

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 31, 2020

Findings Date: July 31, 2020

Project Analyst: Ena Lightbourne

Team Leader: Lisa Pittman

Project ID #: D-11899-20

Facility: AppMedical Services

FID #: 200292

County: Watauga

Applicant(s): Appalachian Regional Medical Associates, Inc.

Project: Acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Appalachian Regional Medical Associates, Inc., referred to hereinafter as “applicant” or “ARMA” proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located in Watauga County. The name of the proposed facility is AppMedical Services. Appalachian Regional Healthcare System, Inc. (ARHS) is the parent company to ARMA.

#### **Need Determination**

The 2020 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional magnetic resonance imaging (MRI) scanners in North Carolina by service area. Application of the need methodology in the 2020 SMFP identified a need for one

additional fixed MRI scanner in Watauga County service area. Therefore, the applicant's proposal is consistent with the need determination in the 2020 SMFP.

### **Policies**

There are two policies in the 2020 SMFP applicable to this review: *Policy GEN-3: Basic Principles*, and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

*Policy GEN-3* on pages 30-31 of the 2020 SMFP states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 20-21; Section N.2, pages 78-79; Section O, pages 81-83, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal would promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project would promote equitable access in Section B, pages 21-22; Section C.11, page 37; Section L, pages 73-75; Sections N.2. page 79, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal would promote equitable access.

### **Maximize Healthcare Value**

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, page 22; Section F, pages 54-59; Section K, page 69-70; Section N.2, page 77; Section Q; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal would maximize healthcare value.

In Section B, pages 20-22, the applicant explains why it believes its application is conforming to *Policy GEN-3*. On pages 20-22, the applicant states:

*“ARHS’s commitment to proving quality care is further demonstrated by its system-wide Quality Management, Imaging Department Quality Management and Improvement, Risk Management, and Organization Integrity Plans...*

...

*The proposed project will improve access to fixed MRI services in the service area and will serve as the first and only freestanding fixed MRI scanner option in Watauga County. ARMA and ARHS have long-promoted economic access to their services as ARMA and ARHS historically have provided services to all persons in need of medical care, regardless of race, color, national origin, age, disability, or sex...*

...

*The proposed application is indicative of ARMA and ARHS’s commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended. The proposed project represents a low-cost alternative for the provision of MRI services.”*

Policy GEN-4 on page 31 of the 2020 SMFP states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 22, the applicant explains why it believes its application is consistent with Policy GEN-4. On page 22 the applicant states:

*“Given that the project includes renovation to existing space rather than new construction, the ability to improve energy efficiencies and conservation of resources such as water rests largely in the efficiencies present in the existing facility. However, the proposed renovation will consist of reusing as much of the existing utilities serving the area to limit the amount of waste for the project. Furthermore, the renovations will meet or exceed the North Carolina building code for energy efficiencies and water conservation. Finally, as with all of ARHS’s services, engineering management constantly seeks ways to improve and conserve energy and more efficiently utilize existing resources. This project will be no different.”*

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more fixed MRI scanners than are determined to be needed in Watauga County.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 because the proposal promotes safety and quality, equitable access and maximizes healthcare value.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 as stated above.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

### C

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located in Watauga County.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as *the same as an Acute Care Bed service area*. Thus, the service area for this facility consists of Watauga County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 27, the applicant states that the proposed facility is not an existing facility and has no historical patient origin. The following table illustrates projected patient origin for the first three full years of operation.

<b>AppMedical Services</b>						
<b>County</b>	<b>1<sup>st</sup> FFY 10/1/2024-9/30/2025 (FFY 2025)</b>		<b>2<sup>nd</sup> FFY 10/1/2025-9/30/2026 (FFY 2026)</b>		<b>3<sup>rd</sup> FFY 10/1/2026-9/30/2027 (FFY 2027)</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
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%
<b>Total</b>	<b>2,775</b>	<b>100.0%</b>	<b>3,431</b>	<b>100.0%</b>	<b>3,477</b>	<b>100.0%</b>

Source: Section C, page 28

\*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.

In Section C, page 28, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- Consistent with its utilization assumptions for the Watauga Medical Center (WMC) and the proposed facility.
- Non-Watauga County MRI patients will be comprised of MRI patients from counties historically served by WMC.

