



**NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

February 28, 2020

Denise M. Gunter
denise.gunter@nelsonmullins.com

Exempt from Review – Replacement Equipment

Record #: 3230
Business Name: MedQuest Associates, Inc.
Business #: 2692
Project Description: Temporarily acquire MQ 16 to service Novant Health Imaging Steele Creek while MQ 9 undergoes repairs
County: Mecklenburg

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of February 25, 2020, 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 temporarily acquire MQ 16, an existing mobile MRI scanner located outside of North Carolina, to replace MQ 9 at Novant Health Imaging Steele Creek without a certificate of need. This determination is based on your representations that this acquisition is temporary while MQ 9 is undergoing repairs and once MQ 9 is repaired, MQ 16 will be removed from the State and will not be used again in the State without first obtaining a certificate of need if one is required.

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.

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Julie M. Faenza
Project Analyst

Martha J. Frisone
Chief

**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: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Host Site	Address	Days of Service
Novant Health Imaging Steele Creek ("Steele Creek")	13557 Steelescroft Pkwy. #1100, Charlotte, NC 28278	Monday, Thursday, Friday
Novant Health Imaging University ("University")	8401 Medical Plaza Dr. #110, Charlotte, NC 28262	Tuesday, Wednesday

To avoid disrupting patient diagnosis and treatment, MedQuest will deploy some of its other mobile MRI assets while MQ 9 is being repaired. No one scanner has the capacity to take over for MQ 9, so MedQuest has assembled a schedule using other mobile scanners ("Temporary Mobile Scanners") to serve Steele Creek and University. It is anticipated that the repairs will take several weeks. The following table shows the schedule of Temporary Mobile Scanners for Steele Creek and University while MQ 9 is being repaired:

Temporary Mobile Scanner	CON Status	Host Site	Days of Service While MQ 9 is Being Repaired
MQ 25	Grandfathered	Steele Creek	Monday and Thursday
MQ 25	Grandfathered	University	Friday
MQ 16	Out of state	Steele Creek	Friday
Presbyterian Mobile Imaging	Project I.D. No. F-7164-04	University	Monday, Wednesday and Thursday
MQ 13	Project I.D. No. F-6626-02	University	Tuesday

Pursuant to our telephone conversation on February 24, it is my understanding the no CON approval is needed for MQ 25 to add host sites since it is a grandfathered unit. MQ 16 is located out of state and does not have a North Carolina CON. MedQuest represents that MQ 16 will only be used in North Carolina to serve Steele Creek while MQ 9 is out of service. When MQ 9 is restored to service, MQ 16 will be taken out of state and will not be brought back to North Carolina without appropriate CON approval. Presbyterian Mobile Imaging was recently approved to serve University (although on different days from what is now contemplated). See **Exhibit A**. MQ 13 was previously approved to serve University. See **Exhibit B**. MQ 13 is now serving sites outside of Mecklenburg County and MedQuest proposes to bring MQ 13 back into Mecklenburg County to serve University on Tuesdays.



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

Received by Healthcare
Planning & CON Section
FEB 25 2020

February 25, 2020

Via Electronic Mail

Martha J. Frisone, Chief
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Material Compliance Letter for Mobile MRI Scanner
Mecklenburg County
Health Service Area III

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. §§ 131E-181 and 189, and on behalf of MedQuest Associates ("MedQuest"), I am writing to request a material compliance determination for the addition of mobile MRI host sites. The host site additions are necessary because one of MedQuest's grandfathered mobile MRI scanners, known internally as MQ 9, is out of service and other mobile resources will need to be used to cover MQ 9's host sites while it undergoes repairs. This letter is in follow up to our telephone conversation on February 24, 2020.

In the early morning hours of February 24, 2020, MQ 9 experienced a magnet quench. Quenching is the process whereby there is a sudden loss of absolute zero of temperature in the magnet coils, so that they cease to be super conducting and become resistive, thus eliminating the magnetic field. This results in helium escaping from the cryogen bath extremely rapidly. Quenching may cause severe and irreparable damage to the super conducting coils.

