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MEMORANDUM

TO: **Linear Accelerator Work Group**
C/o Amy D. Craddock, PhD. Planner
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FROM: Nancy M. Lane, President *Nancy Lane*

DATE: November 6, 2025

SUBJECT: **Comments on Linear Accelerator and State Medical Facilities Plan**

Thank you and members of the Work Group for accepting public comments on this important topic.

Aa mentioned in the first meeting of the Work Group, safety and quality, access, and value are the three basic governing principles for the annual State Medical Facilities Plan. Tools and data available to SHCC members and staff, and lead time associated with the SMFP planning cycle, make it challenging to measure safety, quality, and value. NC Licensure, third party accreditation, and CMS certification standards are the primary data sources available. As a result, the SMFP linear accelerator methodology focuses primarily on access metrics.

For any service subject to CON review, the annual SMFP offers two avenues for limiting and guiding applications: Policies and Methodologies. Presentations at the first Work Group meeting focused primarily on SMFP Methodologies, history, and metrics. Additional important discussion about Policy surfaced during Work Group member comments. SMFP Policies can address issues that Methodologies cannot, and consideration of a new Linear Accelerator Policy deserves the Work Group's careful discussion, for the following reasons.

1. The current Linear Accelerator Need Methodology is entirely retrospective. It adds one unit to a service area when the service area's ESTVs per existing and approved inventory unit reaches the Methodology threshold. One ESTV over the threshold generates a need in the SMFP Linear Accelerator service area. This ensures slow growth in inventory; it risks excess inventory in small markets that will have difficulty absorbing more capacity. It also provides absolute market control for a provider who obtains a CON for a linear accelerator and delays implementation. Under the current methodology, new approved or pending review inventory will be represented in the denominator and not the numerator of any need calculations. Changing the metric from ESTVs to machine time will not address this problem. Adding an imputed use to the numerator will help but will still not address the retrospective nature of the data or the problem of resource distribution within large service areas. Some service areas now have more than one million residents.

2. The retrospective nature of the data has another major problem. By the time the SMFP is published, and a CON is awarded, the justifying threshold data are two to four years old. In a competitive service area, the DHSR CON recommendations can be, and historically have been, appealed. An appellant can delay the linear accelerator CON for another three or more years following the DHSR staff's Recommended Decision. This is the current situation in Service Area 20. A Linear Accelerator that DHSR staff recommended for approval for a special need identified in the 2023 State Medical Facilities Plan was appealed. The appeal is in the Court of Appeals with no timeline for resolution. This situation is not unique. Any linear accelerator that CON Section recommends for award in response to an SMFP Methodology-Defined Need is easily appealed. Final award of the CON can take years and involve expensive litigation. During the litigation, the SMFP Methodology treats that approved linear accelerator as if it were available to the public in the current planning data year, regardless of whether or when a CON has been issued. The practice controls supply. As demand continues to increase when population increases and the appeal goes unresolved, it also creates an opportunity for existing suppliers in the service area to be selective about who they serve.

3. The Methodology could address part of this dilemma by setting a benchmark date at which an approved CON not in operation becomes designated as an "under used" resource. The nursing home and operating room Methodologies in the past have included such adjustments. Even a mathematical adjustment to remove from calculations any linear accelerator not in operation within two years of the CON award date cannot address the out of date nature of the basic methodology data. The methodology would still need forward projections such as occur in the acute bed methodology

For these reasons, SMFP Policies are essential to bridge the access gap, particularly as it relates to underserved groups. North Carolina needs Policies to ensure that its health care services stay consistent with the high quality. high tech, balanced access reputation that the state is developing in every economic sector from mountains to coast.

Several clinician members of the Work Group agreed that a linear accelerator is an essential component of treatment for the major cancers: breast, prostate, lung, head and neck and central nervous system. They noted that [external beam radiation] provided by linear accelerators is standard of care and one of the three treatment tools that patients with these cancers require as part of a complete treatment regimen. By extension, the annual SMFP should have a Policy that enables established cancer programs that offer surgery and chemotherapy on both an inpatient and outpatient basis, a mechanism to acquire and operate a linear accelerator to complete the full cycle of cancer treatment they provide to their patients. Patients should not have to shuttle among providers to complete their cancer treatment regimen.

A Policy to address this should be independent of any Methodology calculation. In fact, with certain safeguards to protect against unnecessary duplication in smaller geographies, the Policy should take priority consideration over a Methodology. A Policy can stay current to within one year of a CON decision. It need not be dependent on a database that is carefully scrubbed prior to SMFP publication. A Policy can also address social determinants of health, something a Methodology cannot do well.

Key limiting elements of a proposed Policy would be:

- Location in a county with 500,000 or more residents or a service area with 750,000 or more residents—The Methodology already provides an entry point for first-time service area linear accelerators – at 120,000. The higher population threshold for this Policy would prevent unnecessary duplication in smaller rural communities.
- Location on a main campus of a licensed North Carolina hospital that provides 24/7 emergency care and that has offered both inpatient and outpatient cancer chemotherapy for at least 300 annual patient treatment cycles and cancer surgery to at least 300 annual patients for each of the three years immediately preceding the application. –This provides assurance of commitment to the other two elements of a complete cancer treatment program.
- Neither the applicant nor a related party may own or operate a linear accelerator in the county or service area where the proposed linear accelerator will locate.
- The applicant must operate an established cancer program that has onsite capacity and history of treating at least these three cancers: breast, prostate, and lung cancer, at the time of the application, and must demonstrate a plan to continue treating those cancers.
- The applicant must demonstrate that its cancer treatment program treats and will treat Medicaid , underinsured and charity patients at ratios of at least 10, 5 and 3 percent of total patients, respectively on the proposed linear accelerator.
- The applicant must agree to obtain either American College of Radiology or American Society for Radiation Oncology("ASTRO") Accreditation Program for Excellence ("APEx") Accreditation[1] of the linear accelerator service within two years of operation.

DHSR can determine qualified hospitals and populations from its databases. Other data associated with these requirements are not collected by DHSR. However, other SMFP Policies also involve data not collected by DHSR , specifically:

- Policy AC-3 – other than designation as an Academic Medical Center, all other requirements are met by applicant data sources
- ESRD-2 – all metrics are applicant reported
- ESRD-3 – third requirement is met by applicant data sources
- NH-2 and LTC -1– data for independent living are not reported to DHSR; DHSR does not collect data from the Department of Insurance
- NH-8 – all data are subjective
- TE-2 – intra operative MRI is not standard of care in surgery but is available to any hospital in a metro area of 350.000 residents.

These comments are provided to encourage discussion and focus consideration on medically underserved groups in the state's larger communities, where competition is supportable.

Thank you again for taking time to consider these comments.

PDA is a North Carolina consulting firm with more than 40 years of experience preparing and reviewing Certificate of Need applications.

[1] ASTRO Accreditation Program for Excellence website https://www.astro.org/practice-support/accreditation