



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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

November 5, 2018

Kenneth Burgess
301 Fayetteville Street, Suite 1900
Raleigh, NC 27601

No Review

Record #: 2748
Facility Name: Mission Hospital
FID #: 943349
Business Name: Mission Health System, Inc.
Business #: 2948
Project Description: Replace major electrical and computer systems for the MRI scanner and renovate and make infrastructure upgrades to the MRI room
County: Buncombe

Dear Mr. Burgess:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in that correspondence is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

You may need to contact the Agency's Construction, Radiation Protection and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Ena Lightbourne
Project Analyst

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

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
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: 2701 Mail Service Center, Raleigh, NC 27699-2701
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3750 • FAX: 919-733-2757

Lightbourne, Ena

From: Burgess, Kenneth L. <KBurgess@poynerspruill.com>
Sent: Wednesday, October 31, 2018 8:55 AM
To: Lightbourne, Ena
Subject: [External] RE: Exemption for MRI upgrade and refurbishment

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to Report Spam.

Ena, thanks for your email. I've confirmed with my client, Mission Imaging, that once the MRI refurbishment project is completed at Asheville Imaging, the mobile MRI will be removed the Asheville Imaging site and will not be utilized again at Asheville Imaging or any other Mission location unless and until another similar project arises for which Mission has obtained an Exemption confirmation or other CON authorization (for example, another future potential MRI replacement) and Mission first notifies the CON Section that a mobile MRI will be used during such project. The mobile MRI at the Asheville Imaging site does not belong to Mission and is leased from a 3d party vendor so I cannot attest to the vendor's future plans for it, except as they relate to Asheville Imaging or to Mission Health System. Please let me know if this response is satisfactory for your purposes. Thanks, Ken Burgess

From: Lightbourne, Ena [mailto:ena.lightbourne@dhhs.nc.gov]
Sent: Tuesday, October 30, 2018 4:11 PM
To: Burgess, Kenneth L. <KBurgess@poynerspruill.com>
Subject: Exemption for MRI upgrade and refurbishment

Hi Kenneth,

I hope is well. I'm finishing up this exemption request but I need some additional information. Can you send me something stating that once the MRI refurbishment project is completed, the mobile MRI will be removed from the site and not used within the State? Please let me know if you have any questions.

Thank you,

Ena Lightbourne

Certificate of Need, Project Analyst

Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section
NC Department of Health and Human Services

Office: 919-855-4610
Ena.lightbourne@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
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Poyner Spruill^{LLP}

October 8, 2018

Kenneth L. Burgess
Partner
D: 919.783.2917
F: 252.972.7045
kburgess@poynerspruill.com

VIA EMAIL

Lisa Pittman, Assistant Chief
Ena Lightbourne, Project Analyst
Healthcare Planning and Certificate of Need Section
N.C. Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: **Mission Health System, Inc. Notice of Exemption Regarding Mission Imaging Services MRI Upgrade and Refurbishment**

Dear Lisa and Ena:

Our law firm represents Mission Health System, Inc. ("Mission"), which owns and operates an existing MRI Scanner located at Mission Imaging Services, 222 Asheland Avenue, Asheville, N.C. Mission plans to undertake a refurbishment and upgrading of the existing MRI scanner at Mission Imaging Services ("Mission Imaging"), the details of which are explained below ("the Upgrade" or "the Project"). The purpose of this letter is to request that the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("the CON Section") confirm that the refurbishment and upgrading of Mission's existing MRI Scanner at Mission Imaging is exempt from certificate of need ("CON") review within the meaning of N.C. Gen. Stat. §131E-184(a)(7).

The CON Statute does not contain an express exemption for the refurbishment or upgrading of existing medical equipment. However, based upon our conversations with CON Section representatives and our review of recent correspondence between other health care providers and the CON Section involving similar equipment upgrades, it appears that the CON Section has analyzed equipment upgrades and refurbishments under the exemption set forth at N.C. Gen. Stat. § 131E-184(a)(7) governing "replacement equipment." As such, we are presenting this notification in that context. Alternatively, this project could be analyzed in the context of a "No Review Analysis" because it does not fit within any of the "new institutional health service" definitional elements set forth at N.C. Gen. Stat. § 131E-176(16) which would trigger the need for CON Section review and a CON. See Attachment 1 (June 1, 2018 correspondence from the CON Section to counsel for Carolinas Medical Center approving an upgrade of existing MRI equipment as replacement equipment under N.C. Gen. Stat. § 131E-184(a)(7)).

