

COMPETITIVE COMMENTS ON
2023 STATEWIDE MOBILE MRI NEED DETERMINATIONS
SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

MAY 31, 2023

Ten applicants submitted CON applications in response to the need identified in the 2023 SMFP for three (3) additional mobile MRI scanners in North Carolina.

J-012378-23	Duke Imaging Mobile MRI
G-012365-23	Alliance Healthcare Services Mobile MRI 2023
J-012357-23	EmergeOrtho Mobile MRI Blue Ridge/Foothills Route
J-012358-23	EmergeOrtho Mobile MRI Triad Route
J-012359-23	EmergeOrtho Mobile MRI Triangle Route
G-012372-23	Novant Health-Norfolk, LLC (1)
G-012373-23	Novant Health-Norfolk, LLC (2)
J-012375-23	PHSNC Mobile MRI Scanner
F-012368-23	Carolina Neurosurgery & Spine (1)
F-012381-23	Carolina Neurosurgery & Spine (2)

These comments are submitted by Duke University Health System, Inc. (“DUHS”) in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the applications, including a comparative analysis and a discussion of the most significant issues regarding the applicants’ conformity with the statutory and regulatory review criteria (“the Criteria”) in N.C. Gen. Stat. §131E-183(a) and (b). Other non-conformities in the competing applications may exist and DUHS reserves the right to develop additional opinions, as appropriate upon further review and analysis.

COMPARATIVE ANALYSIS FOR MOBILE MRI SCANNERS

Pursuant to G.S. 131E-183(a)(1) and the 2023 SMFP, no more than three mobile MRI Scanners can be approved statewide in this review. Because each applicant proposes to acquire one mobile MRI scanner for a total of ten MRI scanners, only three of the applications can be approved. Therefore, DUHS has prepared a comparative analysis of the proposals to determine which proposals are the most effective. The following factors are typically utilized by the Agency in competitive reviews regardless of type of services or equipment proposed:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per Patient/Procedure
- Projected Average Total Operating Cost per Patient/Procedure

Other comparative factors may be utilized based on the facts of the competitive review. The following summarizes the competing applications relative to the potential comparative factors.

Conformity to CON Review Criteria

Ten CON applications have been submitted seeking to develop a mobile MRI scanner in North Carolina. The applicants each propose to develop 10 mobile MRI scanners. Based on the 2023 SMFP’s need determination, only three (3) mobile MRI scanners can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by DUHS demonstrate conformity to all Criteria:

Conformity of Applicants

Applicant	Project I.D.	Conforming/ Non-Conforming
Duke Imaging Mobile MRI	J-012378-23	Yes
Alliance Healthcare Services Mobile MRI 2023	G-012365-23	No
EmergeOrtho Mobile MRI Blue Ridge/Foothills Route	J-012357-23	No
EmergeOrtho Mobile MRI Blue Ridge/Triad Route	J-012358-23	No
EmergeOrtho Mobile MRI Blue Ridge/Triangle Route	J-012359-23	No
Novant Health-Norfolk, LLC (1)	G-012372-23	No

Novant Health-Norfolk, LLC (1)	G-012373-23	No
Carolina Neurosurgery & Spine (1)	F-012368-23	No
Carolina Neurosurgery & Spine (2)	F-012381-23	No
PHSNC Mobile MRI Scanner	J-012375-23	No

The DUHS application is based on reasonable and supported volume projections and adequate projections of cost and revenues. As discussed separately in this document, the competing applications contain errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the DUHS application is the most effective alternative regarding conformity with applicable review Criteria.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

All ten applicants propose to acquire 1.5T mobile MRI scanners; however, the applicants vary greatly with respect to the scope of patients that will be served by the projects. The following table summarizes the scope of patient services proposed by each applicant.

Applicant	Project I.D.	Patient Scope of Services
Duke Imaging Mobile MRI	J-012378-23	Multi-specialty; Hospital-based and Outpatient Clinics
Alliance Healthcare Services Mobile MRI 2023	G-012365-23	Multi-specialty; Hospital-based and Outpatient Clinics
EmergeOrtho Mobile MRI Blue Ridge/Foothills Route	J-012357-23	Orthopaedics Only; Outpatient Clinics Only
EmergeOrtho Mobile MRI Triad Route	J-012358-23	Orthopaedics Only; Outpatient Clinics Only
EmergeOrtho Mobile MRI Triangle Route	J-012359-23	Orthopaedics Only; Outpatient Clinics Only
Novant Health-Norfolk, LLC (1)	G-012372-23	Multi-specialty; Hospital-based and Outpatient Clinics
Novant Health-Norfolk, LLC (1)	G-012373-23	Multi-specialty; Hospital-based and Outpatient Clinics
Carolina Neurosurgery & Spine (1)	F-012368-23	Neurology & Orthopaedics Only; Outpatient Clinics Only
Carolina Neurosurgery & Spine (2)	F-012381-23	Neurology & Orthopaedics Only; Outpatient Clinics Only
PHSNC Mobile MRI Scanner	J-012375-23	Multi-specialty; Outpatient Clinics Only

The three proposals by EmergeOrtho are the narrowest in scope because they will only serve orthopaedic patients in outpatient clinics. Therefore, the proposals by EmergeOrtho are the least effective alternatives regarding this factor.

The two proposals by Carolina Neurosurgery & Spine are also narrow in scope because they will only serve neurology and orthopaedic patients in outpatient clinics. Therefore, the proposals by Carolina Neurosurgery & Spine are less effective alternatives regarding this factor.

The proposal by Pinnacle will serve patients across multiple specialties; however, the Pinnacle project will only serve outpatient clinics and will not serve any hospital sites. Therefore, the Pinnacle proposal is a less effective alternative with respect to scope of services.

The proposals by DUHS, Alliance, and Novant will serve patients across multiple specialties at host sites located at hospital and outpatient clinic locations. Therefore, the respective proposals offer the greatest scope of services and are the most effective alternatives regarding this factor. As discussed separately in this document, the Alliance and Novant proposals do not conform to all statutory review criteria and administrative rules and cannot be approved.

Geographic Accessibility

The service area for mobile MRI scanners is statewide. The following tables compare the host sites proposed in each application in this review.

Applicant	Proposed Host Site	County
DUHS	Duke Imaging Mebane*	Alamance
	Duke Imaging Knightdale*	Wake
	Duke Imaging Heritage	Wake
	Durham Regional Hospital	Durham
Alliance	UNC Caldwell	Caldwell
	Southeastern Sports Medicine	Buncombe
	Wake Forest Outpatient	Forsyth
EmergeOrtho BRFH Route	EmergeOrtho - McDowell St*	Buncombe
	EmergeOrtho – Hendersonville*	Henderson
	EmergeOrtho - Morganton	Burke
	EmergeOrtho – Waynesville*	Haywood
EmergeOrtho Triad Route	EmergeOrtho - Burlington	Alamance
	EmergeOrtho – Summerfield*	Guilford
	EmergeOrtho – Reidsville*	Rockingham
	EmergeOrtho – Asheboro*	Randolph
EmergeOrtho Triangle Route	EmergeOrtho - Wakefield/Wake Forest	Wake
	EmergeOrtho - Clayton	Johnston
	EmergeOrtho – Dunn*	Harnett

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	EmergeOrtho - Oxford	Granville
Novant Health-Norfolk Central	CarolinaEast Medical Center	Craven
	Carolina Imaging	Cumberland
	UNC Lenoir Healthcare	Lenoir
	Orthopedic Specialists of NC	Wake
	UNC Orthopedics-Holly Springs*	Wake
Novant Health-Norfolk West	Cannon Memorial Hospital*	Avery
	Providence Imaging Center*	Henderson
	Open MRI & Imaging of Asheville	Buncombe
Pinnacle	Cardinal Points Imaging Brier Creek	Wake
	Cardinal Points Imaging Cary	Wake
	Atrium Health Wake Forest Baptist OP Imaging Northline*	Guilford
	Atrium Health Wake Forest Baptist OP Imaging Kernersville	Forsyth
	Atrium Health Wake Forest Baptist OP Imaging	Forsyth
CNSA (1) BMMH	CNSA Ballantyne	Mecklenburg
	CNSA Mount Holly*	Gaston
	CNSA Huntersville*	Mecklenburg
CNSA (2) CG	CNSA Charlotte	Mecklenburg
	CNSA Greensboro	Guilford

*New host sites

Applicant	Total Sites	# of Counties	# of New Sites
Duke Imaging Mobile MRI	4	3	2
Alliance Healthcare Services Mobile MRI 2023	3	3	0
EmergeOrtho Mobile MRI Blue Ridge/Foothills Route	4	4	3
EmergeOrtho Mobile MRI Triad Route	4	4	3
EmergeOrtho Mobile MRI Triangle Route	4	4	1
Novant Health-Norfolk, LLC (1) Central	5	4	1
Novant Health-Norfolk, LLC (2) West	3	3	2
PHSNC Mobile MRI Scanner	5	3	1
Carolina Neurosurgery & Spine (1)	3	2	2
Carolina Neurosurgery & Spine (2)	2	2	0

As shown in the two tables above,

- Alliance and Carolina Neurosurgery & Spine (2) do not propose to serve any new host sites. Therefore, the respective applications are the least effective alternatives regarding geographic access.
- Novant Health-Norfolk (1), EmergeOrtho Mobile MRI Triangle Route, and PHSNC each propose to serve only one new mobile MRI host site. Therefore, the respective applications are less effective alternatives regarding geographic access.
- DUHS, Novant Health-Norfolk, LLC (2), and Carolina Neurosurgery & Spine (1) each propose to serve two new mobile MRI host sites. Therefore, the respective applications are more effective alternatives regarding geographic access.
- EmergeOrtho Blue Ridge/Foothills and EmergeOrtho Triangle each propose to serve three new mobile MRI host sites. However, the EmergeOrtho proposals do not conform to all statutory review criteria and administrative rules and cannot be approved.

Competition (Patient Access to a New or Alternative Provider)

Since 2010, there have been 41 fixed MRI and no mobile MRI units added to the state's inventory. The 2023 SMFP need determination presents an invaluable opportunity to enhance competition by introducing a new provider of mobile MRI services.

Alliance owns more mobile MRI scanners than any other provider in North Carolina and is, therefore, the least effective alternative regarding competition.

Novant also owns several mobile MRI scanners in North Carolina. Novant Health, Inc. operates the second-largest mobile MRI unit fleet in North Carolina, serving 24 host sites across the State.¹ Additionally, Novant Health, Inc. owns a controlling interest in Novant Health-Norfolk, LLC, which recently acquired two grandfathered mobile MRI scanners from Kings Medical Company.² EmergeOrtho, Pinnacle, and Carolina Neurosurgery and Spine each own mobile MRI scanners that serve host sites in North Carolina. Therefore, the respective applications are less effective alternatives regarding competition.

DUHS does not own or operate a mobile MRI scanner. DUHS is the only proposal that will establish a new provider of mobile MRI services in North Carolina. Therefore, DUHS is the most effective alternative regarding competition.

Access By Underserved Groups

The applicants each propose varying models of service agreements with host sites. For example, DUHS, Alliance, and Novant each propose to execute a service agreement with each host site. The host site will pay a flat fee to the applicant for the service and the host site will bill the patient or third-party payor.

¹ <https://info.ncdhhs.gov/dhsr/mfp/pets/2022/summer/T06-NovantHealthMobileMRI.pdf>

² <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4154%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf> & <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4155%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf>

Access to medically underserved groups would be the responsibility of each host site and not the applicants. Additionally, Alliance and Novant’s proposals did not provide payor mix projections. Conversely, EmergeOrtho and Carolina Neurosurgery and Spine will bill patients for the proposed mobile MRI services at each respective host site. Therefore, the DUHS could not compare the applications with respect to projected access to Medicare and Medicaid in this review.

Charity Care Patients

Section L.4 requires the applicant to specify whether the project will provide care to medically indigent or low-income patients at no cost to the patient (i.e., charity care). The following table summarizes the estimated number of charity care patients served by each proposal during the third project year.

Rank	Applicant	Charity Care Patients, Project Year 3
2	Duke Imaging Mobile MRI	63
5	Alliance Healthcare Services Mobile MRI 2023	50
4	EmergeOrtho Mobile MRI Blue Ridge/Foothills Route	62
1	EmergeOrtho Mobile MRI Triad Route	105
2	EmergeOrtho Mobile MRI Triangle Route	63
9	Novant Health-Norfolk, LLC (1)	0
9	Novant Health-Norfolk, LLC (2)	0
6	PHSNC Mobile MRI Scanner	24
7	Carolina Neurosurgery & Spine (1)	3
7	Carolina Neurosurgery & Spine (2)	3

Source: Section L.4 of applications

As shown in the previous table, DUHS, EmergeOrtho Triad, and EmergeOrtho Triangle are the most effective alternatives regarding access by charity care. As discussed separately in this document, the EmergeOrtho proposals do not conform to all statutory review criteria and administrative rules and cannot be approved.

Projected Average Net Revenue per MRI Procedure

The following table shows the projected average net revenue per MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per MRI Procedure – 3rd Full FY

Rank	Applicant	Net Revenue	MRI Procedures	Average Net Revenue Per MRI Procedure
4	Duke Imaging Mobile MRI	\$1,432,365	4,058	\$353
1	Alliance Healthcare Services Mobile MRI 2023	\$865,800	5,044	\$172
7	EmergeOrtho Blue Ridge/Foothills Route	\$1,663,044	4,034	\$412
6	EmergeOrtho Mobile MRI Triad Route	\$1,768,786	4,347	\$407
8	EmergeOrtho Mobile MRI Triangle Route	\$2,143,591	5,058	\$424
3	Novant Health-Norfolk, LLC (1)	\$1,229,100	4,488	\$274
2	Novant Health-Norfolk, LLC (2)	\$1,101,600	4,284	\$257
5	PHSNC Mobile MRI Scanner	\$1,761,586	4,897	\$360
10	Carolina Neurosurgery & Spine (1)	\$1,399,204	3,044	\$460
9	Carolina Neurosurgery & Spine (2)	\$1,317,752	3,082	\$428

Projected Average Operating Expense per MRI Procedure

The following table shows the projected average operating expense per MRI procedure in the third full fiscal year following project completion for each project. Generally, the application projecting the lowest average operating expense per patient is the more effective alternative with regard to this comparative factor to the extent it reflects a more cost-effective service, which could also result in lower costs to the patient or third-party payor.

Projected Average Operating Expense per MRI Procedure – 3rd Full FY

Rank	Applicant	Operating Expenses	MRI Procedures	Average OpEx Per MRI Procedure
5	Duke Imaging Mobile MRI	\$1,258,175	4,058	\$310
1	Alliance Healthcare Services Mobile MRI 2023	\$699,779	5,044	\$139
7	EmergeOrtho Blue Ridge/Foothills Route	\$1,416,838	4,034	\$351
6	EmergeOrtho Mobile MRI Triad Route	\$1,416,889	4,347	\$326
4	EmergeOrtho Mobile MRI Triangle Route	\$1,466,185	5,058	\$290
3	Novant Health-Norfolk, LLC (1)	\$1,107,481	4,488	\$247
2	Novant Health-Norfolk, LLC (2)	\$1,007,911	4,284	\$235
8	PHSNC Mobile MRI Scanner	\$1,735,309	4,897	\$354
10	Carolina Neurosurgery & Spine (1)	\$1,208,935	3,044	\$397
9	Carolina Neurosurgery & Spine (2)	\$1,167,943	3,082	\$379

MRI Technologist Salary

In recruitment and retention of personnel, salaries are a significant factor. The applicants provide the following information in Section Q, Form H.2. The following table compares the proposed salaries for MRI technologists. Generally, the application proposing the highest annual salary is the more effective alternative with regard to this comparative factor.

