

PETITION

Petition for an Adjusted Need Determination for One Linear Accelerator in Service Area 20 in the 2023 State Medical Facilities Plan

Petitioner

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Statement of Proposed Change

WakeMed Health & Hospitals (WakeMed) respectfully petitions the State Health Coordinating Council (SHCC) to include an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP) for one linear accelerator in Service Area 20, which includes Wake and Franklin Counties.

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 chronically underutilized accelerators, which unfairly skews the need calculation. More importantly, the need formula does not account for access disparities in the service area and the resulting impact on minority and economically vulnerable populations. The distribution of existing linear accelerators among Service Area 20 providers is completely controlled by two academic health systems. WakeMed, the largest health system based in Wake County, has no linear accelerator despite caring for a significantly larger portion of Wake County's historically underserved population.

Due to the need for greater access to cancer treatment services in the area, WakeMed has developed a Medical Oncology program. Without a linear accelerator, however, WakeMed is unable to deliver fully integrated and comprehensive cancer treatment within the system, resulting in more fragmented care, a worse and more confusing patient experience, and less access to currently underserved populations. This is especially troubling given the high percentage of WakeMed cancer patients who are uninsured, Medicaid beneficiaries, or members of other traditionally underserved groups, and the documented issues these patients have in accessing timely cancer care, including radiation therapy. As evidence of this last fact, WakeMed cites in this petition statistics that indicate a significant difference between time to oncology appointment for Commercial versus Medicaid versus uninsured patients.

Unfortunately, the concentration of linear accelerators in Wake and Franklin County held only by Duke and UNC creates a lack of prompt access to care for those that are uninsured or underinsured. This lack of access negatively impacts continuity of care, value, and competition, 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 and therefore does not accurately reflect the true need for radiation therapy services among North Carolinians in Service Area 20.

Reasons for the Requested Change

As currently applied, the standard need methodology in the SMFP does not reflect the actual need for linear accelerator services among residents of Service Area 20, particularly those residents who are Medicaid beneficiaries, uninsured, underinsured, or members of historically underserved groups. WakeMed believes that approval of this petition is justified by a number of mitigating factors, including:

1. Disparity in access to cancer care;
2. Development 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;
3. Population growth and aging;
4. Projected growth in cancer patients; and
5. Inventory and utilization of existing linear accelerators in Service Area 20.

Disparities in Cancer Care

According to the NCI's Center to Reduce Health Care Disparities, "the burden of cancer is too often greater for the poor, ethnic minorities, and the uninsured than for the general population. Many ethnic minorities develop cancer more frequently than the majority of the US white population." Masses of reliable data illustrate that members of those minority groups not only develop cancer disproportionately, they also do far worse with regard to accessing quality care and surviving the disease. The data also support the role of poverty and poor education as being highly predictive for the disproportionate development of cancer and for worse outcomes. The following charts show cancer mortality trends by race/ethnicity and gender for North Carolina and Wake County residents.

**2020 NORTH CAROLINA CANCER MORTALITY BY RACE
PER 100,000 POPULATION
AGE-ADJUSTED TO THE 2000 U.S. STANDARD POPULATION**

Site	All Whites		All Minorities		Total	
	Deaths	Rate	Deaths	Rate	Deaths	Rate
Oral Cavity	323	3.0	86	2.7	409	3.0
Esophagus	371	3.5	83	2.6	454	3.3
Stomach	206	2.0	147	5.2	353	2.7
Colon/Rectum	1,193	11.7	393	13.4	1,586	12.1
Liver	702	6.4	251	8.0	953	6.8
Gallbladder	55	0.5	28	1.0	83	0.6
Pancreas	1,127	10.5	391	13.1	1,518	11.0
Larynx	125	1.1	40	1.2	165	1.2
Lung/Bronchus	4,018	36.7	1,001	33.4	5,019	36
Bone	44	0.5	14	**	58	0.5
Soft Tissue	115	1.2	50	1.7	165	1.3
Melanoma (Skin)	257	2.5	9	**	266	2.0
Female Breast	994	17.5	401	23.9	1,395	19.3
Cervix Uteri	70	1.4	54	3.2	124	1.9
Corpus Uteri	239	4.0	169	9.7	408	5.2
Ovary	297	5.1	86	5.2	383	5.2
Prostate	762	17.4	323	31.5	1,085	20
Testes	9	**	3	**	12	**
Bladder	437	4.2	83	3.1	520	4.0
Kidney	367	3.5	102	3.6	469	3.5
Endocrine	54	0.6	30	1.0	84	0.7
Multiple Myeloma	245	2.3	151	5.4	396	3.0
Leukemia	587	5.7	126	4.4	713	5.5
Brain & Other CNS	420	4.2	97	3.2	517	4.0
Hodgkins Disease	19	0.2	4	**	23	0.2
Non-Hodgkins Lymphoma	519	4.9	109	3.8	628	4.7
Other Cancers	1,735	16.4	497	17.3	2,232	16.7
All Cancers	15,290	144.1	4,728	161.4	20,018	148.4

