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Comments in Response to Proposed Policy TE-4: Plan Exemption for Linear Accelerators

Commenter

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Introduction

WakeMed appreciates the opportunity to provide comment regarding *Proposed Policy TE-4*. While WakeMed supports access to standard of care modalities, it requests the State Health Coordinating Council (SHCC) carefully reconsider the adoption of Policy TE-4 in its proposed format, for the reasons discussed below.

Agency Proposed Policy TE-4

At the SHCC meeting on March 6, 2024, the Agency proposed Policy TE-4 to *"allow cancer/oncology programs/centers that do not have a LINAC to obtain one without regard to a need determination in the SMFP."* The Agency's proposed policy cites recent petitions from WakeMed and FirstHealth for adjusted need determinations, both of which were approved by the SHCC, indicating linear accelerators to be considered "standard of care" for hospitals that treat cancer patients. *Proposed Policy TE-4* states it follows the structure of the recently revised Policy TE-3, which allows applicants meeting decidedly specific criteria to apply for a fixed MRI scanner without the prerequisite of a need determination.

Adverse Effects of Policy TE-4

Approval of Proposed Policy TE-4, as written, would result in several adverse effects, as outlined below.

Policy Criterion 1: Amend Language to Clarify Definition of a Cancer Program

Proposed Policy TE-4 states North Carolina is home to 131 linear accelerators across 72 facilities, **all** of which are affiliated with a hospital system, either through ownership or contractual arrangement. These hospital systems providing inpatient and outpatient services pledge equitable access to underserved populations, including radiation therapy services. All of the existing and approved linear accelerators in the SMFP inventory were obtained through the competitive Certificate of Need application process. By yielding approvals for only hospital system-affiliated applicants, the Agency has effectively determined that this contractual affiliation

is a significant advantage to patients. The criticality of preserving this tacit requirement cannot be overstated, as it increases equitable access to quality radiation care for patients.

While Criterion 1 of *Proposed Policy TE-4* endeavors to define a cancer program by referencing American College of Surgeons ("ACS") Commission on Cancer standards, the broad nature of the categories used by the ACS does not align with continuing this precedent. WakeMed suggests that Criterion 1 be amended to support the acquisition of a LINAC by cancer programs that currently offer surgical oncology and medical oncology (i.e., chemotherapy) and lack only radiation therapy services, similarly to the maturity level required of applicants utilizing Policy TE-3.

WakeMed suggests that an applicant utilizing Policy TE-4 must *demonstrate ownership or a contractual affiliation with a hospital system in the proposed LINAC service area that provides inpatient and outpatient services within the subspecialties of Medical Oncology and Surgical Oncology*.

Criterion 2: Amend Language to Ensure Operation of All LINAC Equipment

The Agency has included five criteria in *Proposed Policy TE-4* intended to guide the use of the policy. Criterion 2 states *"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"*. In an effort to ensure applicants utilizing this policy have a demonstrated both the program maturity and gap in services described in Criterion 1, WakeMed submits for consideration the following language for Criterion 2:

> *"the applicant has fully operationalized and demonstrated utilization on all of its currently existing and approved LINACs and has not been approved for a LINAC within the Service Area in the past three years."*

Requiring an applicant demonstrate operation of all owned LINACs incentivizes each applicant to implement current resources prior to requesting additional assets and would prohibit applicants from "stockpiling" needed health resources. This modification assists in avoiding a contingency of non-operational LINACs from artificially maintaining ESTVs below the threshold in Criterion 5. By removing site limitations, applicants utilizing this policy may take advantage of existing infrastructure (such as facilities already equipped with radiation shielding and other construction requirements necessary to the safe operation of a LINAC), thus reducing the cost of expeditiously adding or expanding the service.

Increase of Linear Accelerators

The only performance requirement in *Proposed Policy TE-4* is Criterion 5, which states: *"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."* This is one-half the current performance threshold. The proposed Policy goes on to state that "The performance standards in 10A NCAC 14C.1903 are not applicable."

