

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 28, 2021  
Findings Date: August 2, 2021

Project Analyst: Ena Lightbourne  
Co-Signer: Gloria C. Hale

### COMPETITIVE REVIEW

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Project ID #: B-12023-21  
Facility: EmergeOrtho Blue Ridge Division  
FID #: 210090  
County: Buncombe  
Applicant(s): EmergeOrtho, PA  
Project: Develop a diagnostic center by acquiring a fixed MRI pursuant to the need determination in the 2021 SMFP

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Project ID #: B-12032-21  
Facility: Open MRI and Imaging of Asheville  
FID #: 96027  
County: Buncombe  
Applicant(s): Asheville Open MRI, LLC  
Novant Health, Inc.  
Project: Acquire 1 fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP for a total of 3 fixed MRI scanners

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Project ID #: B-12035-21  
Facility: Mission Imaging Services Asheville  
FID #: 210096  
County: Buncombe  
Applicant(s): MH Mission Imaging, LLLP  
Project: Acquire 1 fixed MRI scanner pursuant to the need determination in the 2021 SMFP to be located at an existing diagnostic center

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Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which

can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

## **REVIEW CRITERIA**

G.S. 131E-183(a): The Department 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-All Applications**

#### **Need Determination**

The 2021 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed MRI scanners in North Carolina by service area. Application of the need methodology in the 2021 SMFP identified a need for one fixed MRI scanner in the Buncombe/Graham/Madison/Yancey service area. Three applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) proposing to acquire one fixed MRI scanner. However, pursuant to the need determination, only one fixed MRI scanner may be approved in this review.

#### **Policies**

Two policies in Chapter 4 of the 2021 SMFP are applicable to the applications received in response to the need determination.

#### **Policy GEN-3**

Policy GEN-3 on page 29 of the 2021 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.”*

## **Policy GEN-4**

Policy GEN-4 on page 29 of the 2021 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, Certificate of Need 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.”*

### **B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, EmergeOrtho Blue Ridge Division in Buncombe County. The applicant does not own an MRI scanner that provides MRI services in the Buncombe/Graham/Madison/Yancey service area. The applicant provides MRI services on a vendor-owned fixed MRI scanner located at its office in Arden in Buncombe County.

*Need Determination.* The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Buncombe/Graham/Madison/Yancey MRI service area.

*Policy GEN-3.* In Section B, pages 24-26, and Exhibits L.4 and L.5, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 27, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the

application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 than one fixed MRI scanner that is determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the Buncombe/Graham/Madison/Yancey counties' MRI service area;
  - The applicant adequately documents how the project will promote equitable access to MRI services in Buncombe/Graham/Madison/Yancey counties;
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

### **B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Open MRI and Imaging of Asheville (Open MRI) in Buncombe County, for a total of three fixed MRI scanners.

*Need Determination.* The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Buncombe/Graham/Madison/Yancey MRI service area.

*Policy GEN-3.* In Section B, pages 28-31, and Exhibit B-20, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 32, and Exhibit B-20, the applicant describes the

project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 than one fixed MRI scanner that is determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the Buncombe/Graham/Madison/Yancey counties' service area;
  - The applicant adequately documents how the project will promote equitable access to MRI services in Buncombe/Graham/Madison/Yancey counties;
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

### **B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

*Need Determination.* The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Buncombe/Graham/Madison/Yancey counties MRI service area.

*Policy GEN-3.* In Section B, pages 28-29, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 30, the applicant describes the project's plan to improve energy efficiency and conserve water.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 than one fixed MRI scanner that is determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the Buncombe/Graham/Madison/Yancey MRI counties' service area;
  - The applicant adequately documents how the project will promote equitable access to MRI services in Buncombe/Graham/Madison/Yancey counties;
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
  - The applicant adequately demonstrates its plan to assure improved energy efficiency and water conservation.

(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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

All Applications

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

The 2021 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.*” There are licensed acute care hospitals located in Buncombe County, however there are no licensed acute care hospitals in Graham, Madison and Yancey counties. Therefore, for the purpose of this review, the fixed MRI service area is a multicounty service area: Buncombe, Graham, Madison and Yancey counties. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin for MRI services at EmergeOrtho Blue Ridge Division.

County	EmergeOrtho, PA Historical Patient Origin MRI Service 10/01/2018-9/30/2019 (FY 2019)	
	Patients	% of Total
Buncombe	1,123	40.6%
Graham	4	0.1%
Madison	45	1.6%
Yancey	31	1.1%
Henderson	1,035	37.4%
Transylvania	135	4.9%
Haywood	95	3.4%
McDowell	45	1.6%
Polk	45	1.6%
Jackson	32	1.2%
Rutherford	24	0.9%
Macon	16	0.6%
Burke	15	0.5%
Swain	13	0.5%
Mitchell	9	0.3%
Other NC Counties*	48	1.7%
South Carolina	17	0.6%
Tennessee	13	0.5%
Florida	11	0.4%
Other States*	12	0.4%
<b>Total</b>	<b>2,768</b>	<b>100.0%</b>

Source: Section C, page 32

\*See page 32 for a listing of the other NC counties and other states.

County	EmergeOrtho Blue Ridge Division Projected Patient Origin, fixed MRI scanner					
	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	01/01/2023 to 12/31/2023		01/01/2024 to 12/31/2024		01/01/2025 to 12/31/2025	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Buncombe	1,704	40.57%	1,916	40.57%	2,137	40.6%
Graham	6	0.14%	7	0.14%	8	0.1%
Madison	68	1.63%	77	1.63%	86	1.6%
Yancey	47	1.12%	53	1.12%	59	1.1%
Henderson	1,570	37.39%	1,766	37.39%	1,969	37.4%
Transylvania	205	4.88%	230	4.88%	257	4.9%
Haywood	144	3.43%	162	3.43%	181	3.4%
McDowell	68	1.63%	77	1.63%	86	1.6%
Polk	68	1.63%	77	1.63%	86	1.6%
Jackson	49	1.16%	55	1.16%	61	1.2%
Rutherford	36	0.87%	41	0.87%	46	0.9%
Macon	24	0.58%	27	0.58%	30	0.6%
Burke	23	0.54%	26	0.54%	29	0.5%
Swain	20	0.47%	22	0.47%	25	0.5%
Mitchell	14	0.33%	15	0.33%	17	0.3%
Other NC Counties	73	1.73%	82	1.73%	91	1.7%
South Carolina	26	0.61%	29	0.61%	32	0.6%
Tennessee	20	0.47%	22	0.47%	25	0.5%
Florida	17	0.40%	19	0.40%	21	0.4%
Other States	18	0.43%	20	0.43%	23	0.4%
<b>Total</b>	<b>4,199</b>	<b>100.00%</b>	<b>4,722</b>	<b>100.00%</b>	<b>5,267</b>	<b>100.0%</b>

Source: Section C, page 34

In Section C, page 34, 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:

- The applicant's projections include an increase in market share based on improving patient access with an in-house fixed MRI scanner and its plan to expand hours of service and the number of referring physicians.
- The applicant projects percentage of patients by County and State based on the historical percentages for the existing MRI scanner.

### Analysis of Need

In Section C, pages 36-44, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.  
 2021 SMFP Need Determination [page 37]

The increase in MRI utilization of the existing and fixed and mobile MRI scanners in the service area as demonstrated by the 2021 SMFP need determination for one additional fixed MRI scanner in Buncombe, Graham, Madison and Yancey counties.



#### Growth and Aging of the Population [pages 37-39]

The projected growth in population in the service area, including contiguous counties, particularly the 65+ age cohort, demonstrates the need for the proposed project. The applicant states that the aging of the population supports continued high demand for healthcare services. The applicant used 2019 data from the North Carolina Office of State Budget and Management (NCOSBM) to illustrate the total service area projected population growth from July 2021 to July 2026 and the total percentages of the 65+ population in the service area.

#### Historical Utilization for MRI at EmergeOrtho [pages 39-40]

EmergeOrtho Blue Ridge Division in Arden experienced a 7.38 percent Compound Annual Growth Rate (CAGR) of unweighted MRI scans from 2016 to 2019, as illustrated in the in the 2018 - 2021 SMFPs. The applicant states that the limitations of the existing vendor-owned MRI scanner caused EmergeOrtho patients to choose their procedure at other facilities. The applicant states that the proposed fixed MRI scanner will enable the facility to improve schedule availability and improve patient preference for the installed full-time fixed MRI scanner which will improve patient satisfaction and market share.

#### COVID-19 preparedness at EmergeOrtho [pages 40-41]

The applicant states that EmergeOrtho remains committed to taking proactive precautions to protect its patients, providers and staff. The applicant states that the high level of preparedness and patient safety at EmergOrtho enabled more patients to obtain MRI procedures in recent months.

#### Current contracted MRI Scanner Limitations and Outmigration [pages 41-42]

The applicant states that the existing vendor-owned MRI scanner has service limitations for obese and claustrophobic patients since the scanner can only accommodate patients weighing 350 pounds or less and that is has a 60 cm closed bore gantry. Patients transported to the scanner are exposed to outdoor weather and extends the overall duration of the MRI procedure. The applicant projects that the proposed MRI scanner will improve patient preference and reduce the outmigration of MRI patients by at least 50 MRI scans per week. Its plans to install the scanner inside the building will accommodate more patients and expand hours of services which will increase schedule options and provide more flexibility.

#### Access to Cost Effective MRI Procedures at EmergeOrtho, PA [page 42-43]

The applicant states that MRI procedures performed at EmergeOrtho have consistently lower total costs as compared to the other providers in the region which is due to the lower cost of performing the procedures in non-hospital settings. The applicant states that that the proposed fixed MRI scanner will hold down operating costs and allow the practice to maintain their competitive charges for MRI procedures.

#### Physician and Physician Assistant Support [page 43]

The applicant states the proposed fixed MRI scanner has extensive support from physicians who are committed to their intention to refer MRI patients. The applicant provides supporting documentation in Exhibit C.4.

Physician Recruitment [page 44]

The applicant states that EmergeOrtho Blue Ridge Division is currently recruiting three new orthopedic surgeons and one psychiatrist which is expected to increase the high utilization at the facility and increase EmergeOrtho’s MRI market share.

EmergeOrtho Blue Ridge Fixed MRI Utilization Projections [page 44]

The applicant states that its utilization projections are conservative and achievable because of EmergeOrtho’s historical utilization. Based on reasonable and conservative assumptions, the applicant projects that the EmergeOrtho’s MRI utilization projections exceed the MRI regulatory performance standard.

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

- The 2021 SMFP identifies the need for one additional fixed MRI scanner in Buncombe, Graham, Madison and Yancey counties.
- Population growth, particularly among the 65+ age cohort is occurring in the service area.
- The limitations of its existing vendor-owned fixed MRI scanner and resulting outmigration.

Projected Utilization

In Section Q, the applicant provides historical and projected utilization, as illustrated in the following tables.

<b>Historical MRI Utilization (Vendor-Owned) EmergeOrtho Blue Ridge Division</b>			
	<b>Last Full FY CY 2020</b>	<b>Interim Full FY CY 2021</b>	<b>Interim Full FY CY 2022</b>
# of MRI scanners	1	1	1
Unweighted Procedures	2,970	3,350	3,696
Weighted Procedures	2,989	3,373	3,721

Source: Section Q, Form C.2a

<b>Projected MRI Utilization EmergeOrtho Blue Ridge Division</b>			
	<b>1<sup>st</sup> Full FY CY 2023</b>	<b>2<sup>nd</sup> Full FY CY 2024</b>	<b>3<sup>rd</sup> Full FY CY 2025</b>
# of MRI scanners	1	1	1
Unweighted Procedures	4,199	4,722	5,267
Weighted Procedures	4,226	4,753	5,302

Source: Section Q, Form C.2b

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

- Obtain historical MRI utilization to calculate EmmergeOrtho current market share trend.

	<b>2016-17</b>	<b>2017-18</b>	<b>2018-19</b>
EmergeOrtho MRI Scans (Unweighted)	2,515	2,685	2,900
Total Service Area MRI Scans (Unweighted)	37,510	37,245	39,210
EmergeOrtho Market Share of Total	6.70%	7.21%	7.40%

Source: Section Q, page 114

- Use historical MRI utilization to calculate Compound Annual Growth Rate (CAGR).

	<b>2016-17</b>	<b>2017-18</b>	<b>2018-19</b>	<b>CAGR</b>
EmergeOrtho MRI Scans (Unweighted)	2,515	2,685	2,900	7.38%
Total Service Area MRI Scans (Unweighted)	37,510	37,245	39,210	2.24%

Source: Section Q, page 114

- Obtain historical MRI utilization by type of scan for EmmergeOrtho MRI scans to calculate percentages.

	<b>2016-17</b>	<b>% of Type</b>	<b>2017-18</b>	<b>% of Type</b>	<b>2018-19</b>	<b>% of Type</b>
Outpatient No Contrast	2,469	98.17%	2,631	97.99%	2,852	98.34%
Outpatient Contrast	46	1.83%	54	2.01%	48	1.66%
EmergeOrtho Total Scans	2,515	100.00%	2,685	100.00%	2,900	100.00%

Source: Section Q, page 114

- Project EmmergeOrtho MRI scans (unweighted) for current and interim years based on the following:
  - 2019-2020 MRI utilization is based on actual MRI utilization for October 1, 2019 to September 30, 2020.
  - 2020-2021 MRI utilization projection is based on 260 scans/month that is annualized (260/month is the average for June 1, 2020 to November 30, 2020 actual).
  - 2021-2022 MRI utilization is based on 7.38% CAGR derived from historical growth.

	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22
EmergeOrtho MRI Scans (Unweighted)	2,515	2,685	2,900	2,842	3,120	3,350

Source: Section Q, page 114

- Project total service area MRI scans (unweighted) for current and interim year and following years based on the following factors:
  - 2019-2020 total service area MRI utilization is based on 98% of previous year utilization due to COVID-19.
  - 2020-2021 total service area MRI utilization is based on 2.24% CAGR based on historical growth.
  - 2021-2022 and following years total service area MRI utilization is based on 2.24% CAGR derived from historical growth.

