

PETITION

Petition for an Adjusted Need Determination for One Linear Accelerator in Service Area 20 in the 2022 State Medical Facilities Plan

Petitioner

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Statement of Requested Adjustment

WakeMed respectfully petitions the State Health Coordinating Council (SHCC) to include an adjusted need determination for one linear accelerator in Service Area 20, which includes Wake and Franklin Counties, in the 2022 State Medical Facilities Plan (SMFP).

Executive Summary

The SMFP standard need methodology for linear accelerators calculates a surplus of accelerators in Service Area 20. This surplus is greatly overstated, as it includes two accelerators that are chronically underutilized and unfairly skew the need calculation. More importantly, the need formula does not account for the distribution of existing linear accelerators among Service Area 20 providers, where two academic health systems control all accelerators in the service area. WakeMed, the largest health system based in Wake County, has no linear accelerators. This concentration of linear accelerator services by academic health systems and resulting lack of capacity negatively impacts competition, continuity of care, access to care, and value, particularly as health care providers seek to employ cost containment measures such as population health management and value-based care. Population growth and aging in Service Area 20, combined with rising incidence of cancer, will exacerbate this problem going forward. The linear accelerator need methodology does not address these qualitative factors.

Reasons for the Requested Change

WakeMed believes that approval of this petition is justified by a number of mitigating factors, including:

1. Population growth and aging;
2. Inventory and utilization of existing linear accelerators in Service Area 20; and
3. Projected growth in cancer patients.

Population Growth and Aging in Service Area 20

Linear Accelerator Service Area 20 consists of Wake and Franklin Counties, both of which have experienced rapid population growth that is projected to continue well into the 2020s. Service Area 20 has the second highest total population among North Carolina’s linear accelerator service areas. According to data from the North Carolina Office of State Budget and Management (OSBM), the total population of Service Area 20 increased 9.7 percent between 2016-2020, and is projected to grow 9.2 percent from 2021-2026. Please see the tables below.

Table 1
Service Area 20 Total Population, 2015-2020

County	2015	2016	2017	2018	2019	2020	Percent Change 2015-20	CAGR% 2015-20	Numeric Change 2015-20
Franklin	64,079	65,292	66,632	68,032	70,157	71,196	11.1%	2.13%	7,117
Wake	1,005,995	1,028,364	1,049,711	1,068,112	1,085,297	1,102,782	9.6%	1.85%	96,787
Total Service Area 20	1,070,074	1,093,656	1,116,343	1,136,144	1,155,454	1,173,978	9.7%	1.87%	103,904

Source: NC OSBM, updated 2/18/2021

Table 2
Service Area 20 Total Population, 2021-2026

County	2021	2022	2023	2024	2025	2026	Percent Change 2021-26	CAGR% 2021-26	Numeric Change 2021-26
Franklin	72,032	73,238	74,390	75,539	76,685	77,831	8.1%	1.56%	5,799
Wake	1,117,556	1,137,863	1,158,291	1,178,919	1,199,735	1,220,683	9.2%	1.78%	103,127
Total Service Area 20	1,189,588	1,211,101	1,232,681	1,254,458	1,276,420	1,298,514	9.2%	1.77%	108,926

Source: NC OSBM, updated 2/18/2021

Service Area 20’s total population grew by over 103,000 residents between 2015-2020, an amount greater than the current population of 73 of North Carolina’s 100 counties, and is projected to increase by nearly 109,000 additional residents by 2026. In particular, Wake County is the state’s second most populous county, with an annual growth rate that is projected to remain strong into the future.

The population of Service Area 20 is also aging, with highest growth rates in the 65 and over age group. Please see the following table.