MQ 9 currently serves two host sites in Mecklenburg County:

Martha J. Frisone, Chief
February 25, 2020
Page 3

When MQ 9 is back in service, MedQuest anticipates that MQ 9 will resume the schedule it had before the quench. As necessary, MedQuest will seek additional CON approval for further host site changes. The Temporary Mobile Scanners will be used to provide the same type of MRI scans that MQ 9 provides. No new health services will be provided. There will be no increase in patient charges as a result of allowing the Temporary Mobile Scanners listed above to cover MQ 9's route while it is being repaired. For the scanners that have CONs, there will be no changes in the scope of those projects. MedQuest will not be operating the projects in a manner that materially differs from the representations in the CON applications, nor in a manner that is inconsistent with any of the conditions that were placed on the CONs.

Accordingly, and to the extent approval from the CON Section is required, MedQuest respectfully requests written confirmation from the Agency that the proposed use of the Temporary Mobile Scanners while MQ 9 is out of service does not require a CON.

Thank you for your time and attention. Please do not hesitate to contact me if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Denise M. Gunter", written in a cursive style.

Denise M. Gunter

Enclosures

Exhibit A



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

February 12, 2020

Denise M. Gunter
denise.gunter@nelsonmullins.com

Material Compliance Approval

Project ID #: F-7164-04
Facility: Presbyterian Imaging, LLC
Project Description: Change in host sites
County: Mecklenburg
FID #: 041314

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of February 7, 2020 is in material compliance with representations made in the application. These changes include resuming service to Novant Health Imaging University and adding service at a new host site, Novant Health Imaging Ballantyne.

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. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Handwritten signature of Julie M. Faenza in cursive.

Julie M. Faenza
Project Analyst

Handwritten signature of Martha J. Frisone in cursive.

Martha J. Frisone
Chief

cc: Melinda Boyette, Administrative Assistant, Healthcare Planning, 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: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704

<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Waller, Martha K

From: Flores, Disraeliza
Sent: Friday, February 7, 2020 11:12 AM
To: Waller, Martha K; Denise Gunter
Subject: FW: [External] Material Compliance Request for Project I.D. No. F-7164-04
Attachments: 20200207104551120.pdf

This request is received, will be logged and forwarded to the Analyst.

Disraeliza Flores
Administrative Assistant
Division of Health Service Regulation
North Carolina Department of Health and Human Services

919-855-3872 office
disraeliza.flores@dhhs.nc.gov

809 Ruggles Drive
Raleigh NC, 27603

2704 Mail Service Center
Raleigh, NC 27699-2704

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From: Denise Gunter <denise.gunter@nelsonmullins.com>
Sent: Friday, February 7, 2020 10:49 AM
To: Flores, Disraeliza <Disraeliza.Flores@dhhs.nc.gov>
Cc: Chelsea Barnes <chelsea.barnes@nelsonmullins.com>; Nicki Diamond <nicki.diamond@nelsonmullins.com>
Subject: [External] Material Compliance Request for Project I.D. No. F-7164-04

[EXTERNAL] External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov

Good Morning,

Attached is another material compliance determination. This is also for Mecklenburg County. Could you please acknowledge receipt and forward to the Project Analyst?

Thanks.

Confidentiality Notice

This message is intended exclusively for the individual or entity to which it is addressed. This communication may contain information that is proprietary, privileged, confidential or otherwise legally exempt from disclosure. If you are not the named addressee, you are not authorized to read, print, retain, copy or disseminate this message or any part of it. If you have received this message in error, please notify the sender immediately either by phone (800-237-2000) or reply to this e-mail and delete all copies of this message.



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February 7, 2020

Via Email

Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Material Compliance Determination Request
Project I.D. # F-7164-04
FID # 041314
Addition of Mobile MRI Host Sites

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. §§ 131E-181 and 189, I am writing on behalf of Presbyterian Mobile Imaging, LLC ("PMI") concerning the addition of two host sites for a mobile MRI scanner (the "Scanner"). Attached as **Exhibit A** is the CON for Project I.D. No. F-7164-04. Novant Health, Inc. ("Novant") is the ultimate parent entity of PMI. A November 2017 declaratory ruling describing the history of this scanner and its multi-county service area is attached as **Exhibit B**. As set forth in the CON and the declaratory ruling, the Scanner was originally approved to serve host sites in Mecklenburg and Union counties. Through declaratory rulings, the Scanner was allowed to serve other sites. See **Exhibit B**. Pursuant to this November 2017 declaratory ruling, the Scanner was approved for use at Novant Health Imaging Monroe (Union County). See **Exhibit B**. **Exhibit C** contains additional relevant correspondence from August 2019.