Background

The existing MRI at Mission Imaging is a GE Signa HDxt 3T scanner. That scanner was purchased new in 2008 and is nearing the end of its useful life. As such, Mission plans to upgrade and refurbish the scanner at the same site and in the same physical location within Mission Imaging as the existing scanner. During the Project, the MRI magnet and core will not be removed or replaced. However, numerous other components of the MRI will be replaced and upgraded. Specifically, the Project will involve the replacement of major electrical and computer systems; renovation of the existing MRI room; and infrastructure upgrades to accommodate the refurbished MRI. See Attachment 2 (letter from GE

Client Executive J. Donovan describing core elements of the Project). The improvements, when completed, will yield a GE Signa Premier 3T MRI scanner system.

For the reasons set forth below, Mission's upgrade and refurbishment of the existing MRI Scanner is exempt from CON review pursuant to N.C. Gen. Stat. §131E-184(a)(7).

Applicable Legal Authorities

The CON Law precludes any person from offering or developing a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178(a). The definition of "new institutional health service" includes, *inter alia*, the following:

- The acquisition by purchase, donation, lease, transfer or comparable arrangement of "major medical equipment," which is defined as a single unit or single system of components used to provide medical and health services which costs more than \$750,000.00, including the costs of the equipment and all studies, drawings, installation and any other activities essential to acquiring and making the equipment operational.

N.C. Gen. Stat. §§ 131E-176(16)(b), (16)(p) and (14o). However, the CON Law contains a specific exemption applicable to "replacement equipment" that costs less than \$2,000,000.00.

Statutory Exemption For Replacement Equipment Which Costs Less Than \$2,000,000.00

N.C. Gen. Stat. §131E-184(a)(7) provides an express exemption from CON review for the acquisition and installation of "replacement equipment" costing less than \$2,000,000.00, provided that the CON Section receives prior written notice from the party proposing to acquire the equipment which explains why the proposed acquisition and installation qualifies under this exemption. The statute and accompanying regulations further define "replacement equipment" as follows:

Equipment that costs less than two million dollars (\$2,000,000.00) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In calculating the total cost of the replacement equipment, the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value or the cost of the equipment, whichever is greater.

N.C. Gen. Stat. §131E-176(22a). Replacement equipment is "comparable" to the equipment being replaced if:

1. it has the same technology as the equipment currently in use, 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 the equipment currently in use and is not used to provide a new health service; and
3. the acquisition of the equipment 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.

10A N.C. Admin. Code 14C .0303(d)(1)-(3).¹

Refurbishing and Upgrading the Existing MRI Scanner at Mission Imaging Is Exempt
From CON Review Under These Authorities

The upgrading and refurbishment of the existing GE Signa HDxt 3T scanner at Mission Imaging falls within the parameters of this exemption because:

1. The equipment being upgraded is currently in use at Mission. See Exhibit 3.
2. The total estimated cost of the project is \$1,999,327.00,² placing the project within the parameters of the statutory exception set forth at N.C. Gen. Stat. §131E-184(a)(7). The total project costs consist of equipment costs of \$1,627,236.00, related construction and materials costs, architect and engineering fees and a generous contingency. See Exhibits 4 (certified Total Capital Cost Worksheet) and 5 (applicable excerpt of price quotation from GE Healthcare).
3. The upgraded MRI scanner will have the same capabilities as the scanner being upgraded, although it may have additional capabilities due to the advancement of MRI scanner technology, is functionally similar to the existing MRI scanner and will be used for the same diagnostic or treatment purposes as the equipment being upgraded. See Exhibit 3.
4. The Project will not increase patient charges or per procedure operating expenses more than 10% within 12 months of the upgraded equipment being installed and becoming operational. See Exhibit 3.³

Temporary Use of a Mobile MRI During Completion of Existing MRI Upgrade and Refurbishing

