

May 31, 2023

Via Electronic Mail to: DHSR.CON.Comments@dhhs.nc.gov and julie.faenza@dhhs.nc.gov

Ms. Micheala Mitchell, Chief
Ms. Julie Faenza, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, North Carolina 27603

Re: Written Comments on Certificate of Need Applications for a Linear Accelerator in Service Area 20

Dear Ms. Mitchell and Ms. Faenza:

WakeMed appreciates the opportunity to comment on the following certificate of need applications for a new linear accelerator, pursuant to the need determination for Service Area 20 in the 2023 State Medical Facilities Plan:

Project No.	Applicant
J-12376-23	WakeMed
J-12371-23	UNC Health Rex Wakefield
J-12379-23	Duke Radiation Oncology Garner

WakeMed recognizes that the Agency's decision for the proposed linear accelerator will be based upon the statutory Review Criteria in G.S 131E-183, and also understands that the Agency can review conforming applications against comparative criteria of its own. Having reviewed all three applications, WakeMed believes that its proposal provides the best option for the adjusted need identified for Service Area 20 in the 2023 SMFP. As noted on SMFP page 323, that need is a response to a petition filed in Summer 2022 by WakeMed. After thoughtful consideration of the petition, the SHCC acknowledged access issues in Service Area 20, particularly those that are associated with underserved groups.

The WakeMed application addresses those access issues, describing the problem in substantial detail in Section C and demonstrating how WakeMed proposes to address it in Sections C, F, H, I, K, L, M, N, O and P. WakeMed also offers the best comparative option among the three applicants, as follows:

- WakeMed, alone, describes plans for Radiation Oncologist staffing;
- WakeMed presently has all ancillary and support services in place;
- WakeMed offers a clear plan for integrating care for patients who need both medical oncology and radiation therapy;
- WakeMed offers the best combined access to Medicaid and Charity Care patients; and
- WakeMed proposes to reach the most net new radiation therapy patients.

Metrics used by the Agency in past reviews to compare CON applications for linear accelerators do not apply in this review, for several reasons. The following seven metrics used in the Agency's most recent competitive review of linear accelerator CON applications¹ are either inappropriate in this review or require modification to ensure a fair comparison, as illustrated below:

Comparative Factor	Score Type	Criterion Reference	Detail – Modification in Bold	Reason
Historical Utilization of the Facility	Higher= better	3 - Historical Utilization	Existing provider with highest historical utilization	<i>Eliminate:</i> Need was not generated by standard methodology
Access by Service Area Residents	Higher= better	3 - Patient Origin	Total new patients from SMFP Service Area 20 (Net new patients x Percent of Service Area patients)	<i>Modify:</i> Should only consider new linear accelerator in terms of net new patients served
Access by Charity Care	Higher= better	13a – Service to Medically Underserved	Charity Care Revenue per ESTV	<i>Eliminate:</i> Metric favors providers with high charges
Access by Charity Care Patients	Higher= better	13a – Service to Medically Underserved	Charity Care Percent of Gross Revenue	<i>Modify:</i> Use gross net revenue; otherwise the metric compares charges to receipts
Access by Medicare Patients	Higher= better	13a – Service to Medically Underserved	Medicare ESTVs (Medicare Percent Gross Revenue x Total new patient ESTVs)	<i>Modify:</i> Criterion 13a describes “contribution to access”, thus the metric should address new access
Access by Medicaid Patients	Higher= better	13a – Service to Medically Underserved	Medicaid ESTVs (Medicaid Percent of Gross Revenue x Total new patient ESTVs)	<i>Modify:</i> Criterion 13a describes “contribution to access”, thus the metric should address new access
Projected Average Net Revenue per Treatment, PY 3	Lower= better	13a – Service to Medically Underserved	Lowest average net revenue per procedure	<i>Eliminate:</i> Cannot compare applicants because not all applicants included physician fees

Additionally, WakeMed included the cost of the Radiation Oncologists in its Form F.3b. The other two applicants, however, indicated that Radiation Oncologists' services would be billed separately and, both, did not describe how they would be provided. Should the Agency decide to compare charges per patient, it should first remove from Total Operating Costs on Form F.3b not only the Radiation Oncologists' salary but also the costs of benefits associated with these physicians. As illustrated in the following table, WakeMed's Project Year 3 operating cost per patient served for its proposed linear accelerator is only \$36 more than proposed by UNC Rex Wakefield.

¹ New Hanover County Linear Accelerator Findings, 2022.

Linear Accelerator Operating Costs per Patient, Excluding Physician Cost

Applicant	Year 3
WakeMed	\$600.58
Duke	\$1,247.82
UNC Rex Wakefield	\$564.27

Source: Form F.2b and Form H

For that additional cost, WakeMed also proposes a much higher ratio of Radiation Therapists per patient and more treatments per patient. The WakeMed program also includes brachytherapy, which is not included in either of the other two programs. This equates to increased access to additional types of services, additional treatments, and increased time with a patient’s Radiation Therapist – all of which can improve patient outcomes and increase patient satisfaction. Those factors must be taken into consideration if using charges per patient as a comparative factor.

The following table provides a fair comparison of the applications in this review on a number of metrics. Scoring is based on rank of the raw data. Tie scores are ranked equally in their respective order.

