

OrthoCarolina

December 1, 2022

Tanya Saporito, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Comments regarding competing Mecklenburg County Fixed MRI Scanner CON Applications

Dear Ms. Saporito:

Enclosed please find comments prepared by OrthoCarolina regarding the competing CON applications to develop one fixed MRI scanner within Mecklenburg County, to meet the need identified in the *2022 State Medical Facilities Plan (SMFP)*. We appreciate your consideration of these comments during your review of the two applications.

If you have any questions about the information presented here, please contact me at 704.315.9012.

Sincerely,

Elizabeth Jones

Elizabeth Jones
Vice President, Operations & Ancillary Services

**COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS
MECKLENBURG FIXED MRI SCANNER NEED DETERMINATION**

**Submitted by OrthoCarolina
December 1, 2022**

Two applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2022 State Medical Facilities Plan (SMFP)* for one additional fixed MRI scanner in Mecklenburg County. These include:

F-12287-22 OrthoCarolina

F-12285-22 Novant Health Matthews Medical Center

In accordance with N.C.G.S. §131E-185(a.1)(1), OrthoCarolina (OC) submits these written comments regarding the competing application from Novant Health, and a discussion about whether the information in the Novant application complies with the Certificate of Need review criteria. These comments also address the issue of which competing proposal represents the comparatively most effective alternative for development of an additional fixed MRI scanner in Mecklenburg County. These written comments are not intended to include any additional information that would represent an amendment to OC’s own CON application.

The 2022 SMFP determined a need right now for one additional fixed MRI scanner in growing Mecklenburg County; therefore, the timeliness of the proposals (e.g. the date of offering of services) is an important comparative consideration. As shown on the table below, OrthoCarolina projects to develop its fixed MRI scanner by January 1, 2024, nine months earlier than Novant Health. Thus, the OrthoCarolina application is the most effective alternative in terms of offering timely access to fixed MRI services for local residents.

Projected Operational Date

OrthoCarolina	Novant Health
1/1/2024	10/1/2024

Source: CON Applications, Section P.

The Novant Health represents a typically expensive hospital project. As shown in the table below, Novant projects that its project capital cost will exceed \$4 million, which is nearly twice as expensive as the projected OrthoCarolina project capital cost of \$2.1 million.

Projected Capital Cost

OrthoCarolina	Novant Health
\$2,158,108	\$4,054,406

Source: CON Applications, Form F.1a.

Part of Novant Health’s higher cost is associated with the choice to propose a 3T scanner. As stated in Section E of OrthoCarolina’s application, although the capital cost of 3T magnets has decreased over the past 10 years, the cost to acquire a 3T scanner is yet higher than that of a lower tesla-strength scanner. Also, upfit costs can be higher because 3T scanners require more shielding than lower tesla-strength scanners because they have greater magnetic field strength. Even with 3T technology available, lower tesla-strength scanners account for the vast majority of MR scanners currently in use, and continue to be the MRI clinical standard. A 1.5T MRI is more cost-effective, provides high quality images, and reasonable scan times. Therefore, a 3T MRI scanner is a more costly, and thus less effective alternative.

Novant Health states its proposed scanner will “aid in the diagnosis and treatment of a variety of conditions” (CON application p.26). Likewise, the OrthoCarolina fixed MRI scanner will be capable of performing a full array of MRI scans not limited exclusively to orthopedics, spine, pain management, physical medicine and rehabilitation, and sports medicine. (OrthoCarolina application, p. 28).

The Agency typically performs a comparative analysis when evaluating competing fixed MRI scanner applications in a need determination batch review. The purpose is to identify the application that would provide the greatest overall benefit to the service area community. The table on the following page summarizes standard metrics that the Agency has previously used for comparing applications in a competitive fixed MRI scanner batch review.

**2022 Mecklenburg County Fixed MRI Scanner Review
 CON Application Comparative Analysis**

	OrthoCarolina	Novant Health Matthews MC
Conformity with Review Criteria & Administrative Rules	Yes	No
Scope of Services	Effective	Not approvable
Historical Utilization	More Effective	Not approvable
Competition (Access to New Provider)	Equally Effective	Not approvable
Ownership of Fixed MRI Scanners in Service Area	More Effective	Not approvable
Geographic Accessibility	More Effective	Not approvable
Access by Service Area Residents	More Effective	Not approvable
Access by Medically Underserved	Effective	Not approvable
Projected Average Net Revenue per MRI procedure	More Effective	Not approvable
Projected Average Operating Expense per MRI procedure	Effective	Not approvable

As the table objectively portrays, aside from being the only approvable application, the OrthoCarolina application is the more effective alternative. The Agency will enable the greatest benefit to local residents by approving the OrthoCarolina application. Specifically:

- **Conformity with Review Criteria.** The OrthoCarolina application is conforming to all CON review criteria. In contrast, the Novant Health application fails to conform to multiple review criteria and to the MRI administrative rules and is not approvable.
- **Scope of Services.** Both applicants propose to acquire and operate a fixed MRI scanner. Although Novant Health proposes to operate the fixed MRI scanner in a hospital setting with availability to both inpatients and outpatients, its application is not conforming to all CON review criteria, and thus is not approvable. Therefore, OrthoCarolina is the more effective alternative.
- **Historical Utilization.** Both applicants have a history of offering fixed MRI services in Mecklenburg County. As shown in the table below, OrthoCarolina has historically had much higher utilization on its fixed MRI scanners compared to Novant Health. Therefore, the OC application is the most effective alternative in terms of historical utilization of fixed MRI scanners.

