



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

Roy Cooper
Governor

Dempsey E. Benton
Interim Secretary DHHS

Mark Payne, Director
Health Service Regulation

May 10, 2017

Kristy Hubard
2131 South 17th Street
Wilmington, NC 28402

No Review

Record #: 2144
Facility Name: New Hanover Regional Medical Center
FID #: 943372
Business Name: New Hanover Regional Medical Center
Business #: 1308
Project Description: Acquire additional CT scanner
County: New Hanover

Dear Ms. Hubard:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of November 18, 2016, additional information received December 9, 2016, and the March 15, 2017 letter from Ms. Gunter 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 your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that 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.

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

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the

Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,



Tanya S. Rupp
Project Analyst



Martha J. Frisone
Assistant Chief, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR
Denise Gunter, Nelson Mullins Riley & Scarborough LLP

Nelson Mullins

Nelson Mullins Riley & Scarborough LLP

Attorneys and Counselors at Law
380 Knollwood Street / Suite 530 / Winston-Salem, NC 27103
Tel: 336.774.3300 Fax: 336.774.3372
www.nelsonmullins.com

Denise M. Gunter
Tel: 336.774.3322
Fax: 336.774.3372
denise.gunter@nelsonmullins.com

March 15, 2017

Hand Delivered

Tanya S. Rupp, JD
Project Analyst
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: New Hanover Regional Medical Center ("NHRMC")
CT Scanner Acquisition Request

Dear Tanya:

This letter is a follow up to Kristy Hubard's November 18, 2016 no review request to acquire a CT Scanner (the "CT Scanner Project") at NHRMC's Military Cutoff Road ("MCR") facility, located at 1135 Military Cutoff Road in Wilmington (the "MCR Location"). The MCR Location is a provider-based, outpatient department of NHRMC. The total capital cost for the CT Scanner Project is \$419,355, which is well below the "major medical equipment" threshold of \$750,000 in N.C. Gen. Stat. § 131E-176(14o). I understand that following Ms. Hubard's submission, you and Ms. Hubard exchanged some emails about the CT Scanner Project. In your February 13 email to Ms. Hubard, you cited the definition of "hospital" in N.C. Gen. Stat. § 131E-76(3) (amended as of August 26, 2009) which excludes from the definition of hospital "any outpatient department including a portion of a hospital operated as an outpatient department, on or off the hospital's main campus, that is operated under the hospital's control or ownership and is classified as Business Occupancy by the Life Safety Code of the National Fire Protection Association as referenced under 42 CFR 482.41." A copy of the amendment, showing its effective date, is attached as **Exhibit A**.

For several years, Alliance Medical Imaging Solutions, LLC ("Alliance") operated the MCR Location as an imaging facility. The MCR Location was not a diagnostic center

Tanya S. Rupp, JD
March 15, 2017
Page 2

pursuant to N.C. Gen. Stat. § 131E-176(7a) as the total cost of the medical diagnostic equipment at the MCR Location that cost more than \$10,000 did not exceed \$500,000.

NHRMC acquired the MCR Location from Alliance on June 30, 2009, before the law changed on August 26, 2009. Accordingly, the above-referenced amendment to § 131E-76(3) does not apply. There is nothing in the amendment to indicate that the General Assembly intended it to apply retroactively. Therefore, the MCR Location is part of the hospital. "It is a well-established rule of construction in North Carolina that a statute is presumed to have prospective effect only and should not be construed to have a retroactive application unless such an intent is clearly expressed or arises by necessary implication from the terms of the legislation." *State v. Green*, 350 N.C. 400, 404, 514 S.E.2d 724, 727 (citation omitted), *cert. denied*, 527 U.S. 1066 (1999). NHRMC acquired the MCR Location with the intention of operating it as part of the hospital. Applying the amendment to N.C. Gen. Stat. § 131E-76 to a transaction that occurred before the amendment took effect would "alter the legal consequences of conduct or transactions completed prior to its enactment." *Gardner v. Gardner*, 300 N.C. 715, 718, 268 S.E.2d 468, 471 (1980); *see also Wood v. J.P. Stevens & Co.*, 297 N.C. 636, 650, 256 S.E.2d 692, 701 (1979) (retroactive application of a statute is unconstitutional "when it interferes with rights which had vested or liabilities which had accrued prior to its passage."). Therefore, a retroactive application of amended § 131E-76(3) is impermissible under North Carolina law.

Since the MCR Location is part of NHRMC, the diagnostic center threshold of \$500,000 does not apply. Rather, the applicable threshold is the major medical equipment threshold of \$750,000. *See* N.C. Gen. Stat. § 131E-176(14o). Since the total cost of the CT Scanner Project is \$419,355, the major medical equipment threshold is not reached. No other provision of the CON potentially applies to the CT Scanner Project. NHRMC respectfully requests that the CON Section confirm in writing that the CT Scanner Project does not require a CON.

Please let me know if you have any questions. Thank you in advance for your prompt reply.

With best personal regards.

Sincerely,



Denise M. Gunter



Enclosure

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2009

SESSION LAW 2009-487
HOUSE BILL 1297

AN ACT PERTAINING TO THE CREDENTIALING OF HEALTH CARE PROVIDERS UNDER HEALTH BENEFIT PLANS; ADDING A DEFINITION, AND AMENDING NOTICE AND CONTRACT NEGOTIATION PROVISIONS FOR HEALTH BENEFIT PLAN AND PROVIDER CONTRACTING; CLARIFYING A CON EXEMPTION CRITERION; AND MODIFYING INSPECTION PRACTICES OF CERTAIN HOSPITAL OUTPATIENT LOCATIONS.

The General Assembly of North Carolina enacts:

SECTION 1. G.S. 58-3-230 reads as rewritten:

"§ 58-3-230. Uniform provider credentialing.

(a) An insurer that provides a health benefit plan and that credentials providers for its networks shall maintain a process to assess and verify the qualifications of a licensed health care practitioner within 60 days of receipt of a completed provider credentialing application form approved by the Commissioner. If the insurer has not approved or denied the provider credentialing application form within 60 days of receipt of the completed application, upon receipt of a written request from the applicant and within five business days of its receipt, the insurer shall issue a temporary credential to the applicant if the applicant has a valid North Carolina professional or occupational license to provide the health care services to which the credential would apply. The insurer shall not issue a temporary credential if the applicant has reported on the application a history of medical malpractice claims, a history of substance abuse or mental health issues, or a history of Medical Board disciplinary action. The temporary credential shall be effective upon issuance and shall remain in effect until the provider's credentialing application is approved or denied by the insurer. When a health care practitioner joins a practice that is under contract with an insurer to participate in a health benefit plan, the effective date of the health care practitioner's participation in the health benefit plan network shall be the date the insurer approves the practitioner's credentialing application.

(b) The Commissioner shall by rule adopt a uniform provider credentialing application form that will provide health benefit plans with the information necessary to adequately assess and verify the qualifications of an applicant. The Commissioner may update the uniform provider credentialing application form, as necessary. No insurer that provides a health benefit plan may require an applicant to submit information that is not required by the uniform provider credentialing application form.

(c) As used in this section, the terms "health benefit plan" and "insurer" shall have the meaning provided under G.S. 58-3-167."

SECTION 2.(a) G.S. 58-50-270, as enacted by S.L. 2009-352, is amended by adding a new subdivision to read:

"(3a) 'Health care provider' – An individual who is licensed, certified, or otherwise authorized under Chapter 90 or Chapter 90B of the General Statutes or under the laws of another state to provide health care services in the ordinary course of business or practice of a profession or in an approved education or training program and a facility that is licensed under Chapter 131E or Chapter 122C of the General Statutes or is owned or operated by the State of North Carolina in which health care services are provided to patients."

