Garner Shift

Patient Zip Code	Catchment	FY 2026 Shift Rate to Garner (Half Year)	FY 2026 Procedure Volumes	FY 2027 Shift Rate to Garner Year 1	FY 2027 Procedure Volumes	FY 2028 Shift Rate to Garner Year 2	FY 2028 Procedure Volumes	FY 2029 Shift Rate to Garner Year 3	FY 2029 Procedure Volumes
27520	Garner	10%	41	20%	82	40%	166	50%	211
27529	Garner	1.0%	73	20%	148	40%	300	50%	380
27545	Garner	5%	32	10%	65	20%	131	30%	199
27592	Garner	5%	11	10%	23	20%	47	30%	71
27601	Garner	5%	10	10%	20	20%	41	30%	62
27604	Garner	8%	46	15%	94	20%	127	35%	225
27605	Garner	5%	5	10%	10	20%	20	30%	30
27608	Garner	10%	13	20%	27	30%	41	45%	63
27610	Garner	8%	74	15%	149	25%	252	40%	408
27539	Garner & GL	5%	34	10%	70	20%	141	30%	214
27603	Garner & GL	8%	61	15%	124	25%	210	40%	340
27606	Garner & GL	5%	26	10%	54	20%	109	30%	165
Total Procedures Shifted to Garner			427		866		1585		2369

Source: DUHS Form C Assumptions and Methodology, p. 96.

To analyze the reasonableness of these projections, UNC Health Rex mapped the location of each of the ZIP codes from which DUHS projects shifts, as well as the locations of two of DUHS's existing linear accelerators in Wake County: Duke Cancer Center Cary Radiation Oncology, and Duke Women's Care Raleigh. UNC Health Rex has also included the 20-minute drive radius from each location – green for Duke Cancer Center Cary Radiation Oncology, red for Duke Women's Care Raleigh, and purple for the proposed location at Duke Radiation Oncology Garner – as DUHS itself notes that the rate of 50 percent is applied "for the closest zip codes to the new LINAC locations, with lower anticipated shifts for other zip codes."⁶ The overlap of each of these drive time radii are also shaded as designated on the legend of the map below.

⁶ Ibid.



Proposed Garner patients within 20 minutes of existing Raleigh and Cary locations.

- Proposed Garner patients within 20 minutes of existing Cary location.
- Proposed Garner patients within 20 minutes of existing Raleigh location.
- Proposed Duke Radiation Oncology Garner
- Duke Cancer Center Cary Radiation Oncology
- Duke Women's Care Raleigh

Source: Esri.7

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As seen from the map above, Duke Radiation Oncology Garner's proposed linear accelerator 20minute drive time radius overlaps significantly with the 20-minute drive time radii of both linear accelerator locations identified on the map above. The table below identifies which ZIP codes – as pulled from DUHS's projections for Duke Radiation Oncology Garner, above – overlap with the existing DUHS facilities identified above, as well as the percentage of projected patients to be shifted by PY3 that account for the overlapped area.

⁷

Esri is a leading GIS provider that utilizes U.S. Census data projected forward using proprietary methodologies.

ZIP Code	PY3 Shift	Overlap	% within 20- minute drive time
27520	211		
27529	380		
27545	199	Raleigh	8.4%
27592	71		
27601	62	Raleigh and Cary	2.6%
27604	225	Raleigh	9.5%
27605	30	Raleigh and Cary	1.3%
27608	63	Raleigh and Cary	2.6%
27610	408	Raleigh and Cary	17.2%
27539	214	Cary	9.1%
27603	340		
27606	165	Raleigh and Cary	7.0%
Total	2,368		57.7%

ZIP Codes to Shift Patients to Duke Radiation Oncology Garner Overlap Areas and Percent of Total

Source: DUHS Form C Assumptions and Methodology, Esri.

In short, the table above indicates that the majority of patients DUHS projects to serve by PY3 – <u>over 50 percent of patients</u> – are closer to <u>existing</u> DUHS linear accelerators. If the "specific service area for the proposed Garner facility" is "those zip codes within 20 minutes"⁸ of the facility, then it follows that the service area of DUHS's existing facilities are *also* those ZIP codes within 20 minutes of those facilities. If this holds true, and if such a large proportion of DUHS's projected patients fall under an overlapping drive time radius, as evidenced by the map and table above, then the majority of DUHS's projected patient population would <u>not</u> be closer to the proposed facility in Garner, which refutes its assumption that the proposed project is more accessible for its projected patient population.

While DUHS does state that it "anticipates that some patients from the catchment areas for the new facilities may continue to seek services at existing DUHS locations due to proximity to work or other factors," DUHS's estimation of procedure shift for some ZIP codes is overly ambitious and unreasonable, not only in light of existing DUHS facilities, but also in light of UNC Health facilities in the area that currently offer linear accelerator services, many of which are closer to the included ZIP codes than the proposed project. This is particularly unreasonable, given DUHS's assumed market share gains, as discussed below.

DUHS also uses an aggressive and unreasonable market share growth assumption as a basis for attributing volume to the proposed Garner facility. DUHS estimates it will gain an additional 6.5 percent market share in the Garner catchment area, resulting in 109 incremental radiation oncology patients in PY3.⁹ However, DUHS fails to acknowledge the existing UNC Radiation Oncology at Clayton facility in Johnston County. This facility is located in the 27520 ZIP code, part of DUHS's service area, and is only 11 miles from the proposed Duke Radiation Oncology Garner

⁸ CON Project ID # J-012379-23, p. 92.

⁹ Ibid, p. 98.

location.¹⁰ Despite the existence of this linear accelerator within a short distance from the proposed DUHS location, DUHS unreasonably projects to gain market share resulting in 109 additional patients by PY3, which equates to almost 40 percent of the total patient volume for the proposed facility.¹¹ A majority of patients in Duke Radiation Oncology Garner's service area of south Wake County and northern Johnston County already have reasonable access to radiation oncology services, which DUHS itself defines as being within a 20-mile radius of an existing facility. As such, DUHS fails to demonstrate that its projected patient volume is reasonable, or that the proposed project is needed in light of the existing services in the area that it proposes to unnecessarily duplicate.

