

**Open MRI & Imaging of Asheville, LLC's
Comments in Opposition to
Mission Imaging's Certificate of Need Application for
One Fixed MRI Scanner in Buncombe County
March 1, 2021 Review Cycle**

INTRODUCTION

The 2021 State Medical Facilities Plan (SMFP) identified a need for one fixed MRI scanner in Buncombe County. In response to the need determination, three applicants have submitted Certificate of Need applications:

Open MRI and Imaging of Asheville (Open MRI) (Project ID No. B-12032-21)

Emerge Ortho (Project ID No. B-12023-21), and

Mission Imaging (Project ID No. B-12035-21).

Pursuant to N.C. Gen. Stat. §131E-185(a)(1), Open MRI submits the following comments pertaining to the application filed by Mission Imaging to acquire one fixed MRI scanner in Buncombe County as identified in the 2021 SMFP. As discussed in the following comments, the application submitted by Mission Imaging fails to meet all necessary standards and review criteria and should be disapproved. In addition, for the reasons explained in the comparative analysis section below, Open MRI's application is comparatively superior to the other applications.

An important consideration in this review is the actual need for the proposed project. Although each applicant is required to demonstrate need for the proposed service, it is critical for the Buncombe County MRI Service Area and this MRI Review. The availability of MRI need determinations in western North Carolina are few and far between. Prior to 2021 review, the previous MRI need determination was in the **2001** SMFP. Providers in western North Carolina not only have to deal with extended periods without additional need determinations but they must also serve a large geographic area that is predominantly comprised of rural communities. These factors dictate that particular attention should be focused on the provider that is best suited to do the following:

- Provide the widest range of MRI imaging procedures to address the needs of physicians and their patients in the community from general practitioners to neurosurgeons.
- Focus service on residents from the Buncombe County MRI Service Area.
- Offer the most advanced technology for the proposed MRI unit, such as a 3T MRI, in order to provide the community with increased access to enhanced MRI imaging capabilities.
- Provide the MRI service at reasonable costs and charges.

- Increase accessibility to the medically underserved populations in light of the ongoing economic stress due to the COVID pandemic.

The importance of this MRI review for Buncombe County cannot be understated. This decision could impact accessibility to MRI services for Buncombe County MRI service area patients for the next decade or more. As discussed below, the application submitted by Mission Imaging failed to demonstrate conformity with all applicable review criteria and should be disapproved.

Comments regarding Mission Imaging’s application:

Criterion (1) – Consistency with State Health Plan

The Mission Imaging application should be found not conforming with Criterion (1) and Policy GEN-3 because it fails to demonstrate how its projected utilization incorporates the concept of maximum value for resources expended. Mission Imaging’s application contains unreliable MRI utilization projections, will result in an unnecessary duplication of existing services and provides unsupported financial projections, and projects insufficient staffing. See additional discussion under Criteria (3), (4), (5), (6), (7), and (18a).

Criterion (3) – Need and Population to be Served

Mission currently controls 70% of the fixed MRI scanners in Buncombe County. Mission’s five (5) hospital-based MRI units are averaging only **3,961** scans per unit, which is significantly below the area average threshold of 4,805 scans. According to the 2021 SMFP, three of Mission’s existing MRI units are critically underutilized, which raises questions regarding the need for additional resources for this provider.

Mission’s Existing Underutilized MRI Scanners					
Facility	No. of Fixed MRIs	FY 2018-19 (2021 SMFP)		FY 2019-2020#	
		Unweighted Volume	Weighted Volume	Unweighted Volume	Weighted Volume
Mission – St Josephs	1	1,176	1,797	233	329
Mission – Carolina Spine	1	2,768	3,258	2,222	2,697
Mission – Childrens	1	1,572	1,908	1,285	1,544

Source: 2021 SMFP; 2021 License Renewal Application and 2021 Medical Equipment Inventory reports from Mission Hospital and Mission Imaging. See Mission Imaging, application page 68.

Mission fails to adequately address the underutilization of the three (3) existing MRI scanners that they own and operate. In its application, Mission states that due to the need for breast MRI imaging it requires an eighth fixed MRI scanner to provide this service. Mission indicates that Mission-Asheland currently offers the breast imaging service that it proposes in this application for Mission-Biltmore.