Current and Interim Years	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22
Total Service Area MRI Scans (Unweighted)	37,510	37,245	39,210	38,426	39,287	40,167

Source: Section Q, page 115

Projected Years	2022-23	2023-24	2024-25	2024-26
Total Service Area MRI Scans (Unweighted)	41,066	41,986	42,927	43,888

Source: Section Q, page 115

- Calculate EmergeOrtho market share for current and interim years.

	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22
EmergeOrtho MRI Scans (Unweighted)	2,515	2,685	2,900	2,842	3,120	3,350
Total Service Area MRI Scans (Unweighted)	37,510	37,245	39,210	38,426	39,287	40,167
EmergeOrtho Market Share of Total	6.7%	7.2%	7.4%	7.4%	7.4%	8.3%

Source: Section Q, page 115

- Project EmergeOrtho MRI utilization for 2022-2023 and the following years based on the following assumptions:
  - Assume that the fixed MRI scanner begins operation in January 1, 2023.
  - Assume EmergeOrtho increased market share due to having an in-house MRI scanner and expanding hours of service plus physician recruitment.
  - Assume a reduction in the number of EmergeOrtho MRI patients that choose other MRI scanners.

<b>Projected Years</b>	<b>2021-22</b>	<b>2022-23</b>	<b>2023-24</b>	<b>2024-25</b>	<b>2024-26</b>
Total Service Area MRI Scans (Unweighted)	40,167	41,066	41,986	42,927	43,888
EmergeOrtho Market Share Assumptions	8.3%	9.0%	10.0%	11.0%	12.0%
EmergeOrtho MRI Scans (Unweighted)	3,350	3,696	4,199	4,722	5,267

Source: Section Q, page 115

- Convert EmERGEOrtho MRI projections for 2021, 2022, 2023 to calendar years based on the following assumptions and methodology:
  - Provide EmERGEOrtho MRI procedures for interim quarter 10/01/2020 to 12/31/2020 based on actual unweighted procedures.
  - Calculate total service area MRI procedures for interim quarter based on 25% of projected MRI utilization for 01/01/2021 to 12/31/2021 period.
  - Assume EmERGEOrtho increased market share due to having an in-house MRI scanner and expanding hours of service plus physician recruitment.
  - Assume that the fixed MRI scanner begins operation in January 1, 2023.
  - Assume that the scheduled adjustments from the October 1 to September 30 fiscal years (Sept 7) to the calendar year does not change the projected MRI utilization for the 12 months period.

	<b>2016-17</b>	<b>2017-18</b>	<b>2018-19</b>	<b>2019-20</b>	<b>Interim Quarter</b>
Total Service Area MRI Scans (Unweighted)	37,510	37,245	39,210	38,426	10,042
EmergeOrtho Market Share Assumptions	6.7%	7.2%	7.4%	7.4%	8.6%
EmergeOrtho MRI Scans (Unweighted)	2,515	2,685	2,900	2,842	859

Source: Section Q, page 115

	<b>CY 2021</b>	<b>CY 2022</b>	<b>PY 1 CY 2023</b>	<b>PY 2 CY 2024</b>	<b>PY 3 CY 2025</b>
Total Service Area MRI Scans (Unweighted)	40,167	41,066	41,986	42,927	43,888
EmergeOrtho Market Share Assumptions	8.3%	9.0%	10.0%	11.0%	12.0%
EmergeOrtho MRI Scans (Unweighted)	3,350	3,696	4,199	4,722	5,267

Source: Section Q, page 115

- Calculate the EmERGEOrtho MRI Utilization for the previous year through the third year based on the type of scan percentages previously calculated and applying the following assumptions:
  - Assume that the projections for the previous year, interim quarter, interim years and Year 1 through 3 are based on historical 2018-19 percentages.

- Assume that MRI projections for year 1, 2, and 3 are unweighted.

	% of Type	2018-19	2019-20	Interim QTR
EmergeOrtho Total Scans	100.00%	2,900	2,842	859
Outpatient No Contrast	98.34%	2,852	2,795	845
Outpatient Contrast	1.66%	48	47	14

Source: Section Q, page 116

	CY 2021	CY 2022	PY 1 CY 2023	PY 2 CY 2024	PY 3 CY 2025
EmergeOrtho Total Scans	3,350	3,696	4,199	4,722	5,267
Inpatients No Contrast	0	0	0	0	0
Inpatient Contrast	0	0	0	0	0
Outpatient No Contrast	3,295	3,635	4,129	4,644	5,179
Outpatient Contrast	56	61	70	78	87

Source: Section Q, page 116

- Calculate the weighted MRI scan values for EmmergeOrtho based on the weighted values in the 2021 State Medical Facilities Plan.

	Weights	2018-19	2019-20	Interim Quarter
Outpatient No Contrast/Sedation	1.0	2,852	2,795	845
Outpatient Contrast/Sedation	1.4	67	66	14 [20]
Total EmmergeOrtho Weighted MRI Procedures		2,919	2,861	859

	CY 2021	CY 2022	PY 1 CY 2023	PY 2 CY 2024	PY 3 CY 2025
Outpatient No Contrast/Sedation	3,295	3,635	4,129	4,644	5,179
Outpatient Contrast/Sedation	78	86	98	110	122
Total EmmergeOrtho Weighted MRI Procedures	3,373	3,721	4,226	4,753	5,302

Note: The Project Analyst's correction is in brackets.

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

- There was a need determination in the 2021 SMFP for a fixed MRI scanner in the Buncombe, Graham, Madison, and Yancey counties MRI service area and this proposed project will meet that need determination by developing a fixed MRI scanner in Buncombe County.
- The applicant's projections for interim and the first three years of the project are supported by the historical market trends at EmmergeOrtho and in the service area. The applicant applies the historical growth of the existing fixed MRI scanner to project MRI utilization.

- The applicant reasonably projects an increase in market share based on an expansion of hours of service, physician recruitment, and the transition from a vendor-owned fixed MRI scanner located outside of the facility to an in-house fixed MRI scanner.
- The applicant adequately demonstrates that EmergeOrtho’s existing, approved, and proposed fixed MRI scanners are reasonably expected to perform more than 4,805 weighted MRI procedures in the third year of operation following the completion of the proposed project, as required in 10A NCAC 14C .2703(b)(3).

### **Access to Medically Underserved Groups**

In Section C, page 52, the applicant states:

*“...we do not discriminate or restrict access to services on the basis of age, race, color, ethnicity, religion, sex, disability, or ability to pay.*

...

*“EmergeOrtho will expand access for the medically underserved by providing MRI procedures to patients who are indigent, uninsured, underinsured, or are otherwise medically underserved. EmergeOrtho will provide no charge MRI scans to charity patients referred through Project Access and to low-income persons referred from community health clinics and Federally Qualified Health Centers.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>3<sup>rd</sup> FY % of Total Patients</b>
Low income persons	16.2%
Racial and ethnic minorities	11.0%
Women	55.4%
Persons with Disabilities	26.8%
Persons 65 and older	43.6%
Medicare beneficiaries	38.5%
Medicaid recipients	3.0%

Section C, page 53

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant has historically provided access to services to underserved groups.
- The applicant has existing charity care programs that include no charge MRI scans to patients referred from community health clinics and Federally Qualified Health Centers and discount programs for self-pay patients.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

### **B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

#### **Patient Origin**

The 2021 SMFP defines the service area for a fixed MRI scanner as *“the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.”* There are licensed acute care hospitals located in Buncombe County, however there are no licensed acute care hospitals in Graham, Madison and Yancey counties. Therefore, for the purpose of this review, the fixed MRI service area is a multicounty service area: Buncombe, Graham, Madison and Yancey counties. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin for MRI services at Open MRI.



County	Open MRI & Imaging of Asheville MRI Services Historical Patient Origin 01/01/2020-12/31/2020 (CY 2020)	
	Patients	% of Total
Buncombe	5,677	50.70%
Henderson	1,523	13.60%
Haywood	717	6.40%
Madison	459	4.10%
McDowell	403	3.60%
Transylvania	325	2.90%
Yancey	280	2.50%
Jackson	280	2.50%
Burke	196	1.75%
Macon	168	1.50%
Rutherford	168	1.50%
Mitchell	145	1.30%
Polk	123	1.10%
Swain	123	1.10%
Graham	56	0.50%
Other*	554	4.95%
<b>Total</b>	<b>11,197</b>	<b>100.00%</b>

Source: Section C, page 42

\*Cherokee, Avery, Catawba, Watauga, Clay, Cleveland, Caldwell, Alleghany, Surry, Orange, Durham, Wake, New Hanover, Mecklenburg, Ashe, Harnett, Onslow, Pitt, Moore, Forsyth, Guilford, Union, Lincoln, Gaston, Wilkes and other states.

County	Open MRI & Imaging of Asheville MRI Services Projected Patient Origin					
	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	7/1/2022-6/30/2023 (FY 2023)		7/1/2023-6/30/2024 (FY2024)		7/1/2024-6/30/2025 (FY 2025)	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Buncombe	6,834	50.70%	6,960	50.70%	7,088	50.70%
Henderson	1,833	13.60%	1,867	13.60%	1,901	13.60%
Haywood	863	6.40%	879	6.40%	895	6.40%
Madison	553	4.10%	563	4.10%	572	4.10%
McDowell	485	3.60%	494	3.60%	503	3.60%
Transylvania	391	2.90%	398	2.90%	405	2.90%
Yancey	337	2.50%	343	2.50%	350	2.50%
Jackson	337	2.50%	343	2.50%	350	2.50%
Burke	236	1.75%	240	1.75%	245	1.75%
Macon	202	1.50%	206	1.50%	210	1.50%
Rutherford	202	1.50%	206	1.50%	210	1.50%
Mitchell	175	1.30%	178	1.30%	182	1.30%
Polk	148	1.10%	151	1.10%	154	1.10%
Swain	148	1.10%	151	1.10%	154	1.10%
Graham	67	0.50%	69	0.50%	70	0.50%
Other*	668	4.95%	679	4.95%	691	4.95%
<b>Total</b>	<b>13,479</b>	<b>100.00%</b>	<b>13,727</b>	<b>100.00%</b>	<b>13,980</b>	<b>100.00%</b>

Source: Section C, page 44

\*Cherokee, Avery, Catawba, Watauga, Clay, Cleveland, Caldwell, Alleghany, Surry, Orange, Durham, Wake, New Hanover, Mecklenburg, Ashe, Harnett, Onslow, Pitt, Moore, Forsyth, Guilford, Union, Lincoln, Gaston, Wilkes and other states.

In Section C, page 44, 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:

- The applicant based its projected patient origin on Open MRI's historical patient origin for MRI services from CY 2020.
- The applicant does not anticipate any significant shifts in patient origin.

**Analysis of Need**

In Section C, pages 47-52, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 47-52, the applicant states:

High Utilization of the Existing MRI Scanners at Open MRI (page 47)

The applicant states that Open MRI consistently performed over 11,000 unweighted MRI scans annually at its outpatient facility in Buncombe County.

Impact of the COVID-19 Pandemic on CY 2020 Volume (pages 47-48)

The applicant states that the COVID-19 restrictions on elective surgeries and the reduction in in hours of operation and caseloads of referring physicians reduced the volume of MRI scans performed in early 2020 at Open MRI. The applicant states that the disruption in routine care may increase morbidity and mortality risk associated with treatable and preventable health conditions.

The Impact of COVID-19 Related Downtime at Open MRI (pages 48-49)

The applicant states that the COVID-19 downtime resulted in the loss of approximately 1,000 MRI scans at Open MRI during CY 2020. However, under normal circumstances, the applicant estimates that Open MRI would have performed nearly 12,200 unweighted MRI procedures during CY 2020, for an increase of approximately 3.8% from the 11,753 unweighted MRI scans performed in CY 2019. The applicant states that Open MRI rebounded in the last half of 2020, performing 11,197 unweighted MRI scans for the year, indicating the high demand for Open MRI services in the community.

Charting Future Growth for Open MRI (pages 49-50)

The applicant states that the impact of COVID-19 on historical growth rates is not expected to continue in the future based on the Open MRI's strong performance of MRI volume in the last half of 2020. The applicant conservatively projects utilization of Open MRI's unweighted MRI volume during the interim periods through Project Years 1-3 using half of its CAGR for CY 2017-CY 2019.

<b>Open MRI's Projected Unweighted MRI Volume</b>					
Time Period	Interim 1	Interim 2	PY 1	PY 2	PY 3
	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Unweighted MRI Volume	12,996*	13,235	13,479	13,727	13,980
% Change		1.84%	1.84%	1.84%	1.84%

Source: Open MRI internal data

\*Annualized based on actual data for 7/1/20-12/31/20

Comparison to Buncombe County (pages 50-51)

The applicant states that as a comparison measure, it reviewed Open MRI's total unweighted MRI volume performed in Buncombe County and its historical market share percentage. According to data from the 2018-2021 SMFPs, Open MRI had an average market share percentage of 28.5%. The CAGR for Buncombe County's MRI volume for this period was 5.28%. The applicant used the CAGR for Buncombe County's MRI's volume and Open MRI's historical market share to estimate Open MRI's volume for the first three project years. The applicant states that its projected unweighted MRI volume is reasonable based on its past performance in the service area and its historical market share percentage of total unweighted MRI volume in Buncombe County.

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

- The 2021 SMFP identifies the need for one additional fixed MRI scanner in Buncombe, Graham, Madison, and Yancey counties.
- Open MRI's historical utilization and its consistent MRI market share in the service area.

Projected Utilization

In Section Q, page 124, the applicant provides historical and projected utilization, as illustrated in the following table.