In order to prevent the interruption of MRI services to Mission patients during the upgrade and refurbishment of Mission Imaging's existing MRI Scanner, Mission will lease a mobile MRI scanner from Insight Health Corporation to provide mobile MRI services at Mission Imaging. The mobile MRI will operate only while Mission's existing scanner at Mission Imaging is out of service and its use will be

¹ Pursuant to 10A NCAC 14C .0303, equipment does not qualify as "replacement equipment" where equipment which was second-hand or reconditioned is being replaced with new equipment within three (3) years of the acquisition of the equipment being replaced, or leased equipment is being replaced with purchased equipment. The existing MRI scanner which is being upgraded was purchased new in 2008. As such, 10A NCAC 14C .0103 does not apply to this Project.

² In calculating construction costs, our clients relied upon prior Agency determinations that the construction costs "essential to acquiring and making operational the replacement equipment" should include only those costs directly related to removing the old equipment, installing the new equipment and making sure that equipment operates properly. In the case of a CT scanner, for example, such cost should include upfit of the CT room related solely to the operation of the CT scanner (e.g., shielding, extra electrical connections), but need not include other construction costs associated with that room. Similarly, the Agency has previously determined that costs associated with the installation of equipment in the control room for the CT scanner should be included only to the extent that those costs would be different from construction related to general office space. Mission Hospitals, Inc. v. NC DHHS, ___ N.C.App. ___, 696 S.E.2d 163 (2010).

³ Pursuant to N.C. Gen. Stat. § 131E-176(22a), existing equipment which is being replaced must be sold or disposed of upon installation of the new replacement equipment. Because this Project involves the upgrading of existing equipment, there is no existing equipment to be sold or disposed of, and that element of N.C. Gen. Stat. § 131E-176(22a) is, therefore, not applicable.

Lisa Pittman, Assistant Chief
October 8, 2018
Page 4

Poyner Spruill^{LLP}

terminated once the existing MRI refurbishment and upgrading project is completed and the upgraded MRI is back online and in use. We have confirmed verbally with CON Section officials that the use of a mobile MRI in lieu of Mission's existing, fixed MRI during this project is permitted since the mobile MRI is essentially operating under Mission's existing authorization for its fixed MRI scanner which will be out of operation during the refurbishment and upgrading project. Unless indicated otherwise by the CON Section's response to this correspondence, we will assume that the CON Section's written confirmation that the refurbishment and upgrading of the existing MRI at Mission Imaging is exempt from CON Section review includes the interim use of the mobile MRI as described herein.

Conclusion

For the reasons set forth herein, we believe the proposed upgrading and refurbishment of Mission's existing MRI Scanner is exempt from CON review and that no CON is required for the Project. We respectfully request that the CON Section provide written confirmation that Mission may proceed with the Project as described without CON Section Review and without obtaining a CON.

Please feel free to let me know if you have questions or need additional information regarding this project.

Very truly yours,



Kenneth L. Burgess
Partner

cc: Garrett Shreffler

Attachments

October 8, 2018

Kenneth L. Burgess
Partner
D: 919.783.2917
F: 252.972.7046
kburgess@poynersprull.com

VIA EMAIL

Lisa Pittman, Assistant Chief
Ena Lightbourne, Project Analyst
Healthcare Planning and Certificate of Need Section
N.C. Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: *Mission Health System, Inc. Notice of Exemption Regarding Mission Imaging Services MRI Upgrade and Refurbishment*

Dear Lisa and Ena:

Our law firm represents Mission Health System, Inc. ("Mission"), which owns and operates an existing MRI Scanner located at Mission Imaging Services, 222 Asheland Avenue, Asheville, N.C. Mission plans to undertake a refurbishment and upgrading of the existing MRI scanner at Mission Imaging Services ("Mission Imaging"), the details of which are explained below ("the Upgrade" or "the Project"). The purpose of this letter is to request that the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("the CON Section") confirm that the refurbishment and upgrading of Mission's existing MRI Scanner at Mission Imaging is exempt from certificate of need ("CON") review within the meaning of N.C. Gen. Stat. §131E-184(a)(7).