**Analysis of Need**

In Section C, pages 29-34, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 29, the applicant states that the services are needed based on the following factors:

**2020 State Medical Facilities Plan Need Determination (pages 29-30)**

The 2020 SMFP has determined a need for one fixed MRI scanner in Watauga County. The applicant states that the utilization of the only fixed MRI scanner in Watauga County has driven the need determination. According to the 2020 SMFP, the existing MRI scanner located at WMC provided 3,936 adjusted MRI scans in FY 2018, exceeding the adjusted threshold for one scanner.

2020 SMFP Planning Threshold for MRI Scanner		
Service Area fixed Scanners	Inpatient and Contrast Adjusted Thresholds	Planning Threshold
4 and over	4,805	70.0%
3	4,462	65.0%
2	4,118	60.0%
1	3,775	55.0%
0	1,716	25.00%

Source: Section C, page 30

Need for a Freestanding Fixed MRI Scanner in Watauga County (pages 30-34)

The only existing fixed MRI scanner in Watauga County is located at WMC, an acute care hospital. The applicant states that a freestanding fixed MRI scanner is needed in Watauga County for the following reasons:

- Significant growth in utilization of the existing MRI scanner in Watauga County

The applicant states that the existing scanner experienced a 17.9 percent increase in utilization from 2017 to 2019. Outpatient scans had the highest percentage of growth during the same period of time. The applicant states that the proposed project will meet the growing demand for outpatient scans by accessing a freestanding MRI facility.

- Provide a high-quality, low-cost, and convenient MRI service option for patients in the region

The applicant states that for outpatients who do not require a hospital-based setting for MRI services, a freestanding facility eliminates hospital-based expenses resulting in lower charges and an increase in affordability of services.

- Eliminate the need for patients to travel outside of the county to access freestanding MRI services

The applicant states that the nearest freestanding fixed MRI scanner is located approximately three hours from Watauga County. The proposed project will eliminate the need to travel a far distance in order to access a freestanding MRI facility by creating local access at a convenient location in Watauga County.

- Provide additional fixed MRI capacity to support ongoing program development within ARHS.

The applicant states that in 2019, ARHS, the parent company of ARMA, developed a breast MRI program to enhance women services. In addition, ARHS has received interest from local oncologists and cardiologists in performing prostate and rectal MRI scans and conducting cardiac MRI studies. The applicant states that the proposed project will provide additional capacity and the capability to ensure access for these scan types as demand continues to increase.

Growth of Watauga County (pages 33-34)

In Exhibits C.4-1 and C.4-2, the applicant provides data from the North Carolina Office of State Budget and Management (NCOSBM) to illustrate the historical and projected population growth in Watauga County. The county experienced a 15.2 percent growth in population from 2010 to 2020. In addition, Watauga County’s population is projected to have the second highest population growth in HSA 1 from 2020 to 2025 in that Health Service Area. The applicant states that the population growth in Watauga County supports the need for additional MRI capacity.

The information is reasonable and adequately supported based on the following:

- There is a need for one fixed MRI scanner in Watauga County, as stated in the 2020 SMFP.
- The applicant adequately demonstrates the need for a freestanding fixed MRI scanner in addition to the existing hospital-based fixed MRI scanner.
- The applicant relies on growth trends and historical utilization to support the need.

*Projected Utilization*

In Section Q, Form C, the applicant provides historical and projected utilization, as illustrated in the following table. The applicant presented its projections for the first three years of the project as FY 2025 (10/01/2024-9/30/2025), FY 2026 (10/01/2025-9/30/2026), and FY 2027 (10/01/2026-9/30/2027).

<b>Projected Utilization of Proposed Fixed MRI Scanner</b>				
	<b>Interim 1/1/2024- 9/3/2024</b>	<b>1<sup>st</sup> FY FY 2025</b>	<b>2<sup>nd</sup> FY FY 2026</b>	<b>3<sup>rd</sup> FY FY 2027</b>
# of Units	1	1	1	1
# of Procedures	2,307	3,033	3,751	3,801
# of Weighted Procedures	2,394	3,147	3,892	3,945

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

*Step 1: Identify the Reasons for Watauga County’s Low MRI Use Rate*

In Section Q, Form C, pages 1-2, the applicant begins its projections by identifying the reasons for Watauga County’s low MRI use rate. MRI use rate is the utilization percentage per 1,000 population. The applicant states that although the only fixed MRI scanner in Watauga County is well utilized, Watauga County has a low MRI use rate. The applicant states that Watauga County’s geographical location contributes to access issues. In addition, Watauga County has a significant number of college-age residents due to the presence of the university. The applicant states that these factors make Watauga County unique compared to other counties in the western mountains of North Carolina.

