

COMPETITIVE COMMENTS ON
2023 SERVICE AREA 20 LINEAR ACCELERATOR NEED DETERMINATION
SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

MAY 31, 2023

Three applicants submitted CON applications in response to the need determination identified in the 2023 SMFP for an additional linear accelerator in Service Area 20 (Wake and Franklin Counties):

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| J-12371-23 | Rex Hospital, Inc. / UNC Rex Hospital / Acquire one linear accelerator pursuant to the 2023 SMFP need determination / Wake |
| J-12376-23 | WakeMed / WakeMed Medical Park Imaging/Lab Services / Acquire one linear accelerator pursuant to the 2023 SMFP need determination / Wake |
| J-12379-23 | Duke University Health System, Inc. / Duke Radiation Oncology Garner / Acquire one linear accelerator pursuant to the 2023 SMFP need determination / Wake |

These comments are submitted by Duke University Health System (“Duke”) in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the various applications, including a comparative analysis and a discussion of some of the most significant issues identified regarding the applicants’ conformity with the statutory and regulatory review criteria in N.C. Gen. Stat. §131E-183(a) and (b). Other non-conformities in the competing applications may exist and Duke reserves the right to develop additional opinions, as appropriate upon further review and analysis.

COMPARATIVE ANALYSIS

The Healthcare Planning and Certificate of Need Section has developed a list of suggested comparative factors for competitive batch reviews. The following factors are suggested for all reviews:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per Patient
- Projected Average Total Operating Cost per Patient

The following provides context for analysis of certain of these comparative factors.

Geographic Accessibility

Duke's is the only linear accelerator proposal that will significantly increase geographic accessibility to patients in Service Area 20. UNC Rex is proposing a second machine at an existing service location (Wakefield). WakeMed is proposing a new location; however, that location is in northwest Raleigh, approximately one mile from existing radiation oncology services at UNC Rex Cancer Care of East Raleigh. It is also in the same part of Wake County as Duke Raleigh Hospital and Duke Women's Cancer Care Raleigh.

In contrast, Duke's proposed project will be located in Garner, a fast-growing municipality without radiation oncology services, and at a significant distance from the existing and approved sites in the service area.

Historical Utilization

WakeMed has no historical utilization. As set forth in the draft tables 15C-1 for the 2024 SMFP reflecting data provided by each linear accelerator operator in their license renewal applications and equipment registration forms, DUHS's average utilization per machine is significantly higher than UNC Rex's. While the performance standards allow providers to demonstrate conformity based on either number of discrete patients or ESTVS, ESTV volumes, which are based on actual procedures performed on the equipment, reflect the actual utilization of a machine for purposes of determining relative capacity.

2022 Linear Accelerator Volumes (2024 Draft SMFP)			
Provider	Number of Linacs	ESTVs	ESTVs/Machine
Duke Raleigh Hospital	4	23,733	5,933
UNC Rex Hospital	4	21,356	5,339
UNC Rex Cancer Center of East Raleigh	1	4,240	4,240
UNC Hospital Radiation Oncology - Holly Springs	1	(not yet in service)	
Franklin County Cancer Center <i>Approved for acquisition by Duke University Health System</i>	1	0	

Duke University Health System has 5 existing and approved linear accelerators, with an average ESTV/machine of 4747 (5933 ESTVs/existing machine). The UNC Rex system has 6 existing and approved linear accelerators, with an average ESTV/machine of 4266 (5119 ESTVs/existing machine).

Furthermore, as set forth in UNC Rex’s application and described further below, UNC Rex’s shares of service area volume is shrinking. Duke’s historical utilization is stronger than UNC Rex’s.

Competition (Patient Access to a New or Alternative Provider)

The introduction of a new provider in the service area may often be the most effective alternative based on the assumption that increased patient choice will improve quality or lower costs.

However, in this case, simply creating a new provider does not lead to those benefits. WakeMed’s proposal is for a hospital-based facility that will receive higher reimbursement from Medicare than Duke’s non-grandfathered, off campus site. A new off-campus site such as Duke’s will receive reimbursement that is 40% of a hospital-based site such as WakeMed’s (or Rex’s, which Duke believes to be grandfathered for CMS reimbursement purposes).