**Service Area 20 Linear Accelerator CON Applications
Analysis of Comparative Factors with Review Criterion References**

Comparative Factor	Raw Data Score Type	Review Criterion Reference	Detail	RAW DATA			RANKED SCORE (lower scores are more favorable)		
				WakeMed	Duke	UNC Rex	WakeMed	Duke	UNC Rex
Conformity with All Review Criteria	Higher= better	All	See attached discussion of competing applications (Yes=2/No=1)	2	1	1	1.0	2.0	2.0
Scope of Services	Higher= better	3 – Scope of Services	Project includes LINAC and simulator? (Yes=2/No=1)	2	2	2	1.5	1.5	1.5
Geographic Accessibility	Lower= better	3 - Geographic Accessibility	Location within Service Area 20/Area where no LINAC is currently located	2	1	3	2.0	1.0	3.0
Access by Service Area Residents	Higher= better	3 - Patient Origin	Total new patients from Service Area 20, PY 3 (Net new patients x Percent of patients from SA 20)	344	128	96	1.0	2.0	3.0
Access by Charity Care: 1	Higher= better	13c – Service to Medically Underserved	Total Charity Care revenue, PY 3 (Form F.2b)	\$1,401,666	\$1,111,588	\$169,737	1.0	2.0	3.0
Access by Charity Care: 2	Higher= better	13c – Service to Medically Underserved	Charity Care as percent of Gross Revenue, PY 3 (Form F.2b)	6.8%	7.5%	1.1%	2.0	1.0	3.0
Access by Medicare: 1	Higher= better	13c – Service to Medically Underserved	Medicare revenue as percent of Gross Revenue, PY3 (Form F.2b)	50.6%	47.9%	59.2%	2.0	3.0	1.0
Access by Medicare: 2	Higher= better	13c – Service to Medically Underserved	Medicare ESTVs (Medicare percent of Gross Revenue x Total new patient ESTVs), PY 3	3,571	1,180	613	1.0	2.0	3.0
Access by Medicaid: 1	Higher= better	13c – Service to Medically Underserved	Medicaid revenue as percent of Gross Revenue (Form F.2b), PY 3	4.7%	6.6%	0.6%	2.0	1.0	3.0

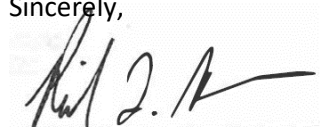
**Service Area 20 Linear Accelerator CON Applications
 Analysis of Comparative Factors with Review Criterion References**

Comparative Factor	Raw Data Score Type	Review Criterion Reference	Detail	RAW DATA			RANKED SCORE (lower scores are more favorable)		
				WakeMed	Duke	UNC Rex	WakeMed	Duke	UNC Rex
Access by Medicaid: 2	Higher= better	13c – Service to Medically Underserved	Medicaid ESTVs (Medicaid percent x Total new patient ESTVs), PY 3	330	164	7	1.0	2.0	3.0
Competition	Lower= better	18(a) - Competition	Access to provider proposing new or alternative site	2	1	3	2.0	1.0	3.0
Projected Average Operating Expense per Treatment, PY 3	Lower= better	5 - Reasonable Costs/Charges	Operating Expense per ESTV, net of MD cost, PY 3	\$600.58	\$1,247.82	\$564.27	2.0	3.0	1.0
Project is Self-Sustaining	Higher= better	12 - Cost effective capital expenditure	Positive net income by PY 3? (Yes=2/No=1)	2	1	2	1.5	3.0	1.5
Staffing	Lower= better	7 - Staffing adequacy	LINAC patients per Radiation Therapist, PY 3	88.6	46.4	153.2	2.0	1.0	3.0
Unused capacity	Lower= better	6 - Unnecessary duplication; 12 - Increased cost 18(a) - Cost effectiveness;	Approved LINAC in Service Area 20 not in use? (Yes=2/No=1)	1	2	2	1.0	2.0	2.0
TOTALS							24.5	30.5	37.5

With the lowest total score representing the best alternative, this comparison clearly shows WakeMed as the superior choice among applicants.

Thank you for your careful consideration of these comments. Please do not hesitate to contact us if you have questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Rick Shrum", is written over a light gray rectangular background.

Rick Shrum
Vice President & Chief Strategy Officer

ATTACHMENTS

Comments Re: UNC Health Rex Cancer Center of Wakefield	A
Comments Re: Duke Radiation Oncology Garner	B

Attachment A

Competitive Review of UNC Health Rex Cancer Center of Wakefield Project No. J-12371-23

Overview

UNC Health proposes to add a second linear accelerator to an existing satellite outpatient department of UNC Rex Hospital located in the Wakefield area in northern Wake County. If approved, this would be the seventh LINAC owned by UNC Health at four existing and proposed locations in Service Area 20. Of note, UNC has had CON approval for a sixth linear accelerator in Service Area 20 since 2016 but has yet to develop the unit.

By the end of the third operating year, the proposed \$10.6 million project would serve only 98 more patients than the same facility is projected to treat in Fiscal Year 2023 (See Form C, 766 patients, compared to 668). The project will serve only 2 “net new” patients by Project Year 3; nearly all projected growth is expected to shift from UNC Rex Hospital.

As described in the following paragraphs, the UNC Rex Wakefield application is non-conforming to Review Criteria 1, 3, 4, 6, 7, 12, 13 and 18a.