*Step 2: Identify Counties Comparable to Watauga County*

To project utilization, the applicant identified counties that were similar to Watauga County’s unique situation. The applicant determined that there are four counties that are comparable to Watauga County based on the median age of the county, as illustrated in the table below.

<b>Five North Carolina Counties with Lowest Median Age</b>		
<b>County</b>	<b>FFY 2020 Median Age</b>	<b>FFY 2020 North Carolina County Median Age Rank</b>
Onslow	25.7	100
Watauga	29.7	99
Pitt	32.7	98
Cumberland	32.8	97
Hoke	33.7	96
North Carolina	39.2	

Source: Section Q, Form C, page 2

However, Onslow, Pitt, and Cumberland counties are comparable to Watauga County, upon completion of the proposed project, based on its access to hospital-based and freestanding fixed MRI capacity.

*Step 3: Project MRI Use Rate in Watauga County Based on MRI Use Rate of Comparable Counties*

The table below illustrates the comparison of 2018 MRI use rates of Watauga County and the three comparable counties. The applicant reasonably assumes that the MRI use rate will increase upon completion of the project. The applicant conservatively projects that Watauga County MRI use rate will increase gradually to be equivalent to Onslow County’s 2018 MRI use rate, which is the second lowest of the four counties. In addition, Onslow County has the lowest median age of the four counties and has existing hospital-based and freestanding MRI capacity.

<b>County</b>	<b>FFY 2018 MRI Patients</b>	<b>FFY 2018 Population</b>	<b>FFY 2018 MRI Use Rate per 1,000 Population</b>
Cumberland	25,329	331,764	76.3
Pitt	10,519	178,440	58.9
Onslow	11,370	198,740	57.2
Watauga	2,415	57,067	42.3
North Carolina	733,727	10,389,148	70.6

Source: Section Q, Form C, page 2

*Step 4: Project Total Watauga County MRI Patients*

Based on data from NCOSBM, Watauga County’s population is projected to grow at a Compound Annual Growth Rate (CAGR) of 1.4 percent between 2019 and 2027.



Year	Population
FFY 2019	57,899
FFY 2020	58,731
FFY 2021	59,561
FFY 2022	60,393
FFY 2023	61,223
FFY 2024	62,053
FFY 2025	62,886
FFY 2026	63,716
FFY 2027	64,547
<b>2019-2027 CAGR</b>	<b>1.4%</b>

Source: Section Q, Form C, page 3

To project the total Watauga County MRI patients, the applicant applied its projections that Watauga County’s MRI use rate will increase gradually to be equivalent to Onslow County’s 2018 MRI use rate to the projected growth in Watauga County’s population. The applicant projects that Watauga County’s MRI use rate will reach 100% of Onslow County’s 2018 MRI use rate by FFY 2027, as illustrated in the table below.

Watauga County Projected MRI Patients				
	FFY 2024	FFY 2025	FFY 2026	FFY 2027
Projected Population	62,053	62,886	63,716	64,547
Projected MRI Use Rate	42.9	51.5	57.2	57.2
% of Onslow County’s 2018 MRI Use Rate	75.0	90.0	100.00	100.0
<b>Total Watauga MRI Patients</b>	<b>2,663</b>	<b>3,238</b>	<b>3,645</b>	<b>3,693</b>

Source: Section Q, Form C, page 3

*Step 5: Project the Percentage of Watauga County MRI Patients Receiving MRI Scans in the County*

The applicant assumes that by expanding access to an additional MRI scanner, the number of MRI scans performed on Watauga County residents in their home county on the proposed MRI scanner and the existing MRI scanner located WMC will increase. The applicant projects that this increase will be equivalent to Onslow County’s percentage of in-county patients receiving MRI scans in Onslow County in 2018. The applicant states that based on data from DHSR database, 68 percent of Onslow County MRI patients were scanned in Onslow County. The applicant projects that Watauga County’s in-county percentage will reach 68 percent by the third year of operation, FFY 2027. The applicant states that its projections are reasonable based on the comparable factors previously stated and the fact that Onslow County is not geographically isolated like Watauga County.