SECTION 2.(b) G.S. 58-50-271(b), as enacted by S.L. 2009-352, reads as rewritten:

"(b) ~~Date of receipt for~~ Means for sending all notices provided under a contract shall be one or more of the following, calculated as (i) five business days following the date the notice is placed, first-class postage prepaid, in the United States ~~mail~~; mail; (ii) on the day the notice is



hand delivered; (iii) for certified or registered mail, the date on the return receipt; or (iv) for commercial courier service, the date of delivery. Nothing in this section prohibits the use of an electronic medium for a communication other than an amendment if agreed to by the insurer and the provider."

SECTION 2.(c) G.S. 58-50-272, as enacted by S.L. 2009-352, is amended by adding a new subsection to read:

"(d) Nothing in this Part prohibits a health care provider and insurer from negotiating contract terms that provide for mutual consent to an amendment, a process for reaching mutual consent, or alternative notice contacts."

SECTION 3. G.S. 131E-184(e), as enacted by Session Law 2009-145, reads as rewritten:

"(e) The Department shall exempt from certificate of need review a capital expenditure that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(16)b. if all of the following conditions are met:

- (1) The proposed capital expenditure would:
 - a. Be used solely for the purpose of renovating, replacing on the same site, or expanding an existing:
 1. Nursing home facility,
 2. Adult care home facility, or
 3. Intermediate care facility for the mentally retarded; and
 - b. Not result in a change in bed capacity, as defined in G.S. 131E-176(5), or the addition of a health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.
- (2) The entity proposing to incur the capital expenditure provides prior written notice to the Department, which notice includes documentation that demonstrates that the proposed capital expenditure would be used for only one or more of the following purposes:
 - a. Conversion of semiprivate resident rooms to private rooms.
 - b. Providing innovative, homelike residential dining spaces, such as cafes, kitchenettes, or private dining areas to accommodate residents and their families or visitors.
 - c. Renovating, replacing, or expanding residential living or common areas to improve the quality of life of residents."

SECTION 4.(a) G.S. 131E-76(3) reads as rewritten:

"(3) "Hospital" means any facility which has an organized medical staff and which is designed, used, and operated to provide health care, diagnostic and therapeutic services, and continuous nursing care primarily to inpatients where such care and services are rendered under the supervision and direction of physicians licensed under Chapter 90 of the General Statutes, Article 1, to two or more persons over a period in excess of 24 hours. The term includes facilities for the diagnosis and treatment of disorders within the scope of specific health specialties. The term does not include private mental facilities licensed under Article 2 of Chapter 122C of the General Statutes, nursing homes licensed under G.S. 131E-102, ~~and adult care homes licensed under G.S. 131D-2, 131D-2,~~ and any outpatient department including a portion of a hospital operated as an outpatient department, on or off of the hospital's main campus, that is operated under the hospital's control or ownership and is classified as Business Occupancy by the Life Safety Code of the National Fire Protection Association as referenced under 42 C.F.R. § 482.41. Provided, however, if the Business Occupancy outpatient location is to be operated within 30 feet of any hospital facility, or any portion thereof, which is classified as Health Care Occupancy or Ambulatory Health Care Occupancy under the Life Safety Code of the National Fire Protection Association, the hospital shall provide plans and specifications to the Department for review and approval as required for hospital construction or renovations in a manner described by the Department."

SECTION 4.(b) G.S. 131E-80(a) reads as rewritten:

"(a) The Department shall make or cause to be made inspections as it may deem necessary. Any hospital licensed under this Part shall at all times be subject to inspections by the Department according to the rules of the Commission. Except as provided under G.S. 131E-77(b) of this Part, after the hospital's initial licensing, any location included or added to the hospital's accreditation through an accrediting body approved pursuant to section 1865(a) of the Social Security Act, shall be deemed to be part of the hospital's license; provided, however, that all locations may be subject to inspections which the Department deems necessary to validate compliance with the requirements set forth in this Part."

SECTION 5. G.S. 122C-55(a1) reads as rewritten:

"(a1) Any facility may share confidential information regarding any client of that facility with the Secretary, and the Secretary may share confidential information regarding any client with a facility when necessary to conduct quality assessment and improvement activities or to coordinate appropriate and effective care, treatment or habilitation of the client. For purposes of this subsection and subsection (a6) of this section, the purposes or activities for which confidential information may be disclosed include, but are not limited to, case management and care coordination, disease management, outcomes evaluation, the development of clinical guidelines and protocols, the development of care management plans and systems, population-based activities relating to improving or reducing health care costs, and the provision, coordination, or management of mental health, developmental disabilities, and substance abuse services and related services. As used in this section, "facility" includes an LME and "Secretary" includes the Department's Community Care of North Carolina Program or other primary care case management programs that contract with the Department to provide a primary care case management program for recipients of publicly funded health and related services."

SECTION 6. Section 1 of this act becomes effective January 1, 2010. Sections 2(a), 2(b), and 2(c) of this act become effective January 1, 2010, and apply to health benefit plan contracts between health care providers and health benefit plans or insurers delivered, amended, or renewed on or after that date. The remainder of this act is effective when it becomes law.

In the General Assembly read three times and ratified this the 5th day of August, 2009.

s/ Walter H. Dalton
President of the Senate

s/ Joe Hackney
Speaker of the House of Representatives

s/ Beverly E. Perdue
Governor

Approved 1:40 p.m. this 26th day of August, 2009

Rupp, Tanya

From: Rupp, Tanya
Sent: Monday, February 13, 2017 11:28 AM
To: 'Kristy Hubbard'
Subject: Exemption, New Hanover Regional Medical Center

Hi Kristy,

Thank you for forwarding the additional information as requested with regard to the equipment currently in place in the Military Cut Off Facility. Although you provided a list of equipment that is valued at \$10,000 or more, we still need the FMV of the equipment on that list, so that we can determine the total cost associated with the proposed CT Scanner to be installed at the Military Cutoff Facility.

According to N.C. Gen. Stat. §131E .76(3):

“(3) "Hospital" means any facility which has an organized medical staff and which is designed, used, and operated to provide health care, diagnostic and therapeutic services, and continuous nursing care primarily to inpatients where such care and services are rendered under the supervision and direction of physicians licensed under Chapter 90 of the General Statutes, Article 1, to two or more persons over a period in excess of 24 hours. The term includes facilities for the diagnosis and treatment of disorders within the scope of specific health specialties. The term does not include private mental facilities licensed under Article 2 of Chapter 122C of the General Statutes, nursing homes licensed under G.S. 131E-102, adult care homes licensed under Part 1 of Article 1 of Chapter 131D of the General Statutes, and any outpatient department including a portion of a hospital operated as an outpatient department, on or off of the hospital's main campus, that is operated under the hospital's control or ownership and is classified as Business Occupancy by the Life Safety Code of the National Fire Protection Association as referenced under 42 C.F.R. § 482.41. Provided, however, if the Business Occupancy outpatient location is to be operated within 30 feet of any hospital facility, or any portion thereof, which is classified as Health Care Occupancy or Ambulatory Health Care Occupancy under the Life Safety Code of the National Fire Protection Association, the hospital shall provide plans and specifications to the Department for review and approval as required for hospital construction or renovations in a manner described by the Department.” Emphasis added

Therefore, although the Military Cutoff Facility is licensed as part of New Hanover Regional Medical Center, according to the statute above, it is not considered part of the hospital for purposes of determining whether or not the cost of the proposed equipment and the existing equipment valued at or above \$10,000 totals more than \$500,000.

Thank you in advance. I look forward to hearing from you. If you have any questions, please contact me.

Tanya S. Rupp, JD
Project Analyst
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services

919-855-3873 office
Tanya.rupp@dhhs.nc.gov

809 Ruggles Drive
2704 Mail Service Center
Raleigh, NC 27699-2704

Rupp, Tanya

From: Kristy Hubard <Kristy.Hubard@nhrmc.org>
Sent: Friday, February 03, 2017 5:49 PM
To: Rupp, Tanya
Subject: NHRMC no review request for CT replacement



Tanya,

Per our phone conversation earlier this week, please find below a listing of all equipment valued at >\$10,000 at our Health & Diagnostics site on Military Cutoff Road. Without pursuing a fair market value for each of these, an exact value is not available. As we discussed, this site is operated as a department of the hospital, listed accordingly on our hospital license renewal application.

