

**Comments in Opposition to WakeMed’s Petition
for an Adjusted Need Determination for a Linear Accelerator in Service Area 20
in the *Proposed 2023 State Medical Facilities Plan***

COMMENTER

UNC REX Hospital
4420 Lake Boone Trail
Raleigh, NC 27607

Ernie Bovio
President
919-784-1365
Ernie.Bovio@unchealth.unc.edu

INTRODUCTION

WakeMed filed a petition for an adjusted need determination in the *Proposed 2023 SMFP* for one additional linear accelerator in Service Area 20, which includes Wake and Franklin counties. WakeMed’s most recent petition mostly duplicates a 2021 petition WakeMed filed for an adjusted need determination in the *2022 SMFP*, also for one additional linear accelerator in Service Area 20. That petition was properly denied by the State Health Coordinating Council. In its concluding remarks, the Agency report stated that “the *historical and trending LINAC utilization in Service Area 20* does not support an additional LINAC outside of the methodology”¹ (emphasis added). While WakeMed’s most recent petition does include additional arguments relating to “[d]isparity in access to cancer care” and “[d]evelopment of Medical Oncology services at WakeMed, in addition to the existing surgical expertise, in order to provide more comprehensive cancer services to existing patient population,” these arguments are largely qualitative, are outside of the scope of the methodology, and do not change the quantitative reality of the “historical and trending LINAC utilization in Service Area 20” that ultimately drove the Agency’s recommendation for denial in 2021.

As will be discussed below, that quantitative reality, with respect to linear accelerator need determination, has not changed since 2021, and the qualitative factors expressed by WakeMed are similarly unpersuasive. As such, UNC REX Hospital (“UNC REX”) opposes the petition and requests that it be denied.

UNC REX’S RATIONALE FOR OPPOSITION

As was the case in 2021, UNC REX believes that there are numerous reasons to deny the WakeMed petition. Most importantly, there is no evidence that the existing methodology fails to appropriately evaluate linear accelerator utilization and need in Service Area 20, which shows no need for an additional linear accelerator. To the contrary, and as described in more detail below, Service Area 20 has a significant surplus, which would be made even larger if the WakeMed petition is approved. Such approval would be contrary to the standard need methodology and contrary to the purpose of CON Law, which recognizes that the development of unnecessary health care services “results in costly duplication . . . with the

¹ https://info.ncdhhs.gov/dhsr/mfp/pdf/2021/tec/05_WakeMed_LINAC_Agency_Report.pdf

availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services,” as stated in NCGS § 131E-175(4). Another linear accelerator in Service Area 20 continues to be unnecessary, as there has been no significant change to the need for linear accelerators in Wake County.

1. Surplus of linear accelerators

As WakeMed correctly notes, the methodology shows that Service Area 20 has a surplus of linear accelerators. What is not noted, however, is that the surplus is the second largest in the state, with an excess of nearly four linear accelerators, based on the procedures performed in the service area. Although WakeMed notes that linear accelerator utilization increased from 2015 through 2021, data from 2018 to 2019, before the pandemic, shows that the growth is flat. Moreover, even if the compound annual growth rate (CAGR) from 2015 to 2019 (5.8 percent) continues, Service Area 20’s existing linear accelerators would still not exceed the 6,750 ESTV threshold until **2029**, as shown below.

<i>Year</i>	<i>Total ESTVs</i>	<i>Linacs</i>	<i>ESTVs/ Linac</i>
2021	47,861	11	4,351
2022	50,631	11	4,603
2023	53,562	11	4,869
2024	56,662	11	5,151
2025	59,942	11	5,449
2026	63,411	11	5,765
2027	67,082	11	6,098
2028	70,965	11	6,451
2029	75,072	11	6,825
CAGR	5.8%		

Thus, even if the growth trend from 2018 does not continue, with sustained long-term growth, Service Area 20 will not need another linear accelerator until at least the end of the decade, after adding more than 30,000 ESTVs in utilization—all of which can be accommodated on the existing linear accelerators in the service area. Moreover, while total linear accelerator volume has increased slightly--by a mere 16 ESTVs—in the service area since 2018, the resulting CAGR for 2015 through 2021 is even smaller, 3.9 percent, which indicates that it will likely take even longer to fully utilize the existing equipment in the service area.

