

**Technology and Equipment Committee
Agency Report
Petition Regarding the Specialized Breast
Magnetic Resonance Imaging (MRI) Scanner, Forsyth County
2022 State Medical Facilities Plan**

Petitioners:

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Request:

Novant Health, Inc. (Novant) and MedQuest Associates, Inc (MedQuest) (collectively, the “Petitioners”) request that Novant’s dedicated breast MRI scanner, now shown in Table 17E-2 of the State Medical Facilities Plan (SMFP), be included in the MRI inventory (Table 17E-1) of the 2022 SMFP.

Background Information:

SMFP Provisions

Chapter Two of the SMFP provides, in relevant part, 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 former are submitted in the Spring, while the latter are submitted in the summer. Other matters pertaining to a single service area may also be the subject of summer petitions.

The standard MRI methodology uses the total number of weighted scans 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 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.

The need threshold in Forsyth County, where the Petitioners' dedicated breast MRI scanner is located, is 4,805 weighted scans. The average adjusted procedures per scanner in Forsyth is 4,499. Accordingly, the 2022 SMFP indicates that there is no need for additional MRI scanners in Forsyth County.

As noted above, the SMFP currently lists the MRI inventory in Table 17E-1. The SMFP excludes specialized scanners from the MRI inventory because specialized scanners are precluded from general clinical use; are approved for limited purposes and/or use in special settings; have low utilization rates; and artificially suppress the need for additional scanners when included in the inventory. For these reasons, specialized scanners are exempt from need determination calculations in the SMFP and are separately listed in Table 17E-2 (Existing and Approved Specialized MRI Scanners, Excluded from Inventory) of the SMFP.

Novant's Breast Imaging Scanner

In 2005, Novant submitted a petition for a specialized breast imaging scanner. The petition acknowledged that “[t]he proposed MRI system would not be used for general MRI diagnostic purposes and would not duplicate or compete with existing MRI scanners, that are either in use as dedicated orthopedic-only scanners or as general diagnostic scanners” (Novant Health Triad Region, Barbara L. Freedy, Petition for Adjustment to MRI Need Determination for Specialized MRI for Breast Imaging, received August 5, 2005). The 2006 SMFP included a statewide need determination for such a scanner.

In 2006, the North Carolina Department of Health and Human Services, Division of Health Service Regulation's (the “Agency's”) Certificate of Need (CON) program issued a CON to the Novant Health Breast Clinic for one dedicated breast-only MRI scanner (G-007601-06). This scanner is listed in Table 17E-2.

The Petitioners' breast imaging scanner is currently located at the Novant Breast Center in Winston-Salem. It was fully operational from 2007 until 2015 when the Petitioners determined that the technology was no longer viable. As a result, the scanner was used sparingly until 2017 when it was destroyed in a flood. In the interim, Novant received CON approval in 2015 to replace the original scanner. The replacement scanner, which has not yet been developed, can only be used for breast imaging notwithstanding the technology employed because it must remain within the operational conditions of the original CON.

Analysis/Implications:

The Petitioners state that their goal is to provide greater access to outpatient MRI services in Forsyth County. In order to effectuate that goal, the Agency's Healthcare Planning program and the State Health Coordinating Council (SHCC) must first agree to remove the dedicated breast MRI scanner from Table 17E-2 and include it in the MRI inventory (Table 17E-1); and then the Petitioners must obtain CON approval to replace and relocate the scanner to an imaging center where it would be used for general clinical purposes. (Petitioners expressed the intent to relocate the scanner to Novant Health Imaging-Piedmont.)

As noted above, application of the standard MRI methodology resulted in there being no need for additional MRI scanners in Forsyth County in the Proposed 2022 SMFP. Furthermore, the inclusion of a low utilization scanner in the planning inventory would suppress the need for additional MRI scanners in Forsyth County in subsequent years.

In support of its Petition, the Petitioners' assert that the approval of the two existing breast MRI scanners was tantamount to a demonstration project. This assertion is not consistent with the purpose and scope of a demonstration project. A demonstration project seeks to examine the value and/or efficacy of something whose value and/or efficacy is not currently known. In addition, a demonstration project has a specified end date, after a trial period during which the innovation is tested and evaluated. In fact, the original breast scanner petitions (Charlotte Radiology in 2001 and Novant in 2005) provided detailed information supporting the well-established value and efficacy of MRI breast imaging. It is clear from both petitions that these MRIs were not approved as part of a demonstration project.

The Petitioners' assertion that the inclusion of the breast scanners in Table 17E-2 is evidence that the Agency views it as a demonstration project, because demonstration projects are included in the same table, is also incorrect. Although the 2019 SMFP placed demonstration scanners and specialized scanners into five separate tables based on their purpose, the SHCC approved a consolidation of these separate tables into a single table beginning with the 2020 SMFP. The purpose of this edit was to list all scanners that fall outside the inventory for *any* reason in the same table. Moreover, none of the scanners currently listed in Table 17E-2 are demonstration projects.

Furthermore, if Petitioners' dedicated breast MRI scanner were added to the MRI inventory, Petitioners' CON application to replace and relocate the scanner may be denied. Alternatively, if the CON program were to approve replacement of the dedicated breast scanner with a scanner that could be used for general clinical purposes, only Novant would be able to obtain the new scanner, rendering the competitive review of CON applications from multiple providers impossible.

Agency Recommendation:

The Agency supports the standard methodology and current policies included in the SMFP for the acquisition of MRI equipment. The MRI methodology exists to ensure that all potential providers within the service area can apply for a CON whenever a need exists. The approval of this Petition is contrary to the standard methodology and current policies and would result in suppressing future need determinations. Upon review of all available information submitted by the August 11, 2021 deadline date for comments, and in consideration of factors discussed above, the Agency recommends denial of the Petition submitted by Novant and MedQuest proposing the inclusion of one fixed dedicated breast MRI scanner in the fixed MRI inventory (Table 17E-1) of the final 2022 SMFP.