DUHS also projects the shift rate, by ZIP code, of procedure volumes to Duke Cancer Center Green Level Radiation Oncology, with respect to the linear accelerator approved through Project ID # J-012000-20. DUHS projects that between 15 and 20 percent of patients from certain ZIP codes will shift to Duke Cancer Center Green Level Radiation Oncology for radiation oncology care by project year three (PY3), as shown in the excerpted tables below.

Patient Zip Code	Catchmen t	FY 2026 Shift Rate to GL (Half Year)	FY 2026 Procedure Volumes	FY 2027 Shift Rate to GL Year 1	FY 2027 Procedure Volumes	FY 2028 Shift Rate to GL Year 2	FY 2028 Procedure Volumes	FY 2029 Shift Rate to GL Year 3	FY 2029 Procedure Volumes
	GL &								
27539	Garner	3%	17	5%	35	10%	71	15%	107
27603	GL & Garner	3%	20	5%	41	10%	84	15%	128
27606	GL& Garner	3%	13	5%	27	10%	54	15%	83
27701	GL	3%	19	5%	38	10%	78	15%	118
27703	GL	5%	102	10%	207	15%	315	20%	426
27707	GL	5%	75	10%	152	15%	231	20%	311
27713	GL	5%	109	10%	221	15%	336	20%	454
27709	GL	5%	1	10%	2	15%	3	20%	4

Green Level Shift

¹⁰ Ibid, p. 98.

¹¹ Ibid, p. 100. (109 patients from market share growth / 273 total patients = 39.9%).

Shifted to Green Level			869		1,760		2,836		3,938
Total									
27330	GL	5%	13	10%	27	15%	41	20%	56
27526	GL.	5%	69	10%	139	15%	212	20%	286
27559	GL	5%	2	10%	3	15%	5	20%	7
27540	GL	5%	39	10%	80	15%	121	20%	164
27562	GL	5%	5	10%	9	15%	14	20%	19
27502	GL	5%	37	10%	76	15%	115	20%	155
27518	GL	5%	25	10%	50	15%	76	20%	103
27312	GL	5%	19	10%	39	15%	60	20%	81
27511	GL	5%	38	10%	77	15%	117	20%	158
27607	GL	5%	10	10%	21	15%	32	20%	43
27513	GL	5%	44	10%	89	15%	135	20%	182
27519	GL	5%	71	10%	144	15%	218	20%	295
27523	GL	5%	26	10%	52	15%	79	20%	107
27612	GL	5%	27	10%	54	15%	83	20%	111
27615	GL	3%	18	5%	37	10%	75	15%	114
27617	GL	3%	12	5%	24	10%	50	15%	75
27517	GL	3%	16	5%	33	10%	67	15%	102
27613	GL	3%	22	5%	44	10%	89	15%	135
27560	GL	3%	18	5%	37	10%	75	15%	115

Source: DUHS Form C Assumptions and Methodology, pp. 96-97.

DUHS does not explain or justify the reason for the disparity in procedure shift percentages between Duke Radiation Oncology Garner and Duke Cancer Center Green Level Radiation Oncology. Given DUHS's statements that its projected shifts are based on proximity to the proposed/approved facilities, it is unreasonable to expect that 50 percent of patients from the Garner ZIP code will shift to that facility, when only 20 percent of patients from the Green Level ZIP code (27519) will shift. Given the similarities between the two facilities, including the assumptions regarding 20-minute catchment areas, it is unreasonable and unsupported to assume such significant differences in shift rates for the same relative geographies (i.e., 20-minute drive times).

Finally, in addition to shifts between facilities in Wake County, DUHS also projects that a significant number of patients will shift from its existing facilities outside of Wake County and instead seek service at Duke Radiation Oncology Garner or Duke Cancer Center Green Level Radiation Oncology. While this assumption is not clearly stated in the application, it can be calculated as described in the following analysis. The number of patients remaining at its existing facilities in Wake County following the ZIP code-specific shifts outlined above – Duke Cary, Duke Raleigh Hospital Main Campus, and Duke Women's Cancer Care/Macon Pond, are shown in "Step 7" of "Assumptions – Form C," and replicated below.

Unique Patients	Actual	Projected			Projec	ted, afte. Shift fron	r Garner n Step 3	& GL
	FY22	FY23	FY24	FY25	FY26	FY27	FY28	FY29
				_				_
				1				
Duke Cary	360	364	369	374	375	348	330	311
Duke Cary Duke Raleigh Hospital main	360	364	369	374	375	348	330	311
Duke Cary Duke Raleigh Hospital main campus	360 567	364	369	374 589	375 578	348	330 546	311 522

Source: DUHS Form C Assumptions and Methodology, pp. 100-101.

In order to determine the shifts from facilities outside Wake County, UNC Health Rex first had to determine the number of patients shifted from each of the existing Wake County facilities. However, DUHS does not specifically segment the number of patients to be shifted from each of those three facilities. In order to calculate these shifts, UNC Health Rex projected patient volume at those three locations through FY29 using the same growth rate used in the application to project volume through FY25 – i.e., 1.4 percent – which resulted in the totals below.

Iotals Belore Patient Shirts								
Facility	FY26	FY27	FY28	FY29				
Duke Cary	380	385	390	396				
Duke Raleigh Hospital Main Campus	598	607	615	624				
Women's Cancer Care/Macon Pond	319	323	328	333				

DUHS Facility Unique Patient Projections Totals Before Patient Shifts

Source: DUHS Form C Assumptions and Methodology.

Taking the difference between the table directly above and the table from DUHS's methodology results in the total patients shifted from Duke Cary, Duke Raleigh Hospital Main, and Duke Women's Cancer Care/Macon as seen in the table below, which accounts for the total number of patients shifting from DUHS facilities in Wake County.

DUHS Facility Unique Patient Projections Patient Shifts from Wake County Facilities

Facility	FY26	FY27	FY28	FY29
Duke Cary	5	37	60	85
Duke Raleigh Hospital Main Campus	20	40	69	102
Women's Cancer Care/Macon Pond	11	21	38	56
Total Shifted from Wake County	36	98	168	242

Source: DUHS Form C Assumptions and Methodology.