The CON Statute does not contain an express exemption for the refurbishment or upgrading of existing medical equipment. However, based upon our conversations with CON Section representatives and our review of recent correspondence between other health care providers and the CON Section involving similar equipment upgrades, it appears that the CON Section has analyzed equipment upgrades and refurbishments under the exemption set forth at N.C. Gen. Stat. § 131E-184(a)(7) governing "replacement equipment." As such, we are presenting this notification in that context. Alternatively, this project could be analyzed in the context of a "No Review Analysis" because it does not fit within any of the "new institutional health service" definitional elements set forth at N.C. Gen. Stat. § 131E-176(16) which would trigger the need for CON Section review and a CON. See Attachment 1 (June 1, 2018 correspondence from the CON Section to counsel for Carolinas Medical Center approving an upgrade of existing MRI equipment as replacement equipment under N.C. Gen. Stat. § 131E-184(a)(7)).

Background

The existing MRI at Mission Imaging is a GE Signa HDxt 3T scanner. That scanner was purchased new in 2008 and is nearing the end of its useful life. As such, Mission plans to upgrade and refurbish the scanner at the same site and in the same physical location within Mission Imaging as the existing scanner. During the Project, the MRI magnet and core will not be removed or replaced. However, numerous other components of the MRI will be replaced and upgraded. Specifically, the Project will involve the replacement of major electrical and computer systems; renovation of the existing MRI room; and infrastructure upgrades to accommodate the refurbished MRI. See Attachment 2 (letter from GE

Client Executive J. Donovan describing core elements of the Project). The improvements, when completed, will yield a GE Signa Premier 3T MRI scanner system.

For the reasons set forth below, Mission's upgrade and refurbishment of the existing MRI Scanner is exempt from CON review pursuant to N.C. Gen. Stat. §131E-184(a)(7).

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10A N.C. Admin. Code 14C .0303(d)(1)-(3).¹

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2. The total estimated cost of the project is \$1,999,327.00,² placing the project within the parameters of the statutory exception set forth at N.C. Gen. Stat. §131E-184(a)(7). The total project costs consist of equipment costs of \$1,627,236.00, related construction and materials costs, architect and engineering fees and a generous contingency. See Exhibits 4 (certified Total Capital Cost Worksheet) and 5 (applicable excerpt of price quotation from GE Healthcare).
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purchased equipment. The existing MRI scanner which is being upgraded was purchased new in 2008. As such, 10A NCAC 14C .0103 does not apply to this Project.

² In calculating construction costs, our clients relied upon prior Agency determinations that the construction costs "essential to acquiring and making operational the replacement equipment" should include only those costs directly related to removing the old equipment, installing the new equipment and making sure that equipment operates properly. In the case of a CT scanner, for example, such cost should include upfit of the CT room related solely to the operation of the CT scanner (e.g., shielding, extra electrical connections), but need not include other construction costs associated with that room. Similarly, the Agency has previously determined that costs associated with the installation of equipment in the control room for the CT scanner should be included only to the extent that those costs would be different from construction related to general office space. Mission Hospitals, Inc. v. NC DHHS, ___ N.C.App. ___, 696 S.E.2d 163 (2010).

³ Pursuant to N.C. Gen. Stat. § 131E-176(22a), existing equipment which is being replaced must be sold or disposed of upon installation of the new replacement equipment. Because this Project involves the upgrading of existing equipment, there is no existing equipment to be sold or disposed of, and that element of N.C. Gen. Stat. § 131E-176(22a) is, therefore, not applicable.

Lisa Pittman, Assistant Chief
October 8, 2018
Page 4

that the refurbishment and upgrading of the existing MRI at Mission Imaging is exempt from CON Section review includes the interim use of the mobile MRI as described herein.

Conclusion

For the reasons set forth herein, we believe the proposed upgrading and refurbishment of Mission's existing MRI Scanner is exempt from CON review and that no CON is required for the Project. We respectfully request that the CON Section provide written confirmation that Mission may proceed with the Project as described without CON Section Review and without obtaining a CON.

Please feel free to let me know if you have questions or need additional information regarding this project.