Comparison of Fixed MRI Scanner Historical Utilization

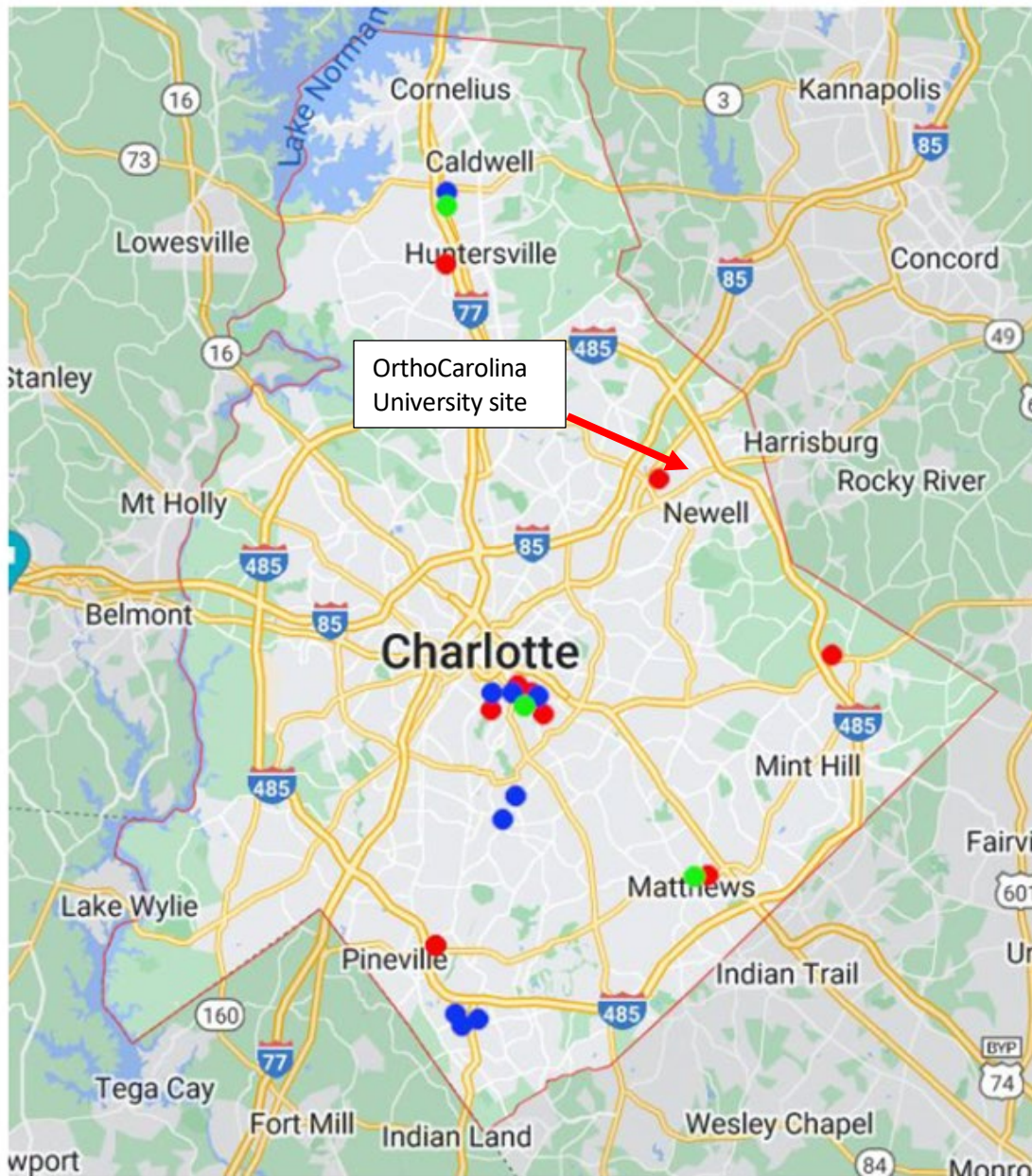
	OrthoCarolina	Novant Health
2021 Unweighted MRI Scans	15,593	46,735
Owned Fixed MRI Scanners	2	12
Average Unweighted Scans/Fixed Scanner	7,797	3,895

Sources: CON applications

- **Competition (Access to a New Provider).** Both applicants currently provide MRI services in Mecklenburg County, so the applications are equally effective as to access to a new provider. However, the Novant Health application is not conforming to all CON review criteria, and thus is not approvable. Therefore, OrthoCarolina is the more effective alternative.

