Technology and Equipment Committee Agency Report

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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Request:

WakeMed Health & Hospitals (*WakeMed*) requests an adjusted need determination for one additional linear accelerator (LINAC) in Service Area 20, which includes Wake and Franklin counties, in the 2023 State Medical Facilities Plan (SMFP or "Plan").

Background Information:

Chapter Two of the SMFP provides that "[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections." The SMFP annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring and petitions requesting adjustments to need projections in the summer. Any person may submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

The standard LINAC methodology in the SMFP incorporates a geographic accessibility criterion (a population base of 120,000), a criterion aimed at assuring efficient use of megavoltage radiation facilities (when Equivalent Simple Treatment Visits [ESTV] procedures divided by 6,750 minus the number of existing linear accelerators equals at least .25), and a patient origin criterion that indicates when a service area has 45% or more of its patients coming from outside the service area. A need determination is generated when two of the three criteria are met within a service area. Application of the methodology to utilization data in the Proposed 2023 SMFP did not generate a need determination for one additional LINAC in Service Area 20.

WakeMed submitted a petition for an adjusted need determination to add a LINAC in Service Area 20 for the following reasons: 1) overall population growth; 2) inventory and utilization of existing linear accelerators in Service Area 20; 3) projected growth in cancer patients; 4) disparity in access to cancer care; and 5) development of Medical Oncology service at WakeMed.

Analysis/Implications:

Service Area 20 has five LINAC service providers and 11 LINACs (see Table 1). WakeMed currently does not operate a LINAC. Service Area 20 reported 47,861 procedures (ESTVs) in the Proposed 2023 SMFP, for an average of 4,351 procedures per LINAC. This number is well below the need determination threshold and results in a surplus of 3.91 LINACs in the service area. None of the existing providers is operating above the need determination threshold.

Table 1: Service Area Trends in LINAC ESTVs, Data Years 2017 – 2021

Location (Number of LINACs)	2019 SMFP	2020 SMFP	2021 SMFP	2022 SMFP	Proposed 2023 SMFP	Total % Change	CAGR
Franklin County Cancer Center (1)	8	33	0	0	0	-100%	-100%
Duke Raleigh(4)	18,146	19,929	21,286	19,985	21,075	16.14%	3.85%
Rex Hospital (4)	24,281	22,514	22,493	22,858	21,639	-10.88	-2.84
UNC Hospital – Holly Springs (1)	0	0	0	0	0	0	0
UNC Rex Cancer Care (1)	275	5,370	3,764	3,443	5,148	1,772%	108%
Service Area Totals	42,709	47,845	47,543	46,286	47,862	12.07%	2.89%

Source: 2018 – 2022 License Renewal Applications and Registration and Inventory Forms. Note: The data in the SMFP is two years earlier than the publication year of the SMFP.

Two of the existing LINACs within Service Area 20 are not operational. The equipment at UNC Hospital-Holly Springs is being developed, and the LINAC at the Franklin County Cancer Center has not been operational since 2018. The Petitioner suggests removing the nonoperational LINACs and only using the nine operational LINACs to assess need. Doing so yields 5,318 average procedures per LINAC, which is still below the required 6,750 ESTV threshold for an additional LINAC in Service Area 20. As reported in the Proposed 2023 SMFP, Service Area 20 has experienced 12.07% annual change in ESTVs over the past 5 years, for a compound annual growth rate (CAGR) of 2.89% (see Table 1).

In addition, Service Area 20 is the second highest populated LINAC service area in the state. According to the Proposed 2023 SMFP, Service Area 20 reported a total population of 1,251,139.

Service Area 20 had a steady growth in population over the last four years with a CAGR of 2.38% (see Table 2).

Table 2: Population Trends in Service Area 20, 2018 – 2022

			Total %	CACD			
	2018	2019	2020	2021	Proposed 2022	Change	CAGR
Service Area 20	1,138,826	1,165,211	1,180,095	1,189,588	1,251,139	9.86%	2.38%
Service Area Annual Change		2.32%	1.28%	0.80%	5.17%		

Source: 2018 – 2022 Proposed SMFP

Note: The data in the SMFP is two years earlier than the publication year of the SMFP.

Utilization in the Proposed 2023 SMFP does not reflect immediate or near-term need for an additional LINAC. However, LINAC utilization should increase once UNC Hospital - Holly Springs is operational. In 2021, a CON was issued to Duke Cancer Center Green Level Radiation Oncology to acquire and relocate the nonoperational LINAC from the Franklin County Cancer Center to Wake County.

In early 2022, WakeMed developed an integrated and comprehensive cancer treatment program. A LINAC is a well-established treatment modality within a medical oncology program. The Petitioner asserts that the absence of a LINAC at WakeMed disadvantages minority and historically underserved populations. The Agency acknowledges that WakeMed is a major provider of medical care to these populations in terms of total patient encounters. However, the Agency is not yet able to quantify the level of access that minority and underserved populations will have to oncology services at WakeMed given the recent implementation of the program.

The Petition provided data on the average number of days to external oncology appointments by payer source. However, it is not clear whether the data is related to the provision of LINAC services because the Petitioner did not identify the oncology appointments by type. Even so, patients with Medicare or Medicaid and people who are uninsured experience substantially longer wait times than those who are commercially insured. The Agency cannot ascertain whether the wait times would be reduced if WakeMed had a LINAC. For Medicare and Medicaid patients, the wait times could be due to the time it takes to receive approval for coverage; presumably, this would occur even if these patients were referred to services within the WakeMed health system.

The Petitioner also states that having a LINAC would improve the continuity of care for their patients. In general, having all needed services in a single location (physically and administratively) improves continuity of care for all types of healthcare needs. However, the Petitioners cite no current issues with continuity of care.

Agency Recommendation:

The Agency supports the standard methodology for LINAC equipment in the Proposed 2023 SMFP. However, in consideration of the above, the Agency recognizes that the historical and trending LINAC utilization in Service Area 20 does not support an additional LINAC outside of the methodology. Given available information submitted by the August 10, 2022 deadline, and in consideration of factors related specifically to LINAC inventory and utilization, the Agency would be inclined to recommend denial of the petition for an adjusted need determination for an additional LINAC in Service Area 20 in the 2023 SMFP. Notwithstanding, the Agency defers to the Technology and Equipment Committee (the "Committee") to evaluate whether a LINAC is considered the "standard of care" for an oncology program. If so, the Committee may choose to recommend approval of the Petition.