

UNC Health Comments on Duke's Petition and Proposed Changes to Policy TE-3

Duke University Health System Inc. ("Duke") filed a summer petition commenting on proposed changes to Policy TE-3 in the 2023 State Medical Facilities Plan ("SMFP"). UNC Health joins Duke in its concern over the proposed version of Policy TE-3 in the 2023 SMFP, and proposes two alternative solutions to address this concern. First, UNC Health suggests that the Agency adopt proposed Policy TE-3 without the Five Year Requirement (as defined below).¹ Alternatively, UNC Health suggests that the Agency adopt proposed revisions contained in WakeMed's spring petition on Policy TE-3. In both of these scenarios, Policy TE-3 would be available to more hospital campuses (expanding access to MRI services), and would not include an arbitrary time restriction, which only serves to limit such access.

The Agency's proposed Policy TE-3, as contained in the Proposed 2023 SMFP, is as follows:

Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners

The applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner shall demonstrate in its certificate of need (CON) application that it is a licensed North Carolina acute care hospital:

- 1. that has licensed acute care beds;
- 2. that provides emergency care coverage 24 hours a day, seven days a week; and
- for which the inventory in the SMFP does not reflect an existing or approved fixed MRI scanner in the five years immediately preceding the filing of the CON application for the proposed scanner.

The "Five Year Requirement"

The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.

The performance standards in 10A NCAC 14C .2703 would not be applicable.

The fixed MRI scanner must be located either:

- 1. on the main campus of the hospital as defined in G.S. 131E-176(14n); or
- 2. at another acute care hospital on a campus that operates under the hospital's license.

The proposed scanner may operate as part of the hospital, a diagnostic center, or an independent diagnostic testing facility (IDTF) location that does not currently provide fixed MRI services.

¹ It is unclear whether the reference to "inventory" (of existing or approved MRI scanners) in the Five Year Requirement refers to inventory for the applicant hospital or for the entire MRI service area. Since it appears Policy TE-3 is intended to allow hospitals which do not already have a fixed MRI to apply for their first fixed MRI scanner, UNC Health presumes the Five Year Requirement is referring to the inventory of existing or approved MRI scanners in the MRI service area where the applicant hospital is located.

Background:

As explained in Duke's petition, WakeMed requested a change to Policy TE-3 in the 2023 SMFP via a spring petition submitted to the State Health Coordinating Council SHCC. Specifically, WakeMed sought increased access to MRI services at satellite hospital campuses by requesting removal of the requirement that only a "main campus" of a hospital could utilize Policy TE-3. Based on the Agency's recommendation, it clearly understood the rationale and the Agency "support[ed] the need to expand Policy TE-3," to include either a main campus or a satellite campus.

However, instead of adopting the language proposed in WakeMed's petition, the Agency drafted language of its own and added the Five Year Requirement, which makes Policy TE-3 more <u>restrictive</u>, not more expansive.

The stated rationale in the Agency report for the proposed language was to "create a broader opportunity for acute care hospitals to obtain a fixed MRI," but the proposed Policy TE-3 included in the 2023 SMFP does the opposite. Instead of broadening the opportunity, the Agency's revised Policy TE-3 includes the additional and unnecessary new limitation of the Five Year Requirement. Specifically, the Agency's proposed revision would only allow a hospital applicant to propose a new MRI scanner using Policy TE-3 if the MRI inventory does not reflect an existing or approved scanner in the preceding five years.²

The Agency's proposed Policy TE-3 included in the Proposed 2023 SMFP made two fundamental changes – it removed the restriction relating to a hospital "main campus" and added the Five Year Requirement. While the change relating to the main campus does promote to expansion of the policy and increases access, the Five Year Requirement does not. There is no explanation in the Agency report why this Five Year Requirement was added, or how this language would serve to broaden access to MRI services at hospitals. For a hospital without a fixed MRI seeking to add this capability in order to serve its patients, it is irrelevant whether another MRI has been added to the inventory in the service area over the past five years.

To address this concern, UNC Health proposes two alternative options. Both options would expand MRI services to more hospital campuses, while not imposing this arbitrary five year "look back" restriction, which only serves to limit access.

Option 1:

UNC Health suggests that the Agency should adopt its proposed Policy TE-3 without the Five Year Requirement. This approach removes the problematic and needlessly restrictive portion, but retains the expansion of the policy to more hospital campuses as originally suggested by WakeMed. This proposed option also makes clear that a qualified applicant is a hospital which does not already have an existing or approved MRI scanner.

² Again, UNC Health presumes the reference to "inventory" means all MRI scanners in the applicant hospital's MRI service area.

Thus, as one option, UNC Health submits that the policy contained in the 2023 SMFP should read as follows:

Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners

The applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner shall demonstrate in its certificate of need (CON) application that it is a licensed North Carolina acute care hospital:

- 1) that has licensed acute care beds;
- 2) that provides emergency care coverage 24 hours a day, seven days a week; and
- 3) that does not currently have an existing or approved fixed MRI scanner as reflected in the applicable SMFP.

The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.

The performance standards in 10A NCAC 14C .2703 would not be applicable.

The fixed MRI scanner must be located either:

- 1) on the main campus of the hospital as defined in G.S. 131E-176(14n); or
- 2) at another acute care hospital on a campus that operates under the hospital's license.

The proposed scanner may operate as part of the hospital, a diagnostic center, or an independent diagnostic testing facility (IDTF) location that does not currently provide fixed MRI services.

Option 2:

Alternatively, there is another method by which access could be expanded without the unnecessary Five Year Requirement. Under this option, the policy could be revised in accordance with the changes originally proposed by WakeMed in its spring petition. Like Option 1, this proposal retains the expansion of the policy to more hospital campuses but does not impose an arbitrary time requirement in terms of how many years have passed since approval or development of a fixed MRI scanner.

In this scenario, the revised Policy TE-3 would read:

Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners

Qualified applicants may apply for a fixed magnetic resonance imaging scanner (MRI).

To qualify, the health service facility proposing to acquire the fixed MRI scanner shall demonstrate in its certificate of need application that it is a licensed North Carolina acute care hospital with, on the same campus, emergency care coverage 24 hours a day, seven days a week, inpatient and outpatient surgical services, and that does not currently have an existing or approved fixed MRI scanner as reflected in the inventory in the applicable State Medical Facilities Plan.

The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.

The performance standards in 10A NCAC 14C.2703 would not be applicable.

The fixed MRI scanner must be located on the hospital's "main campus" as defined in G.S. 131E-176 (14n)a., but it may operate the fixed MRI as part of the hospital, a diagnostic center, or an independent diagnostic testing facility (IDTF).

To the extent the Agency believes it is important to specify that the MRI may be operated as part of a diagnostic center or IDTF, that language could be added back while still making clear that the policy is not limited to a hospital "main campus." This option achieves the same objective – it increases access to MRI services at hospitals and removes unnecessary time limitations based on a historical five year "look back."

Conclusion

By adopting one of the two options outlined by UNC Health above, the intent of the Agency to broaden Policy TE-3 and expand access to MRI services will be achieved. UNC Health urges the SHCC to maintain this important policy and allow it to benefit all hospital campuses, without the unnecessary and counterproductive time limitation. Thank you for your attention and consideration.