

**ATRIUM HEALTH COMMENTS ON PROPOSED POLICY TE-4
PLAN EXEMPTION FOR LINEAR ACCELERATORS
IN THE 2025 STATE MEDICAL FACILITIES PLAN**

COMMENTER

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Atrium Health (Atrium) appreciates the opportunity to comment on the proposed policy TE-4 to exempt linear accelerators (LINACs) from the need methodology in the 2025 State Medical Facilities Plan (SMFP). Based on its detailed review of the proposed policy, Atrium requests the State Health Coordinating Council (SHCC) not approve this policy until more careful consideration and review by provider community and other interested parties. There are potential unintended consequences of the proposed policy that could result in a proliferation of underutilized LINACs and inefficient distribution of medical resources.

The stated rationale for the proposed policy is to create an exemption for linear accelerators similar to Policy TE-3 that creates an exemption from the SMFP for MRI scanners if a CON applicant can meet certain criteria. The proposed policy is intended to allow LINACs to be developed by a “cancer center/program” regardless of the limitations of the SMFP methodology because linear accelerators are viewed as the “standard of care” for cancer treatment. However, MRI as a “standard of care” for acute care hospitals is vastly different than how LINACs are the “standard of care” for cancer treatment. MRI scanners are essential to diagnose medical conditions, frequently on an emergent basis for inpatients and emergency room patients. While LINACs are the “standard of care” for cancer patients, most of the treatment is performed on an outpatient basis and is scheduled in advance after diagnosis and treatment planning. This difference reduces the need to have linear accelerators at every facility that treats cancer patients. Another key difference between MRI scanners and LINACs is the cost to acquire and operationalize the equipment. MRI scanners have a much cheaper equipment acquisition cost and a much lower renovation/installation cost than LINACs. A review of CON capital cost information from CON application logs for 2023 and 2024 show an MRI scanner can be installed for an average cost of around \$5 million. LINAC projects typically cost over \$10 million. In the April 2023 CON application filing cycle there were three applications filed. Two applications were in the \$10 million range, and one was over \$30 million. Exempting LINACs from SMFP methodology restrictions on a broad basis with no requirements to meet minimum volume standards could result in millions of dollars being invested to develop chronically underutilized equipment in service areas that are already being served well by existing LINAC providers.

The background information offered in support of the policy lists the number of special needs petitions for linear accelerators in recent years. Specifically, the WakeMed petition in 2022 and the First Health petition in 2023 are cited as examples of how a specific facility can show a need for additional equipment

even if the methodology does not indicate any additional equipment is needed. However, these two situations were quite different and do not align with the proposed policy. Only WakeMed was an existing cancer center that did not have a LINAC. FirstHealth was asking for a need determination because the outdated methodology was not generating a need for additional equipment due to a population that was not growing fast enough to trigger that part of the methodology, and one existing underutilized provider was keeping the service area from reaching the volume required threshold. The circumstances listed in the FirstHealth petition are a perfect example of what the special needs petition process was created for.

As the aforementioned FirstHealth petition indicated, the LINAC methodology is convoluted and outdated requiring two of three different factors be met before a new LINAC is needed in a service area. In addition, the service areas are multi-county service areas which can lead to a high growth area being constrained by lower growth areas or providers with lower utilization in a different community. The LINAC need methodology in the SMFP has remained unchanged for at least 20 years. There has been some discussion on the need to update the methodology several times over this period, but due to staff constraints and other priorities, no effort has been undertaken to modernize this methodology. Atrium would suggest that a methodology review might be a more prudent action than an exemption policy.

Atrium also has significant concerns with some of the proposed criteria a CON applicant for a LINAC would be required to meet under the policy. The concerns are listed below for each criterion.

- Criterion 1
 - The first criterion would allow an applicant that “proposes to be a cancer center/program” to file a CON application for a LINAC. Atrium would propose that a CON applicant would need to be an existing program with at least a three-year trend of new cancer patients.
 - Atrium also has concerns over the proposed definitions from the American College of Surgeons Commission on Cancer included as Table 2. This table includes 11 different classifications or types of programs. We would recommend the list be limited to the Community Cancer Program (CCP) or Comprehensive Community Cancer Program (CCCP) choices that include minimum numbers of newly diagnosed cancer cases each year.
- Criterion 2
 - No objections or concerns
- Criterion 3
 - Requiring an affiliation with at least one radiation oncologist is an exceptionally low bar. We would propose an applicant have an agreement with a group of more than one radiation oncologist to allow better physician coverage and care management of cancer patients.
- Criterion 4
 - No objections or concerns
- Criterion 5
 - The ESTV average for the service area is too low at only 3,375, which is 50 percent of the capacity defined in the SMFP. Only six of the 28 service areas do not meet this volume level in the 2024 SMFP. Raising this threshold to 75 percent of capacity (5,062 ESTVs) would result in only 9 service areas meeting that target. Staff could also consider lowering the ESTV threshold only in more rural areas.
- Exemption from CON performance standards

- The CON applicants under this policy would not be subject to the CON performance standards that all applicants under the existing methodology must adhere to. The current performance standards require an applicant to project volume of 6,750 ESTVs per LINAC or serve 250 or more patients in the third year of operation.

As it is currently proposed this policy allows a CON application when there is extremely low service area utilization level, and the applicant is not accountable to meet a future minimum volume requirement. Atrium is concerned that without modifications to the criteria the addition of this policy to the SMFP could result in a proliferation of LINACs in the state that would be chronically underutilized.

An additional area of concern Atrium would like the SHCC to consider is the potential for this petition to impact the quality of care provided if there is a proliferation of LINACs in North Carolina. Providing radiation therapy requires skilled physicians, nurses, technicians, dosimetrists, and physicists with considerable experience in the field. There is a national shortage of radiation therapists, dosimetrists, and physicists. A proliferation of LINACs and new radiation therapy centers could impact the quality and safety of the radiation therapy delivered.

In summary, Atrium agrees there may be some service areas where the current LINAC methodology does not accurately reflect the need for additional equipment capacity. However, we do not agree that the proposed policy is the best method to address these issues. Atrium would like to recommend the SHCC not adopt the policy as proposed to allow for additional discussion and feedback from existing providers and experts in the field of radiation oncology. This delay will reduce the likelihood of potential negative unintended consequences of the policy. Atrium appreciates the opportunity to provide these comments.