CON Review Criteria

- 1. The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, ambulatory surgery operating rooms, or home health offices that may be approved.**

SMFP Policy GEN-3 states:

A certificate of need applicant applying to develop or offer a new institution health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will provide safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.

Access

See discussion of Review Criterion 3 and 13. UNC Rex Wakefield’s stated commitment to Charity Care patients and Medicaid beneficiaries is not matched by forecasts. UNC Rex’s projected Charity Care and Medicaid Gross Revenues and percentages of Gross Revenue are by far the lowest among the applicants, despite currently providing radiation therapy at the Wakefield location.

Value

See discussion of Review Criterion 12 below. The UNC Rex Wakefield project proposes to spend \$10.6 million to add another linear accelerator to its existing roster to treat fewer than 100 additional patients in Project Year 3, including only 2 “net new” patients. These patients could be easily served by existing linear accelerator resources, which have excess capacity.

Thus, the UNC Rex project does not conform with Policy GEN-3 and by extension does not conform with Review Criterion 1.

- 3. The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.**

Need of the Population for the Services Proposed

Patients

The UNC Rex Wakefield application objects to the Adjusted Need Determination of one additional linear accelerator for Service Area 20 in the 2023 SMFP:

While some of these changes do support the need for another LINAC in Service Area 20, UNC Health Rex does not believe they support the allegations made by WakeMed regarding its purported need.... [Page 43]

According to the latest Agency report on the demonstration project, services are being provided to a percentage of African American patients commensurate with the incidence of prostate cancer in that population.¹⁰ [Page 43]

The table on Application page 43 shows that annualized LINAC utilization at UNC Rex Hospital increased in FY 2023 after declining steadily from FYs 2020 through 2022. Decreases in volume continued at UNC Rex Cancer Care of East Raleigh, and volume was basically unchanged at UNC Rex Wakefield. The application demonstrates that LINAC utilization at the Wakefield site has remained static in recent years, increasing by only 0.1 percent from FY 2019 through projected FY 2023.

Table 1: UNC Health Rex Historical LINAC Patient Utilization

	FY19	FY20	FY21	FY22	FY23(A)	FY19-FY23 CAGR*
UNC Health Rex Hospital	1,532	1,670	1,458	1,424	1,748	3.3%
Cancer Care of Wakefield	665	708	682	664	668	0.1%
Cancer Care of East Raleigh	491	497	475	474	386	-5.9%
Total UNC Health Rex	2,688	2,875	2,615	2,562	2,802	
UNC Health Rex Total LINACs	5	5	5	5	5	
Average Patients per LINAC	538	575	523	512	560	

Source: UNC Rex application, Form C Utilization – Methodology and Assumptions, page 3

Projected Utilization

Project UNC Rex Wakefield **patient** increases in the application Section Q Methodology are based on a CAGR developed from only 8 months of FY 2023 data for UNC Rex Hospital.

The UNC Rex Wakefield application justifies this forecasted increase with an assumption that patients could be “redirected” to the UNC Rex Wakefield location because the new equipment will offer SBRT and SRS, which are not currently available at Wakefield. However, those data show only 50 patients originating from the UNC Rex Wakefield service area would meet this criterion in FY 2023. To reach the forecasted 95 patients who will be redirected to Wakefield, the methodology relies on a CAGR calculated in Table 3 on Methodology page 3. A CAGR derives from two data points, the starting and the ending points. In this case, the CAGR is high because of a one-time estimated increase between FY 2022 and partial FY 2023:

Table 3: Potential LINAC Patients that Would Shift from UNC Health Rex Hospital - Historical

	FY19	FY20	FY21	FY22	FY23	FY19-FY23 CAGR
Potential LINAC Patients from Panther Creek/Holly Springs ZIP Codes*	501	653	563	490	636	6.1%
Potential SRS and SBRT Patients from Northern Wake/Franklin^	27	24	24	25	50	16.4%

Source: UNC Health Rex Internal Data
 *See accompanying map with the ZIP codes representing the LINAC patients that would shift to the previously approved Panther Creek location.
 ^Includes all SRS and SBRT patients from Franklin County and northern Wake County ZIP codes (27587, 27614, 27615, 27617, 27571).

Source: UNC Rex application, Form C Utilization – Methodology and Assumptions, page 3

The Methodology assumes, without justification, that this one-year change represents a trend that will continue for five years, after years of little to no change in utilization.

Table 4: Potential LINAC Patients that Would Shift from UNC Health Rex Hospital - Projected

	FY23	FY24	FY25	FY26	FY27	FY28	FY24-FY28 CAGR
Potential LINAC Patients from Panther Creek/Holly Springs ZIP Codes*	636	675	717	761	807	857	6.1%
Potential SRS and SBRT Patients from Northern Wake/Franklin^	50	58	67	78	91	106	16.4%

*See accompanying map with the ZIP codes representing the LINAC patients that would shift to the previously approved Panther Creek location.
^Includes all SRS and SBRT patients from Franklin County and northern Wake County ZIP codes (27587, 27614, 27615, 27617, 27571).

Source: UNC Rex application, Form C Utilization – Methodology and Assumptions, page 4

The Methodology provides no linkage between the population to be served and this generous forecast of specialized procedures. The forecast more than doubles the number of SRS and SBRT patients originating from the proposed service area in the five-year period FY 2024 through FY 2028.