MRI Technologist Salary – 3rd Full FY

Rank	Applicant	MRI Technologist Salary
2	Duke Imaging Mobile MRI	\$91,153
5	Alliance Healthcare Services Mobile MRI 2023	\$87,412
7	EmergeOrtho Blue Ridge/Foothills Route	\$85,677
7	EmergeOrtho Mobile MRI Triad Route	\$85,677
7	EmergeOrtho Mobile MRI Triangle Route	\$85,677
1	Novant Health-Norfolk, LLC (1)	\$99,300
10	Novant Health-Norfolk, LLC (2)	N/A*
6	PHSNC Mobile MRI Scanner	\$87,164
3	Carolina Neurosurgery & Spine (1)	\$90,423
3	Carolina Neurosurgery & Spine (2)	\$90,423

*Novant Health-Norfolk, LLC (2) did not include Form H in its application; therefore, the MRI technologist salary is not identified in the application as submitted.

Summary

The following table lists the comparative factors and indicates the relative rank of each applicant for each metric, taking at face value the representations of each applicant regarding their costs and revenues. A value of “1” reflects the most effective alternative as well as equally effective alternatives. A value of “2” reflects the second most effective alternative, and so forth. A value of “10” reflects the least effective alternative. The following table makes no assumptions on the factor “Conformity with Review Criteria.”

Comparative Factor	DUHS	Alliance	EO BR/ Foothills Route	EO Triad Route	EO Triangle Route	Novant- Norfolk Central	Novant- Norfolk West	Pinnacle	CNSA (1) BMMH	CNSA (2) CG
Scope of Services	1	1	3	3	3	3	3	3	3	3
Proposed Counties Served by Mobile MRI	5	5	1	1	1	1	5	5	9	9
# of New MRI Locations (no existing fixed or mobile)	3	9	1	1	6	6	3	6	3	9
Patient Access to an Alternate Provider	1	2	2	2	2	2	2	2	2	2
Projected Avg Net Revenue per MRI Procedure	4	1	7	6	8	3	2	5	10	9
Projected Avg Operating Expense per MRI Procedure	5	1	7	6	4	3	2	8	10	9
MRI Technologist Salary	2	5	7	7	7	1	10	6	3	3
Estimated Number of Charity Care Patients	2	5	4	1	2	9	9	6	7	7
Total (Lowest # = Most Effective) (Highest # = Least Effective)	23	29	32	27	33	28	36	41	47	51

Overall, DUHS’s proposal is the most effective alternative based on a comparison of the collective comparative factors in this statewide mobile MRI scanner competitive review. The application submitted by CUHS is comparatively superior and should be approved.

**COMMENTS SPECIFIC TO ALLIANCE HEALTHCARE SERVICES, INC.
PROJECT ID No. G-012365-23**

Competition

Since 2010, there have been 41 fixed MRIs and no mobile MRI units added to the state's inventory. The 2023 SMFP need determination presents an invaluable opportunity to enhance competition by introducing a new provider of mobile MRI services. Alliance owns more mobile MRI scanners than any other provider in North Carolina. Within North Carolina, Alliance owns 30 mobile MRI scanners.³ Awarding another mobile MRI scanner to Alliance will not enhance competition for statewide mobile MRI services.

Furthermore, Alliance's proposal will do nothing to enhance geographic access. Alliance intends to locate the proposed mobile MRI unit at UNC Caldwell, Southeastern Sports Medicine, and Atrium Health Wake Forest Baptist Outpatient Imaging, each of which already offers MRI services via fixed or mobile scanner. Therefore, there is little to no value added with respect to Alliance proposal and geographic access

For these reasons and the reasons previously described in this document, the Alliance application is comparatively inferior to DUHS's CON application.

Comments Regarding Criterion (3) and 10A NCAC 14C.2703

Alliance failed to identify the population to be served by the proposed project. Specifically, Alliance failed to provide any projections regarding the number of patients by county or other geographic area of origin as required by Section C.3 of the application form. See application page 34. Alliance provided MRI projections for each of the proposed host sites; however, the MRI host site is not the same as the geographic area where a patient lives or resides. Absent this information, Alliance failed to adequately identify the population to be served by the proposed project as required by Criterion (3) and is, thus, non-conforming.

Alliance provided a meager two paragraph response to Section C.4, which requires applicants to "*explain why the patients projected to be served*" by the project need the proposal. By failing to identify what patients are proposed to be served by Alliance's project, it is impossible for Alliance to demonstrate the need patients have for a mobile MRI scanner. Moreover, Alliance's response to Section C.4 seemingly relies solely on the SMFP statewide need determination for three (3) mobile MRI scanners and the public comments made by an unrelated third party during a State Health Coordinating Council public hearing. Notably, the public hearing comments were related to a petition submitted by Appalachian Regional Health System regarding mobile MRI need in the "High Country" of western North Carolina. The "High Country" of North Carolina includes seven counties: Alleghany, Ashe, Avery, Mitchell, Watauga, Wilkes, and Yancey.⁴ Alliance's project proposes serving host sites in Buncombe, Caldwell, and Forsyth counties, none of which are in the "High Country" of western North Carolina.

In response to 10A NCAC 14C .2703(b)(1), Alliance states that it owns and operates an existing mobile MRI scanner that served Buncombe County during the 12 months before the application review period, i.e.,

³ Section A.6, application page 22

⁴ <https://www.visitnc.com/high-country>, <https://highcountry.guide/>

Scanner ESP43. However, ESP43 performed only 2,579 adjusted MRI procedures during FY2022, which is well below the performance standard of 3,120 adjusted MRI procedures. Alliance projects mobile MRI procedures performed ESP43 will increase by a compound annual growth rate (CAGR) of 10.3% to perform 4,085 adjusted MRI procedures during 2027.⁵ Alliance failed to provide sufficient assumptions and methodology to justify the reasonableness of ESP43's projected utilization. For example, there is no supporting documentation or information to support the increase of MRI procedures at UNC Eastowne Medical Office from 8.3 procedures per day, 2 days a week during 2022 to 10.6 procedures per day, 3 days per week during 2027.⁶ Therefore, the Alliance application does not conform to 10A NCAC 14C .2703(b)(8).

Also, in response to in response to 10A NCAC 14C .2703(b)(1) Alliance states that it owns and operates a second mobile MRI scanner that provided mobile MRI services at host sites in the service area during the 12 months before the application review period, i.e., Scanner Signa480. 10A NCAC 14C .2703(b)(6) requires applicants proposing to acquire a mobile MRI scanner to "*provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of 10A NCAC 14C.* However, Alliance failed to provide projected utilization for Signa480 as required by 10A NCAC 14C .2703(b)(6). Without any projected utilization for Signa480, Alliance cannot demonstrate conformity with 10A NCAC 14C .2703(b)(8), which requires the applicant to project utilization for the mobile MRI scanners identified in 10A NCAC 14C .2703(b)(1)-(2) to perform 3,120 or more adjusted MRI procedures.

For these reasons, the Alliance application should be found non-conforming to Criterion (3) and 10A NCAC 14C.2703. Additionally, based on the facts for which the Alliance application fails to conform to Criterion (3), it should also be found non-conforming to review criteria (1), (4), (5), (6), and (18a).

Comments Regarding Criterion (5)

Alliance failed to budget for necessary MRI technologist staff. See Criterion (7) for discussion. Therefore, expenses and average cost per procedure are understated. It is also unclear the extent to which Alliance's projected net revenues reflect its actual current pricing for mobile MRI services.

Comments Regarding Criterion (6)

10A NCAC 14C .2701(9) states, "Mobile MRI scanner service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period." The 2023 SMFP identifies a statewide mobile MRI service area.

However, in response to review criterion (6) (application Section G), Alliance incorrectly identified a three-county mobile MRI service area and provided county-based total historical MRI utilization. Alliance failed to properly respond to Sections G.1 and G.2.

⁵ Application page 44

⁶ During 2022, UNC Eastowne Medical Office performed 864 unadjusted MRI procedures, with mobile MRI access 2 days per week: 2 days/week x 52 weeks/year = 104 days per year; 864 ÷ 104 = 8.3 MRI procedures per day. Alliance states the previous scanning day utilized by Southeastern Sports Medicine will be reallocated to UNC Eastowne. During 2025, Alliance projects the UNC Eastowne Medical Office host site will perform 1,654 unadjusted MRI procedures: 3 days/week x 52 weeks/year = 156 days per year; 1,654 ÷ 156 = 10.6 MRI procedures per day. See application pages 45-45.

The 2023 SMFP indicates that there were 47 mobile MRI scanners in operation in the state during the 2020-2021 reporting period. Alliance owns 30 of the 47 mobile MRI scanners. Alliance's application provides historical utilization for only one of its 30 existing mobile MRI scanners in North Carolina. Alliance claims there is "little to no capacity on its existing 26 legacy con operated units." However, absent any data or historical utilization in the application as submitted, Alliance's claim cannot be substantiated. Absent any historical utilization for its mobile MRI scanners, Alliance failed to adequately demonstrate how the proposed mobile MRI scanner will not unnecessarily duplicate its existing 30 existing mobile MRI scanners in North Carolina.

Additionally, two of the proposed host sites (Southeastern Sports Medicine and Wake Forest Outpatient) are presently served by an Alliance mobile MRI scanner. Alliance did not discuss why it needs a new mobile MRI scanner to replace the mobile service it presently provides to the respective sites.

For these reasons, the Alliance application should be found non-conforming to Criterion (6). Additionally, based on the facts for which the Alliance application fails to conform to Criterion (6), it should also be found non-conforming to review criteria (1), (3), (4), and (18a).

Comments Regarding Criterion (7)

Alliance failed to demonstrate sufficient evidence of the availability of health manpower for the provision of the proposed mobile MRI services. Form H in Section Q provides staffing for the Alliance project and identifies only 1.0 FTE radiologist technologist for the proposed mobile MRI service. Application pages 28-29 identify the projected weekly service schedule for the proposed mobile MRI scanner, which will operate six (6) days per week and 10 to 12 hours per day during the third project year. The following calculations summarize the minimum radiation technologist staffing requirements for Alliance's proposed schedule:

6 days per week x 10 hours per day x 52 weeks per year = 3,120 hours ÷ 2,080 hours per FTE = 1.5 FTEs

6 days per week x 12 hours per day x 52 weeks per year = 3,744 hours ÷ 2,080 hours per FTE = 1.8 FTEs

Alliance's projected staffing of 1.0 FTE radiologist technologist is insufficient to support the health manpower needs of the proposed project. Therefore, the application fails to conform to Criterion (7).

Comments Regarding Criterion (13)

Alliance failed to provide any evidence regarding the extent to which medically underserved populations currently use its existing mobile MRI services and the extent to which the medically underserved populations will have access to the proposed mobile MRI service.

Application page 77 states, "Alliance is committed to provide at least 1.0% of Charity Care in the form of no-cost procedures to the host sites. The 1.0% Charity Care is reported as a deduction from revenue." However, Form F.2b does not include any deductions from revenue. See application page 92. Therefore, the application lacks sufficient evidence to demonstrate Alliance's commitment to provide access to medically underserved populations.

Additionally, the Alliance application provides no projections regarding access for charity care patients, racial and ethnic minorities, Medicare beneficiaries, or Medicaid beneficiaries.

For these reasons, the Alliance application does not conform to Criterion (13).

Comments Regarding Criterion (18a)

According to the Federal Trade Commission, competition in health care markets benefits consumers because it helps contain costs, improve quality, and encourage innovation. Similarly, the 2023 SMFP states the State Health Coordinating Council recognizes the importance of balanced competition and market advantage to encourage innovation, insofar as those innovations improve safety, quality, access, and value in health care delivery.

Alliance owns more mobile MRI scanners than any other provider in North Carolina. The 2023 SMFP indicates that there were 47 mobile MRI scanners in operation in the state during the 2020-2021 reporting period. Within North Carolina, Alliance owns 30 mobile MRI scanners or 64 percent of available mobile MRI capacity.⁷ Awarding another mobile MRI scanner to Alliance will not enhance competition for statewide mobile MRI services.

⁷ Section A.6, application page 22

**COMMENTS SPECIFIC TO EMERGEORTHO MOBILE MRI BLUE RIDGE/FOOTHILLS
PROJECT ID NO. J-012357-23**

Comments Regarding Criterion (3) and 10A NCAC 14C .2703

EmergeOrtho proposes to serve four host sites in Asheville, Hendersonville, Morganton, and Waynesville, respectively. The Morganton host site is presently served by one of EmERGEOrtho's two existing mobile MRI scanners two days per week.⁸ Table 17E-1 of the 2023 SMFP indicates EmERGEOrtho-Morganton performed 1,571 adjusted mobile MRI procedures during FY2021. EmERGEOrtho's 2022 Registration and Inventory of Medical Equipment included in Exhibit C.2 reports the mobile MRI scanner was available at EmERGEOrtho-Morganton for 1,248 total hours during FY2021. Based on the 2023 SMFP average MRI procedure time of 33 minutes, the existing EmERGEOrtho mobile MRI scanner was utilized at only 69% at the Morganton host site during FY2021: $1,571 \text{ adjusted MRI procedures} \times (33 \div 60) = 864 \text{ hours} \div 1,248 \text{ total hours at host site} = .6923$. According to Section C.3, EmERGEOrtho-Morganton performed 1,538 MRI procedures during FY2022, a decrease of 1.3%. EmERGEOrtho did not discuss why it needs a new mobile MRI scanner in addition to the mobile service it presently provides at the Morganton host site. Furthermore, EmERGEOrtho does not provide projected utilization for EmERGEOrtho BRFH Mobile 2 by host site. Therefore, it is impossible to evaluate whether the projected total number of MRI procedures at the EmERGEOrtho-Morganton host site (provided by the applicant's existing and proposed mobile scanners) is reasonable and supported.

In Step 4 of EmERGEOrtho's utilization methodology included in Section Q, the applicant calculates a ratio of MRI scans per person based on the median ratio of the "sample" reflected in Table 3.⁹ EmERGEOrtho calculates a ratio of 1.18 MRI scans per person based on a sample of 11 provider: 8 hospital-based and four freestanding. The proposed mobile MRI service will be located at freestanding host sites; thus, the use of hospital-based data to determine a ratio of MRI scans per person is inconsistent with the proposed project. Furthermore, EmERGEOrtho owns and operates two mobile MRI scanners and five fixed MRI scanners. The applicant failed to explain why its own historical experience is not a reasonable proxy to project the ratio of MRI scans per patient.

A review of EmERGEOrtho's historical utilization reveals the ratio of MRI scans per patient on one of its existing mobile MRI scanners is 1.0. Exhibit C.2 includes a copy of the 2022 Registration and Inventory of Medical Equipment for the EmERGEOrtho mobile MRI scanner that presently serves host sites throughout western North Carolina, including the proposed host site in Morganton (BRFH Mobile 2). The 2022 Registration and Inventory Report indicates that the number of MRI procedures at each host site is equivalent to the number of patients served at each host site. See the following table.

⁸ Application page 59

⁹ Application page 136

**EmergeOrtho BRFH Mobile 2
MRI Utilization, FY2021**

Host Site (City)	MRI Procedures	MRI Patients	Ratio of Procedures: Patient
Hickory	2,056	2,056	1.0
Lenoir	1,475	1,475	1.0
Morganton	1,559	1,559	1.0
Newton	393	393	1.0
Total	5,483	5,483	1.0

Source: Exhibit C.2, 2022 Registration and Inventory of Medical Equipment Report; Exhibit C.5, page 23

EmergeOrtho’s application of 1.18 ratio of MRI scanner per patient is inconsistent with its own experience and artificially inflates the projected MRI procedures the applicant projects to serve within the identified counties.