<b>Historical and Projected MRI Utilization Open MRI Imaging of Asheville</b>					
	<b>Interim 1 FY 2021</b>	<b>Interim 2 FY 2022</b>	<b>PY 1 FY 2023</b>	<b>PY 2 FY 2024</b>	<b>PY 3 FY 2025</b>
# of MRI scanners	2	2	3	3	3
Unweighted Procedures	12,996*	13,235	13,479	13,727	13,980
Weighted Procedures	14,311	14,574	14,843	15,116	15,395

\*Annualized based on actual data for 7/1/20-12/31/20

In Section Q, pages 114-125, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

*Step 1: Establish July 1, 2022 as the project year start date based on input from Open MRI's construction, development and operational teams.*

*Step 2: Document the historical MRI volume at Open MRI in order to determine reasonable growth rates.*

<b>Open MRI's Historical Unweighted MRI Volume</b>				
<b>Time Period</b>	<b>CY 2017</b>	<b>CY 2018</b>	<b>CY 2019</b>	<b>CY 2019</b>
With Contrast	2,707	2,726	3,113	2,803
Without Contrast	8,229	8,505	8,640	8,394
Unweighted MRI Total	10,936	11,231	11,753	11,197
% Change		2.7%	4.6%	-4.7%

Source: Section Q, page 115

The applicant demonstrates the impact of COVID-19 on its historical MRI volume at Open MRI. The facility experienced an increase in downtime due to the restrictions related to COVID-19. The applicant states that based on normal hours of operation for Open MRI, the amount of downtime equates to more than an entire month of service and has resulted in the loss of approximately 1,000 unweighted MRI scans during CY 2020.

Open MRI Monthly Comparison of Unweighted MRI Volume			
Month	CY 2020	CY 2019	% of Change from CY 2019 to CY 2020
March	730	959	-23.9%
April	313	932	-66.4%
May	705	981	-28.1%

Source: Section Q, page 116

*Step 3: Charting future growth for Open MRI*

The applicant states that the surge in the MRI volume experience at Open MRI when the COVID-19 restrictions were lifted during the last half of 2020 demonstrates the facility's ability to recapture its prior service levels. The applicant conservatively projects utilization of Open MRI's unweighted MRI volume during the interim periods through Project Years 1-3 using half of its CAGR for CY 2017 - 2019. The applicant states that utilizing a 1.84% growth rate to project utilization is reasonable based on the following:

- Open MRI's CAGR for CY 2017-CY 2019 was 3.67%.
- The Buncombe County MRI volume CAGR for FY 2016-FY2019 (10/1-9/30), was 5.28%.
- The facility would have experienced a of 3.8% increase in unweighted MRI volume from CY 2019 to CY 2020 if the pandemic had not occurred.
- According to the NCOSBM, population growth for Buncombe County is expected to exceed 1.1% annually and the 65+ segment of the service area population is projected to increase from 20.7% of the total population to 22.5% from 2020 to 2025.
- Open MRI is an established imaging provider in Buncombe County with more than 20 years of service and has a substantial physician referral base.

*Step 4: Apply the growth rate of 1.84% to Open MRI's unweighted MRI volume to project interim and project year volume.*

Open MRI's Projected Unweighted MRI Volume					
Time Period	Interim 1	Interim 2	PY 1	PY 2	PY 3
	7/1/20-6/30/21	7/1/21-6/30/22	7/1/22-6/30/23	7/1/23-6/30/24	7/1/24-6/30/25
Unweighted MRI Volume	12,996*	13,235	13,479	13,727	13,980
% Change		1.84%	1.84%	1.84%	1.84%

Source: Section Q, page 121

\*Annualized based on actual MRI data for 7/1/20-12/31/20

*Step 5: Open MRI's projections in comparison to Buncombe County*

The applicant reviewed Open MRI's total unweighted MRI volume performed in Buncombe County and its historical market share percentage. According to data from the 2018-2021 SMFPs, Open MRI had an average market share percentage of 28.5%. The CAGR for Buncombe County's MRI volume for this period was 5.28%. The applicant used the CAGR for Buncombe County's MRI's volume and Open MRI's historical market share to estimate

Open MRI's volume for the first three project years. The applicant states that its projected unweighted MRI volume is reasonable based on its past performance in the service area and its historical market share percentage of total unweighted MRI volume in Buncombe County.

Projected Unweighted MRI Volume in Buncombe County							
Time Period	2021 SMFP (10/1/18-9/30/19)	10/1/19-9/30/20	10/1/20-9/30/21	10/1/21-9/30/22	10/1/22-9/30/23	10/1/23-9/30/24	10/1/24-9/30/25
Buncombe County Total MRI Volume	39,210	41,280	43,459	45,754	48,170	50,713	53,391
CAGR for Buncombe County		5.28%	5.28%	5.28%	5.28%	5.28%	5.28%

Source: Section Q, page 122

Open MRI's Market Share of Projected Unweighted MRI Volume in Buncombe County				
Time Period	Buncombe County Total MRI Volume	Open MRI's Projected Market Share	Estimated MRI Volume for Open MRI	MRI Projections for Open MRI
10/1/22-9/30/23	48,170	28.5%	13,729	13,479 7/1/22-6/30/23
10/1/23-9/30/24	50,713	28.5%	14,453	13,727 7/1/23-6/30/24
10/1/24-9/30/25	53,391	28.5%	15,216	13,980 7/1/24-6/30/25

Source: Section Q, page 122

*Step 6: Utilizing its historical MRI data, Open MRI determined a reasonable contrast percentage and applied it to the projected MRI utilization for the proposed project*

Open MRI's Historical Contrast Percentage			
Scan Type	CY 2018	CY 2019	CY 2020
With Contrast	2,726	3,113	2,803
Without Contrast	8,505	8,640	8,394
Total	11,231	11,753	11,197
% Contrast	24.3%	26.5%	25.0%
<b>3-Year Average Contrast Percentage</b>			<b>25.3%</b>

Source: Section Q, page 123

*Step 7: Open MRI applied the average contrast percentage of 25.3% to determine the unweighted MRI volume for the interim period and Project Years 1-3 to determine the total weighted MRI volume for each period*

The applicant states that the number of contrast MRI scans for each period were multiplied by the factor of 0.4 (consistent with the SMFP methodology) to obtain the contrast adjustment for

each period. The weighted MRI total was determined by adding the contest adjustment to the unweighted MRI total for each year from Step 4.

<b>Open MRI's Projected Unweighted &amp; Weighted MRI Volume</b>					
Time Period	<b>Interim 1</b>	<b>Interim 2</b>	<b>PY 1</b>	<b>PY 2</b>	<b>PY 3</b>
	7/1/20-6/30/21	7/1/21-6/30/22	7/1/22-6/30/23	7/1/23-6/30/24	7/1/24-6/30/25
Unweighted MRI Volume	12,996*	13,235	13,479	13,727	13,982
% Contrast	25.3%	25.3%	25.3%	25.3%	25.3%
Contrast Scans	3,288	3,348	3,410	3,473	3,537
Contrast Adjustments (Contrast scans x .4)	1,315.2	1,339.2	1,364.0	1,389.2	1,414.8
Weighted Procedures	14,311	14,574	14,843	15,116	15,395
# of Fixed MRI	2	2	3	3	3
Average Annual Utilization/Fixed MRI	7,156	7,287	4,948	5,038	5,132

Source: Section Q, page 124

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

- The 2021 SMFP identifies the need for one additional fixed MRI scanner in Buncombe County.
- The applicant's utilization projections are supported by Open MRI's historical market share in Buncombe County and its historical MRI volume prior to COVID-19.
- The methodology and assumptions utilized by the applicant were reasonable and adequately supported.

**Access to Medically Underserved Groups**

In Section C, page 57, the applicant provides the estimated percentage for each medically underserved group during the third full fiscal year, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Women	58.8%
The elderly	37.8%
Medicare beneficiaries	43.0%
Medicaid recipients	3.4%

In Section C, page 57, the applicant states that Open MRI does not request or track data on low-income persons, racial and ethnic minorities, or persons with disabilities.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

### **B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging-Biltmore in Buncombe County.

The 2021 SMFP defines the service area for a fixed MRI scanner as *“the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.”* There are licensed acute care hospitals located in Buncombe County, however there are no licensed acute care hospitals in Graham, Madison and Yancey counties. Therefore, for the purpose of this review, the fixed MRI service area is a multicounty service area: Buncombe, Graham, Madison and Yancey counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical patient origin for Mission System MRIs in Buncombe County.



<b>Mission System MRIs in Buncombe County Historical Patient Origin</b>		
<b>County</b>	<b>Last full FY 10/01/2019-09/30/2020</b>	
	<b># of Patients</b>	<b>% of Total</b>
Buncombe	11,913	56.14%
Henderson	2,005	9.45%
Haywood	1,363	6.42%
Madison	1,024	4.83%
McDowell	742	3.50%
Yancey	541	2.55%
Jackson	468	2.21%
Transylvania	557	2.62%
Macon	393	1.85%
Rutherford	312	1.47%
Burke	227	1.07%
Swain	252	1.19%
Mitchell	256	1.21%
Cherokee	147	0.69%
Graham	146	0.69%
Polk	157	0.74%
Avery	63	0.30%
Clay	42	0.20%
<b>Primary Service Area</b>	<b>20,608</b>	<b>97.12%</b>
Other: North Carolina	238	1.12%
South Carolina	86	0.41%
Tennessee	89	0.42%
Georgia	33	0.16%
Other States	166	0.78%
<b>In-Migration</b>	<b>612</b>	<b>2.88%</b>
<b>Total</b>	<b>21,220</b>	<b>100.00%</b>

Source: Section C, page 38

The following table illustrates projected patient origin for MRI services at Mission Imaging-Biltmore.

County	Mission Imaging-Biltmore (MRI Only) Projected Patient Origin					
	1 <sup>st</sup> Full FY CY 2023		2 <sup>nd</sup> Full FY CY2024		3 <sup>rd</sup> Full FY CY 2025	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Avery	8	0.3%	10	0.3%	12	0.3%
Buncombe	1,887	60.5%	2,283	60.5%	2,703	60.5%
Burke	27	0.9%	33	0.9%	39	0.9%
Cherokee	16	0.5%	19	0.5%	23	0.5%
Clay	6	0.2%	7	0.2%	8	0.2%
Graham	11	0.3%	13	0.3%	15	0.3%
Haywood	207	6.6%	250	6.6%	296	6.6%
Henderson	306	9.8%	371	9.8%	439	9.8%
Jackson	50	1.6%	60	1.6%	71	1.6%
Macon	43	1.4%	52	1.4%	62	1.4%
Madison	162	5.2%	196	5.2%	232	5.2%
McDowell	78	2.5%	94	2.5%	111	2.5%
Mitchell	30	1.0%	36	1.0%	43	1.0%
Polk	20	0.6%	24	0.6%	29	0.6%
Rutherford	28	0.9%	34	0.9%	40	0.9%
Swain	13	0.4%	16	0.4%	19	0.4%
Transylvania	71	2.3%	86	2.3%	102	2.3%
Yancey	78	2.5%	94	2.5%	111	2.5%
<b>Primary Service Area</b>	<b>3,041</b>	<b>97.5%</b>	<b>3,680</b> <b>[3,678]</b>	<b>97.5%</b>	<b>4,356</b> <b>[4,355]</b>	<b>97.5%</b>
Other NC	28	0.9%	33	0.9%	40	0.9%
All other States	16	0.5%	20	0.5%	23	0.5%
Tennessee	16	0.5%	19	0.5%	22	0.5%
South Carolina	14	0.4%	16	0.4%	19	0.4%
Georgia	4	0.1%	5	0.1%	6	0.1%
<b>In-Migration</b>	<b>77 [78]</b>	<b>2.5%</b>	<b>93</b>	<b>2.5%</b>	<b>111</b> <b>[110]</b>	<b>2.5%</b>
<b>Total</b>	<b>3,118</b>	<b>100.0%</b>	<b>3,773</b> <b>[3,771]</b>	<b>100.0%</b>	<b>4,467</b> <b>[4,465]</b>	<b>100.0%</b>

Source: Section C, page 39

Note: The Project Analyst's corrections are in brackets.

In Section C, page 39, 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:

- Projected patient origin was based on the historical patient origin for the two freestanding fixed MRIs at Mission Imaging-Asheland. The applicant states that it is the best representation of patient origin because of its location and patient population.
- To calculate patient origin for MRIs at Mission Imaging-Biltmore, the applicant applied the historical patient origin percent of total by county for Mission Imaging-Asheland to the projected MRI volumes at Mission Imaging-Biltmore.

**Analysis of Need**

In Section C, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 43-56, the applicant states:

To demonstrate the need for the proposed project, the applicant begins by identifying the proposed service area for the new MRI scanner. On page 42, the applicant states the service area for Mission System MRIs in Buncombe County is based on the historical patient origin of MRI studies from the Mission System MRIs.

<b>Primary Service Area-Counties*</b>
Avery
<b>Buncombe</b>
Burke
Cherokee
Clay
<b>Graham</b>
Haywood
Henderson
Jackson
Macon
<b>Madison</b>
McDowell
Mitchell
Polk
Rutherford
Swain
Transylvania
<b>Yancey</b>

Source: Section C, page 42

\*Counties in **bold** are included in the state-defined MRI service area.

#### Projected Growth in Service Area Population (pages 43-45)

The applicant used data from the North Carolina Office of State Budget and Management (NCOSBM) to demonstrate the need based on the population growth trends in the service area. Between 2021 and 2026, the primary service area is projected to grow steadily from 478,532 to 503,513, a 5.2 percent growth. The primary service area will experience an increase of over 27,000 residents age 65 and older and the total female population will experience a 4.1 percent growth. The female population at risk for breast cancer, ages 30-75, is expected to grow 2.2 percent.

#### Service Area Utilization and SMFP Need (page 46)

The 2021 SMFP identifies the need for one additional fixed MRI scanner in the Buncombe, Graham, Madison, and Yancey counties' service area. The applicant's proposal demonstrates

that the anticipated growth of Mission Health's total MRI procedures is projected to meet the performance standard by the third full year of operation.

#### Trend in Service Area Utilization by Provider (pages 46-49)

The applicant demonstrates the growth in MRI utilization in service area demand, specifically free-standing and mobile MRI versus hospital fixed MRI utilization during FY 2014-FY 2019. Outpatient scans with contrast are growing at a higher CAGR than other types of scan volume, confirming the growth in complexity of scans.

#### Utilization and Utilization Constraints (pages 49-52)

Mission Imaging-Asheland does not have the capacity to accommodate the increased utilization of MRIs in an outpatient setting, particularly MRI scans with contrast and other complex scans. The facility's utilization has exceeded the SMFP performance standard of 4,805 adjusted scans per unit. In addition, as the only provider of Breast MRI in the service area, the growth in Breast MRI volumes will put a further strain on the facility's capacity.