<b>Percentage of Watauga County MRI Patients Receiving MRI Scans in the County</b>				
	<b>FFY 2024</b>	<b>FFY 2025</b>	<b>FFY 2026</b>	<b>FFY 2027</b>
Watauga County MRI Patients	2,663	3,238	3,645	3,693
Watauga County MRI Patients Receiving MRI Scans in the County	63%	65%	68%	68%
# of Watauga County MRI Patients Served at ARHS (ARMA and WMC Combined)	1,677	2,105	2,479	2,512

Source: Section Q, Form C, page 4

*Step 6: Project the Percentage of Non-Watauga County MRI Patients Receiving MRI Scans in Watauga County*

Based on the most recent Licensed Renewal Application submitted to the Agency, 55.3 percent of MRI patients served by WMC were non-Watauga County residents. The applicant states that this is due to Watauga County geographical location and the limited amount of acute care providers. The applicant assumes that with the addition of the first and only freestanding MRI scanner, the percentage of non-Watauga County residents served by WMC and the proposed facility will increase gradually over the first three years of operation, as show in the table below.

<b>ARMA and WMC Projected MRI Patients</b>				
	<b>FFY 2024</b>	<b>FFY 2025</b>	<b>FFY 2026</b>	<b>FFY 2027</b>
# of Watauga County MRI Patients	1,677	2,105	2,479	2,512
% of Non-Watauga County MRI Patients*	56%	58%	60%	60%
# of Non-Watauga County MRI Patients^	2,135	2,906	3,718	3,768
<b>Total ARMA and WMC MRI Patients</b>	<b>3,812</b>	<b>5,011</b>	<b>6,197</b>	<b>6,280</b>

Source: Section Q, Form C, page 5

\*Percent of Non-Watauga County MRI Patients = (Number of Watauga County MRI Patients / (1- Percent of Non-Watauga County MRI patients)) – Number of Watauga County MRI Patients.

^Total ARMA/WMC Patients = Number of Watauga County MRI Patients + Number of Non-Watauga County MRI Patients.

*Step 7: Project the total MRI scans (Weighted and Unweighted)*

According to the 2020 LRA, WMC performed 1.09 MRI scans per MRI patient. The applicant assumes that the projected performance at ARMA will be consistent with the historical ratio at WMC.

<b>ARMA and WMC Projected MRI Scans</b>				
	<b>FFY 2024</b>	<b>FFY 2025</b>	<b>FFY 2026</b>	<b>FFY 2027</b>
Total ARMA and WMC MRI Patients	3,812	5,011	6,197	6,280
MRI Scan to MRI Patient Ratio	1.09	1.09	1.09	1.09
<b>Total MRI Scans</b>	<b>4,167</b>	<b>5,478</b>	<b>6,774</b>	<b>6,866</b>

Source: Section Q, Form C, page 5

According to the 2020 LRA, WMC performed 1.15 Weighted MRI scans per MRI scan. The applicant assumes that the projected performance at ARMA and will be consistent with the historical ratio at WMC.

<b>ARMA and WMC Projected Weighted MRI Scans</b>				
	<b>FFY 2024</b>	<b>FFY 2025</b>	<b>FFY 2026</b>	<b>FFY 2027</b>
Total MRI Scans	4,167	5,478	6,774	6,866
Weighted MRI Scan to MRI Scan Ratio	1.15	1.15	1.15	1.15
<b>Total Weighted MRI Scans</b>	<b>4,789</b>	<b>6,295</b>	<b>7,784</b>	<b>7,889</b>

Source: Section Q, Form C, page 6

The applicant states that ARMA and WMC will work to ensure consistent utilization of available capacity so that one unit is not overutilized while the other is underutilized. Therefore, the applicant assumes an equivalent amount of weighted scans will be performed on the proposed freestanding fixed MRI and the existing fixed MRI scanner located at WMC.