In Step 16, the applicant projects the number of EmmergeOrtho MRI patients and scans from the Blue Ridge/Foothills counties that were referred to other providers and the percent EmmergeOrtho expects to recapture as a result of the proposed project. As shown in Table 16, EmmergeOrtho utilizes a ratio of 1.06 to convert MRI patients to MRI scans. However, this ratio is also inconsistent with EmmergeOrtho’s historical experience providing mobile MRI services in the identified counties and artificially inflates the projected MRI procedures the applicant projects to recapture within the identified counties. The applicant failed to explain why its historical experience in the Blue Ridge/Foothills market via EmmergeOrtho BRFH Mobile 2 is not a reasonable proxy to project the ratio of MRI scans per patient.

For these reasons, the EmmergeOrtho Blue Ridge/Foothills application should be found non-conforming to Criterion (3) and 10A NCAC 14C.2703. Additionally, based on the facts for which the EmmergeOrtho Blue Ridge/Foothills application fails to conform to Criterion (3), it should also be found non-conforming to review criteria (1), (4), (5), (6), and (18a).

Comments Regarding Criterion (5)

In Form F.1, page 172 of the application, EmmergeOrtho projects the capital cost for the proposed mobile MRI scanner. The following table summarizes the projected capital cost.

EmergeOrtho Blue Ridge/Foothills Projected Capital Cost

Description	Cost
Construction/Renovation Contract(s)	\$587,337
Architect / Engineering Fees	\$20,000
Medical Equipment	\$963,000
Financing Costs	\$2,500
Total Capital Cost	\$1,572,837

Source: Application page 172

Exhibit F.1 includes a detailed vendor’s quote which states, “The PURCHASER agrees to pay SELLER \$900,988.00, and any applicable taxes, as well as any other amounts payable under this Agreement (“Purchase Price”).” However, the applicant failed to include sufficient expenses to adequately fund its tax obligation as a part of the projected capital cost expenses. DUHS calculates the projected taxes as illustrated in the table below based on the vendor’s quote in Exhibit F.1.

EmergeOrtho Blue Ridge/Foothills Projected Tax

Description	Cost
Medical Equipment	\$900,988
<u>Projected Sales Tax @ 7%</u>	<u>\$63,069</u>
Medical Equipment Including Projected Tax	964,057
Construction/Renovation Contract(s)	\$587,337
Architect / Engineering Fees	\$20,000
Financing Costs	\$2,500
Total Capital Cost Including Projected Tax	\$1,573,894
Capital Cost Identified in Form F.1	\$1,572,837

As illustrated in the above table, the projected sales tax of 7% based on the vendor’s quote for medical equipment would total \$63,069. Therefore, the projected total for the mobile MRI scanner and selected options including tax is \$1,573,894. Thus, the applicant did not include in its projected capital cost nor its proformas the total required taxes associated with the proposed mobile MRI scanner.

As noted in the letter from First Citizens Bank located in Exhibit F.2, the loan amount for the proposed project is \$1,572,837. Additionally, the loan amortization schedule included on page 185 is based on a loan value of \$1,572,837. The total capital cost of the project (\$1,573,894) exceeds the funding to be provided for the capital costs (\$1,572,837) by \$1,057. Therefore, EmERGEOrtho failed to demonstrate adequate funds for the capital cost of the proposed project and is non-conforming to Criterion (5).

DUHS would note the Agency has previously found an applicant non-conforming based on its failure to include projected tax for MRI equipment in its capital costs. In the 2009 Onslow County Competitive MRI Review, the Agency found Onslow MRI, LLC non-conforming to Criterion (5) based on its failure to include applicable taxes for MRI equipment in the total capital cost of its project and bank funding. Pages from the Agency’s Findings in the 2009 Onslow County MRI Review are included in Attachment A.

EmerGEOrtho also failed to include applicable expenses for acquisition of a contrast injector in its capital cost. As shown in Section Q, page 169 of the application, EmERGEOrtho projects to perform MRI procedures with contrast; a contrast injector is required to perform these procedures. The vendor quote does not include any reference or expense for a contrast injector. Therefore, the applicable expenses were not included in EmERGEOrtho’s capital costs or funding commitment from First Citizens. Consequently, EmERGEOrtho failed to demonstrate adequate funds for the capital cost of the proposed project.

EmergeOrtho also failed to demonstrate that the financial feasibility of the project is based on reasonable projects of costs and revenues. See Criterion (3) for discussion. Therefore, the application is non-conforming to Criterion (5).

Comments Regarding Criterion (6)

10A NCAC 14C .2701(9) states, "Mobile MRI scanner service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period." The 2023 SMFP identifies a statewide mobile MRI service area. However, in response to review criterion (6), application Section G, EmERGEOrtho incorrectly identified a 12-county mobile MRI service area and provided historical MRI utilization for 24 MRI provider locations. EmERGEOrtho failed to properly respond to Sections G.1 and G.2.

The 2023 SMFP indicates that there were 47 mobile MRI scanners in operation in the state during the 2020-2021 reporting period, two of which are owned and operated by EmERGEOrtho. EmERGEOrtho also operates a third mobile MRI owned by Insight at EmERGEOrtho locations.¹⁰ Historical utilization and discussion of EmERGEOrtho's existing mobile MRI scanners is not included in Section G.

EmERGEOrtho proposes to serve four host sites in Asheville, Hendersonville, Morganton, and Waynesville, respectively. The Morganton host site is presently served by one of EmERGEOrtho's existing mobile MRI scanners two days per week, i.e., EmERGEOrtho BRFH Mobile 2.¹¹ Table 17E-1 of the 2023 SMFP indicates the EmERGEOrtho-Morganton host site performed 1,571 adjusted mobile MRI procedures during FY2021. The 2022 Registration and Inventory of Medical Equipment for EmERGEOrtho BRFH Mobile 2 included in Exhibit C.2 reports the mobile MRI scanner was available at the EmERGEOrtho-Morganton host site for 1,248 total hours during FY2021. Based on the 2023 SMFP average MRI procedure time of 33 minutes, the existing EmERGEOrtho mobile MRI scanner was utilized at only 69% at the Morganton host site during FY2021: $1,571 \text{ adjusted MRI procedures} \times (33 \div 60) = 864 \text{ hours} \div 1,248 \text{ total hours at host site} = .6923$. EmERGEOrtho did not discuss why it needs a new mobile MRI scanner in addition to the mobile service it presently provides at the Morganton host site. The proposed mobile MRI scanner unnecessarily duplicates available capacity of the applicant's existing mobile MRI services at the EmERGEOrtho-Morganton host site.¹²

Furthermore, EmERGEOrtho does not provide projected utilization for EmERGEOrtho BRFH Mobile 2 by host site. Therefore, it is impossible to evaluate the level of MRI utilization at the EmERGEOrtho-Morganton host site.

For these reasons, the EmERGEOrtho application does not conform to Criterion (6). Additionally, based on the facts for which the EmERGEOrtho application fails to conform to Criterion (6), it should also be found non-conforming to review criteria (1), (3), (4), and (18a).

¹⁰ Application page 21

¹¹ Application page 59

¹² According to Section C.3, EmERGEOrtho-Morganton performed 1,538 MRI procedures during FY2022, a decrease of 1.3%.

**COMMENTS SPECIFIC TO EMERGEORTHO MOBILE MRI TRIAD
PROJECT ID NO. J-012358-23**

Comments Regarding Criterion (3) and 10A NCAC 14C .2703

EmergeOrtho proposes to serve four host sites in Burlington, Summerville, Reidsville, and Asheboro, respectively. The Burlington host site is presently served by one of EmERGEOrtho's two existing mobile MRI scanners six days per month.¹³ Table 17E-1 of the 2023 SMFP indicates EmERGEOrtho-Burlington performed 741 adjusted mobile MRI procedures during FY2021 (739 unadjusted MRI procedures). EmERGEOrtho's 2022 Registration and Inventory of Medical Equipment included in Exhibit C.2 reports the mobile MRI scanner was available at EmERGEOrtho-Burlington for 660 total hours during FY2021. Based on the 2023 SMFP average MRI procedure time of 33 minutes, the existing EmERGEOrtho mobile MRI scanner was utilized at only 62% at the Burlington host site during FY2021: $741 \text{ adjusted MRI procedures} \times (33 \div 60) = 408 \text{ hours} \div 660 \text{ total hours at host site} = .6175$. According to Exhibit C.5, EmERGEOrtho-Burlington performed 737 MRI procedures during FY2022, which demonstrates no growth in utilization at the Burlington host site. EmERGEOrtho did not discuss why it needs a new mobile MRI scanner in addition to the mobile service it presently provides at the Burlington host site. Furthermore, EmERGEOrtho does not provide projected utilization for EmERGEOrtho Triangle Mobile 1 by host site. Therefore, it is impossible to evaluate whether the projected total number of MRI procedures at the EmERGEOrtho-Burlington host site (provided by the applicant's existing and proposed mobile scanners) is reasonable and supported.

EmerGEOrtho's proposed host site in Summerville is located in Guilford County where EmERGEOrtho operates a fixed MRI scanner at its office in Greensboro. On application page 35, the applicant provides historical patient origin data for the fixed MRI scanner located in Guilford County, which demonstrates that only 63.2% of patients served on the fixed MRI scanner originate from Guilford County. The remaining 36.8% of patients originated from various other counties throughout the state. In contrast, EmERGEOrtho projects that 100% of patient served at the Summerville host site in Guilford County will be residents of Guilford County.¹⁴ Therefore, EmERGEOrtho's patient origin projections for the Summerville host site are inconsistent with its experience providing MRI services in Guilford County. The applicant failed to provide any explanation to demonstrate why its patient origin patterns will drastically change in Guilford County compared to its historical experience.

In Step 4 of EmERGEOrtho's utilization methodology included in Section Q, the applicant calculates a ratio of MRI scans per person based on the median ratio of the "sample" reflected in Table 3.¹⁵ EmERGEOrtho calculates a ratio of 1.18 MRI scans per person based on a sample of 11 providers: 8 hospital-based and four freestanding. The proposed mobile MRI service will be located at freestanding host sites; thus, the use of hospital-based data to determine a ratio of MRI scans per person is inconsistent with the proposed project. Furthermore, EmERGEOrtho owns and operates two mobile MRI scanners and five fixed MRI scanners. The applicant failed to explain why its historical experience is not a reasonable proxy to project the ratio of MRI scans per patient.

¹³ Application page 29

¹⁴ Application page 37

¹⁵ Application page 134

A review of EmergeOrtho’s historical utilization reveals the ratio of MRI scans per patient for its existing mobile MRI scanner serving the Burlington host site is 1.0. Exhibit C.2 includes a copy of the 2022 Registration and Inventory of Medical Equipment for EmergeOrtho Triangle Mobile 1 which presently serves the Burlington host site. The 2022 Registration and Inventory Report indicates that the ratio of MRI scans per patient is 1.01. See the following table.

**EmergeOrtho Triangle Mobile 1
MRI Utilization, FY2021**

Host Site (City)	MRI Procedures	MRI Patients	Ratio of Procedures: Patient
Apex	36	36	1.00
Oxford	607	590	1.03
Burlington	737	734	1.00
Smithfield	816	812	1.00
Raleigh/Duraleigh	2,665	2,640	1.01
Total	4,861	4,812	1.01

Source: Exhibit C.2, 2022 Registration and Inventory of Medical Equipment Report; Exhibit C.5, page 23

EmergeOrtho’s application of 1.18 ratio of MRI scanner per patient is inconsistent with its own experience and artificially inflates the projected MRI procedures the applicant projects to serve within the identified counties.

In Step 18, the applicant projects the number of EmergeOrtho MRI patients and scans from the Triad counties that were referred to other providers and the percent EmergeOrtho expects to recapture as a result of the proposed project. As shown in Table 17, EmergeOrtho utilizes a ratio of 1.06 to convert MRI patients to MRI scans. However, this ratio is also inconsistent with EmergeOrtho’s historical experience providing mobile MRI services in the identified counties and artificially inflates the projected MRI procedures the applicant projects to recapture within the identified counties. The applicant failed to explain why its historical experience in the Triad market via EmergeOrtho Triangle Mobile 1 is not a reasonable proxy to project the ratio of MRI scans per patient.

For these reasons, the EmergeOrtho Triad application should be found non-conforming to Criterion (3) and 10A NCAC 14C.2703. Additionally, based on the facts for which the EmergeOrtho Triad application fails to conform to Criterion (3), it should also be found non-conforming to review criteria (1), (4), (5), (6), and (18a).

Comments Regarding Criterion (5)

In Form F.1, page 171 of the application, EmergeOrtho projects the capital cost for the proposed mobile MRI scanner. The following table summarizes the projected capital cost.

EmergeOrtho Triad Projected Capital Cost

Description	Cost
Construction/Renovation Contract(s)	\$270,000
Architect / Engineering Fees	\$20,000
Medical Equipment	\$963,000
Financing Costs	\$2,500
Total Capital Cost	\$1,255,500

Source: Application page 172

Exhibit F.1 includes a detailed vendor’s quote which states, “The PURCHASER agrees to pay SELLER \$900,988.00, and any applicable taxes, as well as any other amounts payable under this Agreement (“Purchase Price”).”

However, the applicant failed to include sufficient expenses to adequately fund its tax obligation as a part of the projected capital cost expenses. DUHS calculates the projected taxes as illustrated in the table below based on the vendor’s quote in Exhibit F.1.

EmergeOrtho Blue Ridge/Foothills Projected Tax

Description	Cost
Medical Equipment	\$900,988
<u>Projected Sales Tax @ 7%</u>	<u>\$63,069</u>
Medical Equipment Including Projected Tax	964,057
Construction/Renovation Contract(s)	\$270,000
Architect / Engineering Fees	\$20,000
Financing Costs	\$2,500
Total Capital Cost Including Projected Tax	\$1,256,557
Capital Cost Identified in Form F.1	\$1,255,500

As illustrated in the above table, the projected sales tax of 7% based on the vendor’s quote for medical equipment would total \$63,069. Therefore, the projected total for the mobile MRI scanner and selected options including tax is \$1,573,894. Thus, the applicant did not include in its projected capital cost nor its proformas the total required taxes associated with the proposed mobile MRI scanner.

As noted in the letter from First Citizens Bank located in Exhibit F.2, the loan amount for the proposed project is \$1,255,500. Additionally, the loan amortization schedule included on page 185 is based on a loan value of \$1,255,500. The total capital cost of the project (\$1,256,557) exceeds the funding to be provided for the capital costs (\$1,255,500) by \$1,057. Therefore, EmergeOrtho failed to demonstrate adequate funds for the capital cost of the proposed project and is non-conforming to Criterion (5).

DUHS would note the Agency has previously found an applicant non-conforming based on its failure to include projected tax for MRI equipment in its capital costs. In the 2009 Onslow County Competitive MRI Review, the Agency found Onslow MRI, LLC non-conforming to Criterion (5) based on its failure to include applicable taxes for MRI equipment in the total capital cost of its project and bank funding. Pages from the Agency's Findings in the 2009 Onslow County MRI Review are included in Attachment A.

EmergeOrtho also failed to include applicable expenses for the acquisition of a contrast injector in its capital cost. As shown in Section Q, page 169 of the application, EmergeOrtho projects to perform MRI procedures with contrast and a contrast injector is required to perform these procedures. The vendor quote does not include any reference or expense for a contrast injector. Therefore, the applicable expenses were not included in EmergeOrtho's capital costs or funding commitment from First Citizens. Consequently, EmergeOrtho failed to demonstrate adequate funds for the capital cost of the proposed project.

EmergeOrtho also failed to demonstrate that the financial feasibility of the project is based on reasonable projects of costs and revenues. See Criterion (3) for discussion. Therefore, the application is non-conforming to Criterion (5).