#### High-Risk Breast Cancer and Breast MRIs (page 52-54)

The American Cancer Society's recommendations for annual MRI scans on women identified as high risk for breast cancer has partly resulted in significant increase in demand for Breast MRI scans. According to the North Carolina State Center for Health Statistics, three counties in the applicant's service area had breast cancer mortality rates that exceeded the statewide average between 2014 and 2018. The applicant states that the addition of a new MRI scanner at Mission Imaging-Biltmore will improve access to much needed breast services. The facility is adjacent to the Mission Breast Center. The applicant states that it is the ideal location to allow for a centralized location offering a full continuum of breast imaging services, including breast MRI.

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

- The applicant provides population growth projections for the proposed service area based on data from the North Carolina Office of State Budget and Management (NCOSBM).
- The applicant relies on growth trends and historical utilization of its existing MRI scanners located in the service area to justify the need.
- The applicant demonstrates the growth in service demand for outpatient MRI scans, including breast MRI scans.

#### Projected Utilization

In Section Q, page 121, the applicant provides projected utilization for the proposed fixed MRI scanner, as illustrated in the following table.

<b>Projected Utilization Mission Imaging-Biltmore (MRI Services)</b>			
	<b>1<sup>st</sup> FFY FY 2023</b>	<b>2<sup>nd</sup> FFY FY 2024</b>	<b>3<sup>rd</sup> FFY FY 2025</b>
# of MRI scanners	1	1	1
Unweighted Procedures	3,118	3,773	4,467
Weighted Procedures	4,179	5,031	5,934

In Section C, pages 57-61, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

*Mission Imaging-Biltmore Projected Breast MRI Volumes*

- The applicant assumes that all breast MRI volume will shift to Mission Imaging-Biltmore through its central scheduling system, alleviating capacity restraints at Mission Imaging-Asheland.
- To project breast MRIs and biopsies for interim year CY 2021 at Mission Imaging-Asheland, a quarter (8.5%) of the growth that occurred between FY 2019 and FY 2020 is applied.
- Once the MRI opens the new site, a conservative growth rate of 25% over the prior year is applied to estimate volumes in the first partial year based on the growth in the most recent years. The applicant's projected growth rate is adequately supported by the historical growth in breast MRIs experienced at Mission Imaging-Asheland. Breast MRIs increased by 87% between 2018 and 2019 and 37% from 2019 to 2020.
- Partial year at Mission Imaging-Biltmore is calculated by applying the 25% growth to CY 2021 and dividing by four for a quarter rate, then multiplying by three to get the three quarters of CY 2022 beginning 4/1/2022.
- An annual 10% growth rate for the first three years of the project is assumed based on continued ramp-up of the Risk Assessment Clinic.

<b>Projected Breast MRIs and Breast Biopsies at Mission Imaging-Biltmore</b>							
	<b>Mission Imaging-Asheland</b>			<b>Mission Imaging-Biltmore</b>			
	<b>Historic</b>	<b>Interim</b>	<b>Interim Period Year</b>	<b>Partial Year</b>	<b>1<sup>st</sup> FFY</b>	<b>2<sup>nd</sup> FFY</b>	<b>3<sup>rd</sup> FFY</b>
	<b>FY 2020(1)</b>	<b>CY 2021(2)</b>	<b>Q1 CY 2022(2)*</b>	<b>Q2-Q4 2022(4)</b>	<b>CY 2023</b>	<b>CY 2024</b>	<b>CY 2025</b>
Total Breast MRIs & Biopsies	1,277	1,368	346	1,299	1,810	1,991	2,190
Growth Rate Over Prior Year		8.5%	0%	25%	10%	10%	10%

Source: Section C, page 58

\*It is assumed that the applicant meant (3)

- (1) The interim quarter between FY20 and CY2021 and assumptions included in Section Q, C.2a Form for Mission Imaging-Asheland.
- (2) Actual FY 2020 increased by 8.5% conservatively assuming recovery from the pandemic.
- (3) 1/4 of CY 2021 utilization held constant
- (4) CY 2021 [2022] increased by 25% with and additional available capacity x 3/4 of the year.

*Mission Imaging-Biltmore Projected other MRI Volume (Non-Breast)*

- Subtract Mission Imaging’s breast MRI volume from the total market trend for freestanding fixed MRIs in the service area.

<b>Historic Market Free-Standing Fixed/Mobile MRIs in Buncombe County Less Breast Volumes</b>			
<b>Types of Scans</b>	<b>FY 2014</b>	<b>FY 2019</b>	<b>5-Year CAGR %</b>
Total MRI Scans	20,783	24,844	3.6%
Outpatient No Contrast	14,307	16,532	2.9%
Outpatient Contrast	6,492	8,312	5.1%
Adjusted Total	23,372	28,169	3.8%

Section C, page 59

- FY 2019 is used as the baseline to project the market for free-standing MRIs in Buncombe County without breast volume for CY 2021 through CY 2025. The applicant assumes that based on historical trends, scans with contrast are projected to increase most rapidly.

<b>Projected Market Free-Standing Fixed/Mobile MRIs in Buncombe County Less Breast Volumes</b>							
Types of Scans	Actual FY 2019	5-Year CAGR (FY2014- FY2019)	Interim	Interim	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>
			CY 2021	2022	FFY CY 2023	FFY CY 2024	FFY CY 2025
Total MRI Scans	24,844	3.6%	25,747	26,683	27,652	28,657	29,699
Outpatient No Contrast	16,532	2.9%	17,017	17,516	18,020	18,559	19,103
Outpatient Contrast	8,312	5.1%	8,733	9,176	9,641	10,129	10,642
Adjusted Total	28,169	3.8%	29,243	30,362	31,517	32,739	34,002
<b>Market Incremental Growth by Type</b>							
Outpatient No Contrast			485	984	1,498	2,027	2,571
Outpatient Contrast			421	864	1,329	1,817	2,330
Total			906	1,848	2,826	3,844	4,901

Section C, page 59

- The applicant assumes that the market share percentage of freestanding outpatient scans volumes without breast volume during FY 2019 will remain constant throughout the project period.

Projected Imaging Non-Breast Incremental MRI Volume					
Mission Imaging Incremental Scans			1 <sup>st</sup> FFY	2 <sup>nd</sup> FFY	3 <sup>rd</sup> FFY
Types of Scans	Market Share	Partial Q2-Q4 2022	CY 2023	CY 2024	CY 2025
Outpatient No Contrast	31.1%	229	466	630	799
Outpatient Contrast	63.4%	411	843	1,152	1,478
<b>Total</b>		<b>640</b>	<b>1,308</b>	<b>1,783</b>	<b>2,277</b>

Section C, page 60

- Summary of the combined total projected utilization for Mission Imaging-Biltmore based on breast MRI volume and shift of the projected incremental growth of non-breast MRI volume.

Total Projected MRI Volumes Mission Imaging-Biltmore				
	Partial Year	1 <sup>st</sup> Full Year	2 <sup>nd</sup> Full Year	3 <sup>rd</sup> Full Year
	Q2-Q4 2022	CY 2023	CY 2024	CY 2025
Breast MRI's & Biopsies (w/contrast)	1,299	1,810	1,991	2,190
Non-Breast-No Contrast	229	466	630	799
Non-Breast-Contrast	411	843	1,152	1,478
<b>Total MRI Scans</b>	<b>1,939</b>	<b>3,118</b>	<b>3,773</b>	<b>4,467</b>
<b>Total Weighted Scans</b>	<b>2,623</b>	<b>4,179</b>	<b>5,031</b>	<b>5,934</b>
Fixed Equivalent MRIs	0.75	1	1	1
Average Weighted Per Unit		4,179	5,031	5,934
Performance Standard (b)(3) Threshold				4,805

Section C, page 60

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

- The 2021 SMFP identifies the need for one additional fixed MRI scanner in the Buncombe, Graham, Madison, and Yancey counties' service area.
- The methodology and assumptions utilized by the applicant are reasonable, conservative and well supported. This includes the combination of historical utilization and historical growth rates at Mission Imaging-Asheland and Mission Imaging-Biltmore, the growing demand for scans with contrast and specialized scans such as Breast MRIs, and the reasonable shifting of some Breast MRI procedures to Mission Imaging-Biltmore through its central scheduling system.

In Section C, page 70, the applicant provides historical and projected utilization for Mission System's existing, approved and proposed fixed MRI scanners in Buncombe County, as illustrated in the following table.

<b>Projected Utilization Mission System MRIs-Buncombe County</b>					
	<b>Interim</b>	<b>Interim/ partial</b>	<b>1<sup>st</sup> Full Year</b>	<b>2<sup>nd</sup> Full Year</b>	<b>3<sup>rd</sup> Full Year</b>
	<b>CY 2021</b>	<b>CY 2022</b>	<b>CY 2023</b>	<b>CY 2024</b>	<b>CY 2025</b>
# of MRI scanners	7	7.75	8	8	8
Unweighted Procedures	25,538	26,643	27,683	28,549	29,456
Weighted Procedures	33,033	34,660	36,234	37,637	39,144
Average Weighted Per Unit			4,429	4,705	4,893

In Section C, pages 57-61, and Section Q, pages 119-123, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with the last full fiscal year data for Mission System MRIs from FY 2020. In section Q, page 119, the applicant reports that a total of 21,220 procedures and 27,726 weighted procedures were performed during this period.
- The applicant assumed that the last quarter of 2020 (October 1, 2020-December 31, 2020) would be consistent with the immediate prior four quarters. However, the fixed MRI scanner located at the St. Joseph Campus was offline for two months. The applicant divides the total volume from FY 2020 by four to calculate the volumes for the last quarter of 2020.

$$21,220 / 4 = 5,305 \text{ Procedures}$$

$$27,726 / 4 = 6,932 \text{ Weighted Procedures}$$

- The applicant applies Mission Hospital-based MRIs Five-Year CAGR for FY 2014 – FY 2019 to project volumes for CY 2021. The applicant states that FY 2019 is considered the more accurate baseline in comparison to the COVID-19 decline in procedures the following year. The FY 2019 Five-Year CAGR for the total unweighted procedures was 3.6% and 3.8% for the total weighted procedures. The applicant projects a total of 25,538 unweighted procedures and 33,033 weighted procedures to be performed in CY 2021. However, the applicant applies the FY 2019 CAGR for weighted procedures to project total unweighted procedures and applies the FY 2019 CAGR for unweighted procedures to project total weighted procedures for CY 2021.
- The applicant proposes to begin providing breast imaging services on the new fixed MRI scanner April 1, 2022. To project utilization during the interim/partial year (4/1/2022-12/31/2022), the applicant adds the projections for Mission Hospital MRIs CY2022 and multiplying by .75 then adding the CY 2022 projections for Mission Imaging -Asheland less breast volumes.



- The applicant applies the assumptions and methodology used to project utilization for the proposed fixed MRI scanner for the first three years of the project to project utilization for Mission system MRIs for CY 2023 through CY 2025.

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

- The 2021 SMFP identifies the need for one additional fixed MRI scanner in the Buncombe, Graham Madison, and Yancey counties' service area.
- The methodology and assumptions utilized by the applicant are reasonable, conservative and well supported. This includes the combination of historical utilization and historical growth rates of Mission hospital-based MRI scanners and the two fixed MRI scanners located at Mission Imaging-Asheland.

### **Access to Medically Underserved Groups**

In Section C, page 66, the applicant states:

*“Mission Health already demonstrates its service to all patients, regardless of gender, race, or ability to pay, by being one of the leading providers of indigent and charity care to patients seeking services in the region.”*

The applicant provides the estimated percentage for each medically underserved group during the third full fiscal year, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	12.3%
Racial and ethnic minorities	8.3%
Women	64.4%
Persons with disabilities	26.8%
Persons 65 and older	49.6%
Medicare beneficiaries	53.1%
Medicaid recipients	5.0%

Source: Section C, page 66

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on its historical percentages of its patient demographics.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

- (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, ... persons [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

#### NA-All Applications

None of the applications 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.

#### CA-All Applications

### **B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

In Section E, pages 67-68, 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
- Acquire a Fixed MRI Scanner for an Alternative EmergeOrtho Location in Buncombe County

The applicant currently operates four physician offices in Buncombe County; however only one office currently offers MRI services. The applicant states that the alternatives considered would not be a cost-effective alternative or a long term solution for the following reasons:

- High volume performed on the existing MRI scanner due to patients routinely referred by physicians located at the other EmergeOrtho offices.
- Location of the equipment is inconvenient for patients and staff.
- Patient transport time to the current MRI scanner detracts from productivity.
- Vendor-owned MRI scanner includes the vendor's corporate expenses which can be provided by EmergeOrtho.
- Alternative EmergeOrtho office locations lack sufficient facility space to be an effective location for the proposed fixed MRI scanner and implementing MRI services at one of these locations will disrupt current office visits.

On page 68, the applicant states that its proposal is the most effective alternative because:

- The proposed project will respond to the high utilization and increased demand of the existing MRI scanner.
- The proposed 1.5 T MRI scanner will allow a greater number of MRI procedures in 30-minute slots and provide a broad array of MRI procedures.
- The proposed project is more cost-effective because it will improve MRI scheduling and increase productivity with faster image acquisition.

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 proposed fixed MRI scanner will address the issue of high utilization and increased demand of its existing MRI scanner.
- The proposed fixed MRI scanner will be increase productivity and provide a broader array of MRI procedures.
- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

### **B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

In Section E, pages 69-75, 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:

Continue Mobile MRI Service-The applicant states that services provided by an existing contracted mobile MRI service are limited:

- Cancellation of mobile services due to inclement weather
- Unable to utilize mobile MRI service for patients with additional medical equipment due to space constraints
- The proposed 3.0T MRI unit offers greater detail in the imaging studies as opposed the older mobile 1.5T MRI unit.

Develop a New Facility in the Service Area-The applicant states that this alternative was considered however it would not be feasible because of the higher development and annual operating costs and the limited accessibility in the service area as opposed to the existing Open MRI in Asheville.

Facility Relocation or New Facility within Buncombe County-The applicant states that the relocation of the entire facility to the southern portion of Buncombe County would not only increase the cost of the proposed project due to additional construction requirements, it would increase travel hardships and accessibility issues for patients from Madison, Yancey, Haywood, McDowell, and Jackson Counties, which represent 19.5% of Open MRI's patient origin. The applicant states that the development of a satellite facility would result in higher annual operating costs and cause a delay in availability of services.

