

Technology and Equipment Committee
Agency Report
Petition to Revise Policy TE-3: Plan Exemption for Magnetic Resonance
Imaging Equipment (MRI) Scanners in the
2023 State Medical Facilities Plan

Petitioner:

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Contact:

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Request:

WakeMed requests a revision to Policy TE-3 to remove the requirement that the proposed fixed MRI scanner be located on the “main campus” of a hospital, as defined in G.S. 131E 176 (14n), in the *2023 State Medical Facilities Plan (SMFP)*.

Background Information:

Chapter Two of the SMFP provides that “[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” The SMFP annual planning process and timeline allows for the submission of spring petitions for changes to the SMFP policies and methodologies and summer petitions requesting adjustments to the need projections in the SMFP to the State Health Coordinating Council. It should be noted that any person may submit a certificate of need (CON) application for a need determination in the SMFP. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

The standard methodology uses the total number of weighted procedures in an MRI service area, equivalent values for fixed and mobile MRI scanners, and graduated need determination thresholds based on the number of fixed scanners in a service area. Procedures are weighted according to complexity and then combined to determine a total number of weighted procedures. The fixed equivalent value is 1.00 for approved and existing fixed MRI scanners, including need determinations from previous SMFPs for MRI scanners. For mobile sites, the fixed equivalent is the number of MRI adjusted procedures performed at the site divided by the threshold for the MRI service area. The fixed equivalent for a mobile site can be no greater than 1.00. The sum of the weighted MRI procedures is divided by the number of fixed equivalent scanners to get the average

adjusted procedures per scanner for each service area. A need determination for additional MRI scanners occurs when the average adjusted procedures per scanner for the service area exceeds the threshold established for the service area.

Although most MRI needs are addressed in the methodology, the SMFP contains two Technology & Equipment (TE) Policies that allow applicants to apply for CONs without a need determination. Policy TE-2 creates a pathway for people to apply for a CON to utilize an intraoperative MRI to be used in an operating room suite. Policy TE-3 sets for the specific conditions that allow hospitals to apply for a CON to acquire a fixed MRI scanner.

WakeMed has submitted a petition to revise Policy TE-3 by removing the conditions that require facilities to meet the definition of a “main campus” for the proposed location for a fixed MRI scanner for the following reasons: 1) the history and intent of Policy TE-3; 2) a fixed MRI is considered the standard of care for all acute care hospitals; 3) satellite hospitals operate under the license of a main hospital and are precluded from acquiring a fixed MRI; 4) new satellite acute care hospitals are under development; and 5) the MRI workgroup did not address SMFP policies related to MRI scanners.

Analysis/Implication

Policy TE-3 was developed in 2016 to assist acute care hospitals in rural areas with the acquisition of a fixed unit of MRI equipment to meet the standard of patient care. The intent of TE-3 was to address the needs of rural hospitals that operate in counties unlikely to have a need determination in the SMFP and that would be unlikely to meet the standard CON performance standards should a need determination exist. Since 2016, three rural hospitals that had no fixed MRI scanner have applied for and received a scanner pursuant to Policy TE-3. However, nothing in the language of the policy precludes other separately licensed hospitals without a fixed MRI from applying for a scanner pursuant to Policy TE-3.

The current petition specifically addresses the policy’s applicability to main hospital campuses only. G.S. 131E 176 (14n) defines the main campus of a facility as the “site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.” The development of satellite hospitals has resulted in 11 acute care hospitals with inpatient, surgical, and emergency services that are not located on the main campus but that operate under the license of the main hospital. These locations are expected to provide the same standard of care as the main hospitals. All but one of these hospitals has relocated an MRI scanner to their satellite campuses. WakeMed has not done so because the relocation of a fixed MRI scanner to the WakeMed North campus would leave only one fixed MRI scanner at the main campus of WakeMed, which is a Level I trauma center.

In addition, eight new hospitals are under development, four of which are slated to be campuses an existing hospital. The remaining four are proposed to be separately licensed. As such, they could take advantage of the current Policy TE-3. The four that are proposed as satellite campuses would have to obtain an MRI scanner via a relocation from the main hospital, wait for a need determination generated from the methodology, or contract with a third-party provider to acquire MRI services. As an acute care and emergency facility, these locations need MRI services onsite

24/7 to provide standard of care for patients. In these instances, mobile MRI services are generally insufficient because they do not usually operate 24/7 and cannot serve the same location every day.

In November 2021, the SHCC convened an MRI Methodology Work Group to review the current MRI methodology. The workgroup met four times over a four-month period. The Workgroup reviewed the current MRI methodology, received comments from the public and hereby recommends substantial changes to several areas of the MRI methodology and its assumptions. The workgroup did not discuss any of the policies pertaining to MRI. Recommendations from the workgroup will be presented to the Technology & Equipment Committee during the April 6th meeting.

The Agency believes that the proposed revision of Policy TE-3 will not result in an unnecessary duplication of MRI services or create an influx of MRI's in the state of North Carolina's inventory. In total, it is estimated that no more than five new MRIs would be developed under a revised Policy TE-3, based on CONs approved as of March 31, 2022. The proposed revision will support the basic principles of the SMFP by providing safe and quality care, access to care, and value for the residents of North Carolina.

Agency Recommendation:

The Agency supports the standard methodology and current policies for MRI equipment. Given available information submitted by the March 16, 2022 deadline, and in consideration of factors discussed above, the Agency supports the need to expand Policy TE-3 but recommends denial of the Petition submitted by WakeMed for policy revision in the 2023 SMFP. Instead, the Agency recommends the following alternative Policy TE-3 that will create a broader opportunity for acute care hospitals to obtain a fixed MRI.

Proposed 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) 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 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.