As these shifts are all from Wake County facilities, an additional 128 shifted patients must come from other DUHS facilities, which, logically, must be DUHS facilities in Durham County that offer radiation therapy services: Duke Regional Hospital and Duke University Hospital.

Facility	FY26	FY27	FY28	FY29
Patients Shifted to Garner from Existing Sites	25	51	93	139
Patients Shifted to Green Level from Existing				
Sites	51	103	166	231
Total Patients Shifted from Existing Sites	76	154	259	370
Total Shifted from Wake County	36	98	168	242
Total Shifted from other DUHS Sites	40	56	91	128
% Shifted from Other Sites	52.6%	36.4%	35.1%	34.6%

DUHS Facility Unique Patient Projections Patient Shifts from Other DUHS Facilities

Source: DUHS Form C Assumptions and Methodology.

While it is certainly possible that some patients *could* shift from facilities in Durham County to southern Wake County for treatment, UNC Health Rex believes that the current allotment of shifts in DUHS projections – 35 percent of the total patients to be shifted – is unreasonably high and unsupported, especially for the proposed Garner facility. In particular, these projections assume that patients who have historically sought care in Durham County would instead seek care in Garner, on the eastern side of Wake County farthest from the border with Durham County, and would otherwise not seek care at any other existing facility in *Wake* County, all of which are shown on the map included above, and all of which are existing facilities that are closer to DUHS's facilities in its application and fails to demonstrate that it is reasonable to assume that its utilization projections rely on shifting more than one-third of its projected patients from Durham County facilities.

As a result of these issues, DUHS's application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and (18a), as well as the performance standards for linear accelerators.

3. <u>DUHS fails to demonstrate that its projected payor mix is based on reasonable assumptions.</u>

In Section L.3.b, when detailing the assumptions used to project its payor sources through year three of its proposed project, DUHS states that "a one-time 2.1% adjustment is applied for project years (and then held constant) to account for an anticipated shift in the population from Managed

Care to Medicare based on current DUHS patient age demographics."¹² However, the DUHS system's historical and interim revenues and net income and financial projections, shown in Forms F.2a and F.2b, respectively, do not reflect this shift; in fact, the payor mix is the same for the DUHS system from 2022 and 2029, and no adjustments have been made. As such, despite the statement that the assumption is based on changes in "DUHS patient age demographics," and would thus apply to all DUHS financial statements, DUHS failed to make the adjustment for the system financials and appears to increase Medicare only for the service component, which is typically the source used in the comparative analysis. Given these inconsistencies, the DUHS projected payor mix is unreasonable, and its projected Medicare percentages are unreliable.

Furthermore, as shown in Form F.2b, DUHS projects that Duke Radiation Oncology Garner will not have positive net income by year three of the proposed project. While the application includes projected income statements for DUHS as a whole, showing that combined net revenue will be positive by PY3, that projection does not account for a shift from managed care to Medicare, which would have a negative overall impact on net income. Given the small net income projected for the DUHS system in PY3, and with this error, DUHS has failed to demonstrate the financial feasibility of the proposal.

Therefore, the DUHS application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), and (13c).

4. <u>The scope of services to be offered at Duke Radiation Oncology Garner does not represent the</u> <u>most cost-effective alternative.</u>

In Section C.4, DUHS notes that the proposed project "will be developed in a medical office building complex that will house an array of medical services, including primary and specialty physician services, ambulatory surgery, and imaging." In Section C.1, DUHS makes a similar note, stating that its "new building in a medical office complex...is planned to be home to primary care, urgent care, pediatrics, specialty clinics, physical and occupational therapy, ambulatory surgery, imaging and laboratory services."¹³ In Section F, DUHS projects a capital cost that corresponds with an entire facility—not just a linear accelerator and simulator and related support space.

However, in Exhibit K.1, in which DUHS provides a diagram of the proposed facility, there is no notation for any of the services that DUHS has detailed above;¹⁴ in other words, it is unclear, from either Exhibit K.1, or in either of the descriptions in Section C.1 or C.4, or in its projected capital costs, that DUHS needs to spend the capital it proposes in its application, when it fails to demonstrate that the proposed facility will actually provide any services other than those of a linear accelerator and simulator. In particular, DUHS does not detail its intent to provide coordinated cancer services at the proposed facility, either in Sections C.1 or C.4, or in its diagrams in Exhibit K.1.

Given this issue, the DUHS application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (4) and (12).

¹² Ibid, p. 80.

¹³ Ibid, p. 30.

¹⁴ Duke Radiation Oncology Garner CON Application Exhibits, p. 3 of PDF.

In summary, based on the issues detailed above, the DUHS application is non-conforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria (3), (5), (6), (12), (13c), and (18a), as well as the performance standards for linear accelerators.

WAKEMED, PROJECT ID # J-012376-23

Issue-Specific Comments

1. <u>WakeMed's assumptions regarding the number of patients requiring oncological care cannot be</u> <u>applied to the proposed project.</u>

In Step 7 of its "Utilization Methodology for Section C" in Form Q, WakeMed estimates the number of new radiation oncology cases per county per year, from fiscal year (FY) 2023 through FY 2028. It projects these cases for Wake, Franklin, Harnett, and Johnston counties, the service area of the proposed project. These estimations are calculated by multiplying forecast new cancer cases by county – calculated in a previous table in WakeMed's methodology – by the value 0.523.

The application uses 0.523, or 52.3 percent, as "[the] percent of cancer patients that need radiation oncology," a figure that WakeMed cites from the article "The Role of Radiotherapy in Cancer Treatment."¹⁵ This article, which contains the figure that WakeMed utilizes as the foundation for the entirety of its utilization projections, was published in 2005 - nearly two decades ago. Additionally, the article's concluding figure of 52.3 percent of cancer patients requiring radiation oncology is given with heavy contingency; the study was conducted with an Australian patient set, and the article's first line is "[r]adiotherapy utilization rates for cancer vary widely internationally;" indeed, the article states that "[our] overall estimate of optimal radiotherapy utilization of 52.3% [is] for all notifiable cancer in Australia." Additionally, the results of the article's study indicate that optimal radiotherapy utilization rates also vary widely depending on the site of cancer (see Table 4); for example, the article postulates an 83 percent optimal radiotherapy utilization rate for breast cancer, but only a 23 percent utilization rate for melanoma. WakeMed simply applies this rate across all cancer sites and fails to adjust for different sites as the article suggests. Further, cancer treatment, including radiation therapy, has evolved considerably over the past two decades, and it is clearly unreasonable to rely on such outdated information.