Comments Regarding Criterion (6)

10A NCAC 14C .2701(9) states, "Mobile MRI scanner service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period." The 2023 SMFP identifies a statewide mobile MRI service area.

However, in response to review criterion (6), application Section G, EmergeOrtho incorrectly identified a 7-county mobile MRI service area and provided historical MRI utilization for 23 MRI provider locations. EmergeOrtho failed to properly respond to Sections G.1 and G.2.

The 2023 SMFP indicates that there were 47 mobile MRI scanners in operation in the state during the 2020-2021 reporting period, two of which are owned and operated by EmergeOrtho. EmergeOrtho also operates a third mobile MRI owned by Insight at EmergeOrtho locations.¹⁶ Historical utilization and discussion of EmergeOrtho's existing mobile MRI scanners is not included in Section G.

Additionally, EmergeOrtho did not discuss why it needs a new mobile MRI scanner in addition to the mobile service it presently owns and operates at the Burlington host site. Furthermore, EmergeOrtho does not provide projected utilization for EmergeOrtho Triangle Mobile 1 by host site. Therefore, it is impossible to evaluate whether the projected total number of MRI procedures at the EmergeOrtho-Burlington host site (provided by the applicant's existing and proposed mobile scanners) is reasonable and supported.

For these reasons, the application is non-conforming to Criterion (6). Additionally, based on the facts for which the EmergeOrtho application fails to conform to Criterion (6), it should also be found non-conforming to review criteria (1), (3), (4), and (18a).

¹⁶ Application page 21

**COMMENTS SPECIFIC TO EMERGEORTHO TRIANGLE
PROJECT ID NO. J-012359-23**

Comments Regarding Criterion (3) and 10A NCAC 14C .2703

EmergeOrtho proposes to serve four host sites in Clayton, Dunn, Oxford, and Wake Forest/Wakefield, respectively. Two of the proposed host sites (Clayton and Oxford) are presently served by one of EmERGEOrtho's two existing mobile MRI scanners, i.e., EmERGE Ortho Triangle Mobile 1. The proposed Wake Forest/Wakefield host site is presently served by an Alliance mobile MRI scanner.¹⁷

Table 17E-1 of the 2023 SMFP indicates EmERGEOrtho-Oxford performed 609 adjusted mobile MRI procedures during FY2021 (607 unadjusted MRI procedures). EmERGEOrtho's 2022 Registration and Inventory of Medical Equipment included in Exhibit C.2 reports the mobile MRI scanner was available at EmERGEOrtho-Oxford for 552 total hours during FY2021. Based on the 2023 SMFP average MRI procedure time of 33 minutes, the existing EmERGEOrtho mobile MRI scanner was utilized at only 60.7% at the Oxford host site during FY2021: $609 \text{ adjusted MRI procedures} \times (33 \div 60) = 335 \text{ hours} \div 552 \text{ total hours at host site} = .60.7$. According to application page 35, EmERGEOrtho-Oxford performed 580 MRI procedures during FY2022, which demonstrates a decrease of 4.4% in utilization at the Oxford host site. EmERGEOrtho did not discuss why it needs a new mobile MRI scanner in addition to the mobile service it presently provides at the Oxford host site. Furthermore, EmERGEOrtho does not provide projected utilization for EmERGEOrtho Triangle Mobile 1 by host site. Therefore, it is impossible to evaluate whether the projected total number of MRI procedures at the EmERGEOrtho-Oxford host site (provided by the applicant's existing and proposed mobile scanners) is reasonable and supported.

EmerGEOrtho states it "recently" added EmERGEOrtho-Clayton as a host site.¹⁸ Historical patient origin provided on application page 34 indicates the Clayton host site served 52 MRI patients during FY2022. EmERGEOrtho did not provide a 2023 Registration and Inventory of Medical Equipment for EmERGEOrtho Triangle Mobile 1; thus, the level of utilization at the Clayton host site cannot be evaluated.¹⁹

EmerGEOrtho's proposed host site in Oxford is located in Granville County. On application page 35, the applicant provides historical patient origin data for the existing mobile MRI service at the Oxford host site, which demonstrates that only 36.0% of patients (209) originated from Granville County. Approximately 37.6% of patients (218) originated from Vance County and the remaining 26.4% of patients originated from other counties throughout the state. In contrast, EmERGEOrtho projects that in the third project year 59.2% of patients (232) served at the Oxford host site will be residents of Granville County and 40.2% of patients (156) will be residents of Franklin County.²⁰ However, the Oxford host site has historically served a very small number and percentage of Franklin County residents as shown in the following table.

¹⁷ Application page 29

¹⁸ Application page 57

¹⁹ Despite multiple references to inclusion of a 2023 Registration and Inventory of Medical Equipment Report in Exhibit C.2, EmERGEOrtho provided a copy of the 2022 Registration and Inventory of Medical Equipment Report which includes FY2021 data.

²⁰ Application page 37

**EmergeOrtho-Oxford Host Site
MRI Patient Origin Comparison**

County	FY2022		CY2027	
	Patients	% of Total	Patients	% of Total
Vance	218	37.6%		
Granville	209	36.0%	232	59.8%
<u>Franklin</u>	<u>20</u>	<u>3.4%</u>	<u>156</u>	<u>40.2%</u>
Other	133	22.9%		
Total	580	100.0%	388	100.0%

Source: Application pages 35 and 39

As shown in the previous table, EmmergeOrtho’s patient origin projections for the Oxford host site are inconsistent with its experience providing MRI services in Granville County. The applicant failed to provide any explanation to demonstrate why its patient origin patterns will drastically change at the Oxford host site compared to its historical experience. More specifically, the applicant failed to adequately demonstrate why the number of Franklin County patients will increase to more than seven times the number of Franklin County patients historically served at the Oxford host site simply by adding a new mobile MRI service 2 days per month (24 total additional days per year).

In Step 4 of EmmergeOrtho’s utilization methodology included in Section Q, the applicant calculates a ratio of MRI scans per person based on the median ratio of the “sample” reflected in Table 3.²¹ EmmergeOrtho calculates a ratio of 1.18 MRI scans per person based on a sample of 11 providers: 8 hospital-based and four freestanding. The proposed mobile MRI service will be located at freestanding host sites; thus, the use of hospital-based data to determine a ratio of MRI scans per person is inconsistent with the proposed project. Furthermore, EmmergeOrtho owns and operates two mobile MRI scanners and five fixed MRI scanners. The applicant failed to explain why its historical experience is not a reasonable proxy to project the ratio of MRI scans per patient.

A review of EmmergeOrtho’s historical utilization reveals the ratio of MRI scans per patient for its existing mobile MRI scanner serving the Oxford host site is 1.0. Exhibit C.2 includes a copy of the 2022 Registration and Inventory of Medical Equipment for EmmergeOrtho Triangle Mobile 1 which presently serves the Burlington host site. The 2022 Registration and Inventory Report indicates that the ratio of MRI scans per patient is 1.01. See the following table.

²¹ Application page 137

**EmergeOrtho Triangle Mobile 1
MRI Utilization, FY2021**

Host Site (City)	MRI Procedures	MRI Patients	Ratio of Procedures: Patient
Apex	36	36	1.00
Oxford	607	590	1.03
Burlington	737	734	1.00
Smithfield	816	812	1.00
Raleigh/Duraleigh	2,665	2,640	1.01
Total	4,861	4,812	1.01

Source: Exhibit C.2, 2022 Registration and Inventory of Medical Equipment Report; Exhibit C.5, page 23

EmergeOrtho’s application of 1.18 ratio of MRI procedure per patient is inconsistent with its own experience and artificially inflates the projected MRI procedures the applicant projects to serve within the identified counties.

In Step 17, the applicant projects the number of EmmergeOrtho MRI patients and scans from the Triangle counties that were referred to other providers and the percent EmmergeOrtho expects to recapture as a result of the proposed project. As shown in Table 16, EmmergeOrtho utilizes a ratio of 1.06 to convert MRI patients to MRI scans. However, this ratio is also inconsistent with EmmergeOrtho’s historical experience providing mobile MRI services in the identified counties and artificially inflates the projected MRI procedures the applicant projects to recapture within the identified counties. The applicant failed to explain why its historical experience in the Triangle market via EmmergeOrtho Triangle Mobile 1 is not a reasonable proxy to project the ratio of MRI scans per patient.

For these reasons, the EmmergeOrtho Triangle application should be found non-conforming to Criterion (3) and 10A NCAC 14C.2703. Additionally, based on the facts for which the EmmergeOrtho Triangle application fails to conform to Criterion (3), it should also be found non-conforming to review criteria (1), (4), (5), (6), and (18a).

Comments Regarding Criterion (5)

In Form F.1, page 172 of the application, EmmergeOrtho projects the capital cost for the proposed mobile MRI scanner. The following table summarizes the projected capital cost.

EmergeOrtho Triangle Projected Capital Cost

Description	Cost
Construction/Renovation Contract(s)	\$85,636
Architect / Engineering Fees	\$20,000
Medical Equipment	\$965,250
Financing Costs	\$2,500
Total Capital Cost	\$1,073,386

Source: Application page 172

EmergeOrtho failed to include applicable expenses for the acquisition of a contrast injector in its capital cost. As shown in Section Q, page 169 of the application, EmurgeOrtho projects to perform MRI procedures with contrast and a contrast injector is required to perform these procedures. The vendor quote in Exhibit F.1 does not include any reference or expense for a contrast injector. Thus, the applicant did not include in its projected capital cost nor its proformas the total required expenses associated with the proposed mobile MRI scanner. Also, the applicable expenses were not included in EmurgeOrtho’s funding commitment from First Citizens. Consequently, EmurgeOrtho failed to demonstrate adequate funds for the capital cost of the proposed project.

As noted in the letter from First Citizens Bank located in Exhibit F.2, the loan amount for the proposed project is \$1,073,386. Additionally, the loan amortization schedule included on page 185 is based on a loan value of \$1,073,386. There is no contingency allowance in the applicant’s capital cost to cover additional expenses. Therefore, the additional purchase of a contrast injector would result in the total capital cost of the project exceeding the funding to be provided for the capital costs. Consequently, EmurgeOrtho failed to demonstrate adequate funds for the capital cost of the proposed project and is non-conforming to Criterion (5).

EmergeOrtho also failed to demonstrate that the financial feasibility of the project is based on reasonable projects of costs and revenues. See Criterion (3) for discussion. Therefore, the application is non-conforming to Criterion (5).

Comments Regarding Criterion (6)

10A NCAC 14C .2701(9) states, “Mobile MRI scanner service area” shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.” The 2023 SMFP identifies a statewide mobile MRI service area.

However, in response to review criterion (6), application Section G, EmurgeOrtho incorrectly identified an 8-county mobile MRI service area and provided historical MRI utilization for 69 MRI provider locations. EmurgeOrtho failed to properly respond to Sections G.1 and G.2.

The 2023 SMFP indicates that there were 47 mobile MRI scanners in operation in the state during the 2020-2021 reporting period, two of which are owned and operated by EmurgeOrtho. EmurgeOrtho also

operates a third mobile MRI owned by Insight at EmergeOrtho locations.²² Historical utilization and discussion of EmergeOrtho's existing mobile MRI scanners is not included in Section G.

Additionally, EmergeOrtho did not discuss why it needs a new mobile MRI scanner in addition to the mobile service it presently owns and operates at the Oxford host site. Furthermore, EmergeOrtho does not provide projected utilization for EmergeOrtho Triangle Mobile 1 by host site. Therefore, it is impossible to evaluate whether the projected total number of MRI procedures at the EmergeOrtho-Oxford host site (provided by the applicant's existing and proposed mobile scanners) is reasonable and supported.

EmergeOrtho states it "recently" added EmergeOrtho-Clayton as a host site.²³ Historical patient origin provided on application page 34 indicates the Clayton host site served 52 MRI patients during FY2022. EmergeOrtho did not provide a 2023 Registration and Inventory of Medical Equipment for EmergeOrtho Triangle Mobile 1; thus, the level of utilization at the Clayton host site cannot be evaluated.²⁴

For these reasons, the application is non-conforming to Criterion (6). Additionally, based on the facts for which the EmergeOrtho application fails to conform to Criterion (6), it should also be found non-conforming to review criteria (1), (3), (4), and (18a).

²² Application page 21

²³ Application page 57

²⁴ Despite multiple references to inclusion of a 2023 Registration and Inventory of Medical Equipment Report in Exhibit C.2, EmergeOrtho provided a copy of the 2022 Registration and Inventory of Medical Equipment Report which does not include data for the Clayton host site.

**COMMENTS SPECIFIC TO NOVANT HEALTH NORFOLK, LLC (1) (CENTRAL)
PROJECT ID NO. G-012372-23**

Competition

Since 2010, there have been 41 fixed MRIs and no mobile MRI units added to the state’s inventory. The 2023 SMFP need determination presents an invaluable opportunity to enhance competition by introducing a new provider of mobile MRI services. Novant Health, Inc. operates the second-largest mobile MRI unit fleet in North Carolina, serving 24 host sites across the State.²⁵ Additionally, Novant Health, Inc. owns a controlling interest in Novant Health-Norfolk, LLC, which recently acquired two grandfathered mobile MRI scanners from Kings Medical Company.²⁶ Therefore, Novant’s proposal will not have a positive impact on competition.

Furthermore, Novant’s proposal will do little to enhance geographic access. Novant intends to locate the proposed mobile MRI unit at CarolinaEast Medical Center, Carolina Imaging, UNC Lenoir Healthcare, Orthopedic Specialists of NC, and UNC Orthopedics Holly Springs. All but UNC Orthopaedics already offers MRI services via fixed or mobile scanner. Therefore, there is little to no value added with respect to Novant’s proposal and geographic access to MRI services.

For these reasons and the reasons previously described in this document, the Novant application is comparatively inferior to DUHS’s CON application.

Comments Regarding Criterion (3) and 10A NCAC 14C .2703

Novant failed to identify the population to be served by the proposed project. Novant projects mobile MRI patient origin “based on the number of patients receiving mobile MRI services at each host site and its corresponding county.”²⁷ In other words, of the 612 MRI patients proposed to be served at the CarolinaEast Medical Center host site located in Craven County, Novant assumes 100% of them will be residents of Craven County. However, Novant’s assumptions regarding projected patient origin are inconsistent with publicly available data for three of the five proposed host sites. Please see the tables on the following page.

²⁵ <https://info.ncdhhs.gov/dhsr/mfp/pets/2022/summer/T06-NovantHealthMobileMRI.pdf>

²⁶ <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4154%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf> & <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4155%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf>

²⁷ Application page45

**CarolinaEast Medical Center Host Site
MRI Patient Origin Comparison**

County	Existing Fixed MRI Scanner		Proposed Mobile MRI Host Site	
	FY2021		FY2027	
	Patients	% of Total	Patients	% of Total
Craven	3,377	63.9%	612	100.0%
Carteret	489	9.3%		
Onslow	417	7.9%		
Pamlico	335	6.3%		
Jones	329	6.2%		
Other	338	6.4%		
Total	5,285	100.0%	612	100.0%

Source: 2022 DHSR HPCON MRI Patient Origin Report by Facility (FY2021 Data); Application page 45

**Carolina Imaging Host Site
MRI Patient Origin Comparison**

County	Existing Fixed MRI Scanner		Proposed Mobile MRI Host Site	
	FY2021		FY2027	
	Patients	% of Total	Patients	% of Total
Cumberland	6,365	70.9%	1,428	100.0%
Robeson	733	8.2%		
Hoke	465	5.2%		
Harnett	322	3.6%		
Sampson	314	3.5%		
Other	773	8.6%		
Total	8,972	100.0%	1,428	100.0%

Source: 2022 DHSR HPCON MRI Patient Origin Report by Facility (FY2021 Data); Application page 45

**UNC Lenoir Healthcare Host Site
MRI Patient Origin Comparison**

County	Existing Fixed MRI Scanner		Proposed Mobile MRI Host Site	
	FY2021		FY2027	
	Patients	% of Total	Patients	% of Total
Cumberland	2,094	74.2%	510	100.0%
Robeson	194	6.9%		
Hoke	132	4.7%		
Harnett	110	3.9%		
Sampson	95	3.4%		
Other	197	7.0%		
Total	2,822	100.0%	510	100.0%

Source: 2022 DHSR HPCON MRI Patient Origin Report by Facility (FY2021 Data); Application page 45

As demonstrated in the previous tables, the projected patient origin for three of the five proposed host sites is inconsistent with the respective host site’s actual historical experience. The historical patient origin data is publicly available on the DHSR HPCON website; therefore, the information was available to the applicant. Indeed, Novant included copies of MRI patient origin filed by each facility in Exhibit C. Additionally, Novant’s existing mobile MRI unit MQ17 currently provides service at OrthoNC; thus, historical patient origin information is readily available for the host site.