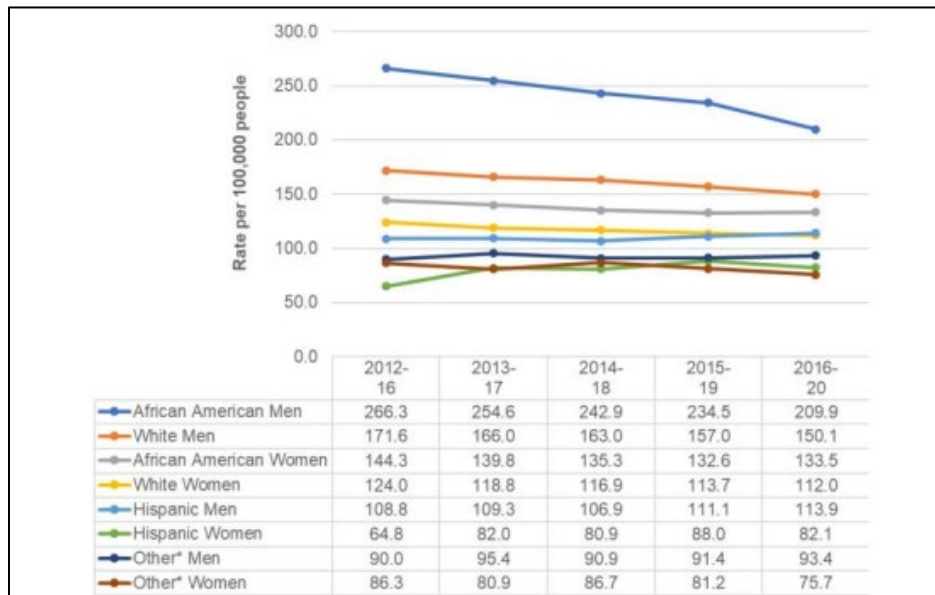
Produced by the NC Central Cancer Registry, 02/2022.

**Cancer mortality rates based on any cancer deaths less than 16 are suppressed as they are not stable.

Cases may not sum to totals due to unknown or other values.

Rates are calculated using the bridged-race population estimates obtained from the National Center for Health Statistics available online at www.cdc.gov/nchs/nvss/bridged_race/data_documentation.htm#vintage2020.

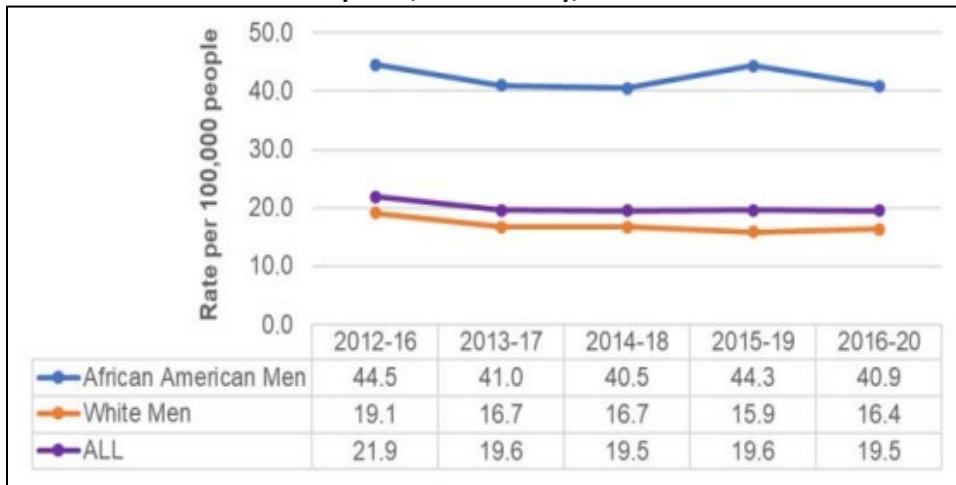
All Cancer Mortality Rates by Race/Ethnicity and Gender, Wake County, 5-Year Trend



*"Other" includes Asian and Pacific Islander but excludes Hispanic and American Indian (the number of American Indian deaths was too small to calculate a rate).