Manufacturer	Model #	Serial #	Date of MFG	
GE Lunar	Prodoigy	12030200L-442	1/1996	Bone Density
GE CT	Optima	439172HM8	5/2016	Cat Scan
GE Logiq E9	5205000-3	96916US2	8/2009	U/S
GE Hologic	Selenia	81405166678	5/2016	Mammography
Siemens	10092611	00326-215	2/2015	Table/chest stand
Fuji	EV-800	EV-800	1/2015	DR
Med Rad	UTC-M515	201563	4/2016	Injector

Please confirm this is what you were seeking and whether or not additional information is needed.

Regards,
Kristy

Kristy Hubard, MHA, FACHE
Vice President, Strategic Services
New Hanover Regional Medical Center
2131 S. 17th Street
Wilmington, NC 28402
910-667-5908 (o)
910-200-5820 (m)

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Rupp, Tanya

From: Laura Rackley <Laura.Rackley@nhrmc.org>
Sent: Friday, December 09, 2016 10:46 AM
To: Rupp, Tanya
Cc: Joshua Tucker; Kristy Hubard
Subject: RE: Exemption Request for Replacement CT scanner
Attachments: Military Cutoff CT Scanner Price Validation Letter.pdf

Hi Tanya,

So sorry for the oversight on the date of the quote. Attached is a letter from the vendor stating that price in December 2015 quote is still valid for this transaction. Please let us know if you have any additional questions. Thanks much!

*Laura L Rackley
Manager of Business & Strategic Planning
Planning & Business Development
(910) 667-5277*

From: Kristy Hubard
Sent: Friday, December 02, 2016 4:06 PM
To: Joshua Tucker; Laura Rackley
Subject: Fwd: Exemption Request for Replacement CT scanner

Yikes, I totally missed this quote being so old. Joshua, could you please confirm pricing w/ vendor?

Sent from my iPhone

Begin forwarded message:

From: "Rupp, Tanya" <tanya.rupp@dhhs.nc.gov>
Date: December 2, 2016 at 3:16:20 PM EST
To: "kristy.hubard@nhrmc.org" <kristy.hubard@nhrmc.org>
Subject: Exemption Request for Replacement CT scanner

**** CAUTION: External Email ****

Good afternoon, Ms. Hubbard,

The Agency received your request for an exemption from CON law for the acquisition of a CT scanner as outlined in your letter dated November 18, 2016. Attached to that letter as Exhibit B, you included a vendor quote for a CT scanner from GE, dated 12/31/2015.

Do you have a more recent quote, or some indication that the cost of the CT scanner has not increased significantly since that 2015 quote was prepared?

Please feel free to respond via email; there is no need to send a separate response via US mail. Thank you in advance; I look forward to hearing from you. Have a good weekend.

Tanya S. Rupp, JD

Project Analyst

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

919-855-3873 office

Tanya.rupp@dhhs.nc.gov

809 Ruggles Drive

2704 Mail Service Center

Raleigh, NC 27699-2704



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Pete Swyt
Senior Client Director
Charleston, SC
P (843) 810-0935
E Peter.Swyt@ge.com

December 9th, 2016

Mr. Joshua Tucker
Director of Imaging Services
New Hanover Regional Medical Center
2131 17th Street
Wilmington, NC 28401

Dear Josh,

Per your request about pricing validity of your Optima CT540 16-Slice CT scanner that will be installed at Military Cutoff outpatient center. As we dsicused, the price of \$396,354.00 from quote PR7-C53380 V2 from December of 2015 is still valid and that will be the price honored for the equipment when it is installed. This price includes delivery and standard medhanical installation, and initial training.

If you have any further questions, please don't hesitate to contact me.

Sincerely,



Pete Swyt



Rupp, Tanya

From: Rupp, Tanya
Sent: Friday, December 02, 2016 3:16 PM
To: 'kristy.hubard@nhrmc.org'
Subject: Exemption Request for Replacement CT scanner

Good afternoon, Ms. Hubbard,

The Agency received your request for an exemption from CON law for the acquisition of a CT scanner as outlined in your letter dated November 18, 2016. Attached to that letter as Exhibit B, you included a vendor quote for a CT scanner from GE, dated 12/31/2015.

Do you have a more recent quote, or some indication that the cost of the CT scanner has not increased significantly since that 2015 quote was prepared?

Please feel free to respond via email; there is no need to send a separate response via US mail. Thank you in advance; I look forward to hearing from you. Have a good weekend.

Tanya S. Rupp, JD
Project Analyst
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services

919-855-3873 office
Tanya.rupp@dhhs.nc.gov

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November 18, 2016

Ms. Martha Frisone
Assistant Chief, Healthcare Planning and Certificate of Need Section
Department of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Bus id 1308
FID 943372
NRid 2144



RE: Request for No Review Determination for Acquisition of CT Scanner to be Located at NHRMC Health & Diagnostics - Military Cutoff / New Hanover County

Dear Ms. Frisone:

New Hanover Regional Medical Center ("NHRMC") intends to acquire and operate a GE Optima CT scanner and requests a determination that the project falls within the definitions of NCGS 131E-176(16)(b) and NCGS 131E-176(14)(o), as exempt from review.

Statement of Facts

NHRMC operates the NHRMC Health & Diagnostics - Military Cutoff facility as an outpatient department of the medical center. On June 27, 2016, the Agency authorized NHRMC to begin offering certain diagnostic imaging services in a Medical Office Building in Onslow County. Please refer to Exhibit A. As a part of that project, NHRMC relocated an existing CT scanner that was operating at the NHRMC Health & Diagnostics - Military Cutoff facility to the Medical Office Building. This "exempt from review request" for the acquisition of a CT scanner will allow CT services to again be offered at the NHRMC Health & Diagnostics - Military Cutoff facility.

Exemption from Review

NCGS 131E-176(16)(b) defines "new institutional health service" as the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars (\$2,000,000).

Furthermore,

NCGS 131E-176(14)(o) defines a "major medical equipment" as a single unit or single system of components with related functions which is used to provide medical and other health services and which

910 815 5908
910 667 5908

costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.

Compliance

1. The estimated cost for the acquisition of the GE Optima CT scanner and all related costs to make the CT scanner operational is \$399,355. Please refer to Exhibit B for the vendor quote.
2. Simple renovation or room up-fit costs associated with this project are estimated to cost \$20,000.
3. Total project costs including costs of the GE Optima CT scanner, other equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the GE Optima CT scanner at NHRMC is \$419,355. Please refer to Exhibit C for the project's capital cost.

Determination Requested

New Hanover Regional Medical Center requests that the Department of Health Service Regulation make a determination that the acquisition of the GE Optima CT scanner, as proposed herein does not constitute a new institutional health service or major medical equipment and is thus exempt from certificate of need review.

If you require additional information concerning this request, please contact me at 910-667-5908.

Sincerely,



Kristy Hubbard
Vice President, Business Planning

Attachments: Exhibit A - Letter of No Review
 Exhibit B - Vendor Quote
 Exhibit C - Proposed Total Capital Cost of Project



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

June 27, 2016

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

No Review

Record #: 1974
Business Name: New Hanover Regional Medical Center
Business #: 1308
Project Description: Offer diagnostic imaging services in Medical Office Building
County: Onslow

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of June 21, 2016 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 your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that 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.

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

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.



