Comments on MRI Petitions and Comments on the 2023 State Medical Facilities Plan and MRI Workgroup

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Thank you for providing an opportunity to comment on the product of the MRI Work Group and on comments and petitions filed in association with the *2023 State Medical Facilities Plan* development. All show considerable thought and effort to grapple with a big issue.

During the Public Hearing on March 2, and related emails, three parties filed one comment and two petitions related to Magnetic Resonance Imaging ("MRI") equipment policies and methodology.

- One petition proposed new policy: TE-4; and
- One petition proposed modification to TE-3.

MRI Work Group Methodology and Recommendations

The charge to the Work Group was substantial and its recommendations are now in a two-week period of written public comment.

The Public Hearing commenter noted that the product of the MRI Work Group is incomplete and asked that the need methodology remain on the table before bringing it to the Technology and Equipment Committee. The commenter appropriately noted the difficulties associated with conducting a detailed and comprehensive Work Group on a teleconferencing platform that did not permit the public to view or interact with the proceedings.

MRI is an important, and now standard, tool in health care diagnosis. Given the breadth of issues and the challenges of the Work Group, allowing for comments and discussion on MRI methodology and policies through the annual SMFP Summer Petition period would provide a systematic and thorough vetting of the entire MRI chapter. Doing so would provide time in the normal SHCC annual planning process for the Technology & Equipment Committee to discuss work to date, present a plan for comment, review feedback, and make a final recommendation to the SHCC for the 2023 SMFP by the September 14 committee meeting.

Limitations of the teleconferencing platform made it difficult for the Work Group to completely execute all of its charges, including review of all prior MRI petitions, and addressing policy or distinctions between mobile and fixed scanners. The Work Group did raise an important question: "Is the distribution of MRI equipment equitable with regard to the distribution of the population?" *but failed to discuss it*. As illustrated in the sample in the following table, the distribution of fixed MRI scanners is geographically

inequitable, even among comparable urban counties. For example, Mecklenburg County's ratio per 100,000 residents is 1.6 times that of Wake, while Cabarrus County's is 2.2 times Wake.

Table 1: 2020 Fixed MRI Scanners per 100,000 Residents, Selected Urban Counties

County	2020 Population	True Fixed Scanners*	Fixed/ 100 K Pop
Alamance	115,160	3	2.6
Brunswick	107,429	2	1.9
Buncombe	238,315	11	4.6
Cabarrus	178,116	7	3.9
Durham	269,998	16	5.9
Forsyth	350,635	19	5.4
Guilford	488,455	13	2.7
Mecklenburg	919,675	26	2.8
Wake	901,036	16	1.8

Sources: Population NCOSBM updated Feb 1, 2022; Fixed Scanners, Table 17E-1, 2022 SMFP;
**Excludes scanners classified as Fixed, that are associated with temporary leases with unrelated parties*

Unfortunately, the Work Group's Recommended Methodology maintains and enhances this geographic disparity. It also increases, across the board, the threshold for calculated need for new fixed scanners. This will slow the expansion of MRI supply. The Work Group recommendations do not publish tables to illustrate the impact of proposed recommendations, so it is very difficult for the general public to understand the true impact. The following comments address underlying issues.

There are basic flaws in both the current and proposed methodologies:

- Both methodologies assume – without testing – that the existing geographic distribution of fixed MRI scanners is fair and equitable. Neither methodology is need-based. Both are based on utilization of existing inventory only.
- Under both existing and proposed methodologies, a service area that has no fixed MRI will only show an MRI need if it has enough mobile utilization to reach the county threshold. This is a problem with limited mobile unit capacity, as it appears true today.
- In the proposed methodology, an over-supplied service area will show need for more MRI units if its population increases. However, according to Work Group Recommendation 6, the expanded need will be based on percent of population increase over three years. The Work Group did not test the possible scenarios, in large part because of timing and the awkward nature of the teleconferencing platform used. The few staff tests were not fully visible to public attendees.
- Both current and proposed methodologies treat mobile and fixed units as if the only difference is in number of scans, when, in fact, the nature of the two is quite different.
    - A collection of scattered mobiles becomes one fixed equivalent on the basis of the sum of weighted scans among the mobiles. Those mobile units may or may not remain in the same place from one year to the next.
    - The number of weighted mobile scans per "fixed equivalent" is not constant. It varies by the number of fixed scanners in the service area.

- As the commenter noted, there is no way to effectively track MRI scanners in North Carolina. They do not require licensure, nor are they registered with the DHSR Radiation Protection Section. Until the SHCC mandates a unique, equipment-related identification system that includes Legacy and Grandfathered scanners, it will be difficult to follow even the fixed units. Development of a unique numbering system should be a Work Group recommendation.
    - Absence of unique numbering makes it impossible to tie procedure counts to specific equipment from one year to the next. As a result, data in SMFP tables often miss and/or double count procedures and scanners.
    - Material Compliance filings permit mobile MRI owners to change the host sites of mobile equipment across service areas, which exacerbates the difficulty in tracking equipment inventory.

