

**Technology and Equipment Committee
Agency Report
Adjusted Need Petition for
Linear Accelerator Equipment in Service Area 20 in the
2026 State Medical Facilities Plan**

Petitioner:

WakeMed
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Contact:

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Request:

WakeMed requests an adjusted need determination in the *2026 State Medical Facilities Plan (SMFP or “Plan”)* for one additional linear accelerator (LINAC) in Service Area (SA) 20, which consists of Wake and Franklin counties.

Background Information:

Chapter Two of the *SMFP* notes that during the summer, the Agency accepts petitions that “involve requests for adjustments to need determinations in the *Proposed SMFP*. Petitioners may submit a written petition requesting an adjustment to the need determination in the *Proposed SMFP* if they believe that special attributes of a service area or institution give rise to resource requirements that differ from those provided by the standard methodologies and policies.” 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.

According the standard LINAC methodology in the *SMFP*, an SA generates a need determination when it meets two of the following three criteria: 1) the population per LINAC in the SA is at least 120,000; 2) at least 45% of LINAC patients seeking services reside in a county outside the SA where the treatment is provided; and 3) total Equivalent Simple Treatment Visit (ESTV) procedures in the SA divided by 6,750 minus the number of existing LINACs is at least 0.25.

SA 20 has 12 LINACs, nine of which are operational. The operational LINACs are located at Duke Raleigh Hospital (4), UNC Health Rex (4), and UNC Rex Cancer Center of East Raleigh (1). Of the three non-operational LINACs, two are CON-approved but not yet developed. The first is a LINAC for which Duke Health System received CON approval in 2021 to relocate from a closed facility in Franklin County to Wake County. According to the most recent progress reports, the site plan has not yet been approved. A second project is to develop a LINAC that was approved for Rex Hospital-Holly Springs in 2016. This project has undergone several revisions; it is now

set to be developed but with no projected completion date available. A third undeveloped LINAC, for which there was a need determination in the *2023 SMFP*, was approved for WakeMed but is currently under appeal.

Analysis/Implications:

This Petition is, in part, based on WakeMed's position that an oncology program cannot provide comprehensive treatment and continuity of care to cancer patients without owning and operating a LINAC. As such, this Petition represents the latest in a series of petitions and proposals, including submissions by WakeMed, that considered LINAC as standard of care for oncology programs, which are summarized below.

- In 2021, the State Health Coordinating Council (SHCC) denied WakeMed's request for an adjusted need determination for a LINAC. The Petitioner's calculation of need only considered utilization of operational LINACs, excluding those that were not yet operational but were planned to be. The SHCC denied the petition because even if only operational LINACs were included in the calculations, the SA would still have ample capacity.
- In 2022, the SHCC approved a petition from WakeMed for an additional LINAC in SA 20 in the *2023 SMFP*, noting that LINAC is considered standard of care for oncology programs. WakeMed received conditional approval, but, as mentioned above, the CON decision is under appeal as of this writing.
- In 2023, the SHCC approved FirstHealth Moore's petition for an additional LINAC in SA 17, which used the standard-of-care rationale.
- In 2024, the Agency proposed a policy addressing LINAC as standard of care for oncology programs. Public comments expressed significant concerns about the policy, leading the SHCC to decline to include the policy in the *2025 SMFP*, but to commit to revisit the issue in the Spring of 2025.
- On February 18, 2025, the Technology and Equipment Committee held an Interested Parties meeting to discuss the issues related to LINAC. Providers and stakeholders offered input on whether LINAC should be considered standard of care and expressed concerns about the methodology.
- In the Spring of 2025, WakeMed petitioned the SHCC to approve a policy allowing certain cancer centers without a LINAC to obtain one without regard to a need determination. The Agency could not assess the feasibility of the policy due to data limitations, and the SHCC denied the petition.
- As a result of the questions and concerns raised at the February 18, 2025 Interested Parties meeting, the SHCC Chair announced plans to form a LINAC workgroup in Fall 2025. The issues regarding LINAC as standard of care will likely also be a part of the workgroup's discussions.

An important consideration in the review of this petition is the status of the appeal of the Agency's 2023 decision approving WakeMed's CON application for a LINAC based on the *2023 SMFP* adjusted need determination. Following a contested hearing, the administrative law judge reversed the Agency's approval but declined to award the LINAC to any of the parties. That decision is currently before the NC Court of Appeals (CoA). However, until the CoA rules, the Agency is unable to confirm that a LINAC will be added to SA 20's planning inventory. If the original CON

is upheld, approval of this petition would lead to a second additional CON-approved LINAC within the SA.

Further, based on the most recently available data, the SA's utilization does not exceed the need determination threshold of 6,750 ESTVs per LINAC (Table 1).

Table 1. Need Determination Calculations, Including Operational LINAC Only, SA 20

| Facility | Number of LINACs | Number of Procedures | Average Procedures per LINAC |
|--|-------------------------|-----------------------------|-------------------------------------|
| Duke Raleigh Hospital | 4 | 27,461 | 6,865 |
| UNC Health Rex | 4 | 22,543 | 5,636 |
| UNC Health Rex Cancer Center of East Raleigh | 1 | 2,899 | 2,899 |
| Total | 9 | 52,903 | 5,878 |

Source: *Proposed 2026 SMFP*

As noted above, three LINACs in SA 20 are not operational, but they are a part of the SA's planning inventory and need determination calculations. Agency staff examined the data to determine whether the delays in developing these LINACs are suppressing need determinations for SA 20. Criterion 1 requires a population greater than 120,000 per LINAC. If only nine LINACs were considered, SA 20 would have a population of 146,877 per LINAC, thus satisfying Criterion 1. However, the SA does not satisfy Criterion 2, which requires more than 45% of patients to reside outside the SA; only 16.71% of SA 20's patients are residents of other SAs. As shown in Table 2, Criterion 3 would also not be satisfied because the methodology would calculate a surplus of 1.16 LINACs in SA 20. Therefore, even if the SA's non-operational LINACs were removed from the planning inventory, the methodology calculations would still not show a need determination for an additional LINAC there.

Table 2. SA 20 Need Determination Calculations for Criterion 3, Nine Operational Units

| A | B | C | D | E | F |
|-----------------------|------------------|-------------------------------|--------------------------------|--|---|
| Facility | Inventory | Step 6 (sum ESTVs) | ESTVs per LINAC | Step 7 (Column C / 6,750) | Step 8 (Column E – Column B) |
| Duke Raleigh | 4 | 27,461 | 6,865 | 4.0683 | 0.0683 |
| UNC Rex Hospital | 4 | 22,543 | 5,636 | 3.3397 | -0.6603 |
| UNC Rex Cancer Center | 1 | 2,899 | 2,899 | 0.4295 | -0.5705 |
| Total | 9 | 52,903 | 15,400 | 7.8375 | -1.1625 |

Source: *Proposed 2026 SMFP*

Finally, even if this petition is approved, it does not mean the lack of LINAC capacity in SA 20 will be quickly resolved because a CON issued pursuant to the 2026 SMFP could face competition and appeals.

Agency Recommendation:

The Agency supports the standard need determination methodology for LINACs. Given available information submitted by the August 6, 2025 deadline, and in consideration of factors discussed above, the Agency recommends denial of the petition.