WakeMed also argues that there are “chronically underutilized” linear accelerators in the service area, and thus that the surplus noted in the *SMFP* data does not accurately reflect the needs of Service Area 20. WakeMed is referring to two linear accelerators in particular: that of Franklin County Cancer Center in Franklin County, and that of UNC Hospital Radiation Oncology – Holly Springs in Wake County.

However, there continue to be extenuating circumstances regarding both linear accelerators that invalidate WakeMed’s claim. The Franklin County linear accelerator, while obtained prior the CON requirement for linear accelerators, has received approval to be acquired by Duke University Health System and be relocated to Wake County, a relocation that is currently pending. The Holly Springs linear accelerator is approved for UNC Health and is the most recently-approved linear accelerator in the service area. That project is under development, although it has been delayed due to the impact of the COVID-19 pandemic. Even with these two linear accelerators still under development, there remains a surplus of two additional linear accelerators among those that are already operational in the service area.

WakeMed’s Position on Excess Capacity/Underutilization

Interestingly, the scenario in WakeMed’s petition mirrors that of previous petitions submitted in 2014, 2015, and 2016, in which UNC REX petitioned (in the spring cycle) to change the methodology for cardiac catheterization equipment or (in the summer cycle) to create an adjusted need determination for an additional unit of fixed cardiac catheterization equipment in Wake County². In all three years, WakeMed opposed UNC REX’s petitions for these services, citing its own capacity to accommodate patients that had chosen UNC REX physicians. In 2016 specifically, WakeMed cited equipment surplus as a reason for the Agency to deny UNC REX’s petition: “In the Wake County service area there is a surplus of *four* units, one of the largest surpluses in any single service area...[b]ased on this data, it is difficult to assert that residents of North Carolina, and Wake County, do not have access to fixed cardiac catheterization equipment.”³ UNC REX disagreed with WakeMed’s position with respect to the cardiac catheterization petition for multiple reasons, including that service requires a physician to perform the procedure, and therefore to have privileges at the hospital that owns the equipment. Such is not the case with a linear accelerator. As the SHCC is aware, any qualified physician may refer patients for radiation oncology services using a linear accelerator, and the referring physician is not required to be on staff at the facility to which the patient is referred. Moreover, cardiac catheterization services are often provided on an emergency basis to provide immediate life-saving interventions; linear accelerator treatments, while often prescribed for curative purposes, are performed as emergent treatments in only the rarest of circumstances. Thus, WakeMed’s purported “need” for a linear accelerator is not supported by the same compelling reasons—medical staff and emergency treatment issues—that supported the need for an additional unit of cardiac catheterization equipment.

Given WakeMed’s strong position against a special need determination for equipment like cardiac catheterization, it is curious that WakeMed has chosen to petition for an additional linear accelerator despite, in its own words, “[s]ervice area 20 [having] a calculated surplus of 3.91 linear accelerators.” UNC REX can only conclude – as WakeMed concluded against UNC REX’s cardiac catheterization petition in 2016 – that it is difficult to assert that residents of North Carolina (and Wake County) do not have access to linear accelerator equipment.

² In both 2014 and 2016, UNC REX petitioned to change the methodology for fixed cardiac catheterization equipment. It is worth noting that WakeMed had this spring petition option available to it, both this year and in prior years, but chose not to utilize it. See the discussion under point 2 for further discussion.

³ https://info.ncdhhs.gov/DHSR/mfp/pets/2016/tec/0816_cc_wake_wm.pdf

Finally, it is worth noting that the linear accelerator methodology in the *SMFP* does not define “chronically underutilized.” Even if it did, it would likely not include either of these undeveloped linear accelerators, given the circumstances outlined above. Of note, if the methodology did exclude these machines, the surplus would still be greater than two linear accelerators, which clearly indicates there is more than sufficient capacity to meet the needs of the service area population for the foreseeable future.