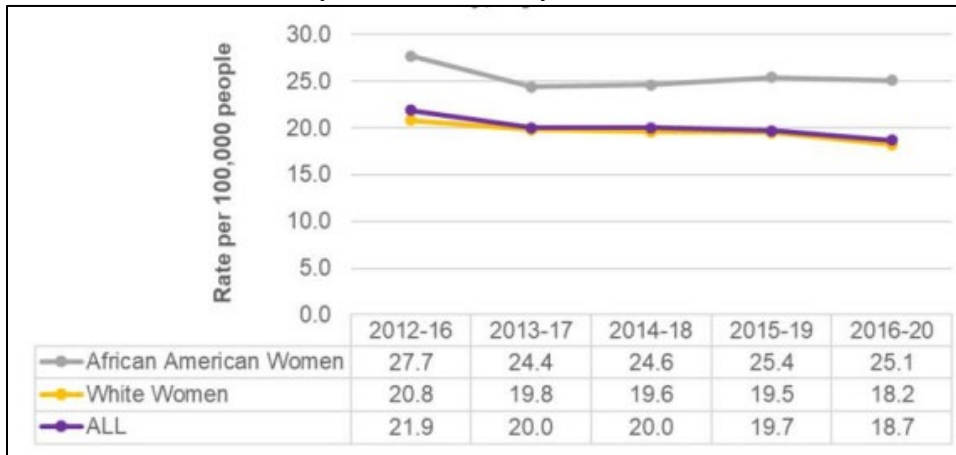
Source: Wake County Health and Human Services Public Health Report, Chronic Disease 2021, Source: 2020-MortalityRatesFinalForWebsite-Race.pdf (ncdhhs.gov)

Prostate Cancer Death Rates by Race, Wake County, 5-Year Trend



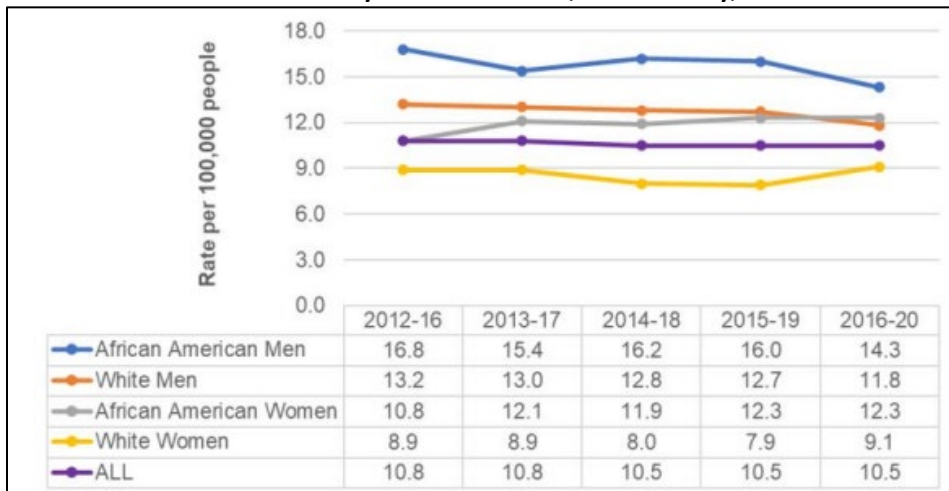
Source: Wake County Health and Human Services Public Health Report, Chronic Disease 2021

Breast Cancer Death Rates by Race, Wake County, 5-Year Trend



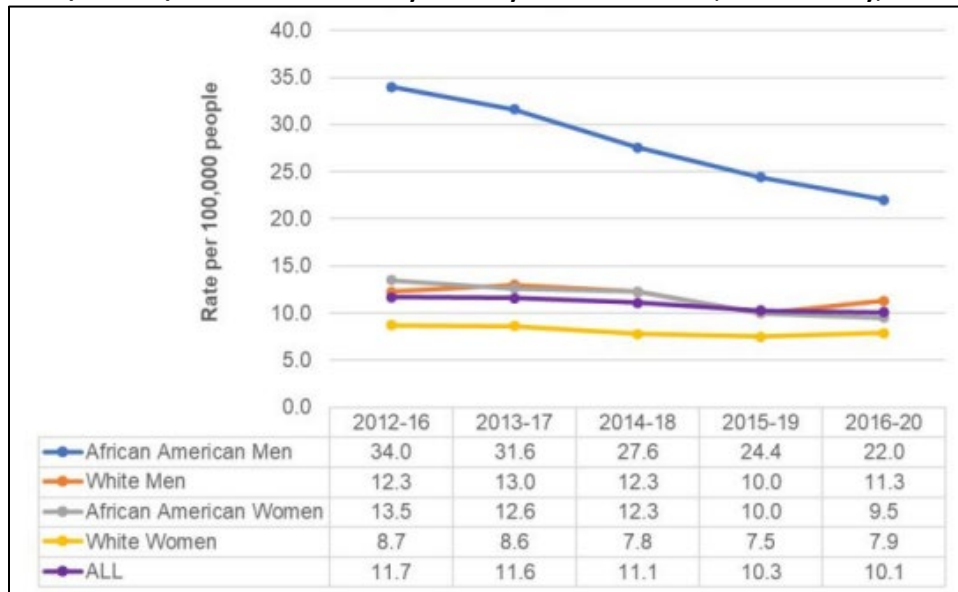
Source: Wake County Health and Human Services Public Health Report, Chronic Disease 2021

