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RE: Comments on Proposed Policy TE-4 Linear Accelerator, 2025 State Medical Facilities Plan

Dear Dr. Greene and Dr. Emmanuel,

Catawba Vally Medical Center (CVMC) wishes to weigh in opposing Proposed Policy TE-4 Linear Accelerator Petition. We understand the Agency's intentions to make life easier. However, for reasons outlined here, we believe the unintended negative consequences outweigh any simplification value.

Not Needed

Limited User Group

The Petition indicates that linear accelerator use is standard of care. This does not mean that the state has substantial unmet need for linear accelerators. For clarification:

- Although external beam radiotherapy provided by a linear accelerator is a standard of care for cancer treatment, every cancer case is not treated with a linear accelerator – about half are.¹
- Not all North Carolina residents have or will have cancer. According to the Centers for Disease Control and Prevention, in 2020, reported new cancer cases occurred at a rate of 650 to 900 per 100,000 residents, varying by county, job, ethnicity and gender² -- approximately 8 in 1,000 residents may have cancer.

The Petition suggests that linear accelerator equipment is like Magnetic Resonance Imaging ("MRI") equipment. This is misleading. MRI is a diagnostic tool. Anyone could need an MRI. Only some people who have cancer need a linear accelerator. This important distinction explains why North Carolina has only 28 linear accelerator service areas compared to 85 MRI service areas. The state may need a few more service areas as its population grows, but the Plan should systematically increase access in areas with shortages, while promoting quality and value.

¹ AvaMed 2022 https://www.advamed.org/wp-content/uploads/2022/03/Advamed_what-is-Radiotherapy-fact-sheet.pdf

² U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2022 submission data (1999-2020); U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; <https://www.cdc.gov/cancer/dataviz>, released in November 2023.

Risk

MRI uses no radiation; it uses electromagnets. Except for possible heat risk and precautions for people who have metallic implants, the risk of harm from an MRI is low. Unlike MRI, linear accelerators use powerful radiation that stays in the body for a while; they are designed to destroy cells. Because of the limited use and higher risk, it is important that the State Medical Facilities Plan emphasize quality and prevent unnecessary duplication of existing linear accelerators.

Cost

Equipment is not the only cost consideration for a linear accelerator. It requires a specially fortified vault to protect staff and the general population from radiation harm. The vault can cost as much as or more than the equipment. Moreover, the linear accelerator cannot function for care without simulator equipment and software cost.

Absence of Pattern

The Petition indicates that two special needs petitions for linear accelerators over a period of two years justify the proposed policy. However, each of those involved a unique situation. WakeMed has no linear accelerator; was providing cancer care to thousands of patients; and was having trouble coordinating care and getting timely radiation therapy referrals for those patients. First Health service area would have shown a need in the next year's Plan. The First Health petition accelerated the timeline. Neither of these special need petitions demonstrates a statewide pattern.

WakeMed and First Health are good examples of why the Plan provides the Special Need petition forum. These two unique, and uniquely different, situations do not represent a statewide issue or pattern. They correctly presented their situations in the Summer as meriting special geographic need determinations.

Potential for Harm

Shifted Burden for Medically Underserved

The proposed policy is not consistent with the Basic Principles of the State Medical Facilities Plan - Access, Quality or Value. If approved, the proposed policy will challenge the capacity of North Carolina health care delivery system to care for underinsured and complex patients. The proposed policy has no limits. A center with a part-time consulting relationship with a radiation oncologist and physicist could qualify for multiple linear accelerator in several locations in the same town (Free Standing Cancer Center Program). Or -- several companies could file CONs to offer linear accelerators at separate locations in the same geographic area.

With no performance standards, the Agency could have difficulty denying competing applications -- or even determining that they are competing. In fact, appeal litigation resulting from this proposed policy could tie up the entire CON staff every year, because the standards for denial are ill-defined.