The Scanner is presently serving Novant Health Imaging Monroe (Union County) and Novant Health Imaging Mooresville (Iredell County). PMI now seeks to resume service at Novant Health Imaging University (Mecklenburg County) and add a new host site at Novant Health Imaging Ballantyne (Mecklenburg County).

CALIFORNIA | COLORADO | DISTRICT OF COLUMBIA | FLORIDA | GEORGIA | MASSACHUSETTS | NEW YORK
NORTH CAROLINA | SOUTH CAROLINA | TENNESSEE | WEST VIRGINIA

Martha J. Frisone
February 7, 2020
Page 2

Novant Health Imaging University and Novant Health Imaging Ballantyne have mobile MRI pads and electrical hookups, so there will be no capital costs associated with providing mobile MRI services at these locations. PMI further represents that the service agreements used at Novant Health Imaging University and Novant Health Imaging Ballantyne will be similar to the service agreements used at other locations in North Carolina where Novant-owned mobile MRI scanners provide mobile MRI service. PMI further represents that there will be no increase in patient charges as a result of adding to these sites to the route for the Scanner. PMI also represents that there will be no change in the scope of services approved for the Scanner.

If this material compliance determination request is approved, PMI contemplates that the route for the Scanner will be as follows:

Monday:	Novant Health Imaging Monroe
Tuesday/Saturday:	Novant Health Imaging University
Wednesday:	Novant Health Imaging Ballantyne
Thursday/Friday :	Novant Health Imaging Mooresville

N.C. Gen. Stat. § 131E-189(b) allows the Agency to withdraw the CON if PMI 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. PMI 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, PMI respectfully requests that the CON Section issue a material compliance determination that it be allowed to provide mobile MRI services at. Because of patient need for the service, PMI respectfully requests that the CON Section issue its determination as soon as possible.

Thank you for your time and consideration. Please let me know if you have any questions or need any other information.

Sincerely,



Denise M. Gunter

Enclosures

05-476

14001

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



CERTIFICATE OF NEED

for

Project Identification Number F-7184-04
FID# 041814

ISSUED TO: Presbyterian Mobile Imaging, L.P.
200 Bayshore Lane
Charlotte, NC 28204

Pursuant to N.C. Gen. Stat. § 131D-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 specified herein and shall make good faith efforts to meet the objectives contained herein. The certificate holder shall not exceed the maximum capital expenditures specified herein during the development of this project, except as provided by N.C. Gen. Stat. §§ 131D-176 (16). This certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. §§ 101B-189 (c). This certificate is valid only for the project, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131D-182 for any of the reasons provided in that law.

SCOPE: Acquire one mobile Magnetic Resonance Imaging (MRI) scanner to be operated at two sites, Presbyterian Medical Plaza (Charlotte) and Southern Piedmont Primary Care (Lincoln County).

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Presbyterian Medical Plaza (Charlotte) and Southern Piedmont Primary Care (Lincoln County)
8407 Medical Plaza Drive
Charlotte, NC
1600 Roosevelt Boulevard
Monroe, NC

MAXIMUM CAPITAL EXPENDITURE: \$2,705,145

UNREPAID: See Reverse Side

ISSUANCE DATE: August 1, 2006

This certificate is effective as of the 25th day of January, 2006.