2. WakeMed’s Choices

WakeMed has been operating in Wake County for 60 years. At any time prior to 2006, WakeMed could have obtained a linear accelerator without a CON, as numerous providers across the state did, including one in Service Area 20. Since 2006, there have been need determinations for linear accelerators in 2007, 2009 and 2014 that added machines in Service Area 20. WakeMed could have taken these need determination opportunities and applied for a linear accelerator, but it did not. Since 2006, at least five linear accelerators in Service Area 20 changed owners, but WakeMed did not purchase any of them. Despite being a health system in the service area for many decades, WakeMed has chosen not to avail itself of numerous opportunities to obtain a CON for a linear accelerator to offer radiation oncology services. WakeMed is critical that two health systems control all accelerators in the service area, but that outcome is due in large part to the choices WakeMed has made. While WakeMed now wants to begin providing the service, the SHCC should not ignore the significant surplus of linear accelerators in the service area. Approval of the WakeMed petition to add another linear accelerator would clearly result in unnecessary duplication of existing resources in the service area and contravene the standard methodology, which does not determine need by provider, as WakeMed is requesting.

Additionally, approval of WakeMed’s petition would suggest that providers need not avail themselves of multiple opportunities to provide a service by applying for an allocation generated by methodology-driven need determinations, and instead merely petition for a special need determination despite previously electing not to apply under the standard methodology. As noted previously, WakeMed could have petitioned for a change to the methodology for linear accelerators if it believes that need for linear accelerators should be allocated when providers initiate a medical oncology program, as it argues is the basis for its need. Instead, WakeMed persistently chose not to petition for a methodology change—unlike UNC REX—and instead requests a need for another linear accelerator in a service area with the second greatest surplus in the state and two approved but undeveloped linear accelerators. In short, WakeMed’s choices and decision not to pursue past opportunities for additional technology have resulted in its current situation.

Finally, as mentioned above, WakeMed argues that its recent development of a medical oncology service would be supported by the availability of a linear accelerator to complement its services. While this may be something WakeMed desires, it chose to recruit medical oncologists to start its program, despite knowing that there was no need for additional linear accelerators in the service area. Moreover, while WakeMed asserts that medically underserved patients experience longer wait times to get an appointment for “Oncology care,” it has not provided any documentation that those delays are for radiation oncology treatment from the existing providers in the service area.

WakeMed states in its petition that it has attempted to develop a formal partnership or other arrangement with existing linear accelerator providers in the area to accelerate the referral process for these patients, “but has yet to find a willing partner.” As UNC Health has shared with WakeMed, it regards WakeMed as a valuable asset and resource for the people of Wake County and believes there is great alignment between the respective missions of the organizations and their shared commitment to care for all patients regardless of ability to pay. UNC Health has been open to discussing partnership opportunities that could enhance access to care for the people of greater Wake County in oncology or other clinical services, and would be happy to meet and talk through any and all options that could be mutually beneficial to both organizations and, most importantly, for the patients in our communities.

Ultimately, WakeMed is requesting a need determination for an additional linear accelerator in a service area with a significant surplus, yet has failed to provide any data regarding its nascent medical oncology program, the lack of ability to refer patients for radiation treatment, or any quantitative evidence that another linear accelerator can be supported in the service area.

3. Service Area Changes

The petition focuses on growth in the service area, particularly in Wake County. UNC REX agrees that the area is growing; it also acknowledges the large and growing health disparities that WakeMed accurately notes between minorities and whites, which necessitate the need for more health services, as well as additional and equitable investment in healthcare solutions that can work to combat this disparity. For several years, UNC REX, WakeMed, Duke and others have collaborated on the county’s Community Health Needs Assessment, in part to address common solutions to these and other healthcare issues in a fast growing service area.

However, that growth has not impacted linear accelerator utilization as it has other services, for multiple reasons. First and foremost, the population of Service Area 20 is roughly the same size today as it was in 2013—nine years ago—despite the population growth. The reason for this is the extraction of Harnett County, which was part of Service Area 20 until 2014, when it reached the 120,000 population-threshold needed to create its own service area. Since that time, Harnett County has been approved to obtain its own linear accelerator, and the remaining linear accelerators in Service Area 20 served a smaller population. According to Table 9I of the *2013 SMFP*, Service Area 20, then including Wake, Franklin and Harnett, had a population of 1,129,916 and nine linear accelerators. Table 17C-4 in the *Proposed 2023 SMFP* shows that Service Area 20 has a current population of 1,251,139 and is served by 11 linear accelerators. Thus, in nine years, Service Area 20’s population has increased by approximately 120,000 people but has two additional linear accelerators. In comparison, Service Area 7 (the Charlotte area) has a population of 1.4 million, is served by 11 linear accelerators (with one additional allocated in the *2022 SMFP*), and still has a surplus (beyond the allocation in the *2022 SMFP*). Service Area 20 may need another linear accelerator in the future, but even with the projected population for 2027 shown in the petition, the population per linear accelerator would still be just at 120,000 and capacity would likely still be available on the existing linear accelerators.

