



APPALACHIAN REGIONAL HEALTHCARE SYSTEM

Petition for a Special Need Adjustment For the Conversion of an Approved or Existing Fixed MRI Scanner to a Mobile MRI Scanner

PETITIONER

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STATEMENT OF THE REQUESTED ADJUSTMENT

Appalachian Regional Healthcare System (ARHS) respectfully petitions the State Health Coordinating Council (SHCC) to create a special need adjustment for the conversion of an approved or existing fixed MRI scanner in Watauga County to a mobile MRI scanner to improve geographic access and effectively serve the same population as served by fixed MRI scanner.

BACKGROUND

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. Across its 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 also has 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

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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.

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.

REASONS FOR THE REQUESTED ADJUSTMENT

SMFP Constraints

The options for acquiring a mobile MRI scanner in the state of North Carolina are limited. As stated in the *Proposed 2024 SMFP*, “the SMFP does not have a methodology to project need for additional mobile MRI scanners. A summer petition is required to place a need in the upcoming SMFP.”¹ Further, there are currently no policies, as listed in Chapter 4 of the *Proposed 2024 SMFP*, that are relevant to the acquisition of a mobile MRI scanner by any qualifying or appropriate health service facility.

In light of the above, 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 scanner or attempt to create a mobile MRI service through a special need determination for a mobile MRI 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. 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*.² 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.

ARHS, recognizing this gap, proposed a solution in March 2022 through its submission of a petition to the SHCC to include a new policy, Policy TE-4, that would, in short, allow providers who had 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. While the Agency denied this petition, it did, in its recommendation, note that “the summer petition process presents an opportunity [for ARHS] to request an adjusted need determination for a mobile MRI scanner.”³

Absent a policy or need determination in the *SMFP* for a mobile MRI scanner there is no regulatory mechanism to convert ARHS’ approved but not yet developed fixed MRI in Watauga County to a mobile MRI. Any material change in scope to a previously approved CON application—such as would be the

¹ *Proposed 2024 SMFP*, p. 339.

² A need determination for three mobile MRI scanners statewide was added to the *2023 SMFP* following an adjusted need determination. See the *2023 SMFP*, p. 359.

³ Technology and Equipment Committee Agency Report: Create Policy TE-4: Conversion of Fixed MRI Scanners to Mobile MRI Scanners, p. 5.

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circumstance with the conversion ARHS is seeking—requires subsequent CON approval of a CON change in scope application. However, in order to submit a change in scope CON application involving the conversion of a fixed MRI to a mobile MRI there must first be a need determination in the *SMFP* under which to submit such an application.

Unique Geography, Demographics and Care Needs

While ARHS’s Spring 2023 petition was indeed a petition for a policy addition, this petition was influenced by ARHS’s own experience as a rural provider, as well as its current situation as a provider of fixed MRI services. In April 2020, ARMA applied, and was approved for, one fixed MRI scanner pursuant to a need determination in Watauga County as identified in the *2020 SMFP* (Project ID # D-011899-20). The fixed MRI scanner was approved for development in an existing medical office building (MOB), AppMedical Services, located less than a half mile from WMC, the location of the only other fixed MRI scanner in Watauga County.

However, the communities that ARHS serve are unique in their care needs, geographic challenges to quality care, and demographic profile. Watauga County is in a 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; three of these seven counties – Watauga, Avery, and Ashe counties – represent 80 percent of WMC’s MRI patient origin, while six of the seven counties – the three above, in addition to Wilkes, Alleghany, and Mitchell counties – are in the top ten counties or locations from which WMC receives MRI patients, as noted in its 2022 LRA volume, replicated below.

Total Patient Origin for WMC MRI Patients by County

NC County/State of Origin	Percent of Total Patients
Watauga	40.8%
Avery	22.1%
Ashe	17.1%
Tennessee	4.2%
Wilkes	3.7%
Other States	2.3%
Caldwell	1.9%
Alleghany	0.8%
Mecklenburg	0.6%
Mitchell	0.6%
Burke	0.5%
Other	5.2%
Total	100.0%

Source: 2022 Watauga Medical Center, Inc. LRA.

In addition, the 2022 Patient Origin reports published by DHSR show that, in 2021, 880 Avery County residents and 692 Ashe County residents received MRI services in Watauga County, while only 642 Ashe County residents received MRI services in their county of origin. In other words, there is a high degree of

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out-migration amongst High Country counties, representing a need for services located beyond Watauga County when volume is sufficient to support alternative locations.

The High Country is also geographically unique, first and foremost because its overall elevation above sea level is striking. Boone, the county seat of Watauga County and the location of WMC, lies at an elevation of just over 3,300 feet. Newland, the county seat of Avery County and the highest county seat in the eastern United States, is 3,606 feet above sea level. In contrast, the elevation of Raleigh, Wake County’s seat, is just 315 feet above sea level, while Charlotte, Mecklenburg County’s seat, is 761 feet above sea level.