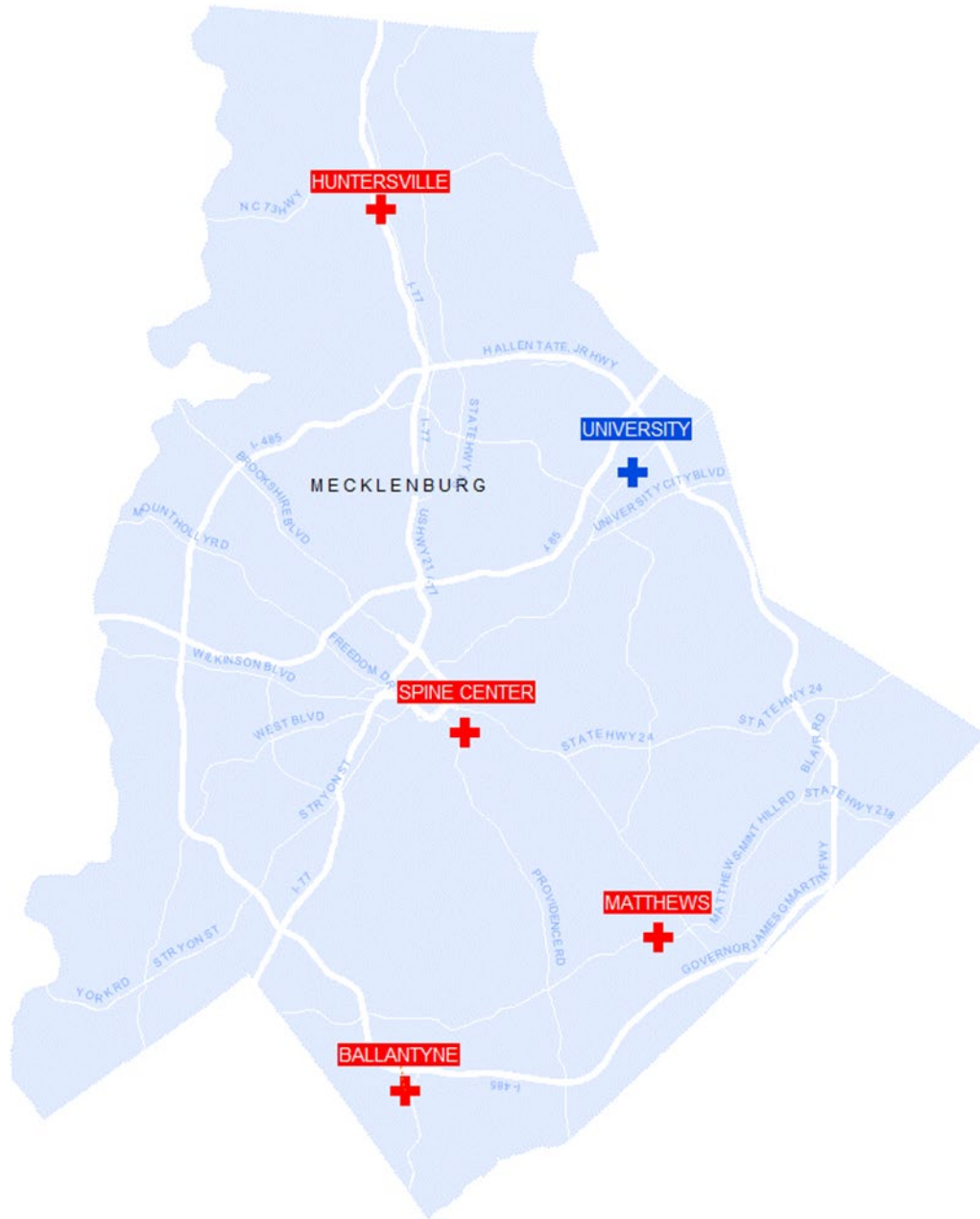
- **Ownership of Fixed MRI Scanners in Mecklenburg County.** According to the Proposed 2023 SMFP, currently 28 fixed MRI scanners operate in Mecklenburg County (see page 87 of the OC application). Novant Health owns and operates 12 fixed MRI scanners in Mecklenburg County (see page 57 of the Novant application), and thus controls 42.9% (12/28) of the existing fixed MRI scanners in Mecklenburg County. OrthoCarolina owns and operates two fixed MRI scanners in Mecklenburg County, and thus controls 7.1% (2/28) of the existing fixed MRI scanners in Mecklenburg County. Approval of the Novant Health application would result in control of 44.8% (13/29) of the Mecklenburg County fixed MRI scanners. By contrast, OrthoCarolina does not operate a fixed MRI scanner at the OrthoCarolina University site, but must lease access to a mobile MRI scanner owned by Alliance Health. Control of 43% (or 45%) of the Mecklenburg County fixed MRI scanner inventory represents a dominant position in the marketplace for Novant Health. Consistent with the 2022 SMFP goal of promoting “a balance of competition” (page 3, 2022 SMFP), the Agency should seek to improve the competitive balance within the local service area via this fixed MRI scanner review. Competition in the Mecklenburg County marketplace will be enhanced with approval of OC for a fixed MRI scanner, while approval of Novant Health for a 13th fixed MRI scanner will not have a positive effect on MRI competition. Clearly, the OC application is the most effective alternative as to ownership of fixed MRI scanners in Mecklenburg County.
- **Geographic Accessibility.** Novant Health proposes to install a fixed MRI scanner at its existing Matthews Medical Center, where it already offers fixed MRI services. Therefore, the Novant Health application offers no benefit in terms of geographic accessibility. By great contrast, as stated beginning on page 46 of its application, OrthoCarolina’s proposed fixed MRI scanner will improve access by creating a new geographic point of access for fixed MRI services in populous and growing Mecklenburg County. Mecklenburg County needs greater geographic diversification of its MRI services. As portrayed on the OC application map recreated below (with the various colored dots which represent existing Atrium Health, Novant Health and other fixed MRI scanners), more than half of the Mecklenburg County fixed MRI scanners are clustered in central Charlotte, with northern and southern Mecklenburg County also hosting multiple fixed MRI scanners. Notably, eastern Mecklenburg County currently only has two fixed MRI scanners, both hospital based.

Mecklenburg County Fixed MRI Locations



OrthoCarolina University is located in northeastern Mecklenburg County, and as shown on the following application map (p.49), this area of the county nicely complements the locations of the other OrthoCarolina fixed and mobile MRI services. Further, the University area of Mecklenburg County does not currently host any freestanding fixed MRI scanners; the only fixed MRI scanner in the University City area is hospital based, at Atrium Health University City.

Location of OrthoCarolina Fixed & Mobile MRI Scanners in Mecklenburg County



As stated on page 49 of its application, OrthoCarolina has been serving residents of northeastern Mecklenburg County for many years, and its University clinic location has been successful in offering closer and more convenient clinical services to these residents. University City (the informal name of the edge city surrounding the University of North Carolina at Charlotte campus) has an estimated population of more than 160,000 within its unofficial borders, which includes parts of Charlotte, Concord and Harrisburg. Were it to be separated from the rest of Charlotte as its own city, University City would be North Carolina's eighth largest city. University is developing as a growing community, and is attracting development of primary and specialty care medical offices. Following the opening of the LYNX Blue Line in 2019, University City has seen an increase in development. As growth and development in the area continues, OrthoCarolina University will be well positioned to offer its needed medical imaging services with installation of a fixed MRI scanner.

