



**NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES**

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

October 31, 2018

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

Exempt from Review – Replacement Equipment

Record #: 2749
Facility Name: Mission Hospital
FID #: 943349
Business Name: Mission Health System, Inc.
Business #: 2948
Project Description: Replacement of an Existing CT scanner
County: Buncombe

Dear Mr. Burgess:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of October 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 GE Revolution EVO CT scanner to replace the existing GE VCT LightSpeed CT scanner. 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, Radiation Protection 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,

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



October 18, 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 for Replacement of CT Scanner No. 2 on Main Campus**

Dear Lisa and Ena:

I'm writing on behalf of our client, Mission Health System, Inc. ("Mission"), to provide advance written notice to the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("the CON Section") of Mission's intent to acquire and install certain replacement equipment currently located at the main hospital. Mission owns and operates a CT scanner now located in the hospital's Radiology Department on the Mission main campus at 509 Billmore Avenue in Asheville, North Carolina ("CT Scanner No. 2"). Mission now desires to replace that CT scanner at the same site within the Radiology Department. I am writing to provide advance written notice of the acquisition of replacement equipment as required under N.C. Gen. Stat. § 131E-184(a)(7) and to request that the CON Section provide written confirmation that the replacement of the CT scanner on the Mission main campus is exempt from certificate of need ("CON") review within the meaning of N.C. Gen. Stat. §131E-184(a)(7).

The existing scanner is a GE VCT Model # 5212920-300, serial number 407657CN6, which was acquired by Mission in 2009 and was new when acquired. Mission proposes to replace the existing scanner with a GE Revolution EVO CT scanner. See Exhibit 1, Letter from John Donovan, Client Executive with GE Healthcare and Exhibit 4 (excerpted GE Healthcare quotation).

As further explained in the remainder of this correspondence, Mission's replacement of the existing CT Scanner No. 2 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

Lisa Pittman, Assistant Chief
October 18, 2018
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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) and (p). However, the CON Law contains a specific exemption which applies to replacement equipment that costs less than \$2,000,000.00. This exemption is described below.

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

Replacement Of Mission's CT Scanner No. 2 Is Exempt From CON Review Under These Authorities

The replacement of CT Scanner No. 2 at Mission falls within the parameters of this exemption because:

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. This section does not apply to Mission's replacement of CT Scanner No. 2 because the existing scanner was new when purchased. See Exhibit 2.

Lisa Pittman, Assistant Chief
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1. The equipment being replaced is part of the Mission Health system, and is located in the hospital's Radiology Department on the hospital's main campus. See Exhibit 2 (Letter from Libby Dore, Executive Director of Imaging Services at Mission Hospital stating that the existing CT Scanner is located on the hospital's main campus which will also be the site of the replacement scanner).
2. The equipment being replaced is currently in use at Mission. See Exhibit 2 (letter from Libby Dore).
3. The total estimated cost of the project is \$1,085,000.00,² placing the project well within the terms of the statutory exception set forth at N.C. Gen. Stat. §131E-184(a)(7). This estimated project cost is inclusive of equipment and related installation costs required to make the CT scanner operational, including a generous contingency. See Exhibits 3 (Certified Total Capital Cost Worksheet) and 4, (Price Quotation from GE Healthcare).
4. The CT Scanner which will be replaced will be sold or otherwise disposed of upon acquisition and installation of the replacement scanner. The existing scanner will be removed by and returned to GE Healthcare. See Exhibit 1 (letter from John Donovan, Client Executive, GE Healthcare).
5. The CT Scanner being replaced was new when purchased by Mission and is more than three years old. See Exhibit 2.
6. The new CT Scanner will have the same capabilities as the scanner being replaced, although it may have additional capabilities due to the advancement of CT scanner technology, is functionally similar to the existing CT scanner and will be used for the same diagnostic or treatment purposes as the equipment being replaced. See Exhibit 2.
7. The project will not increase patient charges or per procedure operating expenses more than 10% within 12 months of the replacement equipment being acquired. See Exhibit 2.

