

NC DEPARTMENT OF
**HEALTH AND
 HUMAN SERVICES**
 Division of Health Service Regulation

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director

May 7, 2018

Denise M. Gunter
 380 Knollwood Street
 Suite 530
 Winston-Salem, NC 27103

Exempt from Review – Replacement Equipment

Record #: 2573
Facility Name: Jacksonville Diagnostic Imaging, LLC
FID #: 050901
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace Existing Mobile MRI Scanner
County: Onslow


Dear Ms. Gunter:


The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of April 13, 2018, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the GE Mobile MRI 1.5T Model #23X Serial #R4378 to replace the GE Mobile MRI 1.5T Model #23X Serial #R0380. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency’s Construction, and Acute and Home Care Licensure and Certification Section, DHSR to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency’s position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,


 Gregory F. Yakaboski
 Project Analyst


 Martha J. Frisone
 Chief, Healthcare Planning and
 Certificate of Need Section

cc: Construction Section, DHSR
 Amy Craddock, Assistant Chief, Healthcare Planning, DHSR
 Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
 MAILING ADDRESS: 2704 Mail Service Center, Raleigh, NC 27699-2704
 www.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Denise M. Gunter
T 336.774.3322 F 336.774.3372
denise.gunter@nelsonmullins.com

NELSON MULLINS RILEY & SCARBOROUGH LLP
ATTORNEYS AND COUNSELORS AT LAW

380 Knollwood Street | Suite 530
Winston-Salem, NC 27103
T 336.774.3300 F 336.774.3299
nelsonmullins.com



April 13, 2018

VIA HAND DELIVERY

Martha J. Frisone, Chief
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: Novant Health, Inc.
Notice of Replacement Equipment and Request for a Material Compliance
Determination
Health Service Area III

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. §§ 131E-181, 184(a)(7) and 189, I am writing on behalf of Novant Health, Inc. ("Novant"). Novant proposes: (1) to replace an existing mobile MRI scanner currently operated by its subsidiary, Jacksonville Diagnostic Imaging, LLC ("JDI"), with another mobile MRI scanner currently owned and operated by another Novant subsidiary, Mecklenburg Diagnostic Imaging, LLC ("MDI"); and (2) to add a new host site to the existing route for the replacement mobile MRI scanner. Each proposal is addressed below.

1. Exemption Request for a Replacement Mobile MRI Scanner

JDI currently operates an existing mobile MRI scanner, known internally as MQ26, pursuant to Project I.D. No. F-6626-02. See **Exhibit A** (the "Existing Scanner"). A 2014 declaratory ruling describing the history of the Existing Scanner is attached as **Exhibit B**. The Existing Scanner has served host sites in Mecklenburg, Rowan, Union and Gaston Counties. Novant proposes to replace the Existing Scanner with another General Electric 1.5T mobile MRI scanner, which MDI already owns and which is known internally as MQ13 (the "Replacement Scanner").

An equipment comparison form comparing the Existing Scanner and the Replacement Scanner is attached as **Exhibit C**. The Existing Scanner was acquired in 2016 for \$835,000, and its current fair market value is \$650,000. The Replacement Scanner was acquired in 2006 for \$1,267,358.12, and its current fair market value is also \$650,000. Since the Replacement Scanner is already in operation, there are no additional costs required to make the unit operational. Upon replacement, the Existing Scanner will be taken out of state and will not be brought back into North Carolina without CON approval. The total inventory of mobile MRI scanners in North Carolina will not change as a result of the proposed replacement.

This proposal meets the definition of "replacement equipment" as set forth in N.C. Gen. Stat. § 131E-176(22a) because:

1. The cost of the equipment and the cost of all activities essential to acquiring and making operational the replacement equipment are less than \$2 million; and
2. The sole purpose of this proposal is to replace comparable medical equipment currently in use, which will be sold or otherwise disposed of when replaced.

Further, this proposal meets the requirements of 10A NCAC 14C .0303(d) because:

- The Replacement Scanner has the same technology as the Existing Scanner; and
- The Replacement Scanner is functionally similar and is used for the same diagnostic or treatment purposes as the Existing Scanner and is not used to provide a new health service; and
- The Replacement Scanner will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months.