Pancreatic Cancer Death Rates by Race and Gender, Wake County, 5-Year Trend



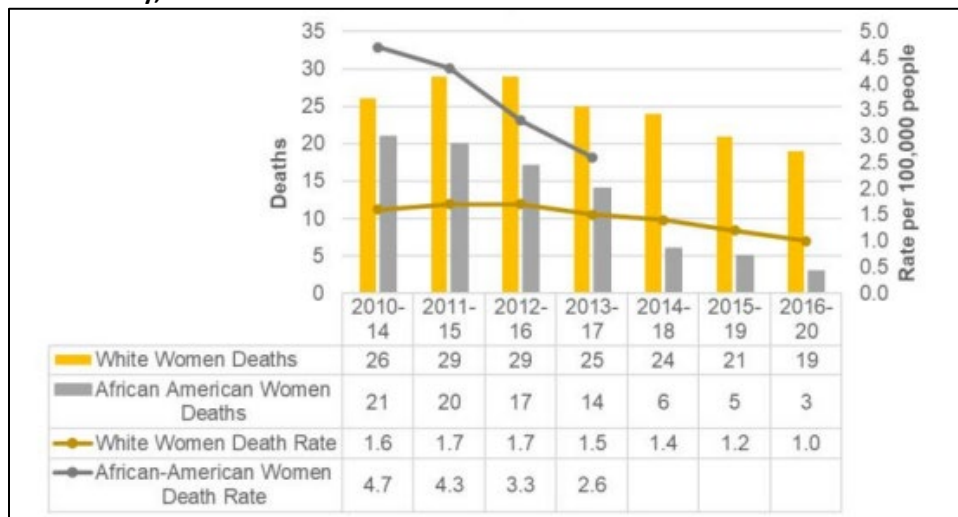
Source: Wake County Health and Human Services Public Health Report, Chronic Disease 2021

Colon/Rectum/Anal Cancer Mortality Rates by Race and Gender, Wake County, 5-Year Trend



Source: Wake County Health and Human Services Public Health Report, Chronic Disease 2021

Cervical Cancer Deaths and Death Rate Comparison, White vs. African American, Wake County, 7-Year Trend



Source: Wake County Health and Human Services Public Health Report, Chronic Disease 2021

Racial disparities in cancer outcomes may occur as the result of differences in social determinants of health (SDoH), comorbidities, and severity of disease presentation with marginalized patient population presenting with advanced stage cancer, treatment, and biological factors including unidentified or underrecognized genetic alterations (or genetic polymorphisms).¹

¹ Manz, Christopher R, Schrag D, Racial Disparities in Colorectal Cancer Recurrence and Mortality: Equitable Care, Inequitable Outcomes?, JNCI: Journal of the National Cancer Institute, 2021;113:(6):656–657. doi:10.1093/jnci/djaa186

To truly ensure proper access for patients, we must define “access” more broadly than simply having X pieces of equipment in Y area. For example, key barriers to access to effective cancer care include:

- **Transportation:** Because of the need for repeated visits for cancer treatment on either an outpatient or an inpatient basis, one of the major issues that patients with cancer must confront is that of arranging for transportation to care. A review of available literature indicates that availability and cost of transportation and distance and time traveled to care “limit access to necessary healthcare services and contribute to suboptimal clinical outcomes across the cancer care continuum.”² Studies show an association between transportation barriers and diagnosis of advanced disease, as well as decreased likelihood of receiving specialist care or adhering to recommended treatment.^{3,4,5,6,7} This in turn contributes to shortened survival and impaired quality of life.^{8,9} The issue is especially acute for older adults, patients living in rural areas, persons of color, those of lower socioeconomic status, and individuals with limited social support.^{3,4,6,7,8,9,10,10,11,12,13}

The Journal of the American Medical Association reported on a 2022 study that identified barriers to transport that can impact patients’ ability to access needed cancer care. Specific barriers identified in the study included difficulties in arranging for and paying for transportation, as well as a lack of reliable transportation. An inability to access reliable, cost-efficient transportation can

² Jazowski et al. Transportation as a barrier to colorectal cancer care. *BMC Health Services Research*. (2021) 21:332

³ Ambroggi M, Biasini C, Del Giovane C, Fornari F, Cavanna L. Distance as a barrier to cancer diagnosis and treatment: review of the literature. *Oncologist*. 2015;20(12):1378–1385. doi: 10.1634/theoncologist.2015-0110.

