# Petition for New Technology and Equipment Policy

**PETITIONER**

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**INTRODUCTION**

Cone Health respectfully petitions the State Health Coordinating Council (SHCC) to add a new technology and equipment policy to the *2026 State Medical Facilities Plan (2026 SMFP).* The proposed Policy TE-5 will function as a plan exemption 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. At present, LINAC providers with high utilization located in service areas that include rural facilities with lower equipment utilization cannot effectively demonstrate need through the standard methodology. The current calculation process in Steps 6, 7, and 8, of the standard methodology, which averages ESTV procedures across the service area, effectively masks the capacity constraints at high-volume facilities when they share a service area with underutilized facilities. As such, this averaging effect creates barriers to expanding capacity at high-volume facilities, potentially limiting their ability to provide timely access to treatment for their patient population.

Under the proposed Policy TE-5, applicants must be established providers of radiation therapy services operating at least one LINAC and must demonstrate that historical average utilization on existing units has exceeded the current methodology's 6,750 ESTVs threshold by 10 percent or more during the two years preceding submission of a CON application. Additionally, applicants may only file a CON pursuant to Policy TE-5 if there has not been a need determination generated in their service area through the standard LINAC methodology in the three years preceding submission of a CON application.

**STATEMENT OF THE PROPOSED CHANGE**

Specifically, Cone Health requests that the following language be used to create Policy TE-5:

> **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 *SMFP*s 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 <u>are</u> applicable to a proposal submitted by a hospital pursuant to this policy.

Notably, the filing of this petition follows recent ongoing discussions regarding potential revisions to the *SMFP* language governing the development of LINACs. In the spring of 2024, the Agency proposed Policy TE-4, a plan exemption that would allow "cancer/oncology programs/centers that do not have a LINAC to obtain one without regard to a need determination in the SMFP."[1] In response, seven health systems filed comments effectively opposing the proposal, out of concern that its adoption, as currently drafted, would result in the proliferation of LINACs, increased costs, and potential patient safety risks through improper utilization of equipment.[2] Specifically, Cone Health filed comments requesting that the Agency proposal be denied and studied for further development and consideration of unintended consequences. In particular, these comments expressed concern over the proposal's lack of clear definitions for either cancer centers or satellite cancer centers, ambiguities which could result in a proliferation of facilities seeking to acquire a LINAC and claiming eligibility under these category designations. As stated in the comments, prospective applicants under proposed Policy TE-4 could use this approach to effectively completely circumvent the standard need methodology.

While both the Agency's proposal and providers' responses demonstrate significant interest in improving pathways for developing additional LINAC capacity, the SHCC tabled the Agency proposal for further discussion in 2025. During an interested parties meeting held on February 18, 2025, providers continued to voice concerns about the Agency proposal and its failure to address safety, quality, and support for

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[1] Proposed Policy TE-4: Plan Exemption for Linear Accelerators Agency Recommendation. While the Agency identified their proposed policy as Policy TE-4 in the petition, the Policy TE-4 that was approved and exists in the *2025 SMFP* is a result of a 2024 Spring petition filed on behalf of Carteret Health. The approved and existing Policy TE-4 is a Plan Exemption for Dual-Functioning PET Scanners in Mid-Size-Cancer Centers.

[2] Comments on the Agency Proposal were filed by Duke University Health System, Catawba Valley Medical Center, CaroMont Health, WakeMed, Atrium Health, UNC Health, and Cone Health.

adequate staffing at facilities in rural areas or without the multiple layers of oversight needed to ensure quality and safety. These concerns, building on those raised in the comments filed when TE-4 was initially proposed, also challenged the comparison of LINACs to MRIs, citing differences in application, and stressed the risks entailed in allowing too broad a range of applicants to apply for a LINAC. Regardless of the ultimate outcome for the Agency's proposal, it differs fundamentally from the Policy TE-5 proposed in this petition in that it does not address the capacity constraints faced by established providers in urban areas who consistently experience high utilization of their existing LINACs. The threshold requirement included in the proposed Policy TE-5, which is consistent with the 6,750 ESTVs threshold found in the current standard need methodology, further differentiates this proposal from the Agency's proposal, which would lower the average ESTVs across all LINACs in the applicant's service area to a minimum of 3,375.