Then the Methodology assumes, without justification, that 90 percent of the trended patients will be “redirected,” resulting in a shift of 95 radiation therapy patients from UNC Rex Hospital to UNC Rex Wakefield by FY 2028:

Table 5: Projected UNC Health Rex Hospital Utilization After Adjustments*

	FY23	FY24	FY25	FY26	FY27	FY28
UNC Health Rex Hospital Before Shifts	1,748	1,806	1,866	1,929	1,993	2,060
Panther Creek/Holly Springs Patient Shift				-380	-404	-429
Franklin/Northern Wake SRS and SBRT Shift				-70	-82	-95

Source: UNC Rex application, Form C Utilization – Methodology and Assumptions, page 5

Table 6: Projected Cancer Care of Wakefield Utilization

	FY23	FY24	FY25	FY26	FY27	FY28
Projected Utilization – Growth*	668	668	669	669	670	671
Shift from UNC Health Rex Hospital^				70	82	95
Utilization After Shift	668	668	669	740	752	766
Cancer Care of Wakefield LINACs	1	1	1	2	2	2
Average Patients per LINAC	668	668	669	370	376	383

*Assumes the historical FY19-FY23 CAGR of 0.1 percent is held constant in FY24-FY28.
^SRS and SBRT patients from Franklin County and northern Wake County ZIP codes (27587, 27614, 27615, 27617, 27571)

Source: UNC Rex application, Form C Utilization – Methodology and Assumptions, page 5

Application Table 6 above shows that, without the shift of patients from UNC Rex Hospital, LINAC patients at Wakefield are projected to increase by only 0.1 percent per year through Project Year 3.

The forecast of 95 shifted patients is a stretch because of its dependence on a one-time event. Moreover, the stretch methodology demonstrates that the project would serve 95 patients who could otherwise continue to receive radiation therapy at UNC Rex Hospital. And these 95 patients, who would save a 26-minute trip, would only receive an average of 10.2 radiation treatments per patient. The projected shift in patients from UNC Rex Hospital to UNC Rex Wakefield represents no “net new” LINAC patients to the UNC Rex system.

On Methodology page 5, the Section Q Need Methodology acknowledges that the project is really intended for “future growth” and “operating efficiency” of Wakefield and not to meet actual need.

Procedures

The application also fails to explain why, with significant new and advanced capabilities, the forecasted ESTVs are still at 10 treatments per patient, which is more consistent with palliative care than treatment care. By comparison, both WakeMed and Duke applications propose 16 ESTVs per patient in their respective applications.

See the following descriptions of palliative and treatment regimens.

*“**Palliative** radiation is not suitable for all types of cancers – it depends on the particular type and the area that the cancer has spread to. Sometimes other treatments such as surgery, chemotherapy, or hormone therapy may be more helpful.*

Palliative radiation therapy is used for many different reasons including:

- *Relieve of bone pain*
- *Treating spinal cord and nerve compression*
- *To treat the symptoms of cancer within the brain*
- *Shrinking a tumor to relieve pressure or a blockage*
- *To stop bleeding*

Long courses of treatment are generally not required, and in most cases, patients are treated with as few as 1 or 2 treatments or up to 10 treatments. In situations where patients are frail or live at a distance from the radiation treatment center or if it is urgent such as a large amount of bleeding, or spinal cord compression, the doctors may offer same day treatments.”² [emphasis added]

*“**What happens during external-beam radiation therapy?***

What happens during your radiation therapy treatment depends on the kind of radiation therapy you receive. External-beam radiation therapy delivers radiation from a machine outside the body. It is the most common radiation therapy treatment for cancer.

Each session is generally quick, lasting about 15 minutes. Radiation does not hurt, sting, or burn when it enters the body. You will hear clicking or buzzing throughout the treatment, and there may be a smell from the machine.

² Source: Radiation Oncology, Targeting Cancer, accessed online May 2023 at:
<https://www.targetingcancer.com.au/treatment-by-cancer-type/palliative-treatment>

Typically, people have treatment sessions 5 times per week, Monday through Friday. This schedule usually continues for 3 to 9 weeks, depending on your personal treatment plan.

This type of radiation therapy only targets tumors. But it will affect some healthy tissue surrounding the tumor. While most people feel no pain when each treatment is being delivered, effects of treatment slowly build up over time and may include discomfort, skin changes, or other side effects, depending on where in the body treatment is being delivered. The 2-day break in treatment each week allows your body some time to repair this damage. ...³ [emphasis added]

For these reasons, the UNC Rex Wakefield application fails to demonstrate the need of the population served for the proposed project.

Likely Access by Low-Income Underserved Groups

According to proforma Form F.2b, UNC Rex Wakefield will provide 2.5 percent of charges as Self-Pay/Charity, and only 0.6 percent of revenue will be associated with Medicaid patients. Application page 74 indicates that only 1.3 percent of patients will be Medicaid beneficiaries, yet Application page 22 emphasizes the high percentage of poverty and low-income residents in Franklin County.

UNC Rex's stated commitment to service low-income persons is not matched by the payer mix projections in the application, nor is it aligned with the SHCC's rationale for approving the adjusted need determination.

For these reasons, the UNC Rex Wakefield application does not conform with Criterion 3.

4. Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

In Section E, the UNC Rex Wakefield application describes various alternatives it considered to the proposed project, including maintaining the status quo, adding an additional LINAC at a different location in Wake County, and developing LINAC services in Franklin County.

Given that UNC Rex has the greatest planning inventory in Service Area 20 with linear accelerators, one of which has not yet been developed, another alternative not discussed in its application would be to develop its non-operational LINAC at UNC Rex Wakefield. This linear accelerator, originally obtained some seven years ago in 2016, has been proposed for development at UNC Rex Cancer Care of East Raleigh, then at UNC Rex Holly Springs and, most recently, at UNC Rex Panther Creek. Based on the most recent CON Progress Report filed for this project, there is no clear timetable or urgency for the development of the 2016 unit. Spending an additional \$10.6 million to acquire yet another unit when the unit awarded seven years ago is still not operational is not the least costly or most effective means of meeting the need identified in the SMFP.

³ Source: Cancer.Net. American Society of Clinical Oncology, accessed online May 2023 at: <https://www.cancer.net/navigating-cancer-care/how-cancer-treated/radiation-therapy/what-expect-when-having-radiation-therapy>

Further, with such a small change in total projected utilization, the applicant failed to discuss the obvious alternative of replacing the current Wakefield equipment or upgrading it to include SRS and SBRT capabilities, both of which would have a substantially lower project capital cost.

Thus, the UNC Rex Wakefield application does not conform with Review Criterion 4.

6. The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

UNC Health has a planning inventory of five operational linear accelerators in Service Area 20, and the UNC Rex Wakefield application acknowledges that UNC has had CON approval for a sixth linear accelerator in Service Area 20 since 2016 but cannot yet provide the date when it will break ground, much less when it will become operational. The application does not explain why that CON could not be developed at UNC Rex Wakefield nor why UNC Rex has need for yet another linear accelerator at a cost of \$10.6 million when it has been unable to develop the unit awarded seven years ago, in 2016. Until this LINAC becomes operational, UNC Rex has excess capacity in Service Area 20. Thus, UNC Rex does not conform with Review Criterion 6.

7. 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.

The UNC Rex Wakefield application proposes low staffing ratios for the number of patients it proposes to serve. The application lists Roger F. Anderson, MD and Courtney Bui, MD, as its medical directors. According to the UNC Health web site, Dr. Anderson sees patients at UNC Rex Wakefield and UNC Hospitals in Chapel Hill⁴. He is the only physician listed at UNC Health Rex Cancer Center of Wakefield Radiation Oncology. Dr. Bui sees patients at UNC Rex Hospital Cancer Center and UNC Hospitals in Chapel Hill; however, she is not listed on the medical staff at UNC Health Rex Cancer Center of Wakefield⁵.

This suggests that UNC Rex Wakefield will have the regulatory minimum of one Radiation Oncologist available on-site to serve 766 patients on two linear accelerators by the third year of project operation. The American College of Radiology reports a national average of 212 patients per Radiation Oncologist⁶. See the following table.

⁴ Source: UNC Health web site, accessed online May 2023 at: <https://www.unchealth.org/care-services/doctors/a/roger-f-anderson-md>

⁵ Source: UNC Health web site, accessed online May 2023 at: <https://www.unchealth.org/care-services/doctors/b/courtney-m-bui-md>

⁶ Source: American College of Radiology, Personnel: Radiation Oncology, revised 8-2-2022, modified 17 Jan, 2023, accessed online May 2023 at: <https://accreditation-support.acr.org/support/solutions/articles/11000049781-personnel-radiation-oncology>

Average Staffing Levels for Radiation Oncology Programs from American College of Radiology

		New Patients Per:					FTE
FACILITY STRATUM		Radiation Oncologist	Physicist	FTE Dosimetrist	FTE Therapist	Treatment Machine	Therapists Per Treatment Machine
All Accredited Facilities		212	258	254	85	232	3.1
Academic/Comprehensive Cancer Center/Main Teaching Hospital of a Med School		187	206	247	79	291	4.3
Hospital-Based	600 or more patients	273	280	297	96	295	3.2
	201-599 patients	225	255	257	84	223	2.9
	200 or fewer patients	139	188	180	65	136	2.4
Free-Standing	600 or more patients	263	343	318	97	328	3.8
	201-599 patients	239	326	285	101	267	3.5
	200 or fewer patients	141	236	209	71	141	2.3

UNC Rex Wakefield proposes light Radiation Therapist staffing as well. The application proposes 5 Radiation Therapists for the 766 patients in Project Year 3, a ratio of 153 patients per Radiation Therapist, which is substantially higher than the ACR average of 85 patients per Therapist for all accredited radiation oncology facilities (see table above).

This suggests that UNC Rex Wakefield’s staffing may not be adequate to meet the needs of the proposed number of patients, and the facility may not conform with Review Criterion 7. It is, at best, less effective than other applicants in the review.

12. Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

This Criterion has many components. The UNC Rex Wakefield application does not meet the spirit or intent of the following clause:

... and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project... [emphasis added]

UNC Rex proposes to spend \$10.6 million to serve only 97 more LINAC patients at Wakefield by the third year of operation, 95 patients shifted from UNC Rex Hospital and 2 patients from continued historical growth at a rate of 0.1 percent per year. This will clearly increase the cost of providing radiation therapy services at UNC Rex Wakefield. Those 97 patients could be treated on one of Rex’s existing or already approved linear accelerators without incurring this additional capital expenditure.