Open MRI’s parent company, Novant Health’s has considerable experience as an acute care provider with multiple hospitals across North Carolina as well as over 20 freestanding imaging centers. Novant Health Forsyth Medical Center is one of two dedicated breast MRI providers in North Carolina. On

March 3, 2021, NHFMC filed a petition with the State Health Coordinating Council to convert the dedicated breast MRI scanner to a general use scanner as breast MRI imaging demand is insufficient to support a full-time fixed MRI scanner.

The following chart is an excerpt from the NH Forsyth Medical Center petition that details the volume of breast MRI scans in Forsyth County:

	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
Acute Care Sites	12470	13625	13915	14746	13411
Breast MRI Procedures	0	29	72	57	41
Breast MRI as % of Total	0	0.21%	0.52%	0.39%	0.31%
Acute Care includes: NHForsyth Medical Center, NHClemmons, NHKernersville					
Outpatient Sites	21055	22499	23241	22059	19899
Breast MRI Procedures	840	1021	1000	898	802
Breast MRI as % of Total	4.00%	4.50%	4.30%	4.07%	4.04%
Outpatient includes: Maplewood, Piedmont Imaging and NHI Kernersville					

This chart details the total breast MRI scan volume for the past 5 years for 3 hospitals and 3 freestanding imaging centers operating a total of 10 fixed MRI scanners in Forsyth County. As shown in this chart, breast MRI volume has not exceeded 1,100 MRI scans in the past five years. As a population reference, Forsyth County’s 2020 population is 380,964 residents compared to Buncombe County’s 2020 population of 264,408 residents.

In Novant’s experience, third-party payors are continuing to steer providers towards low-cost modalities that are widely utilized for the majority of women for the detection of breast cancer such as 3D mammography, ultrasound and stereotactic biopsy when medically appropriate. It would appear that Mission Imaging has overstated the demand for breast MRI scans in the service area. Mission Imaging provides the following letter from a radiologist regarding breast MRI demand.

Dr. Brown’s letter of support in **Exhibit C-4.2, Tab 2** supports the anticipated potential for expanded Breast MRI demand based on the new 2018 protocols:

“We currently perform approximately 1,100 breast MRIs annually but should be performing closer to 5,000 given the number of screening mammograms performed across our health system. The root cause is due to constraints in MRI capacity, suboptimal utilization of cancer risk assessment tools in our population and MRI resources that are physically separated from our breast imaging program. Advisory Board market analysis tools forecast a 35% growth in breast MRI over the next 5 years.” – Dr. Andy Brown, MD

Dr. Andy Brown, a radiologist, has likely overestimated the number of breast MRI scans at 5,000 scans annually. Dr. Brown’s statement is inconsistent with the information contained in the application that suggests an estimated 3,921 breast MRIs in Year 3 of operation based on mammogram screenings. See Mission Imaging application, page 55. Much larger health systems in more heavily populated areas of

North Carolina are not performing 5,000 breast MRI scans annually as demonstrated by the Forsyth County breast MRI volume in the chart above.

While breast cancer detection is an important health issue, Mission fails to explain why more efficient utilization of its existing MRI resources are not being considered as viable options. Three of the seven MRI units owned by Mission are critically underutilized and have operated in that manner for many years. It is not possible for an applicant to demonstrate need for additional MRI equipment when its existing MRI resources have significant unused capacity.