⁴ Thomas AA, Gallagher P, O’Ceilleachair A, Pearce A, Sharp L, Molcho M. Distance from treating hospital and colorectal cancer survivors’ quality of life: a gendered analysis. *Support Care Cancer*. 2015;23(3):741–751. doi: 10.1007/s00520-014-2407-9.

⁵ Fazio L, Cotterchio M, Manno M, McLaughlin J, Gallinger S. Association between colonic screening, subject characteristics, and stage of colorectal cancer. *Am J Gastroenterol*. 2005;100(11):2531–2539. doi: 10.1111/j.1572-0241.2005.00319.x.

⁶ Campbell NC, Elliott AM, Sharp L, Ritchie LD, Cassidy J, Little J. Impact of deprivation and rural residence on treatment of colorectal and lung cancer. *Br J Cancer*. 2002;87(6):585–590. doi: 10.1038/sj.bjc.6600515.

⁷ Sacerdote C, Baldi I, Bertetto O, Dicuonzo D, Farina E, Pagano E, et al. Hospital factors and patient characteristics in the treatment of colorectal cancer: a population based study. *BMC Public Health*. 2012;12(1):775. doi: 10.1186/1471-2458-12-775.

⁸ Cramb SM, Mengersen KL, Turrell G, Baade PD. Spatial inequalities in colorectal and breast cancer survival: premature deaths and associated factors. *Health Place*. 2012;18(6):1412–1421. doi: 10.1016/j.healthplace.2012.07.006.

⁹ Sineshaw HM, Robbins AS, Jemal A. Disparities in survival improvement for metastatic colorectal cancer by race/ethnicity and age in the United States. *Cancer Causes Control*. 2014;5(4):419–423. doi: 10.1007/s10552-014-0344-z.

¹⁰ Goins RT, Williams KA, Carter MW, Spencer M, Solovieva T. Perceived barriers to health care access among rural older adults: a qualitative study. *J Rural Health*. 2005;21(3):206–213. doi: 10.1111/j.1748-0361.2005.tb00084.x.

¹¹ Syed ST, Gerber BS, Sharp LK. Traveling towards disease: transportation barriers to health care access. *J Community Health*. 2013;38(5):976–993. doi: 10.1007/s10900-013-9681-1.

¹² Zullig LL, Jackson GL, Provenzale D, Griffin JM, Phelan S, van Ryn M. Transportation: a vehicle or roadblock to cancer care for VA patients with colorectal cancer? *Clin Colorectal Cancer*. 2012;11(1):60–65. doi: 10.1016/j.clcc.2011.05.001.

¹³ Guidry JJ, Aday La, Zhang D, Winn RJ. Transportation as a barrier to cancer treatment. *Cancer Pract*. 1997;5(6):361–366.

have significant consequences for cancer patients and may leave patients unable to timely access necessary treatment.^{14,15}

Having difficulty getting to important appointments can have significant consequences, including delay in receiving necessary treatment as soon as possible. Missing ongoing treatments can also lead to new or worsening health problems and can result in a need for emergency care or hospitalization.

- **Care Fragmentation:** Even when a linear accelerator is located within a relatively close geographic distance to a patient's oncologist, fragmentation of care occurs when a patient must visit different providers to receive surgical oncology, medical oncology, and radiation oncology services. Studies show fragmented care is associated with inferior outcomes, including increased time to treatment, increased cost, inferior treatment decisions and reduction in survival when compared to care delivered by a single institution.^{16,17,18} Care fragmentation increases time to treatment as it is more difficult for providers to coordinate their services and share necessary clinical information about the patient. Providing comprehensive care to the patient across the care continuum ensures prompt follow-up, encourages providers to consult together on a plan of care for the patient, and provides ease of access to the patient.

As discussed below, the delay caused by care fragmentation is exacerbated for individuals who fall in traditionally underserved groups. WakeMed's internal data indicates our uninsured and Medicaid cancer patients wait on average 52 days longer and 19.2 days longer, respectively, to receive oncology care than our patients with commercial insurance. This delay is simply unacceptable. Given the importance of timely radiation therapy treatment to patient outcomes, WakeMed 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 a safety net disproportionate share care provider, WakeMed provides the majority of care to patients from minority and historically underserved communities who are most negatively impacted by lack of access to comprehensive cancer care.