<b>ARMA and WMC Projected Weighted MRI Scans</b>				
	<b>FFY 2024</b>	<b>FFY 2025</b>	<b>FFY 2026</b>	<b>FFY 2027</b>
ARMA Weighted MRI scans	2,394	3,147	3,892	3,945
WMC Weighted MRI scans	2,394	3,147	3,892	3,945
<b>Total Weighted MRI Scans</b>	<b>4,789</b>	<b>6,295</b>	<b>7,784</b>	<b>7,889</b>

Source: Section Q, Form C, page 6

The applicant analyzed historical experience at Coastal Imaging, a freestanding facility in Onslow County, to project the number of unweighted MRI scans by scan type at ARMA. The 2020 SMFP states that Coastal Imaging’s ratio of weighted to unweighted MRI scans in 2019 was 1.04 (1.04 = 5,625 weighted MRI scans / 5,420 MRI unweighted MRI scans). The applicant projects that the proposed facility’s ratio will be consistent with Coastal Imaging. The applicant states that this is a reasonable assumption since Onslow County is located in a county determined to be comparable to Watauga County, as previously stated, and has hospital-based and freestanding MRI capacity. The following table illustrates the total number of MRI scans.

<b>ARMA Projected MRI Scans</b>				
	<b>FFY 2024</b>	<b>FFY 2025</b>	<b>FFY 2026</b>	<b>FFY 2027</b>
Total Weighted MRI scans	2,394	3,147	3,892	3,945
Ratio of Weighted to Unweighted MRI scans	1.04	1.04	1.04	1.04
<b>Total Number of MRI Scans*</b>	<b>2,307</b>	<b>3,033</b>	<b>3,751</b>	<b>3,801</b>

Source: Section Q, Form C, page 7

\*Total Weighted Scans / Ratio of Weighted to Unweighted scans

*Step 8: Project the number of patients to be served at the proposed facility*

To project the number of patients to be served at the proposed facility, the applicant assumes that the ratio of MRI scans to MRI patients will be equivalent to 1.09, WMC’s 2019 ratio. The applicant projects that 3,477 patients will be served at the proposed facility by the third year of operation, as shown in the table below.

<b>ARMA Projected MRI Patients</b>				
	<b>FFY 2024</b>	<b>FFY 2025</b>	<b>FFY 2026</b>	<b>FFY 2027</b>
Total MRI scans	2,307	3,033	3,751	3,801
MRI scans to MRI Patient Ratio	1.09	1.09	1.09	1.09
<b>Total MRI Patients*</b>	<b>2,111</b>	<b>2,775</b>	<b>3,431</b>	<b>3,477</b>

Source: Section Q, Form C, page 8

\*Total MRI Patients = Total MRI Scans / MRI Scan to MRI Patient Ratio

Projected utilization is reasonable and adequately supported based on the following:

- There is a need determination in the 2020 SMFP for a fixed MRI scanner in the Watauga County MRI service area and this project will meet that need determination by developing a fixed MRI scanner in Watauga County.
- The applicant's utilization projections are supported by the historical utilization of MRI scanners owned by the applicant and MRI scanners located in comparable counties.
- The applicant provided adequate support for the increase in incremental projections.
- The applicant provided adequate support for the projected population growth in Watauga County.
- The application meets the Performance Standards in 10A NCAC 14C 2700.

### Access

In Section C, page 39, the applicant states:

*“ARHS is a tax-exempt, not-for-profit organization established to serve the High Country of North Carolina by providing high quality, affordable, and comprehensive care to all patients, regardless of their economic status. ARMA and ARHS do not discriminate against low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent, the uninsured, and the underinsured.*

...

*As a facility operated by ARMA, AppMedical Services will follow similar guidelines and as such, AppMedical Services also will not discriminate against low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or any other underserved groups.”*

In Section L, page 74, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>Payor Source</b>	<b>MRI Services as Percent of Total</b>
Self-Pay	3.0%
Medicare*	53.0%
Medicaid*	7.0%
Insurance*	34.0%
Worker's Compensation	1.0%
TRICARE	2.0%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on current actual payor mix of MRI patients at WMC and the applicant does not expect payor mix for the proposed MRI services to change.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

The applicant proposes to acquire a fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located in Watauga County.