According to the Methodology in Section Q, the proposed project will result in an increase of only 2 “net new” patients served in the third project year. Those 2 patients are not enough to justify such a significant capital expenditure. See the following table.

Table 1. Annual Change in LINAC Patients at UNC Rex Wakefield Through Project Year 3

Note	Metric	FY 2025 Interim	FY 2026	FY 2027	FY 2028
a.	Patients Served at UNC Rex Wakefield	669	740	752	766
b.	Additional annual patients served at UNC Rex Wakefield	NA	71	83	97
c.	SRS/SBRT patients shifted from UNC Rex Main Campus to UNC Rex Wakefield	NA	70	82	95
d.	Net new patients served by UNC Rex Wakefield	NA	1	1	2

Notes/Calculations:

- a. From UNC Rex Wakefield application, Form C.2a
- b. Row a, current year minus FY 2025 baseline
- c. From UNC Rex Wakefield application, Section C Methodology Table 5, page 5
- d. Row b minus Row c

Even generously accepting the “shifted” patients that make up the projected net increase of 97 patients served, a capital expenditure of \$10.6 million and the added annual operating costs of \$2.1 million represent an undue increase in costs of providing radiation therapy services at UNC Rex. As illustrated below, at 97 patients, the **annual increase in cost for each new patient served will be more than \$22,000**, in the third project year. **At 2 new patients, the increase will be more than \$1.0 million per new patient served.** Data in Form F.3a and Form C.2.a demonstrate that without the project, the annual operating cost per patient served at UNC Rex Wakefield was \$3,360 (\$2,247,561 / 669 patients = \$3,360).

Table 2. Change in Operating Costs per LINAC Patient Served at UNC Rex Wakefield

Note	Metric	FY 2025 Interim	FY 2026	FY 2027	FY 2028
a.	Form F 3a Total Expense before Project	\$2,247,561			
b.	Form F.3b Total Expense with Project		\$3,902,566	\$4,299,179	\$4,403,599
c.	Project's Net Increase in Total Expense		\$1,655,005	\$2,051,618	\$2,156,038
d.	Additional annual patients served at UNC Rex Wakefield	NA	71	83	97
e.	Net new patients served by UNC Rex Wakefield	NA	1	1	2
f.	Operating cost/ Incremental Patient served at Wakefield with shift		\$23,310	\$24,718	\$22,227
g.	Operating cost/ Incremental Patient served at Wakefield without shift		\$1,655,005	\$2,051,618	\$1,078,019

Notes/Calculations:

- a. Form F.3a, p 12, Total Expense
- b. Form F.3a, p 14, Total Expense
- c. Row b Current Year minus Row a FY 2025 baseline
- d. Row b from Table 3 above
- e. Row d from Table 1 above
- f. Row c divided by Row d
- g. Row c divided by Row e

Clearly the proposed construction project will unduly increase the costs of providing health services by the person proposing the construction project. Hence, the project does not conform with Review Criterion 12.

13. The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of 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 the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;
- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;
- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physician.**

The UNC Rex Wakefield application proposes a meager 0.6 percent of Gross Revenue for Medicaid beneficiaries, a percentage well below that of the other applicants. UNC Rex Wakefield's Charity Care is projected to be 1.1 percent of Gross Revenue, again far below the levels proposed by the other applicants. This runs counter to UNC Rex's contention that locating a new LINAC at its Wakefield site will enable it to serve a greater proportion of patients from Franklin County, which is characterized on Application pages 47-52 as having far higher proportions of poor and indigent residents than Wake County. The UNC Rex Wakefield application does not conform with Review Criterion 13(c); at the very least, it is not comparatively superior to other applicants in this review, nor does it support the SHCC's decision that Service Area 20 be granted an additional linear accelerator to improve access to underserved patients. Therefore, the UNC Rex Wakefield application does not conform with Review Criterion 13(c).

- 18a. The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.**

Competition

Approval of the UNC Rex Wakefield LINAC project would not enhance competition for radiation oncology services in Service Area 20. Currently, UNC Health and Duke Health control all existing linear accelerators the service area, and each system has one linear accelerator it has yet to develop. Approval of Project No. J-12371-23 would only serve to maintain the status quo for radiation oncology in Service Area 20 by increasing the planning inventory of an existing provider.

On page 53, the application states: "Notably, UNC Health Rex served an average of 68.9 percent of the total patients served in Service Area 20 over these three years ($2,731 / 3,964 = 0.689$)." With control of more than one-half of the operational LINACs in Service Area 20, it is not unreasonable to assume that UNC Rex treated a large proportion of radiation therapy patients. UNC Health and Duke Health maintain a duopoly on linear accelerators in the service area, which will only continue without approval of a new market entrant.

As illustrated in the discussion of Criterion 4 and Criterion 12, this project will increase capacity for an existing provider that has available capacity at the location proposed and an existing, undeveloped unit in its inventory. Moreover, approval of the project would not provide a new competitor in Service Area 20 but would simply reinforce the existing duopoly in Wake County.

Cost Effectiveness

The UNC Rex application is not a cost-effective proposal. See the discussion regarding Criterion 12.