Similarly, a new entrant with a single machine such as WakeMed will not offer the quality benefits that an existing provider like Duke can:

- 1) WakeMed does not have an established safety and quality program and has not demonstrated that they will devote the resources to do so.
- 2) WakeMed will not have alternatives available when its equipment needs maintenance or repair. With several machines in the service area that are matched in physics characteristics, Duke is readily able to transfer patients to other machines for care without any disruption or need to recalibrate.
- 3) WakeMed is not otherwise conforming to all criteria and cannot be approved.

As discussed above, between Duke and UNC Rex, Duke has fewer existing and approved linear accelerators in the service area, with a higher average utilization. Its proposal best achieves the benefits of increased competition in the service area.

Access By Underserved Groups

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

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

The following reflects the projected percentage of patients in various payor categories as set forth in Section L of each application:

Payor source	Duke Garner	WakeMed	UNC Rex/Wakefield
Charity	1.8%	1.7% (included in self-pay)	1.4%
Medicare	47.9%	50.8%	59.2%
Medicaid	6.1%	4.7%	0.6%

Duke Garner projects the highest percentage of Medicaid patients within its projected utilization, based on its historical patients from the Garner area. Duke also projects the highest percentage of charity care patients. While it has the lowest projected percentage of Medicare patients, Duke’s proposal nonetheless provides superior access to Medicare recipients by providing a lower cost option based on reimbursement each proposed facility would receive. Freestanding and non-grandfathered hospital facilities such as the proposed Duke Garner facility receive 40% of the OPPS rates that apply to UNC’s grandfathered and WakeMed’s on-campus proposed sites. See Medicare Claims Process Manual, Chapter 4, 20.6.11). Duke’s application therefore provides the greatest access to all categories of underserved patients.

**COMMENTS SPECIFIC TO WAKEMED
PROJECT ID No. J-12376-23**

WakeMed proposes to acquire a linear accelerator and simulator on its hospital campus in Raleigh. This application fails to demonstrate the need for the project, the reasonableness of its projected utilization, nor its financial feasibility.

Need for Proposed Project (Criterion 3)

WakeMed's asserted need for a linear acceleration is based on a faulty characterization or interpretation of data.

First, WakeMed asserts that there is a delay in scheduling radiation oncology procedures with existing providers in the service area. This is incorrect and reflects a fundamental misunderstanding of oncology services. As support for this inaccurate claim, WakeMed provides data about average number of days between cancer diagnosis and first radiation oncology appointment. This time period in no way equates to any delay in access to radiation oncology services. Rather, there may be a variety of other services that are needed before an oncology patient is ever referred for radiation oncology. For example, a typical patient may have surgery, then chemotherapy, and only then followed by radiation oncology. This reflects care needs and a comprehensive and staged approach to cancer treatment, not any access issue for a particular modality.

In fact, directly contrary to WakeMed's assertion, median lead time for a new Radiation Oncology patient in Wake County at a Duke University Health System location is consistently around **8 days**. If it is an urgent referral, providers will add new patient slots to get them in. Duke routinely extends treatment hours to get patients in to meet their treatment needs. Moreover, to the extent that there are any "wait times" caused by capacity constraints, those could be addressed by capacity increases at any location, not specifically at WakeMed.

WakeMed also repeatedly references a figure of "4006" patients served at WakeMed within its first 8 months of providing medical oncology services. It is unclear what this number reflects, or how it demonstrates need for WakeMed's proposed linear accelerator. In Duke's long experience as an NCI-Designated Comprehensive Cancer Center since 1972, a medical oncologist can typically treat approximately 200 newly diagnosed patients per year. WakeMed currently has 5 providers. That would equate to approximately 660 patients over an 8-month period. If WakeMed asserts that its 5 medical oncologists have a roster of 4006 patients, that would be an extraordinary figure.

