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

Petitioner:

Cone Health 1200 North Elm Street Greensboro, NC 27401

Contact:

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Request:

Cone Health requests that the State Health Coordinating Council (SHCC) add a new policy "to address the disproportionate treatment of facilities with high linear accelerator (LINAC) utilization whose need for additional LINAC capacity is not addressed through the current methodology."

Background Information:

Chapter Two of the *North Carolina 2025 State Medical Facilities Plan (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) the LINAC(s) in a service area has 45% or more of its patients seeking services from outside the service area.

Need determinations are based on the total utilization in the service area, rather than the utilization of individual providers or facilities. As such, the Petitioner states that providers with high-volume facilities can be precluded from acquiring additional needed equipment if they are in a service area with low-volume facilities requiring the high-volume facilities to continually operate near or above capacity. The Petitioner further states that this situation disrupts treatment and extends patient wait

times. Patients may also have to receive treatment at alternate facilities, which can compromise continuity of care.

To address these concerns, the Petitioner proposed the following policy:

Policy TE-5: Plan Exemption for Linear Accelerators

The applicant proposing to acquire a linear accelerator (LINAC) shall demonstrate in its Certificate of Need (CON) application that:

- 1. It is a licensed North Carolina acute care hospital or a hospital campus that has the following characteristics:
 - a. has licensed acute care beds;
 - b. provides emergency care coverage 24 hours a day, seven days a week.
- 2. Historical average ESTV Procedures per existing LINAC have exceeded the LINAC methodology threshold of 6,750 by 10% or 7,425 average ESTV procedures per LINAC as published in the current SMFP and for SMFPs published in the two years preceding submission of the CON application.
- 3. A need determination has not been generated through the standard LINAC methodology in the facility's LINAC service area in the three years preceding submission of the CON application.
- 4. The proposed LINAC will be located: a. on the main campus of the hospital as defined in G.S. § 131E-176(14n); or b. on an acute care hospital campus that operates under the main hospital's license.

The performance standards in 10A NCAC 14C .1903 are applicable to a proposal submitted by a hospital pursuant to this policy.

Analysis/Implications:

Given that most need determination methodologies in the *SMFP* consider utilization for the service area as a whole, it is true that low-volume facilities may suppress need determinations. However, a few methodologies have components that address this disparity. For example, the operating room methodology considers the utilization of individual health systems when calculating need determinations. Also, the methodology calculations for PET scanners bases need determinations on utilization in individual facilities. The LINAC methodology considers the service area as a whole as a way to avoid unnecessary duplication of services, as do the cardiac catheterization and magnetic resonance imaging scanner methodologies, for example.

The Agency examined the data for the current year and the past two years to ascertain the number of hospitals that would become exempt under the Petitioner's proposed policy. Doing so has allowed staff to assess whether the proposed policy would permit the development of a large number of new LINACs (see Table).

Table. Hospitals Eligible to Submit CON Application under the Proposed Policy TE-5

				2023 SMFP	2024 SMFP	2025 SMFP
Facility Name	Service Area Number	County	Number of LINACs	Average Procedures per Unit 10/1/2020- 9/30/2021	Average Procedures per Unit 10/1/2021- 9/30/2022	Average Procedures per Unit 10/1/2022- 9/30/2023
Atrium Health Carolinas Medical Center	7	Mecklenburg	3	6,078	6,499	6,310
Atrium Health Pineville*	7	Mecklenburg	2	11,783	6,508	6,701
Atrium Health University City	7	Mecklenburg	1	8,089	7,918	8,714
Matthews Radiation Oncology Center	7	Mecklenburg	2	5,535	5,544	6,981
Novant Health Huntersville Medical Center	7	Mecklenburg	1	9,013	4,263	11,391
Novant Health Presbyterian Medical Center	7	Mecklenburg	2	6,448	6,350	3,178
Atrium Health Union	7	Union	1	8,080	8,279	8,996
Cone Health Wesley Long Hospital	12	Guilford	4	7,127	7,617	7,973
High Point Medical Center	12	Guilford	2	4,912	4,988	4,862
UNC Rockingham Hospital	12	Rockingham	1	3,104	2,505	2,684

^{*} CON issued to Atrium Health Pineville in 2022 for second LINAC, based on 2022 need determination. Second LINAC not yet operational as of 9/30/2023, but utilization includes LINAC under development in the 2024 and 2025 SMFPs. Utilization in 2023 SMFP is based on one LINAC.

The above data shows that three hospitals in two service areas are likely to qualify to submit a CON application pursuant to the proposed policy. According to 2023 data, Service Area 7 has seven LINAC providers, four of which had volumes greater than 6,750 procedures per LINAC. In addition, Service Area 7 was fairly close to having a need determination in the 2025 SMFP. However, the application of the LINAC need methodology would have produced a need for one LINAC in the service area whereas the proposed policy would allow two facilities to apply for a new LINAC.

The Agency appreciates the Petitioner's concerns regarding increased wait times in high volume facilities. The Petitioner presents data for Cone Health Wesley Long Hospital ("Wesley Long") showing that wait times between referral and treatment have increased from 48 days in 2019 to 79 days in 2024. This increase mirrors the increase in utilization for Wesley Long during a similar period. In 2019, Wesley Long's four LINACs performed 29,095 procedures (7,274 per LINAC) and in 2023 the facility performed 31,893 procedures (7,973 per LINAC). The Petitioner has chosen to address its concern regarding the impact of low-volume facilities on need determinations by proposing Policy TE-5. This approach is appropriate when a statewide impact needs to be corrected or when the addition of a policy would be clearly beneficial statewide. However, recently available data indicates that only two service areas are similarly affected. Alternatively, the

summer petition process presents an opportunity for the Petitioner and/or other providers to request the addition of a need determination for any service areas that they believe have special attributes that require resources that are not addressed by the standard methodologies in the SMFP.

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. However, the Agency invites Cone Health to consider submitting a summer petition for an adjusted need determination.