



APPALACHIAN REGIONAL HEALTHCARE SYSTEM

Petition for New Technology and Equipment Policy

PETITIONER

Appalachian Regional Healthcare System
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STATEMENT OF REQUESTED ADJUSTMENT

Appalachian Regional Healthcare System (ARHS) respectfully petitions the State Health Coordinating Council (SHCC) to add a new policy to the *2024 State Medical Facilities Plan (2024 SMFP)*. Specifically, ARHS requests that the following language be used to create Policy TE-4:

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-3; 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.

BACKGROUND OF THE PETITIONER

Appalachian Regional Healthcare System, the parent organization and sole member of Appalachian Regional Medical Associates, Inc. (ARMA), is the leading provider of healthcare services in Watauga and Avery counties. ARHS owns and operates two existing acute care hospitals, Watauga Medical Center (WMC) and Charles A. Cannon, Jr. Memorial Hospital (CMH), with extensive experience providing diagnostic imaging services, including MRI services. In addition, ARHS operates Appalachian Regional Behavioral Healthcare Hospital, an acute psychiatric hospital. Currently, ARHS owns a fixed MRI scanner that is located at WMC and is approved to develop a second fixed MRI scanner at AppMedical Services, a freestanding diagnostic center in Boone. Across its two hospital campuses, ARHS offers a broad spectrum of healthcare services, including emergency services; a broad spectrum of imaging services; an array of medical and surgical care, including orthopedics, cardiology, pulmonology, gastroenterology, urology, and stroke; inpatient and outpatient behavioral health services; and extensive ancillary services, such as pain management, wound care, physical and occupational rehabilitation therapy, and cardiopulmonary rehabilitation. In 2022, ARHS's Watauga Medical Center was named a "Top Rural Hospital" by The Leapfrog Group, a national watchdog organization widely acknowledged as the toughest standard-setters for healthcare safety and quality. The Leapfrog Group also awarded WMC an "A" Hospital Safety Grade in 2022, and WMC has also received honors from the American Heart Association (the GoldPlus Get With The GuideLines® Stroke Quality Achievement Award) and The Joint Commission (the Gold Seal of Approval® for Disease-Specific Care Certification for Chest Pain), also both in 2022. In addition, CMH received a 2022 Human Experience Guardian of Excellence Award® from Press Ganey, a global healthcare experience solutions and service company. This award places CMH in the top five percent of healthcare providers in delivery patient experience in the last year. To expand healthcare services and improve access for the region, ARHS affiliated with UNC Health in 2022, enabling ARHS to invest in services, technology, equipment, and facilities managed by UNC Health.

ARHS operates facilities in a rural region of western North Carolina referred to as the "High Country" due to its elevation and location in the Appalachian Mountains. The High Country is a large swath of the state that encompasses several North Carolina counties, including Alleghany, Ashe, Avery, Mitchell, Watauga, Wilkes, and Yancey counties. Because the High Country is a large, rural, and geographically expansive area of North Carolina that has historically been medically underserved – according to the Health Resources & Services Administration, all seven High Country counties qualify as designated medically underserved areas¹ – patients in counties neighboring or not far from Watauga County must often travel to Watauga County for essential care. This is challenging, as the high elevations of High Country counties result in difficult terrain, inclement weather conditions including snow and ice, and unpredictable weather patterns, including frequent fog and haze, during all times of the year. Further, no interstates pass through this part of the state, which leaves long circuitous highways and back roads as the only options for travel. In other words, it can often be difficult for the over 200,000² residents of High Country to access healthcare, especially during the more treacherous winter months. ARHS is familiar with the difficulties of providing care for rural, broadly dispersed and geographically challenging patient populations.

¹ <https://data.hrsa.gov/tools/data-explorer?paramServiceId=MUA¶mFilterId=D>.

² Combined 2021 populations of Alleghany, Ashe, Avery, Mitchell, Watauga, Wilkes, and Yancey counties as listed by the North Carolina Office of State Budget and Management (NC OSMB), <https://www.osbm.nc.gov/facts-figures/population-demographics/state-demographer/county-population-estimates/county-population-estimates>.

REASONS FOR THE REQUESTED ADJUSTMENT

Under the current *SMFP* policies and methodologies, providers have two options for developing MRI services: apply for a fixed MRI scanner once a need is identified in their service area or apply for a statewide mobile MRI scanner when one becomes available via an adjusted need determination. In other words, providers must either serve their patient population with a fixed MRI or create a mobile MRI service and potentially compete with other mobile providers across the state that serve disparate locales. Those options are limiting, especially for providers who are focused on serving their patient population effectively and do not want to be a statewide mobile MRI vendor. This petition proposes a third alternative: allow providers who have demonstrated sufficient volume to support a fixed MRI scanner the flexibility to improve geographic accessibility to the service by developing a mobile MRI scanner instead.