Also, the University area of northeastern Mecklenburg County has a high minority population concentration, as described on pages 50 – 53 of the OrthoCarolina application. The fixed MRI scanner will greatly increase access to value-based MRI service for this medically underserved population.

Clearly, the OC application is the most effective alternative for enhancing geographic access to fixed MRI scanners in Mecklenburg County.

- **Access by Service Area Residents.** The following table shows the projected patient origin percentages of the two competing applications. OrthoCarolina projects to serve the highest percentage of residents of Mecklenburg County (the SMFP-designated MRI service area). Therefore, the OC application is the most effective alternative for improving access to fixed MRI services by service area residents.

Projected Mecklenburg County Patient Origin, PY3

OrthoCarolina	Novant Health MMC
71.9%	60.4%

Source: CON applications, Section C.3.

- **Access for the Medically Underserved.** Each applicant projects Medicare and Medicaid access, based on their historical experience. Both are effective alternatives as to access for Medicare and Medicaid patients; however, the Novant Health

application fails to conform to multiple review criteria and to the MRI administrative rules and the application is not approvable.

OC projects to offer charity care for MRI patients at OrthoCarolina University. As a not-for-profit hospital that receives exemption from paying taxes, Novant Health MMC has an obligation to provide charity care. Thus, not surprisingly, Novant Health portrays higher charity care, as summarized in the following table. However, the Novant Health application fails to conform to multiple review criteria and to the MRI administrative rules and the application is not approvable. Therefore, OrthoCarolina is the more effective alternative.

Projected Charity Care

Year 3	OrthoCarolina	Novant Health MMC
Charity Care \$/MRI Procedure	\$23.69	\$91.54
Charity Care % of Gross Revenue	1.68%	2.10%
Charity Care % of Net Revenue	4.52%	8.00%

Source: CON Applications, Section Q, Form F.2b.

- **Projected Average Net Revenue per MRI Procedure.** As a value-based imaging provider, OC offers market-competitive charges for MRI services in Mecklenburg County, projecting the lowest average net revenue per unweighted MRI procedure of the two competing applicants. Therefore, the OC application is the most effective alternative.

Projected Average Net Revenue/Unweighted MRI Procedure

	OrthoCarolina	Novant Health MMC
Average Net Revenue, Year 3	\$478	\$1,144

Source: CON Applications, Section Q, Form F.2b. To equalize the comparison, the OC total excludes professional fees.

- **Projected Average Operating Expense per MRI Procedure.** OC offers cost-effective operating expenses for its MRI service in Mecklenburg County; its application shows a low average operating expense per unweighted MRI procedure. Because Novant Health MMC is proposing to add a second fixed scanner, its average operating expense reflects the benefit of spreading costs over a higher MRI scan total. However, Novant Health’s application is not conforming to all CON review criteria, and thus is not approvable, and therefore, the OC application is the more effective alternative.

Projected Average Operating Expense/Unweighted MRI Procedure

	OrthoCarolina	Novant Health MMC
Average Operating Expense, Year 3	\$397	\$301

Source: CON Applications, Section Q, Form F.3b. To equalize the comparison, the OC total excludes professional fees.

Competitive Comparison Conclusion

As described in the above comparative analysis, OrthoCarolina ranks most favorably on the comparative metrics, is the only approvable application, and thus is the most effective alternative for development of the need-determined fixed MRI scanner in Mecklenburg County.

Specific comments regarding the Novant Health MMC application (F-12285-22)

Criterion (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.*

Novant Health does not adequately demonstrate the need for the proposed project based on reasonable utilization projections, did not propose the least costly or most effective alternative, and did not show that its proposal is not unnecessarily duplicative of existing MRI resources. Therefore, Novant Health fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2022 SMFP. The discussions regarding analysis of need, including projected utilization, found in Criterion (3), alternative methods in Criterion (4), reasonable projection of capital costs in Criterion (5), unnecessary duplication in Criterion (6), and the applicable .2703 MRI Scanner administrative rules, are incorporated herein by reference. Therefore, the Novant Health application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

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

The Novant Health application proposal does not adequately demonstrate the need that its identified population has for the services proposed. As described in Section Q of its application (Step 6 of the Projected Novant Health MRI Scans, in the Form C.2 assumptions and methodology), Novant Health projects highly aggressive increases in projected MRI scan volume at Novant Health Matthews Medical Center during the three project years. As portrayed in the table below (reproduced from the Novant Health application, Step 6 of the utilization projection methodology), Novant Health projects a 10% MRI scan volume increase during each of the three project years.

Novant Health Matthews Medical Center MRI Scan Projection

Step 6. Projected Novant Health MRI Scans, Adjusted MRI Scans, and MRI Scanners

- NH Matthews projects that the Novant Health fixed MRI scanners will experience a 1.0% annual increase in MRI scans. This increase is less than both the calculated CAGRs and the Mecklenburg County's and Union County's annual increase in population. NH Matthews projected MRI scans by multiplying the previous year's MRI scans by 1 + the Annual Growth of 1.0% in Row A in the following table.
- NH Matthews projects that its fixed MRI scanners will experience a 10.0% annual increase in MRI scans during the first three project years in Row A. This increase is directly related to the operation of the 3T MRI scanner, and those factors discussed in the Section C of the application.
- NH Matthews calculated the average Adjusted MRI Ratio by summing the Adjusted MRI Ratios calculated in Step 3, Row C in the following table and dividing the total by the number of operational years.
- NH Matthews calculated the Adjusted MRI Scans by multiplying the MRI Scans in Row A by average Adjusted MRI ratio in Row B in the following table.
- Finally, NH Matthews calculated the Adjusted MRI Scans per MRI Scanner in Row E by dividing the Adjusted MRI Scans in Row C in the following table by the number of fixed MRI scanners in Row D in the following table.