Very truly yours,

Kenneth L. Burgess
Partner

cc: Garrett Shreffler

Attachments

ATTACHMENT 1



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

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

June 1, 2018

Gary S. Qualls
430 Davis Drive, Suite 400
Morrisville, NC 27560

Exempt from Review - Replacement Equipment
Record #: 2586
Facility Name: Carolinas Medical Center
FID #: 943070
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Replace virtually all components of an existing MRI scanner except for the magnet
County: Mecklenburg

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of May 18, 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 upgraded replacement components of the MRI scanner referenced in your letter to replace the existing components of the MRI scanner.

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,

Julie M. Faenza
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: 609 Ruggles Drive, Edison Building, Raleigh, NC 27603
MAILING ADDRESS: 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhs.gov/dhsr • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

K&L GATES



May 18, 2018

Gary S. Qualls
D 919.466.1182
F 919.316.2182
gary.qualls@kligates.com

Via Hand Delivery

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

RE: Carolinas Medical Center – No Review Request or, in the alternative, Exemption
Notice for Upgrade of Existing MRI Scanner, Mecklenburg County

Dear Ms. Frisone:

Our client, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (“CMC”) is requesting a “No Review” determination that an upgrade (the “Upgrade”) to the electronics and equipment in the control room associated with the operation of its existing 3T MRI Scanner is not reviewable as a new institutional health service under the North Carolina Certificate of Need (“CON”) law, and does not otherwise triggers CON review.

The MRI Scanner requiring the Upgrade is a Siemens Verio 3T MRI with a serial number of 40230. This MRI Scanner was replaced pursuant to an Exempt from Review Letter issued on July 13, 2009 (Exhibit 1) and is located at the Morehead Imaging Center on CMC’s Main Campus. There are three rooms associated with the operation of the MRI Scanner; (1) one for the magnet itself; (2) one for the electronics; and (3) a control room. The Upgrade will be for the electronics and the equipment located in the control room, along with some covers for the magnet. The magnet itself will not otherwise be involved.

There are two key components to magnet strength and capability. The first component is the “tesla” strength. This is a 3T MRI versus the more typical 1.5T units and is located at the busiest outpatient imaging center in the CHS network. The facility is on the CMC main campus and provides imaging at a very advanced level, supporting research and progressive programs.

The second component is related to “gradient strength” and “channel capability.” With MRI, specifically 3T, robust gradients that can drive signal through a higher number of channels integrated into the systems coils will drive a much higher resolution, faster imaging speed, and an improved capability to differentiate between pathology at a very detailed level.

Martha J. Frisone, Chief
March 18, 2018
Page 2

Although all routine MRI exams will benefit from this, quantitative analysis becomes much more accurate and precise with advanced techniques like functional MRI or prostate segmentation for integration with biopsy guidance systems. With this, the planned upgrade will essentially replace every component of the MRI system except the magnet itself. The control console, operating system, electronics cabinets, gradients, and most of the coils will be replaced. With the higher gradient strength, the unit will go from a 16-channel capability to 48-channels. The newer operating system enhances throughput with the latest generation software and faster image reconstruction speed. This is an advance which will extend the useful life of this existing magnet.

The cost of the proposed Upgrade is \$1,001,722. See Exhibits 2 and 3. Exhibit 2 is the original Price Quotation and Exhibit 3 is the recent Revised Price Quotation, which modifies some of the original Price Quotation items and takes the total cost from \$900,000 to \$1,001,722. The few additional costs associated with the upgrade – per N.C. Gen. Stat. § 131E-176(16)(b) – are included in the capital cost sheet attached as Exhibit 4. The location of the upgrade is shown in the floor plans attached as Exhibits 5A and 5B.

Thus, the proposed Upgrade does not constitute a new institutional health service under N.C. Gen. Stat. § 131E-176(16)(b). Because the proposal pertains to the existing MRI Scanner, which has been operational for years at the current location, there is no new MRI Scanner or major medical equipment being acquired. Rather, this is merely an upgrade of the existing MRI Scanner. Accordingly, the proposed Upgrade does not require CMC to obtain a CON pursuant to any of the new institutional health service triggers in the CON statute.

Based upon the foregoing information and the attached document, CMC hereby requests that the Agency provide a written response confirming that the Upgrade described herein does not require a CON pursuant to any of the new institutional health service triggers in the CON statute.

