



## Comments Regarding 2025 LINAC Workgroup

### CONTACT

Kristy Kubida  
Director, Strategy & Planning  
(336) 207-0823  
[Kristy.Kubida@conehealth.com](mailto:Kristy.Kubida@conehealth.com)

### INTRODUCTION

Cone Health, an existing provider of radiation oncology services in Service Areas (SAs) 12 and 15, submits the following comments in response to potential reforms to the linear accelerator (LINAC) methodology proposed at the October 22, 2025 LINAC workgroup meeting hosted by the State Health Coordinating Council (SHCC). While not formally represented in the workgroup's membership, having recently submitted petitions in the spring and summer of this year, Cone Health has been an active participant in conversations surrounding updates to the regulatory framework for LINACs and remains deeply invested in any initiative to improve access to radiation therapy services and quality of care. As such, the comments detailed below offer a point-by-point response to several suggestions shared hitherto and feature clinical perspective provided by Dr. Benjamin Sintay, Executive Director of Radiation Oncology and Chief Physicist at Cone Health as well as Chief Innovation Officer at Fuse Oncology. Additionally, these comments identify alternative modifications to the existing LINAC methodology and proposed areas for further investigation by the workgroup.

### MEASURING LINAC UTILIZATION

#### Considerations Related to Brachytherapy

Cone Health supports the exclusion of brachytherapy procedures in LINAC utilization analysis, as the collocation of these services stems from operational business decisions rather than capacity limitations or CON requirements. Given the nature of brachytherapy, which involves the placement of radioactive materials inside a patient's body, procedures are required to be performed in spaces with sufficient shielding to protect clinical staff and the general public from radiation exposure. While the vaults housing LINAC equipment can be utilized to administer these treatments, the decision to do so is often the result of a business strategy to repurpose existing space rather than develop dedicated space. Accordingly, these circumstances cannot be assumed as universal across all or even most health systems. Even in cases where brachytherapy and LINAC-based radiation therapy share the same facility infrastructure, these remain two distinct services and volume associated with the former should not be conflated with healthcare needs for the latter. In particular, regardless of the space used for brachytherapy, it is not a procedure that utilizes a LINAC, and as such, it is properly not considered in determining the capacity or utilization of a LINAC. For these reasons, Cone Health submits that access issues stemming from brachytherapy utilization fall outside the primary objectives of the workgroup and should not be considered as an appropriate measurement of LINAC utilization.

## Use of ESTVs

Although a number of alternative models were suggested to measure utilization across existing LINACs, Cone Health believes that equivalent simple treatment visits (ESTVs) remain the most appropriate and accurate means of calculating facility volume. Specifically, ESTVs align with Current Procedural Terminology (CPT) codes – the same reimbursement standard used by the Centers for Medicare & Medicaid Services (CMS) to determine payment rates for radiation oncology services. This alignment is not coincidental; it reflects clinical consensus that CPT code mappings appropriately capture the time, effort, and resources associated with providing each type of radiation therapy treatment, thereby accounting for significant variations in clinical complexity. As noted in the “Assumptions of the Methodology” published in the *SMFP*, the use of ESTVs was implemented with the support of health systems, in the form of comments submitted during public hearings, and is also recommended by the American College of Radiology (ACR), a position grounded in decades of clinical practice standardization.<sup>1</sup> To that end, ESTVs or analogous approaches to weighting procedures are used in other states with CON requirements for LINACs. Georgia defines “equivalent simple visits” as its utilization metric and assigns higher weights to non-simple treatments (e.g., intermediate, complex, IMRT and SRS/SBRT) to account for longer treatment times. Tennessee defines capacity based on the capabilities of the LINAC, from non-IMRT/IGRT to IMRT to SRS/SBRT, with the number of procedures each unit is capable of performing annually decreasing in proportion to the complexity of procedures being performed. Given the need to ensure that capacity and utilization are tied to the actual resources needed to perform the procedures, Cone Health believes that ESTVs remain the best method of assessing utilization for each facility.

To address potential concerns regarding the adequacy of the current ESTV table, Cone Health recommends that the workgroup consider revisions to the *SMFP* ESTV table in light of recently announced updates to CPT codes effective in 2026.<sup>2</sup> Should the workgroup believe that the current ESTV assignments do not sufficiently reflect clinical effort or acuity differences, the remedy is refinement of the valuation table rather than departure from a CPT-based framework. Such refinements would reinforce the general applicability of a broadly accepted standard for defining utilization and identifying need while avoiding the unintended consequences that may result from substituting metrics less grounded in clinical experience and institutional guidelines.

Alternative approaches to utilization measurement warrant critical examination. For example, transitioning to a system based on patient scheduling fails to account for meaningful variations among facility-specific practices, clinical workflows, and operational efficiencies. Scheduling decisions are driven by facility logistics and resource management rather than clinical acuity or treatment intensity. This approach carries substantial risk of inadvertently penalizing efficient practices while potentially rewarding operational inefficiency. Moreover, there is no standardized consensus across the radiation oncology field regarding appropriate scheduling protocols for different treatment types, making any scheduling-based metric difficult to apply consistently across diverse practice settings. The CPT code framework, by contrast, represents an established field standard supported by CMS reimbursement policy and professional guidelines.

