

**MH Mission Imaging, LLLP**  
**Comments in Opposition to**  
**EmergeOrtho, PA (B-012023-21) and Asheville Open MRI, LLC (B-012032-21)**  
**Certificate of Need Applications for One Fixed MRI Scanner in**  
**Buncombe/Madison/Yancey/Graham Counties**  
**March 1, 2021 CON Review Cycle**

**INTRODUCTION**

The 2021 State Medical Facilities Plan ("SMFP") recognized a need for one fixed magnetic resonance imaging unit ("MRI") in the Buncombe/Madison/Yancey/Graham Counties ("service area"). Three total applicants have filed a Certificate of Need ("CON") application in response to the identified need, including Project I.D. B-012035-21 – MH Mission Imaging, LLLP (applicant to be referred to as "Mission Imaging" and project to be referred to as "Mission Imaging-Biltmore"). The other two applicants include:

- Project I.D. B-012023-21 – EmergeOrtho, PA ("EmergeOrtho")
- Project I.D. B-012032-21 – Asheville Open MRI, LLC ("Open MRI").

Mission Imaging-Biltmore has completed a detailed review of each project and found that the other applicants fail to meet one or more of the applicable review criteria and cannot be approved. Mission Imaging-Biltmore also completed a comparative review based on most relevant factors that the CON Section has previously considered in the review of fixed MRI units. This comparison clearly reveals that Mission Imaging-Biltmore is the best applicant to meet the identified need in the Buncombe/Madison/Yancey/Graham County based on the following factors:

- Mission Imaging operates the most highly utilized MRIs in the MRI service area and Mission Imaging, along with its affiliate, Mission Hospital, drove the need recognized in the SMFP.
- Mission Imaging-Biltmore is the only applicant that has significant experience in providing complex and comprehensive MRI services to service area patients as opposed to applicants such as EmergeOrtho that only provide orthopedic scans and Open MRI that does not offer nearly the same plethora of complex and specialized MRI scans as Mission proposes to offer.
- Mission Imaging-Biltmore is the only applicant that documents the growth in the need to enhance access to more complex MRI scans and the specific experience in administering those scans.
- Mission Imaging-Biltmore projects the shortest time frame to initiate operations and ramp up utilization based on its location, presence in the market, and experience providing MRI services.
- Mission Imaging-Biltmore has a history of providing accessible MRI services, including services to Medicaid, Medicare, and charity care patients, and is comparatively superior to the competing applicants regarding this issue.

- Mission Imaging-Biltmore fully documents all resources needed to establish the proposed new fixed MRI service based on its existing presence in the service area and existing resources through its affiliates Mission Health System (“Mission Health”) and HCA Healthcare (“HCA”).

For these reasons and the reasons documented below, Mission Imaging-Biltmore is the best applicant to meet the need identified for an additional fixed MRI unit in the service area.

## **OVERVIEW OF APPLICANTS**

EmergeOrtho proposes one freestanding fixed MRI unit at the EmmergeOrtho Blue Ridge Division campus in Arden, Buncombe County, North Carolina. EmmergeOrtho, PA is an affiliate of Triangle Orthopedics and both are orthopedic physician practices. While EmmergeOrtho is an experienced provider of fixed MRI services in the state of North Carolina, and by contract within the service area, its application is flawed by the lack of support for its projections and its failure to establish need for the proposed project. More specifically, EmmergeOrtho proposes an outpatient, orthopedic-focused MRI project, which will be primarily available to the patients from EmmergeOrtho’s practice only (see page 43-44). This is supported by the fact that all of the letters of support provided for the proposed project are EmmergeOrtho providers. Moreover, EmmergeOrtho is an existing provider of fixed MRI within Buncombe County via its contracted MRI from InSight Health. Given the historically low utilization of that contracted MRI, EmmergeOrtho does not adequately document the need for another fixed MRI. Without a sufficient historical base of utilization and without meeting the needs of the service area population published in the SMFP, EmmergeOrtho has not adequately demonstrated the need for its proposed project.

Open MRI, affiliated with Novant Health, proposes to obtain a fixed MRI unit at its freestanding imaging center along with its two existing MRI units in close proximity to Mission Imaging-Biltmore’s proposed location in Asheville, Buncombe County, North Carolina. Open MRI, by way of Novant Health and its many affiliated facilities, is an experienced provider of fixed MRI services in the state of North Carolina and within the service area. Open MRI however fails to establish a supported and convincing need for its project. While Open MRI provides several letters of support for its proposed project, none of the letters actually commit to a specific number of referrals to support Open MRI’s projected volume. Furthermore, Open MRI concludes, just as Mission Imaging-Biltmore does, that enhanced access to more complex MRI scans is needed in the service area. However, Open MRI does not come close to projecting the same volume of contrasted MRI scans as Mission Imaging-Biltmore. Open MRI will not meet the needs of the service area population and, therefore, has not adequately demonstrated the need for its proposed project.

Mission Imaging-Biltmore, affiliated with Mission Health, proposes the addition of a fixed MRI unit at its freestanding imaging center, Mission Imaging-Biltmore campus, in Asheville, Buncombe County, North Carolina. Mission Imaging-Biltmore’s proposed project is located adjacent to Mission Hospital and adjacent to the Mission Breast Center. Mission Health is currently

the only MRI provider in the service area that performs breast MRIs. Additionally, Mission Health provides certain specialized MRI imaging procedures of the prostate, liver, brain, and vascular system that are not offered by any other MRI provider in the region. Increased demand for breast MRIs and other specialized MRI imaging is what drives the demand for additional MRI scans in the service area. Mission Imaging operates the two most highly utilized MRI units in the service area and clearly has a need for additional capacity to meet continued growth in demand. This fact, coupled with the cost-effective nature of a freestanding MRI setting, makes Mission Imaging-Biltmore's proposed project the superior CON application in this review cycle.

EmergeOrtho's historical operations do not justify a second MRI unit, its analyses are focused on its practice patients only, and its proposed project ignores the needs of all service area patients, rendering it non-conforming with the review criteria and fixed MRI Performance Standards. Open MRI, while proposing to offer some complex MRI imaging, will not offer the same level of complex MRI scans as Mission Imaging-Biltmore. Additionally, Open MRI does not adequately provide support for its projected utilization, and its projection methodology and source data are inconsistent. As such, EmERGEOrtho and Open MRI cannot be approved as will be described in detail below.

## **COMMENTS ON INDIVIDUAL APPLICATIONS**

In accordance with N.C. Gen. Stat. § 131E-185(a)(1), Mission Imaging-Biltmore submits the following comments related to the applications submitted by EmERGEOrtho and Open MRI to acquire a fixed MRI scanner pursuant to the need determination as published in the 2021 SMFP. To facilitate the Agency's review of these comments, Mission Imaging-Biltmore has organized its discussion by issue, citing the general CON statutory review criteria and specific regulatory criteria and standards. Mission Imaging-Biltmore also presents a comparative analysis of all of the applications.

### **EMERGEORTHO NON-CONFORMITY WITH REVIEW CRITERIA**

#### **Criterion (1) Policy GEN-3 – EmERGEOrtho's Project is Not Consistent with the 2021 SMFP**

EmERGEOrtho should be found non-conforming with Criterion (1) and Policy GEN-3 because:

- EmERGEOrtho does not adequately explain how its projected utilization incorporates the concept of maximum value for resources. EmERGEOrtho's flawed utilization projections, unnecessary duplication of services, lack of financial feasibility, and the availability of more effective cost-alternatives demonstrate that EmERGEOrtho's project does not maximize resources for value. More detailed discussions of each of these factors can be found, below, in Mission's comments concerning EmERGEOrtho's non-conformity with Criterion (3), Criterion (4), Criterion (5), and Criterion (6), respectively.

The proposed project does not maximize healthcare value and is not an efficient use of healthcare resources. Thus, it is not consistent with Policy GEN-3: Basic Principles and is non-conforming with Criterion (1).