Healthcare Planning and Certificate of Need Section

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Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

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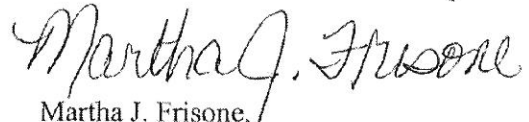


Denise Gunter
June 27, 2016
Page 2 of 2

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,


Jane Rhoe-Jones
Project Analyst

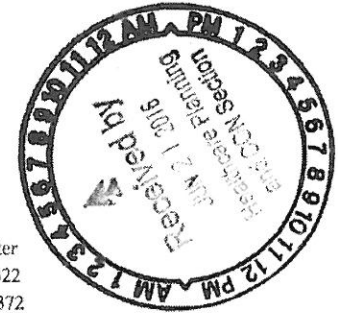

Martha J. Frisone,
Assistant Chief, Certificate of Need

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

Nelson Mullins

Nelson Mullins Riley & Scarborough LLP

Attorneys and Counselors at Law
380 Knollwood Street / Suite 530 / Winston-Salem, NC 27103
Tel: 336.774.3300 Fax: 336.774.3372
www.nelsonmullins.com



Denise M. Gunter
Tel: 336.774.3322
Fax: 336.774.3372
denise.gunter@nelsonmullins.com

June 21, 2016

Hand Delivered

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

Re: New Hanover Regional Medical Center
Letter of No Review for Diagnostic Imaging Equipment in Medical Office
Building
Onslow County
Health Service Area VI

Dear Ms. Frisone:

On behalf of New Hanover Regional Medical Center ("NHRMC"), I am writing to confirm that the following proposal with a capital cost of \$202,897 does not constitute a diagnostic center under N.C. Gen. Stat. § 131E-176(7a) and does not otherwise require a CON pursuant to N.C. Gen. Stat. § 131E-176(16).

Facts

NHRMC, either directly or through an affiliate¹ (collectively referred to as NHRMC in this letter), proposes to lease space in a medical office building ("MOB") located at 2000 Brabham Avenue in Jacksonville, North Carolina. The MOB will be owned by a third party developer, Summit Healthcare Group, LLC ("Summit"), which submitted a separate exemption letter for the MOB. The CON Section issued an exemption letter to Summit on June 1, 2016. Summit does not provide any healthcare services. NHRMC is only a tenant in the MOB and

¹ NHRMC and the radiology group, Delaney Radiologists ("Delaney"), which provides services at NHRMC facilities, intend to form a joint venture (the "Joint Venture") to operate an imaging suite in the MOB. The joint venture is currently in the process of being formed.

Martha J. Frisone
June 21, 2016
Page 2

will not own any part of the MOB. The lease between NHRMC and Summit will be an operating lease, not a capital lease.

The Joint Venture will offer certain diagnostic imaging services in the MOB (the "Project"). The imaging space will total approximately 5,995 square feet. The imaging services to be offered are x-ray, CT, ultrasound, mammography, and bone density testing. NHRMC already owns the x-ray machine, the CT scanner, the Medrad injector used to administer contrast for CT scans, the ultrasound machine, the mammography unit and the bone density machine. NHRMC is contributing the x-ray machine, the CT scanner, the Medrad injector, the ultrasound machine, the mammography unit and the bone density machine to the Joint Venture as NHRMC's initial capital contribution and assessing these pieces of equipment at their current fair market value ("FMV"). These pieces of equipment are currently located at NHRMC in Wilmington and will be transported by truck to Jacksonville. In accordance with the Court of Appeals' decision in *Mission Hospitals, Inc. v. NCDHHS*, 205 N.C. App. 35, 54, 696 S.E.2d 163, 176-77 (2010), NHRMC has used the FMV of the x-ray machine, the CT scanner, the Medrad injector, the ultrasound machine, the mammography unit and the bone density machine, rather than their original acquisition cost, to determine whether the \$500,000 diagnostic center threshold is reached. *See also Susi v. Aubin*, 173 N.C. App. 608, 612, 620 S.E.2d 682, 684 (2005) (fair market value ". . . is generally defined as '[t]he price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arm's-length transaction.'") (quoting *Black's Law Dictionary* 1587 (8th ed. 2004)).

The table on the next page shows the capital costs associated with the project. In accordance with N.C. Gen. Stat. § 131E-176(7a), only the items with an FMV of \$10,000 or greater are included to determine whether the \$500,000 diagnostic center threshold is met. The x-ray machine (FMV = \$6,000) and ultrasound machine (FMV = \$7,000) each has a fair market value of less than \$10,000, so they are excluded from the cost calculations below.

Table 1: Costs

Imaging Specific Cost for the Construction of the CT and CT Control Rooms	\$41,397
CT FMV	\$60,000
Mammography Machine FMV	\$26,000
Bone Density FMV	\$18,500
Medrad Injector for CT	\$10,000
Cost of Moving/Installing Equipment	\$35,000
Physicist Visits	\$12,000
Total	\$202,897

See Capital Cost Sheet, attached as Exhibit A.²

Analysis

N.C. Gen. Stat. § 131E-176(16)a. defines "new institutional health service" to mean, *inter alia*, "[t]he construction, development, or other establishment of a new health service facility." "Health service facility" is defined to include "diagnostic center." See N.C. Gen. Stat. § 131E-176(9b).

"Diagnostic Center" means:

. . . a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs the

² The construction costs to make the x-ray area suitable for x-rays are \$18,400; however, since the x-ray machine has an FMV of less than \$10,000, x-ray area construction costs are not included. However, even if these costs were included, the total cost of the Project would still be well below the \$500,000 threshold.

Martha J. Frisone
June 21, 2016
Page 4

equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

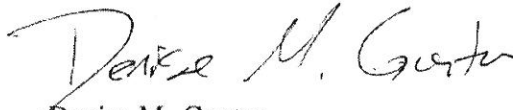
N.C. Gen. Stat. § 131E-176(7a).


As the foregoing demonstrates, the total cost of the Project, \$202,897, is well below the \$500,000 threshold. None of the equipment NHRMC proposes to use in the MOB independently requires a CON.

Accordingly, NHRMC respectfully requests that the CON Section confirm in writing that the Project does not require a CON.

Thank you for your time and attention.

Sincerely,


Denise M. Gunter



Enclosure

Exhibit A

PROPOSED CAPITAL COSTS

Project Name: Imaging Equipment in MOB
 Proponent: New Hanover Regional Medical Center

A. Site Costs			
(1)	Full purchase price of land.....	\$	_____
(2)	Acres _____ Price per Acre \$ _____		
(3)	Closing costs.....	\$	_____
(4)	Site Inspection and Survey.....	\$	_____
(5)	Legal fees and subsoil investigation.....	\$	_____
Site Preparation Costs			
	Soil Borings.....	\$	_____
	Clearing-Earthwork.....	\$	_____
	Fine Grade For Slab.....	\$	_____
	Roads-Paving.....	\$	_____
	Concrete Sidewalks.....	\$	_____
	Water and Sewer.....	\$	_____
	Footing Excavation.....	\$	_____
	Footing Backfill.....	\$	_____
	Territe 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.....	\$	_____
(9)	Cost of Labor.....	\$	_____
C.	Other (Specify).....	\$	_____
D.	Sub-Total Construction Contract.....	\$	_____
E.	Miscellaneous Project Costs		
(10)	Building Purchase.....	\$	_____
(11)	Fixed Equipment Purchase/Lease.....	\$	_____
(12)	Movable Equipment Purchase/Lease.....	\$114,500	
(13)	Furniture.....	\$	_____
(14)	Landscaping.....	\$	_____
(15)	Consultant Fees		
	Architect and Engineering Fees.....	\$	_____
	Legal Fees.....	\$	_____
	Market Analysis.....	\$	_____
	Other (Specify).....	\$	_____
	Sub-Total Consultant Fees.....	\$	_____
(16)	Financing Costs (e.g. Bond, Loan, etc.).....	\$	_____
(17)	Interest During Construction.....	\$	_____
(18)	Other (Specify) moving and installing equipment (\$35,000) and physicist (\$12,000)	\$47,000	
(19)	Sub-Total Miscellaneous.....	\$	_____
(20)	Total Capital Cost of Project (Sum A-C above).....	\$	202,897

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 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.