Access

The UNC Rex Wakefield project proposes to add linear accelerator capacity to an existing location that is not currently operating above practical capacity. While the application touts improved access to radiation oncology services for residents of Franklin County, it is apparent that most Franklin County patients who utilize UNC Rex for radiation therapy are voluntarily bypassing the Wakefield site to seek services at the UNC Rex Hospital main campus.

The application shows an increase in equipment but reduced ratios of staff to patients served. See discussion regarding Criterion 7 above Increased patient access is questionable.

For these reasons, the application does not conform to Review Criterion 18a.

Attachment B

**Competitive Review of Duke Radiation Oncology Garner
Project No. J-12379-23**

Overview

Duke University Health System (Duke) proposes to spend in excess of \$33 million in fixed and working capital to develop a linear accelerator at a new outpatient radiation oncology center to be located in Garner, which will be a department of Duke Raleigh Hospital. More than half of the patients to be served at this new site will be “shifted” from other Duke linear accelerators. As described below, the shortcomings in the application make it non-conforming with Review Criteria 1, 4, 5, 6, 7, and 18a.

CON Review Criteria

- 1. The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, ambulatory surgery operating rooms, or home health offices that may be approved.**

SMFP Policy GEN-3 states:

A certificate of need applicant applying to develop or offer a new institution health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will provide safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.

This project involves a capital expenditure of at least \$33 million to serve 134 new-to-DUHS patients by the third full operating year (see discussion in Review Criterion 3 below). In its first three and a half years of operations, the project’s expenses exceed revenue every year. The application provides no evidence that existing Duke linear accelerators in Wake County could not serve the proposed population to be served. For these reasons alone, the proposed utilization does not demonstrate value for the project cost and does not conform with Policy GEN-3, and thus, does not conform with Review Criterion 1.

- 3. The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.**

The application proposes to develop a sixth Duke LINAC at a fifth location in Wake County. Duke currently operates existing LINACs at Duke Raleigh Hospital (2 units), Duke Women’s Cancer Care Raleigh (1 unit) and Duke Cancer Center Cary Radiation Oncology (1 unit) and has CON approval to develop a LINAC at its Duke Green Level campus.

Need of the Population for the Services Proposed

Patients

Much of the patient volume at the proposed Duke Radiation Oncology Garner location is expected to be shifted from existing Duke locations. In its Assumptions – Form C in Section Q, Duke describes its Need Methodology for the proposed project. On Application page 96, Duke identifies 866 LINAC procedures originating in the Garner catchment area that might shift to the Garner LINAC in Project Year 1, increasing to 2369 procedures by Project Year 3. LINAC patients are derived by dividing procedures by 17.

The Methodology indicates that approximately 44 percent of the proposed Duke Garner LINAC patients in Project Year 1 will be shifted from existing Duke locations to the Garner site, increasing to 51 percent by Project Year 3. The balance of patients will come from increased market share within the service area and from in-migration. See the table below.

Total Garner Radiation Oncology Patients				
	2026	2027	2028	2029
Patients Shifted from Existing Sites	25	51	93	139
Patients Shifted from Growth in Share	14	55	82	109
Patients from In-migration	4	11	18	25
Total Patients	43	116	193	273

Source: Duke Garner application, Form C Utilization – Methodology and Assumptions, page 100

Of the 273 patients proposed to be served at Duke Garner in Project Year 3, only 134, or less than one-half $((109 + 25) / 273 = 49\%)$, will be “net new” to Duke. The proposed project represents a significant capital investment to serve only 134 new patients in Year 3, patients who could be served by existing or approved LINACs in the Duke system.

The application does not consider serving these patients at Duke’s three existing radiation therapy locations in Wake County, even though on page 66, the application acknowledges that Duke Cancer Cary Radiation Oncology is only 15 miles and Duke Raleigh Hospital is 16 miles from the proposed Duke Garner site.

Impact of In-Migration

Duke Garner’s proposed in-migration of 25 patients in Year 3 conveniently ensures the project’s conformity with the Performance Standards for Radiation Therapy Equipment found in 10A NCAC 14C .1903(5), which requires applicants to either perform 6750 or more ESTVs per LINAC or serve

250 or more patients per LINAC. If Duke Garner's in-migration were only 22 patients in Year 3, the application would not meet this Performance Standard.

For these reasons, the Duke Garner application does not conform with Review Criterion 3.

4. Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

In Section E, Duke describes the alternatives it considered to the proposed project, including maintaining the status quo, developing the LINAC in a new location, developing the LINAC at an existing Duke location, and developing affiliations to offer radiation therapy services. Given that Duke has an undeveloped linear accelerator in its planning inventory, an alternative not discussed was relocating an existing or approved Duke linear accelerator to the Garner site.

The Duke Garner application is nonconforming with Review Criterion 4.

5. Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs, as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

This application demonstrates neither immediate nor long-term feasibility for the project.

Under-Reported Working Capital Requirements

Form F.2b for Duke Oncology Garner shows significant **losses** in each of the first three project years.

Table 3. Net Income Form F.2b Duke Oncology Garner

Partial 2025	FY 2026	FY2027	FY 2028
(\$2,020,770)	(\$3,935,689)	(\$3,246,286)	(\$2,306,994)

Section F narrative indicates that the project will be cash positive in the third year, because depreciation is not an expense. Though true in concept, the amount is too low. Working capital in application Section F is not correctly calculated. Table 2 shows the project will require more than \$3.7 million in operating cash subsidy through FY 2027.