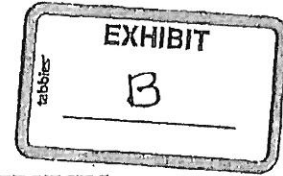
Wesley H. Hoffmann
Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS

1. Presbyterian Mobile Imaging, LLC shall materially comply with all representations made in its certificate of need application as modified by additional information submitted to the Certificate of Need Section on June 3, 2005, November 15, 2005, and January 3, 2006. In those instances in which any of these representations conflict, Presbyterian Mobile Imaging, LLC shall materially comply with the last-made representations.
2. Presbyterian Mobile Imaging, LLC shall acquire one mobile MRI scanner with transporting equipment that will result in establishment of PMI as a possible diagnostic program. The mobile MRI scanner shall be moved each week to provide MRI services at least two host sites.
3. 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 Presbyterian Mobile Imaging, LLC.
4. Presbyterian Mobile Imaging, LLC shall operate the mobile MRI scanner only at Presbyterian Medical Plaza University, 8401 Medical Plaza Drive, Charlotte, North Carolina and Southern Piedmont Primary Care, 1640 East Roosevelt Boulevard, Monroe, North Carolina. ~~PMI shall not change or add host sites unless it first obtains a declaratory ruling authorizing the change in location of the equipment pursuant to North Carolina Statute 150-B4 and the rules of the Department of Health and Human Services, Division of Facility Services.~~
5. Presbyterian Mobile Imaging, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in the materials submitted to the CON Section dated June 3, 2005, November 15, 2005 and January 3, 2006, or that would otherwise require a certificate of need.
6. The approved capital expenditure is \$2,705,185.

WARRANTY:

Order Equipment _____ February 16, 2006
 Operate Equipment _____ July 26, 2006



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

IN RE: REQUEST FOR DECLARATORY)
RULING BY PRESBYTERIAN MOBILE)
IMAGING, LLC,) DECLARATORY RULING
Project I.D. # F-7164-04)

I, Mark Payne, 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.

On September 11, 2017, Presbyterian Mobile Imaging, LLC, (hereinafter, "PMI"), requested a declaratory ruling allowing PMI to cease serving two (2) host sites and to add one (1) host site for a mobile MRI scanner for Project I.D. No. F-7164-04 ("Project") on the grounds that the change does not constitute a material change in scope or a failure to materially comply with the representations made in the Certificate of Need ("CON") application for the Project, pursuant to N.C.G.S. §§ 131E-181(a) and (b). This ruling will be binding upon the Department and the entity 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 PMI and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

On January 25, 2006, the Certificate of Need Section issued a CON to PMI allowing PMI to acquire one (1) mobile MRI scanner to serve two (2) host sites each week: Presbyterian Medical Plaza University in Charlotte, Mecklenburg County, North Carolina, and Southern Piedmont Primary Care in Monroe, Union County, North Carolina. Through subsequent Declaratory Rulings, the mobile scanner has been allowed to serve other sites. The mobile scanner now serves the following sites: Novant Health Imaging Mooresville ("Mooresville") in Mooresville, Iredell County, North Carolina; Novant Health Imaging Steele Creek ("Steele Creek") in Charlotte, Mecklenburg County, North Carolina; and Novant Health Imaging University ("University") in Charlotte, Mecklenburg County, North Carolina. PMI now proposes to cease serving the Steele Creek and University sites in Charlotte, Mecklenburg County, North Carolina, and add the following host site for the mobile MRI scanner: Novant Health Imaging Monroe ("Monroe"), located at 2000 Wellness Boulevard, Suite 110, Monroe, Union County, North Carolina.

ANALYSIS

The CON law would require a full review of PMI's addition of the host site if the addition were to represent a material change in the scope or physical location of the Project. N.C.G.S. § 131E-181(a). The addition of the proposed host site does not constitute a material change in the scope or physical location of the Project because the proposed host site is located approximately 7.1 miles from Southern Piedmont Primary Care, Monroe, Union County, North Carolina, which was one of the original host sites approved for the mobile MRI scanner. In addition, PMI states that the proposed host site already has the required mobile MRI docking pad and electrical connections. Therefore, there will be no capital costs associated with adding this site. Further, the Mooresville site in Iredell County combined with the addition of the proposed site would provide

mobile MRI services consistent with the condition placed on the CON that the mobile MRI scanner serve at least two (2) sites each week.

N.C.G.S. § 131E-189(b) allows the Agency to withdraw PMI's CON if PMI 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. PMI states that it will not develop the Project in a manner that is materially different from the representations made in the application or in a manner that is inconsistent with any of the conditions that were placed on the CON.

