Technology and Equipment Committee Agency Report Adjusted Need Petition for Linear Accelerator Equipment in the 2025 State Medical Facilities Plan

Petitioner:

Wayne Memorial Hospital, Inc. 2700 Wayne Memorial Drive Goldsboro, NC 27534

Contact: Howard Whitfield, OT/L, MHA Chief Operating Officer 919-731-6908 Howard.whitfield@unchealth.edu

Request:

Wayne Memorial Hospital, Inc. requests an adjusted determination in the 2025 State Medical Facilities Plan (SMFP) for one additional linear accelerator (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 LINAC.

Background Information:

Chapter Two of the *SMFP* notes that during the summer, the Agency accepts petitions that "involve requests for adjustments to need determinations in the *Proposed SMFP*. Petitioners may submit a written petition requesting an adjustment to the need determination in the *Proposed SMFP* if they believe that special attributes of an SA or institution give rise to resource requirements that differ from those provided by the standard methodologies and policies." Any person may submit a certificate of need (CON) application for a need determination in the *SMFP*. The CON review could be competitive and there is no guarantee that the Petitioner would be the approved applicant.

The standard LINAC methodology incorporates: (1) a geographic accessibility criterion requiring a population base of 120,000; (2) a criterion aimed at assuring efficient use of megavoltage radiation facilities such that Equivalent Simple Treatment Visits (ESTV) procedures divided by 6,750, minus the number of existing linear accelerators equals at least .25; and (3) a patient origin criterion requiring 45% or more of an SA's patients to come from outside the SA. A need determination is generated when an SA meets two of the three criteria.

Service Area 23 consists of Duplin, Lenoir, and Wayne Counties and has two LINACs. The only hospital-based LINAC is at UNC Lenoir in Lenoir County. It reported 6,015 ESTVs for this LINAC in 2023. The other LINAC is at North Carolina Radiation Therapy Management Services (GenesisCare) in Goldsboro, Wayne County. This outpatient facility reported 5,595 ESTVs on its

LINAC. This total of 11,610 is less than the need determination threshold of 13,500 for two LINACs. Thus, SA 23 does not have a need determination in the *Proposed 2025 SMFP*.

Analysis/Implications:

To support its request, the Petitioner first points out that need determinations for LINAC that are based on the standard methodology have become rare. The *SMFP* has had six LINAC need determinations from 2019 through 2024. The Petitioner noted that four of these were the result of petitions for adjusted need determinations (see Table 1).

SMFP	Service Area	Constituent Counties	Notes
2019	18	Bladen, Cumberland, Robeson, Sampson	-Based on petition and designated for Robeson County. -CON issued to Southeastern Medical Center.
2020	N/A		
2021	19	Brunswick, Columbus, New Hanover, Pender	-Standard need determination. -CON issued to Novant Health New Hanover – Scotts Hill
2022	7	Anson, Mecklenburg, Union	-Standard need determination. -CON issued to Atrium Health Pineville.
2022	24	Carteret, Craven, Jones, Pamlico	-Based on petition and designated for Carteret County. -CON issued to Carteret General Hospital.
2023	20	Franklin, Wake	-Based on a petition. -Applications received from Duke, UNC, and WakeMed for Wake County locations, under appeal.
2024	17	Hoke, Lee, Montgomery, Moore, Richmond, Scotland	Based on petition and designated for a cancer center in the SA.Application received from FirstHealth, Moore County, under review.

Table 1. LINAC Need Determinations, 2019-2024 SMFPs

The Agency has not received any petitions requesting review of the methodology over the past 10 years. However, SHCC members have suggested, within that time period that a review of various equipment methodologies, including the LINAC methodology, might be appropriate. Specifically, members questioned whether ESTVs are the most appropriate measure of utilization. In addition to convening a workgroup, an investigation into alternative measures is likely to require either additional data collection by the Agency for a sample of providers for a limited time or the addition of items to the Hospital LRA and Registration and Inventory Forms.

The Petitioner next states that all other hospitals in the state of similar size to UNC Health Wayne and that provide a similar scope of cancer services have at least one LINAC. UNC Health Wayne has 316 acute care beds. Agency staff examined hospitals within 20% of that number (250-380) and verified that all these hospitals have at least one LINAC. However, the Agency has no specific data on the range of cancer services at these facilities.

As mentioned above, the need determination methodology has three criteria and an SA must meet two of them to have a need determination. The Petitioner argues that, although SA 23 does not meet any of the three criteria, it is relatively close on Criterion 1 and Criterion 3. Table 2 shows how each criterion applies in SA 23 in the *Proposed 2025 SMFP*.

Criterion	Description	Service Area 23
1.	The service area has greater than 120,000 population	Population $=$ 220,332, or
	per LINAC.	110,166 per LINAC
2.	More than 45% of the patients served reside outside the	12.76% of patients are outside
	SA	SA
3.	- Divide the total number of ESTVs by 6,750 (the planning capacity).	-0.28
	- Subtract the numbers of LINACs from this result. If the difference is at least +0.25, a need is determined.	

 Table 2. LINAC Methodology Criteria Applied to Service Area 23

The Petitioner claims that SA 23 is rather close on Criterion 1, presumably because is only about 10,000 residents shy of 120,000 per LINAC. However, census data from the NC Office of State Budget and Management (OSBM) projects average annual population growth from 2023 through 2028 in SA 23 to be 0.13%, which is considerably lower than the state average of 1.13%. In raw numbers, SA 23 is projected to gain about 1,500 residents in the next five years, making it extremely unlikely that SA 23 could come close to satisfying Criterion 1 during that time.