This elevation is not only a geographic contrast to the rest of the state, but also results 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 200,000⁴ residents of the High Country to seek healthcare, especially during the more treacherous winter months.

Making access to care even more difficult for High Country residents is the fact that many of them are elderly, with that cohort only projected to increase. According to the NC OSBM, over a quarter of the population of Ashe and Avery counties is projected to be over the age of 65 by the year 2028. Additionally, nearly a fifth of the population of Watauga County is projected to be over the age of 65 by the same year. Of note, all three counties are projected to have a higher percentage of their population over the age of 65 than the State of North Carolina overall.

**Ashe, Avery, and Watauga Counties
Percentage of Population Age 65 and Older (2028)**

County	% of Population Age 65 and Older (2028)
Ashe	28.6%
Avery	25.0%
Watauga	19.6%
North Carolina	19.4%

Source: NC OSBM.

As mentioned above, the approval of ARMA’s April 2020 CON allowed it to develop a fixed MRI scanner at its MOB at AppMedical Services in Watauga County. However, as also mentioned above, this MOB is less than a mile away from the county’s only other existing fixed MRI scanner. This fixed MRI scanner, while approved, has not been developed yet and has not yet served any patients. While ARHS believes that Watauga County and the patients in the surrounding service area still have a need for the previously approved additional MRI capacity, it believes that more cost-effective and accessible MRI services can be provided to the unique patient population of both Watauga County and the North Carolina High Country

⁴ Combined 2021 populations of Alleghany, Ashe, Avery, Mitchell, Watauga, Wilkes, and Yancey counties as listed in 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>.

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by developing a mobile MRI scanner instead of the fixed MRI scanner approved through Project ID # D-011899-20.

Of note, ARHS does not – and would not, provided its petition were to be approved – suggest that a converted mobile MRI scanner would serve a new or alternate patient population than that of its fixed MRI scanner approved for AppMedical Services. In its application for that fixed MRI scanner, ARHS proposed the following projected patient population for that fixed MRI scanner:

3. Projected Patient Origin

- (a) For each service component, provide the number of patients by county of residence or other geographic area projected to utilize that service component at the facility identified in Section A, Question 5 during the first three full fiscal years by completing the table below.

Projected Patient Origin for MRI Services – AppMedical Services

County or other geographic area such as ZIP code	1 st Full FY 10/01/2024 to 09/30/2025		2 nd Full FY 10/01/2025 to 09/30/2026		3 rd Full FY 10/01/2026 to 09/30/2027	
	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients	% of Total
Watauga	1,165	42.0%	1,372	40.0%	1,391	40.0%
Avery	560	20.2%	716	20.9%	726	20.9%
Ashe	522	18.8%	667	19.5%	676	19.5%
Wilkes	99	3.6%	127	3.7%	129	3.7%
Other*	428	15.4%	548	16.0%	555	16.0%
Total	2,775	100.0%	3,431	100.0%	3,477	100.0%

*Other includes Alamance, Alexander, Alleghany, Brunswick, Buncombe, Burke, Cabarrus, Caldwell, Carteret, Catawba, Clay, Cleveland, Columbus, Craven, Cumberland, Davison, Durham, Forsyth, Gaston, Guilford, Haywood, Henderson, Iredell, Jackson, Lee, Lenoir, Madison, McDowell, Mecklenburg, Mitchell, Moore, Nash, New Hanover, Onslow, Pender, Pitt, Randolph, Richmond, Rockingham, Rowan, Rutherford, Stanly, Stokes, Transylvania, Tyrrell, Union, Wake, Yadkin, and Yancey counties in North Carolina, as well as other states.

Source: Project ID # D-011899-20, p. 28.

This projected patient origin is very similar to the “Total Patient Origin for WMC MRI Patients by County” table presented on page 3 of this petition used to describe the service area affected by this petition; given that the Agency approved ARMA’s proposed project with these projected patient origin values, it follows that a mobile MRI scanner purporting to serve the same counties also would be likely to be approved for a similar patient origin.

Further, this mobile MRI scanner would not compete with or duplicate the statewide need determination for three mobile MRI scanners as allocated in the 2023 SMFP, nor would it duplicate MRI services currently available in Watauga County. While the Agency’s decision regarding mobile MRI CON approval is still pending at the time of this petition’s submission, it should be noted that, of the ten applications submitted for the 2023 SMFP need determination, only one identified a host site located in Ashe, Avery, or Watauga counties, which, again, comprise over 80 percent of ARHS’s approved fixed MRI scanner’s projected patient population, shown in the table above.⁵ Assuming that one application were approved, it would not serve the need proposed to be served by this population.

⁵ Project ID # G-012373-23, submitted by Novant Health-Norfolk, lists one of its proposed host sites as located in Avery County. See p. 32 of that application.

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ARHS believes that the proposed change as requested in this petition is the most appropriate method for effectuating the change needed, that of allowing a provider with an existing or approved fixed MRI scanner in Watauga County the opportunity to convert that scanner to a mobile MRI scanner to improve geographic access for its patient population. As proposed, the petition does not seek any additional MRI capacity, simply the path for conversion to mobile MRI that is not otherwise available at present.