Table 3
Service Area 20 Population by County by Age Group, 2021 and 2026

Franklin County					
Age Group	2021 Population	2021 Percent of Total Population	2026 Population	2026 Percent of Total Population	Percent Change 2021-26
0-17	15,015	20.8%	15,374	19.8%	2.4%
18-44	23,748	33.0%	25,919	33.3%	9.1%
45-64	20,063	27.9%	20,445	26.3%	1.9%
65+	13,206	18.3%	16,093	20.7%	21.9%
Total	72,032	100.0%	77,831	100.0%	8.1%
Wake County					
Age Group	2021 Population	2021 Percent of Total Population	2026 Population	2026 Percent of Total Population	Percent Change 2021-26
0-17	251,713	22.5%	255,273	20.9%	1.4%
18-44	422,476	37.8%	454,621	37.2%	7.6%
45-64	300,101	26.9%	325,677	26.7%	8.5%
65+	143,266	12.8%	185,112	15.2%	29.2%
Total	1,117,556	100.0%	1,220,683	100.0%	9.2%
Total Service Area 20					
Age Group	2021 Population	2021 Percent of Total Population	2026 Population	2026 Percent of Total Population	Percent Change 2021-26
0-17	266,728	22.4%	270,647	20.8%	1.5%
18-44	446,224	37.5%	480,540	37.0%	7.7%
45-64	320,164	26.9%	346,122	26.7%	8.1%
65+	156,472	13.2%	201,205	15.5%	28.6%
Total	1,189,588	100.0%	1,298,514	100.0%	9.2%

Source: NC OSBM, updated 2/18/2021

In both Franklin and Wake Counties, the 65+ age group is the fastest-growing cohort, both in total population and in percent of total. In Franklin County, the 65+ age group population is projected to grow by nearly 22 percent, increasing to 20.3 percent of total by 2026. Wake County's 65+ age group is projected to increase by nearly 30 percent, and will represent over 15 percent of the population by 2026. The increase in population of older adults is important, because cancer incidence tends to increase with aging. According to the National Cancer Institute, the median age for cancer diagnosis is 66. Approximately 60 percent of cancer patients are age 65 or older. A growing and aging population is likely to experience a greater incidence of cancer cases.

Existing Linear Accelerators in Service Area 20

There are currently 11 linear accelerators located in Service Area 20, as shown in the table below.

Table 4
Linear Accelerator Inventory in Service Area 20

Facility	County	Number of Linear Accelerators
Franklin County Cancer Center	Franklin	1
Duke Raleigh Hospital	Wake	4
UNC Rex Hospital	Wake	4
UNC Hospital Radiation Oncology - Holly Springs	Wake	1
UNC-Rex Cancer Care of East Raleigh#	Wake	1
Total		11

- formerly the Prostate Health Center Demonstration Project
 Source: Proposed 2022 SMFP, page 327

Two of the 11 linear accelerators located in the Service Area, Franklin County Cancer Center and UNC Hospital Radiation Oncology-Holly Springs, have had very low/no procedure volume over the last several years. Franklin County Cancer Center has never reported more than 33 procedures in a single year (and the unit there has sat idle since 2018), and UNC Radiation Oncology-Holly Springs has yet to open. Please see the following table.

Table 5
Service Area 20 Linear Accelerator Utilization (ESTV Procedures)

Facility	2015	2016	2017	2018	2019	2020
Franklin County Cancer Center	15	13	8	33	0	0
Duke Raleigh Hospital	17,963	17,633	18,146	19,929	21,286	19,985
UNC Rex Hospital	19,983	22,699	24,281	22,514	22,493	22,858
UNC Hospital Radiation Oncology - Holly Springs	0	0	0	0	0	0
UNC-Rex Cancer Care of East Raleigh#	0	0	275	5,370	3,764	3,443
Total Service Area 20	37,961	40,345	42,710	47,846	47,543	46,286

- 2015-2017 volumes associated with Demonstration Project not counted in SMFPs.
 Source: 2017-2021 SMFPs, and Proposed 2022 SMFP

Table 5 shows that, despite very low/no utilization of two accelerators in the Service Area, overall procedure volume increased 21.9 percent during the period 2015-2020. If 2020 volumes are not considered due to the impact of the COVID-19 pandemic, utilization increased 25.2 percent between 2015-2019.

According to Table 17C-5 in the Proposed 2022 SMFP, Service Area 20 has a calculated surplus of 4.14 linear accelerators, with average utilization of 4,208 ESTV procedures per accelerator. However, because two linear accelerators have been chronically underutilized, WakeMed believes this surplus is greatly overstated. The table below shows linear accelerator need in Service Area 20 if the two underutilized accelerators are removed from the methodology calculation.