As such, the WakeMed application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (6), (18a), and the performance standards for linear accelerators.

2. <u>WakeMed's patient projections do not adequately propose to provide service to Service Area 20.</u>

In Step 19 of its "Utilization Methodology for Section C" in Form Q, WakeMed calculates patient origin for its proposed linear accelerator and CT simulator, using the patients retained and not referred to other providers from FY23 through FY28 (Table 15) and multiplying that by its projected patient distribution by county (Table 1).

¹⁵ <u>https://acsjournals.onlinelibrary.wiley.com/doi/10.1002/cncr.21324</u>.

Step 19: Calculate Patient Origin for linear accelerator and simulator.

The applicant calculates patient origin by multiplying the patients in Table 15 by the percent distribution by county in Table 1.

Geography	FY26	FY27	FY28
Wake	189	253	327
Franklin	10	13	17
Harnett	19	26	33
Johnston	11	15	19
All other NC	24	32	41
Out of State	3	3	4
Total Patients	255	342	442

Table 18 Patient Origin Linear Accelerator and Simulator.

Calculation: Multiply Total Patients, Table 15, row d by percent distribution in each county, Table 1

Source: WakeMed Form C Assumptions and Methodology, p. 191.

In doing so, WakeMed projects that only 17 patients from Franklin County will be served by the proposed linear accelerator by PY3, despite Franklin County being one of two counties in Service Area 20. This is in line with WakeMed's projection that only 3.87 percent of its projected patient population will originate from Franklin County, as seen in Table 1.

Geography	% of Total
Wake County	74.00%
Franklin County	3.87%
Harnett County	7.56%
Johnston County	4.25%
All Other NC Counties	9.30%
Out of State	1.00%
Total	100.0%

Table 1: Projected WakeMed Radiation Therapy Patient Origin

Source: WakeMed Form C Assumptions and Methodology, p. 171.

WakeMed's projections for Franklin County are low despite WakeMed itself noting that "Franklin County has no linear accelerator and is easily accessible to WakeMed."¹⁶

While Franklin County is much smaller than Wake County, this distribution of projected patients is disproportionately low, considering that the need determination is for a linear accelerator in Service Area 20 that includes Franklin County, and is not limited to Wake County. Indeed, according to WakeMed's methodology for estimating the number of new cancer patients, Franklin County would have 299 patients requiring radiation oncology services in 2028, the third project year.¹⁷ WakeMed estimates that it will treat 17 Franklin County patients in PY3, or 5.7 percent of the county's need. This does not demonstrate a measurable improvement in access to care for Franklin County residents requiring linear accelerator services.

¹⁶ Project ID # J-12376-23, p. 170.

¹⁷ Ibid, p. 178.

WakeMed is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (6), and (18a).

3. <u>WakeMed does not adequately and consistently identify the proposed site of its linear accelerator.</u>

In Section A.4.a of WakeMed's application, it notes the facility where the proposal will be developed or offered as "23 Sunnybrook Road" in Raleigh.¹⁸ According to its website, that address is the location of an existing building, which contains Capital City Surgery Center, a new diagnostic center, and other outpatient services.¹⁹ In Section A.4.e, WakeMed further notes that "[a] new building will be constructed and owned by the applicant," and that it, as the applicant, currently owns both the land and the facility on which the service will be located.²⁰ Thus, based on the discussion in Section A.4.a, it is unclear where the site of the "new building" will be, given the existing facility there.

Then, in Section C.1 of its application, WakeMed details that the project involves "upfit of the first floor of a medical office building in Raleigh Medical Park."²¹ In Section K, WakeMed identifies that no new construction will take place, and that the project involves only renovation of "existing" space, further diagramed in Exhibit K.1.²² However, in Section K.4.a, WakeMed lists 23 Sunnybrook Road as a "Proposed Site" for the proposed project, consistent with its answer to Section A.4.a but inconsistent with its answer to Section K.2, immediately above.²³ Based on the site plan in Exhibit K.1, it appears that the cancer center will be located in a new building, to be constructed beside the existing building at 23 Sunnybrook Road. While this would be consistent with the description in Section A.4.a regarding the construction of a "new building," it is inconsistent with the description in Sections C.1 and K.1. The construction cost estimate on page 10 of Exhibit K.1 clearly <u>excludes</u> building core and shell costs, which is not consistent with the need to develop a new building.

Finally, in Exhibit K.4, which provides the zoning details for the proposed site, the address listed is 25 Sunnybrook Road – not 23 Sunnybrook Road, as is noted elsewhere in WakeMed's application.²⁴ The deed for 25 Sunnybrook Road also shows another owner—not WakeMed—which is inconsistent with the information regarding the current ownership of WakeMed's proposed site. The exhibit also shows an existing building at that site, and it is unclear whether WakeMed intends to purchase that building and then upfit it for the cancer center, or if it intends to raze the building and build a new one to house the cancer center. In either case, if 25 Sunnybrook Road is the correct site, WakeMed has failed to include the capital costs necessary to develop the proposed project.

Given these inconsistencies, WakeMed has failed to adequately identify the site of the proposed project and whether it will develop a new building or upfit an existing building that it must purchase. If WakeMed intends to develop a new building, then it has failed to include all the necessary capital costs to develop the project. If it intends to renovate an existing building that it

¹⁸ Ibid, p. 17.

¹⁹ https://www.wakemed.org/location/raleigh-medical-park

²⁰ Project ID # J-12376-23, p. 19.

²¹ Ibid, p. 39.

²² Ibid, p. 125.

²³ Ibid, p. 129.

²⁴ Ibid, Exhibits, K.4.

intends to purchase, then it has also failed to identify the cost of acquiring that building or that it is available for purchase. Finally, if the proposed site is not 25 Sunnybrook Road, then the zoning and land ownership information provided in the application is incorrect, and it has failed to provide sufficient information to demonstrate that its proposed construction alternative is in fact the most reasonable alternative.