4. Changes in Service Delivery

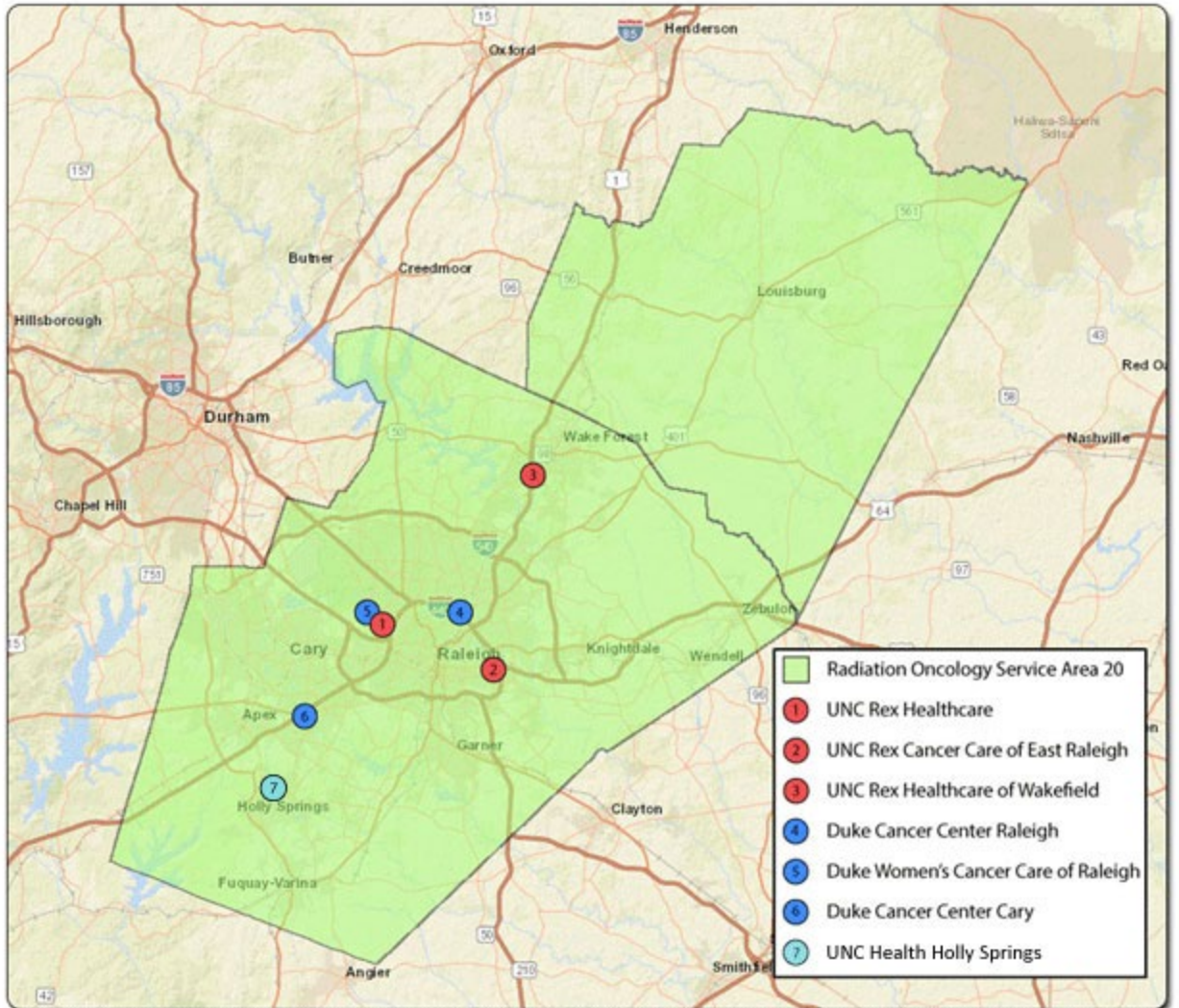
Another factor that impacts the need for linear accelerators is the way in which radiation therapy is delivered. While all providers may deliver care slightly differently, even for the same cancer site,