In addition, none of the exclusions in 10A NCAC 14C .0303(e) applies here.

Based on the foregoing, Novant respectfully requests that the CON Section confirm in writing that the above-referenced proposal is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

2. Material Compliance Request for an Additional Host Site

Novant also respectfully requests that the CON Section issue a material compliance determination to allow the addition of new host site for the Replacement Scanner. As the CON Section is aware, on March 7, 2018, Novant received a declaratory ruling allowing it to submit material compliance determinations for host site changes for its mobile MRI scanners, including JDI.

Pursuant to its CON, JDI currently provides mobile MRI service at three locations in Health Service Area III: (1) Novant Heath Imaging Monroe, located at 2000 Wellness Blvd., Ste. 110, Monroe, NC 28110; (2) Novant Health Imaging Steele Creek, located at 13557 Steelescroft Pkwy. Ste. 1100, Charlotte, NC 28278; and (3) Novant Health Imaging University, located at 8401 Medical Plaza Dr., Ste. 110, Charlotte, NC 28262. Novant proposes to add an additional mobile MRI site to the route of the Replacement Scanner. The new site is Novant Health Imaging Cabarrus, located at 925 Bradley Street, NE, Concord, NC 28025. The proposed site is also within Health Service Area III, and is located in Cabarrus County, which is adjacent to Mecklenburg and Union Counties, where the Replacement Scanner already provides service.

Because Novant Health Imaging Cabarrus has a mobile MRI pad and electrical hookups, there will be no capital costs associated with providing mobile MRI services at Novant Health Imaging Cabarrus. The service agreement used at Novant Health Imaging Cabarrus will be similar to the service agreements used at other locations in North Carolina where Novant-owned mobile MRI scanners provide mobile MRI service. Novant further represents that there will be no increase in patient charges as a result of adding Novant Health Imaging Cabarrus to the route for the Scanner. Novant also represents that there will be no change in the scope of services approved in Project I.D. No. F-6626-02.

N.C. Gen. Stat. § 131E-189(b) allows the CON Section to withdraw the CON if Novant fails to develop the service in a manner consistent with the representations made in the application or with any conditions that were placed on the CON. Novant will not be operating the project in a manner that is materially different from the representations made in the application, nor in a manner that is inconsistent with any of the conditions that were placed on the CON.

Accordingly, Novant respectfully requests that the CON Section issue a material compliance determination that Novant be allowed to use the Replacement Scanner to provide mobile MRI services at Novant Health Imaging Cabarrus. Because of patient need for the service, Novant would appreciate the CON Section issuing its determination as soon as possible.

Martha Frisone
April 13, 2018
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Thank you for your time and consideration. Please let me know if you have any questions or need any other information.

Sincerely,

A handwritten signature in black ink, appearing to read "Denise M. Gunter". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Denise M. Gunter

Enclosures

EXHIBIT

A

STATE OF NORTH CAROLINA
Department of Health and Human Services
Division of Facility Services

CERTIFICATE OF NEED

for

Project Identification Number F-6626-02
FID#020514

ISSUED TO: Imaging Associates of the Carolinas LLC
3614 Haworth Drive
Raleigh, NC 27609

Pursuant to N.C. Gen. Stat. § 131B-175, et seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131B-176(10). The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131B-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131B-189 for any of the reasons provided in that law.

SCOPE: Acquire one mobile magnetic resonance imaging (MRI) scanner to be operated at Orion Imaging, LLC in Pineville and Orion Imaging, LLC in Gastonia.

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Orion Imaging, LLC
10420 Park Road Extension, Suite 100
Pineville, NC 28134
Orion Imaging, LLC
900 Cox Road, Suite C
Gastonia, NC 28054

MAXIMUM CAPITAL EXPENDITURE: \$2,168,705

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: March 1, 2005

This certificate is effective as of the 21st day of October, 2004.