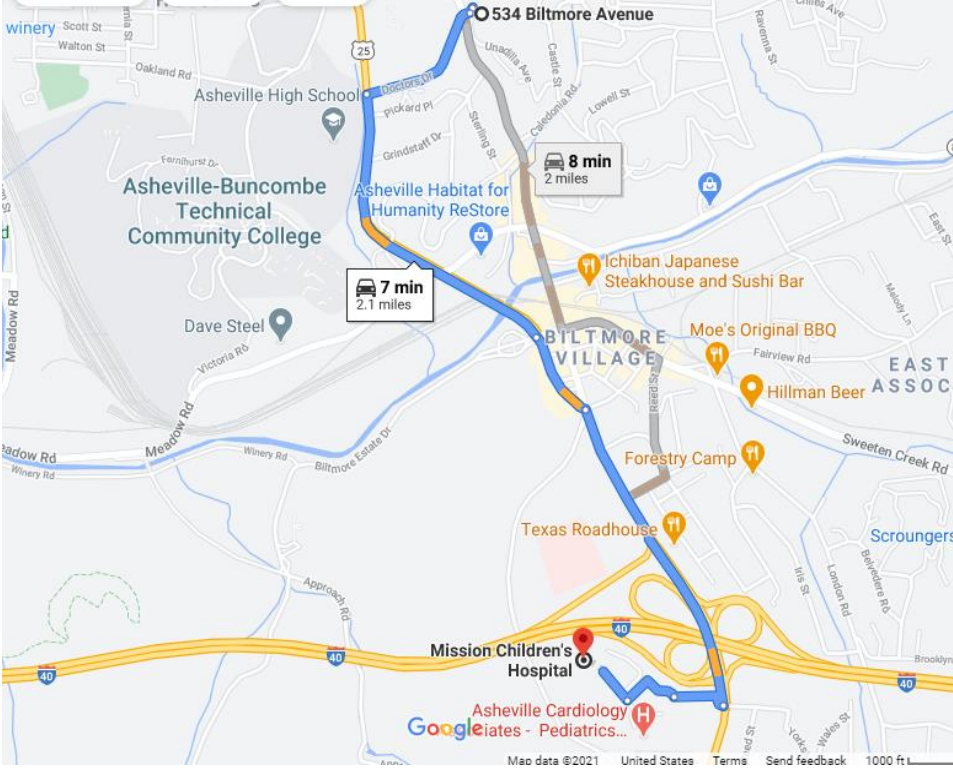
Mission Imaging fails to demonstrate the need for the proposed project as required by Criterion (3) based on unreasonable and unsupported MRI utilization projections.

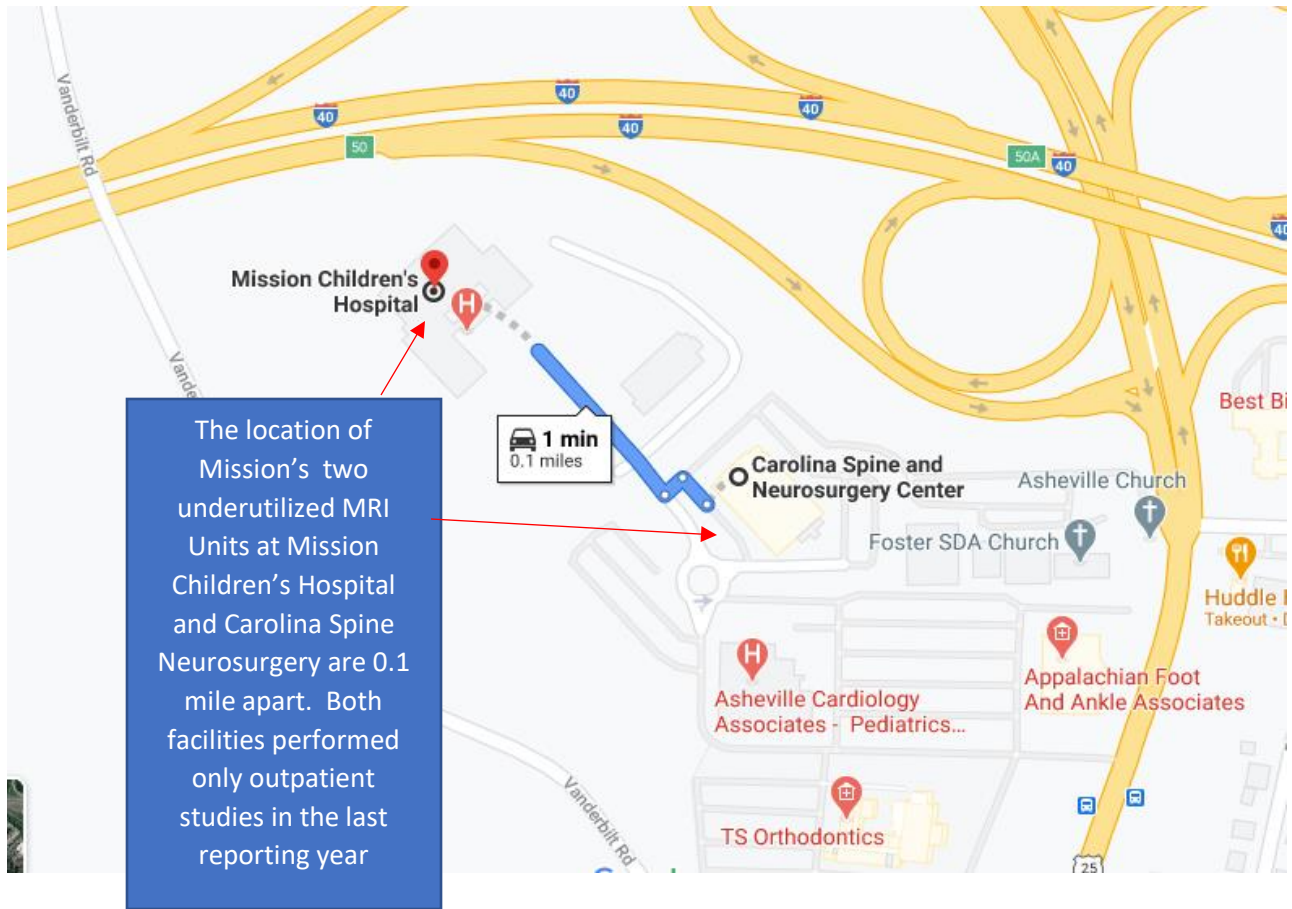
Criterion (4) –Least Costly, Most Effective Alternative