Acquire an Open MRI Unit or 1.5T MRI Scanner-The applicant states that acquiring a 1.5T or 1.2T MRI scanner would not be effective alternatives because these models lack advanced imaging capabilities causing longer scan times or resulting in patient cancellations due to claustrophobia or other discomforts.

On pages 75-76, the applicant states that its proposal is the most effective alternative because the proposed 3T MRI scanner provides enhanced imaging quality, faster scanning times, and the location of the scanner will meet the needs of service area residents by providing a full spectrum of healthcare services to its patients.

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

- Meets the need of patients in the service area by providing enhanced imaging at a convenient location, at a cost that will not impact patient charges.
- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

**B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

In Section E, pages 78-79, 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 Status Quo**-The applicant states that maintaining the status quo would not address the issues related to the growing demand for affordable outpatient MRI's.

**Placing a New MRI at Mission Imaging-Asheland**-The applicant states that it considered placing the new MRI in the same location as the current free-standing MRIs located at Mission Imaging Services -Asheland; however, it would not satisfy the applicant's desire to co-locate MRI services adjacent to the Mission Breast Center allowing immediate access for high risk patients. In addition, this was not a cost-effective alternative since the facility would require expansion to accommodate the new MRI.

**Placing a new MRI within Mission Hospital**-The applicant states that this alternative would not be the most cost-effective since it would require larger and more costly renovations due to the constraints of existing building infrastructure.

On pages 78-79, the applicant states that its proposal is the most effective alternative because:

- The facility is conveniently located adjacent to the Mission Breast Center.
- The facility is an existing Independent Diagnostic Testing Facility (IDTF) equipped with a waiting area, office staffing, radiologists and other support staff and space to accommodate additional equipment.
- The proposed project will not require new construction because the facility has ample space to accommodate an MRI and associated support functions.

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 applicant is proposing the most effective alternative because the proposed fixed MRI scanner will be located in an existing facility adjacent to the Mission Breast Center. The project will require minimal renovation and provide access to women's imaging services in one convenient location.
- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.

- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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  
All Applications

### **B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

### **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>EmergeOrtho Blue Ridge Division Capital Costs</b>	
Construction/Renovation Contract(s)	\$971,000
Architecture/Engineering Fees	\$97,000
Medical Equipment	\$1,498,000
Other (construction, testing fees and contingency)	\$200,000
<b>Total Capital Costs</b>	<b>\$2,766,000</b>

In Exhibits F.1 and K.2, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides documentation of an MRI equipment quote.

- The applicant provides documentation of a construction quote, which includes construction related costs, architecture and engineering fees, and contingency.

In Section F, pages 72-73, the applicant projects that start-up costs will be \$5,000 for a total working capital of \$5,000. There will be no Initial operating costs. On page 72, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions that the existing EmergOrtho office is currently providing services and needs minimal start-up costs.

**Availability of Funds**

In Section F, page 70, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Sources of Capital Cost Financing</b>		
<b>Type</b>	<b>EmergOrtho, PA</b>	<b>Total</b>
Loans	\$2,766,000	\$2,766,000
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$2,766,000</b>	<b>\$2,766,000</b>

\* OE = Owner's Equity

In Section F, page 73, 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>
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$5,000
Lines of credit	\$0
Bonds	\$0
<b>Total</b>	<b>\$5,000</b>

Exhibit F.2 contains a letter dated February 5, 2021, from the Senior Vice President of First Citizens Bank, stating their willingness to discuss their interest in and the financial needs of the proposed project. Exhibit F.3 also contains a letter from the Chief Executive Officer for EmergOrtho, PA, stating the availability of cash to fund the working capital of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the 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 Form F.2b, the applicant projects that

revenues will exceed operating expenses in the first three full fiscal years year following completion of the project, as shown in the table below.

<b>EmergoOrtho MRI Only</b>	<b>1<sup>st</sup> FFY CY 2023</b>	<b>2<sup>nd</sup> FFY CY 2024</b>	<b>3<sup>rd</sup> FFY CY 2025</b>
Total Procedures*	4,199	4,722	5,267
Total Gross Revenues (Charges)	\$4,660,465	\$5,241,345	\$5,845,911
Total Net Revenue	\$1,649,805	\$1,855,436	\$2,069,452
Average Net Revenue per Procedure*	\$392.90	\$392.93	\$392.91
Total Operating Expenses (Costs)	\$1,072,444	\$1,227,208	\$1,253,600
Average Operating Expense per Procedure*	\$255.40	\$259.89	\$238.01
<b>Net Income</b>	<b>\$577,361</b>	<b>\$596,608</b>	<b>\$783,600</b>

\*Unweighted procedures

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant’s assumptions are based on its projected MRI volumes and charges per scan, projected revenue by payor source, and adjustments (charity care, bad debts, contractual) to revenue.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.



**B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

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

<b>Open MRI &amp; Imaging of Asheville Capital Costs</b>	
Construction/Renovation Contract(s)	\$332,500
Architecture/Engineering Fees	\$63,000
Medical Equipment	\$1,695,000
Non-Medical Equipment	\$5,000
Consulting Fees	\$63,000
Other	\$39,000
<b>Total Capital Costs</b>	<b>\$2,197,500</b>

In Exhibit F.1, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions.

In Section F, page 79, the applicant states that there will be no start-up or initial operating costs associated with this project.

**Availability of Funds**

In Section F, page 77, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Sources of Capital Cost Financing</b>			
Type	Asheville Open MRI, LLC	Novant Health, Inc	Total
Loans	\$0	\$0	\$0
Accumulated reserves or OE *	\$0	\$2,197,500	\$2,197,500
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
<b>Total Financing</b>	<b>\$0</b>	<b>\$2,197,500</b>	<b>\$2,197,500</b>

\* OE = Owner's Equity

In Exhibit F.2, the applicant provides a letter from the senior vice-president of Operational Finance and Revenue Cycle for Novant Health, Inc., stating their commitment of accumulated reserves to fund the project. Exhibit F.2 also contains financial statements for Novant Health for year ending December 2019. Novant Health had over \$400 million in cash and cash equivalents and over \$1.5 billion in total current assets to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the needs of the 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 Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

<b>Open MRI &amp; Imaging of Asheville-MRI Services</b>	<b>1<sup>st</sup> FFY FY 2023</b>	<b>2<sup>nd</sup> FFY FY 2024</b>	<b>3<sup>rd</sup> FFY FY 2025</b>
Total Procedures	13,479	13,727	13,980
Total Gross Revenues (Charges)	\$29,165,060	\$29,701,668	\$30,249,094
Total Net Revenue	\$6,982,582	\$7,111,055	\$7,242,117
Average Net Revenue per Procedure	\$518	\$518	\$518
Total Operating Expenses (Costs)	\$3,702,246	\$3,868,688	\$3,940,243
Average Operating Expense per Procedure	\$275	\$282	\$282
Net Income	\$3,280,336	\$3,242,366	\$3,301,874

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Percentage allocation for each payor mix was based on historical payor mix for the entire facility.
- Deductions from revenue for each payor group are based on the difference between the current reimbursement rates by modality.
- Net patient revenue for MRI services is based on MRI utilization multiplied by the average charge for MRI services.
- Operating expenses are based on fiscal year 7/1/2020 actual expenses increased by the appropriate inflation percentage annually.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.

**B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

**Capital and Working Capital Costs**

In Section Q, page 124, the applicant projects the total capital cost of the project, as shown in the table below.

<b>Mission Imaging Services Asheville (Biltmore) Capital Costs</b>	
Construction/Renovation Contract(s)	\$810,000
Architecture/Engineering Fees	\$84,000
Medical Equipment	\$1,429,674
Non-Medical Equipment	\$93,304
Furniture	\$2,140
Consulting Fees (CON prep)	\$5,000
Other (contingency, miscellaneous)	\$79,000
<b>Total Capital Costs</b>	<b>\$2,503,118</b>

In Section Q, page 124, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit F-1.1, the applicant provides the architect's certification of the projected capital cost.
- In Exhibit F-1.2, the applicant provides a manufacturer quote for the proposed 1.5T MRI scanner.
- The applicant's estimated costs for non-medical equipment and furniture are based on items such as MRI safe ladder, extinguisher and injector and side chairs.

In Section F, page 82, the applicant states that there will be no start-up or initial operating costs for the following reasons:

- The applicant currently provides MRI services at its other facilities and Mission Imaging Services Asheville is an existing diagnostic facility that has trained staff available for start-up.
- Revenues will exceed expenses from day one of the proposed project because Mission Imaging Services Asheville is a fully functioning, existing diagnostic center.

**Availability of Funds**

In Section F, page 80, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	MH Mission Imaging, LLLP	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Funding from Parent Company via Inter-Company Loan)	\$2,503,117.52	\$2,503,117.52
<b>Total Financing</b>	<b>\$0</b>	<b>\$0</b>

\* OE = Owner's Equity

In Exhibit F-2.1, the applicant provides a letter from the chief financial officer of the North Carolina Division for HCA Healthcare, Inc., stating their commitment to fund the project through an interest-free inter-company loan. The letter states that for the twelve months ended December 31, 2019, HCA generated \$7.602 billion of cash flow from operating activities.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the 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 Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

MH Mission Imaging-Biltmore	1 <sup>st</sup> FFY CY 2023	2 <sup>nd</sup> FFY CY 2024	3 <sup>rd</sup> FFY CY 2025
Total Procedures*	46,232	47,926	49,686
Total Gross Revenues (Charges)	\$21,424,819	\$23,128,377	\$24,939,002
Total Net Revenue	\$6,195,351	\$6,696,048	\$7,230,101
Average Net Revenue per Procedure	\$134.01	\$139.72	\$145.52
Total Operating Expenses (Costs)	\$3,801,857	\$3,874,918	\$3,949,897
Average Operating Expense per Procedure	\$82.23	\$80.85	\$79.50
Net Income	\$2,393,494	\$2,821,130	\$3,280,204

\*Total Procedures include CT, x-ray, proposed MRI, ultrasound, and DEXA

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 127. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Revenue is based on historical reimbursement per modality that currently exists at Mission Imaging-Biltmore for each payor class multiplied by the partial fiscal year (4/1/22-12/31/22) volume then multiplied by volume projected in fiscal years 1-3; adding reimbursement per MRI that currently exist at Mission Imaging-Asheland multiplied by MRI volume project at Mission Imaging for partial fiscal year going forward.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - 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 revenues and operating expenses for all the reasons described above.
- (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 2021 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.*” There are licensed acute care hospitals located in Buncombe County, however there are no licensed acute care hospitals in Graham, Madison and Yancey counties; Therefore, for the purpose of this review, the fixed MRI service area is a multicounty service area; Buncombe, Graham, Madison and Yancey counties. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in Buncombe/Graham/Madison/Yancey service area, summarized from Table 17E-1 of 2021 SMFP.

<b>Fixed MRI Scanners in Buncombe/Graham/Madison/Yancey Service Area</b>			
<b>Provider</b>	<b># of Fixed MRI Scanners</b>	<b>Total MRI Scans</b>	<b>Adjusted Total</b>
Mission Children’s	1	1,572	1,908
Mission Hospital-Carolina and Spine Neurosurgery	1	2,768	3,258
Mission Hospital-Main	2	7,920	12,213
Mission hospital-St. Joseph Campus	1	1,176	1,797
EmergeOrtho Blue Ridge Division (Insight Imaging)	1	2,900	2,919
Mission Imaging Services (MH Mission Imaging, LLLP)			
Mission Imaging-Asheland	2	11,342	13,822
Open MRI of Asheville (Asheville Open MRI, LLC)	2	11,174	12,370

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

In Section G, page 81, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the Buncombe /Graham/Madison/Yancey counties’ service area. The applicant states:

*“The EmergeOrtho proposal does not propose to acquire and operate more fixed MRI scanners that are determined be needed in the 2021 SMFP. During the previous year, EmergeOrtho physicians, physician assistants and nurse practitioners with the Blue Ridge Division ordered a total 7,200 MRI procedures.*

...

*...EmergeOrtho projects to perform more than 4,805 weighted MRI scans based on reasonable and conservative assumptions.”*

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 2021 SMFP for the proposed fixed MRI scanner in the Buncombe /Graham/Madison/Yancey counties’ service area.
- The applicant adequately demonstrates the high volume of EmergeOrtho orders for MRI scans to be performed at other facilities is due to the limitations of its existing vendor-owned fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

### **B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

In Section G, page 85, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the Buncombe /Graham/Madison/Yancey counties’ service area. The applicant states:

*“The existing two MRI units performed 12,318 weighted procedures in the last year which indicates a need for 2.6 MRI scanners ( $12,318/4,805 = 2.6$ ) ...Patients and their physicians select Open MRI based on the exceptional quality care, knowledgeable staff and the expertise of its medical team. The ability to improve accessibility at Open MRI for its patients will not result in an unnecessary duplication of MRI services in the service area.”*

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 2021 SMFP for the proposed fixed MRI scanner in the Buncombe /Graham/Madison/Yancey counties' service area.
- The proposal will address the existing high demand at Open MRI.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

### **B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

In Section G, page 89, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Buncombe /Graham/Madison/Yancey County service area. The applicant states:

*“MH Mission Imaging, LLLP is basing its projected utilization for the new MRI on utilization experience at its existing Mission Imaging-Asheland location and its existing market share percentages. MH Mission Imaging is not anticipating or projecting additional market share capture as part of this proposal beyond serving those requiring breast MRIs, which no other provider in the region is equipped to provide.”*

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 2021 SMFP for the proposed fixed MRI scanner.
- The current utilization and historic growth of MRI scans warrants the need for access to additional MRI services.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners.



**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described 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.

C  
All Applications

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

In Section Q, Form H.1b, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 2/10/2021	2nd Full Fiscal Year CY 2024
Clerical	0.5	2.0
Patient Transport	0.0	2.0
MRI Technologists	0.0	2.0
<b>TOTAL</b>	<b>0.5</b>	<b>6.0</b>

The assumptions and methodology used to project staffing are provided in Section H, page 83. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 83-84, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately demonstrates its methods to recruit staff, which includes recruitment through facility website, online employment site, advertisement in journals, and contacting clinical training programs.
- As an existing provider of MRI services, the applicant has existing training and continued education programs in place and provides supporting documentation in Exhibit H.3.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

**B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

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.

