



COMMENTS ON PETITION FOR A PLAN EXEMPTION POLICY FOR LINEAR ACCELERATORS

COMMENTER

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INTRODUCTION

Wayne Memorial Hospital, Inc., d/b/a UNC Health Wayne,¹ appreciates the opportunity to comment in support of the recent Spring petition filed by WakeMed to add a new technology and equipment policy to the *2026 State Medical Facilities Plan (2026 SMFP)*. Prior to the filing of WakeMed's petition, UNC Health Wayne notes a similar petition filed by the Agency in 2024, Policy TE-4: Plan Exemption for Linear Accelerators, that would allow cancer/oncology programs without a linear accelerator (LINAC) to obtain a certificate of need (CON) without requiring a need determination in the service area. Both the Agency's proposed policy TE-4 and WakeMed's current proposal for the addition of Policy TE-5 aim to expand access to external beam radiation treatment at hospitals with established cancer programs that do not yet have a LINAC. Additionally, such expansion could significantly improve access in rural areas such as those served by UNC Health Wayne. As the sole acute care facility in Wayne County, UNC Health Wayne expressly supports these objectives as demonstrated by its 2024 filing of a summer petition requesting a special need adjustment in the *2025 State Medical Facilities Plan* for one additional LINAC in Service Area (SA) 23, "to be designated for Wayne County, and/or with the stipulation that it can only be approved for an existing multimodality provider of cancer care that does not have a linear accelerator." UNC Health Wayne urges the State Health Coordinating Council (SHCC) to approve WakeMed's petition, with the proposed minor modifications outlined below:

¹ Wayne Memorial Hospital, Inc. is managed by UNC Health.

COMMENTS

As stated in its petition, WakeMed proposes adding the following language to develop the new policy:

Policy TE-5: Plan Exemption for Linear Accelerators in Cancer Center Hospitals

An applicant proposing to acquire a linear accelerator (LINAC) under this policy shall demonstrate in its certificate of need (CON) application that:

- 1. It offers a cancer program that provides both inpatient and outpatient medical and surgical oncology services, including documentation that it served at least 5,000 annual encounters in the last 12 months prior to submission, employs cancer staff that includes at least two (2) Board-certified medical oncologists that participate in multidisciplinary Tumor Boards, and maintains an active Tumor Registry;*
- 2. The proposed LINAC will not be located at a site where the inventory in the SMFP reflects that there is an existing LINAC or a CON awarded for a LINAC that was obtained in the five years immediately preceding the filing of the CON application;*
- 3. It does not, directly or through a related entity, have an awarded or non-operational LINAC located in the proposed service area;*
- 4. It has identified at least two (2) radiation oncologists who will be employed by the applicant to provide services for patients utilizing the proposed LINAC;*
- 5. It will have physics and dosimetry staffing levels that meet American College of Radiology personnel standards for Radiation Oncology LINAC services;*
- 6. It will meet standards of the American Society for Radiation Oncology (ASTRO) for safety and quality;*
- 7. It has or will have a LINAC simulator located in the same building as the proposed LINAC;*
- 8. If one or more LINACs are located in the applicant's service area, the average annual utilization across all operational LINACs in the service area is at least 4,500 ESTVs;*
- 9. The proposed LINAC's utilization will reach at least 6,750 ESTVs by the third project year; and*
- 10. It is a licensed North Carolina acute care hospital that its Certified by the Center for Medicare and Medicaid Services and has an active, published charity care program at the time of the application.*

While UNC Health Wayne supports the new policy proposed by WakeMed, UNC Health Wayne believes that the language included in several criteria of the policy should be modified for purposes of clarity and to better address circumstances that may exist for facilities operating cancer programs in rural areas. Specifically, these modifications concern policy Criteria 1, 3, 4, and 9, each of which will be discussed in turn.

Firstly, UNC Health Wayne recommends the following modification to Criterion 1 of the new policy proposed by WakeMed. While UNC Health Wayne acknowledges the critical importance of adequate provider coverage in the safe operation of LINAC services, the language of Criterion 1, as currently drafted, would require physicians to be directly employed by the applicant facility. This particular requirement is unduly restrictive and does not allow for situations in which medical oncologists are dedicated to the hospital's cancer program but not as employees of the applicant facility. Rural areas typically have access to a more limited clinician workforce, including oncologists, and may have fewer of the resources necessary to directly employ them; nonetheless, the independent, non-employed providers are just as committed to the success of the service. The modification, as detailed in the revised language below, would maintain high standards for provider coverage while creating appropriate flexibility for the operational realities faced by many cancer programs, particularly those in rural areas:

1. *It offers a cancer program that provides both inpatient and outpatient medical and surgical oncology services, including documentation that it served at least 5,000 annual encounters in the last 12 months prior to submission, employs **or otherwise contracts with** cancer staff that includes at least two (2) Board-certified medical oncologists that participates in multidisciplinary Tumor Boards, and maintains an active Tumor Registry;*