Criterion 4 requires an applicant to demonstrate that the least costly or most effective alternative has been proposed. Mission owns and operates seven (7) existing fixed MRI scanners and of those units three (3) are critically underutilized. See discussion under Criterion 3. Like most large health systems, Mission utilizes central scheduling for its MRI patients. This means that the applicant, Mission, has the ability to steer patients to its facilities. Despite this internal capability, three (3) MRI units are not being utilized to their full potential. Mission Imaging has alternative methods currently available to them to meet the needs outlined in its proposed project.



The distance between the other underutilized MRI units operated by Mission are approximately two miles away.





The three underutilized MRI units are within two miles of the proposed site of Mission Imaging's project. Two of the chronically underutilized MRI units, at Mission Childrens and Carolina Spine, which only serve outpatients and are located within walking distance of each other. With two underutilized MRI units in the same block, it is unclear why Mission would not seek to enhance the utilization of these two existing MRI units to provide the services proposed in its application. Mission has failed to demonstrate that it has proposed the least costly, most effective alternative for the development of the need determination for one MRI scanner in Buncombe County. Mission has substantial unused, existing MRI capacity that should be considered prior to approving this provider for any additional MRI resources.

Further, Mission Imaging does not discuss the alternative of upgrading its existing MRI scanners with a breast coil package that would enable them to perform breast MRI scans. The ability to perform breast MRI imaging does not depend on the purchase of a new MRI scanner. A breast coil package for a 1.5T MRI scanner would cost approximately \$40,000 to \$90,000 and could be utilized with its existing MRI scanners.

Criterion (5) – Financial Feasibility

As discussed under Criterion (3), Mission Imaging's MRI utilization projections and assumptions are both unreliable and unsupported. This calls into question the reasonableness of the financial projections as it is based on the MRI utilization projections.

It does not appear that Mission Imaging provided a Form F.2b Projected Revenues and Net Income upon Project Completion for the MRI only at Mission Imaging-Biltmore. On page 127, Mission Imaging provided projected revenues for “Mission Imaging-Biltmore (All Dx Imaging + new MRI)”. Based on the information provided in the Mission Imaging application, it is not possible to determine projected gross and net revenue associated with the proposed MRI scanner as the information contains both MRI procedures and other imaging modalities. Without the projected gross and net revenue for the proposed MRI scanner, it is not possible to determine the financial feasibility of the proposed project and a comparative analysis cannot be completed. Mission Imaging has failed to provide the necessary financial pro formas for the proposed project.

Mission Imaging has failed to demonstrate that its financial projections are based on supported and reasonable assumptions and should be found non-conforming with Criterion (5).