**BACKGROUND OF THE PETITIONER**

Cone Health operates as a not-for-profit healthcare network serving people in Alamance, Forsyth, Guilford, Randolph, Rockingham and surrounding counties. As one of the largest and most comprehensive networks in the region, Cone Health provides primary and specialty care to its patients across more than 150 locations, including five hospitals, six ambulatory care centers, three outpatient surgery centers, and more than 120 physician practices. Cone Health Cancer Center at Wesley Long (CHCC-WL) was established in 1998 when Cone Health received CON approval to consolidate outpatient oncology services in a comprehensive cancer center. Co-located at Wesley Long Hospital in Greensboro, CHCC-WL houses the inpatient oncology unit for Cone Health's Greensboro hospitals. Since its inception, CHCC-WL has remained committed to providing comprehensive cancer services of the highest quality, including education, prevention, diagnosis, treatment, support, palliative care, and research to residents of Cone Health's service area. Accredited in radiation oncology by the American College of Radiology, CHCC-WL's commitment to providing exceptional care is evident in the distinctions and awards it has received from multiple organizations. CHCC-WL holds the Quality Oncology Practice Initiative Certification from the American Society of Clinical Oncology and is recognized as being high performing for both colon cancer surgery and lung cancer surgery by US News and World Report. Of note, the Cone Health Radiation Oncology Center of Innovation has produced research and commercially successful technologies that are positively impacting the field worldwide.

CHCC-WL is one of North Carolina's leading providers of cancer care and is notable for both the quality of care it provides and the high volume of radiation therapy treatments it performs. Over the course of the past five *SMFP* years, CHCC-WL has performed an increasing number of ESTVs. In the *2025 SMFP*, data reported from FY 2023 shows that CHCC-WL provided the fourth highest volume of ESTVs in the state (31,893) and the fourth highest volume in the state (7,973) as measured by average ESTVs per LINAC unit.

Given the complexity of cancer care, patients frequently receive treatment via other modalities in addition to radiation therapy, and the coordination of these services at CHCC-WL is managed by multidisciplinary teams composed of medical oncologists, radiation oncologists, surgeons, and specialists, who collaborate on diagnosis, continual assessments, treatments, procedures, and follow-up care.

Historical LINAC Utilization at Wesley Long

As a provider of radiation therapy services, CHCC-WL operates four LINACs on an 8-hour clinical day from 7:30 AM to 4:30 PM, Monday through Friday. The scheduling structure is based on 15-minute treatment slots, with additional time allocations required for specialized treatments like stereotactic body radiotherapy (SBRT) and stereotactic radiosurgery (SRS). The facility's current capacity allows for 32 treatment slots daily per LINAC, resulting in a total daily capacity of 128 treatment slots across all four units. This translates to 640 weekly treatment slots and 33,280 slots annually, or the maximum capacity of existing equipment, without factoring in the additional time needed for administering more specialized treatments. Historical utilization trends reveal that volumes at CHCC-WL have not only exceeded the methodology's threshold of 6,750 ESTV procedures per unit since the publication of the *2018 SMFP* but continue to increase and are quickly approaching this maximum capacity.

***SMFP* Trends in Average ESTV Per LINAC Unit at CHCC-WL**

| *SMFP Year* | *2018* | *2019* | *2020* | *2021* | *2022* | *2023* | *2024* | *2025* |
|---|---|---|---|---|---|---|---|---|
| Total ESTVs | 27,786 | 27,175 | 29,379 | 29,095 | 27,711 | 28,509 | 30,468 | 31,893 |
| Number of LINACs | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| ESTVs per LINAC | 6,946 | 6,794 | 7,345 | 7,274 | 6,928 | 7,127 | 7,617 | 7,973 |
| Percent above 6,750 methodology threshold | 2.9% | 0.7% | 8.8% | 7.8% | 2.6% | 5.6% | 12.8% | 18.1% |

As highlighted in the table above, CHCC-WL procedure volumes in the years following the COVID-19 pandemic – reported in *SMFP* years 2023 to 2025 – highlights the level of growth. The *2023 SMFP*, which lists reported data for FY 2021, records CHCC-WL as having performed 28,509 ESTV procedures across the facility's four existing LINACs, or an average of 7,127 procedures per unit. In the following year, the *2024 SMFP*, which lists reported data for FY 2022, shows that CHCC-WL performed 30,468 ESTV procedures across its four existing LINACs, or an average of 7,617 procedures per unit. Similarly, the *2025 SMFP*, which lists reported data for FY 2023, shows CHCC-WL performed 31,893 ESTV procedures across its four existing LINACs, or an average of 7,973 procedures per unit. In FY 2024, as reported on its 2025 hospital license renewal application, CHCC-WL performed 31,476 ESTV procedures across its four existing LINACs, or an average of 7,869 procedures per unit. Notably, the similarity between utilization data from FY 2023 and FY 2024 indicates CHCC-WL's ability to meet current demand for services or accommodate growth in procedure volumes is constrained by the physical and operational limits of the existing inventory of four LINACs - limits that are not sufficiently recognized under the current methodology because the service area average includes units located in smaller, rural areas.