In Section E, pages 52-53, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

**Maintain the Status Quo**-The applicant states that this would not be an effective alternative because Watauga County would continue to demonstrate a need for an addition fixed MRI scanner, as stated in the 2020 SMFP. The applicant states that as demand increases, patients will begin leaving the county to access MRI services.

**Develop a Hospital-Based MRI**-The applicant states that this alternative was not cost effective due to the cost required to develop a hospital-based MRI. In addition, a hospital-based MRI would not address the growing demand or reduce the number of patients leaving the county to access MRI services at a freestanding facility.

**Develop Freestanding MRI at Another Location**-The applicant rejected this alternative because the site proposed in the application is less the one-half mile from the only acute care hospital in Watauga County. The applicant states that the proposed site is also in close proximity to locations that have historically referred a significant number of MRI scans to ARHS facilities.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The application is conforming to all statutory and regulatory review criteria.
- There is a need determination in the 2020 SMFP for the proposed fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is need Watauga County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Appalachian Regional Medical Associates, Inc. shall materially comply with all representations made in the certificate of need application.**

2. **Appalachian Regional Medical Associates, Inc. shall acquire a fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center.**
  3. **Appalachian Regional Medical Associates, Inc. shall acquire no more than one fixed MRI scanner for a total of no more than one MRI scanner to be locate at AppMedical Services.**
  4. **Appalachian Regional Medical Associates, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
  5. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, Appalachian Regional Medical Associates, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. **Payor mix for the services authorized in this certificate of need.**
    - b. **Utilization of the services authorized in this certificate of need.**
    - c. **Revenues and operating costs for the services authorized in this certificate of need.**
    - d. **Average gross revenue per unit of service.**
    - e. **Average net revenue per unit of service.**
    - f. **Average operating cost per unit of service.**
  6. **Appalachian Regional Medical Associates, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire a fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located in Watauga County.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

<b>AppMedical Services Capital Costs</b>	
Construction/Renovation Contract(s)	\$759,222
Landscaping	\$1,000
Architect/Engineering Fees	\$75,000
Medical Equipment	\$2,423,727
Non-Medical Equipment	\$10,000
Furniture	\$8,000
<b>Total</b>	<b>\$3,276,949</b>

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 56, the applicant projects that start-up costs will be \$13,441 and initial operating expenses will be \$20,161 for a total working capital of \$33,602. On page 56, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

**Availability of Funds**

In Section F, page 54, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Sources of Capital Cost Financing</b>		
Type	ARMA	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$ 3,276,949	\$3,276,949
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$0</b>	<b>\$0</b>

\* OE = Owner's Equity

In Section F, page 57, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

<b>Sources of Financing for Working Capital</b>		<b>Amount</b>
(a)	Loans	\$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$33,602
(c)	Lines of credit	\$0
(d)	Bonds	\$0
(e)	<b>Total</b>	<b>\$33,602</b>

Exhibit F-2.1 contains letters from the Chief Financial Officer and the Chief Executive Officer for ARHS, dated April 15, 2020, committing to funding the capital cost of the proposed project. Exhibit F-2.2 contains financial statement for ARHS for the years ending December 31, 2019 and 2018. As of December 31, 2019, ARHS had \$28,017,682 in cash and cash equivalents and \$227,318,184 in net assets to fund the proposed project.



### **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

<b>AppMedical Services</b>	<b>1<sup>st</sup> FFY FY 2025</b>	<b>2<sup>ND</sup> FFY FY 2026</b>	<b>3<sup>RD</sup> FFY FY 2027</b>
Total MRI Procedures	3,033	3,751	3,801
Total Gross Revenues (Charges)	\$2,365,594	\$2,925,599	\$2,964,597
Total Net Revenue	\$891,417	\$1,102,345	\$1,117,343
Average Net Revenue per Procedure	\$293.91	\$293.88	\$293.96
Total Operating Expenses (Costs)	\$830,073	\$866,688	\$869,238
Average Operating Expense per Procedure	\$273.68	\$231.05	\$228.69
<b>Net Income</b>	<b>\$61,344</b>	<b>\$235,657</b>	<b>\$248,105</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to acquire a fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located in Watauga County.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as *the same as an Acute Care Bed service area*. Thus, the service area for this facility consists of Watauga County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 61, the applicant states that WMC is the sole acute care hospital in Watauga County and the only existing provider of MRI services in the county. WMC is part of ARHS, the parent organization of ARMA.

