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VIA EMAIL

March 20, 2024

Sandra B. Greene, DrPH, Chair North Carolina State Health Coordinating Council (SHCC) c/o Healthcare Planning Section NC Division of Health Service Regulation 2704 Mail Service Center Raleigh, NC 27699-2704

RE: Cone Health Comments Regarding Spring 2024 Petitions

Dear Dr. Greene:

Cone Health appreciates the opportunity to submit these comments regarding several petitions filed in the development of the 2025 State Medical Facilities Plan (SMFP). These comments are detailed below.

Acute Care Services Committee

Modify Policy GEN-3: Basic Principles: Health Systems Management on behalf of Wake Forest Outpatient Dialysis Centers

This petition proposes to modify GEN-3 to be applicable to all applicants, not just those applying based on a need determination, as revised below.

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified *in the State Medical Facilities Plan* as well as addressing the needs of all residents in the proposed service area."

Cone Health notes that the words "in the State Medical Facilities Plan" (<u>underlined</u>, **bolded**, and *italicized* above) should also be removed from the paragraph to ensure there is no language in the entire policy that limits its applicability to need identified



in the SMFP. With this additional change, Cone Health supports the petition to modify Policy GEN-3.

Technology and Equipment Committee

Change Policy TE-2 to Allow iMRI Use for Outpatients: Atrium Health

This petition requests a change in the language of Policy TE-2 to allow use of iMRI for outpatients. The current policy states "The iMRI scanner shall not be used for outpatients and may not be replaced with a conventional MRI scanner.", and the petition proposes it be changed to "The iMRI scanner shall not be used for outpatients unless the patient has a simultaneous surgical procedure, interventional procedure or treatment. The iMRI scanner may not be replaced with a conventional MRI scanner." Cone Health believes the word "treatment" is too vague and generic and could be used to broaden the scope of services outside of the intent of Policy TE-2. Cone respectfully requests the petition be denied or be revised to say "The iMRI scanner shall not be used for outpatients unless the patient has a simultaneous surgical or interventional procedure. The iMRI scanner may not be replaced with a conventional MRI scanner."

Develop Policy TE-4: Plan Exemption for Linear Accelerators: Agency Staff Proposal

The Agency proposes to add Policy TE-4 for linear accelerators, similar to Policy TE-3 for MRI scanners. Cone Health respectfully requests that this proposal be denied and studied for further development and consideration of unintended consequences.

Policy TE-3 for MRI scanners is limited to acute care hospitals, which are well defined using accepted definitions, terms, and licensure standards. As the Agency acknowledges, cancer centers are less well defined, especially satellite cancer centers. Without clear definitions, there may be unintended consequences regarding eligible applicants for linear accelerators under a new policy.

Additionally, the Agency states in its report:

"The Agency has no data on the proportion of cancer patients that receive LINAC treatment. Regardless, it is unlikely that the proposed policy would lead to the proliferation of LINACs. LINACs are highly specialized equipment that require considerable financial, physical, and professional resources. Rather, the Agency anticipates that a providers may develop new or additional oncology programs/cancer centers. In addition, new centers may be developed in a few of the 46 counties that do not currently have a LINAC. As always, it is possible that new centers may be developed to compete with existing centers."



Despite the suggested minimum average ESTV requirement for the service area of 3,375 across existing LINACs, Cone Health is concerned that an unintended result of the policy would be a proliferation of satellite cancer centers that would then seek to use this policy to acquire a linear accelerator, and would essentially circumvent the need methodology.

While a Policy change can be helpful for consistency across the state, it can also have unintended consequences in different markets that would not occur if a need were addressed through a Petition for an Adjusted Need Determination. Cone Health respectfully requests that the Technology and Equipment Committee of the SHCC deny the petition and study the matter more closely.

Sincerely,

Melissa K. Shearer

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Executive Director, Strategy and Planning