Table 6
Linear Accelerator Need in Service Area 20
Showing Impact of Removing Underutilized Accelerators from Need Calculation

	2021 Service Area Population	Number of Accelerators	Population within Service Area per Accelerator	Percentage of Patients from Outside Service Area	2019-2020 Total ESTV Procedures	Procedures per Accelerator	ESTV Procedures Divided by 6750 Minus # Accelerators
Proposed 2022 SMFP, p. 334	1,189,588	11	108,144	14.79%	46,286	4,280	-4.14
Modified to Exclude Underutilized Accelerators	1,189,588	9	132,176	14.79%	46,286	5,143	-2.14

The table above shows that if the two underutilized linear accelerators are removed from the denominator, the calculated surplus of accelerators in Service Area 20 is approximately one-half that shown by the standard need methodology, with an average of 5,143 ESTVs per unit, 22 percent higher than if all 11 accelerators are included. Additionally, this recalculated surplus ignores the fact that all linear accelerators in the Service Area are concentrated within two provider systems, and the impact that this fact has on patient access, continuity of care, and population health management.

Projected Increase in Cancer Diagnoses

According to the North Carolina Central Cancer Registry (NCCCR), both Franklin and Wake Counties have cancer incidence rates higher than the State average.

Table 7
Cancer Incidence in Service Area 20 Counties and North Carolina, 2018

	2018 Total Cases	2018 Incidence Rate per 100,000 Population
Franklin County	444	508.5
Wake County	5,269	480.8
North Carolina	60,024	471.6

Source: N.C. Central Cancer Registry, accessed at: <https://schs.dph.ncdhhs.gov/data/cancer/incidence/2018.htm>

The NCCCR projects 5,944 new cancer cases in Wake County in 2021, a 13 percent increase over 2018, and 465 new cases in Franklin County in 2021¹, which represents a 5 percent increase from 2018. The Advisory Board Company, using National Cancer Institute SEER cancer rates and population growth estimates, indicates that overall cancer incidence in Wake and Franklin Counties is projected to grow 25.4 percent from 2019-2024, and 52.9 percent from 2019-2029.

¹ Projected New Cancer Cases and Deaths for Selected Sites by County, 2021, produced by the North Carolina Central Cancer Registry, accessed at: <https://schs.dph.ncdhhs.gov/schs/CCR/ProjectionsByCountyFinal-2021.pdf>.

Growth in cancer incidence is expected to drive growth in radiation therapy procedures. Data from The Advisory Board Company indicates that radiation therapy utilization in Service Area 20 is projected to increase 11.1 percent between 2020-2025 and by 26.3 percent from 2020-2030.

Impact if Petition Not Approved

Adverse Effects on Population

Approval of this petition would have no adverse effects on the population of Service Area 20, and would greatly improve continuity of care for Oncology patients. Increasing the linear accelerator inventory in Service Area 20 from 11 to 12 units would increase total capacity by only 9 percent.

If this petition is not approved, there may be significant negative impact on patient seeking radiation therapy. All linear accelerators located in Service Area 20 are owned by two academic health systems. This concentration of resources is contrary to the stated purpose of the CON Statute, which includes addressing maldistribution of health services, enhancing competition, and ensuring equal access to all population groups. Persons requiring radiation therapy who are not patients at either of these two systems, including the many patients who seek care at safety net hospitals, face obstacles in access to care and in the continuity of their care.

Alternatives to This Petition

The only alternative to this request would be to maintain the status quo, and to wait for linear accelerator procedure volumes to increase to a level where the methodology will trigger need for an additional accelerator in the service area. Per the Proposed 2022 SMFP, Service Area 20 facilities reported an average of 4,280 ESTV procedures per accelerator in 2020, well below the volume threshold required to generate a need determination using the standard need methodology. As shown in Table 6 above, excluding the underutilized units would increase utilization to 5,143 ESTV procedures per accelerator. However, the need for an additional linear accelerator cannot be evaluated only through the quantitative calculation.

Evidence of No Unnecessary Duplication

The approval of this Petition would not result in unnecessary duplication. At least two linear accelerators in Service Area 20 have had very little/no historical utilization in recent years, which suppresses need and precludes an allocation using the standard need methodology in SMFP Chapter 17. Projected population growth in Service Area 20, as well as projected growth in Oncology services over the next decade, suggest the need for additional radiation therapy resources.

Consistency with Basic Principles of the SMFP

Safety and Quality

Radiation therapy, along with medical oncology (chemotherapy and immunotherapy) and surgery, form the three pillars of cancer treatment. Used to treat most forms of cancer, more than one-half of all

cancer patients will receive radiation therapy during their course of illness.² Radiation therapy has become a standard of care in the treatment of cancer.