John A. Guzman

 (Proponent - signature of officer)

Chief Operating Officer

 (Title of officer)

Exhibit B



GE Healthcare

Date: 12-17-2015
 Quote #: PR7-C53380
 Version #: 9

New Hanover Regional Medical Center Attn: Mrs. Margo Abbas
 2131 S 17th St 2131 S 17th St Wilmington
 Wilmington NC 28401-7407 NC 28401-7407

Customer Number : 1-23161C
 Quotation Expiration Date: 12-31-2015

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 its terms and conditions and both in whole if the Governing Agreement identified below or 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, attached to this Quotation: (i) GE Healthcare Warranty; (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 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 he or she agrees to it in writing by authorized representatives of both parties.

Governing Agreement:	Premier
Terms of Delivery:	FOB Destination
Billing Terms:	80% on Delivery/ 20% on Acceptance or First Patient Use
Payment Terms:	NET 30
Total Quote Net Selling Price:	\$396,354.93

INDICATE FORM OF PAYMENT:

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

Cash/Third Party Loan

GE HFS Lease

GE HFS Loan

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

James Benecki 12-17-2015

 Signature Date

Product Sales Specialist

Email: Jim.Benecki@ge.com
 Office: +1 615 390 3634
 Mobile: (615) 390-3634
 Fax: (910) 401-1049



GE Healthcare

Date: 12-17-2015
Quote #: PR7-C53380
Version #: 9

Total Quote Selling Price
Trade-In and Other Credits

\$396,354.93
\$0.00

Total Quote Net Selling Price

\$396,354.93

To Accept this Quotation

Please sign and return this Quotation together with your Purchase Order To:
James Benecki
Office: +1 615 390 3634
Mobile: (615) 390-3634
Email: Jim.Benecki@ge.com
Fax: (910) 401-1049

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 HFS Lease or GE HFS 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: 12-17-2015
Quote #: PR7-C53380
Version #: 9

12-17-2015

GPO Agreement Reference Information

Customer: Mrs. Margo Abbas
Contract Number: PLEASE SEE PREMIER CONTRACT # BELOW
Start Date:
End Date: 09/30/2018

Billing Terms: 80% on Delivery/ 20% on Acceptance or First Patient Use
Payment Terms: NET 30
Shipping Terms: FOB Destination

NOTICE REGARDING COMPUTED TOMOGRAPHY ("CT") PRODUCTS. This notice applies only to the following GE Healthcare products: CT: Revolution CT and EVO, Optima 680 CT and Optima 520 CT. GE Healthcare has reclassified several advanced software tools and associated documentation to a GE Healthcare Technical Service Technology package that GE Healthcare feels will bring greater value and interest to our customers. GE Healthcare will continue to provide trained Customer employees with access to the GE Healthcare Technical Service Technology package under a separate agreement. GE Healthcare will continue to provide customers and their third party service providers with access to software tools and associated documentation in order to perform basic service on the CT, MR and NM products listed above upon a request for registration for such access. This will allow GE Healthcare to react faster to the future service needs of GE Healthcare customers. If you have any questions, you can contact your sales Service Specialist.

Offer subject to the Terms and Conditions of the applicable Group Purchasing Agreements currently in effect between GE Healthcare and Premier Purchasing Partners, L.P. include PP-IM-265(CT) and PP-IM-269 (Molecular Imaging).



GE Healthcare

Date: 12-17-2015
Quote #: PR7-C53380
Version #: 9

Qty	Catalog No.	Description
1		Optima - CT540 - MCO w/ASiR
1	S7540TF	<p>Optima - CT540</p> <p>The Optima CT540 is GE's latest generation intelligent CT system. It is a CT platform that combines many of the advanced ease of use innovations of our Optima CT660 series with the image quality of the BrightSpeed Elite. The CT540 is all about improving your patients experience to make your studies more effective from start to finish. This Optima CT540 is ready to be your diagnostic partner.</p> <p>Key Features:</p> <ul style="list-style-type: none"> • Exclusive VariSpeed allows full 360 degree rotation in 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 2.0 seconds, ensuring short breath holds, more comfortable exams and flexibility. • ASiR* (Adaptive Statistical Iterative Reconstruction) Dose reconstruction technology • Routine thin slice scanning, as thin as 0.625mm helping to optimize lesion detection and facilitating the use of thinner images for sagittal, coronal, oblique, and volume image presentation and review. • Efficient gantry geometry design delivers equivalent imaging flux performance compared to a system with larger geometry and higher generator power. • IQ Enhance (IQE) reconstruction reduces helical Artifact Index in thin slice helical scanning. This reduction in artifacts makes it possible to scan at faster helical pitches. # • GE proprietary, advanced interpolation algorithms balance slice profile, helical pitch, image noise, and required technique. • Image decomposition to: <ul style="list-style-type: none"> - Retrospective thin images from data sets where thicker images were initially reconstructed - Facilitates more detailed image analysis - Improves 3D and reformat visualization • Dose Check, a tool that helps the user to estimate and check the dose delivered in clinical practice. It is based on the standard XR-25-2010 published by the Association of Electrical and Medical Imaging Equipment Manufacturers (NEMA) XR-29 Compliant. <p>Xtream Suite workflow management built to help you maximize productivity:</p> <ul style="list-style-type: none"> • Xtream 12" gantry display enables <ul style="list-style-type: none"> - One Step patient positioning - Personalized patient care - Informational videos for all patients - Distraction videos for pediatric patients • One-touch protocol workflow delivering tailored visualization mode for exam review.



GE Healthcare

Date: 12-17-2015
Quote #: PR7-C53380
Version #: 9

Qty	Catalog No.	Description
		<p>directly built into the protocols, and available "1 click" on the operator console or the post-processing workstation.</p> <ul style="list-style-type: none"> • 3-click scan start workflow with pre-programmable protocol setting functions enables a starting a scan in as few as 3 clicks. • Up to 22 frames per second reconstruction • 10 Prospective Multiple Reconstruction (PMR) can be pre-programmed as part of the scan protocol prior to acquisition • Volume Viewer 3D reconstruction capabilities • Direct Multi-Planar Reformatting (MPR) with Auto-Batch feature, affording automatic real-time direct reconstruction and transfer of fully corrected multi-planar images, in any plane • Exam Split(Optional) allows multi-anatomic exams to be read in separate anatomic sections. This allows specialists to review only those images needed for a given requisition • Direct Connect allows remote Advantage Workstation (AW) access to the Xstream FX console's thin-slice data, eliminating unnecessary network traffic and storage duplication. (AW4.3** and later) • Xstream Injector is a powerful integrated injection option, which begins the IV contrast injection process in synchronization with "Start Scan" on Optima CT540 to simplify the enhancement exam workflow. The enhanced Xstream Injector also supports injector parameters being entered on CT console. • SmartPrep with Auto Trigger allows intermittent monitoring of IV contrast enhancement in an area of interest. • Default Patient Positioning (DPP) provides workflow improvement by preset positioning (Default Patient Positioning) on new gantry display. • Real-time Scout allows image to be displayed simultaneously as the acquisition. With the real-time scout image, you can stop scout acquisition once the necessary anatomy is covered. <p>Compact system design: The minimum installation requirement without short footprint mode is 20.0m2. Other features include:</p> <ul style="list-style-type: none"> • 2 19" monitors, standard, for comfort in in imaging review. • Up to 1700 mm scannable range for full body trauma scans. • In room start button mounted on gantry with countdown display, facilitates single remote gantry tilt from the operator console to enhance workflow. • Built-in breathing lights with a countdown timer, so the patient does not have to guess how much longer to hold their breath. • 0.35mm isotropic microVoxel* image resolution reconstruction algorithms