Novant states it was instructed by the Agency during a pre-application conference that “the proposed mobile MRI service area should only include the counties in which the proposed mobile host sites are located.”²⁸ However, DUHS is not aware of any rule or statute that requires as such. Furthermore, 10A NCAC 14C .2701(9) states, “Mobile MRI scanner service area” shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.” The 2023 SMFP identifies a statewide mobile MRI service area. Moreover, even if the “service area” were to be defined to be only those counties where the mobile host sites are located for purposes of Criterion (6), in light of publicly available data, there is no reasonable basis for Novant to assume or project 100% of patients receiving mobile MRI services at each host site will be residents of the host site’s corresponding county for purposes of projecting patient origin for Criterion (3).

For these reasons, Novant failed to adequately identify the patients to be served by the proposed project and is non-conforming to Criterion (3).

Novant claims “all five proposed host sites have extremely high demand for additional MRI capacity.”²⁹ However, a review of UNC Lenoir Healthcare’s historical MRI utilization indicates there is available capacity to accommodate current and future utilization as shown in the following table.

Host Site	County	MRI Inventory	FY2021		FY2022		MRI Threshold
			Unadjusted	Adjusted	Unadjusted	Adjusted	
UNC Lenoir Healthcare	Lenoir	1 Fixed	2,822	3,797	3,126	4,106	4,368

Table 17E-2 of the 2023 SMFP indicates the threshold for determining need for additional fixed MRI scanners in Lenoir County is 4,368. The existing fixed MRI scanner at UNC Lenoir Healthcare performed only 4,106 adjusted MRI procedures, which is below the SMFP threshold. Therefore, there is capacity available on the UNC Lenoir Healthcare fixed MRI scanner. Novant did not adequately demonstrate why the host site needs the proposed mobile MRI scanner in addition to the fixed MRI services it currently offers.

Novant identifies two existing mobile MRI scanners that it owns and operated within the proposed host site counties during the most recent 12 months prior to the start of the review period, i.e., MQ17 and MQ 23. MQ23 performed only 3,046 adjusted MRI procedures during FY2022, which is below the performance standard threshold of 3,120 adjusted MRI procedures.³⁰ Further, Novant project MQ23’s MRI procedures will increase by a CAGR of 2.3% from FY2022 through FY2027, as shown in the following table.

²⁸ Application page 45

²⁹ Application page 30

³⁰ Application page 78

Novant Mobile MRI Scanner MQ23

	FY2021	FY2022	% Change	FY2027	22-27 CAGR
Unadjusted MRI Procedures	3,130	2,892	-7.6%	3,244	2.3%
Adjusted MRI Procedures	3,329	3,046	-8.5%	3,392	2.2%

Source: Application pages 78 & 80

Novant assumes MQ23 will continue providing six days of service per week at its current host sites; UNC Orthopedics Cary, Raleigh Neurological, Cardinals Point Imaging Brier Creek and Cardinals Point Imaging Cary. Novant does not propose any changes to the current weekly schedule for MQ23's host sites. Specifically, UNC Orthopaedics will continue to have 2 days of mobile MRI service per week, Raleigh Neurological will continue to have one day of mobile MRI service per week, Cardinal Point-Brier Creek will continue to have 2 days of mobile MRI service per week, and Cardinal Point-Cary will continue to have 2 days of mobile MRI service per week.³¹ Novant states the MRI procedure volume for each host site is based on the unweighted mobile MRI volume for each host site for FY2022. MRI volume for each MQ23 host site is assumed to be constant during the first three project years. However, a comparison of unweighted mobile MRI volume for each host site for FY2022 to projected utilization reveals a dramatic increase in MRI utilization for MQ23.

Novant Mobile MRI Scanner MQ23

Host Site	FY2021	FY2022	% Change	FY2025	FY22-FY25 % Change
UNC Orthopaedics Cary	948	833	-12.1%	1,224	46.9%
Raleigh Neurosurgical	467	362	-22.5%	372	2.8%
Cardinal Points-Brier Creek	1,093	1,043	-4.6%	1,061	1.7%
Cardinal Points-Wake Forest	449				
Cardinal Points-Cary		185		587	217.3%
Cardinal Points-Midtown	173	469	171.1%		
Total	3,130	2,892	-7.6%	3,244	12.2%

Source: Application pages 78 & 79

Despite a decrease in MQ23's MRI procedures at UNC Orthopaedics Cary, Raleigh Neurosurgical, and Cardinal Points-Brier Creek during FY2021-FY2022, Novant projects MQ23's MRI procedures will increase by a total of 12.2% during the first project year (FY2025). Novant states Cardinal Point-Brier Creek did not use 4 days of service in March 22 to explain the decrease in volume during FY2022 at the respective host site; however, Novant failed to provide any explanation for the voluminous decrease in MRI procedures at the UNC Orthopaedics Cary and Raleigh Neurosurgical host sites. As previously described, Novant does

³¹ Application pages 78 and 81

not propose any changes to the current weekly schedule for MQ23's host sites. Thus, Novant failed to provide any reasonable justification for the drastic increase in MRI procedures at UNC Orthopaedics Cary. Therefore, the projected MRI procedures for MQ23 are unreasonable and not supported and the application does not conform to 10A NCAC 14C .2703.

For these reasons, Novant failed to demonstrate the need the population has for proposed additional MRI scanner. Additionally, based on the facts for which the Novant application fails to conform to Criterion (3), it should also be found non-conforming to review criteria (1), (4), (5), (6), and (18a).

Comments Regarding Criterion (5)

Novant failed to adequately budget for necessary MRI technologist staff. See Criterion (7) for discussion. Therefore, expenses and average cost per procedure are understated.

Novant did not include any working capital for the proposed MRI scanner. The proposed mobile MRI scanner will require necessary start-up costs including hiring staff, training staff, and purchasing supplies; however, relevant expenses were not included in Section F or funding documentation.

Application page 106 states "NHN has an annual allocation to provide staff training needs and license and certification maintenance;" however, Form F.3 includes no annual allocation of expenses for staff training or license and certification maintenance.

The Novant Central application does not include Form F.1, which requires the applicant to itemize the relevant project capital expenditures. Therefore, it is impossible to evaluate the reasonableness of the projected project cost to develop the project as proposed.

For these reasons, the Novant application does not conform to Criterion (5).

Comments Regarding Criterion (6)

10A NCAC 14C .2701(9) states, "Mobile MRI scanner service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period." The 2023 SMFP identifies a statewide mobile MRI service area.

The 2023 SMFP indicates that there were 47 mobile MRI scanners in operation in the state during the 2020-2021 reporting period. Novant Health, Inc. operates the second-largest mobile MRI unit fleet in North Carolina, serving 24 host sites across the State.³² Additionally, Novant Health, Inc. owns a controlling interest in Novant Health-Norfolk, LLC, which recently acquired two grandfathered mobile MRI scanners from Kings Medical Company.³³ Novant's application provides historical utilization for only two of its existing mobile MRI scanners in North Carolina. However, absent any data or historical utilization in the

³² <https://info.ncdhhs.gov/dhsr/mfp/pets/2022/summer/T06-NovantHealthMobileMRI.pdf>

³³ <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4154%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf> & <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4155%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf>

application as submitted, Novant failed to demonstrate why its existing mobile MRI scanners in North Carolina cannot accommodate the purported need at the proposed host sites.

Additionally, three of the four proposed host sites are presently served by Novant's existing MQ23 mobile MRI scanner. Novant did not demonstrate why it needs a new mobile MRI scanner to replace the underutilized mobile service it presently provides to the respective sites. See comments regarding Criterion (3).

For these reasons, the Novant application should be found non-conforming to Criterion (6). Additionally, based on the facts for which the Novant application fails to conform to Criterion (6), it should also be found non-conforming to review criteria (1), (3), (4), and (18a).

Comments Regarding Criterion (7)

Novant failed to demonstrate sufficient evidence of the availability of health manpower for the provision of the proposed mobile MRI services. Form H in Section Q provides staffing for the Novant project and identifies only 1.4 FTE radiologist technologist for the proposed mobile MRI service. Application pages 70-74 identify the projected weekly service schedule for the proposed mobile MRI scanner, which will operate seven (7) days per week. Novant failed to specifically identify how many hours the proposed mobile MRI scanner will operate each day; however, Novant states on application page 79 that "on MQ17, the host sites are typically providing 10 hours of procedure time." Novant's project year 3 utilization projections for the proposed mobile MRI scanner (4,568 adjusted MRI procedures) far exceed the FY2022 utilization for MQ17 (3,748 adjusted MRI procedures), thus, it is reasonable to assume the proposed mobile MRI scanner will provide at least 10 hours of procedure time at each host site. The following calculations summarize the minimum radiation technologist staffing requirements for Alliance's proposed schedule:

$7 \text{ days per week} \times 10 \text{ hours per day} \times 51 \text{ weeks per year} = 3,570 \text{ hours} \div 2,080 \text{ hours per FTE} = \underline{1.7 \text{ FTEs}}$

Novant's projected staffing of 1.4 FTE radiologist technologist is insufficient to support the health manpower needs of the proposed project. Therefore, the application is non-conforming to Criterion (7).

Comments Regarding Criterion (13)

Novant failed to provide any evidence regarding the extent to which medically underserved populations currently use its existing mobile MRI services and the extent to which the medically underserved populations will have access to the proposed mobile MRI service. Novant provided no historical data regarding access to medically underserved and failed to provide any projections for the proposed payor mix or the estimated number of charity care patients. Therefore, the application is non-conforming to Criterion (13).

Comments Regarding Criterion (18a)

According to the Federal Trade Commission, competition in health care markets benefits consumers because it helps contain costs, improve quality, and encourage innovation. Similarly, the 2023 SMFP states the State Health Coordinating Council recognizes the importance of balanced competition and market advantage to encourage innovation, insofar as those innovations improve safety, quality, access, and value in health care delivery.

Novant Health, Inc. operates the second-largest mobile MRI unit fleet in North Carolina, serving 24 host sites across the State.³⁴ Additionally, Novant Health, Inc. owns a controlling interest in Novant Health-Norfolk, LLC, which recently acquired two grandfathered mobile MRI scanners from Kings Medical Company.³⁵ Awarding another mobile MRI scanner to Novant will not enhance competition for statewide mobile MRI services.

³⁴ <https://info.ncdhhs.gov/dhsr/mfp/pets/2022/summer/T06-NovantHealthMobileMRI.pdf>

³⁵ <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4154%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf> & <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4155%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf>

COMMENTS SPECIFIC TO NOVANT HEALTH-NORFOLK, LLC (2) (WEST)
PROJECT ID NO. G-012373-23

Comments Regarding Criterion (3) and 10A NCAC 14C .2703

Novant failed to identify the population to be served by the proposed project. Novant projects mobile MRI patient origin “based on the number of patients receiving mobile MRI services at each host site and its corresponding county.”³⁶ In other words, of the 3,060 MRI patients proposed to be served at the Open MRI & Imaging of Asheville host site located in Buncombe County, Novant assumes 100% of them will be residents of Buncombe County. However, Novant’s assumptions regarding projected patient origin are inconsistent with publicly available data the Open MRI & Imaging of Asheville host site. Please see the following table.

**Open MRI & Imaging of Asheville Host Site
MRI Patient Origin Comparison**

County	Existing Fixed MRI Scanners		Proposed Mobile MRI Host Site	
	FY2021		FY2027	
	Patients	% of Total	Patients	% of Total
Buncombe	5,200	46.9%	3,060	100.0%
Henderson	1,565	14.1%		
Haywood	777	7.0%		
Madison	591	5.3%		
McDowell	375	3.4%		
Other	2,575	23.2%		
Total	11,083	100.0%	3,060	100.0%

Source: 2022 DHSR HPCON MRI Patient Origin Report by Facility (FY2021 Data); Application page 44

As demonstrated in the previous table, the projected patient origin for the Open MRI & Imaging of Asheville Host Site is inconsistent with the respective host site’s actual historical experience. The historical patient origin data is publicly available on the DHSR HPCON website; therefore, the information was available to the applicant. Indeed, Novant included copies of MRI patient origin filed by Open MRI & Imaging of Asheville in Exhibit C.

Novant states it was instructed by the Agency during a pre-application conference that “the proposed mobile MRI service area should only include the counties in which the proposed mobile host sites are located.”³⁷ However, DUHS is not aware of any rule or statute that requires as such. Furthermore, 10A NCAC 14C .2701(9) states, “Mobile MRI scanner service area” shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.” The 2023 SMFP identifies a statewide mobile MRI service area. Moreover, even if the “service area” were to be defined to be only those counties where the mobile host sites are located for purposes of Criterion (6), in light of publicly available data, there is no reasonable basis for Novant to assume or project 100% of patients

³⁶ Application page45

³⁷ Application page 45

receiving mobile MRI services at each host site will be residents of the host site’s corresponding county for purposes of projecting patient origin for Criterion (3).

For these reasons, Novant failed to adequately identify the patients to be served by the proposed project and is non-conforming to Criterion (3). Additionally, based on the facts for which the Novant application fails to conform to Criterion (3), it should also be found non-conforming to review criteria (1), (4), (5), (6), and (18a).

Comments Regarding Criterion (5)

Novant failed to adequately budget for necessary MRI technologist staff. See Criterion (7) for discussion. Therefore, expenses and average cost per procedure are understated.

Novant did not include any working capital for the proposed MRI scanner. The proposed mobile MRI scanner will require necessary start-up costs including hiring staff, training staff, and purchasing supplies; however, relevant expenses were not included in Section F or funding documentation.

Application page 96 states “NHN has an annual allocation to provide staff training needs and license and certification maintenance;” however, Form F.3 includes no annual allocation of expenses for staff training or license and certification maintenance.

It does not appear that Novant included sufficient expenses to adequately fund its tax obligation as a part of the projected capital cost expenses. Novant included \$2,251,107 for medical equipment costs in Form F.1, located in Section Q. According to Exhibit F, the vendor equipment quote reflects \$2,108,680.80 for the MRI scanner and \$88,375 for optional items totaling \$2,339,482. The medical equipment costs in Form F.1 are insufficient to cover the expenses necessary for the MRI equipment and optional items.

In addition, it does not appear that the applicant included expenses for applicable sales tax. DUHS calculates the projected taxes as illustrated in the table below based on the vendor’s quote in Exhibit F.1.

Novant Health Norfolk West Projected Tax

Description	Cost
Medical Equipment	\$2,339,482
<u>Projected Sales Tax @ 7%</u>	<u>\$163,764</u>
Medical Equipment Including Projected Tax	\$2,503,246
Consultant Fees	\$35,000
Contingency	\$10,000
Total Capital Cost Including Projected Tax	\$2,548,246

As illustrated in the above table, the projected sales tax of 7% based on the vendor’s quote for medical equipment would total \$163,764. Therefore, the projected total for the mobile MRI scanner and selected options including tax is \$2,548,246. Thus, the applicant did not include in its projected capital cost nor its proformas the total required taxes associated with the proposed mobile MRI scanner.