Furthermore, analysis of wait times at CCHC-WL from calendar year (CY) 2019 to CY 2024 particularly underscores the growing impact of delays on patient well-being. In 2019, the total average of days between referral and treatment for all treatment types was approximately 48 days; whereas the same metric for 2024 shows that patients waited approximately 79 days, or more than two and a half months, representing greater than a fifty percent increase and a compound annual growth rate of 10.2 percent in wait times over a five-year period. Presented as average wait times, these figures do not accurately reflect cases where patients must wait even longer periods of time before receiving treatment. If wait times were to continue to lengthen at the same historical rate, due to growth and capacity constraints imposed by limited opportunities to add needed LINAC units, patients could expect to wait an average of 87 days or

almost three months between referral and treatment. Regarding the direct impact on patient outcomes, studies have shown that delays in treatment contribute to higher posttraumatic stress responses (PTSR) and general psychological distress (GPD) as well as increased risk of death for patients diagnosed with common forms of cancer, including breast, prostate, colon, and lung cancers.[3] In this current situation, patients must make an extremely difficult decision, since prioritizing continuity of care in one aspect risks compromising it in another. On the one hand, patients can decide to remain at the health system where they received their diagnosis and may have already started treatment; however, extended wait times at a highly utilized facility can create delays in the delivery of steady, timely care, increasing stress and mortality risks. On the other hand, prioritizing more immediate care by seeking out treatment at an alternate location supports the principle of timeliness, but does not allow a patient to continue receiving treatment and guidance from trusted providers in a familiar, convenient setting and may result in less complete, personalized care.

LINAC Inventory & Current Methodology

The *2025 SMFP* identifies 28 service areas including 72 facilities operating a total inventory of 132 LINACs, which collectively perform a statewide average of 4,925 ESTV procedures per unit. Under the current standard LINAC methodology, a service area must meet two of three criteria to trigger a need determination in the *SMFP*. Criterion 1, which considers geographic accessibility, is satisfied if the population residing in a service area exceeds 120,000 residents per LINAC unit. Criterion 2, a measure of patient origin, is satisfied if 45 percent or more of total patients served on LINACs in a service area reside outside that service area. Criterion 3, aimed at promoting efficient use, is satisfied if a service area's sum of reported ESTV procedures divided by 6,750 and minus the number of LINACs in a service area, is greater than or equal to a deficit of 0.25 units.

A review of historical LINAC need determinations over the past decade, from 2016 to 2025, reveals that there have only been two standard need determinations, occurring in 2021 and 2022. The 2021 need determination was identified for SA 19 (comprised of Brunswick, Columbus, New Hanover, and Pender counties), while the 2022 need determination was identified for SA 7 (comprised of Anson, Mecklenburg, and Union counties). The 2021 need determination in SA 19 was triggered by Criterion 1 and Criterion 3, due to an average population of 126,551 residents per unit, and a 0.56 deficit generated by an average ESTV volume of 7,688 procedures across 4 LINACs. Similarly, the 2022 need determination in SA 7 was also triggered by Criterion 1 and Criterion 3, there being an average population of 127,588 residents per unit, and a 0.30 deficit generated by an average ESTV volume of 6,932 procedures across 11 LINACs.[4] Apart from these two instances of need generated by the standard methodology, adjusted need determinations requested through summer petitions have more frequently resulted in need determinations for LINACs, with successful petitions being filed in 2023, 2022, 2021, and 2018. Most recently, First Health's 2023

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[3] Cone EB, et al. "Assessment of Time-to-Treatment Initiation and Survival in a Cohort of Patients With Common Cancers." *JAMA Netw Open*. 2020. doi: 10.1001/jamanetworkopen.2020.30072.
Khorana AA, et al. "Time to initial cancer treatment in the United States and association with survival over time: An observational study." *PLoS One*. 2019 doi: 10.1371/journal.pone.021320.
Ye Y, et al. "Psychological distress of cancer patients caused by treatment delay during the COVID-19 pandemic in China: A cross-sectional study." *Psychooncology*. 2022. doi: 10.1002/pon.5946. Epub 2022 May 10. PMID: 35506550; PMCID: PMC9347715.