Therefore, the WakeMed application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (4), (5), and (12).

4. <u>WakeMed fails to demonstrate that its financial projections are based on reasonable assumptions.</u>

Although the proposed project will be located in a dedicated outpatient setting, WakeMed states that its proposed facility will be reimbursed under the "hospital (HOPD) arrangement."²⁵

However, in order to meet the CMS reimbursement requirements as a hospital outpatient department (HOPD), the proposed services must be within 250 yards of the main hospital facility. 23 Sunnybrook Road – one of the purported locations of WakeMed's proposed project – is in fact approximately <u>263 yards</u> away from WakeMed Raleigh Campus, thereby preventing it from meeting the requirements to receive HOPD reimbursement, as shown in the following map. Of note, 25 Sunnybrook Road is *also* more than 250 yards away from the main hospital facility at <u>252 yards</u> of distance, as seen below.

²⁵ Ibid, p. 91.



The location of WakeMed's services affects its qualification for CMS reimbursements as an HOPD. As such, WakeMed should instead receive reimbursement as a freestanding radiation facility, which will impact WakeMed's revenue projections as provided in Form F.3b. There is insufficient information in the WakeMed application for the Agency to evaluate the financial feasibility of the project if it is developed as a freestanding radiation facility.

As such, the WakeMed application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(5).

5. <u>WakeMed fails to demonstrate the proposed project will fulfill an unmet need for radiation</u> <u>oncology services.</u>

In Section E of its application, WakeMed states that it is "the only one of the three systems [in Wake County] that offers a Level 1 Trauma Center, and...has a strong history of serving the medically underserved in the community." Using this as support, it concludes that "the community need is more attracted to WakeMed than any other health system in the county."

However, this is not adequate support to ensure that WakeMed is an attractive provider to the medically underserved in Wake County, either in general as a provider of healthcare services, or for the specific provision of linear accelerator treatment services. The accessibility of Level 1

Trauma Centers has no relation to the ability of the medically underserved to access a provider's services; in fact, this has no bearing on accessibility to the underserved, as outlined in Criterion 13.

Further, there is not evidence that the community need is "more attracted to WakeMed," as WakeMed's historical payor mix is not significantly different than that of either DUHS or UNC Health Rex, as replicated in the table below:

Applicant	Medicare %	Medicaid %	Combined
UNC Health Rex Cancer Care of Wakefield	59.3%	1.3%	60.6%
Duke Raleigh Hospital	46.6%	8.3%	54.9%
WakeMed Raleigh Campus	40.7%	18.9%	59.6%

Payor Mix for Last Available Fiscal Year Medicare/Medicaid Only

Source: Section L.1.a of respective applications.

WakeMed's percentages of historically underserved populations that it served at WakeMed Raleigh in the most recently available fiscal year are equally comparable with figures provided by UNC Health Rex and DUHS, as well:

	FY 2022: Last Full FY before Sub	mission of the Application
<wakemed campus="" raleigh=""></wakemed>	Percentage of Total Patients Served	Percentage of the Population of the Service Area *
Female	57.6%	51.1%
Male	42.2%	48.9%
Unknown	0.2%	NA
64 and Younger	78.4%	87.4%
65 and Older	21.6%	12.6%
American Indian	0.3%	0.8%
Asian	3.5%	8.3%
Black or African American	29.0%	21.0%
Native Hawaiian or Pacific Islander	<0.1%	0.1%
White or Caucasian	60.0%	67.1%
Other Race	NA	2.8%
Declined / Unavailable	7.2%	NA

The percentages can be found online using the United States Census Bureau's QuickFacts which is at: https://www.census.gov/quickfacts/fact/table/US/PST045218. Just enter in the name of the county.

Source: WakeMed Section L.2.b, p. 133.

	Last Full FY before Subm	ission of the Application
Duke Raleigh Hospital	Percentage of Total Patients Served	Percentage of the Population of the Service Area *
Female	62.2%	51.1%
Male	37.8%	48.9%
Unknown		
64 and Younger	56.5%	87.4%
65 and Older	43.5%	12.6%
American Indian	0.4%	0.8%
Asian	3.1%	8.3%
Black or African-American	26.5%	21.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	62.6%	67.1%
Other Race	3.3%	2.8% (two or more)
Declined / Unavailable	4.0%	

The percentages can be found online using the United States Census Bureau's QuickFacts which is at: https://www.census.gov/quickfacts/fact/table/US/PST045218. Just enter in the name of the county.

Source: DUHS Section L.2.b, p. 78.

	07/01/2021 to 06/30/2022			
Cancer Care of Wakefield	Percentage of Total Patients Served	Percentage of the Population of the Service Area *		
Female	60.2%	51.1%		
Male	39.8%	48.9%		
Unknown	0.0%	0.0%		
64 and Younger	43.0%	87.4%		
65 and Older	57.0%	12.6%		
American Indian	0.2%	0.8%		
Asian	1.2%	8.3%		
Black or African-American	21.4%	21.0%		
Native Hawaiian or Pacific Islander	0.0%	0.1%		
White or Caucasian	72.0%	67.1%		
Other Race	3.6%	2.7%		
Declined / Unavailable	1.6%	0.0%		

The percentages can be found online using the United States Census Bureau's QuickFacts which is at: https://www.census.gov/quickfacts/fact/table/US/PST045218. Just enter in the name of the county.

Source: UNC Health Rex Section L.2.b, p. 112.

Given this lack of differentiation, there is not ample justification that WakeMed will meet the community need, as it purports to do, and therefore not strong evidence that there is need for WakeMed's proposed project.

As such, WakeMed's application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3).

6. <u>WakeMed's discussion of radiation treatment wait times is not supported by appropriate evidence.</u>

In Section C.4 of its application, WakeMed discusses patient wait times with regards to the start of radiation therapy relative to the time of diagnosis. They cite a study by Definitive Healthcare in claiming that "the average time from diagnosis to radiation treatment was 27 days;" however, they state that this sample "included only private insurance."²⁶

²⁶ CON Project ID # J-012376-23, p. 55.

