

**Technology and Equipment Committee
Agency Report
Petition for Proposed Policy TE-5:
Plan Exemption for Linear Accelerators for Cancer Center Hospitals
Proposed 2026 State Medical Facilities Plan**

Petitioner:

WakeMed
3000 New Bern Avenue
Raleigh, NC 27610

Contact:

Thomas Gough
Executive Vice President and Chief Operating Officer
919-350-1960
tgough@wakemed.org

Request:

WakeMed requests that the State Health Coordinating Council (SHCC) develop and approve a policy allowing certain cancer/oncology programs/centers that do not have an existing or approved linear accelerator (LINAC) to obtain a certificate of need to acquire one without regard to a need determination in the *State Medical Facilities Plan (SMFP)*.

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 annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring.

According the standard LINAC methodology in the *SMFP*, a service area generates a need determination when it meets two of the following three criteria: 1) the population per number of LINACs in the service area is a minimum of 120,000; 2) total Equivalent Simple Treatment Visits [ESTV] procedures in the service area divided by 6,750 minus the number of existing LINACs equals at least .25; and 3) 45% or more of LINAC patients served reside outside of the LINAC(s) service area.

The Petitioner believes that the methodology does not address service gaps for patients who need LINAC treatment. Specifically, WakeMed states that an oncology program cannot provide comprehensive treatment and continuity of care to cancer patients if it does not own and operate a LINAC. This Petition represents the latest in a series of activities regarding LINAC as standard of care for select cancer patients which are summarized below.

- In 2021, the SHCC denied a petition from WakeMed for an adjusted need determination for a LINAC. The Petitioner used a calculation of need based only on utilization of operational LINACs. The SHCC denied the petition because the calculation excluded the non-operational LINACs, which were slated to become operational. In addition, if the standard need determination had been applied using only the operational LINACs, calculations would have shown the service area had ample capacity.
- In 2022, the SHCC approved a petition from WakeMed for an additional LINAC in the service area in the *2023 SMFP*, noting that LINAC is considered standard of care. WakeMed received conditional approval, but the certificate of need (CON) decision is under appeal as of this writing.
- In 2023, the SHCC approved a petition from FirstHealth Moore for an additional LINAC in the service area, using the standard-of-care rationale.
- In 2024, the Agency proposed a policy that addressed LINAC as standard of care to achieve a coordinated approach to the issue. Public comments expressed significant reservations about the policy, however. As a result, the SHCC decided to review 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 as standard of care. Providers from the community offered input regarding whether, and if so how, LINAC should be considered standard of care. They also addressed concerns about the methodology.

The current Petition proposes the following policy:

Policy TE-5: Plan Exemption for Linear Accelerators in Cancer Center Hospitals

An applicant proposing to acquire a linear accelerator (LINAC) under this policy shall demonstrate in its certificate of need (CON) application that:

1. It offers a cancer program that provides both inpatient and outpatient medical and surgical oncology services, including documentation that it served at least 5,000 annual encounters in the last 12 months prior to submission, employs cancer staff that includes at least two (2) Board-certified medical oncologists that participate in multidisciplinary Tumor Boards, and maintains an active Tumor Registry;
2. The proposed LINAC will not be located at a site where the inventory in the SMFP reflects that there is an existing LINAC or a CON awarded for a LINAC that was obtained in the five years immediately preceding the filing of the CON application;
3. It does not, directly or through a related entity, have an awarded or non-operational LINAC located in the proposed service area;
4. It has identified at least two (2) radiation oncologists who will be employed by the applicant to provide services for patients utilizing the proposed LINAC;
5. It will have physics and dosimetry staffing levels that meet American College of Radiology personnel standards for Radiation Oncology LINAC services¹;
6. It will meet standards of the American Society for Radiation Oncology (ASTRO) for

¹ If approved, the ACR staffing standards will appear in Chapter 15 of the 2026 SMFP.
<https://accreditation.support.acr.org/support/solutions/articles/11000049781-personnel-radiation-oncology-revised-7-9-2024>

- safety and quality;
7. It has or will have a LINAC simulator located in the same building as the proposed LINAC;
 8. If one or more LINACs are located in the applicant's service area, the average annual utilization across all operational LINACs in the service area is at least 4,500 ESTVs;
 9. The proposed LINAC's utilization will reach at least 6,750 ESTVs by the third project year; and
 10. It is a licensed North Carolina acute care hospital that its [sic] Certified by the Center [sic] for Medicare and Medicaid Services and has an active, published charity care program at the time of the application.

Analysis/Implications:

WakeMed acknowledges that all facilities that offer cancer treatment may not require a LINAC, but states that facilities that experience a relatively high volume of both inpatient and outpatient cancer treatment patients should be able to obtain one. The proposed policy would allow such facilities to submit a CON application for a LINAC even if there is no need determination for one within service area in the SMFP. The Agency does not dispute that LINAC is the appropriate treatment option for a proportion of cancer patients. Data on cancer incidence, improved diagnosis and treatment, and population indicate that the use of LINAC services will likely increase over time. Even so, the Agency does not have the data required to assess the feasibility or appropriateness of all facets of the proposed policy (e.g., the number of patient encounters, staffing of oncology centers, or certification status.) Therefore, it is unable to recommend approval of the proposed policy.

Agency Recommendation:

Given available information and comments submitted by the March 19, 2025 deadline, and in consideration of factors discussed above, the Agency recommends denial of the petition.