¹⁴ Jiang C, Yabroff KR, Deng L, et al. Self-reported Transportation Barriers to Health Care Among US Cancer Survivors. *JAMA Oncol.* 2022;e220143.doi:10.1001/jamaoncol.2022.0143

¹⁵ Chaiyachati KH, Hubbard RA, Yeager A, et al. Association of Rideshare-Based Transportation Services and Missed Primary Care Appointments: A Clinical Trial. *JAMA Intern Med.* 2018;178(3):383-389. doi:10.1001/jamainternmed.2017.8336.

¹⁶ Hester, Caitlin A., et al. "Effect of fragmentation of cancer care on treatment use and survival in hepatocellular carcinoma." *Cancer* 125.19 (2019): 3428-3436.

¹⁷ Rhodin, Kristen E., et al. "Patterns and impact of fragmented care in stage II and III gastric cancer." *Annals of surgical oncology* (2022): 1-10.

¹⁸ Abelson, Jonathan S., et al. "Fragmented care in the treatment of rectal cancer and time to definitive therapy." *Journal of the American College of Surgeons* 232.1 (2021): 27-33.

Patient Race as Percent of Total System Encounters, Wake & Franklin County Patients

Fiscal Year	Patient Race	Health System			
		Duke	UNC	WakeMed	Other
2021	Caucasian	62.7%	62.4%	49.2%	58.9%
	Minority Race	33.3%	34.7%	47.0%	37.0%
	Unknown	4.1%	3.0%	3.9%	4.2%
2020	Caucasian	62.5%	62.7%	48.1%	57.2%
	Minority Race	34.6%	34.0%	48.1%	39.4%
	Unknown	2.9%	3.3%	3.8%	3.4%
2019	Caucasian	62.2%	64.7%	48.2%	62.5%
	Minority Race	34.7%	32.5%	48.4%	31.9%
	Unknown	3.1%	2.8%	3.4%	5.6%
2018	Caucasian	62.7%	65.4%	48.9%	66.8%
	Minority Race	34.4%	31.6%	48.0%	29.2%
	Unknown	2.9%	3.0%	3.1%	3.9%
2017	Caucasian	62.8%	65.1%	48.9%	67.4%
	Minority Race	34.5%	31.6%	48.5%	26.3%
	Unknown	2.7%	3.3%	2.6%	6.3%

Source: HIDI/N.C. Patient Data System

WakeMed’s internal data shows a significant difference in the average days to appointment for patients referred out for Oncology care, depending on their payor status. Patients who have no insurance, Medicare, or Medicaid must wait two to three times longer for care compared to patients with commercial insurance. For example, patients with commercial insurance are seen, on average, 52 days sooner than patients who are uninsured, 24.5 days sooner than Medicare patients, and 19.2 days sooner than patients with Medicaid. As discussed above, delays in care would translated into higher burden of cancer, sicker patients and worse cancer-specific and overall health outcomes.

Average Days to External Oncology Appointment by Insurance Category

Payor Category	Average Days to Appointment
Commercial	15.8
Medicaid	35.0
Medicare	40.3
Other	41.5
Uninsured	67.9

WakeMed Internal Data, May 2021-April 2022

This significant delay in care for uninsured patients occurs despite the fact that the SMFP currently shows a surplus of linear accelerators in the Service Area – further evidence that the need for radiation therapy of cancer patients in the service area is not being met.

Development of Medical Oncology Services at WakeMed

Long a leader in providing care to medically underserved groups, WakeMed treats a significant number of cancer patients each year and has witnessed the barriers many of these patients face in obtaining prompt access to necessary cancer treatment services. In early 2022, WakeMed formally announced the establishment of its Medical Oncology services under the medical direction of Vijay Chaudhary, MD, MPH, MBA, a board-certified hematology and oncology physician with 14 years’ experience in providing evaluation and management of cancer patients. The new program is designed to complement

WakeMed’s existing imaging, pathology, surgical, and procedural services currently provided in a vast array of clinical specialties, including Breast, Thoracic, Urologic, Gastrointestinal, Colorectal, Head and Neck, and Skull Base Surgery. Two additional physicians will join the program in summer 2022, with a fourth oncologist anticipated to join the team in the fall. Cancer patients will receive care coordinated by oncology nurse navigators along with supportive care provided by dietitians, cancer genetic counselors, financial navigators, social workers, occupation/rehabilitation therapists, behavioral health therapists, and oncology-certified nurses.

While the development of the Medical Oncology program will assist many of WakeMed’s patients, the addition of radiation therapy would ensure that these patients have access to seamless, comprehensive cancer services.

Service Area 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 of 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 10.1 percent between 2017-2022 and is projected to grow 11.0 percent from 2022-2027. Please see the table below.

