

Technology and Equipment Committee
Agency Report
Create Policy TE-4: Conversion of Fixed MRI Scanners to Mobile MRI
Scanners
Proposed 2024 State Medical Facilities Plan

Petitioner:

Appalachian Regional Healthcare System
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Request:

Appalachian Regional Healthcare System (ARHS) is requesting to add Policy TE-4: Conversion of Fixed MRI Scanners to Mobile MRI Scanners in the *2024 State Medical Facilities Plan (SMFP or the “Plan”)*.

Background Information:

Chapter Two of the *North Carolina 2023 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 *Plan’s* annual planning process and timeline allows for the submission of spring petitions for changes to policies and methodologies in the *SMFP* and summer petitions requesting adjustments to need projections in the *SMFP* to the State Health Coordinating Council. It should be noted that any person may submit a certificate of need (CON) application for a need determination in the *SMFP*.

The standard MRI methodology uses the total number of adjusted 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. A need determination for additional fixed MRI scanners occurs when the average adjusted procedures per scanner for the service area exceeds the threshold established for the service area. There is no methodology for mobile MRI scanners in the *SMFP*. A summer petition is required to place a need in the upcoming *SMFP*. If approved, a CON will be required to acquire a new mobile MRI. The service area for mobile MRIs is statewide. The *2023 SMFP* shows need determinations for nine fixed MRI scanners – one each in nine service areas – and a need determination for three mobile MRI scanners. The CON application deadline for the mobile MRI scanners is May 1, 2023.

The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

While the methodology only projects need for fixed machines, the SMFP enumerates three types of MRI scanners in Tables 17E-1 and 17E-2, dependent upon ownership of the scanner: hospital fixed, free-standing fixed, and mobile. Hospitals and non-hospital providers may apply for a CON for either fixed or mobile machines.

Policy TE-1 is the only policy in the *SMFP* that outlines conditions for CON applications to convert a scanner from a fixed machine to a mobile. This policy was first adopted for the 2015 *SMFP* as the result of three summer petitions. The Policy states:

Facilities with an existing or approved fixed PET scanner may apply for a Certificate of Need (CON) to convert the existing or approved fixed PET scanner to a mobile PET scanner if the applicant(s) demonstrates in the CON application that the converted mobile PET scanner:

- 1. shall continue to operate as a mobile PET scanner at the facility, including satellite campuses, where the fixed PET scanner is located or was approved to be located;*
- 2. shall be moved at least weekly to provide services at two or more host facilities; and*
- 3. shall not serve any mobile host site that is not owned by the PET certificate holder or an entity related to the PET certificate holder such as a parent or subsidiary that is located in the county where any existing or approved fixed PET scanner is located, except as required by subpart (1).*

Appalachian Regional Healthcare System is proposing to add *Policy TE-4: Conversion of Fixed MRI Scanners to Mobile MRI Scanners*. As demonstrated below, the proposed policy adopts language similar to that of Policy TE-1 and lists two additional conditions.

(Proposed) Policy TE-4: Conversion of Fixed MRI Scanners to Mobile MRI Scanners

Facilities with an existing or approved fixed magnetic resonance imaging (MRI) scanner may apply for a Certificate of Need (CON) to convert the existing or approved fixed MRI scanner to a mobile MRI scanner if the applicant demonstrates in the CON application that the converted mobile MRI scanner:

- 1. Shall continue to operate as a mobile MRI scanner at the facility, including satellite campuses, where the fixed MRI scanner is located or was approved to be located;*
- 2. Shall be moved at least weekly to provide services at two or more host facilities;*

3. *Shall not serve any mobile host site that is not owned or operated by the MRI certificate holder or an entity related to or affiliated with the MRI certificate holder;*
4. *Shall not have been developed pursuant to Policy TE-3¹; and,*
5. *Shall serve at least one facility in a county that meets the U.S. Census Bureau's criteria (population less than 50,000) for a rural county.*

In North Carolina, there are 70 counties designated as rural.² However, as shown in the 2023 SMFP, during the 2021 data reporting year, only 40 counties had hospitals operating fixed MRI scanners in their facilities. Twenty rural counties received MRI services by mobile providers. As shown in Table 1, in rural counties, the large majority of scans are performed on hospital fixed MRI scanners whereas in urban counties, there is more diversity in the type of scanner accessed.