Assessing the wait time for care of only commercially insured patients does not accurately reflect the true projected payor mix of WakeMed's patients for its proposed project, as reflected in its own application. As noted in Section L.3.b, WakeMed projects that its payor mix will include 50.8 percent Medicare patients, 4.7 percent Medicaid patients, and 1.7 percent self-paying patients - in other words, over half of their projected patient base will not be commercially insured.²⁷ As such, this assessment of wait times excludes more than half of its expected patient base and is not an accurate reflection of the patient population that it claims it will serve.

The WakeMed application, therefore, is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3) and (13c).

In summary, based on the issues detailed above, the WakeMed application is non-conforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria (3), (5), (6), (12), (13c) and (18a), as well as the performance standards for linear accelerators.

²⁷ Ibid, p. 136.

Comparative Analysis for Service Area 20 Linear Accelerator

UNC Health Rex Hospital (UNC Health Rex) proposes to develop one linear accelerator in northeastern Wake County at its UNC Health Rex Cancer Center of Wakefield facility, in response to the need determination for one additional linear accelerator as identified in the *2023 SMFP* for Service Area 20, which includes Wake and Franklin counties. Two other applicants, Duke University Health System, Inc. (DUHS, Project ID # J-012379-23), and WakeMed (Project ID # J-012376-23) also propose to develop one linear accelerator in response to the *2023 SMFP* need determination for linear accelerator Service Area 20. Given that all three applicants propose to meet the need for additional linear accelerator services in Service Area 20, only one can be approved.

To determine the comparative factors that are applicable in this review, UNC Health Rex examined recent Agency findings for proposed linear accelerators. Based on that examination and the facts and circumstances of the competing applications in this review, UNC Health Rex considered the following comparative factors:

- Conformity with Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Access by Underserved Groups
- Competition (Access to a New or Alternative Provider)
- Projected Average Net Revenue per ESTV Treatment
- Projected Average Operating Expense per ESTV Treatment

UNC Health Rex believes that the factors presented above and discussed in turn below should be used by the Project Analyst in reviewing the competing factors.

Conformity with Applicable Statutory and Regulatory Criteria

An application that is non-conforming with all applicable statutory and regulatory review criteria cannot be approved. The competing linear accelerator applications are non-conforming with multiple statutory and regulatory review criteria. In contrast, UNC Health Rex's application conforms with all applicable statutory and regulatory review criteria. Therefore, regarding conformity with statutory and regulatory review criteria, the UNC Health Rex application is the most effective alternative.

Scope of Services

In prior competitive reviews of linear accelerators,²⁸ the Agency has considered the application offering the greater scope of services to be the more effective alternative for this comparative factor.

See the Required State Agency Findings for the 2021 SMFP need determination for linear accelerator services for Service Area 19, containing the findings for Novant Health New Hanover Regional Medical Center – Scotts Hill (Project ID # O-12110-21) and Wilmington Health on Silver Stream Lane (Project ID # O-12120-21), decision date January 26, 2022.

All three applicants propose to offer linear accelerator treatments and provide CT simulation on site for their proposed patients. However, UNC Health Rex Cancer Care of Wakefield proposes to offer stereotactic radiosurgery in addition to traditional radiation therapy, enabling the treatment of a wider range of tumor sites, as well as treatment for metastatic cancers. WakeMed purports to offer this service in its application as well; DUHS, however, does not propose to offer this service.

Given these differences and disparities in the scope of services between the three applications, both UNC Health Rex and WakeMed are more effective with regards to this comparative factor.

Historical Utilization

In prior competitive applications, the Agency has considered the application of the provider with higher historical utilization rates in the proposed service area to be the more effective alternative for this comparative factor. UNC Health Rex, for the purposes of this comparative review, has chosen to consider both total linear accelerators operated by each applicant in the service area, as well as the number of average patients per linear accelerator in the service area.

The table below lists the linear accelerators operated by UNC Health Rex and DUHS in linear accelerator Service Area 20, which includes both Wake and Franklin counties. WakeMed does not currently operate any linear accelerators in linear accelerator Service Area 20.

Applicant	Number of Linear Accelerators
UNC Health Rex	5
DUHS	4

Linear Accelerators Operated in Service Area 20 UNC Health Rex and DUHS

As shown above, UNC Health Rex operates five linear accelerators in the service area, while DUHS operates four linear accelerators in the service area. Of note, UNC Health applied for and was approved to develop a linear accelerator in Wake County (Project ID # J-01038-14); that project is currently under development but not yet operational.

The tables below list data related to the average patients per linear accelerator for both UNC Health Rex and DUHS, from FY 2018 through FY 2023. Please note that UNC Health Rex did not provide historical data for ESTVs.

	FY18	FY19	FY20	FY21	FY22	FY23
ESTVs					25,461	27,772
Patients		2,688	2,875	2,615	2,562	2,802
Linear Accelerators		5	5	5	5	5
Average ESTVs per Linear Accelerator					5,092	5,554
Average Patients Per Linear Accelerator		538	575	523	512	560

UNC Health Rex Average Patients per Linear Accelerator

Source: UNC Health Rex Form C Methodologies and Assumptions.

Duke University Health System, Inc. Average Patients per Linear Accelerator

	FY18	FY19	FY20	FY21^	FY22^	FY23
ESTVs	19,929	21,286	19,958	21,075	23,733	
Patients	1,063	1,283	1,179	1,237	1,363	
Linear Accelerators	4	4	4	5	5	
Average ESTVs per Linear Accelerator	4,982	5,322	4,990	4,215	4,747	
Average Patients Per Linear Accelerator	266	321	295	247	273	

Source: DUHS Form C Methodologies and Assumptions.

^ Linear accelerator inventory includes the approved relocation from Franklin County to Green Level Cancer Center (Project ID # J-012000-20).

UNC Health Rex averaged more patients per linear accelerator than DUHS for each of the last six fiscal years. Even when totaling all linear accelerators at all UNC Health entities – i.e., all UNC Health Rex linear accelerators and the one linear accelerator not yet developed – UNC Health still averages more patients per linear accelerator than DUHS, as seen below.

	FY18	FY19	FY20	FY21	FY22	FY23
Linear Accelerators		6	6	6	6	6
Average ESTVs per Linear Accelerator					4,244	4,629
Average Patients Per Linear Accelerator		448	479	436	427	467

UNC Health Average Patients per Linear Accelerator Including Undeveloped Wake County Linear Accelerator

Source: UNC Health Rex Form C Methodologies and Assumptions.