---

<sup>1</sup> *Proposed 2026 SMFP*, p. 298.

<sup>2</sup> O’Reilly, Kevin B. “288 New CPT Codes Cover Digital Health, AI and More.” *American Medical Association*. September 2025. <https://www.ama-assn.org/practice-management/cpt/288-new-cpt-codes-cover-digital-health-ai-and-more>.

## Ensuring Quality of Care

The workgroup has emphasized quality of care as a priority; however, the workgroup's discussion to date has not provided a clear definition of what constitutes "quality" in the LINAC context or identified specific deficiencies in current regulatory mechanisms. Cone Health believes that existing quality assurance frameworks already provide robust oversight and that the most effective role for the SHCC is to defer to the CON statutes and application process which require documentation of quality as well as the specialized regulatory and accrediting bodies that possess the technical expertise necessary to establish and enforce quality standards.

Following certificate of need (CON) approval, providers of radiation therapy services must obtain a license from the North Carolina Radiation Protection Commission, which requires compliance with detailed operational, training,<sup>3</sup> and safety standards, along with the submission of a quality management plan.<sup>4</sup> Of note, the Radiation Protection Commission Rules enforced by this body were reviewed and significantly revised earlier this year, incorporating risk analysis considerations and overall modernization. Separate from these state-specific regulations, which represent the minimum standard for safety and quality, providers of radiation therapy services also have the opportunity to pursue accreditation from the ACR<sup>5</sup> and the American Society for Radiation Oncology (ASTRO),<sup>6</sup> two of the foremost professional medical associations in the field. As assurances of quality, accreditation by these two institutions reflects a facility's dedication to and superior achievements in safety and exceptional care. Taken together, this combination of factors creates sufficient incentives for existing and prospective facilities to achieve and maintain excellence in the provision of services. Not only would the interpretation and integration of highly technical regulatory language place unnecessary demands on the time and resources of the workgroup, it would also duplicate systems already in place. As such, Cone Health recommends that the Agency continue to defer to the expertise of these third parties in determinations related to appropriate use of equipment and professional standards of care.

Furthermore, patient choice represents an important but frequently overlooked indicator of quality in a competitive market. High utilization and reduced service area outmigration when a preferred provider lacks adequate capacity directly reflect patient preference driven by reputation and positive past experiences. In a functioning market, this patient-driven choice mechanism creates powerful incentives for facilities to achieve and maintain excellence in the provision of services. When patients consistently choose one provider over another despite geographic proximity to alternatives, this choice itself demonstrates sufficient reputational quality to support that preference.

---

<sup>3</sup> Chapter 15 – Radiation Protection Section .0100 – General Provisions. See 10A NCAC 15 .0214 for Training and Educational Requirements for Equipment Services. <https://radiation.ncdhhs.gov/documents/chapter%2015%20rules.pdf>.

The most recent version of the Radiation Protection Rules went into effect October 1, 2025. <https://info.ncdhhs.gov/dhsr/rules/rpr2024-4.html>.

<sup>4</sup> Application Guide for Medical Accelerator. [https://radiation.ncdhhs.gov/rms/docs/Medical%20Accelerator%20Guide%20\(Rav%2011-18\).pdf](https://radiation.ncdhhs.gov/rms/docs/Medical%20Accelerator%20Guide%20(Rav%2011-18).pdf).

<sup>5</sup> American College of Radiology. "Complete Accreditation Information: Radiation Oncology." [Complete Accreditation Information: Radiation Oncology \(Revised 4-9-2025\) : Accreditation Support](#). Revised April 2025.

<sup>6</sup> American Society for Radiation Oncology. *ASTRO's APEx- Accreditation Program for Excellence - APEx Standards Guide*. <https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/APExStandards.pdf>.

## CONSIDERATIONS FOR CHANGE

### Clarifying Language

As the workgroup continues to explore various potential solutions, Cone Health would like to request clarification on two terms that would be relevant to any changes made in LINAC utilization metrics or the need determination methodology. Current discussion has made use of both “patient” and “course of treatment,” and it has been suggested that one patient should be understood as equivalent to one course of treatment.<sup>7</sup> To ensure consistent reporting across facilities - both in the present and going forward - Cone Health believes that clear definition of these terms, including their sources and relationship to each other, is an essential first step in any methodology revision.

Radiation oncology practice demonstrates that these terms are not interchangeable. A single patient may receive multiple distinct treatment courses, particularly when an initial treatment regimen is followed by an immediate boost regimen. Because these regimens occur in succession without substantial clinical breaks, they constitute a single episode of care from the patient's perspective, yet they may be reported as separate treatment courses from an operational standpoint. This distinction creates ambiguity in utilization reporting.