If you have any questions about this request, please feel free to contact me.

Sincerely,


Gary S. Qualls

Martha J. Frisone, Chief
March 18, 2018
Page 3

Exhibits

1. Excerpt from Review Letter issued on July 13, 2009
2. Original Quote for MRI Scanner Upgrade
3. Modified and Updated Quote for MRI Scanner Upgrade
4. Capital Cost Sheet
5. Floor Plans showing MRI upgrade area (Exhibits 5A and 5B)

ATTACHMENT 2



GE Healthcare

September 27, 2018

Mrs. Rita Edwards
Chief Ancillary Officer
Mission Health System, Inc
509 Biltmore Avenue
Asheville, NC 28801

Dear Mrs. Edwards:

This letter is to inform you that GE Healthcare will be performing an upgrade on the current 3T MRI located at 222 Asheland Avenue in Asheville. This upgrade will entail new electronics but the magnet itself will remain at the site and will not be removed or replaced. We will be ramping down the current magnet during the electronics upgrade and will re-ramp the system once the upgrade is completed to make it available for patient use.

Please let me know if you have any questions or concerns. I can be reached at 864-415-3886.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Donovan'.

John Donovan
Client Executive
GE Healthcare
864-415-3886

ATTACHMENT 3



October 5, 2018, 2018

Re: Information/Items Needed for 3T MRI Replacement Exemption Letter to CON Section

To whom it may concern:

Mission Imaging Services will be upgrading one MRI scanner physically located at 222 Asheland Avenue, Asheville North Carolina. The MRI scanner is currently in use. The upgrade of this scanner will not result in more than a 10% increase in patient charges or per procedure operating expense within the first twelve months after upgrade. All new functionality associated with the new scanner will be due to advancement of technology.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Newman".

Michael Newman
Regional Director, Carolina Vascular & MISM
222 Asheland Avenue, NC 28801
Office 828-213-8163
Mobile 919-749-9946
Michael.newman@msj.org

ATTACHMENT 4

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: MISM 3T MRI

Provider/Company: Mission Health

A. Site Costs

(1) Full purchase price of land.....		\$ _____	
Acres _____ Price per Acre _____	\$ _____		
(2) Closing costs.....		\$ _____	
(3) Site Inspection and Survey.....		\$ _____	
(4) Legal fees and subsoll investigation		\$ _____	
(5) Site Preparation Costs			
Soil Borings.....	\$ _____		
Clearing-Earthwork ..	\$ _____		
Fine Grind For Slab...	\$ _____		
Roads-Paving.....	\$ _____		
Concrete Sidewalks...	\$ _____		
Water and Sewer.....	\$ _____		
Footing Excavation...	\$ _____		
Footing Backfill.....	\$ _____		
Termite Treatment...	\$ _____		
Other (Specify).....	\$ _____		
Sub-Total Site Preparation Costs:		\$ _____	
(6) Other (Specify)		\$ _____	
(7) Sub-Total Site Costs		\$ _____	

B. Construction Contract

(8) Cost of Materials			
General Requirements	\$ _____		
Concrete/Masonry	\$ _____		
Woods/Doors & Windows/Finishes	\$ _____		
Thermal & Moisture Protection	\$ _____		
Equipment/Specialty Items	\$ _____		
Mechanical/Electrical	\$ _____		
Other (Specify)	\$ _____		
Sub-Total Cost of Materials.....		\$155,964	
(9) Cost of Labor.....		\$103,976	
(10) Other		\$10,000	
(11) Sub-Total Construction Contract			\$269,940

C. Miscellaneous Project Costs

(12) Building Purchase.....		\$ _____	
(13) Fixed Equipment Purchase/Lease		\$1,627,236	
(14) Movable Equipment Purchase/Lease		\$ _____	
(15) Furniture		\$ _____	
(16) Landscaping		\$ _____	
(17) Consultant Fees			
Architect and Engineering Fees	\$47,000		
Legal Fees.....	\$ _____		
Market Analysis.....	\$ _____		
Other (Specify).....	\$ _____		
Other (Specify).....	\$7,000		
Sub-Total Consultant Fees.....		\$54,000	
(18) Financing Costs (e.g. Bond, Loan, etc.)		\$ _____	
(19) Interest During Construction		\$ _____	
(20) Other (contingency)		\$48,151	
(21) Sub-Total Miscellaneous			\$1,729,287
(22) Total Capital Cost of Project (Sum A-C above)			\$1,999,227

I certify that to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.