Service Area 20 Total Population, 2017, 2022 & 2027

County	2017	2022	Percent Change, 2017-22	CAGR% 2017-22	2027	Percent Change, 2022-27	CAGR% 2022-27
Franklin	64,554	72,018	11.6%	2.21%	80,278	11.5%	2.20%
Wake	1,071,499	1,179,121	10.0%	1.93%	1,308,878	11.0%	2.11%
Total	1,136,053	1,251,139	10.1%	1.95%	1,389,156	11.0%	2.11%

Source: NC OSBM

Service Area 20’s total population grew by over 115,000 residents between 2017-2022, an amount greater than the current population of 75 of North Carolina’s 100 counties, and is projected to increase by approximately 118,000 residents by 2027. Wake County is North Carolina’s most populous county, with an annual growth rate projected to remain strong well into the future.

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

Service Area Population by County by Age Group, 2022 and 2027

Franklin County					
Age Group	2022	2022 Percent of Total Population	2027	2027 Percent of Total Population	Percent Change 2022-27
0-17	14,836	20.6%	15,788	19.7%	6.4%
18-44	23,785	33.0%	26,675	33.2%	12.2%
45-64	19,971	27.7%	21,036	26.2%	5.3%
65+	13,426	18.6%	16,779	20.9%	25.0%
Total	72,018	100.0%	80,278	100.0%	11.5%
Wake County					
Age Group	2022	2022 Percent of Total Population	2027	2027 Percent of Total Population	Percent Change 2022-27
0-17	253,315	21.5%	260,557	19.9%	2.9%
18-44	457,359	38.8%	500,282	38.2%	9.4%
45-64	314,935	26.7%	349,761	26.7%	11.1%
65+	153,512	13.0%	198,278	15.1%	29.2%
Total	1,179,121	100.0%	1,308,878	100.0%	11.0%
Total Population					
Age Group	2022	2022 Percent of Total Population	2027	2027 Percent of Total Population	Percent Change 2022-27
0-17	268,151	21.4%	276,345	19.9%	3.1%
18-44	481,144	38.5%	526,957	37.9%	9.5%
45-64	334,906	26.8%	370,797	26.7%	10.7%
65+	166,938	13.3%	215,057	15.5%	28.8%
Total	1,251,139	100.0%	1,389,156	100.0%	11.0%

Source: NC OSBM

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 25 percent, increasing to 20.9 percent of total by 2027. Wake County’s 65+ age group is projected to increase by nearly 30 percent and will represent over 15 percent of the population by 2027. The increase in population of older adults is significant, because cancer diagnoses tend to increase with age. 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 and have a greater need for comprehensive cancer care that includes surgical oncology, medical oncology, and radiation oncology.

Existing Linear Accelerators in Service Area 20

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

Linear Accelerator Inventory in Service Area 20

Facility	County	Number of Linear Accelerators
Franklin County Cancer Center ¹⁹	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 2023 SMFP, page 317

Two of the 11 linear accelerators located in Service Area 20, Franklin County Cancer Center and UNC Hospital Radiation Oncology-Holly Springs, have had little or no procedure volume over the last several years. Franklin County Cancer Center has never reported more than 33 procedures in a given year, and UNC Radiation Oncology-Holly Springs has yet to open. Please see the following table.

Service Area 20 Linear Accelerator Utilization (ESTV Procedures), 2015-2021

Facility	2015	2016	2017	2018	2019	2020	2021
Franklin County Cancer Center	15	13	8	33	0	0	0
Duke Raleigh Hospital	17,963	17,633	18,146	19,929	21,286	19,985	21,075
UNC Rex Hospital	19,983	22,699	24,281	22,514	22,493	22,858	21,639
UNC Hospital Radiation Oncology - Holly Springs	0	0	0	0	0	0	0
UNC-Rex Cancer Care of East Raleigh#	0	0	275	5,370	3,764	3,443	5,148
Total Service Area 20	37,961	40,345	42,710	47,846	47,543	46,286	47,862

- 2015-2017 volumes associated with Demonstration Project that were not counted in SMFPs.
 Source: 2017-2022 SMFPs, and Proposed 2023 SMFP

As illustrated in the table above, overall ESTV procedure volume increased 26.1 percent in Service Area 20 during 2015-2021, despite little/no utilization of two accelerators in the Service Area.

According to Table 17C-5 in the Proposed 2023 SMFP, Service Area 20 has a calculated surplus of 3.91 linear accelerators, with average utilization of 4,351 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 need methodology calculation.

¹⁹ Acquired by Duke Health System, and approved for replacement and relocation to Wake County in CON Project No. J-12000-20.