### **Criterion (3) – EmergeOrtho’s Projected Utilization is Unrealistic and Unsupported**

EmergeOrtho fails to demonstrate the need for its proposed project as required by Criterion (3) for several reasons, including unsupported and unrealistic utilization projections and important factors that have been disregarded in its application. These flaws include:

- EmergeOrtho’s projections rely solely on its own orthopedic practice volume and do not take into consideration the service area population, such as patients needing breast, prostate, or other types of specialized scans;
- EmergeOrtho’s projected utilization is unreasonable and unsupported. EmergeOrtho proposes to shift volume from its already under-utilized MRI scanner, which will not meet the need in the SMFP, and the projected utilization is heavily reliant on patients from outside of the service area established in the SMFP;
- EmergeOrtho proposes to replace an existing, contracted MRI scanner, not add a new MRI scanner to the service area, which does not meet the need published in the SMFP;
- EmergeOrtho’s proposed location is in south Buncombe County near the Henderson County border, which is reflected in its projected patient origin. EmergeOrtho has existing offices in Asheville (Buncombe County) and Hendersonville (Henderson County). The project EmergeOrtho proposed in this review cycle relies heavily upon and focuses heavily on serving Henderson County patients, which is not part of the service area and does not meet the need in Buncombe County;
- EmergeOrtho’s current MRI unit at its Arden campus is operated by the applicant under a service contract with InSight Imaging (“Insight”). EmergeOrtho does not account for the underutilization of this unit and what will happen to this unit if its current CON application is approved; and
- Once it puts a fixed MRI unit at the Arden campus, EmergeOrtho could simply relocate the InSight MRI unit to one of its other offices, therefore creating an unnecessary duplication of services and taking market share from existing MRI providers in the service area.

For these and other reasons detailed herein, EmergeOrtho fails to clearly document that it will provide access to all of the service area patients, not just orthopedic patients, and fails to provide reasonable and clearly documented utilization projections.

### EmergeOrtho's Projected Utilization Focuses on Orthopedic Patients and is Unsupported

EmergeOrtho's need demonstration and projected utilization is flawed for multiple significant reasons. First, EmmergeOrtho is an existing provider of MRI services in Buncombe County at the very location it proposes to operate the proposed MRI.<sup>1</sup> The unit operated by EmmergeOrtho is underutilized and is by far the least utilized freestanding, outpatient MRI in the service area. EmmergeOrtho does not control or claim to know what will happen to the existing MRI unit and assumes all utilization will shift to the proposed unit. If the existing unit leaves the service area, then EmmergeOrtho's project does not meet the need for an "additional" MRI. If the unit stays in the service area, such as at another affiliated EmmergeOrtho location, then insufficient volume has been projected for two units. Moreover, EmmergeOrtho's utilization projections are unsupported based on historical operations of the existing MRI at the very same location, which are anything but "high" as suggested on page 36 of the application.

Second, EmmergeOrtho's proposed project will be heavily focused on serving orthopedic patients and its own practice's patients. The published need for one additional fixed MRI scanner in the 2021 SMFP is not for a scanner that will serve mostly orthopedic patients, but for a scanner that will meet the needs of all service area patients. The fact that EmmergeOrtho's project will not serve all service area patients should be enough to deny EmmergeOrtho's proposal.

Third, EmmergeOrtho focuses heavily on the need for patients from outside of the MRI service area including Henderson County. There is no published need for an additional MRI unit in Henderson County according to the 2021 SMFP. Again, EmmergeOrtho's project is not focused on meeting the need recognized in the SMFP.

Finally, EmmergeOrtho projects just 1.7 percent of its scans will be provided with contrast. This compares to 39.2 percent of outpatient scans offered with contrast by all outpatient Buncombe county MRI providers and 43 percent of all outpatient scans provided by providers other than EmmergeOrtho based on the 2021 SMFP. EmmergeOrtho's contrast percent will not meet the service area need.

### EmergeOrtho's Utilization Projections are Unreasonable

EmergeOrtho's projected utilization is unsupported as is explained through **Exhibit 1** and **Exhibit 2**, below. First, the existing MRI unit operated by EmmergeOrtho is significantly underutilized, operating at just 2,989 weighted scans in FY 2020, far short of the required 3,328 weighted scans required for historical operation of an existing MRI. While EmmergeOrtho may not technically be required to meet this standard, the referring providers and patient population for the proposed MRI are the same as those using the existing InSight MRI and therefore can be directly related to the under-utilization of the existing MRI. This current low utilization undermines the need for the project and the reasonableness of its projected utilization. In terms of meeting the projected

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<sup>1</sup> While this unit is technically owned by InSight Health, it is operated by EmmergeOrtho. This unit is underutilized and does not meet the performance standards for existing MRI units.

performance standard, EmergeOrtho will require a 37.8 percent increase in utilization above its historical utilization levels to meet the projected utilization, while serving the exact same patient base. As will be shown, this is not reasonable.

**Exhibit 1**  
**EmergeOrtho Historic vs. Projected Volume**

<b>Last Full Fiscal Year vs. Projected 1<sup>st</sup> Full Fiscal Year</b>			
	<b>Last FFY</b>	<b>1<sup>st</sup> FFY</b>	<b>% of Capacity Standard</b>
<b>Last Full Fiscal Year vs. Historical Performance Standard</b>	2,989	3,328	89.8%
<b>Last Full Fiscal Year vs. Projected Performance Standard</b>	2,989	4,805	62.2%

*Source: EmergeOrtho CON Application*

To meet this standard, EmergeOrtho is projecting to provide 4,129 scans in Year 1, a 47.7 percent increase over its last FFY 2020, based simply on one quarter of data that could be anomalous. However, EmergeOrtho projects a 15.4 percent increase from FFY 2020 to 3,295 scans in CY 2021 (1.25 years). From that point through Year 3, EmergeOrtho projects annual growth rates of 10.3 percent to 13.6 percent. As will be shown, this growth rate is wholly unsubstantiated (see **Exhibit 2**).

**Exhibit 2**

					<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
	<b>2019-2020</b>	<b>Interim Quarter</b>	<b>CY 2021</b>	<b>CY 2022</b>	<b>CY 2023</b>	<b>CY 2024</b>	<b>CY 2025</b>
Outpatient No Contrast	2,795	845	3,295	3,635	4,129	4,644	5,179
Outpatient Contrast	47	14	56	61	70	78	87
<b>Total</b>	<b>2,842</b>	<b>859</b>	<b>3,351</b>	<b>3,696</b>	<b>4,199</b>	<b>4,722</b>	<b>5,266</b>
<b>Annual Growth Rate</b>			<b>15.4%</b>	<b>10.3%</b>	<b>13.6%</b>	<b>12.5%</b>	<b>11.5%</b>

*Source: EmergeOrtho CON, p. 44.*

The projected growth in utilization is unsubstantiated both quantitatively and from a practical standpoint. First, not a single year of historical growth substantiates the high level of growth in scan volume presented nor does it support the rapid growth rates projected by EmergeOrtho (see **Exhibit 3**). From a quantitative basis, EmergeOrtho cannot support its double-digit projected growth rates that it has never experienced in the past. The highest historical growth presented is only 8 percent, and EmergeOrtho experienced a decline between FY 2019 to FY 2020. Furthermore, EmergeOrtho only presents a historical CAGR of 7.38 percent on page 40 of its application.

**Exhibit 3**  
**EmergeOrtho Historic Annual Growth Rates**

	2016-2017	2017-2018	2018-2019	2019-2020
Outpatient No Contrast	2,469	2,631	2,852	2,795
Outpatient Contrast	46	54	48	47
Total	2,515	2,685	2,900	2,842
<b>Annual Growth Rate</b>		<b>6.8%</b>	<b>8.0%</b>	<b>-2.0%</b>

Source: *EmergeOrtho CON pp. 40 and 114.*

From a practical standpoint, EmergeOrtho’s interim year projected growth demonstrates that the existing contract MRI can meet growth demand, and therefore, EmergeOrtho does not need its own MRI. This contradiction is a fundamental flaw in this application. EmergeOrtho cannot claim capacity limitations of its contract MRI as a basis for need and then project 15.4 percent growth in to CY 2021 and 10.3 percent growth to 2022. EmergeOrtho states that it is seeing its largest volume for its practice ever in the last quarter of last year due to increasing operating hours in October 2020. This fact directly contradicts EmergeOrtho’s claim that it has limited ability to increase its operating hours due to its contract with InSight Health. This claim of increased capacity should readily allow EmergeOrtho to meet even its unreasonable projected growth rates to the point that this scanner actually meets performance standards. The fallacy of these claims will be discussed in more detail below.