Table 4. Working Capital Requirements Duke Oncology Garner

	Partial 2025	FY 2026	FY2027	FY 2028
Depreciation	\$1,160,646	\$2,321,291	\$2,321,291	\$2,321,291
Net income	(\$2,020,770)	(\$3,935,689)	(\$3,246,286)	(\$2,306,994)
Net Income plus depreciation	(\$860,124)	(\$1,614,398)	(\$924,995)	\$14,297

Net cash flow before positive year	(\$3,399,517)
Startup Section F	(\$316,002)
Total working capital	(\$3,715,519)

The pattern of losses suggests that FY 2029 will also require some subsidy before the net income is positive.

The application demonstrates that the Duke Radiation Oncology Garner project is not a sound investment; it does not show long term financial feasibility. The proposed project would not fund its depreciation, would not accumulate funds for repair and maintenance, and would rely on cash reserves from the parent company indefinitely. Even though the application shows that parent DUHS has cash on its balance sheets, this application does not show how the proposed project would be sustainable in the long term. The subsidy from the parent company, DUHS, cannot come from operations. Form F.2b for DUHS shows an operating subsidy from DUHS would not be available before the third project year. Therefore, DUHS would have to use unobligated cash reserves. DUHS projections on Form F.2b show that DUHS itself will substantially drain those cash reserves.

Working capital forecasts allow for no delay in payments for this new site, and the application provides no information about the financial viability of the rest of the Radiation Oncology program at Duke Raleigh Hospital. That program may also have operating losses.

The application indicates in Section C that the project will operate under the Duke Raleigh Hospital provider number. However, the application provides no historic or projected financial information about Duke Raleigh Hospital. The application is missing Form F.2a & F.3a Financial History and Forms F.2b and F.3b Projected Financials for Duke Raleigh Hospital. Recent Hospital License Renewal Applications and page 315 of the 2023 SMFP indicate that Duke Raleigh Hospital has four linear accelerators that provided an average of 5,269 ESTVs in FY 2021. Thus, the application for an expansion of Duke Raleigh Hospital should have included information about the financial performance of that equipment and program.

Application Section I indicates that ancillaries are not in place at the proposed Duke Garner location. Presumably, getting these services in place would require an additional capital investment that is not included in the application. Without those ancillaries, the project cannot function, and the capital costs for the project are incomplete and understated.

Because the application did not demonstrate the availability of all funds required for the capital and operating needs, as well as the long-term financial feasibility of the proposal, this application should be found non-conforming with Review Criterion 5.

6. The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

Duke Health has not yet opened its Green Level LINAC, approved for relocation from Franklin County in Project No. J-12000-20. The Duke Garner application projects utilization for that facility but does not account for the financial drain of working capital for that program. Until the Green Level LINAC becomes operational, Duke has excess capacity in the service area and is unable to demonstrate it will not be duplicating this approved capacity. According to the 2023 SMFP, Duke's four existing LINACs performed 21,075 ESTVs, an average of 5,269 ESTVs per unit, well below the Performance Standard of 6,750 ESTVs.

As noted in the discussion of Criterion 4, the proposed Duke Garner LINAC project will serve only 134 "net-new" patients in the third year for a total capital investment of over \$33 million. The project will require a subsidy for about four years and will require ancillary and support services that are not yet in place. Section G of the application does not address any of these issues. Nothing in the application shows that existing and approved Duke linear accelerators could not absorb the 134 additional patients that the proposed project purports to serve.

The Duke Garner application does not demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities. Therefore, the project is nonconforming with Review Criterion 6.

7. 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.

As noted in the discussion of Criterion 5, ancillary services for the project are not in place and the application includes no cost or timeline to put them in place.

For these reasons, the Duke Garner application does not conform with Review Criterion 7.

8. The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

While DUHS is an existing provider with a long-standing oncology program, all Certificate of Need applications must stand on their own without assumptions to the applicant's capabilities. Notably absent from this application are the necessary wraparound services that are essential for patients and the survival of such a remote department that is heavily reliant on seamless coordination. Without the explicit commitment, funds, and forethought to these services, it is unclear when and if this project could become operational.

18a. The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.

Duke provides no support for its Form F.2b assumptions regarding Charity Care and Medicaid. Assumptions for Form F.2b indicate that DUHS, the parent company, historically provides 4.5 percent charity care. In Section L, Application page 77 indicates that Duke Raleigh provides 3.0 percent care and 8.3 percent Medicaid.

Competition

Approval of the Duke Radiation Oncology Garner LINAC would not have a positive impact competition for radiation oncology services in Service Area 20. Duke Health and UNC Health currently control all existing and approved linear accelerators in the service area, and approval of either Project No. J-12379-23 or Project No. J-12371-23 would represent a continuation of the status quo, with all linear accelerators in Service Area 20 owned by existing providers.

Access

While approval of Project No. J-12379-23 would represent a new location for provision of radiation oncology in Service Area 20, the application provided no evidence that residents of the Garner area do not have sufficient access to this service. The Duke Garner LINAC would be located only 15 miles from radiation therapy services at Duke Raleigh Hospital and 16 miles from the Duke Radiation Oncology Cary LINAC.

For these reasons, the Duke Garner application does not conform with Review Criterion 18a.