With respect to Criterion 3, UNC Health Wayne requests further clarification be added to provide the precise definition of a related entity. For example, SA 23 (consisting of Duplin, Lenoir, and Wayne counties) includes both UNC Health Wayne and UNC Lenoir. While both facilities are managed by UNC Health, they are not related entities as defined by 10A NCAC 14C .0202(10). Apart from that point of ambiguity, UNC Health Wayne also suggests that this criterion addressing the matter of related entities be focused on the county level rather than applied at the service area level, since the vast majority of the LINAC service areas identified in the 2025 SMFP – twenty-three out of the existing twenty-eight– are multicounty groupings. In order to make this criterion less prohibitive for smaller or rurally-based applicants experiencing a need for LINAC capacity, UNC Health Wayne suggests that Criterion 3 reference related entities in the county where the LINAC is being proposed instead of the service area as written below.

3. *It does not, directly or through a related entity (**as defined in 10A NCAC 14C .0202(10)**), have an awarded or non-operational LINAC located in the **same county as proposed by the applicant**;*

UNC Health Wayne's recommended modifications to Criterion 4 of the proposed policy are fundamentally similar to those already set forth in relation to Criterion 1 and reflect the same intent. The basic requirement to identify a radiation oncologist is appropriate to the aims of staffing the proposed equipment and maintaining patient safety. However, UNC Health Wayne would like to acknowledge the extreme difficulty involved in requiring an applicant to have secured multiple radiation oncologists for employment (e.g., "who will be employed") prior to actually having obtained CON approval to develop a LINAC. Therefore, instead of requiring the identification of two radiation oncologists employed by the applicant facility, UNC Health Wayne suggests requiring the identification of at least one radiation oncologist, willing and capable of providing radiation oncology services upon development of a LINAC. As previously stated, smaller cancer programs in rural areas simply do not have access to a large workforce of specialists such as radiation oncologists, nor are two full-time radiation oncologists necessary for smaller radiation oncology programs, particularly during the initial implementation phase of these services. Criterion 4 should therefore be modified to recognize the development of relationships aimed at securing coverage by physicians who are interested in and capable of carrying out the full range of duties and responsibilities prior to the development of a LINAC. The language suggested below allows for greater flexibility in obtaining adequate staffing and safeguards in the provision of LINAC services.

4. It has identified at least *one (1)* radiation oncologist *who has expressed interest in providing services for patients utilizing the proposed LINAC*:

Lastly, UNC Health Wayne believes that the requirement of 6,750 ESTVs specified in Criterion 9 is largely duplicative of the threshold found in the Performance Standards contained in 10A NCAC 14C .1903 and therefore should be eliminated or amended to allow greater flexibility in demonstrating adequate projected utilization. Specifically, the existing LINAC Performance Standards allow applicants flexibility in meeting either the threshold of 6,750 ESTVs by the third project year or the alternative metric of serving 250 or more patients per LINAC in the third project year. This alternate threshold of projecting to serve greater than 250 patients accommodates the treatment of certain types of cancer that may require fewer ESTVs than would be demonstrated solely by an ESTV total. Of note, eliminating or modifying Criterion 9 would be consistent with previous proposals attempting to address unidentified LINAC need. As one example, the Agency's 2024 spring petition proposed eliminating the Performance Standard for applicants under the policy, which UNC Health Wayne would also support. With its threshold of 6,750 ESTVs, Criterion 9 also overlaps with the primary means of developing LINAC capacity since meeting or exceeding 6,750 ESTVs already triggers a need determination in the current standard LINAC methodology. To remain consistent with existing LINAC Performance Standards, UNC Health Wayne recommends the inclusion of a patient count along with an ESTV count as indicated below, allowing for flexibility in the demonstration of adequate treatment volumes. Finally, if this Criterion remains in the policy, UNC Health Wayne also suggests that the language be modified to reflect, like the performance standards, that the applicant is required to reasonably project sufficient utilization and cannot otherwise be held to a definitive standard that it "will reach," which implies certainty.

9. The proposed LINAC's utilization *is reasonably projected to reach at least 6,750 ESTVs per LINAC or serve 250 or more patients per LINAC* by the third project year; and

[revised language]

Please note that the modifications proposed by UNC Health Wayne are consistent with the intent of WakeMed's petition – to support the existing methodology contained in the SMFP and create a policy designed to "address a critical imbalance in access to LINAC services." The modifications detailed in these comments are recommended to remove ambiguity with regard to certain definitions and adapt the policy to make it more inclusive toward facilities currently providing radiation therapy services in rural areas with limited access to workforce resources.

SUMMARY

UNC Health Wayne believes that Policy TE-5 proposed by WakeMed to create an alternative pathway for facilities to develop additional LINAC capacity outside the standard LINAC need methodology, is appropriate and should be approved with the minor modifications suggested herein. Not only does the proposed policy uphold the principles of the CON law, but it will also serve to improve patient access to these critical services and enable greater flexibility for providers.

Thank you for your time and consideration.