Criterion (6) – Unnecessary Duplication of Existing Services

As discussed under Criterion (3), Mission Imaging fails to explain why its proposed project will not result in an unnecessary duplication of existing services. Mission fails to explain why more efficient utilization of its existing MRI resources are not being considered as viable options. Three of the seven MRI units owned by Mission are critically underutilized and have operated in that manner for many years. Mission Imaging has failed to demonstrate that its proposed project will not result in an unnecessary duplication of existing services and should be found non-conforming with Review Criterion 6.

Criterion 7- Staffing

Mission Imaging states that it will add 5 radiology techs for the new MRI and the average salary is approximately \$53,000. This is substantially lower than current salary rates in the market. This issue means that Mission Imaging’s staffing expenses could be underestimated and should be considered unreliable.

Criterion (18a) – Positive Impact on Competition

Mission Imaging’s application will not enhance competition in the service area nor will it have a positive impact on cost-effectiveness, quality and access. Currently, Mission controls 70% of the fixed MRI scanners in Buncombe County. As discussed in these comments, 3 of the 7 Mission MRI units are critically underutilized with no apparent plan to increase utilization of its existing MRI resources. Mission proposes to focus on breast MRI studies for the proposed MRI unit. There are unresolved questions about the accuracy of Mission’s breast MRI demand, which may impact the ability of the proposed MRI scanner to be fully utilized. Considering it has taken 20 years for a new MRI need determination in Buncombe County, the proposed MRI scanner should be fully open and available to all patient populations and their referring physicians.

Comparative Analysis

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2021 SMFP, there is a need for one fixed MRI scanner in Buncombe County. There are three applicants in this review but only one applicant can be approved. The last MRI need determination available in Buncombe County was over 20 years ago. It is critical that the proposed MRI scanner is awarded to a provider that can provide high quality scans to the broadest patient population in a cost-effective outpatient setting.

Geographic Accessibility

All applicants propose a location within Buncombe County.

Applicant	Proposed Location
Open MRI	Asheville (Buncombe)
Mission Imaging	Asheville (Buncombe)
Emerge Ortho	Arden (Buncombe/Henderson County Line)

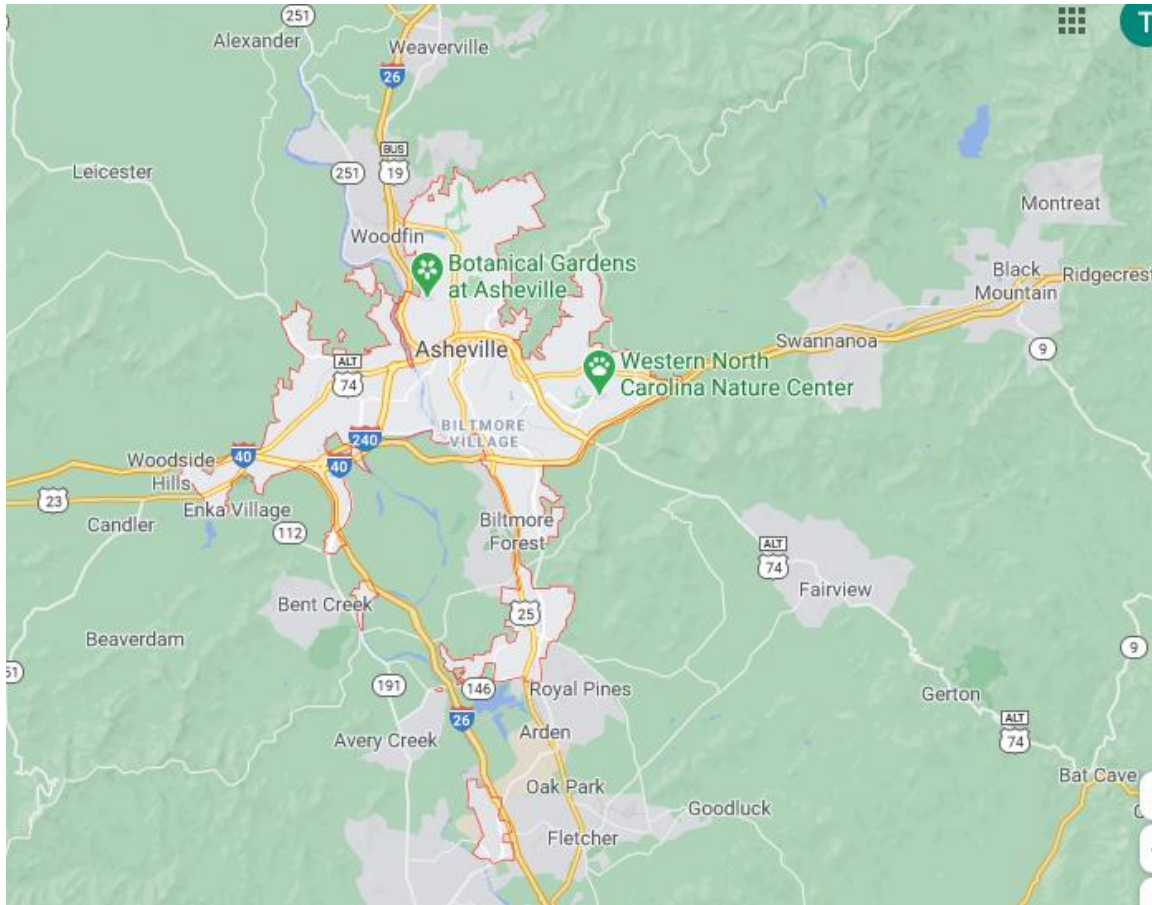
According to the Office of Budget and State Management (OBSM), Buncombe County has increased its population by 10.2% from 2010-2019. The most substantial growth has occurred in Asheville, with population increases of 12% over the last decade. Other communities experiencing high growth in Buncombe County are areas like Montreat (33.75% growth) and Weaverville (28.62%), which are east and north of Asheville.