Position	Current FTE Staff	Projected FTE Staff
	As of 12/31/2020	2nd Full Fiscal Year FY 2024
Radiology Technologists	6.5	7.5
Tech Assistants	2.0	3.0
Administrator/CEO	1.0	1.0
Marketer	1.4	1.4
Clerical	9.0	10.0
<b>TOTAL*</b>	<b>20.0</b>	<b>23.0</b>

Totals may not foot due to rounding

The assumptions and methodology used to project staffing are provided in Section H. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 87-88, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant has access to Novant Health’s existing corporate and regional human resources personnel for purposes of recruiting staff.
- Novant Health’s existing corporate employee education department offers classes such as computer skills, Basic and Advanced Cardiac Life Support, clinical orientation and other continuing education programs.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

**B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

In Section Q, page 130, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 2/12/2021	2nd Full Fiscal Year CY 2024
Registered Nurses	0.50	0.50
Radiology Technologists	12.74	17.24
Administrator/ CEO (supervisor)	1.00	1.00
Other (Paramedics)	2.00	2.00
<b>Total</b>	<b>16.00 [16.24]</b>	<b>21.00 [21.24]</b>

Note: The Project Analyst’s corrections are in brackets.

The assumptions and methodology used to project staffing are provided in Section O, page 130. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3a. In Section H, pages 91-92, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant assumes a 2 percent annual salary increase due to inflation.
- The applicant assumes a staff increase of 4.5 MRI radiologic technicians beginning the first year operation to fulfill hours of operation.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described 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  
All Applications

### **B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

### **Ancillary and Support Services**

In Section I, page 85, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 85-86, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant is an existing provider of MRI services with ancillary and support services in place.
- The applicant provides letters from those that currently provide the radiology professional services, stating their willingness to continue providing these services.

### **Coordination**

In Section I, page 87, the applicant describes its existing and proposed 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 based on the following:

- The applicant is part of the medical staff at HCA Mission Hospital, Adventist Park Ridge, and Pardee Hospital.
- EmergeOrtho Blue Ridge Division has multiple offices in Western North Carolina.
- The applicant has an existing referral relationship with Western Carolina Medical Society Project Access.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

### **B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

In Section I, page 90, the applicant identifies the necessary ancillary and support services for the proposed services. On page 90, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on Open MRI being a well-established diagnostic imaging center with long-standing ancillary and support services in place.

### **Coordination**

In Section I, page 91, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit C.4. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- Open MRI has established a substantial physician referral base consisting of 1,700 physician providers.

- Open MRI works with Western North Carolina Community Health Services (WNCCHS) providing healthcare services to low income, indigent and uninsured patients in the service area.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

### **B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

### **Ancillary and Support Services**

In Section I, page 93, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 93-94, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the facility's shared service agreement with Mission Hospital to provide all services necessary to operate and maintain the facility and patient services. Other services, such as housekeeping and waste management, are provided through independent contractors.

### **Coordination**

In Section I, page 94, the applicant describes its existing 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 based on the following:

- Hospitals in the region refer patients to Mission Imaging based on its affiliation with Mission Hospital.
- The facility's shared service agreement with Mission Hospital to provide all services necessary to operate and maintain the facility and patient services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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  
All Applications

None of the applicants 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, none of the applicants 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  
All Applications

None of the applicants are 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  
All Applications

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

In Section K, page 90, the applicant states that the project involves constructing 1,368 square feet of new space. Line drawings are provided in Exhibit K.1.

On pages 90-91, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that the installation of the proposed fixed MRI scanner will be planned and directed by an experienced architect and construction professionals.
- The construction involves limited renovation with low risk for escalated costs.

On page 91, 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 based on the following:

- The convenient location of the proposed mixed MRI scanner will increase productivity, allowing the facility to maintain operating costs.
- Freestanding MRI service charges are less than those from a hospital-based MRI scanner.

On pages 91-92, 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
- Written comments
- Responses to comments



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

### **B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

In Section K, page 95, the applicant states that the project involves renovating 1,800 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 95, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the estimated renovation costs from the applicant's architect that were based on their experience, current market conditions, inflation factors and contingency dollars.

On page 96, 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 based on the applicant's proposal to place the fixed MRI scanner in an existing space in Open MRI's facility as opposed to constructing new space at a higher cost.

On page 96, 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
- Written comments
- Responses to comments

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

### **B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

In Section K, page 97, the applicant states that the project involves renovating 1,188 square feet of existing space. Line drawings are provided in Exhibit K-1.1.

On page 97, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The project involves interior renovations as opposed to the more costly construction of exterior additions.
- The applicant's proposal will represent the most reasonable alternative because of its efforts to minimize the square footage of renovation and avoid costly relocation of existing occupied spaces and existing building infrastructure systems.

On page 98, 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 based on the following:

- The applicant states that charges to the public are based on historic charges for MRI services at MH Mission Imaging, LLLP (Asheland) and not on the cost of the project.
- The applicant will continue to accept reasonable and customary payment for services from governmental and commercial payors. The applicant states that these rates are negotiated without consideration of cost of the project.

On page 98, 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
- Written comments
- Responses to comments

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

- (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 ... persons [with disabilities], 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;

C  
All Applications

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

In Section L, page 94, the applicant provides the historical payor mix during fiscal year 2020 (10/1/2019-9/30/2020) for the proposed services, as shown in the table below.

<b>EmergeOrtho Blue Ridge Division (Vendor-Owned MRI) Historical Payor Mix, FY 2020</b>	
<b>Payor Category</b>	<b>MRI Services as Percent of Total</b>
Self-Pay	0.8%
Charity Care	0.0%
Medicare*	38.5%
Medicaid*	1.5%
Insurance*	52.8%
Workers Compensation	4.8%
TRICARE	1.5%
<b>Total</b>	<b>100.0%</b>

\*Including any manage care plans.

In Section L, page 95, the applicant provides the following comparison for 10/1/2019-9/30/2020:

<b>EmergeOrtho MRI service</b>	<b>Percentage of Total Patients Served</b>	<b>Percentage of the Population of the Service Area*</b>
Female	55.4%	51.9%
Male	44.6%	48.1%
Unknown	0.0%	0.0%
64 and Younger	56.4%	78.8%
65 and Older	43.6%	21.1%
American Indian	0.0%	0.7%
Asian	0.4%	1.2%
Black or African-American	3.5%	5.5%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	89.0%	90.3%
Other Race	1.5%	2.1%
Declined / Unavailable	5.6%	0.0%

\*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>.

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

**B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

In Section L, page 98, the applicant provides the historical payor mix during CY 2020 for the proposed services, as shown in the table below.

<b>Open MRI &amp; Imaging of Asheville Historical Payor Mix, CY 2020</b>	
<b>Payor Category</b>	<b>MRI Services as Percent of Total</b>
Self-Pay	4.38%
Charity Care	0.08%
Medicare*	43.2%
Medicaid*	3.37%
Insurance*	42.01%
Workers Compensation	5.61%
TRICARE	1.35%
<b>Total</b>	<b>100.00%</b>

\*Including any managed care plans

In Section L, page 99, the applicant provides the following comparison.

<b>Own MRI &amp; Imaging of Asheville</b>	<b>Percentage of Total Patients Served</b>	<b>Percentage of the Population of the Service Area*</b>
Female	58.80%	52.1%
Male	41.04%	47.9%
Unknown	0.16%	0.0%
64 and Younger	62.20%	79.5%
65 and Older	37.80%	20.5%
American Indian	0.05%	0.5%
Asian	0.12%	1.4%
Black or African-American	0.71%	6.3%
Native Hawaiian or Pacific Islander	0.02%	0.2%
White or Caucasian	17.67%	83.4%
Other Race	0.29%	6.8%
Declined / Unavailable	81.14%^	1.4%

\*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>.

^Open MRI does not require patients to identify their racial background or ethnicity

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

**B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

In Section L, page 100, the applicant provides the historical payor mix during CY 2020 for Mission Imaging-Asheland, as shown in the table below.

<b>Mission Imaging-Asheland<sup>^</sup> Historical Payor Mix, CY 2020</b>	
<b>Payor Category</b>	<b>MRI Services as Percent of Total</b>
Self-Pay	1.2%
Charity Care	1.7%
Medicare*	42.4%
Medicaid*	5.0%
Insurance*	46.2%
Workers Compensation	0.7%
TRICARE	0.6%
Other (federal & state)	2.2%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

<sup>^</sup>To demonstrate historical payor mix for MRI services, the applicant provides historical payor mix for the two MRI scanners located at Mission Imaging-Asheland. Mission Imaging-Biltmore does not currently provide MRI services.

In Section L, page 102, the applicant provides the following comparison.

<b>Mission Imaging- Biltmore</b>	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY</b>	<b>Percentage of the Population of the Service Area</b>
Female	62.35%	51.31%
Male	37.64%	48.69%
Unknown	0.01%	0.00%
64 and Younger	48.47%	76.72%
65 and Older	51.53%	23.28%
American Indian	0.44%	1.33%
Asian	0.74%	1.26%
Black or African- American	4.30%	4.40%
Native Hawaiian or Pacific Islander	0.00%	0.12%
White or Caucasian	91.80%	87.59%
Other Race	2.72%	5.31%
Declined / Unavailable	0.00%	0.00%

\*The percentages can be found online using the United States Census Bureau's QuickFacts which is at:  
<https://www.census.gov/quickfacts/fact/table/US/PST045218>.

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

- (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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

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 All Applications

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 96, the applicant states:

*“EmergeOrtho has no requirements to provide uncompensated care, community service, or access by minorities and persons with disabilities.”*

In Section L, page 96, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

### **B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

In Section L, page 100, the applicant states that there is no federal obligation to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 100, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments



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

**B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 103, the applicant states:

*“MH Mission Imaging, LLP, a freestanding diagnostic center, is not under a federal obligation to provide uncompensated care. However, the HCA Mission Health System has several policies relating to financial assistance, including a Charity Financial Assistance Policy for Uninsured and underinsured...”*

In Section L, page 104, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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

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All Applications

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

In Section L, page 97, 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>EmergeOrtho Blue Ridge Division Projected Payor Mix, CY 2025</b>	
<b>Payor Category</b>	<b>MRI Services as Percent of Total</b>
Self-Pay	0.8%
Charity Care	1.5%
Medicare*	40.0%
Medicaid*	3.0%
Insurance*	48.4%
Workers Compensation	4.8%
TRICARE	1.5%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.8% of total services will be provided to self-pay patients, 1.5% to charity care patients, 40.0% to Medicare patients and 3.0% to Medicaid patients.

On pages 97-98, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant's commitment to increase referrals and improve access to medically indigent patients and low-income Medicaid patients.
- The applicant's projected payor percentage increase in Medicare is based on the assumption that the 65+ population will increase due to disease rates, injuries and health conditions.
- The applicant's projected payor percentage decrease in insurance is based on projected increase in Medicare, charity care and Medicaid patients.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

### **B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

In Section L, page 101, 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>Open MRI &amp; Imaging of Asheville Projected Payor Mix, FY 2025</b>	
<b>Payor Category</b>	<b>MRI Services as Percent of Total</b>
Self-Pay	3.98%
Charity Care	1.00%
Medicare*	43.08%
Medicaid*	3.56%
Insurance	41.05%
Worker's Compensation	5.88%
TRICARE	1.45%
<b>Total</b>	<b>100.00%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.98% of total MRI services will be provided to self-pay patients, 1.00% to charity care patients, 43.08% to Medicare patients and 3.56% to Medicaid patients.

On page 101, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- Projected payor mix is based the historical payor for each category percentage for the MRI service component at Open MRI.
- The applicant assumes an increase is charity care patients and a decrease in commercial insurance patients due to COVID-19 pandemic's impact on the economy in the service area.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

**B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

In Section L, page 105, 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>Mission Imaging-Biltmore MRI Services Projected Payor Mix, CY 2025</b>	
<b>Payor Category</b>	<b>MRI Services as Percent of Total</b>
Self-Pay	1.2%
Charity Care	1.7%
Medicare*	42.4%
Medicaid*	5.0%
Insurance*	46.2%
Worker's Compensation	0.7%
TRICARE	0.6%
Other (federal & state)	2.2%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.2% of total services will be provided to self-pay patients, 1.7% to charity care patients, 42.4% to Medicare patients and 5.0% to Medicaid patients.

On page 105, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported. The applicant projects payor mix based on historical payor mix at Mission Imaging-Asheland where the applicant currently operates two MRI scanners.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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  
All Applications

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

In Section L, pages 99-101, 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
- Written comments
- Responses to comments

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

**B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

In Section L, page 104, 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
- Written comments
- Responses to comments

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

**B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

In Section L, page 106, 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
- Written comments
- Responses to comments

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

All Applications

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

In Section M, page 102, 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-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the applicant's plan to have a clinical training affiliation agreement with Asheville-Buncombe Community College and Southwestern Community College.

**Conclusion**

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Responses to comments

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

### **B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

In Section M, page 105, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- Novant Health, Inc., parent company Asheville Open MRI, LLC, has established clinical education agreements with health education programs in the market area that include Open MRI.
- Open MRI states it will continue to provide health professional learning opportunities from a variety of schools.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

### **B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

In Section M, page 108, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant's support of their residency programs through its affiliation with the Mountain Area Health Education Centers (MAHEC).
- As part of their training, residents and fellows have the ability to refer patients to the facility for MRI scans which enhances their educational experience.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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.



The 2021 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.*” There are licensed acute care hospitals located in Buncombe County, however there are no licensed acute care hospitals in Graham, Madison and Yancey counties. Therefore, for the purpose of this review, the fixed MRI service area is a multicounty service area: Buncombe, Graham, Madison and Yancey counties. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in Buncombe/Graham/Madison/Yancey service area, summarized from Table 17E-1 of the 2021 SMFP.

