



### **UNC Health Comments on Proposed Policy TE-4**

UNC Health submits these brief comments in response to the proposed Policy TE-4: Plan Exemption for Linear Accelerators recommended by the Agency for inclusion in the 2025 SMFP. UNC Health urges the SHCC not to approve the Agency's adoption of Policy TE-4 in the 2025 SMFP.

The Agency's proposed Policy TE-4, as presented at the March 6, 2024 meeting of the SHCC, is as follows:

#### **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;<sup>2</sup> 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.

As described in the Agency's proposal, the SHCC approved a petition from WakeMed in 2022 for an adjusted need determination for a linear accelerator in Service Area 20 in the 2023 SMFP and a petition from FirstHealth of the Carolinas in 2023 for an adjusted need determination for a linear accelerator in Service Area 17 in the 2024 SMFP. The Agency cites the approval of these two petitions as the rationale for proposing Policy TE-4, which would allow any existing or proposed cancer center without a linear accelerator to obtain one through a CON without regard to a need determination in the SMFP.

The Agency states in its proposal that "it is unlikely that the proposed policy would lead to the proliferation of LINACs" given that "LINACs are highly specialized equipment that require considerable financial, physical, and professional resources." However, UNC Health is concerned that Policy TE-4, if adopted, may in fact result in excess linear accelerator capacity in the state with negative consequences on patient safety, quality of care, and cost to the healthcare system.

While it is true that linear accelerators are costly to develop, more providers may be financially incentivized to do so with such significantly loosened restrictions on their ability to acquire one. UNC Health believes that adoption of Policy TE-4 would be contrary to the purpose of the CON law, which recognizes that the development of unnecessary healthcare services “results in costly duplication...with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of healthcare services,” as stated in N.C.G.S. 131E-175(4). UNC Health believes that the adoption of Policy TE-4 is likely to lead to an excess capacity of linear accelerators, which may lead to unnecessary overuse of radiation therapy with financial incentives interfering with the best interest of patients.

Specifically, UNC Health has the following concerns about the proposed policy’s impact on the provision of linear accelerator services in the state.

1. In its proposal, the Agency cites the National Cancer Institute definition of “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...” to support its rationale for the proposed policy. However, whether or not a linear accelerator is standard of care for a cancer program is not the determining factor of whether or not a cancer program needs a linear accelerator. The premise put forth in the Agency’s proposal suggests that every provider of cancer services, regardless of any other factors, has an equal need for its own linear accelerator.
2. The proposed policy would apply not only to applicants with existing, established cancer centers, but also to applicants with mere intentions to develop a cancer center or program, which is not itself regulated by CON law. Further, the proposed policy would apply to an existing or proposed cancer center falling into any of the 11 categories defined by the American College of Surgeons Commission on Cancer. These categories range widely in terms of size and scope of service from a Free Standing Cancer Center Program, which is defined as offering at least one cancer-related treatment modality and has no minimum caseload requirement, to an Academic Comprehensive Cancer Program, which is defined as participating in postgraduate medical education in at least four program areas with more than 500 newly diagnosed cancer cases each year. The need that a Free Standing Cancer Center Program has for a dedicated linear accelerator is vastly different than the need of an Academic Comprehensive Cancer Program, yet either could apply under the proposed policy.
3. The proposed policy requires only that the cancer center where the linear accelerator will be developed be affiliated with at least one radiation oncologist and be affiliated with one medical physicist or make one available by referral. The requirement of simply an “affiliation” with a radiation oncologist and medical physicist can be loosely interpreted. With such a vague definition of the involvement of these providers who are essential to the delivery of radiation therapy services, concerns arise around patient safety and quality of care.
4. In service areas with at least one existing linear accelerator, an applicant under Policy TE-4 would be required to demonstrate only that the average ESTVs across all linear accelerators in the service area be at least 3,375. This is one-half the threshold of 6,750 ESTVs per linear accelerator currently required by the standard need methodology. Further, an applicant applying for a linear accelerator under Policy TE-4 would not be required to meet the performance standards for linear accelerators

in 10A NCAC 14C .1903. These policy provisions combined would greatly reduce the burden of the applicant to demonstrate that its proposed linear accelerator is needed and would be well utilized even in service areas with existing excess linear accelerator capacity.

While UNC Health believes that comprehensive, high-quality cancer care requires access to both radiation and chemotherapy, it does not believe that the provision of cancer care creates an automatic need for a linear accelerator to be owned by the same entity providing cancer care nor that separation of these services equates to substandard care. Indeed, many centers that provide cancer care services do not have radiation therapy capabilities, and their patients are able to receive radiation therapy at nearby facilities. Physicians of all types routinely share patient care responsibilities with physicians at other centers/locations. This is standard across many areas of medicine, including cancer. Indeed, the proliferation of cell phones, electronic health record systems (that can share data between various centers), and other means of rapid communication readily facilitate this type of coordinated care. **Alternatively stated: While the use of radiation therapy is the standard of care for many patients with cancer, it is not standard of care for all centers that provide cancer-care services to have radiation therapy services.**

Further, excess capacity and overutilization of healthcare services such as linear accelerator services may in fact have a negative impact on patient safety, quality of care, and costs. The proposed Policy TE-4 would allow for the development of linear accelerators even in service areas with significant excess capacity merely because that excess capacity is owned by another entity.

In addition, several people from UNC (including representatives of UNC Health) were at the SHCC meeting in September 2022 when the WakeMed petition was discussed. It is their recollection that the SHCC decided to approve WakeMed's petition based on WakeMed's allegation that *their* patients were waiting for radiation therapy and that *their* patients were having issues accessing radiation therapy services at the existing locations in the service area. They do not recall any discussion of the SHCC determining that possession of radiation therapy services is now the standard of care for centers that provide cancer care services. Further, a review of the minutes from the September 2022 SHCC meeting does not identify anything to suggest that possession of radiation therapy services is now the standard of care for centers that provide cancer care services.

In summary, UNC Health believes that adoption of Policy TE-4 could have wide-sweeping implications that would have a negative impact on safety, quality, and cost to the healthcare system. As demonstrated in the Agency's proposal, two special need petitions have been approved for linear accelerators in the last two years. UNC Health believes that the summer petition process is a more appropriate way for the need for additional linear accelerators outside the standard need methodology to be considered on a case-by-case basis than would be the broader adoption of Policy TE-4.

UNC Health supports the standard methodology for linear accelerator equipment and the summer petition process, which allows a provider to demonstrate special circumstances that are not addressed by the need methodology. For these reasons, UNC Health urges the SHCC not to approve the adoption of the proposed Policy TE-4.