In Section G, page 61, the applicant explains why it believes its proposal would not result in the unnecessary duplication of approved MRI services in Watauga County. The applicant states:

*“The proposed project involves the development of the first and only freestanding fixed MRI scanner in Watauga County in response to the need identified in the 2020 SMFP and the growing demand for MRI services in Watauga County. The proposed project will provide a local, convenient, and cost-effective alternative that will meet the needs of the significant number of patients that currently migrate into Watauga County for MRI services at WMC and those who live in Watauga County that leave and travel considerable distances in order to access a freestanding fixed MRI facility.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2020 SMFP for the proposed fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing fixed MRI scanner in Watauga County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

<b>Position</b>	<b>Projected FTE Staff</b>
	<b>2<sup>nd</sup> FFY (FY 2026)</b>
Radiology Technologists	2.0
<b>TOTAL</b>	<b>2.0</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, page 63, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibit H.3, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

### C

In Section I, page 65, the applicant states that support services needed to support the proposed MRI service include, but are not limited to, patient scheduling and registration, medical records, human resources including necessary personnel, housekeeping and maintenance, billing and collections, and professional interpretation services.

On page 65, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I.1 and I.2.

In Section I, pages 65-66, the applicant describes its efforts to develop relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

### C

In Section K, page 69, the applicant states that the project involves renovating 852 square feet of existing space. Line drawings are provided in Exhibit C.1-2.

On page 69, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On pages 69-70, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 70, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA

Neither the applicant nor any related entities own, operate or manage an existing diagnostic center located in the service area. Therefore, Criterion (13a) is not applicable to this review.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA

Neither the applicant nor any related entities own, operate or manage an existing diagnostic center located in the service area. Therefore, Criterion (13b) is not applicable to this review.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 74, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>Payor Source</b>	<b>MRI Services as Percent of Total</b>
Self-Pay	3.0%
Medicare*	53.0%
Medicaid*	7.0%
Insurance*	34.0%
Worker's Compensation	1.0%
TRICARE	2.0%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

On page 74, the applicant states that ARHS's internal data does not include charity care as a payor source for patients, however, patients in any payor category can and will receive charity care.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3% of total services will be provided to self-pay patients, 53% to Medicare patients and 7% to Medicaid patients.

On page 74, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on current actual payor mix of MRI patients at WMC and the applicant does not expect payor mix for the proposed MRI services to change.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 75, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 76, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

### C

The applicant proposes to acquire a fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located in Watauga County.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as *the same as an Acute Care Bed service area*. Thus, the service area for this facility consists of Watauga County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 61, the applicant states that WMC is the sole acute care hospital in Watauga County and the only existing provider of MRI services in the county. WMC is part of ARHS, the parent organization of ARMA.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 77, the applicant states:

*“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to MRI services...”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 77, the applicant states:

*“The proposed application is indicative of ARMA and ARHS’s commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended.*



*The proposed project represents a low-cost alternative for the provision of MRI services, as services provided in a freestanding (nonhospital-based) setting are less expensive for payors and patients.”*

...

*“Through the increased image clarity, radiologists can see details that otherwise would not be detected on a 1.5T scan, thereby improving diagnostic accuracy, which ultimately reduces the occurrence of costly duplicate scans or the expense of other unnecessary treatment.”*

Regarding the impact of the proposal on quality, in Section N, page 78, the applicant states:

*“ARHS is dedicated to providing the highest quality care and is continually recognized locally and nationally for its commitment to delivering efficient, quality care. Each year, ARHS facilities are recognized by many of the top accrediting and ranking organizations in the industry.”*

...

*“The proposed project will serve to improve the quality of MRI services provided within ARHS.”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 79, the applicant states:

*“The proposed project will improve access to fixed MRI services in the service area and will serve as the first and only freestanding fixed MRI scanner option in Watauga County. ARMA and ARHS have long-promoted economic access to their services as ARMA and ARHS historically have provided services to all persons in need of medical care, regardless of race, color, national origin, age, disability, or sex...”*

...