<b>Fixed MRI Scanners in Buncombe/Graham/Madison/Yancey Service Area</b>			
<b>Provider</b>	<b># of Fixed MRI Scanners</b>	<b>Total MRI Scans</b>	<b>Adjusted Total</b>
Mission Children’s	1	1,572	1,908
Mission Hospital-Carolina Spine & Neurosurgery	1	2,768	3,258
Mission Hospital-Main	2	7,920	12,213
Mission hospital-St. Joseph Campus	1	1,176	1,797
EmergeOrtho Blue Ridge Division (Insight Imaging)	1	2,900	2,919
Mission Imaging Services (MH Mission Imaging, LLLP)			
Mission Imaging-Asheland	2	11,342	13,822
Open MRI of Asheville (Asheville Open MRI, LLC)	2	11,174	12,370

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 103, the applicant states:

*“The proposed fixed MRI scanner will promote positive competition by offering patients a new alternative provider for a fixed MRI. Approval of the proposed fixed MRI scanner will enable EmergeOrtho to provide more cost effective and patient-friendly MRI capacity to respond to the increased demand and provide timely diagnostic services to patients. The fixed MRI scanner will enable EmergeOrtho to more effectively compete in terms of enhancing patient convenience, expanding access to cost effective MRI service with lower out-of-pocket costs and while increasing access to advanced diagnostic imaging capabilities for patients with special needs.*”

...

*The majority of MRI capacity is owned by HCA Mission with five hospital-based fixed MRIs and two MRIs that are in freestanding imaging locations...hospital-based MRI scanners generally have higher charges as compared to the freestanding MRI.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 104, the applicant states:

*“Staffing and scheduling for higher productivity can be realized through improved patient flow that provides greater capacity and flexibility. Having the fixed MRI scanner within the facility allows for EmergeOrtho to control the schedule, staff and entire patient experience. The proposed new fixed MRI has faster image acquisition that combined with the shorter transport distance within the interior of EmergeOrtho will enable the staff to schedule more patients in 30-minute time slots and increase the MRI throughput.*

...

*Boosting the overall productivity of the MRI service at EmergeOrtho will be highly effective to hold down operating costs that will more than offset the depreciation costs that come with the renovation and new equipment.”*

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 105, the applicant states:

*“EmergeOrtho’s proposal to acquire a fixed MRI scanner will promote quality because the MRI scanner will be installed and operated in accordance with the manufacturer’s requirements and in accordance with applicable local, state and federal requirements. The EmergeOrtho MRI scanner will obtain accreditation by the American College of Radiology (ACR). The applicant has an existing quality improvement program for its mobile MRI scanner and its fixed MRI scanners located other service areas.”*

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 105, the applicant states:

*“EmergeOrtho will expand access for the medically underserved by providing MRI procedures to patients who are indigent, uninsured, underinsured, or are otherwise medically underserved. It has always been EmergeOrtho’s policy-and will continue to be-that we do not discriminate or restrict access to services on the basis of age, race, color, ethnicity, religion, sex, disability, or ability to pay.”*

See also Sections L and C of the application and any exhibits.

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, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

### **B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 106, the applicant states:

*“The additional MRI capacity at Open MRI will provide the facility with improved accessibility for patients in need of imaging services. The availability of a 3T MRI scanner in a convenient and affordable outpatient setting committed to provide patients with the highest clinical quality of care will set a standard in the service area for other providers to model.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 106, the applicant states:

*“Open MRI avoids duplicating unnecessary costs by centralizing all services at its existing facility. The result is staffing and operational efficiencies that allow Open MRI to keep patient charges low.”*

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 106, the applicant states:

*“Open MRI adheres to all applicable Novant Health quality and safety policies.*

...

*Open MRI employs all of Novant Health policies applicable to MRI service related to quality of care.”*

See also Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 107, the applicant states:

*“Open MRI will continue to provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin or ability to pay. Based on historical data, Open MRI currently provides a substantial amount of service to the medically underserved groups.”*

See also Section B, C and L of the application and any exhibits.

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, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

**B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 110, the applicant states:

*“Mission is not projecting any additional market share capture beyond the share gained via the projected growth of the breast MRI volumes, for which Mission Imaging is the only provider of that service. Therefore, the non-Mission providers in the service area will maintain the growth and share of general MRI services.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 110, the applicant states:

*“...the additional MRI scanner will be placed in the existing Mission Imaging-Biltmore location, which is a registered IDTF. As such, reimbursement for services under Medicare typically is more affordable than those in a hospital setting. Placing the MRI at Mission Imaging-Biltmore is the most cost-effective option for patients, an increasing number of whom are self-pay, have high-deductible plans, or are covered under government payers Medicare and Medicaid.”*

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 111, the applicant states:

*“The addition of a new MRI at Mission Imaging-Biltmore is not intended to serve only women at risk for breast cancer... highly specialized radiologists and surgical specialists at Mission Health System are experiencing an increasing reliance on MRI as a tool to evaluate disease of prostate, liver, brain, and vascular system. MRI is used to plan surgical interventions and to measure effectiveness of various treatments. Adding an additional MRI to Mission Imaging-Biltmore, where these specialized physicians collaborate with physicians locally and across the region to provide treatment for patients with prostate, liver, brain, and vascular disease, will facilitate timely service and coordination of care.”*

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 112, the applicant states:

*“It will also ensure that residents of the health service area have timely access to high quality, affordable diagnostic imaging...Mission Imaging-Biltmore facility proposes to serve both Charity Care patients and patients who need services at reduced cost.”*

See also Section B, L and C of the application and any exhibits.

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, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described 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  
All Applications

**B-12023-21/ EmergeOrtho Blue Ridge Division/ Acquire one fixed MRI scanner**

**EmergeOrtho, P.A. [EmergeOrtho]** The applicant proposes to develop a diagnostic center, by acquiring one fixed MRI scanner pursuant to the need determination in the 2021 SMFP.

In Section Q, Form O, the applicant identifies diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of seven of this type of facility located in North Carolina.

In Section O, page 108, the applicant states that, during the 18 months immediately preceding the submittal of the application, all of the MRI scanners at its facilities have provided quality care during the 18 months immediately preceding the application. The applicant provides supporting documentation in Exhibit O.3. Exhibit O.3 contain letters from the Chief Executive Officer for EmergeOrtho Blue Ridge Division, stating that none of the EmergeOrtho MRI scanners or its facilities were found by the Division of Health Service Regulations or CMS to have any incidents resulting in a finding of immediate jeopardy during the 18-month look-back period. After reviewing and considering information provided by the applicant and considering the quality of care provided at all seven facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**B-12032-21/Open MRI & Imaging of Asheville/Acquire one fixed MRI scanner**

**Asheville Open MRI, LLC and Novant Health, Inc. [Open MRI]** The applicant proposes to acquire one fixed 3T MRI scanner pursuant to the need determination in the 2021 SMFP, for a total of three fixed MRI scanners.

In Section Q, Form O, the applicant identifies diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 32 of this type of facility located in North Carolina.

In Section O, page 110, the applicant states that all facilities identified have provided quality care during the previous 18 months and have maintained their American College of Radiology certifications. The applicant provides supporting documentation in Exhibit O.3. After reviewing and considering the quality of care provided at all 32 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**B-12035-21/ Mission Imaging Services Asheville/ Acquire one fixed MRI scanner**

**MH Mission Imaging, LLLP [MH Mission Imaging]** The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville (Mission Imaging-Biltmore) in Buncombe County.

In Section Q, page 131, the applicant identifies the diagnostic centers North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one diagnostic center located in North Carolina.

In Section O, page 114, the applicant states that, during the 18 months immediately preceding the submittal of the application, MH Mission Imaging, LLP has not been subject of any state or federal complaints, citations, finding of noncompliance or similar quality of care violations or complaints and has maintained ACR accreditation for all locations and equipment additions, as required by CMS for Medicare Reimbursement. The application provides supporting documentation on Exhibit O-3.3. After reviewing and considering information provided by the applicant, 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.

G.S. 131E-183(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-All Applications

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- All Applications-** None of the applicants 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;*

**-NA- EmergeOrtho, PA.** Neither EmergeOrtho nor any related entity owns a controlling interest in or has any existing fixed MRI scanners in the proposed MRI service area.

**-C- Asheville Open MRI, LLC.** The MRI service area is Buncombe, Graham, Madison and Yancey counties. In Section C, page 59, the applicant states that it owns and operates two fixed MRI scanners in the proposed service area, at its Open MRI & Imaging of Asheville facility. During the most recent 12-month period (January 1, 2020 – December 31, 2020) Open MRI performed 6,159 weighted MRI procedures per scanner which exceeds the required average of 3,328 weighted MRI procedures per scanner in this performance standard.

**-C- MH Mission Imaging, LLLP.** The MRI service area is Buncombe, Graham, Madison and Yancey counties. In Section C, page 46, the applicant states that it owns and operates seven fixed MRI scanners in the proposed service area at its five locations. During the most recent 12-month period (October 1, 2019 – September 30, 2020) an average of 3,961 weighted MRI procedures per scanner were performed 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- EmergeOrtho, PA.** Neither EmergeOrtho nor any related entity owns a controlling interest in and operates existing mobile MRI scanners in the proposed MRI service area.

**-NA- Asheville Open MRI, LLC.** Neither Asheville Open MRI, LLC nor any related entity owns a controlling interest in and operates existing mobile MRI scanners in the proposed MRI service area.

**-NA- MH Mission Imaging, LLLP.** Neither MH Mission Imaging, LLLP nor any related entity owns a controlling interest in and operates existing mobile MRI scanners in the proposed MRI service area.

(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 2021 SMFP shows that there are more than ten fixed MRI scanners located in the fixed MRI service area of Buncombe/Graham/Madison/Yancey counties. Therefore, each 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 Buncombe/Graham/Madison/Yancey counties will be at least 4,805 weighted MRI procedures in the third operating year.

**-C- EmergeOrtho, PA.** In Section Q the applicant states that it projects to perform 5,302 weighted MRI procedures on its proposed fixed MRI scanner during the third operating year (CY 2025) of the proposed project, which exceeds the required average of 4,805 weighted MRI procedures per scanner in this performance standard. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

**-C- Asheville Open MRI, LLC.** In Section Q the applicant states that it projects to perform 15,395 weighted MRI procedures on its existing (2) and proposed (1) MRI scanners during the third year (FY 2025) of the proposed project for an average of 5,132 weighted MRI scans per scanner [ $15,395 / 3 = 5,132$ ] which exceeds the required average of 4,805 weighted MRI procedures per scanner in this performance standard. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

**-C- MH Mission Imaging, LLLP.** In Section C, page 70 the applicant states that it projects to perform 39,144 weighted MRI procedures on its existing (7) and proposed (1) MRI scanners during the third year (CY 2025) of the proposed project for an average of 4,893 weighted MRI scans per scanner [ $39,144 / 8 = 4,893$ ] which exceeds the required average of 4,805 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;*
- NA- EmergeOrtho, PA.** Neither EmergeOrtho nor any related entity owns a controlling interest in existing or approved MRI scanners in the proposed MRI service area.
- NA- Asheville Open MRI, LLC.** The proposed MRI scanner will not be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity. The proposed MRI scanner will be located at Open MRI where there are two existing MRI scanners.
- C- MH Mission Imaging, LLLP.** 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 4,805 weighted MRI procedures in the third year following completion of the proposed project. In Section C, page 71, the applicant states that it projects to perform 5,934 weighted MRI procedures on its proposed fixed MRI scanner during the third year (CY 2025) of the proposed project which exceeds the requirement of 4,805 weighted MRI procedures per scanner in this performance standard. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.
- (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- EmergeOrtho, PA.** Neither EmergeOrtho nor any related entity owns a controlling interest in and operates existing, approved or proposed mobile MRI scanners in the MRI service area.

- NA- **Asheville Open MRI, LLC.** Neither Asheville Open MRI, LLC nor any related entity owns a controlling interest in and operates existing mobile MRI scanners in the proposed MRI service area.
- NA- **MH Mission Imaging, LLLP.** Neither MH Mission Imaging, LLLP nor any related entity owns a controlling interest in and operates existing mobile MRI scanners in the proposed MRI service area.
  - (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- C- **EmergeOrtho, PA.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- C- **Asheville Open MRI, LLC.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Sections C and Q.
- C- **MH Mission Imaging, LLLP.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Sections C and 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- **All Applications-** None of the applicants propose to acquire a fixed dedicated breast 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- **All Applications-** None of the applicants propose to acquire a 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- All Applications-** None of the applicants propose to acquire a fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.

## COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2021 State Medical Facilities Plan, no more than one fixed MRI scanner may be approved for Buncombe County in this review. Because the three applications in this review collectively propose to develop three additional fixed MRI scanners to be located in Buncombe County, all the applications cannot be approved for the total number of fixed MRI scanners proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review.

- **Project ID #B-12023-21/ EmergeOrtho Blue Ridge Division / (EmergeOrtho)** Acquire one fixed MRI Scanner to be located at EmergeOrtho Blue Ridge Division, an existing non-hospital licensed diagnostic center located at 2582 Hendersonville Road, Arden, Buncombe County. The applicant proposes to perform 5,302 total weighted MRI procedures on the proposed fixed MRI scanner from January 1, 2025–December 31, 2025, the third full year of operation following completion of the project.
- **Project ID #B-12032-21/ Open MRI and Imaging of Asheville / (Open MRI)** Acquire one fixed MRI Scanner to be located at Open MRI and Imaging of Asheville, an existing non-hospital licensed diagnostic center located at 675 Biltmore Avenue, Suite A, Asheville, Buncombe County. The applicant proposes to perform 5,132 total weighted MRI procedures on the proposed fixed MRI scanner from July 1, 2024–June 30, 2025, the third full year of operation following completion of the project.
- **Project ID #B-12035-21/ Mission Imaging Services Asheville / (MH Mission Imaging)** Acquire one fixed MRI Scanner to be located at Mission Imaging Services Asheville, an existing non-hospital licensed diagnostic center located at 535 Biltmore Avenue, Asheville, Buncombe County. The applicant proposes to perform 5,934 total weighted MRI procedures on the proposed fixed MRI scanner from January 1, 2025–December 31, 2025, the third full year of operation following completion of the project.

### **Conformity with Statutory and Regulatory Review Criteria**

The applications submitted by **EmergeOrtho**, **Open MRI**, and **MH Mission Imaging** are conforming with all applicable statutory and regulatory review criteria.