Another challenge under the current *SMFP* MRI framework is that, given the evolution of MRI methodology over more than two decades, need determinations for mobile MRI scanners have been exceedingly rare prior to the *2023 SMFP*. Further, such need determinations are often either allocated statewide or across a large geographic area, with the purpose of creating a supply of mobile service vendors focused on serving unrelated, lower-volume mobile sites across the state. The purpose of this petition is quite different: to allow providers that otherwise would serve their patient population with a fixed MRI at a single location to serve those same patients at multiple locations using mobile MRI scanner.

The proposed policy will not expand MRI capacity in any way; it simply allows providers more flexibility in how existing capacity may be distributed. For rural providers across the state, flexibility is essential, as factors outside of their control often necessitate adapting services to increase patient access. As previously stated, the High Country has highly mountainous terrain, as well as many residents who are extremely hesitant to leave their outlying, close-knit communities, even for medical care. In other rural communities, the challenge may be serving a large, but sparsely populated geography. For example, there are several rural counties that span nearly 1,000 square miles each but have population densities (population per square mile) of 65.0 or lower (compared to the state average population density of 214.7), according to 2020 estimates from the U.S. Census Bureau.³ Both the High Country and other counties across the state could benefit from a more flexible policy for the provision of MRI services. These examples demonstrate that the two existing options do not provide sufficient alternatives for appropriately accessible care.

In short, ARHS proposes that the *SMFP* should allow for a third alternative: a means by which providers who already have demonstrated sufficient volume for a fixed MRI scanner may convert that scanner to a mobile MRI scanner, thereby expanding geographic access to the service. Given that the State of North Carolina is largely rural, with many rural healthcare providers, ARHS believes the most effective and equitable solution is to add a new policy to the *SMFP* that establishes a reasonable alternative for providers experiencing similar conditions to better serve their communities. Finally, and of note, the language included in the proposed petition closely mirrors that used to create currently-existing Policy TE-1, by which a “[facility] 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;” as providers

³ <https://www.census.gov/library/stories/state-by-state/north-carolina-population-change-between-census-decade.html>.

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currently have increased flexibility with regard to PET scanners, it follows that they should also have similar flexibility with MRI scanners.

Adverse Effects on Patients If the Petition Is Not Approved

Currently, there is no existing means by which a provider can convert a fixed MRI scanner to a mobile MRI scanner in response to the disparate geographic needs of the patients served by that provider. For rural providers, and especially for providers in challenging geographies like the North Carolina High Country, such a policy would be especially meaningful, as it would allow providers with multiple locations, such as ARHS, to move the MRI scanner throughout the service area based on demographic need and patient demand. As such, patients would find MRI services more accessible.

Alternatives Considered

As noted previously, currently there are only two options for providers to develop MRI services: apply for a fixed MRI scanner or apply for a mobile MRI scanner when available. Neither of these options addresses the issue to be resolved by the proposed policy, and neither is an effective alternative to approval of the petition.

Apply for a fixed MRI scanner pursuant to a need determination in the SMFP

A provider could apply for a need determination for a fixed MRI scanner as that need determination is allocated to its county by the *SMFP*. However, this alternative limits a provider to serving its patient population in one location, rather than serving patients across multiple locations, as a mobile MRI scanner would. For providers that serve a large geography or difficult terrain, this option does not provide a means of enhancing geographic access to the service as the proposed Policy TE-4 enables. Additionally, as explained further below, the proposed policy requires that an applicant have an existing or approved fixed MRI scanner prior to applying to convert that approved fixed MRI scanner to a mobile MRI scanner; in other words, this alternative is a functionally necessary step for an applicant to utilize the proposed policy at all. An applicant cannot make use of the proposed policy *without*, at some point, having applied for a fixed MRI scanner. A fixed MRI scanner also has a fundamentally different means of access than a mobile MRI scanner and does not fulfill the same access that a provider may be seeking through a mobile MRI scanner.