As noted in the letter from Novant Health-Norfolk, LLC located in Exhibit F, the funding commitment for the proposed project is \$1,296,107. The total capital cost of the project (\$2,548,246) exceeds the funding to be provided for the capital costs (\$2,296,108) by \$252,139. Therefore, Novant failed to demonstrate adequate funds for the capital cost of the proposed project and is non-conforming to Criterion (5).

For these reasons, the Novant application does not conform to Criterion (5).

Comments Regarding Criterion (6)

10A NCAC 14C .2701(9) states, "Mobile MRI scanner service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period." The 2023 SMFP identifies a statewide mobile MRI service area.

The 2023 SMFP indicates that there were 47 mobile MRI scanners in operation in the state during the 2020-2021 reporting period. Novant Health, Inc. operates the second-largest mobile MRI unit fleet in North Carolina, serving 24 host sites across the State.³⁸ Additionally, Novant Health, Inc. owns a controlling interest in Novant Health-Norfolk, LLC, which recently acquired two grandfathered mobile MRI scanners from Kings Medical Company.³⁹ Novant's application provides historical utilization for only one of its existing mobile MRI scanners in North Carolina. However, absent any data or historical utilization in the application as submitted, Novant failed to demonstrate why its remaining existing mobile MRI scanners in North Carolina cannot accommodate the purported need at the proposed host sites.

For these reasons, the Novant application should be found non-conforming to Criterion (6). Additionally, based on the facts for which the Novant application fails to conform to Criterion (6), it should also be found non-conforming to review criteria (1), (3), (4), and (18a).

Comments Regarding Criterion (7)

Novant failed to demonstrate sufficient evidence of the availability of health manpower for the provision of the proposed mobile MRI services. Specifically, Novant failed to include Form H in Section Q, which requires applicants to identify annual staffing projections by position. Without any information regarding the number of FTEs projected for each project year, it is impossible to determine whether the Novant West application includes sufficient clinical staffing to cover projected utilization. Therefore, the application is non-conforming to Criterion (7).

Comments Regarding Criterion (13)

Novant failed to provide any evidence regarding the extent to which medically underserved populations currently use its existing mobile MRI services and the extent to which the medically underserved populations will have access to the proposed mobile MRI service. Novant provided no historical data regarding access to medically underserved and failed to provide any projections for the proposed payor

³⁸ <https://info.ncdhhs.gov/dhsr/mfp/pets/2022/summer/T06-NovantHealthMobileMRI.pdf>

³⁹ <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4154%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf> & <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4155%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf>

mix or the estimated number of charity care patients. Therefore, the application is non-conforming to Criterion (13).

Comments Regarding Criterion (18a)

According to the Federal Trade Commission, competition in health care markets benefits consumers because it helps contain costs, improve quality, and encourage innovation. Similarly, the 2023 SMFP states the State Health Coordinating Council recognizes the importance of balanced competition and market advantage to encourage innovation, insofar as those innovations improve safety, quality, access, and value in health care delivery.

Novant Health, Inc. operates the second-largest mobile MRI unit fleet in North Carolina, serving 24 host sites across the State.⁴⁰ Additionally, Novant Health, Inc. owns a controlling interest in Novant Health-Norfolk, LLC, which recently acquired two grandfathered mobile MRI scanners from Kings Medical Company.⁴¹ Awarding another mobile MRI scanner to Novant will not enhance competition for statewide mobile MRI services.

⁴⁰ <https://info.ncdhhs.gov/dhsr/mfp/pets/2022/summer/T06-NovantHealthMobileMRI.pdf>

⁴¹ <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4154%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf> & <https://info.ncdhhs.gov/dhsr/coneed/reviews/2023/mar/4155%20Mecklenburg%20Novant%20Health-Norfolk%20Exemption.pdf>

**COMMENTS SPECIFIC TO PINNACLE HEALTH SERVICES OF NORTH CAROLINA, LLC
PROJECT ID NO. J-012375-23**

Comments Regarding Criterion (3) and 10A NCAC 14C .2703

Pinnacle’s proposal will do little to enhance geographic access. Pinnacle intends to locate the proposed mobile MRI unit at Cardinal Point Imaging Brier Creek, Cardinal Point Imaging Cary, Atrium Health Wake Forest Baptist Outpatient Imaging Northline, Atrium Health Wake Forest Baptist Outpatient Imaging Kernersville, and Atrium Health Wake Forest Baptist Outpatient Imaging. All but Atrium Health Wake Forest Baptist Outpatient Imaging Northline already offer MRI services via fixed or mobile scanner. Therefore, there is little to no value added with respect to Pinnacle’s proposal and geographic access

Both Pinnacle and Alliance propose to serve the same host site, i.e., Atrium Health Wake Forest Baptist Outpatient located in Forsyth County (Wake Forest Outpatient), which also recently developed its second fixed MRI scanner. Pinnacle proposes to serve Wake Forest Outpatient 2 days per week and Alliance (G-012365-23) proposes to serve the same site 3 days per week (5 days total). The following table summarizes projected mobile MRI procedures at the proposed host site per the respective applications.

**Wake Forest Outpatient Host Site – Winston Salem
Projected MRI Procedures (Unadjusted)**

Wake Forest Outpatient – Winston Salem	Project Year 3, CY2027
Fixed MRI Procedures	7,211 ⁴²
Pinnacle Mobile MRI Procedures	2,060 ⁴³
Alliance Mobile MRI Procedures	3,432 ⁴⁴
Total Projected MRI Procedures	12,703

The Pinnacle application does not acknowledge Alliance’s mobile MRI projections at the Wake Forest Outpatient host site. Therefore, the Pinnacle application does not demonstrate that it is reasonable to project a total of 12,703 MRI procedures at the respective site. Thus, at a minimum, both Alliance and Pinnacle cannot be approved in this review because the cumulative projections for the Wake Forest Outpatient host site are not supported.

Pinnacle provides a two-sentence justification to project MRI procedures at the new Atrium Health Wake Forest Baptist Outpatient Imaging Northline host site. Specifically, Pinnacle “assumed 6.5 scans per mobile MRI day during the first project year (6.5 x 52 = 338). This is based on PHSNC’s historical experience in opening diagnostic imaging centers and offering MRI scans.” However, Pinnacle failed to provide any of its historical experience regarding opening diagnostic imaging centers to substantiate this claim.

⁴² Pinnacle application page 130

⁴³ Pinnacle application page 130

⁴⁴ Alliance application page 87

Furthermore, Pinnacle did not provide the assumptions to project MRI procedures at Atrium Health Wake Forest Baptist Outpatient Imaging Northline during the second and third project years, respectively. Pinnacle also failed to discuss what impact the new Atrium Health Wake Forest Baptist Outpatient Imaging Northline host site will have on mobile MRI procedures at the existing Atrium Health Wake Forest Baptist Outpatient Imaging host sites it projects to serve in Winston-Salem and Kernersville. For these reasons, mobile MRI projections are not reasonable or supported. Consequently, the application is non-conforming to Criterion (3).

Additionally, based on the facts for which the Pinnacle application fails to conform to Criterion (3), it should also be found non-conforming to review criteria (1), (4), (5), (6), and (18a).

Comments Regarding Criterion (5)

As stated on application page 95, "PHSNC will not directly bill patients for mobile scans performed at the three AHWFBFI host sites, but will charge a "wholesale" scan fee to the host medical facility." Pinnacle failed to provide the assumptions and rationale for the projected per diem rates will be for the WFBI sites; thus, the veracity of the projected revenues cannot be determined.

Pinnacle’s assumptions for Form F.2 state the average gross charges are “based on historical.” Pinnacle projects an Average MRI gross charge of \$2,478 during the first project year (2025) with an annual inflation rate of 3.0%. However, the projected average gross charge is substantially higher compared to Pinnacle’s historical experience reflected in recent CON applications. Specifically, Pinnacle submitted a CON application in response to the 2021 SMFP Wake County need determination in which it projected an average MRI gross charge of \$1,834 during 2024. A comparison of Pinnacle’s projected average MRI gross charges is provided in the following table.

	Pinnacle 2021 Wake Co. Fixed MRI CON J-12063-21	Pinnacle 2023 Mobile MRI CON J-12375-23
2024 Average MRI Gross Charge	\$1,834 ⁴⁵	
2025 Average MRI Gross Charge		\$2,478 ⁴⁶
<i>2024-2025 Increase in Average MRI Gross Charge</i>		<i>35.1%</i>

Pinnacle’s projected average MRI gross charge for 2025 reflects an increase of over 35% compared to its 2024 average MRI gross charge provided in its previous MRI application that was filed just two years ago.

A comparison of Pinnacle’s projected average net revenue per MRI procedure reveals an even greater inflation rate. As an example, the following table compares the projected commercial payor revenues during 2024 and 2025 of Pinnacle’s 2021 and 2023 MRI CON applications, respectively. The commercial

⁴⁵ Project ID J-12063-21, page 132

⁴⁶ Project ID J-12375-23, page 135

payor source was selected because it accounts for the highest percentage of Pinnacle’s projected payor mix for the proposed project (54.53%).

	Pinnacle 2021 Wake Co. Fixed MRI CON	Pinnacle 2023 Mobile MRI CON
2024 Average MRI Gross Charge	\$1,834	
Insurance Contractual Adjustment	76.5%	
2024 Average Net Revenue Per MRI (Commercial)	\$431	
2025 Average MRI Gross Charge		\$2,478
Insurance Contractual Adjustment		71.3%
2025 Average Net Revenue Per MRI (Commercial)		\$711
2024-2025 Increase in Avg Net Revenue Per MRI Procedure (Commercial)		65.0%

Source: Project ID J-12063-21, Form F.2, page 132; Project ID J-12375-23, Form F.2, page 135

The vast increase in MRI gross charges and net revenues between the recently filed 2021 Wake County MRI CON application and Pinnacle’s proposed mobile MRI CON application calls into question the reasonableness of Pinnacle’s projected revenues.

Pinnacle’s assumptions for billing fees also changed between its 2021 and 2023 CON applications. The 2021 Wake County MRI application projected a billing fee of 10% of net patient revenue, whereas the 2023 mobile MRI application projects a billing fee of only 5% of net patient revenue. DUHS notes Pinnacle’s projected net income during project year 3 is only \$26,277; thus, one can reasonably speculate the arbitrary change in billing fees in the 2023 CON application compared to the 2021 application was necessary to demonstrate financial feasibility and/or to anticipate a comparative analysis. At a minimum, Pinnacle demonstrates inconsistent assumptions regarding expenses as represented in its 2021 and 2023 MRI CON applications, respectively.

For these reasons, Pinnacle’s revenues and expenses are unreasonable and not supported. Therefore, the application is non-conforming to Criterion (5).

Additionally, based on the facts for which the Pinnacle application fails to conform to Criterion (5), it should also be found non-conforming to review criteria (1), (4), (5), and (18a).

COMMENTS SPECIFIC TO

**CAROLINA NEUROLOGY & SPINE (1) BHMH PROJECT ID NO. F-012368-23
&
CAROLINA NEUROLOGY & SPINE (2) BHMH PROJECT ID NO. F-012381-23**

Section Q, page 1 states, “CNSA’s two applications largely rely on complementary methodologies in order to support the quantitative need for each proposed project, and as the Performance Standards for MRI scanners require applicants to project utilization for all current and proposed MRI scanners as owned and/or operated by that applicant (10A NCAC 14C .2703 (b)), the utilization projections below largely outline the need for both of CNSA’s proposed projects, by necessity. As such, some aspects of these two complementary methodologies are duplicative.” Therefore, due to the duplication of assumptions presented in CNSA (1) and CNSA (2), the following written comments are relevant to both of CNSA’s mobile MRI applications.

Comments Regarding Criterion (3) and 10A NCAC 14C .2703

CNSA owns and operates one fixed multi-position MRI and one mobile MRI in HSA III. After failed attempts petitioning the State Health Coordinating Council (SHCC) to create Policy TE-4, in summer 2022 CNSA petitioned the SHCC for an adjusted need determination to the Proposed 2023 SMFP for one additional mobile MRI scanner for HSA III. The SHCC denied CNSA’s petition, but SHCC ultimately identified a statewide adjusted need determination for three statewide mobile MRI scanners in the 2023 SMFP.

CNSA’s summer 2022 petition did not mention the need for two additional mobile MRI scanners in HSA III. However, CNSA has now submitted two CON applications proposing to develop two additional mobile MRI scanners in HSA III, which, if approved, would increase its inventory of mobile MRI scanners from one to three. CNSA’s request for two additional mobile MRI scanners is excessive and will result in unnecessary duplication of services.

CNSA’s MRI volume has yet to rebound to its pre-COVID FY2019 MRI utilization as demonstrated in the following table.

CNSA and Vendor-Owned Total Weighted MRI Volumes by CNSA Office/Service Location

Location	Service Type	FY19	FY20	FY21	FY22	FY23*	19-23 CAGR
Cabarrus	Vendor-Owned Mobile	1,412	1,301	1,269	1,298	1,367	-0.8%
Guilford	Vendor-Owned Mobile	1,891	1,661	1,883	1,887	1,825	-0.9%
Mecklenburg – Charlotte	Vendor-Owned Mobile	1,436	1,492	1,398	1,375	1,384	-0.9%
Vendor-Owned Subtotal		4,739	4,454	4,550	4,559	4,576	-0.9%
Mecklenburg – Charlotte	CNSA-Owned Mobile	5,344	4,720	4,797	4,821	5,074	-1.3%
Mecklenburg – Ballantyne	CNSA-Owned Mobile	1,730	1,603	1,555	1,595	1,636	-1.4%
CNSA-Owned Mobile Subtotal		7,075	6,324	6,352	6,416	6,710	-1.3%
Mecklenburg – Charlotte	CNSA-Owned Fixed	4,505	4,113	4,055	4,082	4,199	-1.7%
CNSA-Owned Mobile/Fixed Subtotal		11,580	10,436	10,406	10,498	10,909	-1.5%
CNSA/Vendor-Owned Grand Total		16,319	14,890	14,956	15,057	15,484	-1.3%

Source: CNSA (1) application pages 40 & 42; CNSA (2) application pages 40 & 42

*FY 2023 totals are annualized based on eight months of data.

Three years after the onset of COVID, CNSA has yet to rebound to pre-COVID FY2019 MRI utilization. By comparison, DUHS’s outpatient MRI volume in Wake and Durham counties has rebounded well beyond FY2019 utilization.