In fact, WakeMed's own utilization projections reflect a mismatch between this purported number of patients "served by the medical oncology program" and its stated number of referrals of 385 patients for radiation oncology treatment (pages 54-55). In its projections, WakeMed estimates that 52.3% of oncology patients typically will receive radiation oncology treatment. Either its stated number of cancer patients is grossly overestimated or its assumption that 53% of oncology patients will be referred for radiation oncology is unreasonable. It is possible that the 4006 patients reflects the number of total patient encounters, or perhaps the number of patients who may have received a cancer diagnosis at some time but not necessarily any further cancer treatment at WakeMed. Those patients may have chosen

other providers for medical and surgical care, not just radiation oncology, and this number does not support any particular demand for radiation oncology services at WakeMed.

Finally, WakeMed also claims that its proposal is necessary to avoid disruptions to care or duplications or delays in service necessitated by patients receiving services at multiple locations. WakeMed already provides medical oncology services at multiple locations, so even WakeMed's existing patients receiving medical oncology at a location other than the main campus would need to travel for radiation oncology. Moreover, oncology providers in Wake County already collaborate closely to coordinate care. WakeMed's patients have access to coordinated care with other providers with care navigators available at Duke and elsewhere. WakeMed also touts its participation in disease-specific tumor boards which provide further opportunities for coordination of care. Contrary to WakeMed's assertion, repetition of diagnostics that may occur at a second provider are not the result of lack of sharing such studies between organizations, but are more related to the quality of the studies and their interpretation. Studies may be repeated to ensure the best information is available to inform the treatment decisions, not because information is not available among providers.

Finally, Duke takes specific exception to WakeMed's characterization that the Duke-WakeMed Cancer Care Plus collaboration ended when "WakeMed and Duke agreed that Duke's resources were needed for Duke Health patients." (WM Application, p. 40) This is simply not objectively true. Duke has provided access for WakeMed patients before, during, and after Cancer Care Plus. Duke routinely provides access for all modalities for patients referred by WakeMed, even if they choose to continue receiving certain components of care from WakeMed.

Utilization Projections (Criterion 3)

WakeMed's utilization methodology similarly relies on unreasonable assumptions, and bases its projections on unsupported volume projections.

In Section Q, WakeMed first projects that the cancer case rate for each county in its identified service area will increase linearly over the next 6 years. This projection results in a total increase of 25% in the cancer case rate over the decade between FY 2018 and FY 2028. This is aggressive in light of a factor that WakeMed identifies: FY 2020 and FY 2021 may have seen a decrease in routine health screenings such that the FY 2022 new cancer care rate may actually reflect delayed diagnoses. Therefore, using the FY 2022 rates to calculate the future "linear trend" may skew any resulting further increase in case rates.

More fundamentally, WakeMed also provides unreasonable assumptions for the projected radiation oncology treatments per oncology patient. Its assumptions are solely based on an almost 20-year old study from Australia that found that 52.3% of oncology patients received radiation oncology (See "The Role of Radiotherapy in Cancer Treatment" identified at WakeMed page 178 n.3). WakeMed then adds an additional percentage of those same patients who will need "retreatment" based on the same 2005 Australian study to create projected new "radiation oncology cases."

As a preliminary matter, it is simply unreasonable to rely on 20-year-old data from another country for these projections. This article itself states that "[t]here are significant variations in actual radiotherapy utilization rates reported in Australia, the United States, Canada, and the Nordic countries, where

utilization ranges from 20–55% of all new cancer cases.” (Delaney at 1130, emphasis added.) In addition, cancer treatments continue to evolve as the ability to diagnose cancers at an earlier stage and the technology to treat them improve. There is no basis for assuming that a 20-year-old use rate for radiation oncology in another country – which at the time reflected “significant variations” as compared to other countries including the United States – provides support for WakeMed’s projections for North Carolina patients in 2023.

The reliance on this study is compounded by a critical mischaracterization and misapplication of data by Wake Med. As stated above, WakeMed adds “retreatment” cases to reach its total “radiation oncology cases.” However, the 2005 Australian paper expressly states:

For every 1000 cancer cases in a population, 523 patients would need radiation as an optimal part of their management based upon the results of this project (calculated optimal radiotherapy utilization rate of 52.3%). A further 120 patients, of the above 523 patients, will require retreatment (based upon an actual retreatment rate of 23%).