some radiation therapy providers have moved towards providing the needed dose of radiation in fewer treatments (fractions) or “hypofractionation.” Due in part to improvements in linear accelerator technology that allows more accurate radiation delivery, treatments with higher doses per day can be given without significantly increasing side effects. As a result, patients that used to have 25 or 30 fractions are treated in as few as 10 or 15, or even fewer. This trend has anecdotally accelerated due to the pandemic, since patients were reluctant to spend more time than necessary in public or in healthcare settings. Providers also wanted to deliver the necessary treatment to patients without subjecting them to increased risk of COVID-19 exposure that might occur with a standard number of treatments (i.e., standard approaches result in a higher number of visits to the facility). Therefore, while population growth and cancer rates may increase the number of patients needing radiation, the utilization of the machines at providers with higher rates of hypofractionation is not increasing as much. Thus, the need for additional capacity is diminished, despite the growth in patients, and this effect is shown in the standard methodology, which indicates a sufficient number of linear accelerators in the service area.

5. Geographic Distribution

The existing linear accelerators are also well distributed throughout Wake County. While the Franklin County linear accelerator was approved to be relocated, as mentioned above, the other 10 linear accelerators are located or under development in multiple locations across the county, as shown in the map below.

Existing/Approved Radiation Therapy Locations in Service Area 20



As shown, the existing linear accelerators are dispersed throughout the county, with one of UNC Health's linear accelerators located near WakeMed's main campus on New Bern Avenue. Thus, patients who present at WakeMed can receive radiation therapy at an existing facility right beside WakeMed, or at one of the many centers distributed throughout Service Area 20 (or elsewhere in the area; see section below on patient choice) that might be closer to their home.

6. Patient Choice

Despite the availability of linear accelerators across Wake County, many patients still choose to obtain radiation therapy in other counties. As shown by the patient origin reports from DHSR,⁴ nearly 24 percent of Wake County patients sought radiation therapy outside the county in FY

⁴ https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2022/27-PatientOrigin_Linac-2022.pdf

2021, mainly in Durham and Orange counties, where academic medical centers such as Duke and UNC Hospitals exist. Whether stemming from patients working in other counties and choosing sites closer to their place of employment, or whether patients facing a cancer diagnosis would rather travel out of their home county to nearby academic centers, the result is less demand for Wake County residents within Wake County. Conversely, as shown in Table 17C-5 of the *Proposed 2023 SMFP*, only 17.45 percent of patients treated on linear accelerators in the service area were from outside the service area. It is clear that another linear accelerator in Service Area 20 will not prevent patients from leaving the area for radiation if that is their preference, nor is it likely to provide increased access to patients from other service areas, given the already existing capacity of the linear accelerators in Service Area 20.

WakeMed also cites “transportation” as a key barrier to access, claiming that “availability and cost of transportation and distance and time traveled to care ‘limit access to necessary healthcare services.’” However, UNC REX is unaware of any existing linear accelerators in the service area that are not located within a short distance from public transportation stops, and, as noted above, UNC REX Cancer Care of East Raleigh is located less than one mile from WakeMed’s Raleigh campus.