[4] *2021 SMFP*, Tables 17C-5 and 17C-6, p. 335-336.
*2022 SMFP*, Tables 17C-5 and 17C-6, p. 332-333.

summer petition in SA 17 (comprised of Hoke, Lee, Montgomery, Moore, Richmond, and Scotland counties) resulted in an adjusted need determination being granted for one LINAC only to be approved for a cancer center within the service area. WakeMed's 2022 petition in SA 20 (comprised of Franklin and Wake counties) was also approved, and Carteret Health Care's 2021 petition in SA 24 (comprised of Carteret, Craven, Jones, and Pamlico counties) led to an adjusted need determination for one LINAC, specifically designated for Carteret County. Southeastern Regional Medical Center's petition in 2018 for SA 18 (comprised of Bladen, Cumberland, Robeson, and Sampson counties), the earliest summer petition within the last decade, was similarly approved in the form of an adjusted need determination for a LINAC to be developed exclusively in Robeson County. The prevalence of these adjusted need determinations, particularly the three consecutive recent petitions, as well as their approval by the SHCC, underscores the necessity of change in how LINAC need is evaluated and the importance of offering established providers with highly utilized units an additional means to increase capacity. If Policy TE-5 were in place, two of these four most recent adjusted need petitions would not have been necessary: First Health's 2023 summer petition in SA 17 and Southeastern Regional Medical Center's petition in 2018 for SA 18. Both of these facilities would have met Policy TE-5's requirements for 7,425 or more average ESTV procedures per LINAC in the current *SMFP* and two preceding *SMFP*s and the requirement that no need determination had been generated for the service area through the standard LINAC methodology in the three years preceding submission of a CON application. As such, First Health and Southeastern Regional Medical Center could have submitted CON applications under the proposed Policy TE-5 without filing a petition for an adjusted need determination. In the case of WakeMed and Carteret Health Care, their respective petitions in 2022 and 2021 would have still been necessary to develop additional LINAC capacity.

***2016-2025 SMFP* LINAC Need Determinations**

| | ***2016*** | ***2017*** | ***2018*** | ***2019*** | ***2020*** | ***2021*** | ***2022*** | ***2023*** | ***2024*** | ***2025*** |
|---|---|---|---|---|---|---|---|---|---|---|
| Standard Methodology | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 |
| Adjusted Need Determinations | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 1 | 0 |

While the current standard LINAC need methodology appropriately recognized the need for additional capacity in SA 19 and SA 7 in 2021 and 2022, respectively, it does not take into account additional unique circumstances that contribute to need, specifically the impact of underutilized LINACs on other providers within a service area. The current methodology's limitations when applied to situations such as these are particularly evident in CHCC-WL's case. The *2025 SMFP* data shows that CHCC-WL, as a single facility, exceeds the threshold of 6,750 ESTV procedures by 1,223 ESTV procedures, or 18.1 percent per individual LINAC. When CCHC-WL's total ESTV procedures (31,893) for FY 2023 are compared against the number of ESTV procedures if each of the four existing LINACs performed at the same threshold amount of 6,750 ESTV procedures (6,750 x 4 = 27,000), the excess of 4,893 ESTV procedures at the facility (31,893 – 27,000 = 4,893) represents nearly 72% of the 6,750 ESTV procedures required by the CON rules to justify adding a fifth LINAC.[5]

[5] 10A NCAC 14C .1903 Performance standards require that applicants filing a CON for a LINAC unit must project that the proposed LINAC shall "perform during the third full fiscal year of operation following completion of the project either: (a) 6,750 or more ESTVs per LINAC; or (b) serve 250 or more patients per LINAC."

However, this high rate of utilization is obscured by grouping with underutilized LINACs at the two other providers that comprise SA 12: High Point Medical Center, which operates 2 LINACs averaging 4,862 procedures per unit, and UNC Rockingham, which operates a single LINAC averaging 2,684 procedures per unit. Not only are LINACs at High Point Medical Center and UNC Rockingham performing significantly below the 6,750 threshold, but procedure volume at these two other service area facilities has been trending downward over the course of the past three years, further reducing the likelihood of triggering need through the standard methodology. The disparity between CHCC-WL's utilization (7,973 procedures per unit) and the service area average (6,328 procedures per unit), shown in the table below, illustrates how the application of the current methodology can mask significant capacity constraints at high-performing facilities.

**Service Area 12 Average ESTVs per LINAC Data Years 2019-2023**

| *Facility (LINAC Inventory)* | *2021 SMFP* | *2022 SMFP* | *2023 SMFP* | *2024 SMFP* | *2025 SMFP* | *CAGR* |
|---|---|---|---|---|---|---|
| CHCC-WL (4) | 7,274 | 6,928 | 7,127 | 7,617 | 7,973 | 1.9% |
| Percent above 6,750 threshold | 7.8% | 2.6% | 5.6% | 12.8% | 18.1% | |
| High Point Medical Center (2) | 5,428 | 5,180 | 4,912 | 4,988 | 4,862 | (2.2%) |
| UNC Rockingham (1) | 5,255 | 6,254 | 3,104 | 2,505 | 2,684 | (12.6%) |
| **Total SA 12 (7)** | **6,458** | **6,332** | **5,920** | **6,136** | **6,328** | **(0.4%)** |

Of note, Cone Health recognizes and supports the need for patients in rural areas, like Rockingham County, to have local access to radiation oncology treatment options; however, the table above clearly demonstrates that available capacity on other units within the service area—particularly in rural areas—does not offset the need for capacity at large, comprehensive cancer centers such as CHCC-WL. As the SHCC is certainly aware and has recognized through its approval of past petitions, patients from urban areas like Guilford County are unlikely to seek care in rural areas like Rockingham County; similarly, patients within one health system like Cone Health that offers radiation oncology services are likely to desire to stay within that health system for care, rather than changing providers to an unfamiliar system for their weeks of radiation treatment. These facts, and the continued growth of volume at CHCC-WL compared to the decline at the other service area facilities demonstrate the need for the proposed Policy TE-5.

