

**COMMENTS REGARDING PROPOSED LINEAR ACCELERATOR POLICIES**  
**Submitted by Duke University Health System, Inc.**

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Duke University Health System, Inc. submits these comments regarding the separate petitions filed by WakeMed and Cone Health to create exemptions from the standard linear accelerator need methodology. Given the multiple competing proposals as well as the proposed policy previously circulated by the Agency, a work group or other forum to discuss these potential changes in tandem and review the existing methodology with more input and time to discuss the potential options would be appropriate. Radiation oncology services provided on linear accelerators are a complex treatment with serious health implications in their delivery, and further analysis is warranted for significant changes to the planning process.

Duke incorporates by reference and attaches the comments it filed in in 2024 regarding the proposed linear accelerator policy then identified as Policy TE-4. In addition, Duke provides the following comments regarding the specific petitions for consideration.

WakeMed

WakeMed proposes an exception to the standard need determination requirement for certain identified hospital applicants who “offer a cancer program.” Duke recognizes that WakeMed’s petition includes a narrower definition of eligible providers than the Proposed Policy TE-4 evaluated in 2024. However, its proposed definition is ambiguous. WakeMed defines an eligible applicant as one that “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.” This definition creates the following questions:

- It is not specified whether a “Program” is limited to a single provider or site that meets the other criteria or could include an applicant who participates in a joint venture or other affiliation that collectively constitutes such a Program.
- “Cancer staff” is not defined.
- “Encounters” is not defined, nor is any support provided for the relationship of such encounters to a volume of patients with a cancer diagnosis or resulting radiation oncology utilization. Encounters presumably includes multiple appointments or treatments for a single patient, including those who do not need radiation oncology, could include appointments unrelated to a cancer diagnosis.

In addition, WakeMed's justification for the proposed policy is based largely on the purported inadequacies of the current methodology to keep pace with the need for linear accelerators and the effect of underutilized or undeveloped equipment on the need determinations. These potential factors suggest that an evaluation of the methodology, rather than the creation of exceptions, may be warranted.

### Cone Health

In seeking an exception for certain highly utilized linear accelerators, Cone Health identifies circumstances that affect only 3 providers in the state, which might be better addressed as a special needs petition to reflect individual circumstances. To the extent that Cone's petition would create a statewide change, such a change may be more properly considered in connection with an update to the need methodology, for example with consideration of system needs (as in operating room methodology) and/or adjustments to reflect chronically underutilized equipment. This would allow consideration of WakeMed's proposed change at the same time.

### Conclusion

A multiplicity of exceptions to the standard need methodology would threaten to undermine the methodology itself. A better approach may be to reevaluate and update the methodology as needed.