Table 1. MRI Scanners and Scans in Counties Designated Rural and Urban, Data Year 2021

MRI Scanner Type	Rural				Urban				Statewide Totals	
	Number of Scanners Serving Area	% of All MRI Scanners in Rural Counties	Number of Scans	% of Scans in Rural Counties Performed on Scanner Type	Number of Scanners Serving Area	% of All MRI Scanners in Urban Counties	Number of Scans	% of Scans in Urban Counties Performed on Scanner Type	Scanners	Scans
Hospital Fixed	48	64.0%	143,794	76.0%	64	40.0%	416,637	53.0%	112	560,431
Free-standing Fixed	9	12.0%	19,831	10.5%	63	39.4%	226,895	28.8%	72	246,726
Mobile*	18	24.0%	25,646	13.5%	32	20.6%	143,089	18.2%	46**	168,735
State	75		189,271		160		786,621		235	975,892

* MRI mobile scanners may be owned by a hospital or a non-hospital provider. Statewide, eight mobile MRI scanners were hospital-owned during the 2021 data reporting year. One hospital in a rural county provided mobile MRI services. Seven hospitals in urban counties provided mobile MRI services.

** Nine MRI mobile scanners served both rural and urban counties.

Source: *Registration and Inventory of Medical Equipment, Mobile Magnetic Resonance Imaging Scanners, January 2022*

¹ Policy TE-3 was first adopted in the 2016 SMFP under the assumption that MRI scanners provide a standard of care to patients. The intent of Policy TE-3 is to address the MRI needs of rural hospitals that operate in counties unlikely to have a need determination in the SMFP and that would be unlikely to meet CON performance standards. The policy was revised in the 2023 SMFP to allow a hospital that is not located on the main campus of another hospital, but operates under the license of the hospital on the main campus, to obtain a fixed MRI and to add that hospitals may acquire a fixed MRI if they have not had an existing or approved fixed MRI scanner in the five years immediately preceding the filing of a CON application for a fixed scanner. Since 2016, this policy has been instrumental in adding fixed MRI scanners in three rural hospitals that previously had no fixed MRI scanner. This footnote was not included in the Petitioner's proposed policy.

² Office of Rural Health, North Carolina Department of Health and Human Services. *County Designations of Core Based Statistical Areas*, March 2020. <https://www.ncdhhs.gov/media/10486/download>

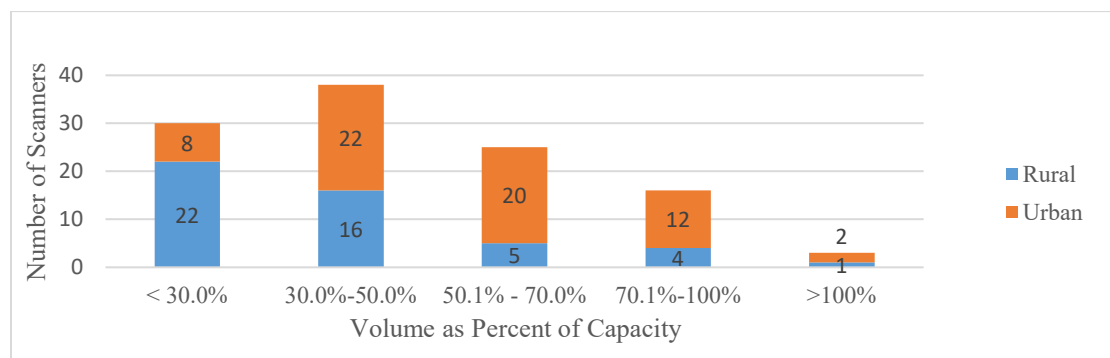
Analysis/Implication

According to the Petitioner, the geography and climate of the western region of the State and the dispersion of its population combine to create barriers for patients seeking MRI services. Policy TE-4 is proposed with the goal of providing more flexibility in existing MRI capacity. The Petitioner emphasizes the proposed policy is not designed to place more MRI scanners in the inventory. Instead, the intent of the policy is to eliminate travel challenges by bringing MRI services closer to patients.