EmergeOrtho did not adequately provide support for its projected utilization. It is critical to keep in mind that EmergeOrtho will continue to serve the exact same base of patients that it has always served, according to its own statements in its CON application. EmergeOrtho has not experienced anywhere near the level of scan volume or growth it projects in its application.

Despite stating it has support from several area primary care providers, EmergeOrtho provided support for its projected utilization only from its own affiliated physicians via letters of support. Aside from EmergeOrtho providers, there were no other letters provided within the application. Based on EmergeOrtho’s own internally generated provider volume, the proposed project would fall short of its projected volume by 1,000 scans by the 3<sup>rd</sup> project, a significant number. (see **Exhibit 4**). If EmergeOrtho does not meet its projected volume, the financial feasibility of its project then comes into question, which will be discussed in further detail under Criterion (5).

**Exhibit 4**  
**EmergeOrtho Provider Projected Volume vs. Overall Projected Volume**

	Year 1 CY 2023	Year 2 CY 2024	Year 3 CY 2025
<b>Projected EmergeOrtho Provider Volume</b>	3,454	3,845	4,280
<b>Overall Projected Volume*</b>	4,199	4,722	5,267
<b>Unsupported Volume</b>	<b>745</b>	<b>877</b>	<b>987</b>

Source: *EmergeOrtho CON Application, p. 43.*

\*Note: *Unweighted scans provided in analysis from page 44.*

### *EmergeOrtho Will Not Meet Community Need*

The limitation of EmERGEOrtho's letters of support and basis for projected utilization demonstrates two shortcomings in meeting the community need. First, its projections are limited to orthopedic volume, which is just a subcomponent of the larger need and does not meet the need for a broad range of other scans including neuro, oncology, gastroenterology, and other important scans. Next, EmERGEOrtho only projects 1.7 percent contrast scans which is just a fraction of the overall 39 percent outpatient scans with contrast in FY 2019, according to the 2021 SMFP. Over time, scan volume has become increasingly complex with substantial growth in the percentage of contrast scans. EmERGEOrtho is significantly limited in meeting this demand.

Most importantly, EmERGEOrtho's project simply replaces one MRI in the service area with another keeping the inventory and availability of capacity in the service area the same. As such, the project cannot meet the need for an **additional MRI unit** in the service area.

### *EmergeOrtho is Focused on Serving Henderson County Which is Outside the Service Area*

EmERGEOrtho states that its proposed project will expand geographic access to MRI services for service area patients, yet there is already an existing fixed MRI at the very same address where EmERGEOrtho proposes to develop the project. There will be absolutely no change in geographic access associated with the proposed project. As seen in **Exhibit 5**, below, EmERGEOrtho is proposing to serve nearly as many patients from Henderson County as it does from Buncombe County. This is problematic since Henderson County falls outside of the MRI service area of Buncombe/Madison/Yancey/Graham Counties, and, therefore, Henderson County patients do not feed into the published need. In total, over a third of EmERGEOrtho's patients will come from Henderson County, with an increase from 1,035 (historical presented patient origin) to 1,969 (projected Year 3 patient origin). This is a 90 percent increase in utilization and represents 934 scans from Henderson County, which is not in the service area.

### *EmergeOrtho's Claims of Capacity Constraints and Patients Leaving Due to its Contract with InSight are Misleading*

As previously mentioned, EmERGEOrtho stated that it was experiencing capacity constraints with its current MRI unit due to its contract with InSight Health and the inability to extend operating hours (see EmERGEOrtho CON, p. 40). EmERGEOrtho then followed up that claim with a statement about experiencing its highest MRI volume in the practice's history due to extending its operating hours (see EmERGEOrtho CON, p. 41). The two statements completely contradict one another.

The applicant also claims that some patients cannot or do not want to use the current scanner due to obesity and claustrophobia. Such claims of limitations are completely undermined by the projected double-digit growth EmERGEOrtho projects for interim years CY 2021 and CY 2022.



EmergeOrtho also makes a statement that its physicians are uncomfortable performing contrast scans at the current MRI location and that the proposed project will allow for its physicians to conduct more of these types of scans (see EmERGEOrtho CON, p. 41). EmERGEOrtho’s historical MRI scans with contrast are nominal at 1.7 percent of total scans. Undermining this claim, EmERGEOrtho then continues to project only 1.7 percent contrast scans for its first three years of operation (see **Exhibit 5**). If contrast scans were in fact limited, then EmERGEOrtho would have projected an increase in contrast scan volume with a new MRI, which it did not.

**Exhibit 5  
Historical and Projected Contrast Scan Percentage**

					Year 1	Year 2	Year 3
	2019-2020	Interim Quarter	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025
Outpatient No Contrast	2,795	845	3,295	3,635	4,129	4,644	5,179
Outpatient Contrast	47	14	56	61	70	78	87
Total	2,842	859	3,351	3,696	4,199	4,722	5,266
<b>Percent Contrast</b>	<b>1.7%</b>	<b>1.6%</b>	<b>1.7%</b>	<b>1.7%</b>	<b>1.7%</b>	<b>1.7%</b>	<b>1.7%</b>

Source: EmERGEOrtho CON, pp. 40 and 44.

*EmERGEOrtho Can Relocate the InSight MRI to One of its Other Office Locations and Avoid CON Review*

EmERGEOrtho states in its application that if its proposal is approved, InSight Health could simply move the MRI scanner currently servicing its office to another provider that is willing to contract for MRI services since InSight has a legacy scanner that is not subject to CON regulations (See EmERGEOrtho CON, p. 82). This then raises the like scenario that, if approved, nothing would stop EmERGEOrtho from contracting with InSight Health at one of its other Asheville offices or its office in Hendersonville, effectively doubling its capacity and creating an unnecessary duplication of services in the service area. EmERGEOrtho has certainly not demonstrated that its practice can support two MRI units in the service area based on data in the application.

By contrast, if the InSight MRI unit actually does leave the service area then there will still be the same number of fixed MRI units in the service area and EmERGEOrtho’s project has not met the need for **one additional** MRI unit in the service area. Therefore, it has not met the MRI need identified in the 2021 SMFP and that need will remain unfilled if the EmERGEOrtho application is approved.

In summary, EmERGEOrtho’s application for one fixed MRI unit to be placed at its Arden location has unsupported projections and proposes to only serve orthopedic patients, which means the project will not meet the needs for all service area patients, but just a subset. EmERGEOrtho will not provide sufficient contrast scans to meet the need. Critically, EmERGEOrtho does not project to add

an MRI to the service area. It will simply substitute existing capacity with proposed capacity for a net neutral project, which does not meet the identified need.

For all of the reasons detailed above, EmergeOrtho's proposed project should be found nonconforming with Criterion (3) and, as a result, EmergeOrtho's proposed project should be denied.

**Criterion (4) – EmergeOrtho is Not an Effective Alternative to Existing Fixed MRI Providers**

EmergeOrtho claims that its other office locations were not considered best alternatives due to space not being available for the proposed project. However, the same can be said for its Arden office location. Ultimately, EmergeOrtho's Arden office location will require renovations and an addition to the space in order to accommodate its proposed MRI scanner. Given that EmergeOrtho has several Asheville office locations, one of those offices would have better served the published need for an additional fixed MRI given that the majority of the service area population is located there.

In its CON application, EmergeOrtho acknowledges that it has experienced its highest MRI volume in practice history while operating at 50 hours per week. The highest volume was experienced in the last 3 months of 2020 as shown in the table in EmergeOrtho's application on p. 41. Given that EmergeOrtho is well below the MRI Performance Standard of 4,805 weighted scans per year, while also steadily increasing capacity, there is no need for its proposed project. Mission is an existing MRI provider in the service area which is truly experiencing capacity constraints, and which provides more complex scans to service area patients. The same is not true for EmergeOrtho. A better alternative would be to add capacity at a highly utilized project.