GE Healthcare

Date: 12-17-2015
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Qty	Catalog No.	Description
		<ul style="list-style-type: none"> • Hyperplane* and Crossbeam*, providing virtually artifact-free images and optimized slice profile at any pitch, by solving the technical challenges of cone beam and high pitch helical scanning • Includes reference protocols and the ability to customize your own for a total of 6840 protocols • 250,000 uncompressed 512 image files storage capacity, and 9600 scan seconds of scan data storage capacity • Chest Kernel can let the user perform only one reconstruction (instead of twice-using lung kernel and standard kernel separately) for chest exams, which may speed up the image review process. Filter sharpness is automatically adapted to the lung or mediastinum when the user adjusts window width or window level. • IQE enables faster anatomical coverage using faster pitch helical scanning at similar artifact index levels compared to slower helical scanning without IQE. This coverage speed is equivalent to that of wider detectors (50 slice equivalent) at same table speed. # <p># Helical Artifact Index is defined as: $((SD \text{ value at ROI1})^2 - (SD \text{ value at ROI2})^2)^{1/2}$. Two helical data sets were acquired to compute a Helical Artifact Index. Both helical acquisitions were acquired using kV:120, Gantry Rotation: 0.8S, Slice Thickness: 1.25mm, SFOV: Large, DFOV: 32cm, Start/End: S200-I370 and reconstructed using 512 matrix. One data set was acquired at 1.75:1 pitch with table speed of 37.5mm per rotation with IQ Enhance ON at 260mA and the other using 0.562:1 pitch with table speed of 11.25mm per rotation with IQ Enhance OFF at 160mA.</p> <p>Dose Management Leadership</p> <p>OptiDose management features: new bowtie filters optimized for adult and pediatric body exams, full 3D dose modulation, color coding for kids, tracking collimator hardware and software for x-ray beam tracking to name a few of GE's dose optimization features, all based on the ALARA principle.</p> <ul style="list-style-type: none"> • ASiR* (Adaptive Statistical Iterative Reconstruction) Dose reduction technology • Dynamic Z-axis tracking provides automatic and continuous correction of the x-ray beam shape to block unused x-ray at the beginning and end of a helical scan to reduce unnecessary patient radiation • 3D Dose modulation - Before the scan, clinicians must select the desired Noise Index as well as the minimum and maximum mA setting. The system automatically accounts for the changing dimensions of the patient's anatomy, enabling patient to patient reproducibility in this aspect of image quality and real-time x-y-z during each scan. • Volumetric Image Space Reconstruction (VISR) are 3D filters that reduce image noise (standard deviation) without compromising spatial resolution to provide clear



GE Healthcare

Date: 12-17-2015
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Qty	Catalog No.	Description
		<p>visualization in neuro and cardiac imaging, to deliver diagnostic image quality with potentially lower mA.)</p> <ul style="list-style-type: none"> Tracking collimator hardware and software for x-ray beam tracking to minimize patient dose Filtration of the x-ray beam is optimized independently for body and head applications Dose Display, DLP (dose length product), and dose efficiency display during scan prescription provides the patient's dose information to the operator prior to scanning Dose Reporting provides access to the CTDIvol and DLP with the patient record prior and post exam. DICOM Structured Dose Report is also supported Dose Check provides the user with tools to help them manage CT dose in clinical practice and is based on the standard XR-25-2010 published by The Association of Electrical and Medical Imaging Equipment Manufacturers (NEMA). Dose Check provides the following: <ul style="list-style-type: none"> Checking against a Notification Value if the estimated dose for the scan is above your site established value Checking against an Alert Value where the user needs specific authority to continue the scan at the current estimated dose without changing the scan parameters if the estimated dose exceeds the alert value The ability to define Alert Values for Adult and Pediatric with age threshold Audit logging and review capabilities ProtocolChange Control capabilities <p>***The ASiR reconstruction algorithm may allow reduced mA in the acquisition of diagnostic images, thereby reducing the dose required. The use of ASiR may also allow for scanning at lower mA and less anode heat input, thereby reducing the likelihood of encountering tube cooling delays.***</p> <p>\$mA modulation is designed to optimize the dose for the user prescribed noise index. Its effect on dose depends on the patient body habitus, and prescribed noise setting.</p> <p>Gantry:</p> <ul style="list-style-type: none"> Advanced slip ring design continuously rotates generator, tube, HiLight matrix detector and data acquisition system around the patient. Performix Ultra tube Matrix II detector and digital data acquisition system 70cm Aperture with scan field of 50cm Short geometry design: 94.9cm tube-to-detector distance Rotational speeds: 360 degrees in 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 2.0 seconds Tilt: +/- 30 degrees in half-degree increments with a speed of 1 degree/second Remote tilt from operator's console



GE Healthcare

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Qty	Catalog No.	Description
-----	-------------	-------------

- Integrated breathing lights & countdown timer
- Integrated start scan button with countdown timer to indicate when x-ray will turn on
- Scan plane toward front of gantry for improved positioning access
- Laser Alignment Lights: Define both internal and external scan planes to E 1 mm accuracy

Table:

- Controls on gantry for table up/down and cradle in/out, and tilt. Foot pedals on both sides of table for fast elevation. Cradle position controlled from OC for prescribed scans
- 1700 mm scannable range for full body trauma scans
- Table load capacity of 227 kg (500 lb) with +/- 0.25 mm of position repeatability
- Vertical range: 490 mm to 991 mm
- Vertical scannable range: 791 mm to 991 mm
- Horizontal range: up to 1700 mm
- Horizontal scannable range: up to 1730 mm (axial) and 1630 mm (helical) & 1600 mm (Scout)
- Horizontal speed: up to 125mm/sec (150mm/sec at ISD)
- Table automatically re-centers on scan plane with changes in vertical position under alignment light turned on condition

Detector and DAS:

The Volara 30-bit Digital data Acquisition System (DAS), with 1968 views per rotation, delivers high processing power for high-resolution images and low-dose performance. It reduces noise up to 33% for outstanding image quality, even in difficult areas such as the shoulders and hips, and in large patients.

Other features include:

- 21,888 cells over 24 rows, allowing the following type of acquisition-collimation:
- 10mm (0.625 mm rows) for high resolution mode
- 20mm (1.25 mm rows) high speed mode
- Collimated slice thickness available: 0.625, 1.25, 2.5, 3.75, 5, 7.5, 10
- Generating slices at fine intervals enables image reconstruction that exceed 32 slices (images) per gantry rotation
- The high image quality provided by the Optima CT540 is enabled by the HiLight matrix detector, with 98% absorption efficiency

X-ray Tube:

Performix Ultra tube unit offers an optimized design for exams requiring a large number of



GE Healthcare

Date: 12-17-2015
Quote #: PR7-C53380
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Qty	Catalog No.	Description
		<p>scans without tube cooling delays.</p> <ul style="list-style-type: none"> Anode Heat Storage Capacity: 6.3 MHU Heat Dissipation: Anode (max) 840 KHU/min ASiR*** allows you to achieve the same image noise (SD) at a lower mA with less tube heat output, which enables the tube for longer duration helical scan. <p>Dual Focal Spots</p> <p>Small Focal Spot:</p> <ul style="list-style-type: none"> 0.8 x 0.7 nominal value (IEC 336/2005) 0.7 x 0.6 nominal value (IEC 60 336/93) <p>Large Focal Spot:</p> <ul style="list-style-type: none"> 1.1 x 1.0 nominal value (IEC 336/2005) 0.9 x 0.9 nominal value (IEC 60 336/93) <p>High Voltage Generator</p> <p>High Frequency on-board generator allows for continuous operation during scan.</p> <ul style="list-style-type: none"> 53.2 kW output power kVp: 80, 100, 120, 140 mA: 10 to 440 mA, 5 mA increments to better adapt to the patient. <p>Xtream Operator Console</p> <p>The console and table are designed to enable the efficient use of space while enhancing clinical workflow and technologist comfort. Attributes include:</p> <ul style="list-style-type: none"> Fully adjustable monitor arms Adjustable height for improved patient visibility Flexible location of OC hardware Sitting or standing position Xtream FX operator console 22fps is standard Split tabletop allows unrestricted patient viewing while supporting 2xLCD 19 inch color monitors. Two 19 inch color LCD monitors support scan and recon, as well as image display, processing, analysis, and management. Each work surface can be adjusted to accommodate operator preferences and a wide variety of site requirements. Xtream(TM) FX, built on the LINUX operating system and delivering fast reconstruction of 22 ips with full fidelity images and fast network transfer rates of up to 16 ips.