Municipal Population Estimates for 2010-2019

Buncombe		238,330	262,659	24,329	10.21
	Asheville	83,393	93,413	10,020	12.02
	Biltmore Forest	1,343	1,357	14	1.04
	Black Mountain	7,848	8,515	667	8.50
	Montreat	723	967	244	33.75
	Weaverville	3,120	4,013	893	28.62
	Woodfin	6,123	6,673	550	8.98

Source: NC OBSM, Municipal Estimates for 2010-2019

As the major population center in Buncombe County, Asheville is the most easily accessible location from all points in the service area due to its proximity to both Interstates 40 and 26. Asheville is the central hub for healthcare services in western North Carolina. Due to the travel hardships that many western North Carolina residents face, service area residents benefit from the ability to access necessary healthcare services in a centralized location like Asheville.



The development of the proposed MRI scanner in Asheville would decrease travel hardships and accessibility issues for patients from Madison, Yancey, Haywood, McDowell and Jackson Counties. Madison and Yancey Counties do not have access to mobile or fixed MRI services and are included as part of the MRI Service Area for Buncombe County.

Due to the extended time periods between need determinations for Buncombe County, the priority should be providing service to Buncombe County MRI Service Area residents. This is particularly true considering the excess capacity currently available on the existing MRI units located within Henderson County.

With respect to geographic accessibility, Open MRI is the most effective alternative. Open MRI will offer a convenient outpatient location in Asheville, which is easily accessible for all patients in the Buncombe County MRI service area less than a mile from Interstate 40, which runs the length of western North Carolina. Asheville is the central population hub of the MRI Service Area and is closest to where the growth in population has occurred for the last decade.

Access by Underserved Groups

During this time of economic strain, the medically underserved populations are in even greater need of access to the proposed MRI scanner. Open MRI’s projected payor source is based on its long-standing history of providing high quality MRI services for the community. Open MRI’s commitment to provide high-quality MRI services to all patients is reflected in its application and overwhelming support from the medical community for its project.

The following table provides the payor source data for each applicant.

Payor	Open MRI- Year 3		Mission Imaging – Year 3		Emerge Ortho- Year 3	
	Percentages	Patients	Percentages	Patients	Percentage	Patients
Charity Care	1.0%	140	1.7%	76	1.5%	79
Self Pay	3.98%	556	1.2%	54	0.8%	42
Medicare	43.08%	6,023	42.4%	1,894	40.0%	2,107
Medicaid	3.56%	498	5.0%	223	3.0%	158
Totals	51.62%	7,217	50.3%	2,247	45.3%	2,386

Source: Application Section L for each applicant. Mission Imaging patients based on projected patient numbers for Year 3 (4,467 patients) from Projected Patient Origin chart on page 39.

