



North Carolina Department of Health and Human Services
Division of Health Service Regulation

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Division Director

May 26, 2015

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

Exempt from Review - Replacement Equipment

Facility: Novant Health Imaging – Museum
Project Description: Replacement of existing fixed MRI with a temporary mobile MRI
County: Mecklenburg
FID #: 943501

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of May 20, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, a MQ-16 GE 1.5T mobile MRI to use temporarily while upgrading the existing fixed Echosped GE 1.5T MRI from an 11X MRI platform to a 25X HD MRI platform. This determination is based on your representations that the temporary unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections 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,

Fatimah Wilson

Fatimah Wilson
Project Analyst

Martha J. Frisone

Martha J. Frisone
Assistant Chief, Certificate of Need

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



Healthcare Planning and Certificate of Need Section

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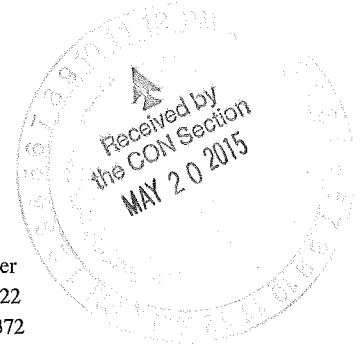
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May 20, 2015

Hand Delivered

Martha J. Frisone, Assistant 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: Notice of Temporary Replacement Equipment for Novant Health Imaging –
Museum: CON Project F-2332-85
Mecklenburg County
Health Service Area III

Dear Ms. Frisone:

Novant Health Imaging – Museum (“NHI-Museum”) operates a GE 1.5T MRI scanner (the “Existing MRI Unit”), which currently provides fixed MRI services in Mecklenburg County. In an effort to enhance the functionality of the Existing MRI Unit, NHI-Museum is seeking to upgrade the Existing MRI Unit from a 11X MRI platform to a 25X HD MRI platform.¹ Essentially, this is an upgrade that allows the existing MRI Unit to operate at a higher definition (HD) for enhanced images. The Existing MRI Unit will be upgraded onsite but it will be out of service for 4-6 weeks while the upgrade process is being completed (the “Replacement Period”). The capital cost for this upgrade is less than \$500,000.

NHI-Museum does not want to inconvenience its patients during this time. Therefore, NHI-Museum is requesting that the MedQuest MQ-16 mobile unit (the “MQ-16 Temporary Replacement Scanner”), which is currently in service in South Carolina, be permitted to

¹ The serial number of the Existing MRI Unit will not change as a part of this upgrade. The upgrade should not be considered a replacement of the Existing MRI Unit because a different machine is not being acquired.

provide temporary mobile service for NHI-Museum while the Existing MRI Unit is being upgraded. To that end, during the Replacement Period, NHI-Museum will contract with MedQuest to have the MQ-16 Temporary Replacement Scanner provide mobile MRI service at NHI-Museum on a temporary basis during the Replacement Period.

As soon as the Existing MRI Unit has completed its upgrade, the MQ-16 Temporary Replacement Scanner will leave the State of North Carolina and will not be brought back into North Carolina without CON approval. At no time during the Replacement Period will NHI-Museum be concurrently operating the Existing MRI Unit and the MQ-16 Temporary Replacement Scanner.

There are no capital costs involved in utilizing the MQ-16 Temporary Replacement Scanner at NHI-Museum's facility as it currently has a mobile pad.

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

1. All costs essential to acquiring and making operational the MQ-16 Temporary Replacement Scanner are less than \$2 million;
2. The Existing MRI Unit is currently in use;
3. The MQ 16 Temporary Replacement Scanner will be removed from North Carolina when the Existing MRI Unit has completed its upgrade and will not be brought back to North Carolina without CON approval; and
4. The sole purpose of this proposal is to temporarily replace comparable medical equipment.

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

- The MQ-16 Temporary Replacement Scanner has comparable technology to the Existing MRI Unit;
- The MQ-16 Temporary Replacement Scanner is functionally similar and is used for the same diagnostic or treatment purposes as the Existing MRI Unit and is not used to provide a new health service; and
- The temporary use of the MQ-16 Temporary Replacement Scanner will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the Existing MRI Unit is upgraded.

None of the exclusions in 10A NCAC 14C .0303(e) applies here.

An equipment comparison form is attached as Exhibit A.

Martha J. Frisone
May 20, 2015
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Based on the foregoing, NHI-Museum respectfully requests that the CON Section confirm in writing that: (1) the above-referenced temporary replacement is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7); and (2) the above-referenced HD upgrade for the Existing MRI Unit is not a new institutional health service that requires a CON pursuant to N.C. Gen. Stat. § 131E-183.

As NHI-Museum would like to begin the upgrade process as quickly as possible, we would appreciate your response on or before June 5, 2015.

Thank you for your time and attention.

Sincerely,

Denise M. Gunter

Denise M. Gunter



Enclosures

EQUIPMENT COMPARISON
MQ 16 TEMPORARY EQUIPMENT REPLACEMENT

<u>NHI-MUSEUM - MRI UPGRADE</u>	EXISTING EQUIPMENT	TEMP. REPLACEMENT EQUIPMENT (MQ 16)
Type of Equipment (List Each Component)	MRI Scanner	MRI Scanner
Manufacturer of Equipment	General Electric	General Electric
Tesla Rating for MRIs	1.5T	1.5T
Model Number	Echospeed	Signa Horizon
Serial Number	R3362	926924
Provider's Method of Identifying Equipment	Serial #	MQ 16
Specify if Mobile or Fixed	Fixed	Mobile
Mobile Trailer Serial Number/VIN #	N/A	1S9FA482351182791
Mobile Tractor Serial Number/VIN #	N/A	
Date of Acquisition of Each Component	2004	2008
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired		Used
Total Capital Cost of Project (Including Construction, etc.) < Use Attached Form >	\$1,874,907.34	
Total Cost of Equipment		
Fair Market Value of Equipment		
Net Purchase Price of Equipment		
Locations Where Operated	Charlotte, NC	SOUTH CAROLINA
Number Days In Use/To Be Used in N.C. Per Year	255	30-60 days
Percent of Change in Patient Charges (by Procedure)	N/A	N/A
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	N/A
Type of Procedures Currently Performed on Existing Equipment	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