**IMPACT OF PROPOSED CHANGE**

In analyzing facilities with average ESTV volume consistently at or over the 6,750 threshold by 10 percent or more, Cone Health identified the three facilities whose historical record of utilization over the past two years, as demonstrated in *2025* and *2024 SMFP* data, may constitute eligibility to submit a CON application pursuant to proposed Policy TE-5. See the table below for information regarding those facilities and their utilization.

**Facilities with Average Utilization 10 Percent Above Threshold**

| *Average ESTV Procedures* | | | | | |
|---|---|---|---|---|---|
| ***Facility (LINAC Inventory)*** | ***SA*** | ***2025 SMFP*** | ***% Above Threshold*** | ***2024 SMFP*** | ***% Above Threshold*** |
| Atrium Health University City (1) | 7 | 8,714 | 29.1% | 7,918 | 17.3% |
| Atrium Health Union (1) | 7 | 8,996 | 33.3% | 8,279 | 22.7% |
| Cone Health Wesley Long (4) | 12 | 7,973 | 18.1% | 7,617 | 12.8% |

Of note, if proposed Policy TE-5 were in the *2025 SMFP*, the two facilities in Service Area 7 would not qualify to apply, since there has been a need determination in that area within the past three years. Cone Health also notes that the *2025 SMFP* shows a deficit of 0.11 units in that service area, indicating that if it has continued to experience growth in the last year, a need determination may be generated as early as the *2026 SMFP*, in which case the facilities in Service Area 7 would not qualify under the proposed policy but could apply pursuant to the standard need determination.

**REASONS FOR THE PROPOSED CHANGE**

The current LINAC methodology creates significant barriers to expanding capacity where it is most needed. Patients receiving care at facilities experiencing high LINAC utilization rates, such as CHCC-WL, encounter several challenges due to providers' limited capacity and the difficulty of addressing these constraints through the current need methodology.

The impact of operating consistently above capacity creates multiple challenges for patients. Treatment initiation is often delayed due to extended wait times, and existing patients frequently experience disrupted treatment schedules that may compromise optimal care timing. Many patients face increased travel burden when forced to seek care at alternate facilities, leading to potential interruption in continuity of care. These circumstances add unnecessary stress and anxiety during an already challenging time for patients and their families. Furthermore, patients may incur additional financial burden from increased travel requirements and potential care fragmentation if services cannot be received at and coordinated by a single provider.

Radiation therapy represents a critical modality of cancer treatment often employed alongside medical oncology and surgical interventions. Accordingly, delays in administering radiation therapy can affect a patient's entire treatment plan, which assumes timely coordination of various services to ensure the greatest possible efficacy and reduce the overall level of risk to a patient's safety and holistic well-being. Without a means for increasing LINAC capacity at highly utilized facilities, patients must choose between extended wait times at their preferred provider or seeking care elsewhere, potentially delaying and thereby compromising the delivery of their complete treatment plan.

Beyond losing the services and support of a care team familiar with the clinical and personal details of a patient's case, transferring care to another location or service provider places a considerable burden on patients and their families. Not only does this process require them to review insurance coverage and navigate unfamiliar health systems and new physical environments, in some cases, it may entail significant travel time. This is particularly concerning for patients whose compromised physical condition can exacerbate the hardship of changing the location of their care. Additionally, the process of becoming

reestablished at another provider requires the handoff of critical health information from one provider to another, a transfer which carries the risk of miscommunication and the possibility of a decreased offering of comprehensive services at alternate facilities.

Within this context, the proposed policy would enable facilities to expand LINAC capacity based on consistently high utilization and demonstrated need, ensuring patients can receive timely care at their preferred location without compromising treatment plans or timely access to care. Of note, additional LINAC capacity developed under TE-5 would not only enable providers to better meet the current demand for services during normal hours of operation, but would also support uninterrupted delivery of services when highly utilized LINAC units experience scheduled or unexpected downtime or maintenance, since the redundancy enables providers to continue treating patients and shift volume from one unit to another as needed.