With regard to access by the medically underserved, Open MRI is the most effective alternative.

Open MRI proposes to serve the highest number of patients from the medically underserved groups listed above. Open MRI’s proposed MRI scanner will provide the most enhanced accessibility for the medically underserved patient population for the following reasons:

- Open MRI’s proposed MRI scanner will be available to a wide range of physicians from general practice to neurosurgery, unlike the other applicants that will primarily focus on orthopedics and women’s services.
- Open MRI’s 3T scanner will offer exceptional quality at a low cost for the service area’s complex MRI imaging needs. Open MRI is the only applicant proposing a 3T MRI scanner.
- Open MRI has existing relationships and the support of community providers, like Western North Carolina Community Health Services, that work closely with the service area’s indigent populations. See Open MRI Exhibit C, for a letter of support from the health professionals at WNCCHS.

Open MRI is the most effective alternative regarding the provision of service to the medically underserved populations in Buncombe County.

Projected Average Gross Revenue per MRI Procedures

The projected average gross revenue per MRI procedure is a comparative factor used by the Agency but it has its limitations. The average gross revenue per MRI procedure for each facility is directly linked to the types of MRI scans performed by the facility as each individual MRI CPT code has a different monetary value. If a facility is performing more complex MRI studies, the facility’s average gross revenue per procedure could be higher as result. Further, third-party payors such as Medicare,

Medicaid and commercial insurers have negotiated rates that are lower than the charge schedule for each facility.

Comparison of Average Gross Revenue per Procedure – PROJECT YEAR 3

Applicant	Gross Revenue	# of Unweighted Procedures	Total Gross Revenue Per Procedure
Open MRI	\$30,249,094	13980	\$2163
Mission Imaging	Info not provided	5934	---
Emerge Ortho	\$5,845,911	5267	\$1110

Source: Form C and Form F.2 from each application.

This review represents a prime example of why a comparison of gross revenue per procedure is not an effective measure for competitive MRI reviews. A facility’s case mix will in part determine a facility’s gross charges. A provider like Open MRI that offers complex MRI procedures involving contrast will have a higher average gross charge per procedure than a facility focused on simple, non-contrast procedures. The allowable charges for contrast MRI scans are higher than non-contrast scans due to the increased expense of providing contrast scans that require a contrast agent, additional staff supervision and physician oversight. Generally, in an outpatient setting, the percentage of contrast scans will range from 20% to 40%.

A review of other MRI providers in Health Service Area I (HSA I) illustrates that in every community in western North Carolina the demand for outpatient-based contrast scans is consistently in excess of 20% of MRI volume. See the following chart.

County	Total Outpatient Scans – All Providers	Number of OP Scans without Contrast	Number of OP Scans with Contrast	% Contrast – Outpatient Studies
Buncombe County	31384	19096	12288	39.2%
Transylvania County	1716	1314	402	23.4%
Burke County	7074	5234	1841	26.0%
Catawba County	14685	10242	4443	30.3%
Cleveland County	5872	3945	1927	32.8%
Henderson County	6895	4346	2549	36.9%
Haywood County	4020	2872	1148	28.6%
Watauga County	3467	2471	996	28.7%
Wilkes County	2530	1705	825	32.6%
McDowell County	2595	1917	678	26.1%
Macon County	2791	2157	634	22.7%

Source: 2021 SMFP.

Open MRI reviewed data in the 2021 SMFP related to total outpatient MRI scans, including contrast and noncontrast scans, for various counties in Health Service Area I. This data shows that in HSA I the percentage of outpatient contrast scans typically falls between 22.7% to 39.2% based on information reported in the 2021 SMFP.

With regard to projected average gross revenue per MRI procedure, Open MRI is the most effective alternative.

Projected Average Net Revenue per MRI Procedures

The following table presents the projected average net revenue per MRI procedures for the third year of operation for the applicants based on the information provided in Form C and Form F.2 of each application.