7. Disparities/Care Fragmentation

UNC REX agrees that patients need continuity of care, and sometimes that continuity is optimally provided by offering services within the same health system. While the petition discusses disparities in cancer mortality rates, WakeMed’s petition fails to demonstrate that any cancer patients in the area are not receiving high quality care in a coordinated manner, much less that the lack of a linear accelerator operated by WakeMed is the reason for such disparities. As shown on page 3 of the petition, the difference in mortality rates is a statewide phenomenon, not limited to Wake County. The SHCC has previously attempted to address this issue by allocating a linear accelerator as a demonstration project to focus on enhancing access for African-American men with prostate cancer. While the demonstration project has officially concluded, the linear accelerator approved as part of the project is operating at UNC REX Cancer Care of East Raleigh, near WakeMed’s campus. While WakeMed notes that it has recruited a medical oncologist and is working to recruit more this year, WakeMed’s website and its medical staff roster still indicate that the majority of WakeMed’s hematologist/oncologists are Duke physicians, along with two independent physicians in Cary.⁵ Thus, many cancer patients being diagnosed at WakeMed are treated by a Duke physician; as such, it is unclear why WakeMed believes that it would be prudent to actually fragment the patients’ care by preventing them from also accessing Duke or other providers for their radiation treatments.

Moreover, WakeMed has historically chosen to align with Duke for oncology services. In 2017, WakeMed started a collaboration with Duke to provide cancer care, called Cancer Care+⁶. WakeMed’s own press release referred to this arrangement as:

⁵ WakeMed’s website lists the following non-WakeMed hematologist-oncologists on staff: Drs. James Smith, Sean Wang, Vijay Paryani, Neeraj Agrawal, Sundhar Ramalingam, Stacy Telloni, Xiang Wang, and Haley Moss, all with Duke; Dr. Mark Graham of Waverly Hematology/Oncology; and Dr. Amit Mehta of Premier Hematology.

⁶ <https://www.newsobserver.com/news/business/article145223679.html>

“a comprehensive, high-quality, fully integrated, value-based cancer care network – establishing a broad network of cancer care locations, enhancing access to oncology services and improving the coordination of cancer care for patients in Wake County.”⁷

Despite failing to address this issue in its 2021 petition or the current petition, WakeMed’s most recent audited financial statements for FY 2021 continue to refer to this arrangement and the positive benefit it was expected to have on the organization’s financial results.⁸ WakeMed’s public statements regarding its relationship with Duke clearly indicate that it believes high quality, integrated, value-based and coordinated care for cancer patients can be developed without WakeMed’s ownership of an additional linear accelerator in the service area. And since most of these patients are already treated by a Duke physician at a WakeMed facility, if they also receive radiation at a Duke facility, then they would seem to already be part of a “fully integrated, value-based cancer care network” as WakeMed has described.

SUMMARY

UNC REX supports the standard methodology for linear accelerators and believes that it correctly shows no need for additional capacity in Service Area 20 at this time. In short, nothing has fundamentally changed since 2021, when WakeMed also petitioned unsuccessfully for an additional linear accelerator in Service Area 20. While WakeMed has provided additional points to make its argument, those points fail to demonstrate that the allocation of another linear accelerator in the service area will positively impact these issues. Even if the Agency believes there is some merit in WakeMed’s position, the petition calls for a fundamentally different approach to the linear accelerator methodology, and as such, these changes should be considered in a broader context and are not reflective of a need particular to Service Area 20 that would justify a special needs adjustment.

In reaching the recommendation on the 2021 petition, the Agency’s analysis rested on three factors:

- The average number of procedures per linear accelerator in the service area were “well below the need determination threshold;”
- The number of linear accelerators in the service area were geographically dispersed, even when accounting for those not developed or non-operational;⁹
- The population of the service area had been relatively constant, with “not an influx of patients leaving or coming into the service area for treatments.”

In short, these factors analyzed by the Agency last year continue to be true for this petition, and nothing in WakeMed’s petition refutes the Agency’s analysis of the petition from 2021. UNC REX believes that the standard methodology continues to be sound, and appropriately reflects that there currently is no need for another linear accelerator in the service area. On this basis, the SHCC should deny WakeMed’s petition. Thank you.

⁷ <https://www.wakemed.org/about-us/news-and-media/wakemed-news-releases/wakemed-and-duke-announce-cancer-care-collaboration>

⁸ <https://emma.msrb.org/P11557371-P11202415-P11621234.pdf>

⁹ This included one linear accelerator at UNC Hospital-Holly Springs that was not yet developed, as well as a linear accelerator at the Franklin County Cancer Center that had not been operational since 2018 but is approved to be replaced at Duke Cancer Center Green Level.