[Signature]
 (Signature of Licensed Architect or Engineer)

I assure that to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

[Signature]
 (Signature of Officer Authorized to Represent Provider/Company)
 (Title of Officer)

ATTACHMENT 5



GE Healthcare

Date: 07-02-2018
Quote #: PR13-C44351
Version #: 1
Q-Exp-Date: 09-26-2018

Issued By:
GE Healthcare
FEIN: 14-0689340

Customer Address:
Mission Imaging Services
222 Asheland Ave
Asheville NC 28801-4016

Attention:
William Moss
222 Asheland Ave Asheville
NC 28801-4016

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

- i) This Quotation that identifies the Product offerings purchased or licensed by Customer;
- ii) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranties; (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions. In the event of conflict among the foregoing terms, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above for the Governing Agreement, if any, shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation.

No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties.

Governing Agreement:	Mission Master Relationship Agreement
Customer Number:	I-248KLT
Terms of Delivery:	FOB Destination
Billing Terms:	80% delivery / 20% installation
Payment Terms:	NET 30
Total Quote Net Selling Price:	\$1,627,235.93
Sales And Use Tax Status:	No Exemption Certificate on File

** The following ship to states do not impose a sales/use tax (AK, DE, MT, NH, OR). No exemption certificate required.

INDICATE FORM OF PAYMENT:

If "GE HEF Loan" or "GE HEF Lease" is NOT selected at the time of signature, then you may NOT elect to seek financing with GE Healthcare Equipment Finance (GE HEF) to fund this arrangement after shipment.

Cash/Third Party Loan/Check GE HEF Loan
 GE HEF Lease Third Party Lease (please identify financing company)

By signing below, each party certifies that it (i) has received a complete copy of this Quotation, including the GE Healthcare terms, conditions and warranties, and (ii) has not made any handwritten or electronic modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

Each party has caused this agreement to be executed by its duly authorized representative as of the date set forth below.

CUSTOMER

Authorized Customer Signature Date

Print Name Print Title

Purchase Order Number (if applicable)

GE HEALTHCARE

Kevin Morris 07-02-2018

Signature Date

Imaging Account Manager

Email: Kevin.Morris@ge.com
Office: +1 803 608 2460
Mobile: 803-608-2460



GE Healthcare

Date: 07-02-2018
Quote #: PR13-C44351
Version #: 1
Q-Exp-Date: 09-26-2018

Total Quote Selling Price	\$1,676,735.93
Trade-in and Other Credits	\$49,500.00
Total Quote Net Selling Price	\$1,627,235.93

To Accept this Quotation
Please sign and return this Quotation together with your Purchase Order To:
Anthony Morris
Office: +1 803 608 2460
Mobile: 803-608-2460
Email: Kevin.Morris@ge.com

Payment instructions
Please Remit Payment for invoices associated with this quotation to:
GE Healthcare
P.O. Box 96483
Chicago, IL 60693

To Accept This Quotation

- Please sign the quote and any included attachments (where requested).
- If requested, please indicate your form of payment.
- If you include the purchase order, please make sure it references the following information
 - The correct Quote number and version number above
 - The correct Remit To information as indicated in "Payment Instructions" above
 - The correct SHIP TO site name and address
 - The correct BILL TO site name and address
 - The correct Total Quote Net Selling Price as indicated above

*Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms. Signature page on quote filled out with signature and P.O. number.

Verbiage on the purchase order must state one of the following: (i) Per the terms of Quotation # _____; (ii) Per the terms of GPO# _____; (iii) Per the terms of MPA # _____; or (iv) Per the terms of SAA # _____. Include the applicable quote/agreement number with the reference on the purchase order. In addition, source of funds (choice of: Cash/Third Party Loan or GE HEF Lease or GE HEF Loan or Third Party Lease through _____) must be indicated, which may be done on the quote signature page (for signed quotes), on the purchase order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare)."