Outpatient MRI Utilization at DUHS Facilities (Wake & Durham Counties)

	FY2019	FY2020	FY2021	FY2022	FY2023*	19-23 CAGR
OP MRI Procedures	57,680	53,886	66,163	70,892	73,702	6.3%

*Annualized based on seven months data (July-Jan)

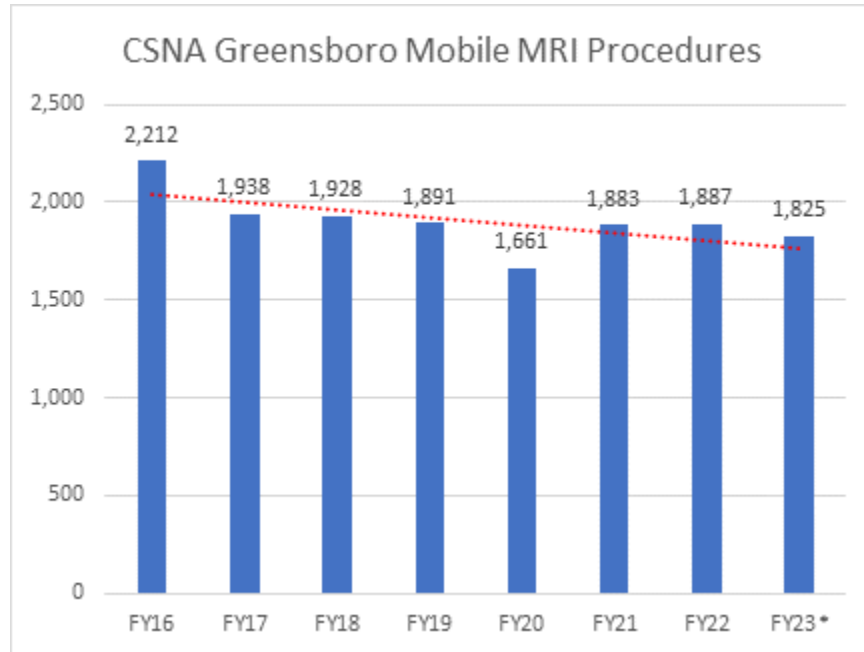
To project future volume for its existing mobile MRI sites, CNSA assumes that each site will continue to grow at the growth rate each experienced from FY2020 through FY2023.⁴⁷ CNSA’s assumption is problematic because it utilizes FY2020 as the baseline for determining growth. CNSA acknowledges its FY2020 MRI utilization was impacted by COVID which decreased MRI volume.⁴⁸ Therefore, a growth rate based upon FY2020 volume utilizes an artificially low baseline, and subsequent annual volume may not be reflective of organic growth. Given CNSA’s MRI utilization has yet to rebound to pre-pandemic volume, the FY2020-FY2023 calculated “growth rates” are inappropriate and artificially inflated by the low volume FY2020 baseline.

For example, CNSA projects the number of mobile MRI procedures at its Greensboro clinic will increase by its FY2020-FY2023 CAGR of 3.2%.⁴⁹ However, a review of CNSA Greensboro’s pre-COVID MRI utilization reveals a decreasing trend in volume.

⁴⁷ Section Q, page 7

⁴⁸ CSNA (1) application page 42; CSNA (2) application page 42

⁴⁹ CSNA (1) Section Q, 7; CSNA (2) Section Q, 7



Source: CSNA (1) Section Q, 4; CSNA (2) Section Q, 4

As demonstrated in the chart above, CNSA Greensboro’s mobile MRI procedures decreased during FY2017, FY2018, and FY2019. The red trendline displays the linear trend from FY2016-FY2023, which reflects a decreasing trend in volume. Therefore, the projected growth rate of 3.2% for CNSA Greensboro mobile MRI procedures is not supported by historical utilization.

For these reasons, mobile MRI projections are not reasonable or supported. Consequently, the applications are non-conforming to Criterion (3). Additionally, based on the facts for which the CNSA applications do to conform to Criterion (3), they should also be found non-conforming to review criteria (1), (4), (5), (6), and (18a).

Comments Regarding Criterion (14)

CNSA does not have on-site training programs in place. CNSA stated the programs were halted due to the COVID-19 pandemic. However, North Carolina’s state of emergency ended on August 15, 2022. There are no restrictions in place that prevent CNSA from being able to accommodate the clinical needs of health professional training programs in the area. CNSA operates a fixed MRI scanner and mobile MRI scanner, both of which were subject to CON approval. CNSA is required to materially comply with the representations made in the respective CON applications, which include access for health professional training programs. Therefore, CNSA has failed to demonstrate that its MRI services accommodate the clinical needs of health professional training programs in the area.

For these reasons, the CSNA applications should be found non-conforming to Criterion (14).

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: September 22, 2009
PROJECT ANALYST: Bernetta Thorne-Williams
TEAM LEADER: Helen E. Alexander

PROJECT I.D. NUMBERS: P-8326-09 / Jacksonville Diagnostic Imaging, LLC d/b/a Coastal Diagnostic Imaging / Acquire a fixed MRI scanner for an existing facility / Onslow County

P-8332-09 / Onslow MRI, LLC / Develop a new diagnostic center and acquire one fixed MRI scanner / Onslow County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC

Both Applicants

The 2009 State Medical Facilities Plan [SMFP] provides a methodology for determining the need for additional fixed Magnetic Resonance Imaging (MRI) scanners in North Carolina by service area. Application of the need methodology in the 2009 SMFP identified a need for one fixed MRI scanner in Onslow County. Two applications were submitted to the Certificate of Need Section, each proposing to acquire a fixed MRI scanner for Onslow County. Although, the applications propose to develop a total of two fixed MRI scanners for Onslow County, only one may be approved. Each proposal is briefly described below.

Jacksonville Diagnostic Imaging, LLC (JDI) d/b/a Coastal Diagnostic Imaging (CDI) is a limited liability company with Triad Imaging, LLC as the sole member of Jacksonville Diagnostic Imaging, LLC. MedQuest, Inc., a Delaware corporation, is

NC
Both Applicants

CDI. In Section III.3, pages 74-75 of the applications, the applicant describes the following alternative solutions that were considered: 1) maintain the status quo; 2) additional days of mobile MRI service; and 3) acquire a fixed 1.5T MRI unit. However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (18a) and Criteria and Standards for Magnetic Resonance Imaging Scanners in 10A NCAC 14C .2700. Therefore, the applicant did not adequately demonstrate that its proposal is an effective alternative and the application is nonconforming with this criterion.

OMLLC. In Section III, pages 65-68 of the application, the applicant describes the following alternative solutions that were considered: 1) maintain the status quo; 2) develop the proposed facility at a different geographical location in Onslow County; 3) contract with a mobile MRI provider; and 4) acquire a different scanner. However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (18a) and Criteria and Standards for Magnetic Resonance Imaging Scanners in 10A NCAC 14C .2700. Therefore, the applicant did not adequately demonstrate that its proposal is an effective alternative and the application is nonconforming with this criterion.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

NC
Both Applicants

CDI. In Section VIII, page 115 of the application, the applicant projects the capital cost for the proposed fixed MRI scanner. The following table summarizes the projected capital cost as stated in Section VIII, page 115 of the application.

CDI Projected Capital Cost **Table 16**

<i>Description</i>	<i>Cost</i>
<i>Construction Contract/Labor</i>	<i>\$380,480</i>
<i>Fixed Equipment Purchase/Lease</i>	<i>\$1,323,651</i>
<i>Furniture</i>	<i>\$10,000</i>
<i>Consultant Fees:</i>	
➤ <i>Architect & Engineering</i>	<i>\$15,000</i>
<i>Contingency</i>	<i>\$50,000</i>
<i>Total</i>	<i>\$1,779,132</i>

Note: Includes cost of MRI scanner, MRI injector, 7% sales tax on both, rigging, shipping and insurance. MRI quote includes chiller and application training.

In Section IX, page 122, as an existing facility, the applicant projects no start-up or initial operating cost associated with the proposed project. See Attachment 29 for a detailed vendor's quote and Attachment 30 for a list of projected capital cost for the purchase of CDI's proposed fixed MRI scanner. In Section VIII, 2, (c), page 114 of the application, the applicant states, *"The straight line method of depreciation will be used."* In Section VIII.3, page 116, CDI indicates that the proposed project will be financed by Accumulated Reserves of Novant Health, Inc. Attachment 32 contains funding letters. The first letter dated April 6, 2009 from Dean Swindle, President Ambulatory Services and Chief Financial Officer, Novant Health, Inc., states:

"As the President Ambulatory Services and Chief Financial Officer, Novant Health, Inc., I have the authority to obligate funds from accumulated reserves of Novant Health for projects undertaken by MedQuest, an affiliate of Novant Health, Inc. Novant Health, Inc. is the not-for-profit parent company of MedQuest. ..."

I can and will commit Novant's reserves to cover all the capital costs associated with the project, including the project capital cost of \$1,799,132."

The second letter, dated March 30, 2009 from Dean Swindle, President Ambulatory Services and Chief Financial Officer, Novant Health, Inc., states:

"Please allow this letter to confirm the availability of funds of MedQuest, Inc. through Novant Health Inc.'s \$425 million Revolving Line of Credit. As of December 31, 2008, MedQuest, Inc. had in excess of \$12.6 million of availability under this Revolving Line of Credit. I commit that Novant Health, Inc. will furnish to MedQuest, Inc. all funds that are needed from the Revolving Line of Credit so that MedQuest, Inc. can undertake the project described ..."

The final funding letter, dated April 10, 2009 from Edward Williams, Chief Accounting Officer MedQuest Associates which states:

"This letter confirms the availability of funds for Jacksonville Diagnostic Imaging, LLC, d/b/a Coastal Diagnostic Imaging ("CDI") to support the capital expenditure required for the acquisition of the fixed MRI that CDI proposes. The cost of the proposed fixed MR system in CDI's Certificate of Need is \$1,279,042 including tax. The total capital expenditure required for the proposed project is \$1,779,132, which includes the cost of the MR system and other related equipment, and common consulting fees."

Triad Imaging, Inc. is the sole member of Jacksonville Diagnostic Imaging, LLC. MedQuest, Inc. is the sole member of Triad Imaging, Inc. MedQuest will make available all funds necessary to finance the proposed project and required working capital, as well [sic] any unforeseen expenses related to the

CON application, through its accumulated reserves and through MedQuest Inc.'s \$425 million revolving Line of Credit with Novant Health, Inc. ..."

Attachment 33 of the application contains *Novant Health, Inc. and Affiliates combined Financial Statements as of December 31, 2007 and 2006*. According to the financial statements, Novant had \$321,913,000 in cash and cash equivalents as of December 31, 2007. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

Additionally, in Section VIII.3, page 116, CDI indicates that the proposed project will be financed by Accumulated Reserves of Novant Health, Inc. However, in Attachment 32, a letter from Dean Swindle, President Ambulatory Services and Chief Financial Officer Novant Health, Inc., it states, *"I commit that Novant Health, Inc. will furnish to MedQuest, Inc. all funds that are needed from the Revolving Line of Credit so that MedQuest, Inc. can undertake the project described ..."* Further, Attachment 32 also contains a letter from Edward Williams, Chief Accounting Officer MedQuest Associates which states, *"MedQuest will make available all funds necessary to finance the proposed project and required working capital ... through its accumulated reserves and through MedQuest Inc.'s \$425 million revolving Line of Credit with Novant Health, Inc. ..."*

In the financial pro formas for Jacksonville Diagnostic Imaging, LLC d/b/a Coastal Diagnostic Imaging, pages 133-143 of the application, the applicant projects CDI's average gross, net revenue, and average net revenue per patient for the first three operating years as illustrated in the table below. See Pro Forma Tab.

Projected Gross and Net Revenue for Proposed MRI Services **Table 17**

Year	# Of Patients	Budgeted Gross Revenue	Net Revenue	Average Net Revenue Per Patient	Net Income
Interim Full FY 07/01/09-6/30/10	5,275	\$10,694,817	\$3,056,278	\$579.39	\$1,228,821
FY 1 (7/10-6/11)	6,522	\$13,223,561	\$3,778,922	\$579.41	\$1,239,766
FY 2 (7/11-6/12)	7,304	\$14,810,388	\$4,232,392	\$579.46	\$1,504,020
FY 3 (7/12-6/13)	7,889	\$15,995,219	\$4,570,984	\$579.41	\$1,807,649

As illustrated in the table above, the applicant's average net revenue per patient will stay consistent for the first three years of operations following the proposed project. The applicant projects that the proposed project will show a profit during its first three years of operations.

The applicant does not differentiate as to how much of the proposed project will be financed by MedQuest's accumulated reserves or through Novant Health, Inc., revolving Line of Credit. Nor does the applicant provide the rate of interest to be paid on the revolving Line of Credit. The applicant accounts for some interest expenses on the line of credit to be paid in the pro formas. Further, in the pro forma section, *"Expenses Calculation Basis"* it states, *"Interest Expenses based on LOC*

agreement with applicant's ultimate parent company." However, as the applicant did not provide a copy of the agreement, it is unclear as to how much of the proposed capital cost will be paid through Novant's revolving Line of Credit and the interest rate to be paid. Therefore, it is impossible to determine if the applicant has accounted for all related expenses.

Furthermore, the applicant is asked in Section X.2, (a), page 124 of the application to, *"Provide a Balance Sheet for the entire facility for the last full fiscal year immediately prior to submission of the application."* However, CDI did not provide the requested information. Thus, it can not be determined if the applicant's cash flow projections are reasonable.

Additionally, the applicant is asked in Section X.2, (b), page 124 of the application to, *"Provide a Statement of Revenues and Expenses for the entire facility for the last full fiscal year immediately prior to submission of the application."* However, CDI did not provide the requested information. Thus, it can not be determined if the applicant's projected revenues and expenses are reasonable.

Further, the applicant is asked in Section X.2, (c), page 125 of the application to, *"Provide a Statement of Revenues and Expenses for each Service Component included in the Proposed Project for the last full fiscal year immediately prior to submission of the application."* However, CDI did not provide the requested information. Thus, it can not be determined if the applicant's projected revenues and expenses for the proposed MRI services are reasonable.

In Section II, page 34 of the application, the applicant provides the projected charges for the top 20 MRI procedures for the first three years following completion of the proposed project. The Applicant states the following in Section II, page 33:

"CDI will bill patients for the MRI diagnostic studies performed... CDI has not assumed any inflation in its charges during the first three years of operation following implementation. These are global charges, which include both the technical component and the radiologist's professional fee. CDI will pay the radiologists, which is reflected in the expenses for the proposed project."

However, CDI does not include the charges for its professional fees in its *Statement of Revenues and Expenses* in the Pro Formas. The project analyst calculates the projected professional fee based on the lowest fee reported in Section II, page 34 for the first three years of services following project completion as illustrated in the table below.

Projected Professional Fee **Table 18**

Year	Radiologist Professional Fee	Projected Number of Procedures	Minimum Total of Professional Fees
FY 1 (7/10-6/11)	\$212	6,522	\$1,382,664
FY 2 (7/11-6/12)	\$212	7,304	\$1,548,448
FY 3 (7/12-6/13)	\$212	7,889	\$1,672,468

As illustrated in the above table, project analyst calculates the projected professional fees for FY1 through FY3 based on the number of procedures the applicant projects to perform from FY1 through FY3, as reported in the Pro forma Section of the applicant, and by the lowest professional fee (MRA Head without contrast) reported by the applicant. Thus, at minimum, the applicant failed to include in its Pro forma professional fees totaling at least \$1,382,664 in FY1, \$1,548,448 in FY2, and \$1,672,468 in FY3. Thus, in all three operating years, addition of the minimal professional fee reported by the applicant will result in a loss as shown below.

Net Income and Projected Professional Fee FY1- FY3
Table 19

Year	Net Income	Professional fee	Loss
Yr 1	\$1,239,766	\$1,382,666	(-\$142,900)
Yr 2	\$1,504,020	\$1,548,448	(-\$44,428)
Yr 3	\$1,807,649	\$1,672,468	\$135,181

The applicant's stated professional fee for the twenty top MRI procedures on page 34 of the application, range from \$212.00 to \$454.00. Thus, the expenses for the professional fee are likely to be greater than shown above.

Therefore, expense projections proposed by CDI are understated because no expense is included for the professional fee. Therefore, the applicant's expense projections are unreasonable and unreliable.

In the Pro Forma, form B, the applicant projects the following direct/indirect expenses associated with the proposed fixed MRI as illustrated in the table below.