SA 23 primarily serves patients from the three counties that comprise it and thus is far from meeting Criterion 2. The Petitioner does not claim that the SA is close to meeting this criterion.

The Petitioner also states that SA 23 is close to meeting Criterion 3. To satisfy Criterion 3, SA 23 must have a total of 13,500 ESTVs. It had 11,610 in 2023, which is 1,890 short of a need determination. That number reflects almost 70% full utilization of one LINAC. Put another way, SA 23 has 2 LINACs, but it currently uses approximately 1.7 LINACs. Therefore, it appears that SA 23 has sufficient LINAC capacity.

Cancer Incidence. Apart from LINAC utilization considerations, it is useful to examine the cancer incidence rate in the SA to help project future need. The NC Central Cancer Registry provides cumulative data from two five-year periods (see Table 3). It does not publish annualized data at the county level.

Location	Incidence Rate per 100,000 population (age adjusted to the US Census)*		
	2014-2018	2018-2022	
Duplin County	413.4	465.7	
Lenoir County	513.2	515.9	
Wayne County	502.1	518.4	
Statewide	484.9	476.4	

Table 3. Cancer Incidence Rate, Counties in Service Area 23

Source: NC Central Cancer Registry

* It is not possible to calculate the incidence rate for SA 23 as a whole because the Central Cancer Registry does not publish the population figures used to calculate the rates.

Two of the three constituent counties have cancer incidence rates higher than the state rate. Moreover, the state incidence rate has declined over this same period, but the incidence rate in all counties in SA 23 has increased. It is not possible to translate changes in the incidence rate into need for LINAC treatment. However, given the increase in cancer incidence it is logical to project that the need for LINAC treatment may increase in SA 23 to a greater degree compared to the state as a whole.

While age is not a determining factor, the incidence of cancer is related to increasing age.¹ The median age for the State is about 42. It is not projected to change appreciably from 2023 to 2028 (NC OSBM). The median age for Lenoir County is similar to that of the state, while the median age in Duplin and Wayne counties is several years younger: 36 in Duplin and 37 in Wayne. The median age in these counties is also not expected to change by 2028. However, Duplin and Wayne appear to have a higher cancer incidence than might be expected based on the median age of the population. This situation, too, may signal a need for more cancer treatment in SA 23 than the state average might suggest.

LINAC as Standard of Care. A 2022 petition from WakeMed Health and Hospitals (WakeMed) argued that LINAC is standard of care for an oncology program. The Agency was inclined to deny the petition, based on the lack of need. However, the Agency deferred to the Committee to determine whether LINAC was considered standard of care, and, if so, to approve the petition. The Committee recommended approval of the petition and the SHCC concurred.

In part, as a result of this petition, the Agency proposed Policy TE-4 at the March 2024 SHCC meeting. Specifically, it proposed to allow development of a LINAC for cancer centers/programs that: (1) did not currently have an existing or approved LINAC obtained in the past five years before the CON application; (2) have at least one radiation oncologist; (3) have a medical physicist on staff or available by referral; and (4) if the SA has a LINAC, the average ESTVs for the SA would be at least 3,375. The Agency received several negative comments from providers in response to this proposal. It is notable that one theme of the comments (including from UNC Health) was that an oncology program does not necessarily require a LINAC to provide standard

¹ <u>https://www.cancer.gov/about-cancer/causes-prevention/risk/age</u>

of care for cancer treatment. The Technology and Equipment Committee discussed the policy and voted to consider the issue in more detail in the Spring of 2025.

Although the SHCC approved the WakeMed petition, there is one salient difference in the situation between SA 20 (Wake and Franklin counties) and SA 23 (Duplin, Lenoir, and Wayne counties). In Wake County, the only existing LINACs are at hospitals that are direct competitors to WakeMed (i.e., UNC Rex Hospital and Duke Raleigh Hospital). WakeMed argued that this situation hampered continuity of care. The hospital-based LINAC in SA 23 is at another facility in the UNC health system. The existing LINAC in Wayne County is not hospital-based. Rather the other LINAC is at a free-standing center, NC Radiation Therapy Management (GenesisCare). It is not a competitor for patients in the same way that a hospital or oncology practice would be. In fact, this facility may be serving many oncology patients referred from UNC Health Wayne, based on the Agency's patient origin data that shows that 79% of NC Radiation Therapy's patients come from Wayne County.

The current petition from UNC Health Wayne appears to reflect the issues raised by the Agency as part of the rationale for Policy TE-4. If the policy is ultimately approved in 2025 as proposed, the Petitioner would meet the requirements for a LINAC in the 2026 *SMFP*.

Agency Recommendation:

Currently, SA 23 has sufficient LINAC capacity. One of the two existing LINACs in SA 23 is in Wayne County; it is located at a free-standing facility about one-half mile from UNC Health Wayne. Also, the Technology & Equipment Committee intends to revisit Proposed Policy TE-4 in the Spring of 2025. The Agency supports the standard methodology for LINAC. Given available information submitted by the August 7, 2024 deadline, and in consideration of factors discussed above, the Agency recommends denial of this petition at this time.