Adverse Effects on Patients If the Petition Is Not Approved

For rural patients, and especially patients in challenging geographies like the North Carolina High Country, a lack of mobile MRI services would limit access to necessary imaging services. In fact, these imaging services are currently challenging to access due to the geographic and demographic factors listed above. Patients may have to travel in inclement and taxing conditions to Boone for imaging services that, if mobile MRI services were available, could potentially be provided to them nearer to their homes. Additionally, the rural providers of the North Carolina High Country – would be able to more easily provide care to patients by moving an MRI scanner through Watauga and surrounding counties based on demographic need and patient demand. As such, patients would find MRI services more accessible via provider flexibility, as well.

Alternatives Considered

Continue Developing Fixed MRI Scanner at AppMedical Services in Watauga County

ARHS could develop its freestanding fixed MRI scanner at AppMedical Services, approved pursuant to Project ID # D-011899-20. However, given the unique geography of the proposed service area, maintaining this status quo limits access for the patients of the North Carolina High Country, as discussed above. First, it restricts ARHS to serving patients with this approved MRI at one location. The proposed petition, however, would enable ARHS to serve patients across multiple potential locations in the High Country through mobile MRI services. This is necessary, as a large portion of ARHS's current patient base is from multiple High Country counties, such as Ashe and Avery counties, as detailed above. A mobile MRI scanner would therefore provide a much more accessible alternative to patients than a fixed MRI scanner, making it a more viable option from an accessibility standpoint. Additionally, and as will be discussed further below, mobile MRI scanners are also more cost-effective to both develop and maintain, thereby making a mobile MRI scanner a less costly option that simply continuing to develop the already-approved fixed MRI scanner.

Request an Adjusted Need Determination for a Mobile MRI Scanner

ARHS considered requesting a special need determination for one mobile MRI to serve at least Ashe, Avery and Watauga counties– three counties in the North Carolina High Country that are in particular need of mobile MRI services. However, in consideration of the current inventory of fixed MRIs for Watauga County, inclusive of the approved but not yet developed fixed MRI for which ARHS holds a CON, this alternative could create excess MRI inventory in the High Country, which is not ARHS's intent. Additionally, depending ultimately on which CON applicant were to be approved, such an adjusted need determination could also potentially create excess inventory for mobile MRIs, given the SHCC's approval just last year of an adjusted need determination for three mobile MRI scanners for inclusion in the 2023 SMFP. Therefore, to avoid the

potential duplication of MRI inventory, a conversion petition was found to be the most feasible and regulatory conforming alternative.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

If the proposed special need adjustment were to be approved, it would not result in unnecessary duplication. Given that ARHS has already been approved to develop one fixed MRI scanner in Watauga County, the special need adjustment would not add any MRI capacity to the service area, which would still be served by one fixed MRI scanner at WMC in Watauga County and the newly converted mobile MRI scanner, following the special need adjustment. Rather, the proposal would expand geographic access to MRI services and allow for greater accessibility for patients who ARHS already proposed to serve through Project ID # D-011899-20, as detailed above. As such, no new services or duplication of services would be incorporated into the service area.

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 special need adjustment will improve the quality of care that ARHS or the potential provider of mobile MRI services will be able to provide for their patients by allowing them the flexibility to distribute needed MRI capacity throughout a large, geographically challenged service area, rather than force patients to travel to a single fixed location for services. The improved convenience of mobile 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 adjusted need determination will grant existing fixed MRI providers in the service area additional flexibility to deliver essential MRI services to patients in a way that is appropriate for patient demand of the greater High Country service area, thereby emphasizing safety, resulting in care of the utmost quality.

Access

The proposed special need adjustment will greatly increase access to MRI services for reasons largely already stated above. For rural providers across the state like ARHS, flexibility is essential, as factors outside of their control necessitate adapting services to increase patient access. Given that fixed and mobile MRI scanners are largely the same in terms of the technology itself, the proposed adjusted need determination would simply allow for more flexibility and geographic access to MRI services for both its providers and for patients of the service area, thereby improving the overall quality and speed of access of care provided.

Value

Approval of the petition also promotes value. By allowing patients to more easily seek MRI services closer to home, the proposed adjusted need determination, in increasing access in the manner detailed above, inherently increases the value that patients experience. Additionally, by ensuring that MRI capacity can be flexibly utilized across multiple rural environments, particularly those that are less accessible, potential providers in the proposed service area can utilize existing MRI capacity more effectively and efficiently. There are also potential cost-saving benefits to owning and operating a mobile MRI scanner versus a fixed MRI scanner for certain settings, given the often relatively-lower start-up costs associated with developing mobile MRI services.⁶ As such, the proposed petition grants a provider of mobile MRI services the option to optimize capacity and increase value.

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.

⁶ As noted in <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7145907/>.