CONCLUSION

For the foregoing reasons, assuming the statement of facts and representations in the request to be true, I conclude that PMI's proposal to cease serving the Steele Creek and University sites in Charlotte, Mecklenburg County, North Carolina, and its addition of Novant Health Imaging Monroe, located at 2000 Wellness Boulevard, Suite 110, Monroe, Union County, North Carolina, as a host site for the mobile MRI scanner will not constitute a material change in the scope or physical location of the Project, will not violate N.C.G.S. § 131E-181, and will not constitute a failure to satisfy a condition of the CON in violation of N.C.G.S. § 131E-189(b).

This the _____ day of November, 2017.

Mark Payne, 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 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
NELSON MULLINS RILEY & SCARBOROUGH, LLP
308 Knollwood Street
Suite 530
Winston-Salem, North Carolina 27103
ATTORNEY FOR PRESBYTERIAN MOBILE
IMAGING, LLC

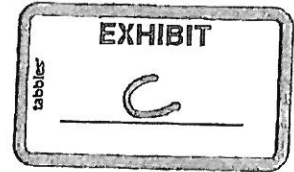
This the ____ day of November, 2017.

Diana Barbry
Executive Assistant to the Director
Division of Health Service Regulation



NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation



VIA EMAIL ONLY

August 16, 2019

Denise Gunter
Denise.Gunter@nelsonmullins.com

Material Compliance Approval

Project ID #: F-7164-04
Facility: Presbyterian Imaging, LLC
Project Description: Changes to host sites
County: Mecklenburg
FID #: 041314

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of August 12, 2019 is in material compliance with representations made in the application. These changes include no longer providing mobile MRI service to Novant Health Imaging University and Novant Health Imaging Steele Creek.

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. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Julie M. Faenza
Project Analyst

Martha J. Frisone
Chief

cc: Melinda Boyette, Administrative Assistant, Healthcare Planning, 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: 809 Ruggles Drive, 2704 Mall Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



Denise M. Gunter
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 denise.gunter@nelsonmullins.com

NELSON MULLINS RILEY & SCARBOROUGH LLP
 ATTORNEYS AND COUNSELORS AT LAW

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 Winston-Salem, NC 27103
 T 336.774.3300 F 336.774.3288
 nelsonmullins.com



August 12, 2019

VIA EMAIL

Martha J. Frisone, Chief
 Healthcare Planning and Certificate of Need Section
 North Carolina Department of Health and Human Services
 Division of Health Service Regulation
 809 Ruggles Drive
 Raleigh, North Carolina 27603

Re: Facility Name: Presbyterian Mobile Imaging, LLC
 FID#: 041314
 Business Name: Presbyterian Mobile Imaging, LLC
 Business #: 1467
 Project Description: Replace existing mobile MRI scanner with existing mobile MRI scanner MQ 27
 County: Mecklenburg

Dear Ms. Frisone:

On July 17, 2019, the Agency issued an exemption determination for the above-referenced project based on my July 8, 2019 letter to the Agency. Copies of these letters are attached. Since that time, there has been one change in the facts. Effective August 15, 2019, MQ 27 will leave Mecklenburg County and will no longer be providing service in Mecklenburg County. Instead, MQ 27 will be providing service in Iredell County and Union County, at the Mooresville Diagnostic Imaging and Novant Health Imaging Monroe sites listed in my July 8, 2019 letter.

Effective August 15, 2019, Novant proposes the following route for MQ 27:

Monday: Monroe
 Tuesday: Monroe
 Wednesday: Mooresville
 Thursday: Mooresville
 Friday: Mooresville
 Saturday: Mooresville

Martha J. Frisone
August 12, 2019
Page 2

Otherwise, the facts remain the same as stated in my July 8, 2019 letter to the Agency.

I would appreciate the Agency's written confirmation that the Agency's July 18, 2019 exemption determination still applies to the facts contained in this letter.

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 cursive script, appearing to read "Denise M. Gunter".