FY2021-FY2027

Historical, Projected, and Annual Growth of Novant Health MRI Scans, Adjusted MRI Scans, and MRI Scanners

	Historical	Projected						Annual	Row
	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027	Growth	
NH Presbyterian Medical Center - Main									
MRI Scans	13,465	13,600	13,736	13,873	14,012	14,152	14,293	1.0%	A
AVG Adjusted MRI Ratio		1.32	1.32	1.32	1.32	1.32	1.32		B
Adjusted MRI Scans	18,538	17,949	18,129	18,310	18,493	18,678	18,865		C
MRI Scanners	3	3	3	3	3	3	3		D
Adj MRI Scans / Scanner	6,179	5,983	6,043	6,103	6,164	6,226	6,288		E
NH Huntersville Medical Center									
MRI Scans	9,792	9,890	9,989	10,089	10,190	10,291	10,394	1.0%	A
AVG Adjusted MRI Ratio		1.19	1.19	1.19	1.19	1.19	1.19		B
Adjusted MRI Scans	11,367	11,784	11,901	12,020	12,141	12,262	12,385		C
MRI Scanners	2	2	2	2	2	2	2		D
Adj MRI Scans / Scanner	5,684	5,892	5,951	6,010	6,070	6,131	6,192		E
NH Matthews Medical Center									
				Project Year Growth = 10.0%					
MRI Scans	6,613	6,679	6,746	6,813	7,495	8,244	9,069	1.0%	A
AVG Adjusted MRI Ratio		1.24	1.24	1.24	1.24	1.24	1.24		B
Adjusted MRI Scans	8,335	8,252	8,334	8,418	9,259	10,185	11,204		C
MRI Scanners	1	1	1	1	2	2	2		D
Adj MRI Scans / Scanner	8,335	8,252	8,334	8,418	4,630	5,093	5,602		E

Note: Also refer to the Utilization Methodology and Assumptions Spreadsheet and Calculations.

These are highly aggressive annual growth rates for a facility that, as Novant itself portrays in Step 3, has shown a six-year CAGR for Matthews Medical Center MRI scans of 1.11%. To put this in context, during the historical six-year period from FY2015 – FY2021, the MRI scan volume at Matthews MC increased by a total of 6.82%. By contrast, Novant projects that during the six-year period from FY2021 – FY2027, MRI scan volume at Matthews MC will increase by a total of 37.14%, more than five times the historical growth rate. This is unreasonable.

Novant Health Matthews Medical Center Historical MRI Scan Growth Rate

Step 3. Historical Novant Health MRI Scans, Adjusted MRI Scans, and MRI Scanners

- NH Matthews identified the Novant Health MRI Scans, Adjusted MRI Scans, and MRI Scanners reported in the 2017-Proposed 2023 SMFPs as shown in Row A, Row B, and Row D, in the following table, respectively.
- NH Matthews calculated the 6-Year CAGR for the following Novant Health MRI scanners using the following formula: $(\text{FY2021 MRI Scans} / \text{FY2015 MRI Scans})^{(1/6)} - 1$
- NH Matthews calculated the Adjusted MRI Ratio for the following Novant Health MRI scanners using the following formula: $(\text{Adjusted MRI Scans Row B} / \text{MRI Scans Row A})$

FY2015-FY2021

Historical Novant Health MRI Scans, Adjusted MRI Scans, and MRI Scanners

	Historical							CAGR	Row
	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021		
NH Presbyterian Medical Center - Main									
MRI Scans	12,312	11,831	9,452	9,967	11,073	11,372	13,465	1.50%	A
Adjusted MRI Scans	15,428	15,157	12,542	13,287	14,644	15,299	18,538		B
Adjusted MRI Ratio	1.25	1.28	1.33	1.33	1.32	1.35	1.38		C
MRI Scanners	2	2	2	2	2	2	3		D
NH Huntersville Medical Center									
MRI Scans	6,217	6,513	6,530	6,328	6,450	7,735	9,792	7.87%	A
Adjusted MRI Scans	7,431	7,691	7,728	7,617	7,759	9,384	11,367		B
Adjusted MRI Ratio	1.20	1.18	1.18	1.20	1.20	1.21	1.16		C
MRI Scanners	1	2	2	2	2	2	2		D
NH Matthews Medical Center									
MRI Scans	6,191	6,102	7,102	7,011	6,647	6,151	6,613	1.11%	A
Adjusted MRI Scans	7,666	7,537	8,691	8,564	8,179	7,619	8,335		B
Adjusted MRI Ratio	1.24	1.24	1.22	1.22	1.23	1.24	1.26		C
MRI Scanners	2	2	2	1	1	1	1		D
NH Presbyterian Medical Center - NHI Museum									
MRI Scans	2,217	2,476	2,663	3,041	3,084	2,472	2,908	4.63%	A
Adjusted MRI Scans	2,471	2,796	3,065	3,505	3,569	2,837	3,159		B
Adjusted MRI Ratio	1.11	1.13	1.15	1.15	1.16	1.15	1.09		C
MRI Scanners	1	1	1	1	1	1	1		D
NHI Ballantyne									
MRI Scans	2,406	2,431	2,395	3,311	3,270	2,855	2,970	3.57%	A
Adjusted MRI Scans	2,628	2,691	2,691	3,743	3,645	3,201	3,157		B
Adjusted MRI Ratio	1.09	1.11	1.12	1.13	1.11	1.12	1.06		C
MRI Scanners	1	1	1	1	1	1	1		D

Note: Also refer to the Utilization Methodology and Assumptions Spreadsheet and Calculations.

