

**Technology and Equipment Committee
Agency Report
Petition for Amendment or New Policy for the Substitution of Vendor Owned
Magnetic Resonance Imaging Equipment (MRI) Scanner in the
2021 State Medical Facilities Plan**

Petitioner:

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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 *2021 State Medical Facilities Plan (SMFP)*.

Raleigh Radiology requests an amendment to Policy TE-3 permitting freestanding non-hospital providers who contract with a vendor for MRI services the option to apply for a CON to acquire their own fixed MRI scanner to substitute for the vendor-owned MRI scanner regardless of need determination in the *2021 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.

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, there are currently two Technology & 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 to utilize 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.

Carolina Neurosurgery & Spine Associates (CNSA) has submitted a petition to add a new policy allowing the substitution of a vendor-owned mobile MRI scanner with a provider-owned mobile MRI scanner providing they demonstrate the following: 1) the applicant will bill third party payors for at least the technical component of the mobile MRI services; 2) the provider already owns at least one mobile MRI and bills for the technical component for procedures performed on that scanner; 3) utilization of the vendor-owned mobile MRI scanner was at least 3,328 weighted MRI procedures as required by 10A NCAC 14C .2703; 4) that the proposed mobile MRI scanner will conform with the performance standards in 10A NCAC 14C .2703; and 5) the ability to lower costs by offering provider-owned mobile MRI services.

Raleigh Radiology has submitted a petition to amend Policy TE-3 to also allow freestanding non-hospital facilities to obtain a CON for a fixed MRI scanner providing they meet the following conditions: 1) currently operate equipment as a fixed MRI unit; 2) annual weighted MRI procedures are equal to or exceed SMFP service area threshold for a need determination; 3) maintain service to Medicare/Medicaid and other underserved patients; 4) cost to patients will not increase for 1 year after installation; 5) providers terminate existing service agreement for fixed MRI scanner; and 6) new fixed MRI is accredited by an entity recognized by the Centers for Medicare and Medicaid Services.

Analysis/Implications:

Throughout the Petitions, both Petitioners mention the unintended consequences to having leased equipment from a non-related entity. The State does not have any involvement in the contracts between the lessee and leaser lessor for equipment. The availability of equipment and maintenance of equipment is not under the state regulation. Both Petitions propose a policy that will implement a statewide impact on the inventory of MRIs. CNSA's petition can potentially bring more mobile MRIs into the state. Any mobile units substituted under the proposed policy will undoubtedly serve new locations and, if grandfathered, will be able to operate anywhere in the state. Raleigh Radiology's Petition will increase the number of fixed MRI's in the state. Adding more fixed and/or MRI units to a service area could reduce the likelihood of need determinations.

CNSA’s Petition included an analysis of the MRI methodology that has been used in the SMFP. The Petitioner mentions that there is no methodology to obtain a mobile MRI, yet mobile MRI procedures are being used in the calculation for a fixed MRI need determination. Some service areas report enough weighted procedures performed on a mobile MRI to generate a need determination for a fixed MRI, with no allowance in the need determination for a mobile MRI unit.

According to the 2020 SMFP there are 50 mobile MRI scanners operated by 24 providers within the state. Of those 50 scanners, 20 are grandfathered units. There are 9 providers that provide mobile MRI services to 7 different non-related entities that would meet the CON mobile MRI performance standard of 3,328 weighted procedures annually. CNSA has offices in 9 different cities. They also own a fixed MRI and a mobile MRI, and contract with a non-related entity for mobile MRI services. In the 2020 SMFP (shown in Table 1 below), the Petitioner reported 9,115 weighted procedures from the mobile MRI scanners at all the CNSA locations combined.

Table 1: Mobile MRI Service Sites (with Vendor Service) that Exceed the Mobile MRI CON Performance Standard

Provider	Vendor(s)	2020 SMFP Weighted Procedures at All Locations*
Carolina Neurosurgery & Spine Associates	Alliance Healthcare Services	9,115
Delaney Radiologists	Insight Imaging Porter’s Neck Imaging, LLC	6,519
EmergeOrtho, P.A.	Alliance HealthCare Services Carolina Orthopedic Specialists	5,465
New Hanover Regional Medical Center	Alliance Healthcare Services	3,868
Novant Health	King’s Medical Group Presbyterian Mobile Imaging, LLC	8,431
OrthoCarolina, P.A.	Alliance Healthcare Services	12,190
Southeastern Orthopedic Specialists	Alliance Healthcare Services	5,139

Source: 2020 State Medical Facilities Plan
**Total weighted procedures are the result of one or multiple mobile MRI scanners used by provider.*

Raleigh Radiology suggested in their Petition that an addition should be made to policy TE-3 allowing providers under service agreements to obtain a fixed MRI without a need determination in the current SMFP. Petitioner mentions that due to only 1 need determination for a service area, the qualified freestanding provider applicant must compete with new entrants for the CON award. All qualified applicants (even providers under service agreements) can apply for a CON based on the available need determination. Based on the 2020 SMFP, 242 fixed MRI scanners were operational or CON-approved as of September 30, 2018. Of these scanners, 63 are freestanding fixed and 47 of those are under a service agreement. There are 5 freestanding fixed MRIs operated by a non-related entity that exceed the fixed MRI threshold for their respective service areas (shown in Table 2 below).

Table 2: Fixed MRI Service Sites (with Vendor Service) that Exceed the Fixed MRI Need Determination Threshold

County	Provider	Vendor	Threshold	2020 SMFP Weighted Procedures
Moore	Pinehurst Surgical Center	Alliance Healthcare Services	4,805	5,586
Wake	Raleigh Neurology Imaging	Alliance Healthcare Services	4,805	5,988
Wake	Raleigh Radiology Blue Ridge	Alliance Healthcare Services	4,805	6,004
Wake	Raleigh Radiology Cary	Alliance Healthcare Services	4,805	7,511
Wake	Raleigh Radiology Cedarhurst	Pinnacle Health Services of NC	4,805	8,111

Source: 2020 State Medical Facilities Plan

There are likely to be few providers and vendors impacted directly by the requests based on the information in the Petitions. However, the possible impact to the state inventory must be considered. Each Petition places a strong emphasis on issues between the provider and the vendor in their respective petitions. Those items are not mentioned in this Agency Report because the Agency does not have any 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 18, 2020 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the Agency recommends denial of the Petitions submitted by Carolina Neurosurgery & Spine Associates and Raleigh Radiology for policy revision in the 2021 SMFP. Instead, the Agency recommends the approval of Policy TE-4, which will create an opportunity for providers that contract with a non-related entity for MRI services to convert to provider-owned MRI services.