GE Healthcare

Date: 12-17-2015
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Qty	Catalog No.	Description
		<ul style="list-style-type: none"> • Size: 1300mm Wide x 620mm Deep x 683-912mm adjustable height 44 kg in weight <p>Image Networking Exams</p> <p>Images can be selected and moved between the Optima CT540 CT Scanner and any imaging system supporting the DICOM 3.0 protocol for network send, receive and pull/query.</p> <p>Other networking attributes include:</p> <ul style="list-style-type: none"> • Standard Auto-configuring Ethernet • Direct Network Connection • Supports 10/100/1000 BaseT Ethernet • Supported Protocols <ul style="list-style-type: none"> - DICOM 3.0 Network - Advantage Net - InSite Point-to-Point - TCP/IP (for System Administration) <p>DICOM Conformance Standards:</p> <ul style="list-style-type: none"> • DICOM 3.0 Storage Service Class • Service Class User (SCU) for image send • Service Class Provider (SCP) for receive • DICOM 3.0 Query/Retrieve Service Class • DICOM 3.0 MOD Media Service Class • DICOM 3.0 Storage Commitment Class Push • DICOM 3.0 Modality Worklist (incl:Performed Procedure Step through ConnectPro option) • DICOM 3.0 Print <p>Applications and Clinical Performance</p> <ul style="list-style-type: none"> • When selecting a CT scanner to meet your needs the primary concern should be the clinical performance of the system, not specifications. Specifications alone don't tell you how the scanner will perform. To understand true clinical performance of the system, you have to consider how well the scanner delivers three things - image quality, coverage, exam speed - and whether it can deliver all three at once. The Optima CT540 CT Scanner offers a balanced design enabling it to deliver clinical performance. <p>Image Quality</p> <ul style="list-style-type: none"> • Axial Low Contrast Detectability (LCD) Statistical LCD: on 8 Inch CATPHAN Phantom <ul style="list-style-type: none"> - 5 mm @ 0.3% at 13.3 mGy - 3 mm @ 0.3% at 37.2 mGy • Helical Noise -on an AAPM Water Phantom or GE Quality Assurance Phantom = < 0.32%



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nominal +/- 0.03% at 28.5 mGy

- High Contrast Spatial Resolution - on GE Performance Phantom
 - Standard Algorithm - 8.5 lp/cm @ 0% MTF
 - Hi-res Algorithm - 15.4 lp/cm @ 0% MTF

Pitches

- 0.562:1, 0.938:1, 1.375:1, and 1.75:1 Helical Pitches for 16 Slice Modes
- 0.625:1, 0.875:1, 1.35:1, and 1.675:1 Helical Pitches for 8 Slice Modes

Exam Speed: The Optima CT540 CT Scanner delivers flexible and fast scan speeds by combining 16 slice acquisition, 1.75:1 helical pitch and 0.5 rotation. Because of these very quick exam speeds, scan speed is no longer what determines the systems throughput of a multi-slice scanner. Other tasks are equally important to determine the performance of the CT scanner:

- Scan Setup
- Image Reconstruction
- Reformat and 3D Processing
- Networking, Archiving, Filming

The Optima CT540 with Xstream FX suite workflow management is designed to deliver outstanding workflow in each of these tasks:

- One-touch protocol workflow, delivering tailored visualization mode for exams review, directly built into the protocols, and available in "1 click" on the Operator Console or the Post-processing workstation.

Xstream Display

Xstream Display is a multi-purpose LCD display and can show basic patient information on the Gantry monitor. The user can confirm patient information in the scan room potentially improving workflow and reducing the opportunity for error. Xstream Display provides workflow improvement with preset positioning (One Step patient positioning) on gantry display. Xstream Display has a Movie function to assist the user in explaining the CT examination to patients.

Other features include:

- Minimum 3-click scan start workflow is a pre-programmable protocol setting that enables the start of scan in as few as 3 clicks.
- Up to 6fps reconstruction speed (16fps option)
- Direct MPR with Auto-Batch feature, affording automatic real-time direct reconstruction and transfer of fully corrected multi-planar images, in any plane.
- Up to 10 fps transfer speed of images, real-time during acquisition, to up to 4 different destinations.
- DVD interchange capability, for archiving of up to 7168 uncompressed 512 images.
- Data Export capability, ensuring the relevant images and reports can be visualized by the



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		<p>referrals in PC friendly format(MPEG, AVI.)</p> <ul style="list-style-type: none"> • Auto Transfer by Series to distribute images where you need them when you need them. • Exam Split(Optional) allows multi-anatomic exams be read in separate anatomic sections. This allows specialists to review only those images needed for a given requisition • Grayscale Presentation State saves display presentation of WW, WL, flip, rotate, zoom, roam, user annotation and measurements for transfer to a remote viewing station using DICOM GSPS object. • Direct Connect allows remote Advantage Workstation (AW) access to the Xstream FX console's thin-slice data, eliminating unnecessary network traffic and storage duplication. (AW4.3** and later) • Xstream Injector: Xstream Injector is a powerful integrated injection option, which starts the Injection process in synchronization with "Start Scan" on CT system to simplify the enhancement exam workflow. The enhanced Xstream Xstream Injector supports injector parameters to be entered on CT console. • Graphic Retro: Graphic Retro allows users to prescribe retro recon graphically on appropriate prospective image by mouse. Visual adjustment parameters such as DFOV, AP/RL center improve retro recon productivity. <p>Scan Modes</p> <ul style="list-style-type: none"> • Helical scan mode offers continuous 360 degree scanning with table incrementation and no interscan delay. Axial scan mode allows for up to 16 contiguous axial planes to be acquired simultaneously. • Helical Multi-slice Modes: Helical scanning has been simplified by grouping all critical acquisition parameters within helical pitches optimized for image quality and speed 0.5625:1, 0.9375:1, 1.375:1, 1.75:1 for 16 slice acquisition. These clinically derived helical scan modes offer a wide range of selections that carefully balance acquisition speed, image thickness, and provide table speeds up to 35 mm per rotation enabling scan speeds that are up to 12 times faster than 4 slice helical scanners. • Prospective Multiple Thickness Reconstruction: For any helical scan modes, the operator can choose to reconstruct images prospectively in any of 7 nominal image thicknesses 0.625, 1.25, 2.5, 3.75, 5, 7.5, and 10 mm. The operator may also prospectively specify additional image sets to be reconstructed. These images can be reconstructed at any of the defined nominal image thicknesses available for a given table speed and scan mode. Direct MPR may also be prospectively specified which quickly enables the move from 2D review to prospective 3D image review of axial, sagittal, coronal and oblique planes automatically. <p>Axial Scans: Multi-slice axial acquisitions and short interscan delays significantly reduce</p>