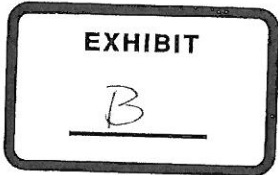
Geoff Hoffmann
Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS

1. Imaging Associates of the Carolinas, LLC shall materially comply with all representations made in its certificate of need application as modified by additional information submitted to the CON Section. In those instances in which any of these representations conflict, Imaging Associates of the Carolinas, LLC shall materially comply with the last-made representation.
2. Imaging Associates of the Carolinas, LLC shall operate its mobile magnetic resonance imaging scanner no more than four days per week in Mecklenburg County at 10420 Park Road Extension, Suite 100 Pineville, and no more than four days per week in Gaston County at 900 Cox Road, Gastonia.
3. Imaging Associates of the Carolinas, LLC shall acquire one mobile MRI scanner with transporting equipment. The mobile MRI scanner shall be moved each week to provide MRI services to at least two host sites.
4. The mobile MRI shall not, at any time, be converted to a fixed MRI scanner and such equipment shall not, at any time, serve less than two host sites each week. The acquisition of the mobile MRI scanner shall not result in the creation of a diagnostic center located at any of the host sites or any other facility owned, operated or otherwise affiliated with Imaging Associates of the Carolinas, LLC.
5. Imaging Associates of the Carolinas, LLC shall not change or add host sites unless they first obtain a declaratory ruling authorizing the change in location of the equipment pursuant to N.C. Gen. Stat. § 150B-4 and the rules of the Department of Health and Human Services, Division of Facility Services.
6. Imaging Associates of the Carolinas, LLC shall not, acquire as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.

TIMETABLE

Ordering equipment	November 15, 2004
Arrival of equipment	January 15, 2005
Operation of equipment	January 15, 2005



**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

**IN RE: REQUEST FOR DECLARATORY)
RULING BY JACKSONVILLE DIAGNOSTIC)
IMAGING, LLC) DECLARATORY RULING
Project I.D. No. F-6626-02)**

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services (“Department” or “Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statutes § 150B-4 and 10A NCAC 14A .0103, under the authority granted me by the Secretary of the Department of Health and Human Services.

Jacksonville Diagnostic Imaging, LLC (hereinafter “JDI”) (formerly Imaging Associates of the Carolinas) has requested a declaratory ruling allowing for an additional host site - Novant Health Imaging Monroe at 2000 Wellness Boulevard, Suite #110, Monroe, North Carolina 28110 (hereinafter “the Monroe site”) in Union County for a mobile MRI scanner for Project I.D. No. F-6626-02 (the “Project”) on the grounds that the change does not constitute a material change in the scope or physical location of the Project. N.C.G.S. §§ 131E-181(a) and (b). This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Denise M. Gunter of Nelson, Mullins, Riley & Scarborough, LLP has requested this ruling on behalf of JDI and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

On October 21, 2004, the CON Section issued a CON to Imaging Associates of the Carolinas, LLC (“IAC”) for Project I.D. No. F-6626-02 to acquire one mobile MRI scanner (the “JDI Scanner”) to provide MRI services at “at least two host sites” each week. The issued CON specified the two host sites as Orion Imaging, LLC, 10420 Park Road Extension, Suite 100, Pineville, North Carolina (Mecklenburg County) and Orion Imaging, LLC, 900 Cox Road, Suite C, Gastonia, North Carolina (Gaston County). A declaratory ruling dated May 3, 2007 permitted the addition of a third site located at 10710 Ballantyne Commons Parkway, Winslow Building, Charlotte, North Carolina. On February 20, 2008, the Department issued an exemption for Novant Health, Inc. and/or its subsidiaries to acquire IAC. JDI is the Novant subsidiary which owns the assets of IAC. Through a series of Declaratory Rulings, JDI was permitted to drop the Gaston County site from the route and add other sites, including Novant Health Imaging Centers located at University and Steele Creek in Mecklenburg County and a Novant owned physician practice in Rowan County, RoMedical. Through a Declaratory Ruling issued March 27, 2012, JDI was permitted to resume service at the site in Gaston County. JDI currently provides mobile MRI services at four sites in Health Service Area (“HSA”) III, including one site in Gaston County and three sites in Mecklenburg County (the Ballentyne Site, the University Site and the Steele Creek Site).