*“...the proposed project will increase access to ARMA and ARHS’s services, including to medically underserved groups.”*

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any exhibits)

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

Neither the applicant nor any related entities own, operate or manage an existing diagnostic center located in North Carolina. In Section G, page 61, the applicant states that WMC is the sole acute care hospital in Watauga County and the only existing provider of MRI services in the county. WMC is part of ARHS, the parent organization of ARMA. In Section O, page 82, the applicant states that the existing fixed MRI service at WMC is currently accredited by ACR, and ARMA intends to seek accreditation of the proposed freestanding fixed MRI services at AppMed Services. After reviewing and considering information provided by the applicant regarding the quality of care provided at the three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

### C

The Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700, are applicable to this review.

## **SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER**

### 10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (a) *An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:*
- (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;*
  - (2) *demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and*
  - (3) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule*

-NA- The applicant does not propose to acquire a mobile MRI scanner. Therefore, this rule is not applicable to this review.

- (b) *An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:*
- (1) *demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;*

-C- The MRI service area is Watauga County. In Section C, page 43, the applicant states that it owns and operates one fixed MRI scanner in Watauga County, at WMC. During the most recent 12-month period for which the applicant has data (01/01/2019-12/31/2019), WMC performed 4,433 weighted MRI procedures which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.

- (2) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];*

-NA- The MRI service area is Watauga County. The applicant states that neither the applicant or a related entity owns a controlling interest in an existing mobile MRI scanner in the Watauga County.

(3) *demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

- (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
- (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

The 2020 SMFP shows that there is one fixed MRI scanner located in the MRI service area of Watauga County. Therefore, the applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Watauga County will be at least 3,775 weighted MRI procedures in the third operating year.

-C- In Section Q the applicant states that it projects to perform 7,810 weighted MRI procedures on its existing and proposed MRI scanners in the third year of the proposed project for an average of 3,905 weighted MRI scans per scanner [ $7,810 / 2 = 3,905$ ] which exceeds the required average of 3,775 weighted MRI procedures per scanner in this performance standard. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

(4) *if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

- (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
- (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

- C- The proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or related entity. Therefore, pursuant to the rule, the applicant must demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform 3,775 weighted MRI procedures in the third year following completion of the proposed project. In Section Q, Form C, page 8, the applicant calculated the number of weighted MRI scans during the third project year by converting fiscal year volumes to project year volumes. The applicant projects that the proposed MRI scanner will perform 3,905 weighted MRI procedures in the third year of operation (CY2026), which is greater than the 3,775 weighted MRI procedures required by the Rule.

<b>ARMA and WMC Projected Weighted MRI Scans</b>				
	<b>FFY 2024</b>	<b>FFY 2025</b>	<b>FFY 2026</b>	<b>FFY 2027</b>
ARMA Weighted MRI scans	2,394	3,147	3,892	3,945
WMC Weighted MRI scans	2,394	3,147	3,892	3,945
<b>Total Weighted MRI Scans</b>	<b>4,789</b>	<b>6,295</b>	<b>7,784</b>	<b>7,889</b>

Source: Section Q, Form C, page 6

$$CY\ 2026 == (0.75 \times FFY\ 2026) + (0.25 \times FFY\ 2027) = (0.75 \times 3,892) + (0.25 \times 3,945) = (2,919 + 986) = 3,905\ \text{weighted MRI scans}$$

<b>Projected Weighted MRI Scans</b>	<b>PY3</b>
ARMA Weighted MRI scans	3,905

Section Q, Form C, page 8

- (5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*
- NA- The applicant states that neither the applicant or a related entity owns a controlling interest in an existing, approved or proposed mobile MRI scanner in Watauga County.
- (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- C- The applicant’s assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- (c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*
  - (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*

- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA- The applicant does not propose the acquisition of a dedicated fixed breast MRI scanner. Therefore, this Rule is not applicable to this review.
- (d) *An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*
- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*
  - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA- The applicant does not propose the acquisition of a dedicated fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.
- (e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*
- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
  - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA- The applicant does not propose the acquisition of a dedicated fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.