EmergeOrtho does not even propose to add capacity in the service area. Instead, its proposed project simply substitutes a new MRI for the one already operating at its very same existing office. This is not an alternative that meets the identified need.

Additionally, EmergeOrtho does not effectively establish that the alternative proposed in this application is the most effective alternative to meet the identified need because the application does not adequately document its projected utilization, financial feasibility, or financial accessibility as documented in other sections of this document.

Based on these issues, EmergeOrtho should be found non-conforming with Criterion (4).

### **Criterion (5) – EmergeOrtho’s Project is Not Financially Feasible**

EmergeOrtho does not present reasonable, or supported, projected utilization and therefore the financial feasibility of its project is not adequately supported. The large number of patients projected to come from Henderson County is unreasonable, especially given that Henderson County falls outside of the MRI service area where the published need exists. Furthermore, the physician support provided by EmergeOrtho is insufficient to support its projected volume as discussed above in **Exhibit 4**. Because of these unreasonable utilization projections, EmergeOrtho does not demonstrate that its project is financially feasible.

Based on these issues, EmergeOrtho should be found non-conforming with Criterion (5).

### **Criterion (6) – EmergeOrtho Represents an Unnecessary Duplication of Services**

As described above, EmergeOrtho’s claims of improved competition and access among existing MRI providers in the service area are unfounded. The proposed project will inevitably result in unnecessary duplication of existing health service capabilities because EmergeOrtho’s proposed project will be focused on its orthopedic patients only. An MRI scanner dedicated to orthopedic patients only does very little for competition, and only provides access for orthopedic patients. There are already several existing, freestanding MRI providers in the service area that provide not only orthopedic scans, but also other types of MRI scans, fully encompassing the needs of service area patients and providing a greater value. Moreover, the proposed project does not extend access to orthopedic patients as it simply substitutes one fixed MRI for an existing one without adding capacity. This is unnecessary duplication as that term is used in the CON Statute and applicable review criteria.

EmergeOrtho does not adequately demonstrate that the fixed MRI scanner it proposes to develop in Buncombe/Madison/Yancey/Graham Counties is needed and it will not expand capacity in the service area. Thus, it is clear that EmergeOrtho’s project is a duplication of existing services, in fact it is an exact substitution of an existing MRI unit, and should be found non-conforming with Criterion (6).

### **Criterion (7) – EmergeOrtho’s Projected Staffing is Flawed**

In its Form H.1a, EmergeOrtho did not properly calculate total salary for Patient Transport for the 1<sup>st</sup> and 2<sup>nd</sup> FFYs. The total salary was not calculated in the 2<sup>nd</sup> and 3<sup>rd</sup> FFY. This calculating error then understates projected operating costs presented in Form F.3b by \$64,504 plus benefits in the 3<sup>rd</sup> FFY, which subsequently effects the proposed project’s financial feasibility. (see **Exhibit 6**). For this reason, EmergeOrtho should be found non-conforming with Criterion (7).

**Exhibit 6**  
**EmergeOrtho Corrected Salary Calculation for Patient Transport**

	2nd FFY			3rd FFY		
	# of FTEs	Average Annual Salary	Total Salary*	# of FTEs	Average Annual Salary	Total Salary*
<b>Patient Transport</b>	2	\$ 31,620	\$ 63,240	2	\$ 32,252	\$ 64,504

*Source: EmergeOrtho, Section Q, Form H.1a*

*\* Note: Calculation was left blank in applicant's Section Q, Form H.1a presentation.*

**Criterion (13) – EmergeOrtho’s Proposed Payor Mix Falls Short of Displaying Enhanced Access to the Medically Underserved**

G.S. 131E-183(a)(13)(d) requires that the Applicant show 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.” Due to the unsupported projected utilization, it is unclear the extent to which medically underserved individuals will actually be expected to utilize the proposed MRI services. Accordingly, EmergeOrtho should be found non-conforming with Criterion (13). EmergeOrtho’s own historical payor mix displays its disproportionate service to medically underserved groups by payor. Form F.2a (MRI Only) shows that historically only 1.5 percent of revenue (and presumably patients) have been Medicaid and only 2.2 percent of revenue (and presumably patients) are self-pay. This minimal provision of Medicaid and charity care demonstrate that EmergeOrtho has not been historically financially accessible. EmergeOrtho does not meet this Criterion.

**Criterion (18a) – EmergeOrtho’s Proposed Project Will Not Positively Impact Competition in the Service Area**

As previously stated, EmergeOrtho’s CON application will not enhance competition in the service area, nor will it have a positive impact upon cost-effectiveness, quality, and access. EmergeOrtho highlights throughout its application that it will serve only its own orthopedic patients. While there are claims of other referrals, none have been demonstrated. Any existing freestanding MRI provider in the service area that already serves a wide array of MRI patients can also serve the orthopedic patients that EmergeOrtho proposes to serve. Furthermore, only proposing to serve orthopedic patients and ignoring all other service area patients does nothing to improve competition or access. EmergeOrtho only projects 1.7 percent contrast scans -- a tiny fraction of the demand in the service area. EmergeOrtho will not meet the need for this growing and important MRI imaging component.

Most importantly, EmergeOrtho’s project proposes an expenditure of \$2,766,000 to simply replace an existing scanner in the service area. There will be no change in location that would impact geographic access, no change in policies that would impact financial access, and no change in the percent of contrast scans offered. Even the claimed increase in capacity is undermined by

EmergeOrtho's own interim projections. There will be absolutely no meaningful demonstrated improvements associated with the proposed project and the project simply represents a duplication of the existing MRI unit without adding the very needed incremental capacity to the service area. In fact, EmmergeOrtho cannot meet its utilization projections without impacting existing providers given its historical low utilization and unsubstantiated projected volume.

Based on these issues, EmmergeOrtho's application should be found non-conforming with Criterion (18a).

### **EMERGEORTHO FAILS TO MEET THE MRI PERFORMANCE STANDARDS**

Though this review criteria would technically be considered not applicable, EmmergeOrtho does operate an MRI scanner at its proposed location, and it is considered a fixed MRI unit in the SMFP. 10A NCAC 14C .2703 sets the criteria and standards for Magnetic Resonance Imaging units. As such, 10A NCAC 14C .2703(b)(3)(e) states that:

*(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... (e) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

As previously discussed, EmmergeOrtho is nowhere near meeting the performance standard with its current unit at just 2,989 weighted scans in the last FFY, which while not technically applicable, calls into question the need for the project. Furthermore, EmmergeOrtho lacks sufficient support for its projected utilization calling into question its ability to meet the performance standard of 4,805 weighted scans by its 3<sup>rd</sup> FFY.

Accordingly, it is unclear how EmmergeOrtho's proposed project will reach the requirement of at least 4,805 weighted MRI procedures in the third year of operation as projected. Based on these issues alone, EmmergeOrtho fails to meet the Performance Standards and should be denied.

### **OPEN MRI NON-CONFORMITY WITH REVIEW CRITERIA**

#### **Criterion (1) Policy GEN-3 – Open MRI's Project is Not Consistent with the 2021 SMFP**

Open MRI should be found non-conforming with Criterion (1) and Policy GEN-3 because:

- Open MRI does not adequately explain how its projected utilization incorporates the concept of maximum value for resources. Open MRI's grouped utilization projections, unnecessary duplication of services, lack of financial feasibility, and the availability of more effective cost-alternatives demonstrate that Open MRI's project does not maximize resources for value. More detailed discussion of each of these factors can be found below in Mission Imaging-Biltmore's comments concerning Open MRI's non-conformity with Criterion (3), Criterion (4), Criterion (5), and Criterion (6), respectively.
- Open MRI does not adequately demonstrate need for the proposed project. More detailed discussion regarding failure to establish need can be found below in Mission Imaging-Biltmore's comments concerning Open MRI's non-conformity with Criterion (3).

The proposed project does not maximize healthcare value and is not an efficient use of healthcare resources. Thus, it is not consistent with Policy GEN-3: Basic Principles and is non-conforming with Criterion (1).