Average Procedure Cost **Table 20**

Year	FY1 7/10-6/11	FY2 7/11-6/12	FY3 7/12-6/13
Charge for MRI	\$2,027.63	\$2,027.63	\$2,027.63
Total Projected Net Revenue	\$3,778,922	\$4,232,392	\$4,570,984
Total Projected Expenses	\$2,539,155	\$2,728,372	\$2,763,334
CDI Projected # of MRI Procedures	6,522	7,304	7,889
Total average cost/procedure	\$389.32	\$373.54	\$350.28

In the illustrated table above, the project analyst projects the total average cost per procedure based on the total projected expenses and the projected number of procedures for FY2010 through FY2012 (expenses/procedures=average cost per procedure). As illustrated above, the average cost per procedure is projected to decrease during the first three years of operations following the completion of the proposed project. In FY1 the total average cost is projected at \$389.32 with a \$15.78 or 4.05% decrease by 2011 for a total average cost of \$373.54. By FY2012 the total average cost is projected at \$350.28 which reflects a \$23.26 or 6.2% decrease in the cost. However, as the applicant did not provide the historical direct/indirect expenses for the facility, it can not be determined if the applicant's projected expenses are reasonable.

Furthermore, in Section VI, page 101 of the application, the applicant provides CDI's payor mix for Year 2. The project analyst calculated CDI's contractual allowance based on its projected payor mix and its Pro forma as illustrated in the tables below.

Year 2 07/01/2011-06/30/012 Payor Source and Contractual Allowance **Table 21**

Year 2011 Projected Number of Procedures 7,304				
Payor Source	Percent	Procedures Total*	Contractual Allowance Total Pro forma	Pro Forma # of Procedures
Self Pay/Indigent/Charity	4.5%	328.68	\$548,959	299
Medicare/Medicare Managed Care	18.2%	1,329.33	\$1,903,496	1,193
Medicaid	7.7%	562.41	\$860,005	567
Commercial Insurance	5.2%	379.81		299
Managed Care	62.0%	4,528.48		1,590
Other	2.5%	182.6	\$6,961,923	3,356
Total	100%	7,311.31	\$10,274,383	7,304

* Calculated by project analyst

In the table below, the project analyst calculated the contractual allowance based on Pro forma data times the number of procedures calculated by the percentages listed on page 101 of the application.

Year 2 07/01/2011-06/30/012 Contractual Allowance **Table 22**

Year 2011		Projected Number of Procedures 7,304	
Payor Source	Pro Forma # of Procedures	Per Procedures	Contractual Allowance
Self Pay/Indigent/Charity	299	\$1,835.98	\$548,959.00
Medicare/Medicare Managed Care	1,193	\$1,595.55	\$1,903,496.00
Medicaid	567	\$1,516.76	\$860,005.00
Commercial Insurance	299	\$2,016.78	\$603,016.36
Managed Care	1,590	\$2,016.78	\$3,206,675.62
Other	3,356	\$2,016.78	\$6,768,304.02
Total	7,304		\$13,890,456.00

As illustrated in the table above, based on the number of procedures reported by CDI in its Pro forma, the contractual allowance differs from that projected by the applicant. In Table 22, the contractual allowance totals \$10,274,383, however, based on the number of procedures projected to be performed by the applicant in the Pro forma, the contractual allowance is calculated to be \$13,890,456.00. This is a difference of \$3,616,073.00 [$13,890,456.00 - 10,274,383 = 3,616,073.00$]. Therefore, CDI under estimates its contractual allowance by over 3 million dollars. Thus, any revenues based on those projections are overstated and unreliable.

In the *projected revenue and expense statement* provided in Form B-2 of the Pro Forma section, the applicant projects that revenues will exceed operating costs in each of the first three years of operation. The applicant provides the assumptions used to project revenue and expenses in the pro forma tab. However, the applicant projected number of MRI procedures to be performed in each of the first three operating years is unreasonable. Consequently, costs and revenues which are based on the number of procedures to be performed are also unreliable and unsupported. See Criterion (3) for discussion. Furthermore, expenses are understated because no professional fee expenses are included in the Pro forma statement of revenue and expenses. Thus, cost and revenues are unreliable and unsupported.

In summary, the applicants failed to adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenue. Therefore, the application is not conforming to this criterion.

OMLLC. In Section VIII, page 102 of the application, the applicant projects the capital cost for the proposed fixed MRI scanner. The following table summarizes the projected capital cost as stated in Section VIII, page 102 of the application.

OMLLC Projected Capital Cost **Table 21**

<i>Description</i>	<i>Cost</i>
<i>Sub-Total Cost of Materials</i>	<i>\$133,200</i>
<i>Cost of Labor</i>	<i>\$162,800</i>
<i>Other(Design/construction contingencies)</i>	<i>\$59,200</i>
<i>Sub-Total Construction Contract</i>	<i>\$355,200</i>
<i>Fixed Equipment Purchase/Lease</i>	<i>\$1,996,706</i>
<i>Movable Equipment Purchase/Lease</i>	<i>\$55,646</i>
<i>Equipment and Furniture</i>	<i>\$5,000</i>
<i>Consultant Fees:</i>	
➤ <i>Architect & Engineering</i>	<i>\$28,000</i>
➤ <i>Admin. and Legal Fees</i>	<i>\$45,000</i>
<i>Financing Costs (bond, load [sic])</i>	<i>\$25,000</i>
<i>Interest During Construction</i>	<i>\$10,656</i>
<i>Sub-Total Miscellaneous</i>	<i>\$2,166,008</i>
<i>Total Capital Cost of Project</i>	<i>\$2,521,208</i>

See Exhibit 5 for a detailed vendor’s quote which states, “*Freight charges and taxes, if any, are payable upon receipt ...*”. Further in the *Terns and Conditions of Sale* item number 3. *Taxes*, in the vendor’s quote section, Exhibit 5 it states:

“Any sales, use or manufacturer’s tax which may be imposed upon the sale or use of Products, or any property tax levied after readiness to ship, or any excise tax, license or similar fee required under this transaction, shall be in addition to the quoted prices and shall be paid by the purchaser [emphasis added].”

However, the applicant failed to include the taxes and freight charges as a part of OMLLC’s expenses. The project analyst calculates the projected taxes as illustrated in the table below based on the MRI scanner options located in Section VIII, page 103 of the application and the Vendor’s Extended Quote in Exhibit 5.

OMLLC Projected Tax **Table 22**

Description	Cost
Vendor's Quote Extended Total	\$1,615,956
MRI Scanner Options:	
➤ 1 7-channel breast coil	\$85,000
➤ 1 iPat extensions	\$25,000
➤ 1 SWI #Tim	\$25,000
➤ 1 8-channel knee coil #Av, Es	\$60,000
➤ 1 8-channel foot/ankle coil #Es	\$63,000
➤ 1 8-channel wrist coil Tim	\$55,000
➤ 1 Flow Quantification #Av	\$20,000
➤ 1 Argus flow /MRC #MR	\$15,000
➤ 1 Argus 4D Ventr.Function syngo	\$27,000
➤ 1 Initial onsite training 12hrs	\$3,250
➤ 1 Additional onsite training 6 hrs	\$2,500
Total Scanner Options	\$380,750
Total	\$1,996,706
Projected Taxes @ 6.5%	\$129,786
Total Price Including Projected Tax	\$2,126,492

Note: Tax total rounded up from #126,785.89

As illustrated in the above table, the projected sales tax of 6.5% based on the extended Vendor's Quote and the selected options would total \$129,786. Therefore, the projected total for the MRI scanner and selected options including tax is \$2,126,492. Thus, the applicant did not included in its projected capital cost nor its Pro Formas the required taxes and fees associated with the proposed MRI scanner. Furthermore, the freight cost for the projected equipment could not be calculated as the Vendor nor the applicant provided the charges associated with the freight cost. The freight cost is normally determined, according to Business Dictionary by, *"Total-cost incurred in moving goods (by whatever means). It includes packing, palletizing, documentation and loading unloading charges, transport (carriage) costs, and marine insurance costs."*³ Consequently, the projected capital cost would increase with the inclusion of the sales tax as illustrated below:

OMLLC adjusted Projected Capital Cost
Table 23

Description	Cost
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³ Business Dictionary.com

Sub-Total Construction Contract	\$355,200
Fixed/Movable Equipment Purchase/Lease	\$2,057,352
*Sales Tax @6.5%.	\$133,728
Total equipment including tax	\$2,191,080
Consultant Fees:	
➤ Architect & Engineering	\$28,000
➤ Admin. and Legal Fees	\$45,000
Financing Costs (bond, loan)	\$25,000
Interest During Construction	\$10,656
Total Cost Consultant Fees/ Financing Cost/Interest	\$108,656
Total Capital Cost of Project (excluding freight charges)	\$2,654,936

Note: *Sales tax rounded up to nearest dollar amount

As noted in the table above, the projected capital cost for the proposed project, excluding freight cost, is \$2,654,936. However, OMLLC projects in Section VIII and in the Pro forma that the projected capital cost for the proposed project is \$2,521,208. Thus, the applicant failed to demonstrate that its projected capital cost are reasonable and reliable.

In Section VIII, 2, (c), page 104 of the application, the applicant states, “*OMLLC uses straight line depreciation over a five-year useful life.*” In Section VIII.3, page 105, OMLLC indicates that the proposed project will be financed by conventional loans. Exhibit 15 contains a funding letter from William P. Franklin, Jr., Senior Vice President, First Citizens Bank, dated April 3, 2009. The letter states:

“First-Citizens Bank & Trust Company (“First Citizens Bank”) has been contacted by Onslow MRI, LLC (“Onslow MRI”) in regards to its application ... It is our understanding that as part of its application, Onslow MRI is obligated to demonstrate the availability of funds for the capital and working capital needs as part of its proposal. In this regard, Onslow MRI has requested that First Citizens Bank consider providing financing for the Project on the following general terms:

*Loan Amount: \$2,052,352
Purpose of Loan: Purchase of MRI
Type of Loan: Term loan – fully amortizing
Term: 7 years
Interest rate: LIBOR plus 1.5% (with a 4.00% floor)
Repayment Terms: Monthly payment of principal and interest
Loan Amount: \$383,200
Purpose of Loan: Leasehold improvements
Type of Loan: Term loan – not fully amortizing
Term: 5 years*

Interest rate: LIBOR plus 1.5% (with a 4.00% floor)
Repayment Terms: Monthly payment of principal and interest ... with a balloon payment due at maturity.

First Citizens Bank has conducted a preliminary review of the financial condition of Onslow MRI (which consisted almost exclusively of a preliminary review of its two members, Eastern Radiologist, Inc., and Costal Radiology Associates, PLLC), and based upon this review, we are willing to consider providing financing for the Project. ”

As noted in the letter from First Citizens Bank, the loan amount for the proposed project is \$2,052,352 for the MRI equipment and \$383,200 for Leasehold improvements which total \$2,435,552. Additionally, the total capital cost of the project (\$2,654,611) exceeds the funding to be provided for the capital costs (\$2,435,552). Therefore, the applicant failed to demonstrate funds for the capital cost of the proposed project.

In Section IX, page 109 of the application, the applicant projects the start-up cost to be \$50,000, initial operating cost associated with the proposed project to be \$100,000, with the total working capital for the start-up and initial operating expenses to be \$150,000. The applicant further states on page 109 that the projected expenses to be covered are as follows:

“OMLLC is projecting start-up expenses related to the facility opening, equipment testing, staff training and supply inventory. OMLLC assumes rent and utilities, four weeks of staff training and management agreement, a physicist consultation for equipment setup, off-site application training for a physician, and two weeks of on-hand medical supply inventory prior to offering of services.”

In Section IX, page 109, the applicant indicates that the start-up and initial operating expenses will be financed through a commercial loan. See Exhibit 15 for a letter from William P. Franklin, Jr., Senior Vice President, First Citizens Bank, dated April 3, 2009 which states:

“ ... Onslow MRI has requested that First Citizens Bank consider providing financing for the Project on the following general terms:

Loan Amount: \$250,000
Purpose of Loan: Working capital for start-up and operating expenses
Type of Loan: Term loan – interest only with principal due at maturity
Term: 1 year
Interest rate: LIBOR plus 1.5% (with a 4.00% floor)

Repayment Terms: Monthly interest ... interest and principal due at maturity.”

As noted on page 109 of the application, the applicant projects that the initial start-up and working capital of the proposed project totals \$150,000. First Citizens Bank is considering providing financing of \$250,000 for the initial start-up and working capital of the project. Even with the addition of the extra \$100,000 [250,000-150,000=100,000], the applicant failed to demonstrate adequate provision of working capital for \$51,988 in CY2011, the net operating loss shown in Pro forma B *Statement of Revenue and Expenses* as illustrated in the table below.

Net Operating Income Loss **Table 24**

Year	CY1 2011
Total Projected Revenue	\$1,273,574
Total Projected Expenses	\$1,325,562
Projected Operating Loss	\$51,988

In summary, the applicant did not adequately demonstrate the availability of funds for the capital and operating needs of the project.

In the financial Pro formas for Onslow MRI, LLC, Section XIII, page 127 of the application, the applicant states OMLLC’s projected average charge of \$1,135.00 will remain consistent during the first three years of the proposed project.

In Section II, page 24 of the application, the applicant provides the projected charges for the top 20 MRI procedures for the first three years following completion of the proposed project. The Applicant states in Section II, page that, *“The radiologists will bill patients directly for professional services.”*

In the *projected revenue and expense statement* provided in Form B-2 of the Pro Forma section, the applicant projects that revenues will not exceed operating costs during the first year of service for the proposed project. The applicant projects that during year two and three revenues will exceed the operating cost. The applicant provides the assumptions used to project revenue and expenses in the pro forma tab. However, the applicant’s projections of the number of MRI procedures to be performed in each of the first three operating years are not based on reasonable assumptions and methodology.

In the Pro Forma, form B, the applicant projects the following direct/indirect expenses associated with the proposed fixed MRI as illustrated in the table below.

Average Procedure Cost **Table 25**

Year	CY1 2011	CY2 2012	CY3 2013
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Charge for MRI	\$1,135.00	\$1,135.00	\$1,135.00
Total Projected Net Revenue	\$1,273,574	\$1,807,218	\$2,095,903
Total Projected Expenses	\$1,325,562	\$1,571,794	\$1,641,754
OMLLC Projected # of MRI Procedures	2,093	3,018	3,558
Total average cost/procedure	\$633.33	\$520.81	\$461.43

In the illustrated table above, the project analyst projects the total average cost per procedure based on the total projected expenses and the projected number of procedures for CY2011 through CY2013 (expenses/procedures=average cost per procedure). As illustrated above, the average cost per procedure is projected to decrease during the first three years of operations following the completion of the proposed project. In CY1 the total average cost is projected at \$633.33 with a \$112.52 or 17.8% decrease by 2012 for a total average cost of \$520.81. By CY2013 the total average cost is projected at \$461.43 which reflects a \$59.38 or 11.4% decrease in the cost. However, the applicant failed to budget for necessary administrative staff. See Criterion (7) for discussion. Therefore, expenses and average cost per procedure are understated.

In summary, OMLLC failed to document the availability of sufficient funds for the capital and working needs of the project. OMLLC also failed to demonstrate that the financial feasibility of the project is based on reasonable projects of costs and revenues. See Criterion (3) for discussion. Therefore, the application is not conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC
Both Applicants

CDI proposes to acquire no more than one fixed MRI scanner to operate at its existing facility in Onslow County. The 2009 SMFP determined a need for one fixed MRI scanner in the Onslow MRI service area. However, the applicant does not adequately demonstrate the need the population it proposes to serve has for the proposed fixed MRI services. See Criterion (3) for discussion. Therefore, the applicant did not adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved MRI services and is not conforming with this criterion.

OMLLC proposes to acquire no more than one fixed MRI scanner and to establish a diagnostic center at a new medical office complex in Onslow County. The 2009 SMFP determined a need for one fixed MRI scanner in the Onslow MRI service area. However, the applicant does not adequately demonstrate the need the population it proposes to serve has for the proposed fixed MRI services. See Criterion (3) for