

**Technology and Equipment Committee  
Agency Recommendation for  
Proposal to Develop Policy TE-4 for Inclusion in the  
Proposed 2025 State Medical Facilities Plan**

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***Agency Proposal:***

The Agency set forth a proposal for consideration by the Technology and Equipment Committee and the State Health Coordinating Council (SHCC) regarding the inclusion of Proposed Policy TE-4 in the 2025 State Medical Facilities Plan (SMFP or the “Plan”). Currently, a prerequisite to the filing of a certificate of need (CON) application to acquire a Linear Accelerator (LINAC) is a need determination in the Plan. Proposed Policy TE-4 would allow cancer treatment centers/oncology programs that do not have a linear accelerator (LINAC) to obtain one without regard to a need determination in the SMFP. The proposed policy language is as follows:

**Proposed Policy TE-4: Plan Exemption for Linear Accelerators**

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

1. it is or proposes to be a cancer center/program as defined in one of the categories used by the American College of Surgeons Commission on Cancer; and
2. the proposed LINAC will not be located at a site where the inventory in the SMFP reflects that there is an existing or approved LINAC obtained in the five years immediately preceding the filing of the CON application; and
3. it has at least one radiation oncologist affiliated with the center; and
4. it has at least one medical physicist affiliated with the center or available by referral; and
5. if the service area has at least one LINAC, the average ESTVs across all LINACs in the applicant’s service area is at least 3,375.

The performance standards in 10A NCAC 14C .1903 are not applicable.

***Background Information:***

The National Cancer Institute defines “standard of care” as “[t]reatment that is accepted by medical experts as proper treatment for a certain type of disease and that is widely used by health care professionals...” In 2022, the SHCC determined that the use of LINAC technology is the standard of care for cancer treatment in approving a WakeMed petition for an adjusted need determination for one LINAC in Service Area 20 in the 2023 SMFP. In 2023, the SHCC approved a petition submitted by FirstHealth of the Carolinas to include an adjusted need determination for a LINAC in Service Area 17 in the 2024 SMFP on the same basis.

***Analysis/Implications:***

In 2022, the SHCC determined that the use of LINAC technology is the standard of care for cancer treatment. The rationale for this proposal is analogous to that of Policy TE-3, which allows acute care hospitals with 24-hour emergency care that do not have a magnetic resonance imaging (MRI) scanner to obtain one without regard to a need determination because access to and use of MRI technology is considered standard of care for such facilities. The Agency set forth the language in Proposed Policy TE-4 with the goal of increasing access to LINAC treatment to cancer patients within the state.

The Agency received comments from seven health system and hospital representatives; all comments were in opposition to the inclusion of Proposed Policy TE-4 in the 2025 SMFP. In sum, commentors expressed support for the current process, which requires a provider to petition the SHCC to add an adjusted need determination for a LINAC to the following year's SMFP when application of the need methodology fails to yield a need determination within a given service area. Below is a summary of some of the thoughts and concerns that commentors shared:

- The existing SMFP LINAC methodology is effective in determining the need for LINACs within the state. Only four adjusted need determination petitions have been filed since 2018.
- There is no need for additional LINACs because the total statewide equivalent simple treatment visits (ESTVs) have trended downward in the last three years.
- Policy TE-3 is not truly analogous to Proposed Policy TE-4 because an MRI scanner is a diagnostic tool that is the standard of care for use in an acute care hospital emergency department. Conversely, LINAC is a treatment tool for which patients can be referred to outside providers, as appropriate.
- Not all patients diagnosed with cancer will require LINAC treatment. Even if LINAC is standard of care for a cancer program, it is not the determining factor of whether a cancer program needs a LINAC.
- Research indicates that higher volume centers tend to have better patient outcomes. Proposed Policy TE-4 would eliminate volume thresholds and performance thresholds for applicants proposing to acquire a LINAC.
- There may be a risk of over-referral by providers that own LINACs.
- There may be a negative impact on quality of care and safety if there is a proliferation of LINAC equipment that leads to unnecessary duplication.

***Agency Recommendation:***

The Agency supports all policies for health services and equipment in the *SMFP*. The Agency also appreciates the concerns raised by the commentors in response to this proposal. Given the available information submitted by the March 20, 2024 deadline, the Agency gives deference to the committee to further deliberate upon this proposal to determine whether it is appropriate for inclusion in the 2025 SMFP.