Also, it appears that Novant Health did not account for a mobile MRI scanner that is owned by a related entity, and which serves a host site in Mecklenburg County. Please see the attached 2022 DHSR Registration and Inventory of Medical Equipment report for the mobile MRI scanner (CON #F-6626-02) owned by Jacksonville Diagnostic Imaging, LLC. This entity is owned and controlled by MedQuest Associates, which is owned and controlled by Novant Health. As shown on page 4 of the annual equipment report, this mobile MRI scanner serves the Novant Health Imaging University site in Charlotte. In its application Novant Health did not account for this MRI scanner, nor did Novant portray historical or projected MRI scans for the scanner.

For these reasons, the Novant Health application fails to demonstrate the need of the population to be served. Novant Health failed to demonstrate that the projected procedure volume for all of its existing and proposed fixed MRI scanners is based on reasonable and supported assumptions. Therefore, the Novant Health application is nonconforming to Criterion 3.

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

Novant Health does not adequately demonstrate that the alternative proposed in its application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria and administrative rules. An application that cannot be approved cannot be the most effective alternative.

Also, the Novant Health proposal is not the most effective or least costly option because Novant Health’s capital cost of \$4.05M is by far the highest of the two applications.

Novant Health states that it currently leases a mobile MRI scanner at Matthews Medical Center, but claims that it is not able to add mobile MRI days because of “a shortage of available mobile MRI days statewide” (Novant CON application p.69). However, Novant fails to note that it owns the mobile MRI scanner that is currently serving Matthews Medical Center, and does not explain or provide data to support that it cannot make the mobile scanner available for additional days at Matthews MC.

Therefore, the Novant Health application is not conforming to Criterion (4).

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.”*

Novant Health’s financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments. Consequently the financial projections are unreliable, and therefore the application is not conforming to Criterion (5).

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.”*

Novant Health fails to demonstrate that its proposal would not result in unnecessary duplication of fixed MRI service because the utilization projections are unreasonable, as discussed in the Criterion 3 comments. An application that cannot be approved cannot demonstrate that the project will not result in unnecessary duplication of existing capacity.

Also, Novant Health fails to demonstrate that its proposal would not result in unnecessary duplication of fixed MRI service because Novant Health recently received approval for one additional Mecklenburg County fixed MRI scanner in Charlotte (CON Project ID# F-11946-20, see page 69 of Novant Health application). Therefore, Novant Health is proposing the unnecessary duplication of a fixed MRI scanner that Novant Health has been recently approved for and only recently became operational. Therefore the application is not conforming to Criterion (6).

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

Novant Health’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate that it will promote cost-effective services. The applicant’s projected utilization is not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization, alternatives, financial feasibility, and unnecessary duplication are found in Criteria (3), (4), (5), and (6), are incorporated herein by reference.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (7) project that the fixed MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project as follows:*
 - (A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;*

The Novant Health application does not conform to the .2703(a)(7) performance standard applicable for the review of fixed MRI scanners. Utilization projections for the proposed Novant Health Matthews Medical Center fixed MRI scanners are not based on reasonable assumptions and methodology. Also, Novant Health did not account for or provide utilization projections for a mobile MRI scanner which a related entity owns and operates within Mecklenburg County. The discussions regarding projected utilization found in Criterion (3) is incorporated herein by reference.



Registration and Inventory of Medical Equipment
Mobile Magnetic Resonance Imaging Scanners
January 2022

Instructions

This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for mobile magnetic resonance imaging (MRI) scanners. Please complete all sections of this form and return to Healthcare Planning by **Friday, January 28, 2022**.

1. **Submit one completed Registration and Inventory form per MRI scanner.**
2. Complete and sign the form
3. Return the form by one of two methods:
 - a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.
 - b. Mail the form to Trenesse Michael, Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Trenesse Michael in Healthcare Planning at (919) 855-3867 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Section 1: Contact Information

1. Full legal name of corporation, partnership, individual, or other legal entity that acquired the equipment by purchase, donation, lease, transfer, or comparable arrangement:

Jacksonville Diagnostic Imaging, LLC (MO13)
(Legal Name)

2. Address of the corporation, partnership, individual, or other legal entity that acquired the equipment:

3606 Henderson Drive
(Street and Number)

Jacksonville NC 28546 (910) 937-7226
(City) (State) (Zip) (Phone Number)

3. Chief Executive Officer or approved designee who is certifying the information in this registration form:

Kelly A. Israel Sr. Mgr. Development & Mobile Ops
(Name) (Title)

3480 Preston Ridge Road, Suite 600 Alpharetta GA 30005
(Street and Number) (City) (State) (Zip)

(770) 300-0101 kisrael@medquestmail.com
(Phone Number) (Email)

4. Information Compiled or Prepared by: Kelly Israel
(Name)

(678) 992-7235 kisrael@medquestmail.com
(Phone Number) (Email)



Section 2: Equipment and Procedures Information

Reporting Period: 10/01/2020 – 9/30/2021 Other time period: _____

Do not make extra copies of this page if the entity has multiple MRIs. Submit a complete, separate R&I form for each scanner.

(Please make additional copies of this page as needed for additional Service Sites.)