The Centers for Medicare & Medicaid Services (CMS) addressed this challenge through the Radiation Oncology (RO) Model, which established a framework for determining episode boundaries based on time-based clinical thresholds. Under the CMS model, services rendered within defined time frames are grouped within a single episode of care. Conversely, if a specified number of days elapse between clinical services, the subsequent services qualify as a distinct episode. This time-based approach aligns episode definitions with clinical realities—specifically, the expected interval between treatment planning, initial treatment delivery, and boost therapy—while providing clear operational guidance for consistent reporting.

Cone Health respectfully recommends that the SHCC consider examining the CMS RO Model episode framework as a potential basis for workgroup guidance, especially in regards to the substitution of “episode of care” for terminology such as “patient” and “course of care,” which otherwise require much more explicit definition. Such alignment would promote consistency with national CMS standards, facilitate cross-system benchmarking, and reduce reporting ambiguity across North Carolina radiation oncology providers.

### Adjusted Need Determinations and Reevaluation of Proposed Policy TE-5

As the Agency is already aware, Cone Health recently received approval for its 2025 Summer petition requesting an adjusted need determination for one LINAC in Guilford County on the basis of consistently high volumes at Wesley Long Cancer Center and underutilization at other service area providers.<sup>8</sup> While the Agency's approval of this petition has the potential to relieve the identified capacity constraints should the CON be awarded to Wesley Long Cancer Center, utilization trends for SA 12 indicate that access to radiation therapy services will be a recurring issue. More broadly, the increase in adjusted need

---

<sup>7</sup> Linear Accelerator Services Workgroup, Meeting 1 PowerPoint, Slide 31. [PPTmeeting-10-22-25.pdf](#)

<sup>8</sup> Petition for an Adjusted Need Determination. [https://info.ncdhhs.gov/dhsr/mfp/pets/2025/summer/T01\\_Add\\_ND\\_for\\_LINAC\\_in\\_SA12\\_Cone\\_Health.pdf?ver=1.1](https://info.ncdhhs.gov/dhsr/mfp/pets/2025/summer/T01_Add_ND_for_LINAC_in_SA12_Cone_Health.pdf?ver=1.1).

determinations for LINACs across the state calls for a more permanent, wider-reaching solution to address situations not sufficiently represented in the existing need determination methodology.

Given this context, Cone Health continues to believe that the addition of a policy offers an appropriate means to identify and address otherwise unrecognized need. It is notable that the Agency itself, in the Spring of 2024, first suggested a policy in the form of proposed Policy TE-4.<sup>9</sup> Although the content of the Agency Recommendation was generally opposed on the grounds that it too indiscriminately opened eligibility to cancer centers/programs and imposed a requirement of only 3,375 ESTVS across all SA LINACs, the concerns expressed in the comments filed by health systems were not directed to the approach taken by introducing a potential new policy.

To this end, Cone Health respectfully recommends that the Agency revisit proposed policy exemption TE-5, submitted by Cone Health as a Spring 2025 petition.<sup>10</sup> As outlined in the petition, Policy TE-5 created a pathway to develop additional capacity for existing providers of radiation therapy services whose historical average ESTVs per LINAC exceeded the current methodology threshold of 6,750 ESTV procedures by 10 percent, or 7,425 average ESTV procedures per unit, in the most recent *SMFP* and two years prior. To avoid the proliferation of underutilized units developed by unqualified providers, proposed Policy TE-5 includes provisions affirming that applicants meet the performance standards specified in 10A NCAC 14C .1903 and that no standard need determination have been generated in the three years preceding submission of a CON. If implemented, the proposed policy exemption would be both effective and targeted, especially for high utilization facilities that continue to operate over capacity due to grouping with underutilized facilities in a service area. As demonstrated in the petition, two of the four most recent adjusted need petitions would not have been necessary under Policy TE-5: First Health's 2023 summer petition in SA 17 and Southeastern Regional Medical Center's petition in 2018 for SA 18.

Cone Health recognizes that further study and refinement may be necessary and is willing to provide additional information or recommendations to the workgroup as needed.

In conclusion, Cone Health thanks the members of the workgroup for their dedication to this issue and appreciates the opportunity to contribute on behalf of its physicians, patients, and other providers of LINAC services.

---

<sup>9</sup> Proposed Policy TE-4: Plan Exemption for Linear Accelerators Agency Recommendation. [https://info.ncdhhs.gov/dhsr/mfp/pets/2024/spring/T05\\_PolicyTE-4\\_LINAC\\_Agencyproposal.pdf](https://info.ncdhhs.gov/dhsr/mfp/pets/2024/spring/T05_PolicyTE-4_LINAC_Agencyproposal.pdf).

<sup>10</sup> Petition for New Technology and Equipment Policy. [https://info.ncdhhs.gov/dhsr/mfp/pets/2025/spring/T03\\_P\\_ConeHealth\\_LINAC.pdf](https://info.ncdhhs.gov/dhsr/mfp/pets/2025/spring/T03_P_ConeHealth_LINAC.pdf).