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

	2022 Service Area Population	Number of Accelerators	Population within Service Area per Accelerator	Percentage of Patients from Outside Service Area	2020-2021 Total ESTV Procedures	Procedures per Accelerator	ESTV Procedures Divided by 6750 Minus Number of Accelerators
Proposed 2023 SMFP, p. 324	1,251,139	11	113,740	17.45%	47,861	4,351	-3.91
Modified	1,251,139	9	139,015	17.45%	47,861	5,318	-1.91

If the two underutilized linear accelerators are removed from the denominator, the actual surplus of accelerators in Service Area 20 is approximately one-half that calculated by the standard need methodology, with an average of 5,318 ESTVs per unit, 22 percent higher than if all 11 accelerators are included.

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.

Historic and Projected Cancer Incidence in Service Area 20 Counties and North Carolina, 2018 and 2022

	2018 Cancer Cases	2018 Incidence Rate per 100,000	2022 Projected Cases	Percent Change in Cases 2018-22
Franklin County	444	508.5	476	7.2%
Wake County	5,269	480.8	6,277	19.1%
North Carolina	60,024	471.6	65,706	9.4%

Source: N.C. Central Cancer Registry, <https://schs.dph.ncdhhs.gov/data/cancer.cfm>

The NCCCR projects 6,277 new cancer cases in Wake County in 2022, a 19 percent increase over 2018, and 476 new cases in Franklin County in 2022²⁰, a 7 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 21.5 percent from 2020-2025, and 42.6 percent from 2020-2030.

Growth in cancer incidence is expected to drive growth in radiation therapy need. 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.

²⁰ Projected New Cancer Cases and Deaths for Selected Sites by County, 2022, produced by the North Carolina Central Cancer Registry, accessed at: <https://schs.dph.ncdhhs.gov/schs/CCR/ProjectionsByCountyFinal-2022.pdf>.

Impact if Petition Not Approved

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 patients 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. As discussed above, WakeMed disproportionately serves patients from groups that historically have had trouble accessing timely, comprehensive cancer care. These patients need the same coordinated, “one-stop shop” cancer care services that other patients from less marginalized groups currently enjoy.

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 WakeMed’s Oncology patients, who must be referred to other facilities to receive radiation therapy. Increasing the inventory of linear accelerators in Service Area 20 from 11 to 12 would result in a nominal increase in total capacity.

If this petition is not approved, there may be significant negative impact on patients requiring radiation therapy. All linear accelerators 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 ensure equal access to all population groups. Patients requiring radiation therapy who are not patients at either of these two systems, including many patients who seek care at safety net hospitals, face obstacles in access to care in also in the continuity of their care.

Alternatives to This Petition

The only alternative to this request is to maintain the status quo and await linear accelerator procedure volumes to increase to a level where the methodology will trigger a need for an additional accelerator in the service area. Per the Proposed 2023 SMFP, Service Area 20 facilities reported an average of 4,351 ESTV procedures per accelerator in 2021, well below the volume threshold required to generate a need determination using the standard need methodology. As shown in Table 5 above, exclusion of the underutilized units would increase average utilization to 5,318 ESTV procedures per accelerator.

The need for an additional linear accelerator in a given service area cannot be evaluated only through the quantitative calculation. With two linear accelerators showing no ESTV volume, the likelihood of a need determination being triggered in the near-term under the current methodology is small. Additionally, the current methodology does not take into account the critical health equity and health outcome factors outlined in this petition, and therefore does not truly reflect the need of the community to be served.

Evidence of No Unnecessary Duplication

Approval of this Petition would not result in unnecessary duplication of linear accelerator equipment. At least two linear accelerators in Service Area 20 have had 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 incidence over the next decade, suggests the need for additional radiation therapy resources.

Consistency with Basic Principles of the SMFP

Safety and Quality

Approval of this proposed adjusted need determination will result in improved patient safety and quality. Radiation therapy, 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.²¹

WakeMed routinely treats over 2,000 patients in its hospitals and outpatient facilities with a cancer diagnosis each year, with a significant proportion being Medicaid and uninsured. 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 (and the largest health system in the state 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.

²¹ "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>.

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 – many of whom struggle with transportation and other factors that impact health equity - 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 20. Patients presenting to WakeMed with a cancer diagnosis must seek radiation therapy at facilities outside the WakeMed system. This creates 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. An additional provider of linear accelerator care in Service Area 20 will provide additional opportunities for value-based care.

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 2023 SMFP is overstated, but more importantly, does not address the maldistribution of radiation therapy resources and its negative impact on quality, safety, and value. Most importantly, the calculated surplus does not address the shocking access statistics for Medicaid and uninsured patients. WakeMed appreciates the SHCC’s thoughtful consideration of this request and urges its approval.