For DHSR Planning Use Only:									
Manufacturer/Tesla	GE / 1.5T								
Model number	23x Echospeed								
Open or closed (including open bore) scanner	<input type="checkbox"/> Open <input checked="" type="checkbox"/> Closed								
Serial or I.D. Number	R4378								
Date of acquisition									
Purchase price (if purchased)									
Certificate of Need Project ID (or Legacy)	F-6626-02 <input type="checkbox"/> Legacy								
Certificate holder, as listed on Certificate of Need									
If equipment went to only 1 site, is it permanently parked at that site?	<input type="checkbox"/> Parked <input type="checkbox"/> Not Parked								
	Service Site Number <u> 1 </u>								
Service Site Information: Please include all the information requested for each location.	Service Site <u> Novant Health Imaging-Monroe </u> Address <u> 2000 Wellness Blvd., Ste#110 </u> City: <u> Monroe </u> Zip <u> 28100 </u> County <u> Union </u>								
Procedures*: - with Contrast or Sedation - without Contrast/ Sedation -Total inpatient/outpatient	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">Inpatient:</td> <td style="width: 33%;">Outpatient:</td> </tr> <tr> <td>with: _____</td> <td>with: <u> 326 </u></td> </tr> <tr> <td>w/out: _____</td> <td>w/out: <u> 921 </u></td> </tr> <tr> <td>Total: _____</td> <td>Total: <u> 1247 </u></td> </tr> </table>	Inpatient:	Outpatient:	with: _____	with: <u> 326 </u>	w/out: _____	w/out: <u> 921 </u>	Total: _____	Total: <u> 1247 </u>
Inpatient:	Outpatient:								
with: _____	with: <u> 326 </u>								
w/out: _____	w/out: <u> 921 </u>								
Total: _____	Total: <u> 1247 </u>								
Total Number of Procedures	Total: _____								
For each day of the week, enter the number of hours the scanner is in operation.	<table style="width: 100%; border: none;"> <tr> <td>___ Sunday</td> <td><u> 8 </u> Thursday</td> </tr> <tr> <td>___ Monday</td> <td><u> 8 </u> Friday</td> </tr> <tr> <td>___ Tuesday</td> <td>___ Saturday</td> </tr> <tr> <td><u> 8 </u> Wednesday</td> <td></td> </tr> </table>	___ Sunday	<u> 8 </u> Thursday	___ Monday	<u> 8 </u> Friday	___ Tuesday	___ Saturday	<u> 8 </u> Wednesday	
___ Sunday	<u> 8 </u> Thursday								
___ Monday	<u> 8 </u> Friday								
___ Tuesday	___ Saturday								
<u> 8 </u> Wednesday									
Total number of hours in operation for reporting period	1,248 hours								

*An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. **The total number of procedures should be equal to or greater than the total number of patients reported on the MRI Patient Origin Table on page 3 of this form.**

Name of entity that acquired the equipment (from page 1) Jacksonville Diagnostic Imaging, LLC (MQ13 Mobile)



Section 2: Equipment and Procedures Information

Reporting Period: 10/01/2020 – 9/30/2021 Other time period: _____

Do not make extra copies of this page if the entity has multiple MRIs. Submit a complete, separate R&I form for each scanner.

(Please make additional copies of this page as needed for additional Service Sites.)

For DHSR Planning Use Only:									
Manufacturer/Tesla	GE / 1.5T								
Model number	23x Echospeed								
Open or closed (including open bore) scanner	<input type="checkbox"/> Open <input checked="" type="checkbox"/> Closed								
Serial or I.D. Number	R4378								
Date of acquisition									
Purchase price (if purchased)									
Certificate of Need Project ID (or Legacy)	F-6626-02 <input type="checkbox"/> Legacy								
Certificate holder, as listed on Certificate of Need									
If equipment went to only 1 site, is it permanently parked at that site?	<input type="checkbox"/> Parked <input type="checkbox"/> Not Parked								
	Service Site Number <u> 2 </u>								
Service Site Information: Please include all the information requested for each location.	Service Site <u> Novant Health Imaging Mooresville </u> Address <u> 118 Gateway Blvd., Ste# E </u> City: <u> Mooresville </u> Zip <u> 28117 </u> County <u> Iredell </u>								
Procedures*: - with Contrast or Sedation - without Contrast/ Sedation -Total inpatient/outpatient	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Inpatient:</td> <td style="width: 50%;">Outpatient:</td> </tr> <tr> <td>with: _____</td> <td>with: <u> 138 </u></td> </tr> <tr> <td>w/out: _____</td> <td>w/out: <u> 290 </u></td> </tr> <tr> <td>Total: _____</td> <td>Total: <u> 428 </u></td> </tr> </table>	Inpatient:	Outpatient:	with: _____	with: <u> 138 </u>	w/out: _____	w/out: <u> 290 </u>	Total: _____	Total: <u> 428 </u>
Inpatient:	Outpatient:								
with: _____	with: <u> 138 </u>								
w/out: _____	w/out: <u> 290 </u>								
Total: _____	Total: <u> 428 </u>								
Total Number of Procedures	Total: _____								
For each day of the week, enter the number of hours the scanner is in operation.	<table style="width: 100%; border: none;"> <tr> <td>___ Sunday</td> <td>___ Thursday</td> </tr> <tr> <td><u> 8 </u> Monday</td> <td>___ Friday</td> </tr> <tr> <td>___ Tuesday</td> <td>___ Saturday</td> </tr> <tr> <td>___ Wednesday</td> <td></td> </tr> </table>	___ Sunday	___ Thursday	<u> 8 </u> Monday	___ Friday	___ Tuesday	___ Saturday	___ Wednesday	
___ Sunday	___ Thursday								
<u> 8 </u> Monday	___ Friday								
___ Tuesday	___ Saturday								
___ Wednesday									
Total number of hours in operation for reporting period	416 Hours								

*An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. **The total number of procedures should be equal to or greater than the total number of patients reported on the MRI Patient Origin Table on page 3 of this form.**

Name of entity that acquired the equipment (from page 1) Jacksonville Diagnostic Imaging, LLC (MQ13 Mobile)



Section 2: Equipment and Procedures Information

Reporting Period: 10/01/2020 – 9/30/2021 Other time period: April -Aug '21

Do not make extra copies of this page if the entity has multiple MRIs. Submit a complete, separate R&I form for each scanner.

(Please make additional copies of this page as needed for additional Service Sites.)