### **Criterion (3) – Open MRI's Projected Utilization is Unsupported**

Open MRI fails to demonstrate the need for its proposed project as required by Criterion (3) for several reasons, including unsupported utilization projections and important factors that have been disregarded in its application. These flaws include:

- On p. 52 of its CON application, Open MRI states that it provided over 100 letters of support for its proposed project. In actuality, Open MRI provided 94 form letters of support that do not commit to any specific volumes and come mainly from primary care physicians;
- Open MRI uses inconsistent methods to project its utilization, switching between calendar year data and fiscal year;
- Open MRI inappropriately used 6 months of rebound volume from pent up demand from the pandemic to project its utilization forward, far overstating growth for 2021;
- Open MRI claims that it will provide increased access to complex scans such as oncology and orthopedic scans, but does not provide letters from such specialty physicians; and
- Open MRI held its percent of contrast scans constant despite the growing demand for contrast scans in the service area, yet another indication that the Open MRI project will not be the best proposal to serve the market area demand.

For these and other reasons detailed herein, Open MRI fails to clearly document that it will provide enhanced access to complex MRI services and fails to provide reasonable and clearly documented utilization projections.

Open MRI's Utilization Projections Cannot be Confirmed

Open MRI used an inconsistent methodology in projecting its utilization:

First, Open MRI relied on historical internal data for its projected utilization and did not report validated data such as the data that would be reported through the Registration and Inventory of Medical Equipment questionnaire or data reported in the annual SMFP. Second, the internal data that Open MRI relied on went back and forth between calendar year data and fiscal year data. Relying on two different reporting periods does not result in accurate projections. As seen below in **Exhibit 7**, Open MRI relied on calendar year data to establish its annual growth rate and to establish the percent of MRI scans that would be done with contrast (to be discussed further below). Additionally, Open MRI used a two-year period before the pandemic to establish historic “trend” utilization in order to create an annual growth rate for its projections, which is not a meaningful trend.

**Exhibit 7**  
**Historic Open MRI Data Used to Establish Annual Growth Rate and**  
**Percent of Contrast Scans**

Time Period	CY 2017	CY 2018	CY 2019	CY 2020
Unweighted MRI Total	10,936	11,231	11,753	11,197
% Change		2.70%	4.65%	-4.73%
CAGR 17-19			<b>3.67%</b>	
CAGR 17-20				<b>0.79%</b>

Source: Open MRI CON, p. 118.

After presenting unverifiable calendar year data, Open MRI then pivots to using fiscal year reporting to establish its projected utilization. Open MRI uses 6 months of data from July 2020 to December 2020 annualized, which is not a realistic starting point for projections. This period represents an unusual surge of pent-up demand following low levels in early 2020. By taking half of a fiscal year of data and then annualizing it, Open MRI doubled an annual growth rate of 20.26%, which is completely unreasonable based on previous fiscal years (see **Exhibit 8**, below).

**Exhibit 8**  
**Open MRI Projected Utilization**

	7/1/17- 6/30/18	7/1/18- 6/30/19	7/1/19- 6/30/20	Interim Year 1*	Interim Year 2	Year 1	Year 2	Year 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			
Outpatient No Contrast	8,265	8,340	8,010	9,713	9,891	10,073	10,259	10,447
Outpatient Contrast	2,737	2,879	2,797	3,283	3,344	3,405	3,468	3,532
Total	11,002	11,219	10,807	12,996	13,235	13,479	13,727	13,979
<b>Annual Growth Rate</b>	<b>1.97%</b>	<b>-3.67%</b>	<b>20.26%</b>	<b>1.84%</b>	<b>1.84%</b>	<b>1.84%</b>	<b>1.84%</b>	<b>1.84%</b>

Source: Open MRI CON, pp. 117 and 124.

\*Note: Annualized Interim Year 1 as base for projections.

To achieve this unreasonable 20.26 percent single year growth rate, Open MRI takes the highest 6-month period of volume that it has achieved in the last three and half years and doubles this period, completely ignoring that this peak was due to pent up demand from COVID during the first six months of 2020. This is not a reasonable basis to project interim FY 2021 demand.

Period	Scans
Jan-June 17	5,591
July-Dec 17	5,345
Jan-June 18	5,657
July-Dec 18	5,574
Jan-June 19	5,645
July-Dec 19	6,108
Jan-June 20	4,699
July-Dec 20	6,498

Open MRI’s historical growth rate of 3.67 percent is significantly lower than the market growth rate which is 5.28 percent (see Open MRI CON, p. 119). However, Open MRI uses the higher market growth rate to project demand and applies its current market share (see Open MRI CON, p. 122). This does not reflect the fact that Open MRI has actually lost market share as it has grown slower than the market. Furthermore, Open MRI’s projected volume in Section Q is inconsistent with the projected market share model provided. (see Open MRI CON, p. 122). It is completely unclear why Open MRI bothered to present a market demand projection when their actual projected utilization is simply based on skewed historical internal data.

*Open MRI’s Projected Utilization is Unsupported by Physician Letters*

Open MRI based its projected utilization on its claimed 100+ letters of support, its historic market share of 28.5 percent, and its historical ability to reach at least 11,000 MRI scans, annually. First, Open MRI provided just 94 letters of support, not over 100 letters of support. While this is an impressive number, none of the authors of such letters of support commit to any specific number or type of referrals that will amount to projected scans for the proposed project (see Open MRI CON p. 52). Without committing to referrals for the project, these letters are meaningless and do not support Open MRI’s projected volume. Moreover, the letters are also disconnected from the needs claimed by Open MRI. For example, Open MRI discusses the importance of oncology scans but does not provide a letter from a single oncologist. Likewise, Open MRI discusses the importance of orthopedic scans but only provided a letter from a single orthopedic surgeon. The vast majority of the letters of support are from primary physicians who comparatively refer less patients for MRI scans than specialists. It is not clear from the letters of support that physicians will refer the projected volume of scans presented by the applicant.



Open MRI's Projected Contrast Volume Does Not Meet the Need for Complex Scans

Open MRI claims it will meet the need for complex scans such as neuro, oncology, and orthopedic patients. As noted, this is not consistent with the physician letters of support. Moreover, it is not supported by the historical and projected percent of patients with contrast. Many of these more complex scans are done with contrast. As previously stated, Open MRI used its historical calendar year data to illustrate its level of contrast scans provided and used a 3-year average of those percentages as a basis for its projected contrast scans (see **Exhibit 9**, below).

**Exhibit 9**  
**Open MRI Historic Percent of Contrast MRI Scans**

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

Source: Open MRI CON, p. 123.

In fact, despite claims of offering increased access to more complex MRI scans (i.e., MRI scans with contrast), Open MRI held its percent of contrast scans constant at 25.3 percent for its projections. If Open MRI were truly going to enhance access to MRI scans with contrast, the percent of scans with contrast it proposes would be reflected in its projections. However, that is not the case. Furthermore, Open MRI's projected percent of MRI scans with contrast, which is held constant, is lower than the total percent of contrast scans for the total market for outpatient scans. As shown below in **Exhibit 10**, market outpatient MRI scans with contrast have steadily increased at a greater rate than scans without contrast from FY 2014 to FY 2019.

**Exhibit 10**  
**Total Market Outpatient Contrast MRI Scans**

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019*	% CAGR
<b>Market with Contrast</b>	9,282	10,033	10,823	11,445	11,591	13,361	7.6%
<b>Market without Contrast</b>	20,026	20,272	17,816	21,410	21,088	21,004	1.0%
<b>Total Market OP Scans</b>	<b>29,308</b>	<b>30,305</b>	<b>28,639</b>	<b>32,855</b>	<b>32,679</b>	<b>34,365</b>	3.2%
<b>Market % Contrast</b>	<b>31.7%</b>	<b>33.1%</b>	<b>37.8%</b>	<b>34.8%</b>	<b>35.5%</b>	<b>38.9%</b>	

Source: 2016-2021 SMFP

\*Corrected Mission utilization

Open MRI has not documented that it will meet the high and growing level of demand for outpatient scans with contrast. As previously stated, outpatient scans with contrast are growing faster by far than non-contrast scans for the market, yet Open MRI projects the same lower percent contrast scans throughout its projection period.

