Technology and Equipment Committee Agency Report Petition regarding existing and approved Specialized Breast Magnetic Resonance Imaging Equipment (MRI) Scanners, excluded from 2022 State Medical Facilities Plan

Petitioner:

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Request:

Novant Health, Inc. (Novant) and MedQuest Associates, Inc (MedQuest) (collectively "Petitioners") petition that the two dedicated breast MRI scanners now shown in Table 17E-2 of the 2021 State Medical Facilities Plan (SMFP) be included in the fixed MRI inventory (Table 17E-1) of the 2022 SMFP.

Background Information:

Chapter Two of the SMFP allows for "[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 allow for submission of petitions for changes to policies and methodologies in the spring and petitions requesting adjustments to need projections in the summer. It should be noted that any person might submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

Although most MRI needs are addressed in the methodology, there are currently two Technology and Equipment (TE) Policies contained in the SMFP to allow qualified applicants to apply for CONs without a need determination. Policy TE-2 provides the opportunity for qualified applicants to apply for a CON for an intraoperative MRI to be used in an operating room suite. Policy TE-3 provides the opportunity for qualified applicants to apply for a CON to acquire a fixed MRI scanner in a hospital under specific conditions.

In Forsyth County, the Petitioners operate one of the two dedicated breast MRI scanners reported in Table 17E-2 (Existing and Approved Specialized MRI Scanners, Excluded from Inventory) of the 2021 SMFP. The other dedicated breast MRI scanner is operated by the Charlotte Radiology Breast Center in Mecklenburg County.

The Petitioner seeks to "move the Breast MRI Scanners from Table 17E-2 to Table 17E-1" (Petition, page 2). Based on the purpose of a Spring petition, doing so would require a new policy. Approval of the petition would affect both the Forsyth and Mecklenburg county service areas by adding the breast scanners to the planning inventory in those counties. Specifically, as stated in the Petition, the Petitioners' goal is to replace their breast scanner with a general purpose scanner and relocate it from the breast center to a freestanding imaging center (Petition, page 10).

Analysis/Implications:

The Petitioners received an adjusted need determination in 2006 for a dedicated and specialized breast MRI scanner. It has not been in service since 2017 and has not been replaced. Charlotte Radiology received an adjusted need determination in 2002 for a specialized breast MRI scanner. They replaced their scanner in 2020 by way of an exemption from CON. The Certificates of Need (CON) limit these scanners to breast scanning. They may not be used for general diagnostic purposes.

The Agency acknowledges that there have been advancements in the technology of MRI scanners, such that the original dedicated breast scanners are no longer available or needed. The providers have the option to replace the existing breast scanners with general purpose scanners, as Charlotte Radiology did. However, the new scanners must remain within the operational guidelines of the original CON which approved their utilization for dedicated breast scans only. As Novant acknowledges, CON would have to approve a change of scope for the scanners to be used for general clinical purposes. Doing so would first require that the scanners be in the MRI planning inventory (Table 17E-1).

Petitioners argue that placing the former dedicated breast scanners in the planning inventory would not suppress the need for a new fixed MRI scanner in either service area. However, unless that scanner meets or exceeds the need determination threshold, it will, by definition, suppress the need. Charlotte Radiology's scanner reported just over 2,000 weighted breast scans in 2020. Clearly, a replacement MRI would suppress the need if it was used for breast scanning only.

The Petitioners also cite precedents to support their request. They point out that other specialized scanners have been placed in the planning inventory. The Agency finds that these situations are not parallel to the current request. They cite two situations in which multi-positional scanners were replaced and the new scanners were included in the planning inventory, Triangle Orthopaedic Associates (now EmergeOrtho, Durham County) and Carolina Neurosurgery & Spine Associates (Mecklenburg County). When replaced, these multi-positional scanners remained in the practices that had the original CONs. The multi-positional scanners are used for any orthopedic or neurological purpose. Similarly, the replacement scanners are used for the same purposes, and remain in the same two locations as the original multi-positional scanners. They are not general purpose scanners in the context of the SMFP. However, the Petitioners request that their breast

scanner be relocated to a freestanding diagnostic imaging facility and be approved for all types of scans, not just breast scans.

They also cite the Bone & Joint Surgery Center's approval to replace their fixed extremity scanner with a general purpose scanner (which is under appeal). This situation was a demonstration project and, as such, is not comparable to the above situations or to the Petitioners' situation. When a demonstration concludes, the SHCC will make a decision regarding the disposition of the asset (e.g., MRI scanner, OR) used in the demonstration. Normally, the asset is placed in the planning inventory.

The Agency concludes that placing the requested dedicated breast MRI scanners into the planning inventory will suppress the need for additional scanners because of their low utilization. In addition, the Agency does not find it reasonable to propose a policy that is a general response to a specific situation. In this case, Charlotte Radiology may have no interest in placing its dedicated breast scanner in the planning inventory but would be required to do so. Similarly, changes to the status of other types of specialized equipment should be made on an individual basis, if the SHCC were to receive any such requests. Moreover, approval of this request and subsequent authorization by CON would give Novant an additional general purpose scanner. Under normal circumstances, there would have had to be a need determination in the SMFP for Forsyth County for the service area to have an additional general purpose scanner. It appears that Novant proposes to circumvent this requirement.

Agency Recommendation:

The Agency supports the standard methodology and current policies for MRI equipment. Given available information submitted by the March 17, 2021 deadline date for comments, and in consideration of factors discussed above, the Agency recommends denial of the Petition proposing that the two dedicated breast MRI scanners be included in the fixed MRI inventory (Table 17E-1) of the 2022 SMFP. Instead, the Petitioners and any other interested people are invited to petition the SHCC in the Summer for an adjusted need determination for a fixed MRI scanner. As usual, such a petition would need to support the need for an additional scanner in the service area.