Petitioners’ request for a declaratory ruling sets forth the following additional material facts and representations in support of its request. The Proposed Site at Monroe is in Union County, which is adjacent to Mecklenburg County and is also located in HSA III. Novant Health Imaging Centers presently serve Union County residents on mobile scanners owned by Novant or its subsidiaries and operated at the host sites in Mecklenburg County.

Allowing the JDI Scanner to serve the Monroe Site will improve the convenience and access to MRI services for those Union County residents. JDI represents that allowing it to use the mobile unit at the Monroe Site will not change the scope of the Project or increase costs and charges to JDI or the public. JDI states that the service agreements for the Monroe Site will be substantially similar to those in place at the existing sites served by the JDI Scanner. JDI further represents that it will comply with all other representations in the original CON for the Project and that there are no capital costs associated with JDI's request because the Monroe Site already has a mobile MRI pad and the required electrical connections.

ANALYSIS

The CON law would require a full review of JDI's proposed addition of one new host site if that change were to represent a material change in the physical location or scope of the project. N.C.G.S. §131E-181(a) provides that a CON "shall be valid only for the defined scope, physical location, and person named in the application." The proposed addition of the Monroe Site as a host site does not affect the scope of the project because the addition will not affect the scope of services offered to patients served by the JDI Scanner. The addition of the proposed host site in Monroe would simply allow JDI to provide mobile MRI services to MRI patients in Union County where they reside, rather than serving many of them at one of its other mobile MRI host sites in Mecklenburg County. Neither does the addition of the proposed host site in Monroe constitute a material change in the physical location of the project because the Monroe Site in Union County is adjacent to and in the same HSA as Mecklenburg County, one of the counties identified in the CON. The proposed addition of the Monroe Site is therefore in material compliance with the CON. There is no proposed change in ownership of the CON that would result in a violation of N.C.G.S. §131E-181(a).

Moreover, there will be no additional capital costs incurred since a mobile MRI pad and the required electrical connections already exist at the proposed Monroe site and there will be no increase in costs or charges for the provision of the proposed mobile MRI services.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the addition of the proposed Monroe site as a host site for JDI's mobile MRI scanner, Project I.D. No. F-6626-02, will not constitute a material change in the physical location or scope of the project and will not violate N.C.G.S. §131E-181.

This the ____ day of December, 2014.

Drexdal Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this day served a copy of the foregoing Declaratory Ruling upon the PETITIONER by certified mail, return receipt requested, by causing a copy of same to be placed in the United States Mail, first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Denise M. Gunter, Esquire
Nelson, Mullins, Riley & Scarborough, LLP
380 Knollwood Street, Suite 530
Winston-Salem, NC 27103

This the _____ day of December, 2014.

Cheryl Ouimet
Chief Operating Officer



EQUIPMENT COMPARISON - MR REPLACEMENT
 MQ26 Replacement - Project ID No.F-6626-02

MQ26 MQ13

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Mobile MRI Scanner	Mobile MRI Scanner
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	1.5T	1.5T
Model Number	23X	23X
Serial Number	R0380	R4378
Provider's Method of Identifying Equipment	Serial Number	Serial Number
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1JJV482W5XL512394	1S9FA482X61182868
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	2016	2006
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	Used	New
Total Capital Cost of Project (Including Construction, etc.) < Use Attached Form >	\$835,000	\$1,267,358.12
Total Cost of Equipment	\$835,000	\$1,267,358.12
Fair Market Value of Equipment	\$650,000	\$650,000
Net Purchase Price of Equipment	Same	Same
Locations Where Operated	NHI-Monroe NHI-Steele Creek NHI-University	NHI-Monroe NHI-Steele Creek NHI-University
Number Days In Use/To Be Used in N.C. Per Year	255	255
Percent of Change in Patient Charges (by Procedure)	NA	NA
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	NA
Type of Procedures Currently Performed on Existing Equipment	General Outpatient MR Scans of the Body/ Extremities	General Outpatient MR Scans of the Body/ Extremities
Type of Procedures New Equipment is Capable of Performing	General Outpatient MR Scans of the Body/ Extremities	General Outpatient MR Scans of the Body/ Extremities