Apply for a mobile MRI scanner pursuant to a need determination in the SMFP

A provider could also apply for a need determination for a mobile MRI scanner as that need determination is made available in the *SMFP*. However, this is unviable, for reasons largely detailed above: mobile MRI need determinations are rare and are almost always made following a special need petition for a statewide allocation. Further, this scenario would unnecessarily duplicate services compared to the proposed policy, as it would create additional capacity when the need is for more flexibility in use of existing or approved capacity, not more. It is also worth reiterating that the goal of the proposed policy is *not* to provide an avenue for a provider to establish service as a mobile vendor and thereby serve unrelated sites across a large geography, but, rather, to allow a provider flexibility to use existing or approved capacity in a way that best supports access for their respective patient population.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

ARHS believes that the proposed Policy TE-4 clearly avoids unnecessary duplication. As detailed in the language of the proposed policy, the policy does not permit adding capacity to a proposed service area, but rather allows for a provider to substitute one type of MRI scanner for another in an effort to improve geographic accessibility for its patient population. In other words, in the language of the proposed policy, there is no duplication of services being proposed. For example, in April 2020, ARMA applied, and was approved for, one fixed MRI scanner to be located at AppMedical Services pursuant to a need determination in Watauga County as identified in the *2020 SMFP* (Project ID # D-011899-20). In other words, this need has already been approved. If the proposed policy were to be applied to ARMA's approved fixed MRI scanner, there would be no duplication of services, simply the replacement of capacity with an alternative that provides more geographic flexibility. Further, the proposed policy is mindful of existing mobile MRI vendors' vital role in providing care statewide and does not wish to usurp the role that those vendors play in providing care to low-volume sites across the state. Rather, the policy simply seeks to allow providers across the state to tailor their care to geographic need and patient demand.

EVIDENCE THAT THE PROPOSED CHANGE IS CONSISTENT WITH THE THREE BASIC PRINCIPLES

ARHS believes the petition is consistent with the three basic principles: safety and quality, access, and value.

Safety and Quality

The proposed policy change will improve the quality of care that providers like ARHS will be able to provide for their patients by allowing them the flexibility to distribute needed MRI capacity throughout a large or geographically challenged service area, rather than force patients to travel to a single fixed location for services. In some of the locales served by ARHS, the improved convenience of MRI services may prompt patients who otherwise would not travel through difficult terrain to seek MRI services or would not leave their remote community to do so. For these patients, bringing the modality to them will enable patients to access the care that they need in a timely and safe manner, thereby allowing providers to deliver care that is of a higher quality. If care is not accessible – due to geographic or other reasons – it becomes far more difficult for a provider to deliver care at all, let alone deliver quality care. The proposed policy will allow providers flexibility to utilize their existing services in a way that is appropriate for their patient demand, thereby emphasizing safety, resulting in care of the utmost quality.

Access

The proposed policy change will greatly increase access to MRI services, for reasons already stated above. To reiterate, current MRI policies pose difficulties with regards to providing care for rural, broadly dispersed and geographically challenging patient populations. For rural providers across the state, flexibility is essential, as factors outside of their control necessitate adapting services to increase patient access. The proposed policy does not permit more MRI capacity but simply allows providers more flexibility in how existing capacity may be distributed. ARHS proposes that the *SMFP* should allow for a third alternative: a means by which providers who already have demonstrated sufficient volume for a fixed MRI scanner may convert that scanner to a mobile MRI scanner, thereby, above all else, expanding geographic access to the service.

Value

Approval of the petition also would promote value. By allowing patients to easily seek the right care at locations closer to home, the proposed policy, in increasing access to MRI services, inherently increases the value that patients experience. Additionally, by ensuring that MRI capacity can be flexibly utilized across a number of rural environments, particularly those that are less accessible, providers can utilize existing MRI capacity more effectively and efficiently. The proposed petition grants providers the option to optimize capacity and increase value.

As a final consideration, ARHS notes that questions raised during the SHCC public hearing on March 1, 2023 were largely supportive of ARHS's desire to convert its approved fixed scanner to a mobile scanner. One question in particular asked whether a special need petition filed in the summer would be more suited to this issue. While ARHS is not opposed to a special need adjustment, it notes that it would not be asking for a special need determination for an additional MRI scanner; rather, it would be requesting permission to file a CON application to convert a fixed scanner to a mobile scanner. Moreover, the current need methodology allocates fixed scanners largely to single county service areas, while a mobile scanner by nature can serve multiple counties; historically, petitions to address more than a single service area have been considered in the spring cycle. Given the SHCC's creation of Policy TE-1, noted above, ARHS believes that development of a similar policy for MRI providers is a prudent approach. However, if the SHCC believes that a summer petition is more appropriate, ARHS respectfully requests that the SHCC affirms that it would be amenable to a special need petition for this issue that, by its nature, must include multiple service areas.

ARHS appreciates your consideration of this petition. Please let us know if we can assist the Council, its committees, and the staff during the process.

Thank you.