**ADVERSE EFFECTS IF PETITION IS NOT APPROVED**

Not adopting Policy TE-5 will result in adverse effects on providers with high LINAC utilization, including CHCC-WL, and, most importantly, on patients needing timely access to LINAC services.

If the petition is not approved, patients will continue to face significant challenges accessing timely radiation therapy services within the system where they have received their diagnosis from providers who they have come to trust and rely upon for their care. The decreased patient access will manifest in several ways: extended wait times for treatment initiation, limited ability to accommodate urgent cases, reduced flexibility in scheduling follow-up treatments, and increased travel burden for patients under the clinical necessity of seeking more immediate care elsewhere. Time-sensitive treatments may face delays, treatment schedules may be disrupted affecting optimal care delivery, and continuity of care may be compromised when patients must seek treatment at multiple facilities. In both the long and short term, the unpredictability of these circumstances together with the various hardships they impose have a detrimental effect on patients' physical and emotional wellbeing, contributing to a higher degree of anxiety as well as an increased risk of morbidity or mortality. As previously noted, patients who experience delays, including prolonged wait times between referral and treatment, are more likely to suffer from stress-related psychological conditions and outcomes characterized by a worsened rate of survival. Furthermore, it is important to recognize that the effects described herein also extend to family members and caregivers who can experience similar emotional burdens and hardships when a loved one's treatment initiation is delayed or moved to an alternate provider. These individuals share in the ordeal of long wait times, and in some cases, bear additional logistical and financial burdens, which can increase in the face of unpredictable or fragmented care.

From a provider perspective, the inability to generate additional capacity as needed gives rise to significant operational challenges, challenges which only further compound the patient access issues the proposed Policy TE-5 is designed to address. Without a means of developing capacity outside the standard LINAC methodology, existing equipment at facilities experiencing consistently high procedure volumes must perform above capacity for extended periods of time, which increases the likelihood of more frequent, more extensive, and costly maintenance. Over time, the accommodation of excessive procedure volume translates to higher overall operational expenses as well as a shorter lifetime for equipment. Moreover, the downtime necessary for both expected and unexpected maintenance reduces procedure capacity, leading to delays that must be counterbalanced by adding hours of operation which may not be convenient

for patients who are rescheduled due to such delays. The necessity of extending hours has the further consequence of placing greater strain on the staff operating the equipment, a circumstance that can negatively affect not only efficiency but safety and quality of care.

**ALTERNATIVES CONSIDERED**

As part of the analysis involved in this proposal, Cone Health considered alternatives to the recommendation of Policy TE-5 which it evaluated against the set of circumstances present in SA 12 and ultimately rejected as less comprehensive and less effective. The alternatives considered are described below.

Maintain Status Quo

Maintaining the status quo would require waiting for a need determination to be triggered in SA 12 through the standard methodology. This alternative was rejected for several reasons. First, SA 12 includes a large metropolitan county, Guilford County, and a smaller rural county, Rockingham County, and it is highly unlikely that the average ESTV procedures will rise sufficiently in the near future to trigger a need through Criterion 1 or Criterion 3. Historical analysis of procedure volumes at CHCC-WL and High Point Medical Center shows that if utilization at these facilities remained constant, procedure volumes at UNC Rockingham, the most underutilized of the service area LINACs, would need to increase by 173 percent to effectively bring up the service area average and trigger a need determination. Alternatively, if procedure volumes at CHCC-WL and UNC Rockingham remained constant, High Point Medical Center, the provider with the second most utilized LINACs in the service area, would need to show a substantial (48 percent) increase to impact the overall utilization metrics and trigger a need determination. Conversely, if High Point Medical Center and UNC Rockingham remained constant in their procedure volumes, CHCC-WL would need to increase by 15 percent to make up for the underutilization at its counterpart providers and raise the service area average. The 36,531 ESTV procedures CHCC-WL would need to perform in this last scenario would represent each existing LINAC performing an average of 9,132 ESTV procedures, or 35 percent above the methodology threshold of 6,750, an unsustainable volume based on the significant capacity constraints already experienced at current volumes. Notably, this hypothetical volume of 36,531 ESTV procedures exceeds CHCC-WL's actual maximum capacity (33,280 ESTVs) by 3,251 ESTVs, or nearly 10 percent. Please see the table below for the percent increase of volume independently needed at each facility in SA 12 to trigger a need determination through the standard methodology.