<u>Spring 2022 Petitions</u>

Two petitioners addressed recommended policy changes. The <u>policy change for TE-3 is reasonable</u> and adds important clarifying language about qualified community hospitals.

The petition regarding Proposed Policy TE-4 is a good first step. It illustrates the inherent problems with the current SMFP approach to MRI, regarding transition from temporary leases to permanent owned equipment. It shows that the problems extend to both policy and methodology.

The SMFP should have an MRI policy that systematically lays out how to address temporary leased scanners. The 2022 TE-4 petition, and prior discussions from 2020, shed light on a potential simple mechanism for systematically transitioning and improving MRI access statewide.

<u>Creation of a New SMFP Policy Regarding Transition of Temporary Leased MRI Equipment</u>

The SHCC could create <u>one consolidated MRI policy to permit facilities that utilize MRI services to transition from leased to owned MRI scanners</u>, if:

- The proposed owned scanner will cost less than the leased unit (This policy is now buried in the need methodology at Item 8, page 342 of 2022 SMFP);
- Qualified applicants lease MRI equipment from an unrelated party and have a demonstrated history of weighted MRI scans as calculated in Table 17E-1 of current SMFP in one of the following three conditions:
    1. If the applicant proposes to convert a “fixed (or single site)” lease to a “fixed site”, it would qualify when its weighted MRI scans reach the weighted fixed threshold for its respective service area;
    2. If the applicant proposes to convert a leased mobile to a “mobile,” it would qualify if <u>all</u> the following conditions apply:
        - The history on the mobile units demonstrates an average annual weighted scans at the mobile performance standard (now 3,328 weighted scans);
        - It will offer mobile MRI scans at a minimum of two sites; and
        - The proposed owned scanner must remain mobile.

3. If the applicant proposes to convert a leased mobile to a “fixed” it would qualify if its historical utilization demonstrated an annual number of fixed equivalent scans at the fixed performance threshold for the service area. This would occur where the applicant is leasing the same mobile equipment at more than one site.

This new policy would provide a means to release back into the statewide MRI inventory a needed supply of mobile scanners. Today, it is difficult to find mobile capacity that can keep up with population changes.

The number of sites likely to qualify under the consolidated policy is small, less than ten. (See attached tables based on the 2022 SMFP.) This represents less than a one half of one percent change in the statewide MRI scanner inventory. Moreover, not every qualified applicant will choose to do so, because many leases have time limits on termination and applicants may not want to carry the cost of both the existing lease and the replacement equipment.

This solution would address some of the geographic distribution access problem. Today, in many places, the only available option to provide needed MRI scans is leasing equipment from the mobile inventory.
The solution would incorporate elements of the Agency’s Recommended 2020 TE-4 policy. The Agency’s Recommended 2020 mechanism permitted qualified entities to file Certificate of Need applications to transition from leased to owned MRI scanners when scanners reached a performance threshold. The Agency’s Spring 2020 Recommendation addressed both mobile and fixed MRIs.

The expanded TE-4 policy would be consistent with the **State Medical Facilities Plan Basic Principles – 2. Access Principle**, first paragraph.

> *Equitable access to timely, clinically appropriate, and high-quality health care for all the people of North Carolina is a foundational principle for the formulation and application of the North Carolina State Medical Facilities Plan…. The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers.*

With better supply, competition ameliorates economic barriers and with a better distribution, time and geographic barriers are mitigated.

These comments are on behalf of PDA, Inc., a consulting firm that has worked with *the North Carolina State Medical Facilities Plan* for more than 35 years. Comments are filed in the interest of sharing observations.

Attachments:

A. *Tables of Qualified Applicants*
B. *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*

Attachment A:
Sample Qualified Applicants 2022 State Medical Facilities Plan

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

Std	County	Provider	2022 SMFP Wtd. Proc. All Locations*	Qualifies: Over Std
3328	Guilford, Mecklenburg, and Cabarrus	Carolina Neurosurgery & Spine Associates	4,156	x
3328	New Hanover	Delaney Radiologists	7,399	x
3328	Guilford	Southeastern Orthopedic Specialists	4,404	x
3328	Wake	Duke Raleigh Hospital	3,918	x
3328	Wake	Wake Radiology	4,658	x
		Total Impact		***5***

Source: 2020 State Medical Facilities Plan and 2022 SMFP Table 17E-1
**Total weighted procedures are the result of one or multiple mobile MRI scanners used by provider.*

Table 2: Fixed MRI Service Sites with Vendor Service that Exceed the Fixed MRI Performance Standard

Std	County	Provider	2022 SMFP Wtd. Proc.	Qualifies: Over Std
4,805	Moore	Pinehurst Surgical Center	6,219	x
4,805	Wake	Raleigh Neurology Imaging	5,856	x
4,805	Wake	Raleigh Radiology Blue Ridge	5,951	x
4,805	Wake	Raleigh Radiology Cary	6,400	x
		Total Impact		***4***

Source: 2020 State Medical Facilities Plan
Note: RR Cedarhurst became Cardinal Points Midtown in 2020

Attachment B:
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

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

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Petitioner:

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Charlotte, NC 28204

Raleigh Radiology
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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 vender-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.