For the reasons discussed above, Open MRI should be found non-conforming to Criterion (3).

#### **Criterion (4) – Open MRI is Not an Effective Alternative to Existing Fixed MRI Providers**

Prior to the current CON, Open MRI acquired a 3.0T MRI scanner in 2018, similar to the scanner that it is requesting approval for now. Since 2018 Open MRI has had the capability to offer advanced MRI scans on its new 3.0T equipment. However, Open MRI is not providing such advanced scans. Their percent of scans with contrast both before and after the proposed project's implementation are below the service area average. Open MRI's letters of support do not indicate that they will provide any meaningful level of oncology scans or even orthopedic scans as they suggest.

Additionally, the purchase of a 3.0T scanner is a more costly alternative than a 1.5T scanner. Open MRI has not presented a need for a second 3.0T scanner given the fact that the scanner would be limited in its patient pool and minimally used. The 3.0T scanner has a magnetic field that is 2 times stronger than a 1.5T scanner. This means that patients with pacemakers, implants and metal fragments would not be able to utilize the scanner. Of its two existing scanners, Open MRI's 3.0T scanner provided less than half of the scans to its patients in FY 2019. Conceivably, Open MRI would split the volume between the two 3.0T scanners resulting in two underutilized MRI units.

Furthermore, Open MRI does not effectively establish that the alternative proposed in this application is the most effective alternative to meet the identified need because the application does not adequately document its projected utilization, financial feasibility, or financial accessibility as documented in other sections of this document.

Based on these issues, Open MRI should be found non-conforming with Criterion (4).

#### **Criterion (5) – Open MRI's Project is Not Financially Feasible**

As discussed with regard to Criterion (3), Open MRI failed to support the reasonableness of its utilization projections. Without reasonable utilization projections, the financial feasibility of the project is called into question. No tangible volume was provided in its physician letters of support, and the letters do not support the range of specialized procedures Open MRI suggests it will provide.

Based on these issues, Open MRI should be found non-conforming with Criterion (5).

#### **Criterion (6) – Open MRI Represents an Unnecessary Duplication of Services**

As described above, Open MRI does not effectively establish the need for its proposed project and does not adequately support its projected utilization. Due to this fact, the proposed project will inevitably result in unnecessary duplication of existing health service capabilities. Open MRI has

not demonstrated a need for the specific services it describes such as oncology and orthopedic scans as there are no meaningful letters of support from these specialists to support Open MRI's claims. Thus, it is clear that Open MRI's project is a duplication of existing services and should be found non-conforming with Criterion (6).

### **Criterion (7) – Open MRI's Projected Staffing is Flawed**

Open MRI proposes to add just 1 radiology tech and 1 tech assistant for this project. This incremental staff is minimal and raises the question of whether Open MRI has sufficient staff to support 3 MRI units, a CT unit, X-ray, and Dexa bone density. This is 6 total imaging units/modalities with just 7.5 radiology techs. For this reason, Open MRI should be found non-conforming with Criterion (7).

### **Criterion (13) – Open MRI Does Not Demonstrate Financial Access**

G.S. 131E-183(a)(13)(d) requires that the Applicant show 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." In its response to Section C, Question 6, Open MRI did not provide any information on the estimated percentage of low-income persons and racial and ethnic minorities it will serve (see Open MRI CON, p. 57). Open MRI states that it does not request or track income data of its patients, racial background information of its patients, or data on patients with disabilities. Without historically tracking this kind of data, it is difficult to accurately project how these underserved groups will be served by a proposed project. This calls into question Open MRI's accessibility when coupled with its historically low percentage of charity care and Medicaid. As shown in the applicant's Form F.2a (TOTAL), Open MRI provided less than one percent of charity care (0.03%) and only 3.4% Medicaid across all modalities. Likewise, for MRI Only, Open MRI shows 3.6% Medicaid and one tenth of a percent charity care (0.01%) (see Form F.2a (MRI)). This historical level of care of low income and uninsured patients is unreasonable in a service area and HSA with large rural areas and a significant low-income population. This performance includes 2020 data reflecting COVID, a time period when many people lost their jobs and unemployment expanded. To provide so little Medicaid and charity care during this period demonstrates a lack of commitment to serving underserved communities.

Accordingly, Open MRI should be found non-conforming with Criterion (13).

### **Criterion (18a) – Open MRI's Proposed Project Will Not Positively Impact Competition in the Service Area**

Open MRI's CON application will not enhance competition in the service area, nor will it have a positive impact upon cost-effectiveness, quality, and access. As demonstrated, Open MRI's

unreliable and unreasonable projected utilization. Despite the growth in demand for contrasted MRI scans in the service area, Open MRI projects to keep its level of contrast scans constant. Furthermore, the percent of contrast scans currently provided and projected by Open MRI is well below what is provided in the service area. Without its proposed project meeting the demand of MRI scans with contrast in the service area, the need will continue to have to be met by the other existing service area providers of MRI services. Therefore, Open MRI's project does not propose to increase competition within the service area.

Open MRI proposes an additional 3.0T MRI scanner at its imaging center which is a duplication of available services within the service area. Based on these issues discussed above, Open MRI's application should be found non-conforming with Criterion (18a).

### **Open MRI FAILS TO MEET THE MRI PERFORMANCE STANDARDS**

10A NCAC 14C .2703 sets the criteria and standards for Magnetic Resonance Imaging units. As such, 10A NCAC 14C .2703(b)(3)(e) states that:

*(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... (e) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

An applicant is not required to show that each individual MRI that it operates in the service area meets the Performance Standards, but rather must show that the average of all of its MRI scanners meet the standards. From a numerical standpoint it appears that Open MRI meets the criteria set forth. However, as previously stated, Open MRI never showed the projected utilization for just its proposed MRI scanner, nor did Open MRI adequately provide support for its projected utilization. Furthermore, Open MRI's projected utilization is unreliable and unreasonable due to the issues discussed under Criterion (3). Accordingly, it is unclear how Open MRI's proposed project will reach the requirement of at least 4,805 weighted MRI procedures in the third year of operation as projected. Based on these issues alone, Open MRI fails to meet the Performance Standards and should be denied.

## COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2021 SMFP, there is a need for one additional fixed MRI scanner in Buncombe/Madison/Yancey/Graham Counties. Thus, although there are three identified applicants, only one can be approved in this review. Both EmergeOrtho's and Open MRI's applications contain major flaws, particularly with respect to Criterion (3), that should result in denial of both applications. Mission Imaging-Biltmore has provided the following comparative review between the three applicants.

### **Mission Imaging Biltmore's Comparative Analysis**

In order to determine the most effective alternative to meet the identified need for a fixed MRI scanner in Buncombe/Madison/Yancey/Graham Counties, Mission has reviewed and compared the following factors in each application:

- Conformity with Review Criteria
- MRI Setting: Freestanding, Hospital-Based vs. Freestanding
- Geographic Distribution
- Demonstration of Need
- Ownership of Fixed MRI Scanners in Buncombe/Madison/Yancey/Graham Counties
- Access by Underserved Groups
- Projected Average Gross Revenue per MRI Procedure
- Projected Average Net Revenue per MRI Procedure
- Projected Average Operating Expense per MRI Procedure

### *Conformity with CON Review Criteria*

EmergeOrtho and Open MRI do not conform with multiple CON Review Criteria and are therefore not approvable. In contrast, Mission Imaging-Biltmore meets all required Review Criteria. As shown below, Mission Imaging-Biltmore is comparatively superior to the competing applicants. The table below provides a comparison of the competing applications in the context of the applicable CON review criteria:

**Comparative Conformity with Review Criteria**

	<b>Mission Imaging-Biltmore</b>	<b>EmergeOrtho</b>	<b>Open MRI</b>
Criterion (1)	X		
Criterion (3)	X		
Criterion (4)	X		
Criterion (5)	X		
Criterion (6)	X		
Criterion (7)	X		
Criterion (8)	X	X	X
Criterion (9)	X	X	X
Criterion (12)	X	X	X
Criterion (13)	X		
Criterion (14)	X	X	X
Criterion (18a)	X		
Criterion (20)	X	X	X
Performance Standards	X		

*X - Conforms with criterion.*

*MRI Setting and Ownership Affiliation*

As previously established, EmergeOrtho is proposing a freestanding fixed MRI unit at its Arden office location, and Open MRI is proposing an additional freestanding fixed MRI unit at its existing imaging center where it already operates 2 MRI units. Mission Imaging-Biltmore, by contrast, proposes a freestanding, hospital-affiliated unit at its imaging center located in Asheville. Nonetheless, all applicants will be reimbursed on the same freestanding fee schedule and projected charge/reimbursement will not vary significantly other than the complexity of scan volume, which would impact averages.