**Total Annual Procedures Needed to Meet the Service Area Threshold, by Facility**

| *Facility* | *ESTV Procedures Needed** | *% Increase* | *Criterion 3 Threshold* |
|---|---|---|---|
| UNC Rockingham | 7,322 | 173% | 0.25 |
| High Point Medical Center | 14,361 | 48% | 0.25 |
| Wesley Long | 36,531 | 15% | 0.25 |

*Assumes all other providers' volume remains constant

Even if SA 12 meets Criterion 3 through significant volume increases according to one of the three scenarios described above, the requirement of meeting a second criterion under the current methodology is unlikely to be fulfilled in the coming years. Due to population distribution patterns, SA 12 is also unlikely to meet Criterion 1. Based on NC OSBM projections for population growth in Guilford and Rockingham counties, the service area is not projected to reach an average population of 120,000 residents per LINAC

unit for many years. Although Guilford County, with its population of 560,760, is expected to grow by a compound annual growth rate (CAGR) of 1.1 percent from 2025 to 2030, Rockingham County has a population of 92,415 and is not expected to experience any growth from 2025 to 2030.[6] Accordingly, SA 12 would not be able to meet Criterion 1 until 2054, assuming constant growth rates. SA 12 is similarly unlikely to trigger a need by meeting Criterion 2 due to its 21.87 percentage of inmigration.

File Petition for Special Need Adjustment

While special need adjustments have been successfully used in the past, this approach addresses only individual, one-time cases rather than the systemic need for an alternative pathway for facilities with consistently high utilization. As previously stated, the frequency of summer petitions in recent years (2024, 2023, 2022, and 2019) demonstrates the limitations of the current methodology under various circumstances, and these limitations are especially apparent when the methodology is applied to service areas characterized by the grouping of highly utilized LINAC providers with providers operating underutilized equipment. Given that that this latter circumstance arises from inherent factors that are less susceptible to change, special need adjustments do not provide a comprehensive or sustainable means for addressing ongoing capacity constraints at high-performing facilities and may result in inequitable access to additional capacity across the state.

Change to the Existing LINAC Methodology

Cone Health also considered but ultimately rejected proposing a change to the current methodology. Although such an alternative represents a similar strategy, Cone Health realizes that the development of an updated methodology would likely require a work group and would be available, at the earliest, in the *2027 SMFP*. Policy TE-5 as proposed sets forth requirements that promote efficient delivery of LINAC services from established providers. Moreover, as previously stated, the standard methodology has recognized and generated need determinations for SA 7, inclusive of Anson, Mecklenburg, and Union counties, and SA 19, inclusive of Brunswick, Columbus, New Hanover, and Pender counties in 2022 and 2021, respectively, demonstrating its ability to appropriately identify LINAC needs for service areas.

**EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION**

Given the inclusion of several safeguards in the proposed Policy TE-5, Cone Health does not believe that this policy will result in unnecessary duplication of health resources. Conditions specified in the policy as proposed ensure that only existing licensed hospitals who have demonstrated sustained high utilization above the methodology threshold and are projected to comply with existing performance standards can apply to develop additional capacity pursuant to this proposed policy. Under the proposed Policy TE-5, facilities must demonstrate that existing LINACs have consistently exceeded the LINAC methodology threshold of 6,750 by 10 percent or 7,425 average ESTV procedures per LINAC as published in the current *SMFP* and for *SMFP*s published in the two years preceding submission of the CON application. Additionally, Policy TE-5 specifies that the location of the proposed LINAC be limited to the main campus or an acute care hospital that operates under the license of the main campus.

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6 NC OSBM Population Projections, 2020-2030

**EVIDENCE THAT THE PROPOSED CHANGE IS CONSISTENT WITH THE THREE BASIC PRINCIPLES**

Cone Health believes that its proposed Policy TE-5 is consistent with the three basic principles of the North Carolina *State Medical Facilities Plan*: safety and quality, access, and value.

Safety and Quality

The proposed change will allow providers to generate additional capacity when their existing LINACs consistently operate above the 6,750 ESTVs threshold found in the standard methodology. Without this change, a provider could operate significantly above capacity without generating additional need through the standard need methodology. Performing beyond capacity limits the ability to treat patients, leads to delays in care, and ultimately increases healthcare costs.

Policy TE-5 promotes safety and quality care by ensuring patients receive radiation therapy in a timely manner that both adheres to their prescribed course of treatment and promotes the greatest possible efficacy of individual or serial treatments. When facilities are stretched beyond capacity, it impacts the ability to give each patient the personalized attention and precise treatment delivery they deserve. Cancer treatment requires careful timing and coordination - from the initial radiation therapy through to follow-up treatments that often need to be synchronized with other forms of care, which may include chemotherapy or surgery. By allowing providers to generate additional capacity to accommodate consistently high patient volumes, the proposed policy would help support patients as they start and maintain their treatment schedule, reducing the administrative burden of having to keep track of multiple appointments as well as the anxieties that arise from unexpected deviations in care. Furthermore, when equipment needs maintenance or sudden repairs, having additional capacity means patients who are ready or already present for their appointments can be seamlessly transitioned to another unit, preventing any disruption to their critical care schedule.