(Delaney at 1133, emphasis added). This “retreatment” therefore is not an increase in the number of patients needing radiation oncology, but may simply reflect an additional number of total treatments per patient. Given that WakeMed is projecting utilization by discrete patients, there is no basis for increasing the total number of radiation oncology “cases” by a “retreatment” adjustment in estimating patients to be served. By contrast, in identifying linear accelerator patients for its license renewal application, for example, Duke only reports each patient once, even if they receive a separate “retreatment” protocol after their initial radiation oncology treatment. Therefore, even assuming the 2005 Australian study provides support for their projections, WakeMed’s projections for total patients in the service area needing radiation oncology are overstated by this 23% “retreatment” factor.

WakeMed’s utilization projections are specifically based on capturing a percentage of “unserved” radiation therapy patients. If the “retreatment” cases are properly excluded, then the total projected number of radiation oncology patients served by existing providers in FY 2028 (Table 10) will outstrip the total number of projected new radiation oncology cases (Table 6). Therefore, any assumption of volume about the need to serve “unserved” patients based on WakeMed’s own projections is unreasonable and unsupported.

In addition to capturing “unserved patients,” WakeMed also includes an assumption about the percentage of WakeMed patients referred for radiation oncology that would receive services at WakeMed in the future.¹ This component of its projections is also not supported by reasonable assumptions. The 385 patients referred for radiation oncology have not necessarily “chosen WakeMed” as their provider for all of their oncology services. It is unclear what services, if any, such patients have chosen to receive at WakeMed after their initial diagnosis. To the extent those patients have also sought surgical or medical oncology care elsewhere, they would not necessarily seek otherwise radiation oncology at WakeMed.

The assumption about retention of a majority of patients currently referred elsewhere appears overstated for another reason: this volume presumably reflects patients referred to any provider in a

¹ WakeMed states in the narrative that this percentage will be 60%, but in its tables appears to apply a 55% rate.

variety of locations throughout the service area and as well as to Durham and Orange Counties, the sites of major cancer centers. Geographic accessibility can be a prime consideration for patients who need multiple radiation oncology procedures. Even those patients who receive surgery at WakeMed, for example, may prefer one of the 11 existing or approved linear accelerators in Wake County or a linear accelerator in another county closer to home. Similarly, WakeMed currently offers medical oncology services in Cary; any patients referred from that location for radiation oncology would necessarily need to use a different location for those services; one of the existing or approved providers in Cary or Apex may be significantly more convenient for those patients. WakeMed does not identify where the 385 patients live, receive any other WakeMed services, and/or where they currently are referred for radiation oncology services, to support their assumption that 60% (or 55%) would choose the proposed WakeMed location in the future.

Because WakeMed's estimated ESTV totals are based on their patient projections, their ESTV projections are similarly overstated and unsupported.

Financial Feasibility (Criterion 5)

In addition to relying on unsupported volume projections, WakeMed's financial projects are unreasonable as a result of failure to include all costs necessary to establish its new program.

At page 26, WakeMed states that it will contract for "highly experienced physicists and dosimetry staff and consultants from CTSI" to obtain "additional expertise to build the radiation therapy component." However, the actual contract included at Exhibit I.1 and reflected in the operating costs only references the physicists and dosimetrists, and not any additional consulting for the medical or other services.

As a new provider without an existing quality and safety oversight program, such services will be critical for WakeMed, as WakeMed appears to acknowledge. Radiation Oncology errors and quality treatment have been a focus of the Institute of Medicine for many years; one critical component to ensuring patient safety is having experienced and comprehensive teams in place that are required to deliver these complicated treatments. In addition, there are many specialized modalities within radiation oncology which also affect patient side effects and outcomes which are not typically delivered optimally without experienced medical expertise. Wake Med does not provide any allowance for developing that experience.

WakeMed also assumes it will be able to have a "part time" radiation oncologist as projected in its staffing tables to serve the projected patient volume. This assumption is unreasonable for a small program. While a larger provider with several linear accelerators or locations may be able to allocate a partial FTE to a given location (with assignment of the remaining time to a different location), WakeMed expressly assumes "hiring a part-time radiation oncologist in year two."

The same deficiencies cause WakeMed's application to be nonconforming with criteria 7 and 8.

COMMENTS SPECIFIC TO UNC REX/CANCER CARE OF WAKEFIELD PROJECT ID No. J-12371-23

UNC Rex proposes a second linear accelerator at its existing Wakefield service location. This application fails to demonstrate the need for the project, the reasonableness of its projected utilization, nor its financial feasibility.