Beginning in FY21, the calculation of average patients per linear accelerator for DUHS includes the linear accelerator acquired by DUHS that was formerly located in Franklin County and was approved for relocation to the Green Level campus in Cary (Project ID # J-012000-20). As noted above, UNC Health is developing an additional linear accelerator in Wake County. With the addition of this linear accelerator to the inventory, UNC Health Rex and its related entity still show much higher average utilization per linear accelerator than DUHS. In FY22, DUHS averaged 273 patients per linear accelerator, while UNC Health facilities – including the undeveloped Wake County linear accelerator unit – averaged 427 patients. As

such, UNC Health Rex is the more effective alternative with regard to the historical utilization comparative factor.

Geographical Accessibility (Location Within the Service Area)

As shown in the *2023 SMFP*, there are 11 existing and approved linear accelerators located in linear accelerator Service Area 20. Ten of these linear accelerators are located in Wake County, while one of these linear accelerators is located in Franklin County. However, the linear accelerator located in Franklin County (at Franklin County Cancer Center) recorded no procedures in fiscal year 2021, as it was approved to be relocated to Duke Cancer Center Green Level Radiation Oncology in Cary and as such has not been operational since 2018; meanwhile, the UNC Health linear accelerator is still under development, as previously stated. As such, there are nine linear accelerators that are active and operational in Wake County, spread across five service locations. As seen in the following map, these existing linear accelerator at Duke Cancer Center Cary, in western Wake County. Of note, the linear accelerator at UNC Health Rex Cancer Care of East Raleigh is located less than one mile from the location of WakeMed's proposed project. The Cancer Care of East Raleigh linear accelerator in the least-utilized or UNC Health Rex's five linear accelerator units.²⁹

²⁹ CON Project ID # J-012371-23, pp. 53-54.



FFY 2019 - 2021 Average Patients per Linear Accelerator by Facility in Service Area 20

UNC Health Rex Cancer Care of Wakefield is located in northern Wake County, while the proposed Duke Radiation Oncology Garner is located in eastern Wake County. WakeMed's proposed location, WakeMed Raleigh Medical Park, is located in Raleigh, less than one mile from the existing UNC Health Rex Cancer Care of East Raleigh linear accelerator treatment facility. While UNC Health Rex Cancer Care of Wakefield has one existing linear accelerator, it is highly utilized, and it is the most proximate facility to Franklin County, which has no linear accelerators. While there are no linear accelerators in Garner, there is one in Clayton, approximately 11 miles from the proposed site. Given these factors, UNC Health Rex believes it is inconclusive which application is more effective regarding geographical accessibility.

Access by Service Area Residents

The 2023 *SMFP* defines the methodology for determining the service area for a linear accelerator in full; as stated above, the service area of the need determination for which the proposed three applications are applying is Service Area 20, which consists of Wake and Franklin counties. Linear accelerators may

also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the Agency has stated that "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 linear accelerators in or in close proximity to the service area in which they live."

UNC Health Rex proposes adding a linear accelerator to its existing facility (UNC Rex Cancer Care of Wakefield). DUHS and WakeMed both propose to build new facilities in the proposed service area – DUHS in a new building; WakeMed on a new floor of an existing WakeMed campus. Please see the tables below for the projected patients for each facility or proposed facility through project year three, segmented by county (for UNC Health Rex and WakeMed) or ZIP code (for DUHS) through PY3.

Project Year Three						
	FY26	FY27	FY28			
Wake County	528	537	548			
Franklin County	169	172	176			
Total Patients	697	709	724			
Linear Accelerators	2	2	2			
Patients per Linear	3/19	355	362			

UNC Health Rex Cancer Care of Wakefield Projected Patients by County Project Year Three

Source: UNC Health Rex Form C Assumptions and Methodology.

Accelerator

Duke Radiation Oncology Garner Projected Patients by ZIP Code Project Year Three

	FY26	FY27	FY28
27529	13	24	31
27545	8	15	21
27592	6	10	13
27601	6	9	13
27604	10	14	22
27605	5	8	11
27608	6	9	13
27610	13	22	33
27539	9	15	22
27603	12	19	29
27606	8	13	19
In-migration/Other Zips	20	35	46
Total Patients	116	193	273
Linear Accelerators	1	1	1
Patients per Linear Accelerator	116	193	273

Source: DUHS Form C Assumptions and Methodology.

	FY26	FY27	FY28		
Wake County	189	253	327		
Franklin County	10	13	17		
Total Patients	199	266	344		
Linear Accelerators	1	1	1		
Patients per Linear Accelerator	199	266	344		

WakeMed Raleigh Medical Park Projected Patients by County Project Year Three

Source: WakeMed Form C Assumptions and Methodology.

Please note that the ZIP codes included by DUHS, as noted in UNC Health Rex's Issue-Specific Comments, are all within a 20-minute drive of the proposed Garner location and are all in Wake County.

The percentage of patients that each provider projects to serve by their respective PY3s is noted in the table below.

	Patients per Linear Accelerator (PY3)	% of Total
UNC Health Rex	362	36.98%
DUHS	273	27.89%
WakeMed	344	35.14%
Total Patients	979	100.00%

Percentage of Patients Served in Service Area Project Year Three

Source: Form C Assumptions and Methodologies of respective applications.

As shown, UNC Health Rex projects to serve a higher number and the highest percentage of patients from the service area per linear accelerator than both DUHS and WakeMed for each year through PY3. As such, UNC Health Rex is the more effective alternative for this comparative factor.

Access by Underserved Groups

Projected Access by Medicare and Medicaid Recipients

Generally, regarding these comparative factors, the Agency has stated that "the application proposing the provide a higher percentage of gross revenue to Medicare and/or Medicaid patients is the more effective alternative." The following tables compare access by Medicare and Medicaid patients in the third full fiscal year following project completion for each facility using the following metrics: Medicare and Medicaid percentages of total gross revenue, and number of Medicare and Medicaid ESTVs.