The data provided on pages 7-11 of the proposed policy indicates that 22 of the 28 LINAC service areas had average ESTVs above 3,375 in 2021-2022. See *Table 1* below. Contrary to the Policy's intent, service areas with fewer existing linear accelerators are less likely to trigger need. Of the six service areas with average utilization below 3,375 ESTVs, four had inventories of 1 or 2 LINACs

and one had 4 LINACs. For example, *Proposed Policy TE-4* would be immediately active for Service Area 20 where there are two (2) non-operational and one (1) approved linear accelerators, while assisting only one service area with zero (0) or one (1) operational linear accelerators.

Table 1: Average ESTV in Service Area

Service Area	2021-2022 Total ESTV Procedures	Number of Linear Accelerators	Average ESTVs in Service Area
Area 1	3,339	2	1,670
Area 2	33,093	8	4,137
Area 3	2,336	1	2,336
Area 4	11,251	3	3,750
Area 5	21,492	6	3,582
Area 6	31,413	5	6,283
Area 7	76,757	12	6,396
Area 8	20,341	4	5,085
Area 9	16,615	4	4,154
Area 10	33,830	10	3,383
Area 11	3,181	1	3,181
Area 12	42,949	7	6,136
Area 13	3,884	1	3,884
Area 14	39,067	6	6,511
Area 15	9,630	2	4,815
Area 16	50,202	10	5,020
Area 17	20,355	3	6,785
Area 18	29,397	8	3,675
Area 19	34,506	5	6,901
Area 20	49,329	12	4,111
Area 21	0	1	0
Area 22	11,557	2	5,779
Area 23	13,670	2	6,835
Area 24	16,726	4	4,182
Area 25	2,694	1	2,694
Area 26	11,567	4	2,892
Area 27	27,359	6	4,560
Area 28	8,613	2	4,307

Source: 2024 SMFP, page 326

Due to the nature of the proposed policy and absence of Performance Standards, the applications generated through this policy would be non-competitive, which could result in the approval of multiple applicants at new sites within the same Service Area. The unintended consequences of this policy may prevent the standard need methodology from calculating a need for a given service area indefinitely, effectively replacing the standard need methodology altogether.

WakeMed suggests evaluation of whether modifications to the standard need methodology may accomplish comparable goals to those intended by Proposed Policy TE-4.

Diagnostic vs Therapeutic Modalities

The proposed policy states its creation was spurred from the determination that a linear accelerator is "standard of care" for cancer treatment. WakeMed, being the most recent petitioner of change for, and a beneficiary of, Policy TE-3 for MRI service, as well as the recipient of a recently approved linear accelerator through a petition for an adjusted need determination, would like to note that there is a significant difference between the *diagnostic* nature of a Fixed MRI scanner and the *therapeutic* nature of a Linear Accelerator. While Fixed MRI is a diagnostic imaging tool that is widely used and appropriate for patients of numerous medical specialties, a linear accelerator is a highly specialized therapeutic modality used strictly for the treatment of cancer. It is the distinction between these two modalities that should be carefully considered when determining the scope of *Proposed Policy TE-4*. As noted above, WakeMed believes that application of the policy should be limited to providers that currently offer medical oncology and surgical oncology services to ensure comprehensive cancer care is available to all patients and to discourage/minimize fragmentation of care.

Petition Process vs Policy

WakeMed has been a beneficiary of the recent modification to Policy TE-3 for Fixed MRI, as well as an Adjusted Need Determination for a Linear Accelerator by way of the current petition process. WakeMed is supportive of change in SMFP policies when those changes are proven necessary, either by an extenuating circumstance or hardship which cannot be resolved with an Adjusted Need Determination. However, the proposed Policy TE-4, as written, does not appear to be in response to either condition. WakeMed supports the current petition process, and believes that a carefully crafted Policy TE-4 could be beneficial in ensuring that Radiation Therapy services are made available to established cancer programs at hospitals and hospital affiliates.

Summary

WakeMed respectfully recommends that the Technology and Equipment Committee consider alternative wording to Proposed Policy TE-4, particularly Criteria 1 and 2, that would place additional requirements on potential applicants.

WakeMed appreciates the diligence and effort of the SHCC and the Agency in preparation of the SMFP. Thank you for the opportunity to provide comments for your consideration.

Sincerely,

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