History confirms that most parties who will apply for CONs for expensive cancer services favor communities with organized cancer programs. When the area gets more equipment than the community needs, providers compete for staff and patients, putting the quality of all at risk.

The proposed policy has no requirement to serve underserved populations. Facilities applying under this policy could easily favor only those cancer diagnoses that have high reimbursement rates from the best paying parties. The state could even see concierge linear accelerators that serve only the select few who pre-pay. This will leave existing safety-net providers with disproportionate numbers of low-paying and charity patients. The resulting excess linear accelerator capacity in existing facilities could jeopardize the financial viability of critical community safety net cancer centers like CVMC.

The policy has no requirement for the equipment to be hospital-based or even hospital related. Applicants could qualify by meeting the definition of a Freestanding Cancer Program – a part time office with relationships. The policy does not require that the site have accreditation from ACSCOS. It requires only that a proposed facility meet the definition.

Unnecessary Proliferation

Catawba is one of four counties in Service Area 5 –whose collective population in 2023 was 369,403. Four of the five Service Area 5 counties have linear accelerators. Alexander, which does not, has fewer than 37,000 residents. After years of unsuccessful attempts to stay viable, even the hospital in Alexander County closed. Residents of Alexander are well-served by linear accelerators in Catawba and Iredell – about 30 minutes in either direction.

Service Area 5 has six linear accelerators that operated at an average of just over 50 percent capacity in 2022. Through a mistake in the 2022 data for UNC Caldwell, Service Area 5 could get a 7th linear accelerator in 2024. This would put Service Area 5's baseline at 52,700 people per linear accelerator before the policy.

By comparison, Area 17, and Area 20, the two Special Need Linear Accelerator Service Areas cited as justification for the policy, had more than 105,000 persons per linear accelerator in 2022. By setting the capacity standard at 50 percent utilization, this policy would permit an unrestricted number of new linear accelerators in Linear Accelerator Service Areas that start with as few as 38,000 persons per linear accelerator. (See Table 15C-5 in the 2024 SMFP). This represents a major deviation from the linear accelerator standard need methodology³ which says that the population base is 120,000 – a number recommended by the Inter-Society Council for Radiation Oncology.

Too Many Harmful Consequences

Often, modifications to a policy proposal can be tweaked to correct for unintended consequences in the original draft. This proposed policy has too many problems and too many potentially harmful consequences.

The Plan's standard methodology for linear accelerators provides for systematic organic expansion in linear accelerator supply as demand increases. The Plan's Special Need Petition process provides for adjustments when the methodology falls short for certain populations.

This proposed petition provides no evidence that a particular group or population in North Carolina has so many problems regarding access to linear accelerator services that the only solution is the

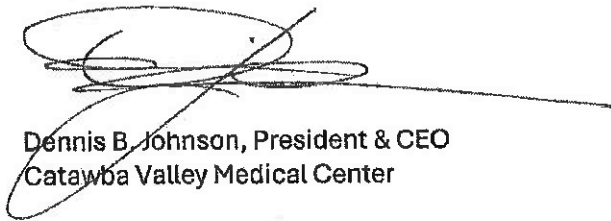
³ 2024 SMFP online page 315, pdf p 338 https://info.ncdohhs.gov/dhsr/ncsmfp/2024/2024_SMFP.pdf

proposed generous new statewide policy. We ask members of the Technology and Equipment Committee to recommend Disapproval of this Petition.

Thank you

CVMC appreciates the many hours of volunteer work contributed by State Health Coordinating Council members. We also appreciate DHR Planning staff's thoughtful consideration of North Carolina's 10 million plus residents' health care facility needs. We value staff's perceptions and are willing to contribute CVMC' planning capacity to ease staff's burden in considering special issues. In this instance, you made us take a hard look at cancer services in our area; and in the end we are satisfied that the proposed policy would do more harm than good. Thank you for carefully considering our remarks.

Sincerely,



Dennis B. Johnson, President & CEO
Catawba Valley Medical Center