Comparison of Average Net Revenue per Procedure – Project Year 3

Applicant	Net Revenue	# of Unweighted MRI Procedures	Average Net Revenue Per MRI Procedure
Open MRI	\$7,242,117	13980	\$518.03
Mission Imaging	Info not provided	5934	---
Emerge Ortho	\$2,069,452	5267	\$392.91

Source: Form C and Form F.2 from each application.

Mission Imaging did not provide the net revenue associated with the proposed MRI scanner only. Open has provided historically, and proposes in its application to provide, a mix of contrast and non-contrast studies that is most consistent with the needs of the community. Open MRI is the most effective alternative with regard to projected average net revenue per MRI procedure.

Projected Average Operating Expense per MRI Procedures

The following table presents the projected average operating expense per MRI procedures for the third year of operation for the applicants based on the information provided in Form C and Form F.3 of each application.

Comparison of Average Operating Expense per Procedure – PROJECT YEAR 3

Applicant	Operating Expenses	# of Unweighted MRI Procedures	Average Operating Expense Per MRI Procedure
Open MRI	\$3,940,243	13980	\$281.85
Mission Imaging	\$3,949,897*	5934	\$665.64
Emerge Ortho	\$1,253,600	5267	\$238.01

Source: Form C and Form F.3 from each application. *Mission Imaging provided this number for Year 3 in Form F.3b but it is unclear if this operating expense includes MRI and other modalities.

As discussed above, Mission Imaging did not provide the financial proformas for the proposed MRI scanner only that would allow its projections to be compared with the other applicants. Open MRI's average operating expense per MRI procedure is reasonable based on its historical operating experience and more complex contrast MRI cases. With regard to projected average operating expense per MRI procedure, Open MRI is the most effective alternative.

Conclusion

Open MRI's application meets all applicable review criteria and standards for MRI services. Based on the comparative analysis, Open MRI application is the most effective alternative for the development of the proposed MRI scanner based on the following factors:

- Open MRI is the most effective alternative regarding geographic accessibility. Asheville is the central population hub of the service area and the most easily accessible area for the residents of the Buncombe County MRI Service Area.
- Open MRI is the most effective alternative regarding average net revenue per procedure.
- Open MRI is the most effective alternative regarding average operating expense per procedure.
- Open MRI is the most effective alternative regarding the provision of service to the medically underserved populations, including Charity Care/Self Pay, Medicare and Medicaid patients.
- Open MRI is the only applicant proposing the advanced imaging technology associated with a 3T MRI scanner. As detailed above, Open MRI is able to offer access to the 3T MRI unit for service area residents at reasonable cost and charges.

- Open MRI proposes to serve a wide range of physician specialties including a case mix of complex MRI procedures that is consistent with the needs of the community. Due to the extended time period between this and the last MRI need determination, it is critical that the proposed MRI scanner focus on providing scans to a diverse range of patients consistent with historical MRI utilization patterns in the service area.

The outcome of this MRI review is critical for the Buncombe County MRI service area. The last MRI need determination for this service area was in **2001**. During the last 20 years, Open MRI has worked nonstop to provide high quality imaging services in a convenient outpatient setting. Each year, Open MRI continues to experience high demand for its MRI services without relief. Open MRI is the only applicant in this review that has a demonstrated need for additional MRI capacity based on its **current** operations. As a “temporary” measure, Open MRI has contracted for additional mobile MRI service for years to continue serving patients in a timely fashion. Mobile MRI service at Open MRI is a stop-gap measure that does not offer a real solution to the capacity constraints that Open MRI is experiencing **today**, not just projected for Project Year 3. With a physician referral base numbering over 1,700 physicians in the community and representing a broad range of specialties from family practice to neurosurgery, Open MRI has demonstrated that the community is in full support of its project. Over **150** letters of support for Open MRI’s project are included with its application for the proposed MRI scanner. The approval of the Open MRI application will benefit the Buncombe County MRI service area by allowing a provider, with a proven track record of high-quality service and outreach to the medically underserved populations, the ability to offer advanced 3T MR imaging for the community at reasonable costs and charges. The approval of Open MRI’s application will provide the greatest good for the greatest number of service area residents and their referring physicians.