FY 2023 annualized patient volumes across the UNC system in Wake County reflect a CAGR of less than 1% compared to FY 2019, the time period UNC uses for its projections:

	FY 2019	FY 2020	FY 2021	FY 2022	FY 23A	CAGR
UNC Heath Rex Hospital	1532	1670	1458	1424	1748	3.3%
Wakefield	665	798	682	664	668	0.1%
East Raleigh	491	497	475	474	386	-5.9%
Total	2688	2875	2615	2562	2802	0.8%

More importantly, they reflect a decline in volume since FY 2020. To the extent that UNC Rex claims that its low volumes in FY 21 and 22 were solely due to COVID, this does not reflect the experience in the service area more broadly. For example, while FY 2020 reflected a drop in linear accelerator procedures at Duke sites when COVID led to the delay of some treatments, Duke’s utilization had rebounded to FY 2019 levels by FY 2021, and had increased significantly in FY 2022.

Duke University Health System – Wake County Linacs					
Year	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
ESTVs	19,929	21,286	19,958	21,075	23,733
Patients	1,063	1,283	1,179	1,237	1,363

That Rex’s utilization trends are not solely a function of COVID is reinforced by the data presented at page 57 of Rex’s application: Both UNC Rex’s absolute volumes and its percentage of Wake County linac patients (at the hospital as well as at all UNC sites) decreased significantly between FY 2020 and FY 2021, even as the total number of Wake County linear accelerator patients increased.

Moreover, even if, as UNC Rex contends, its volumes were depressed from FY 2020 through FY 2022 solely due to COVID, that would suggest that any “rebound” in FY 2023 may reflect patients who had their diagnosis or treatment delayed from earlier years rather than any ongoing and sustained growth in demand for such services that would continue at the same rate in the future.

Volume Projections

Despite this falling share in Wake County linac patients, UNC Rex cherry-picks a period to support an aggressive growth rate not supported by the data more generally. For example, for its future projections at UNC Rex main hospital, UNC Rex calculates a CAGR of 3.3% for FY 2019 to FY 2023, and then applies that rate going forward. However, its FY 20-23 CAGR is only 1.5%. There is no basis for using this more aggressive growth rate in light of UNC Rex’s actual historical experience, especially compared to other providers in the service area.

UNC Rex similarly picks unsupported CAGRs to project the patient populations that would come from various regions. Its “SRS and SBRT patients” from Northern Wake/Franklin remained essentially unchanged from FY 2019-22. (See UNC Rex Form C Assumptions Table 3.) An aberration in partial year 2023 does not support an aggressive future growth trend, especially given the small total number of patients reflected in annualized FY 2023 data. As set forth on page 56 of its application, UNC Rex’s total number of Franklin County patients decreased over FY 2019-2021. UNC Rex does not provide its total number of “Northern Wake/Franklin” linac patients to evaluate whether this aggressive future growth rate in SRS/SBRT patients is otherwise supported.

Similarly, UNC Rex picks the FY 19-23 period to support a misleading CAGR for potential patients from Panther Creek/Holly Springs zip codes, used to project volume at both UNC Rex and the new Panther Creek site under development. As with its total volume, UNC Rex’s utilization for FY 2020-2023 demonstrates no net growth for that patient population (see Table 3). In fact, the patients from those zip codes have been extremely variable over the past 5 years. There is no reason for UNC Rex to look back to FY 2019 volumes except to bolster a growth “trend” that does not exist.

UNC Rex’s projections are similarly unreasonable at its other radiation oncology sites. For example, UNC Health Rex Cancer Care of East Raleigh utilization is projected to hold steady, despite steadily declining volume. It cites undefined efforts to move patients to that site, presumably from other locations. However, it does not then reflect any adjustment to its volume at the main campus or other locations to correspond to such efforts.

In total, these overstated growth rates lead to unreliable and unsupported assumptions not just at UNC Rex’s Wakefield facility but across the UNC Rex system in Wake County. The application’s financial pro formas are based on unsupported volume projections. Its project is therefore not conforming with all applicable criteria.