From the Petitioner’s perspective, the proposed policy would “allow providers who have demonstrated sufficient volume to support a fixed MRI scanner... [to convert it into] a mobile scanner instead.” The Petitioner did not define “sufficient volume.” To understand scanner performance, Agency staff examined scanner volume and capacity. As described in the *2023 SMFP*, one assumption of the need methodology is that a fixed MRI can perform 6,240 scans per year. Based on this assumption, during the 2021 data reporting year, almost 80% of hospital fixed scanners in rural areas operated at less than half capacity. During the same time period, almost half of hospital fixed scanners in urban counties operated at less than half capacity. The Petitioner’s assertion that allowing mobilization of hospital fixed machines may increase the efficiency of some existing low-volume MRIs finds support in this data.

However, the data also demonstrate that statewide, less than 40% of all hospital fixed MRIs could meet a reasonable criterion for “sufficient volume” (Figure 1). Conversely, during 2021, over 60% of all hospital fixed scanners across the State were approaching or had exceeded optimal capacity. There is only one fixed MRI in two-thirds of hospitals statewide. A statewide policy to allow conversion of fixed MRIs to mobile would create the risk that MRI capacity needed in urban hospitals would be reduced.

Figure 1. Hospital Fixed MRI Capacity, Rural and Urban Counties, Data Year 2021

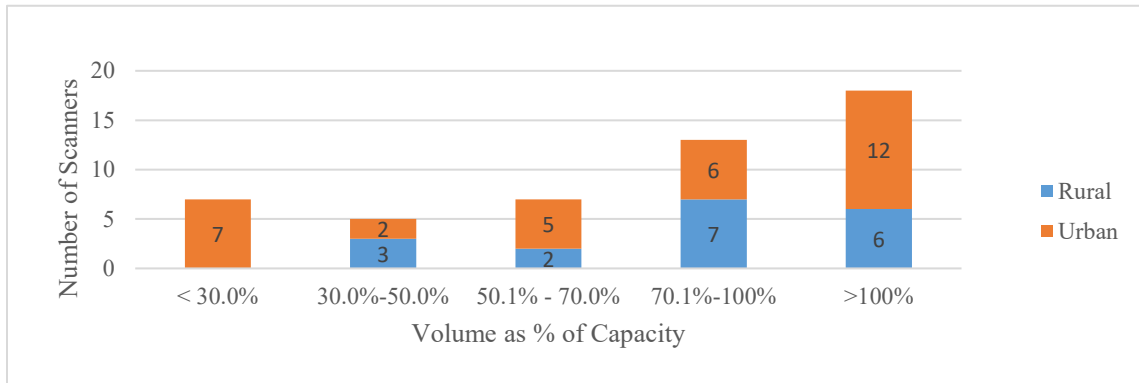


Source: *Registration and Inventory of Medical Equipment, Mobile Magnetic Resonance Imaging Scanners, January 2022*

The impetus for the development of Policy TE-1 was overutilization of the only two mobile PET scanners that existed at that time. While the Petitioner structures the proposed policy similar to Policy TE-1, key characterizations for mobile MRI scanners differ from those of mobile PET scanners. For one, there are 46 mobile MRI scanners across the State with nine mobiles serving both rural and urban counties. Additionally, as shown in Figure 2, similar to hospital fixed MRI

scanners, mobile volume and performance vary widely. The performance standard is 3,120 scans per mobile scanner.³ Of the 18 mobile MRI scanners that served rural areas in 2021, volume for five of the machines was below the 70% capacity threshold used in the MRI need methodology. Of the 32 mobile MRI scanners that served urban counties, 14 were below the 70% capacity threshold. Further, nine mobile MRIs serving urban counties operated at no more than half capacity. Converting hospital fixed MRIs into mobile scanners will duplicate resources in areas where adequate mobile MRI capacity exists.

Figure 2. Mobile MRI Capacity, Rural and Urban Counties, Data Year 2021



Source: *Registration and Inventory of Medical Equipment, Mobile Magnetic Resonance Imaging Scanners, January 2022*

Agency Recommendation:

The Agency supports the standard methodology and current policies for MRI equipment. Given the available information submitted by the March 15, 2023 deadline, and in consideration of factors discussed above, the Agency recommends denial of this petition. The diversity in MRI scanner performance that exists across geographies and scanner type suggests that a statewide policy is an unsuitable approach to increase access. Alternately, the summer petition process presents an opportunity to request an adjusted need determination for a mobile MRI scanner.

³ *North Carolina 2023 State Medical Facilities Plan*, CON Regulation 10A NCAC 14C.2703 Performance Standards (8), p. 410