While freestanding in nature for convenience and billing, the proposed Mission Imaging-Biltmore MRI will fully benefit from the affiliated Mission Health resources. This location and ownership structure provides the best of all scenarios from a highly cost effective and convenient freestanding setting with the complex and specialized scans offerings supported by the majority tertiary hospital provider for the region along with its specialized referral base and reading radiologists. The benefits of clinical complexity and range of scan offerings such as breast MRI are emphasized by the support of Mission Imaging’s physician letters of support like that provided by Dr. Brown in **CON Exhibit C-4.2 (Tab 2) pp. 7-9.**

From the 2021 SMFP, it is apparent that Mission Imaging-Biltmore affiliated fixed MRI providers collectively drove the need for an additional fixed MRI unit in the service area. **Exhibit 11** presents the utilization and capacity for all service area fixed MRI providers as presented in the 2021 SMFP based on a capacity of 6,864 scans per unit as described in the MRI Performance Standards. Collectively, the hospital-based providers operated at 55.9 percent of capacity, but as noted in Mission Imaging’s application, many of the MRI units are dedicated for specialized functions such as the Children’s Hospital. Note that Mission Hospital – Main operates at the highest percent of

capacity (89 percent) for hospital-based providers. The freestanding providers operated at a collective 84.8 percent of capacity, with Mission Imaging Services operating at the highest capacity at 100.7 percent. The Mission-affiliated volume and specifically Mission Imaging’s high utilization drove the recognized 2021 SMFP need. This need would not be addressed by any other applicant. Of note, based on the MRI Performance Standards, EmergeOrtho is operating at the lowest percent of capacity at just 42.5 percent.

**Exhibit 11  
FFY 2018 Fixed MRI Scans and Capacity by Location**

	<i>Adjusted Fixed MRI Scans</i>	<i>Fixed Units</i>	<i>% Capacity</i>
<b>Hospital Fixed MRI Providers</b>			
Mission Children’s	1,908	1.0	27.8%
Mission Hospital - Carolina Spine & Neurosurgery	3,258	1.0	47.5%
<b>Mission Hospital – Main</b>	<b>12,213</b>	<b>2.0</b>	<b>89.0%</b>
Mission Hospital - St. Joseph Campus	1,797	1.0	26.2%
<b>Total Hospital Fixed</b>	<b>19,176</b>	<b>5</b>	<b>55.9%</b>
<b>Freestanding Fixed MRI Providers</b>			
<b>Mission Imaging Services (MH Mission Imaging, LLLP) – Ashland Campus</b>	<b>13,822</b>	<b>2.0</b>	<b>100.7%</b>
Open MRI of Asheville (Asheville Open MRI, LLC)	12,370	2.0	90.1%
EmergeOrtho - Blue Ridge Division (InSight Imaging)	2,919	1.0	42.5%
<b>Total Freestanding Fixed</b>	<b>29,111</b>	<b>5</b>	<b>84.8%</b>

*Source: 2020 Draft SMFP*

It is clear that Mission Imaging is the most highly utilized and that EmergeOrtho’s available freestanding fixed unit has available capacity. EmergeOrtho’s proposed project for a freestanding fixed MRI unit will not best meet the needs of service patients, especially given the fact that it would be utilized for orthopedic scans only.

Furthermore, Mission Imaging-Biltmore’s proposed project will provide more complex scans than proposed by Open MRI. Mission Imaging-Biltmore is the provider of choice in the region for breast, cancer, and other types of specialized care that requires specialized MRI scans. Many of these specialized scans require contrast in order to properly image and diagnose conditions. As noted previously, outpatient scans with contrast are the most rapidly growing scan type. One way to determine which provider will provide the enhanced access to complex MRI imaging is to determine which provider proposes to offer the most MRI scans with contrast. As seen in **Exhibit 12** below, no other applicant proposes to offer as many scans with contrast as Mission Imaging-Biltmore. Mission Imaging-Biltmore will clearly offer enhanced access to more complex scans in a freestanding, low-cost setting than the other applicants. Mission Imaging-Biltmore is the superior applicant.

**Exhibit 12**  
**Percent of Contrast Scans in 3rd FFY**

<b>Facility</b>	<b>Total Unweighted Scans</b>	<b>Unweighted Contrast Scans</b>	<b>% of Scans</b>
Mission Imaging-Biltmore	4,467	3,668	82.1%
EmergeOrtho	5,267	87	1.7%
Open MRI	4,660	1,179	25.3%

*Source: EmERGEOrtho, Open MRI, and Mission Health - Imaging CON Applications*

*Geographic Distribution*

The 2021 SMFP identifies the need for one fixed MRI scanner in the service area. **Exhibit 13** identifies the location of the existing fixed MRI scanners in the service area. There are 10 existing fixed MRI scanners located in Buncombe/Madison/Yancey/Graham Counties. All but one of the existing fixed MRIs are located in Asheville, Buncombe County, North Carolina. The only other existing fixed MRI in the service area is operated by EmERGEOrtho at its Arden, Buncombe County, North Carolina location. There are no fixed MRI scanners located in other cities within the service area. Neither EmERGEOrtho nor Open MRI propose a new location where an MRI does not already exist. In fact, EmERGEOrtho simply plans to replace an existing MRI having no impact on available capacity or location. Mission Imaging-Biltmore creates a new, convenient, freestanding location to offer outpatient MRI services and a unique setting adjacent to Mission Health’s breast center. This unique setting will enhance access and create a specialty MRI center offering the most advanced scans in a convenient, cost-effective setting.

**Exhibit 13**  
**Existing and Approved Fixed MRI Scanners by Location in**  
**Buncombe/Graham/Madison/Yancey Counties**

<b>Facility</b>	<b>City/Town</b>	<b># of Existing Fixed MRI Units</b>
<b>Existing Fixed MRI Units</b>		
Mission Children’s	Asheville	1
Mission Hospital - Carolina Spine & Neurosurgery	Asheville	1
Mission Hospital – Main	Asheville	2
Mission Hospital - St. Joseph Campus	Asheville	1
EmerGEOrtho-Blue Ridge Division (Insight Imaging)	Arden	1
Mission Imaging Services (MH Mission Imaging, LLLP)	Asheville	2
Open MRI of Asheville (Asheville Open MRI, LLC)	Asheville	2
<b>Total Existing Fixed MRI Units</b>		<b>10</b>

*Source: 2021 SMFP*



### Demonstration of Need/Support for the Project

Mission Imaging-Biltmore effectively demonstrates that its projected utilization of the proposed fixed MRI scanner is reasonable, provides adequate documentation of the assumptions and methodologies that support its projections, and establishes the need that the population that it proposes to serve has for Mission's proposed services. While it is clear that specialized scans with contrast are driving the need for more MRI capacity, EmergeOrtho nor Open MRI have grasped this concept and therefore have not presented projects that would meet the needs of service area patients. Neither EmergeOrtho nor Open MRI adequately establish a quantitative need for their proposed projects supporting the need of the population each applicant proposes to serve. EmergeOrtho does not provide adequate documentation for the assumptions and methodologies that support its aggressive projections of growth in scan volume. Open MRI's projected utilization is unsupported due to the use of an unreasonable and unsupported base fiscal year 2021. As discussed above, there is no documented basis for a one-year increase of over 20 percent from which future volume is then projected. Open MRI inaccurately mistakes the backlog of scans during COVID with a sustained growth rate, which is simply unreasonable.