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		<p>potential mis-registration between scans by increasing the number of scans in a single breath hold. Reference protocols make the Optima CT540 scanner system fast & efficient.</p> <p>Axial Multi-slice Modes: The Optima CT540 CT scanner system acquires axial scans in sets of up to 16 contiguous images in one 360 degree rotation. For each rotation of the gantry the system collects 16 rows of scan data. There are five reconstruction modes available for creating images from the multi-slice axial scan scan data.</p> <ul style="list-style-type: none"> • Example- 8i Mode: Produces 8 Images per Rotation • Nominal Thickness: 1.25, 2.5 mm • Example- 16i Mode: Produces 16 Images per Rotation • Nominal Thickness: 0.625, 1.25 mm <p>Image Reconstruction Kernels: Soft, Standard, Detail, Bone, Bone Plus, Lung, and Edge and Chest.</p> <p>InSite Broadband includes: Hardware essential for systems to be connected to high speed internet.</p> <p>For US and Canadian Customers, this quotation includes access to the DoseWatch Explore application for a period of time concurrent with the system warranty. DoseWatch Explore is an introductory dose management software application that provides you secure access, via any PC with internet access, to dose and protocol data from this system. An InSite connection to the system and completion of the registration process is required to use the DoseWatch Explore application.</p> <p>Warranty. The published Company warranty in effect on the date of shipment shall apply. The Company reserves the right to make changes. All specifications are subject to change.</p> <p>Regulatory compliance: this product is designed to comply with applicable standards under the radiation control for health and safety act of 1968. This product is designed to comply with applicable standards under the Radiation Control for Health and Safety Act of 1968. Laser alignment devices contained within this product are appropriately labeled according to the requirements of the Center for Devices and Radiological Health. This product is a CE compliant device which satisfies regulations regarding Electro-Magnetic Compatibility (EMC) and Electro-Magnetic Interference (EMI), pursuant to IEC-60101-1 and all applicable collateral and particular standards.</p> <p>This product complies with NEMA Standard 29-2013 / MITA Smart Dose Standard.</p>
1	B7590EN	English Keyboard Kit
1	B75372CB	Standard length cable set for Optima CT540 and Optima CT520
1	B78552CA	The Freedom workspace is an ergonomic working environment specifically designed for use with the GE Healthcare imaging systems. The sleek table design enables the efficient use of



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		space while enhancing clinical workflow and technologist comfort. The Freedom workspace provides a minimalist footprint to improve patient visibility and giving the user easier access to patients in the imaging suite. It offers sit/stand and horizontal/vertical monitor flexibility. It can also help reduce noise and heat with remote location options of the console. The non-adjustable Freedom workspace version is 1300mm long x 895mm wide x 850mm height and weighs 55.8kg.
1	B77322CA	CT chair
1	B7900WB	The SmartScore 4.0 package provides ECG-gated hardware for both prospective and retrospective gating along with software on the Advantage Workstation for coronary artery calcium scoring. Console ECG Trace The ECG trace provided by the Ivy monitor will be displayed on the CT operator's console with this option. Allowing the user to display the live trace of the patient's heart rate and display the actual location of the window of time when the image is being acquired. It will provide easy access. to patient cardiac output status and assist in providing visual feedback for optimum acquisition start. SmartScore 4.0 software for AW (or newer) with new patient report.
1	B7900LC	This option provides lung screening reference protocols that are tailored to the CT system, patient size (small, average large), and the most current recommendations from a wide range of professional medical and governmental organizations. Now, qualified GE Healthcare CT scanners with this option are formally indicated for, and can be confidently used by physicians for low dose CT lung cancer screening of identified high-risk patient populations. These protocols deliver low dose, short scan times, and clear and sharp images for the detection of small lung nodules. Early detection from an annual lung screening with low dose CT in high-risk individuals can prevent a substantial number of lung cancer-related deaths. ⁱⁱ All new GE 64-slice and greater CT scanners, and virtually all of the 16-slice CT scanners that GE Healthcare sells are qualified for this screening option. This solution is also available to thousands of qualified GE CT scanners currently in use, increasing access to the quality scanners that satisfy both patient and physician needs. The new protocols, do include the choice for the user to be able to utilize GE Healthcare's industry-leading technologies such as ASiRTM, ASiR-VTM and VeoTM that are designed to reduce image noise, which is undesirable for physicians looking for small nodules. This option contains two documents. Lung Cancer Screening Option Reference Protocol Guide, and the Lung Cancer Screening Option User Manual / Technical Reference Manual i The following GE Healthcare CT scanners are qualified to receive the new low dose CT Lung Cancer Screening Option: LightSpeed 16, BrightSpeed Elite, LightSpeed Pro16, Optima CT540, Discovery CT590 RT, Optima CT580, Optima CT580 W, Optima CT590 RT, LightSpeed Xtra,



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		LightSpeed RT16, LightSpeed VCT, LightSpeed VCT XT, LightSpeed VCT XTe, LightSpeed VCT Select, Optima CT660, Revolution EVO, Discovery CT750 HD, Revolution GSI, Revolution. ii Moyer V. Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med. 2014;160:330-338. http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/lu
1	B75792CA	Gantry accessory hardware kit for BrightSpeed
1	B7999ZA	Uninterruptible Power Supply Exide Uninterruptible Power Supply. Custom Designed Firmware to Interconnect with LightSpeed Pro, LightSpeed RT, Optima and BrightSpeed Systems. The UPS Primarily Backs Up the System Computer Functions. Bridges Short Power Outages and Provides Time for Crossover from Normal Main Power to Emergency Power. Must be Located Within Eight Feet of the PDU.
1	B77292CA	Service cabinet for system accessories storage
1	E4502AB	The 90Amp CT system main disconnect panel (MDP) serves as the main facility power disconnect source installed ahead of the system PDU. The MDP will disconnect system power on first loss of incoming power, helping to prevent damage to system components. It also includes an automatic restart control circuit which restores power to the CT System PDU after a power outage. <ul style="list-style-type: none"> • Can reduce installation time and cost by eliminating delays in obtaining individually enclosed components and on site assembly (ex: main circuit breaker, feeder overcurrent devices, magnetic contactors and UPS emergency power off are combined into a single panel) • Configuration flexibility - can be used as a stand-alone main disconnect or with the optional partial system UPS. (On systems where the optional partial system UPS is used the main disconnect panel also provides NEC mandated emergency power off control to both the PDU and UPS • Designed and tested for GEHC CT products Specifications: <ul style="list-style-type: none"> • Automatic restart incorporates an adjustable time delay to delay main power until the power has stabilized for 5 seconds • One flush wall mounted remote emergency off pushbutton furnished with each system • UL, cUL and CE labeled
1	E8007PP	Medrad CT Stelliant D w/ Dual Flow - Medium Post 85 cm



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1	E8007PJ	OCS III MOUNTING PLATE
1	E8007PT	<p>Medrad Stellant P3T Cardiac Protocol Option</p> <p>P3T Cardiac computes custom injection protocols as well as scan timing for each patient, enabling personalized care and patient safety while maintaining efficient workflow.</p> <ul style="list-style-type: none"> Utilizes the power of DualFlow technology (simultaneous injection of contrast and saline) to obtain functional cardiac data Enables more consistent images across varied patients, studies and technologists Eliminates the need to estimate injection protocols for complicated studies
1	W0113CT	<p>TIP CT Basic Training 6 Days Onsite 10 Hours TVA</p> <p>TIP Applications CT Basic Training for LightSpeed, LightSpeed VCT and BrightSpeed Systems includes:</p> <ul style="list-style-type: none"> 6 onsite days covered in two site 10 hrs. TVA <p>All elements of the programs are completed within 36 months post installation. Onsite training and TVA are delivered Monday through Friday between 8AM and 5PM. T&L expenses are included.</p>

Quote Summary:

Total Quote Net Selling Price **\$396,354.93**

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)

PROPOSED CAPITAL COSTS

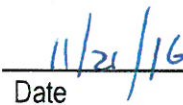
Project name: CT ScannerProponent: New Hanover Regional Medical Center

Construction Contract	
(8) Cost of materials/labor	\$20,000
(9) Other (Contingency)	NA
(10) Sub-Total Construction Contract	\$20,000
Miscellaneous Project Costs	
(11) Building purchase	N/A
(12) Fixed equipment purchase/lease	\$396,355
(13) Mobile equipment purchase/lease	N/A
(14) Furniture	N/A
(15) Landscaping	N/A
(16) Consultant fees	N/A
(17) Financing costs (e.g. bond, loan, etc.)	N/A
(18) Other (Physicist Inspection)	\$3,000
(19) Other (Specify)	N/A
(20) Sub-Total Miscellaneous	\$399,355
(21) TOTAL CAPITAL COST OF PROJECT	\$419,355

To the best of my knowledge, the above capital costs for the proposed project are complete and correct, and it is the intent of New Hanover Regional Medical Center to carry out the proposed project as described.



Tom Walsh, Vice President



Date