Interim Temporary Use of Mobile CT Scanner During Completion of Replacement Project

In order to prevent the interruption of imaging services to Mission patients during the replacement of Mission's CT Scanner No. 2, Mission will lease a mobile CT scanner from Insight Health Corporation to provide mobile CT services. The mobile CT scanner will operate only while Mission's existing CT Scanner No. 2 is out of service and its use will be terminated once the existing CT Scanner No. 2

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, 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).

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October 18, 2018
Page 4

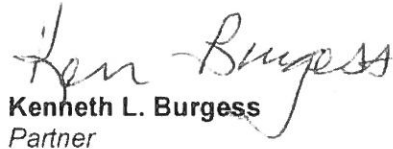
replacement project is completed and the new scanner is online and in use. We have confirmed verbally with CON Section officials that the use of a mobile CT scanner in lieu of Mission's existing, fixed CT scanner during this project is permitted since the mobile scanner is essentially operating under Mission's existing authorization for its fixed CT scanner which will be out of operation during the replacement 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 replacement of Mission's CT Scanner No. 2 is exempt from CON Section review includes the interim use of the mobile CT Scanner as described herein.

Conclusion

As described above, we believe the proposed replacement of Mission's existing CT Scanner No. 2 is exempt from CON review and that no CON is required for the project. We respectfully request that you review the attached documentation and confirm that this is the case.

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 Schreffler
Sonya Greck

Attachments

ATTACHMENT 1



October 5, 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 removing the GE LightSpeed VCT CT Scanner from Mission Hospital on trade as part of the purchase of the GE Revolution EVO CT Scanner. The LightSpeed VCT will be returned to GE Healthcare and will not be reinstalled in the state of NC without the proper CON.

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

Sincerely,

John L. Donovan

John Donovan
Client Executive
GE Healthcare
864-415-3886

ATTACHMENT 2



September 24, 2018

Re: Information/Items Needed for CT scanner replacement Exemption Letter to CON Section

To Whom It May Concern:

Mission Hospital will be replacing our existing CT scanner that is physically located at Memorial Main Campus, 509 Biltmore Avenue in Asheville, NC, Radiology Department, Room F227.06. The scanner to be replaced is currently in use. The replacement 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 replacement. The scanner being replaced was purchased new when acquired and the replacement scanner will be a new unit. All new functionality associated with the new scanner will be due to advancement of technology. The existing equipment will be traded in as part of the purchase of the new equipment.

Best Regards,

A handwritten signature in cursive script that reads "Libby Dore".

Libby Dore, MBA, CRA, RT(R), (BD)

Executive Director, Imaging Services

509 Biltmore Avenue

Asheville, NC 28801

828-213-1333

libby.dore@msj.org

ATTACHMENT 3



GE Healthcare

Date: 06-15-2018
Quote #: PR10-C118645
Version #: 6
Q-Exp-Date: 09-11-2018

| | |
|--------------------------------------|---------------------|
| Total Quote Selling Price | \$800,500.70 |
| Trade-In and Other Credits | \$110,000.00 |
| | ----- |
| Total Quote Net Selling Price | \$690,500.70 |

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.