For DHSR Planning Use Only:									
Manufacturer/Tesla	GE / 1.5T								
Model number	23x Echospeed								
Open or closed (including open bore) scanner	<input type="checkbox"/> Open <input checked="" type="checkbox"/> Closed								
Serial or I.D. Number	R4378								
Date of acquisition									
Purchase price (if purchased)									
Certificate of Need Project ID (or Legacy)	F-6626-02 <input type="checkbox"/> Legacy								
Certificate holder, as listed on Certificate of Need									
If equipment went to only 1 site, is it permanently parked at that site?	<input type="checkbox"/> Parked <input type="checkbox"/> Not Parked								
	Service Site Number <u> 3 </u>								
Service Site Information: Please include all the information requested for each location.	Service Site <u>Novant Health Imaging University</u> Address <u>8401 Medical Plaza Drive, Ste#110</u> City: <u>Charlotte</u> Zip <u>28262</u> County <u>Mecklenburg</u>								
Procedures*: - with Contrast or Sedation - without Contrast/ Sedation -Total inpatient/outpatient	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Inpatient:</td> <td style="width: 50%;">Outpatient:</td> </tr> <tr> <td>with: _____</td> <td>with: <u> 36 </u></td> </tr> <tr> <td>w/out: _____</td> <td>w/out: <u> 102 </u></td> </tr> <tr> <td>Total: _____</td> <td>Total: <u> 138 </u></td> </tr> </table>	Inpatient:	Outpatient:	with: _____	with: <u> 36 </u>	w/out: _____	w/out: <u> 102 </u>	Total: _____	Total: <u> 138 </u>
Inpatient:	Outpatient:								
with: _____	with: <u> 36 </u>								
w/out: _____	w/out: <u> 102 </u>								
Total: _____	Total: <u> 138 </u>								
Total Number of Procedures	Total: _____								
For each day of the week, enter the number of hours the scanner is in operation.	<table style="width: 100%; border: none;"> <tr> <td>___ Sunday</td> <td>___ Thursday</td> </tr> <tr> <td>___ Monday</td> <td>___ Friday</td> </tr> <tr> <td><u> 8 </u> Tuesday</td> <td>___ Saturday</td> </tr> <tr> <td>___ Wednesday</td> <td></td> </tr> </table>	___ Sunday	___ Thursday	___ Monday	___ Friday	<u> 8 </u> Tuesday	___ Saturday	___ Wednesday	
___ Sunday	___ Thursday								
___ Monday	___ Friday								
<u> 8 </u> Tuesday	___ Saturday								
___ Wednesday									
Total number of hours in operation for reporting period	152 Hours								

*An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. **The total number of procedures should be equal to or greater than the total number of patients reported on the MRI Patient Origin Table on page 3 of this form.**

Name of entity that acquired the equipment (from page 1) Jacksonville Diagnostic Imaging, LLC (MQ13 Mobile)



Section 3: Patient Origin Data by Service Site

Please provide the county of residence for each patient who received MRI services during the time period of this report. Provide patient origin data separately for each service site. Make additional copies of this page as needed. The total number of patients receiving services should be equal to or less than the total number of procedures reported on page two of this form.

Service Site Number: 1

Service Site Name: NHI Monroe

County in which service was provided: Union

Patient County	Number of Patients	Patient County	Number of Patients	Patient County	Number of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson	47	40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	2
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett	1	79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson		81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe		47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	9
13. Cabarrus	2	49. Iredell		85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	1018
19. Chatham		55. Lincoln	1	91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland	1	59. McDowell		95. Watauga	
24. Columbus	1	60. Mecklenburg	83	96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery	1	98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	2
31. Duplin		67. Onslow	1	102. South Carolina	74
32. Durham		68. Orange	1	103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other (specify)	3
35. Franklin		71. Pender			
36. Gaston		72. Perquimans		Total Number of Patients	1,247

Name of entity that acquired the equipment (from page 1) Jacksonville Diagnostic Imaging, LLC (MQ13 Mobile)



Section 3: Patient Origin Data by Service Site

Please provide the county of residence for each patient who received MRI services during the time period of this report. Provide patient origin data separately for each service site. Make additional copies of this page as needed. The total number of patients receiving services should be equal to or less than the total number of procedures reported on page two of this form.

Service Site Number: 2

Service Site Name: NHI Mooresville

County in which service was provided: Iredell

Patient County	Number of Patients	Patient County	Number of Patients	Patient County	Number of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	19
9. Bladen		45. Henderson		81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe		47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	1
13. Cabarrus	11	49. Iredell	266	85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba	22	54. Lenoir	1	90. Union	1
19. Chatham		55. Lincoln	21	91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg	98	96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	2
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	
32. Durham		68. Orange	1	103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other (specify)	2
35. Franklin		71. Pender			
36. Gaston	6	72. Perquimans		Total Number of Patients	451

Name of entity that acquired the equipment (from page 1) Jacksonville Diagnostic Imaging, LLC (MQ13 Mobile)



Section 3: Patient Origin Data by Service Site

Please provide the county of residence for each patient who received MRI services during the time period of this report. Provide patient origin data separately for each service site. Make additional copies of this page as needed. The total number of patients receiving services should be equal to or less than the total number of procedures reported on page two of this form.

Service Site Number: 3

Service Site Name: NHI University

County in which service was provided: Mecklenburg

Patient County	Number of Patients	Patient County	Number of Patients	Patient County	Number of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson		81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe		47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus	24	49. Iredell	1	85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba	1	54. Lenoir		90. Union	2
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg	106	96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth	1	70. Pasquotank		105. Other (specify)	
35. Franklin		71. Pender			
36. Gaston	3	72. Perquimans		Total Number of Patients	138

Name of entity that acquired the equipment (from page 1) Jacksonville Diagnostic Imaging, LLC (MQ13 Mobile)