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. All applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, all applications are equally effective alternatives.

### **Scope of Services**

Generally, the application proposing to provide the broadest scope of services is the more effective alternative with regard to this comparative factor. With regard to scope of services, all applications submitted are in response to the 2021 State Medical Facilities Plan (SMFP) which includes a need determination for one fixed MRI scanner. All the applicants propose to acquire and operate a fixed MRI scanner in a freestanding outpatient setting. EmergeOrtho proposes to utilize its proposed fixed MRI for orthopedics, pain management, physical medicine and rehabilitation, sports medicine, and orthopedic urgent care. Open MRI proposes to utilize its proposed fixed MRI for a wide range of imaging, including, but not limited to Neurology, Ophthalmology, Podiatry, and Oncology. MH Mission Imaging proposes to utilize its fixed MRI for multiple types of scans, but will also provide breast MRI scans. Since MH Mission Imaging is the only applicant proposing to offer breast MRI scans, in addition to other types of scans, it will offer a broader scope of services. Thus, MH Mission Imaging is the more effective alternative for this comparative factor.

**Historical Utilization**

The following table illustrates historical utilization of each applicant as provided in the 2021 SMFP representing FY2019 reported utilization.

**Fixed MRI Scanners in Buncombe County  
 2021 SMFP Based on FY2019 Data**

Facility	# of Fixed MRI Scanners*	Weighted Procedures	Weighted MRI Procedures per Scanner
Mission Children's	1	1,908	1,908.0
Mission Hospital-Carolina Spine & Neurosurgery	1	3,258	3,258.0
Mission Hospital-Main	2	12,213	6,256.5
Mission Hospital-St. Joseph Campus	1	1,797	1,797.0
Mission Imaging Services (MH Mission Imaging LLLP) Asheland	2	13,822	6,911.0
<b>Mission System MRIs Total</b>	<b>7</b>	<b>32,998</b>	<b>4,714.0</b>
EmergeOrtho Blue Ridge Division (Insight Imaging)	1	2,919	2,919.0
Open MRI and Imaging of Asheville (Asheville Open MRI, LLC)	2	12,370	5,634.0
<b>Total</b>	<b>10</b>		

Source: 2021 SMFP, page 348

The following table illustrates historical utilization for each applicant over the most recent period, as reported in the 2021 SMFP.

Facility	# of Fixed MRI Scanners*	Weighted Procedures	Weighted MRI Procedures per Scanner
Mission System MRIs Total	7	32,998	4,714
EmergeOrtho Blue Ridge Division (Insight Imaging)	1	2,919	2,919
Open MRI and Imaging of Asheville (Asheville Open MRI, LLC)	2	12,370	5,634

Open MRI and Imaging of Asheville performed the highest number of weighted MRI procedures per fixed MRI scanner in FY 2019. Therefore, Open MRI and Imaging of Asheville is the most effective alternative for this comparative factor.

**Geographic Accessibility (Location within the Service Area)**

The 2021 SMFP identifies the need for one fixed MRI scanner in Buncombe, Graham, Madison, and Yancey counties’ service area. Buncombe County is the only county in the service area that has existing and approved fixed MRI scanners. The following table identifies the location of the existing and approved fixed MRI scanners in Buncombe County.

Facility	# of Fixed MRI Scanners*	Hospital-Based or Freestanding	Location
Mission Children’s	1	Hospital-Based	Asheville
Mission Hospital-Carolina Spine & Neurosurgery	1	Hospital-Based	Asheville
Mission Hospital-Main	2	Hospital-Based	Asheville
Mission Hospital-St. Joseph Campus	1	Hospital-Based	Asheville
EmergeOrtho Blue Ridge Division (Insight Imaging)	1	Freestanding	Arden
Mission Imaging Services (MH Mission Imaging LLLP) Asheland	2	Freestanding	Asheville
Open MRI and Imaging of Asheville (Asheville Open MRI, LLC)	2	Freestanding	Asheville
<b>Proposed MRI Scanners</b>			
<b>EmergeOrtho</b>	1	Freestanding	Arden
<b>Open MRI</b>	1	Freestanding	Asheville
<b>MH Mission Imaging</b>	1	Freestanding	Asheville

All but one of the existing fixed MRI scanners are located in Asheville in Buncombe County. One fixed MRI scanner is located in Arden. **EmergeOrtho** proposes to locate the MRI scanner in Arden. Arden is approximately 9.5 miles from Asheville. **Open MRI** and **MH Mission Imaging** propose to locate the MRI scanner in Asheville. Therefore, all of the applicants propose to locate a fixed MRI scanner in Buncombe County. The applications are equally effective.

**Access by Service Area Residents**

The 2021 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.*” There are licensed acute care hospitals located in Buncombe County, however there are no licensed acute care hospitals in Graham, Madison and Yancey counties; Therefore, for the purpose of this review, the fixed MRI service area is a multicounty service area: Buncombe, Graham, Madison and Yancey counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates access by service area residents during the third full fiscal year following project completion.



Total Number of Residents Projected to be Served in the Buncombe, Graham, Madison, and Yancey Counties Service Area, PY3				
Applicant	# of Fixed MRI Scanners at Site upon Project Completion	Number of Residents Served at Site	Number of Residents per Scanner	Residents Served as a % of Total
EmergeOrtho	1	2,290	2,290	43.4%
Open MRI	3	8,080	2,693	57.8%
MH Mission Imaging	1	3,061	3,061	68.6%

As shown in the table above, **MH Mission Imaging** is projected to serve the highest number and percentage of service area residents. Therefore, regarding projected service to residents of the service area, **MH Mission Imaging** is the most effective alternative.

### Access by Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

*“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 access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

### Projected Charity Care

Generally, the application proposing to provide the most charity care is the more effective alternative with regard to this comparative factor. However, charity care as a percentage of gross or net revenue was not provided by all of the applicants; therefore, charity care as a percentage of gross or net revenue cannot be compared. Charity care in dollar amounts for MRI services or for the entire facility was not consistent with all three applications. The differences in the types of facilities and the number and types services proposed by each of the facilities may impact the analysis. Thus, the result of this analysis is inconclusive.

### Projected Medicaid

The following table shows each applicant’s percentage of gross revenue projected to be provided to Medicaid patients in the applicant’s third full year of operation following completion of their projects, based on the information provided in the applicant’s pro forma financial statements in Section Q for total facility. Generally, the application proposing to provide a higher percentage of gross revenue to Medicaid patients is the more effective alternative with regard to this comparative factor. An analysis of percent of gross revenue to Medicaid patients for MRI services only could not be done because not all applicants provided pro formas for the MRI service only.

<b>Medicaid Project Year 3, Total Facility</b>			
	<b>Medicaid Gross Revenue</b>	<b>Total Gross Revenue</b>	<b>Medicaid % of Total Gross Revenue</b>
EmergoOrtho	\$263,829	\$8,794,301	3.0%
Open MRI	\$1,204,403	\$35,778,755	3.4%
MH Mission Imaging	\$1,256,319	\$24,939,002	5.0%

As shown in the table above, **MH Mission Imaging** projects the highest percentage of Medicaid dollars as a percent of gross revenue. However, the differences in the types of services in addition to the proposed MRI services provided by each of the facilities may impact the averages shown in the table above. **EmergoOrtho** operates a CT scanner and two x-ray machines at EmergoOrtho Blue Ridge in Arden. **Open MRI** operates two existing fixed MRI scanners and equipment to perform arthroscopic procedures at Open MRI & Imaging of Asheville. **MH Mission Imaging** operates two CT scanners, three x-ray machines, three ultrasound units, and DEXA equipment at Mission Imaging-Biltmore. Thus, the result of this analysis is inconclusive.

***Projected Medicare***

The following table shows each applicant’s percentage of gross revenue projected to be provided to Medicare patients in the applicant’s third full year of operation following completion of their projects, based on the information provided in the applicant’s pro forma financial statements in Section Q for total facility. Generally, the application proposing to provide a higher percentage of gross revenue to Medicare patients is the more effective alternative with regard to this comparative factor. An analysis of percent of gross revenue to Medicare patients for MRI services only could not be done because not all applicants provided pro formas for the MRI service only.

<b>Medicare Project Year 3, Total Facility</b>			
<b>Applicant</b>	<b>Medicare Gross Revenue</b>	<b>Total Gross Revenue</b>	<b>Medicare % of Total Gross Revenue</b>
EmergoOrtho	\$3,517,721	\$8,794,301	40.0%
Open MRI	\$15,456,994	\$35,778,755	43.2%
MH Mission Imaging	\$13,320,440	\$24,939,002	53.4%

As shown in the table above, **MH Mission Imaging** projects more than 50 percent of its gross revenue for imaging services will be provided to Medicare patients. However, the differences in the types of services in addition to MRI services provided by each of the facilities may impact the averages shown in the table above. **EmergoOrtho** operates a CT scanner and two x-ray machines at EmergoOrtho Blue Ridge in Arden. **Open MRI** operates two existing fixed MRI scanners and equipment to perform arthroscopic procedures at Open MRI & Imaging of Asheville. **MH Mission Imaging** operates two CT scanners, three x-ray machines, three ultrasound units, and DEXA equipment at Mission Imaging-Biltmore. Thus, the result of this analysis is inconclusive.

**Competition (Access to a New or Alternate Provider)**

Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. The introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, all applicants and/or related entities provide MRI services in the service area of Buncombe, Graham, Madison and Yancey counties; therefore, none of the applicants would qualify as a new or alternative provider in the service area. Thus, with regard to this comparative factor, the proposals are equally effective.

**Projected Average Net Revenue per MRI procedure**

The following table compares projected average net revenue per procedure in the third full fiscal year following project completion for each facility, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, the application proposing the lowest average net revenue per procedure is the more effective alternative with regard to this comparative factor to the extent the average could ultimately result in a lower cost to the patient or third-party payor. However, net revenue for MRI services only was not provided by all of the applicants in this review. Therefore, the net revenue for the entire facility, including MRI services, was compared.

<b>Average Net Revenue per MRI Procedure Project Year 3, Total Facility</b>				
<b>Applicant</b>	<b>Total # of Procedures</b>	<b># of Fixed MRI Scanners</b>	<b>Net Revenue (Entire Facility)</b>	<b>Average Net Revenue per Procedure</b>
EmergeOrtho	5,267	1	\$3,113,183	\$591.07
Open MRI	13,980	3	\$8,566,010	\$612.73
MH Mission Imaging	4,467	1	\$7,230,101	\$1,618.56

As shown in the table above, **EmergeOrtho**, projects the lowest average net revenue per MRI procedure in the third full fiscal year following project completion. However, a larger scope of services will generate a higher net revenue per procedure. Differences in the scope of services offered by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

**Projected Average Operating Expense per MRI Procedure**

The following table compares projected average operating expense per procedure in the third full fiscal year following project completion for each facility, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, regarding this factor, the application proposing the lowest average operating expense per procedure is the more effective since a lower average may indicate a lower cost to the patient or third-party payor or more cost-effective service. Operating expense for MRI services was not provided by all of the applicants in this review. Therefore, operating expenses for the entire facility, including MRI services, were compared.

Average Operating Expense per MRI Procedure Project Year 3, Total Facility				
Applicant	Total # of Procedures	# of Fixed MRI Scanners	Operating Expense (Entire Facility)	Average Operating Expense per Procedure
EmergeOrtho	5,267	1	\$1,660,272	\$315.22
Open MRI	13,980	3	\$6,286,013	\$449.64
MH Mission Imaging	4,467	1	\$3,949,897	\$884.23

As shown in the table above, **EmergeOrtho** projects the lowest average operating cost per procedure in the third full fiscal year following project completion. However, a larger scope of services will generate a higher operating expense per procedure. Differences in the type of facility and the services offered by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

### SUMMARY

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	EmergeOrtho	Open MRI	MH Mission Imaging
Conformity with Statutory and Regulatory Review Criteria	Equally Effective	Equally Effective	Equally Effective
Scope of Services	Less Effective	Less Effective	Most Effective
Historical Utilization	Less Effective	Most Effective	Less Effective
Geographic Accessibility (Location within the Service Area)	Equally Effective	Equally Effective	Equally Effective
Access by Service Area Residents	Less Effective	Less Effective	Most Effective
Access by Charity Care Patients	Inconclusive	Inconclusive	Inconclusive
Access by Medicaid Patients	Inconclusive	Inconclusive	Inconclusive
Access by Medicare Patients	Inconclusive	Inconclusive	Inconclusive
Competition (Access to a New or Alternative Provider)	Equally Effective	Equally Effective	Equally Effective
Projected Average Net Revenue per Procedure	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Procedure	Inconclusive	Inconclusive	Inconclusive

All of the applications are conforming to all applicable statutory and regulatory review criteria, and thus all of the applications are approvable standing alone. However, collectively they propose a total of three fixed MRI scanners, but the need determination is for only one fixed MRI scanner. Therefore, only one fixed MRI scanner can be approved.

As shown in the table above, **MH Mission Imaging** was determined to be a more effective alternative for the following factors:

- Scope of Services
- Access by Service Area Residents

## DECISION

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **MH Mission Imaging** is the most effective alternative proposed in this review for the development of one additional fixed MRI scanner.

While the other applications, **EmergeOrtho** and **Open MRI** are approvable standing alone, the approval of either of them would result in the approval of more fixed MRI scanners than are determined to be needed, and therefore, the applications submitted by **EmergeOrtho** and **Open MRI** are denied.

**MH Mission Imaging** proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville in Buncombe County. The application submitted by **MH Mission Imaging**, is approved subject to the following conditions:

1. **MH Mission Imaging, LLLP (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall acquire one fixed MRI scanner pursuant to the need determination in the 2021 SMFP, to be located at its existing diagnostic center, Mission Imaging Services Asheville in Buncombe County, for a total of one fixed MRI scanner.**
3. **Upon completion of the project, Mission Imaging Services Asheville shall be licensed for no more than one fixed MRI scanner.**
4. **Progress Reports:**
  - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. **The certificate holder shall complete all sections of the Progress Report form.**
  - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. **Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on February 1, 2022. The second progress report shall be due on June 1, 2022 and so forth.**

- 5. The certificate holder 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.**
  
- 6. 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, the certificate holder 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.**
  
- 7. The certificate holder 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.**