Equally important, this policy helps patients maintain established relationships with a healthcare team who knows their unique medical history and personal circumstances. Given the complexity and highly individualized nature of cancer care, treatment decisions require continuous access to providers who are familiar with a patient's clinical and non-clinical needs and can advise accordingly. When capacity constraints force patients to seek radiation therapy elsewhere, they lose the benefit of having their care team – radiation oncologist, medical oncologist, surgeons, and any other specialists involved – collaborating in one place. Beyond a minor inconvenience, patients who find themselves in this position must navigate an unfamiliar facility, develop trust in new care providers, and risk important details about their care getting lost in the handoff between facilities. According to the Agency for Healthcare Research and Quality (AHRQ), handoffs significantly impact quality of care and patient safety, with research linking inadequate communication to adverse effects across various settings.[7] By contrast, the proposed policy, by enabling patients to receive all their treatment at their chosen facility, helps ensure safer, more coordinated care with less risk of gaps or oversights that could occur when care is fragmented across multiple locations.

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[7] "Handoffs and Signouts." *PSNet*. Agency for Healthcare Research and Quality, US Department of Health and Human Services. September 7, 2019. Last updated March 3, 2025. Accessed at Handoffs | PSNet.

In light of the concerns raised by multiple health systems during discussions of proposed policy TE-4, Policy TE-5 includes several provisions that work to avoid the misuse and patient safety risks that could occur as a result of too broad a range of facilities being eligible to apply for a LINAC. Under Policy TE-5, acute care hospitals would be the sole type of facility eligible to apply for a LINAC outside of the standard methodology or an adjusted need determination obtained through a petition. Consequently, the policy would ensure that prospective applicants meet clearly defined, nationally recognized accreditation standards and stand accountable to oversight bodies for safety and quality in the provision of healthcare services. With respect to radiation therapy, the layers of clinical supervision and review built into the infrastructure of hospitals, particularly those affiliated with larger health systems, serve to uphold standards based on quality delivery of care and prevent either mistakes or inappropriate use, the risks of which are more serious when involving radiation. Moreover, hospitals possess the necessary specialist and support staffing resources to safely operate radiation therapy equipment and guide patients through their entire course of radiation treatments. The volume stipulations written into the policy likewise safeguard patients' best interests, since they prevent the development of low-volume centers that end up being underutilized and offer more costly, lower quality care out of operational necessity or motives of profitability. As such, the proposed policy plays an important role in protecting patients and keeping the provision of radiation therapy services in the exclusive management of facilities properly equipped to offer high quality, reputable care.

Access

Policy TE-5 increases access by creating a pathway for capacity expansion in areas with demonstrated need, ensuring both new and existing patients can receive timely treatment at convenient locations suitable for their specific clinical needs. The policy also allows patients to maintain treatment at their preferred provider rather than being forced by capacity constraints to seek care elsewhere. Improved access is particularly important when considering specialized treatments such as SBRT and SRS, which demand longer treatment slots and create unique scheduling challenges under current capacity limitations.

Additionally, the policy promotes access for underserved populations by enabling them to receive treatment at familiar locations, thereby reducing both transportation costs and the challenges of navigating unfamiliar health and insurance systems. By supporting timely administration of coordinated treatments for patients receiving cancer care via multiple modalities, the policy facilitates access to a broader spectrum of services.

Value

Policy TE-5 enhances value by optimizing resource utilization at high-performing facilities while reducing operational inefficiencies caused by overcapacity. The policy supports cost-effective operations through economies of scale, enabling providers to deliver more affordable radiation therapy services to a larger number of patients. By reducing the need for extended hours of operation and minimizing wear and tear on existing equipment, the policy helps control operational costs that could otherwise lead to higher treatment expenses.

Notably, the policy promotes value for patients by minimizing the financial burden associated with fragmented care, including increased travel costs and additional expenses associated with receiving care

at multiple facilities. Furthermore, the policy streamlines coordination between radiation therapy and other treatment modalities, leading to more efficient and effective care delivery that contributes to improved patient outcomes.

**CONCLUSION**

Cone Health requests that the SHCC approve the addition of the proposed Policy TE-5. This policy would provide a clearly defined path for facilities with highly utilized LINACs to expand LINAC capacity where needed, ensuring patients have timely access to radiation therapy services. The policy's requirements maintain appropriate safeguards while addressing the unique needs of facilities located in service areas composed of both high- and low-utilization providers. Most importantly, approval of this policy would support better outcomes for cancer patients by enabling them to receive coordinated, timely care in their communities without unnecessary delays or disruptions to critical, life-saving treatment.

Thank you for your consideration.