Denise M. Gunter

Enclosures



NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

July 17, 2019

Denise M. Gunter
denise.gunter@nelsonmullins.com

Exempt from Review – Replacement Equipment

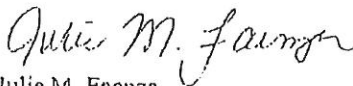
Record #: 2985
Facility Name: Presbyterian Mobile Imaging, LLC
FID #: 041314
Business Name: Presbyterian Mobile Imaging, LLC
Business #: 1467
Project Description: Replace existing mobile MRI scanner MQ with existing mobile MRI scanner MQ27
County: Mecklenburg

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 8, 2019, 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 Siemens Espress 1.5T mobile MRI scanner (ID# 31381) to replace the GE 1.5T HDX mobile MRI scanner (ID# 235487). 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.

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.

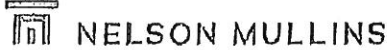
Sincerely,


Julie M. Faenza
Project Analyst


Martha J. Frisone
Chief

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: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr • TEL: 919-856-3873

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 336.774.3289
nelsonmullins.com



July 8, 2019

VIA EMAIL

Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Replacement Equipment Exemption Request for Mobile MRI Scanner

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. § 131E-184(a)(7), I am writing on behalf of Novant Health, Inc. ("Novant") and MedQuest Associates ("MedQuest") (collectively, "Novant") concerning the replacement of a mobile MRI scanner. Novant is MedQuest's ultimate parent entity. This letter supersedes and replaces an earlier version of this letter which was submitted to the Agency on June 17, 2019 (the "June 17 Letter"). I withdrew the June 17 Letter via email to Ms. Faenza on June 28, 2019.

By separate correspondence, Novant has informed the Agency of its intention to replace a grandfathered mobile MRI scanner, MQ 27, with a fixed MRI scanner at Novant Health Presbyterian Medical Center ("NHPMC"). Assuming that request is approved, in this letter, Novant proposes to bring MQ 27 back to North Carolina and replace another mobile, called Presbyterian Mobile Imaging, LLC ("PMI") with MQ 27. PMI's route currently consists of the following sites:

- Mooresville Diagnostic Imaging, 118 Gateway Blvd., Suite E, Mooresville, NC ("Mooresville")
- Novant Health Imaging University, 8401 Medical Plaza Drive, Charlotte, NC 28211 ("University")
- Novant Health Imaging Steele Creek, 13557 Steelcroft Pkwy, Suite 110, Charlotte, NC 28278 ("Steele Creek")
- Novant Health Imaging Monroe, 2000 Wellness Blvd., Monroe, NC 28110 ("Monroe")

Martha J. Frisone
July 8, 2019
Page 2

Since Novant already owns MQ 27 and the trailer, there is no cost to acquire MQ 27 and the trailer. Novant presently estimates the fair market value of the MQ 27 scanner and trailer to be \$800,000; the original purchase price was \$1,144,341.00

This replacement is therefore consistent with N.C. Gen. Stat. § 131E-176(22a) because MQ 27 costs less than \$2 million and it will be used for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

MQ 27 also meets the requirements of 10A NCAC 14C.0303(d) because:

- (1) it has the same technology as PMI, although it may possess expanded capabilities due to technological improvements; and
- (2) It is functionally similar and is used for the same diagnostic or treatment purposes as PMI and is not used to provide a new health service; and
- (3) MQ 27 does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

None of the exclusions contained in 10A NCAC 14C.0303(e) applies here. An equipment comparison form is attached as Exhibit A.

Novant further represents that the service agreement used for MQ 27 will be similar to the service agreements used at other locations in North Carolina where Novant-owned mobile MRI scanners provide mobile MRI service. Replacing PMI with MQ 27 does not increase the inventory of MRI scanners in North Carolina owned by MedQuest or Novant. If this request is approved, PMI would be taken out of North Carolina and would not be brought back to North Carolina without CON approval.

Novant proposes the following route for MQ 27:

Monday:	Mooreville
Tuesday:	Steele Creek or Monroe
Wednesday:	Steele Creek or Mooreville
Thursday:	University
Friday:	University

We would appreciate the Agency's written confirmation that the foregoing replacement equipment exemption request is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

Martha J. Frisone
July 8, 2019
Page 3

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 cursive script, appearing to read "Denise M. Gunter".