*****OR*****

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).*



GE Healthcare

Date: 06-15-2018
Quote #: PR10-C118645
Version #: 6
Q-Exp-Date: 09-11-2018

| Item No. | Qty | Catalog No. | Description | Contract Price | Discount | Ext Sell Price |
|----------|----------|-------------|---|----------------|----------|----------------|
| | 1 | | Revolution EVO** | | | |
| 1 | 1 | S7880EL | <p>Revolution EVO System - EL configuration</p> <p>Today's healthcare environment is about creating new solutions to pressing needs. It's about understanding how one CT exam can improve patient outcomes while lowering the cost of providing care. Revolution EVO is designed with the purpose of operating in this new reality, while anticipating the challenges of tomorrow. It's designed to support the widest variety of patients and applications, from complex trauma or cardiac cases, to large patient backlogs in busy emergency departments that strain workflows and resources. The design of Revolution EVO is made for institutions that are unable to sacrifice advanced capabilities such as high resolution for daily productivity. It is well suited for those who need to provide the lowest dose possible. And it provides options to expand your referral physician base and the services you provide to your community.</p> <p>Revolution EVO is the next generation Volume CT with compact design and advanced technologies including Clarity Imaging system delivering up to 0.28mm of spatial resolution enabling you to see fine anatomical details, providing a pathway to a quick, confident diagnosis and delivering vastly improved image</p> | \$1,300,000.00 | 56.50% | \$565,500.00 |

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: MMH CT W/ FLUORO

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 subsoil investigation | | \$ _____ | |
| (5) Site Preparation Costs | | | |
| Soil Borings..... | \$ _____ | | |
| Clearing-Earthwork... | \$ _____ | | |
| Fine Grade 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..... | | \$135,000 | |
| (9) Cost of Labor..... | | \$90,000 | |
| (10) Other (misc. and mobile CT)..... | | \$118,500 | |
| (11) Sub-Total Construction Contract | | | \$343,500 |

C. Miscellaneous Project Costs

| | | | |
|---|----------|--------------|-----------------------|
| (12) Building Purchase..... | | \$ _____ | |
| (13) Fixed Equipment Purchase/Lease | | \$690,500.70 | |
| (14) Movable Equipment Purchase/Lease | | \$ 2,000 | |
| (15) Furniture | | \$ _____ | |
| (16) Landscaping | | \$ _____ | |
| (17) Consultant Fees | | | |
| Architect and Engineering Fees | \$10,000 | | |
| Legal Fees..... | \$ _____ | | |
| Market Analysis..... | \$ _____ | | |
| Other (Specify)..... | \$ _____ | | |
| Other (Specify)..... | \$5,500 | | |
| Sub-Total Consultant Fees..... | | \$15,500 | |
| (18) Financing Costs (e.g. Bond, Loan, etc.) | | \$ _____ | |
| (19) Interest During Construction. | | \$ _____ | |
| (20) Other (contingency) | | \$33,499.30 | |
| (21) Sub-Total Miscellaneous.. | | | \$741,500.00 |
| (22) Total Capital Cost of Project (Sum A-C above) | | | \$1,085,000.00 |

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

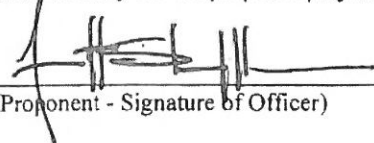


10.18.18

Date Certified: _____

(Signature of Licensed Architect or Engineer)

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


 (Proponent - Signature of Officer)

Director, Facility Planning Design & Construction Date Signed: 10.18.2018
 (Title of Officer)

ATTACHMENT 4



GE Healthcare

Date: 06-15-2018
Quote #: PR10-C118645
Version #: 6
Q-Exp-Date: 09-11-2018

Issued By:
GE Healthcare
FEIN: 14-0689340

Customer Address:
Mission Hospitals Inc
509 Biltmore Ave
Asheville NC 28801-4601

Attention:
Rita Edwards
509 Biltmore Ave Asheville
NC 28801-4601

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:

- 1) This Quotation that identifies the Product offerings purchased or licensed by Customer;
- 2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (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 items, 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 (or 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: | 1-23R6UV |
| Terms of Delivery: | FOB Destination |
| Billing Terms: | 80% delivery / 20% Installation |
| Payment Terms: | NET 30 |
| Total Quote Net Selling Price: | \$690,500.70 |
| 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. | |
| <input type="checkbox"/> Cash/Third Party Loan/Check | <input type="checkbox"/> GE HEF Loan |
| <input type="checkbox"/> GE HEF Lease | <input type="checkbox"/> 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 06-15-2018

Signature Date

Imaging Account Manager

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