WakeMed routinely treats over 2,000 patients with a cancer diagnosis each year, with a significant proportion being Medicaid and Self-Pay/Charity patients. Many WakeMed cancer patients are diagnosed at the time of an emergency department visit, at which point their cancer may already be advanced. Like all cancer patients, they face a regimen that will require one or more modalities of cancer treatment to maximize the probability of a cure.

As the only health system based in Wake County without a linear accelerator, WakeMed's cancer patients must seek radiation therapy care at other facilities. This gap in care, manifested through various delays in treatment, disrupts the continuity of care. Patients must be directed to other health care systems for radiation therapy, requiring referrals to physicians outside the WakeMed system, transfers to another facility, and scheduling of procedures. For patients already faced with the inherent uncertainty that accompanies a cancer diagnosis, this discontinuity of care can prove even more daunting. For low-income patients who have historically struggled to access care, being forced to leave their provider of choice, navigate the referral and insurance systems, and obtain transportation while fighting cancer creates real, significant financial and emotional difficulties and delays in care.

WakeMed physicians and staff work diligently to improve the systems of care by developing a continuum of care that will allow patients to be treated within the WakeMed system. Conversely, radiation therapy services provided at a facility in a different system cannot provide a seamless continuum of care for the patient. WakeMed's inability to obtain a linear accelerator through the certificate of need process or through the open market will have a detrimental effect on its cancer patients who require radiation therapy by delaying care, causing unnecessary patient transfers, and increasing cost, ultimately costing patients valuable time against a disease where treatment is critically time-sensitive.

Approval of this proposed adjusted need determination will result in improved patient safety and quality.

Access

Additional linear accelerator capacity is needed in Service Area 20 to provide sufficient access to radiation therapy care for WakeMed's patients, and to meet the projected growth in service area population described above. WakeMed is the largest health system in Wake County and its acute care hospitals, ambulatory surgical centers and outpatient facilities are based almost exclusively in Wake County, yet WakeMed's cancer patients must seek radiation therapy treatment at facilities owned by other health care systems. Currently, the UNC Health and Duke Health systems control 100 percent of the existing linear accelerators in Service Area 20³. Patients presenting to WakeMed with a cancer diagnosis must seek radiation therapy at facilities outside the WakeMed system. This creates

² "Radiation Therapy and You: Support for People with Cancer", published by the National Cancer Institute, accessed at: <https://www.cancer.gov/publications/patient-education/radiationtherapy.pdf>.

³ With the approval of CON Project No. J-12000-20, Franklin County Cancer Center's linear accelerator is slated to be acquired by Duke Health System, replaced, and relocated to Wake County.

disruptions in the continuity of care for a service where patients typically must undergo a regimen of radiation therapy procedures, and where timeliness of treatment is essential.

Approval of this petition will provide an opportunity for WakeMed to apply for linear accelerator capacity that will improve access to care for residents of Wake and surrounding counties by eliminating barriers and hardships associated with changing medical providers.

Value

Approval of this petition will enhance value by creating additional linear accelerator capacity in Service Area 20, ensuring that patients will have uninterrupted treatment by obtaining radiation therapy care in a timely manner. Patients who seek cancer care at WakeMed must now be referred to non-WakeMed providers for radiation therapy, which is neither operationally efficient nor cost effective. An additional provider of linear accelerator care in Service Area 20 will enhance competition.

As North Carolina and the nation continue to move toward implementation of population health management, value-based care, and whole-person care, it is imperative that health systems have the necessary diagnostic and therapeutic tools, which are now standard-of-care, to effectively treat patients in a cost-effective manner. Health systems must have a full continuum of care to treat and manage all aspects of disease. Third-party payers, including Medicaid, seek to contract with providers that can control costs while ensuring high quality care. When patients must access care through different health systems, health care costs cannot be monitored or controlled effectively. The linear accelerator need methodology does not address this “qualitative” aspect of care provision.

Summary

Based on the information provided above, WakeMed believes that approval of this petition, to add an adjusted need determination for one linear accelerator in Service Area 20, is in the best interest of the residents of Wake and Franklin Counties. The Service Area’s calculated surplus of linear accelerators in the Proposed 2022 SMFP is overstated, but more importantly does not address the maldistribution of radiation therapy resources and its negative impact on quality, safety, access, and value. WakeMed appreciates the SHCC’s thoughtful consideration of this request and urges its approval.