Denise M. Gunter

Enclosures

Exhibit A: Equipment comparison form

EXHIBIT
A

EQUIPMENT COMPARISON

Type	EXISTING EQUIPMENT (Presby)	REPLACEMENT EQUIPMENT (MQ27)
(e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	MRI	MRI
Manufacturer	GE	Siemens
Model number	1.5T HDX	Espree 1.5T
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	235487	31381
Is the equipment mobile or fixed?	Mobile-F-7164-04	Mobile
Date of acquisition	2006	2013
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	NEW	USED-Novant Owned
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	NA	NA
Total cost of the equipment	\$1,651,978.52 650K FMV	\$1,144,341 800K FMV
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Iredell County, Mecklenburg County, & Union County	Iredell County, Mecklenburg County, & Union County
Document that the existing equipment is currently in use	SMFP 2019	NA
Will the replacement equipment result in any increase in the average charge per procedure?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	MRI Scans	MRI Scans
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	MRI Scans	MRI Scans

Date of last revision: 5/17/19



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

July 17, 2019

Denise M. Gunter
denise.gunter@nelsonmullins.com

Exempt from Review – Replacement Equipment

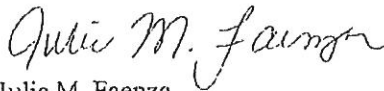
Record #: 2985
Facility Name: Presbyterian Mobile Imaging, LLC
FID #: 041314
Business Name: Presbyterian Mobile Imaging, LLC
Business #: 1467
Project Description: Replace existing mobile MRI scanner MQ with existing mobile MRI scanner MQ27
County: Mecklenburg

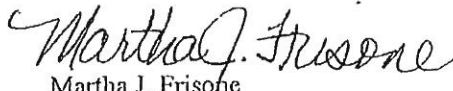
Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 8, 2019, 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 Siemens Espress 1.5T mobile MRI scanner (ID# 31381) to replace the GE 1.5T HDX mobile MRI scanner (ID# 235487). 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.

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,


Julie M. Faenza
Project Analyst


Martha J. Frisone
Chief

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION
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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Exhibit B



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

Material Compliance Approval

Project ID #: F-6626-02
Facility: Jacksonville Diagnostic Imaging, LLC
Project Description: Add a new host site to the existing route for the Mobile MRI Scanner
County: Gaston
FID #: 050901

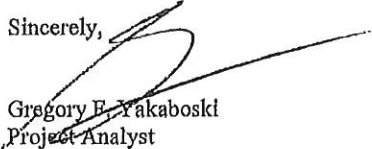
Dear Ms. Gunter:


The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of April 13, 2018 is in material compliance with representations made in the application. These changes include adding Novant Health Imaging Cabarrus located at 925 Bradley Street, NE, Concord, NC 28025 as an additional host site for Jacksonville Diagnostic Imaging, LLC's Mobile MRI. However, you should contact the Agency's Construction Section to determine if they have any requirements pertinent to the proposed change.

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. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,


Gregory E. Yakaboski
Project Analyst


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

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



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

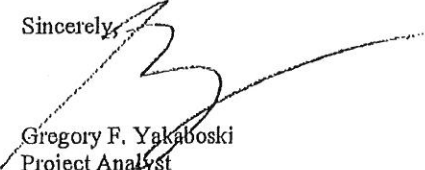
Dear Ms. Gunter:


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

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 ATTORNEYS AND COUNSELORS AT LAW

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 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").

CALIFORNIA | COLORADO | DISTRICT OF COLUMBIA | FLORIDA | GEORGIA | MARYLAND | MASSACHUSETTS | NEW YORK
 NORTH CAROLINA | SOUTH CAROLINA | TENNESSEE | WEST VIRGINIA

Martha Frisone
April 13, 2018
Page 2

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 Health 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
Page 4

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 cursive script, appearing to read "Denise M. Gunter".

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
PID#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(c). The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131B-189(b). 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 Falls Road, Extension, Suite 100, Pineville, NC 28134
Orion Imaging, LLC
900 Cox Road, Suite C, Gastonia, NC 28054

MAXIMUM CAPITAL EXPENDITURE: \$2,100,000

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 Elneville, 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 #	LJV482W5XL512394	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