Applicant	ESTV Treatments	Gross Revenue	Gross Revenue per ESTV	Medicare Revenue	Medicare % of Gross	Medicare ESTVs
UNC Health Rex	7,804	\$15,196,700	\$1,947	\$8,994,433	59.2%	4,619
WakeMed	7,054	\$20,598,982	\$2,920	\$10,464,283	50.8%	3,583
DUHS	4,641	\$14,780,679	\$3,185	\$7,074,886	47.9%	2,221

Projected Access by	v Medicare Rec	ipients – Proi	ect Year Three
Trojected Access b	y miculculculculcul	пріснісь і гој	

Source: Forms C.5 of respective applications.

As seen above, UNC Health Rex projects to provide a higher amount of Medicare as a percentage of gross revenue than both DUHS and WakeMed by PY3. UNC Health Rex also has a higher number of Medicare ESTVs than either DUHS or WakeMed. UNC Health Rex is therefore more effective for this comparative factor.

Applicant	ESTV Treatments	Gross Revenue	Gross Revenue per ESTV	Medicaid Revenue	Medicaid % of Gross	Medicaid ESTVs
UNC Health Rex	7,804	\$15,196,700	\$1,947	\$91,546	0.6%	47
WakeMed	7,054	\$20,598,982	\$2,920	\$968,152	4.7%	332
DUHS	4,641	\$14,780,679	\$3,185	\$981,086	6.6%	308

Projected Access by Medicaid Recipients – Project Year Three

Source: Forms C.5 of respective applications.

For Medicaid patients, DUHS projects to have the highest percentage of gross revenue, while WakeMed projects to have the highest number of ESTVs for Medicaid patients. However, as stated in UNC Health Rex's issue specific comments, both DUHS and WakeMed are non-conforming with N.C. Gen. Stat. § 131E-181(a)(13c), and therefore should not be considered in comparing the applications for this factor. UNC Health Rex is the only conforming applicant and is therefore more effective for this factor.

Competition (Access to a New or Alternate Provider)

Currently, both UNC Health Rex and DUHS operate linear accelerators in linear accelerator Service Area 20; WakeMed does not. It should be noted that, historically, WakeMed has chosen multiple times to ignore need determinations for linear accelerators in Service Area 20, instead opting to refer patients to existing providers in the service area.

It should also be noted that WakeMed is non-conforming to multiple review criteria, as described earlier, and should not be considered in comparing the applications for this factor. UNC Health Rex is the only conforming applicant and is therefore more effective for this factor.

Projected Average Net Revenue per ESTV Treatment

Generally, regarding this comparative factor, the Agency has stated that "the application proposing the lowest average net revenue per ESTV treatment is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor." The following table compares projected average operating expense per ESTV treatment in PY3 following project completion for UNC Health Rex, WakeMed, and DUHS's proposed projects.

Applicant	ESTV Treatments	Net Revenue	Net Revenue per ESTV
UNC Health Rex	7,804	\$6,515,126	\$835
WakeMed	7,054	\$6,698,020	\$950
DUHS	4,641	\$3,664,796	\$790

Projected Average Net Revenue per Treatment – Project Year Three

Source: Forms F.2b of respective applications.

As seen above, UNC Health Rex projects a lower average net revenue per treatment than WakeMed, but a higher average net revenue per treatment than DUHS, by PY3. However, as stated in UNC Health Rex's issue specific comments, DUHS is nonconforming with N.C. Gen. Stat. § 131E-181(a)(5) and (13c), and therefore should not be considered in comparing the applications for this factor. Given this, between UNC Health Rex and WakeMed, UNC Health Rex is the most effective alternative for this comparative factor.

Projected Average Operating Expense per ESTV Treatment

Generally, regarding this comparative factor, the Agency has stated that "the application proposing the lowest average operating expense per ESTV treatment is the more effective alternative sine a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service." The following table compares projected average operating expense per ESTV treatment in PY3 following project completion for UNC Health Rex, WakeMed, and DUHS's proposed projects.

Projected Average Operating Expense per	Treatment – Project Year Three
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Applicant	ESTV Treatments	Operating Expenses	Operating Expenses per ESTV
UNC Health Rex	7,804	\$4,403,599	\$564
WakeMed	7,054	\$5,398,833	\$765
DUHS	4,641	\$5,971,791	\$1,287

Source: Forms F.2b of respective applications.

As seen above, UNC Health Rex projects the lowest operating expense per ESTV by PY3. As such, it is the most effective alternative for this comparative factor.

Summary of Comparative Analysis

The following table summarizes the comparative analysis for the Service Area 20 linear accelerator applications:

Comparative Factor	UNC Health Rex	DUHS	WakeMed
Conformity with Review Criteria	Yes	No	No
Scope of Services	More Effective	Less Effective	More Effective, but Non- Conforming
Historical Utilization	More Effective	Less Effective	Less Effective
Geographic Accessibility (Location within the Service Area)	Equally Effective	Equally Effective	Equally Effective
Access by Service Area Residents	More Effective	Less Effective	Less Effective
Access by Underserved Groups – Medicare	More Effective	Less Effective	Less Effective
Access by Underserved Groups – Medicaid	Less Effective	More Effective, but Non- Conforming	More Effective, but Non- Conforming
Competition (Access to a New or Alternative Provider)	Less Effective	Less Effective	More Effective, but Non- Conforming
Projected Average Net Revenue per ESTV Visit	More Effective	More Effective, but Non- Conforming	Less Effective
Projected Average Operating Expense per ESTV Visit	More Effective	Less Effective	Less Effective

To summarize this comparative factor review, UNC Health Rex believes that not all comparative factors weigh evenly in this review. As shown above, UNC Health Rex has historically provided the most radiation oncology care to the service area of the two applicants with existing service, and also projects to average more patients per linear accelerator in the service area than either DUHS or WakeMed. Further, UNC Health Rex projects to average the lowest operating expense per ESTV treatment, as well as the lowest average net revenue per ESTV treatment amongst all compliant applicants.

UNC Health Rex believes that its application is the most effective alternative for the unmet need for linear accelerator services in Service Area 20. UNC Health Rex's application is also the only application that fully conforms to all applicable statutory and regulatory review criteria. As such, UNC Health Rex's proposal should be approved by the Agency.