Furthermore, neither EmergeOrtho nor Open MRI propose to offer the same level of contrast scans as Mission Imaging-Biltmore, meaning neither applicant will meet the growing demand for more complex MRI scans in the service area as documented by Mission Imaging-Biltmore. EmergeOrtho's small fraction of contrast scans will not address the service area demand in any meaningful way. While Open MRI discusses the need for more contrast scans, its projected scan volume percentage is held constant through the projection period and is far below service area demand. Please see **Exhibit** \_ presented previously. Therefore, the application submitted by Mission Imaging-Biltmore is the superior application with regard to demonstration of need.

Furthermore, Mission Health affiliated physicians provided phenomenal letters of support documenting the need for specialized MRI scans, research on different types of cancers and how MRI imaging has become the standard of care, and tangible volume for the proposed project. The same cannot be said for either EmergeOrtho or Open MRI. EmergeOrtho only provided form letters of support from its own in-house orthopedic physicians and did not provide support from primary care physicians that it claims will reportedly refer patients to its current scanner. By contrast, Open MRI provided mostly letters from primary care physicians, who do not typically refer high volume. In fact, Open MRI discusses the need for more oncology and orthopedic scan volume but does not support this with letters from these specialists.

Additionally, as previously stated under Criterion (4), the project proposed by Open MRI would be a costly alternative. Given Open MRI did not provide adequate support for its project, and the fact that it already owns a 3.0T scanner that does not provide half of its scans, the proposed project will result in two expensive, underutilized scanners in the service area.

### Time to Market

Of the three applicants for a proposed fixed MRI scanner in the service area, Mission Imaging-Biltmore is the only applicant that can realistically come to market first to meet the needs of service area residents. If approved, Mission Imaging-Biltmore proposes to come to market in April of 2022. Given the experience of Mission Imaging-Biltmore and its affiliates with establishing MRI and other imaging services, it is entirely reasonable that it can come to market within the proposed timeframe. Open MRI proposes to come to market behind Mission Imaging-Biltmore with a date of July 2022. Interestingly, EmergeOrtho has a long project timeline, not proposing to offer services until January of 2023. With Mission Imaging-Biltmore's experience in the service area, proposed offering of complex scans, and quick time to market, it is the superior applicant.

### Affiliation of Fixed MRI Scanners in Buncombe/Madison/Yancey/Graham Counties

As shown in **Exhibit 14**, below, there are a total 10 existing fixed MRI scanners in Buncombe/Madison/Yancey/Graham Counties that are owned by four different providers. **Exhibit 14** also provides the number of fixed MRI scanners, the total number of weighted scans, and the average weighted scans per scanner as reflected in the 2021 SMFP. Currently, 5 of the existing fixed MRI scanners are hospital-based and 5 are in a freestanding outpatient imaging facility. Mission Health (parent system of MH Mission Imaging) owns 7 of the 10 existing fixed MRI scanners, EmergeOrtho operates 1 of the 10 fixed MRI scanners, and Asheville Open MRI (affiliated with Novant Health, Inc.) owns 2 of the 10 existing fixed MRI scanners in Buncombe/Madison/Yancey/Graham Counties. As shown below, no other provider offers more weighted scans per scanner than Mission Health's freestanding facility. Additionally, no other provider has the same experience of serving service area patients and providing complex scans as Mission Health.

All the applicants have historically provided fixed MRI services in Buncombe County. The number of fixed MRI providers is not proposed to change by the approval of any of the projects. Therefore, in terms of number of providers, no competition is being added to the service area. However, with regard to improving accessibility to a unique provider of MRI services in Buncombe/Madison/Yancey/Graham Counties, only Mission's proposed project will do that. Mission Imaging-Biltmore is the superior applicant.

**Exhibit 14**  
**Ownership of Existing and Approved Fixed MRI Scanners in**  
**Buncombe/Graham/Madison/Yancey Counties**

<b>Provider</b>	<b>Number of Fixed MRI Scanners</b>	<b>Total Number of Weighted Scans</b>	<b>Average Weighted Scans per Scanner</b>
<b>Hospital Fixed MRI Providers</b>			
Mission Hospital	5.0	19,176	3,835
<b>Freestanding Fixed MRI Providers</b>			
Mission Imaging Services (MH Mission Imaging, LLLP)	2.0	13,822	6,911
Open MRI of Asheville (Asheville Open MRI, LLC)	2.0	12,370	6,185
EmergeOrtho-Blue Ridge Division (Insight Imaging)	1.0	2,919	2,919
<b>Total Existing Fixed MRI Units</b>	<b>10.0</b>	<b>48,287</b>	<b>4,829</b>

Source: 2021 SMFP

Access by Underserved Groups

**Exhibit 15**, below, illustrates the number and percentage of MRI procedures projected to be reimbursed by Medicaid and Medicare, and the number and percentage of MRI services projected to be Self-Pay in Project Year 3 using weighted scans, as stated in Section L.3 and Form F.2 of the respective applications.

**Exhibit 15**  
**Comparison of Section L - Projected Payor Mix 3<sup>rd</sup> FFY**

	<b>Mission Imaging - Biltmore</b>	<b>EmergeOrtho</b>	<b>Open MRI</b>
Number and Percentage of MRI Procedures to <b>Medicaid</b> Recipients	297 (5.0%)	159 (3.0%)	187 (3.56%)
Number and Percentage of MRI Procedures to <b>Medicare</b> Recipients	2,516 (42.4%)	2,121 (40.0%)	2,211 (43.08%)
Number and Percentage of MRI Procedures to be Provided as <b>Self-Pay</b> *	172 (2.9%)	122 (2.3%)	256 (4.98%)
<b>Total Underserved Patients</b>	<b>2,985</b>	<b>2,402</b>	<b>2,654</b>
<b>% of Total</b>	<b>50.3%</b>	<b>45.3%</b>	<b>51.7%</b>

Sources: Section L CON Applications

\*Combined all applicant's payor categories of Self-Pay and Charity Care; see Section L of CON applications, Projected Payor Mix MRI Only.

Mission Imaging-Biltmore proposes to serve the highest number of underserved patients among all of the other applicants. Mission Imaging-Biltmore proposes to receive the highest number and percentage of Medicaid patients and the highest number and percentage of Medicare patients. Open MRI proposes to receive the highest number of Self-Pay patients. EmergeOrtho falls well

short of proposing to adequately serve underserved patients in the service area. Comparatively, Mission Imaging-Biltmore is the superior applicant with regard to access by underserved groups.

In the past, the CON Section has used several additional comparative factors, which in this instance are not relevant. These factors include charge per scan, reimbursement per scan, and cost per scan. All three applicants will charge and be reimbursed on the same freestanding outpatient fee schedule. Thus, any comparison of these factors would merely reflect the average acuity of scans for which we know Mission Imaging-Biltmore will be more complex. Similarly, the cost per scan will be similar in a freestanding setting for all providers and any variation in costs per scan would likely reflect variation in staffing, which in fact more staff (costlier) may result in superior quality of care.

## **CONCLUSION**

EmergeOrtho's and Open MRI's applications are not approvable, as neither applicant conforms to Criteria (1), (3), (4), (5), (6), (13), (18a), and the Performance Standards for MRI services. Mission Imaging-Biltmore's application meets all applicable criteria and standards for MRI services. In addition, for each of the comparative factors provided in this analysis, Mission Imaging-Biltmore is determined to be the superior applicant with regard to:

- MRI Setting: Freestanding, Hospital-Based vs. Freestanding
- Geographic Distribution
- Demonstration of Need
- Access by Underserved Groups

Regardless of the comparative factors, only Mission Imaging-Biltmore clearly meets all CON Review Criteria and the fixed MRI Performance Standards, presenting clear and reasonable documentation throughout its application. Further, Mission Imaging-Biltmore is dedicated to meeting the MRI needs of Buncombe/Madison/Yancey/Graham Counties in the hospital-based, and freestanding, hospital-based setting that drove the need for an additional fixed unit in the first place. Even if EmergeOrtho or Open MRI met the CON Review Criteria, which they do not, Mission Imaging-Biltmore is the best applicant on a comparative basis to ensure access to care and provide the highest level of clinical quality and continuity of care for its patients. Thus, Mission Imaging-Biltmore should be approved.