

Technology and Equipment Committee
Agency Report
Petition for a New Policy to Substitute Vendor-Owned
Mobile Magnetic Resonance Imaging Equipment (MRI) Scanners with
Provider-Owned Mobile MRI Scanners in the
2023 State Medical Facilities Plan

Petitioner:

Carolina Neurosurgery & Spine Associates
225 Baldwin Avenue
Charlotte, NC 28204

Contact:

Mary Cloninger
Chief Executive Officer
(704) 831-3100
Mary.colinger@CNSA.com

Request:

Carolina Neurosurgery & Spine Associates (CNSA) requests a new policy permitting the substitution of vender-owned mobile MRI scanners with provider-owned mobile MRI scanners 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 allow for submission of petitions for changes to policies and methodologies in the spring and petitions to the State Health Coordinating Council (SHCC) requesting adjustments to need projections in the summer. 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 mobile sites, the fixed equivalent is the number of adjusted (weighted) MRI 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 calculate 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 SMFP uses the fixed equivalent of the mobile MRI units in the methodology to project a need determination for a fixed MRI. The SMFP does not have a methodology to generate a need determination for a mobile MRI scanner. In order to obtain a mobile MRI a summer petition for an adjusted need determination must be submitted. Upon approval of the petition, anyone may apply for a CON for the mobile MRI scanner. Mobile MRI scanners have a statewide service area.

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

CNSA proposes to add the following new policy to the SMFP:

Policy TE-4: Substitution of Vendor-Owned Mobile MRIs with Provider-Owned Mobile MRIs

A qualified applicant is a provider who has an executed service contract with an unrelated person for mobile magnetic resonance imaging (MRI) scanner services and is unable to apply to develop a mobile MRI scanner pursuant to a need determination.

The qualified applicant applying for Certificate of Need (CON) for a mobile MRI scanner pursuant to this policy shall demonstrate all the following in the CON application:

1. As reported in the most recent Registration and Inventory form or License Renewal Application (either the one submitted during the same year the CON application is submitted or the form submitted the previous year), the applicant:
 - a. contracts for mobile MRI services using a mobile MRI scanner owned by an unrelated person.
 - b. performed at least 3,328 weighted MRI procedures combined for all service sites owned and operated by the applicant or a related entity.
2. The proposed mobile MRI scanner will provide services at two or more sites each week and one of those sites must be an existing site where the applicant currently offers mobile MRI services using a mobile MRI owned by an unrelated person.
3. Projected utilization is consistent with the performance standards promulgated in 10A NCAC 14C .2703 and is based on reasonable and adequately supported assumptions.

The current Petition mirrors a Spring 2020 petition previously submitted by the Petitioner to the SHCC. The Agency recommended approval of that petition, along with a similar petition permitting the replacement of vendor-owned fixed MRI scanners with provider-owned fixed

scanners and drafted Policy TE-4 for inclusion in the Proposed 2021 SMFP. However, the SHCC ultimately voted not to add Policy TE-4 to the 2021 SMFP in response to a subsequent Spring 2020 petition because the Agency believed the language of the policy needed to be further developed. The Agency also believed an opportunity for interested parties was needed to offer more input regarding the policy.

Analysis/Implication

The proposed Policy TE-4 will have a statewide impact on the mobile MRI inventory. Mobile MRI units can operate anywhere in the state and are minimally restricted from serving new locations. According to the 2022 SMFP North Carolina has 59 mobile MRI scanners operated by 25 providers. Of those 59 scanners, 26 are legacy units.

CNSA has offices in nine different cities. They own both a fixed and a mobile MRI and have a contract with an unrelated entity for mobile MRI services. The 2022 SMFP indicates that the Petitioner reported 11,936 weighted procedures from the mobile MRI scanners at all the CNSA locations combined, 4,156 of those weighted procedures were from an unrelated entity contracted for mobile services.

CNSA's Petition references the current MRI methodology which incorporates into its analysis the number of scans on both fixed and mobile MRI units within the service area. However, in November 2021, the Agency and the SHCC convened a workgroup to evaluate the current MRI methodology. The proposed revised MRI methodology will be presented to the Technology and Equipment Committee of the SHCC in April 2022. If approved by the SHCC, the methodology has the potential to create additional needs for MRI scanners in the state. According to the data submitted for the 2022 SMFP, mobile MRIs make up 17.52% of all adjusted MRI procedures in the state. According to the performance standards in the CON Rules (10A NCAC 14C .2703(b)), proposed mobile scanners must operate at least two locations and project that they will perform at least 3,328 adjusted MRI procedures in each of the first three fiscal years of operation.

The Petitioner, in its Petition, acknowledged the difficulty the MRI workgroup faced in analyzing the need for mobile MRIs versus the need for fixed MRIs when reviewing the methodology. Notwithstanding, CNSA states that the SMFP should include a policy that generates a need for highly utilized mobile MRI units. However, beginning in 2010, the SMFP provided the Petitioner, and similarly situated providers, the opportunity to submit a summer petition for an adjusted need determination to obtain a new mobile MRI. If approved, anyone may apply for the CON to meet that need. However, no petitions for additional mobile MRIs have been submitted to the SHCC in the last 12 years. The Agency believes that the petition process remains a valid mechanism for the development of new mobile scanners. Moreover, if the revised methodology is approved, the SHCC and the Agency will continue to evaluate it to assess its impact on fixed and mobile MRI units.

The Petitioner projects that only a few providers and/or vendors are likely to be directly affected by this request. However, the SHCC must consider the possible impact that the addition of the proposed policy will have on state inventory. CNSA discusses the potential and unintended

consequences of using leased equipment from a contracted vendor, including the availability and maintenance of equipment and issues between the provider and the vendor. However, these items are not governed by state regulations and the Agency has no influence on service agreements between provider and vendor.

Agency Recommendation:

The Agency supports the standard methodology and current policies for MRI equipment. Given available information submitted by the March 16, 2022 deadline date for comments, and in consideration of factors discussed above, the Agency recommends denial of CNSA's Petition for the inclusion of Policy TE-4 to the 2023 SMFP. Rather, anyone wishing to obtain a mobile scanner should avail themselves of the existing summer petition process.