



NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES

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

December 20, 2019

Gary S. Qualls
K&L Gates, LLP
430 Davis Drive, Suite 400
Morrisville NC 27560

No Review

Record #: 3169
Facility Name: Wake Radiology Cary
FID #: 001330
Business Name: Rex Hospital, Inc.
Business #: 1554
Project Description: Relocate an existing PET scanner from the main hospital campus in Raleigh to a diagnostic center operated by Wake Radiology Services located at 300 Ashville Avenue in Cary
County: Wake


Dear Mr. Qualls:

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

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

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Please do not hesitate to contact this office if you have any questions.

Sincerely,


Michael J. McKillop
Project Analyst


Martha J. Frisone
Chief

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Waller, Martha K

From: Hall, Carolyn <Carolyn.Hall@klgates.com>
Sent: Thursday, December 19, 2019 12:38 PM
To: Waller, Martha K
Cc: Qualls, Gary
Subject: [External] No Review Request on behalf of Rex Hospital
Attachments: 20191219115019960.PDF

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report_spam@nc.gov

Ms. Waller,

Attached please find a No Review Request for Rex Hospital. Please confirm receipt.

I hope you have a wonderful holiday.

Best,
Carolyn Hall



Carolyn Hall
Senior Paralegal
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560
Research Triangle Park Office
Telephone: (919)466-1183
Fax: (919)516-2073
E-mail: carolyn.hall@klgates.com
www.klgates.com

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December 19, 2019

Gary S. Qualls
Gary.qualls@klgates.com

T +1 919 466 1182
F +1 919 516 2072



Via Email to martha.waller@dhhs.nc.gov

Martha Frisone
Chief
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: No Review Request to Relocate Rex's Existing PET Scanner to Cary

Dear Ms. Frisone:

My client, Rex Hospital, Inc. ("Rex") requests a no review determination that the relocation of its existing PET Scanner to Cary, Wake County (the "Relocation") does not require a CON. Rex currently operates one (1) PET Scanner in its licensed hospital space in Raleigh. See Exhibit 1 (CON for Existing PET Scanner). Rex wants to relocate that PET Scanner to space operated by Wake Radiology Services, LLC. ("WRS") in Cary at Suite 180, 300 Ashville Avenue, Cary. WRS operates an existing diagnostic center at this location. Rex will enter into a services agreement with WRS pertaining to the Rex PET Scanner. Before and after the Relocation, Rex will retain ownership of the PET Scanner.

We ask that the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") determine that this Relocation is non-reviewable because it does not constitute a new institutional health service under N.C. Gen. Stat. § 131E-176(16).

Under North Carolina law, a CON is required only prior to offering or developing a "new institutional health service." "New institutional health service[s]" include a variety of services and activities, including the acquisition of a PET Scanner. See N.C. Gen. Stat. § 131E-176(16)(f1)(8). However, no one is acquiring a PET Scanner here. Rather, Rex is simply relocating a single piece of existing equipment within the same county and PET Scanner service area, and is not changing the PET Scanner's ownership.

Martha Frisone
Chief
December 19, 2019
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The CON statute provides a lengthy and exclusive list of activities that constitute development of a new institutional health service, requiring a CON. That list does not include relocating an existing PET Scanner within the same service area, under the same ownership. Pursuant to a well-established maxim of statutory construction, *expressio unius est exclusio alterius*, those transactions or events not included in N.C. Gen. Stat. § 131E-176(16) do not require a CON. *See, e.g., In re Miller*, 357 N.C. 316, 325, 584 S.E.2d 772, 780 (2003) (stating that “[u]nder the doctrine of *expressio unius est exclusio alterius*, when a statute lists the situations to which it applies, it implies the exclusion of situations not contained in the list”); *see also Jackson v. A Woman’s Choice, Inc.*, 130 N.C. App. 590, 594, 503 S.E.2d 422, 425 (1998) (internal citations omitted) (“Where a statute is explicit on its face, the courts have no authority to impose restrictions that the statute does not expressly contain.”).

The costs associated with relocating the PET Scanner are projected to be under \$180,000. Any minor renovations are projected to easily be less than \$100,000. Then, all costs associated with de-installing the PET Scanner from the Rex main campus and relocating and re-installing it in Cary are projected to be \$72,974.50. See Exhibit 2 (Siemens Quote to De-install and Re-install Existing Rex PET Scanner). Thus, this Relocation also does not come anywhere close to triggering the \$2 Million threshold in N.C. Gen. Stat. § 131E-176(16)(b).

Rex is not proposing any changes for the newly approved PET Scanner, which was approved via a CON dated June 1, 2019 (Project I.D. No. J-11659-19), and will be located at Rex Hospital. See Exhibit 3 (CON for Newly Approved PET Scanner).

Given that the Relocation does not trigger any “new institutional health service” categories, please confirm that the Relocation is not CON reviewable. If you require additional information, please feel free to contact me at the above number. Thank you in advance for your review of this request.

Sincerely,



Gary S. Qualls

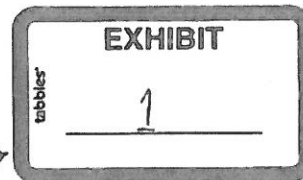
Martha Frisone
Chief
December 19, 2019
Page 3

Exhibits

1. CON for Existing Rex PET Scanner
2. Siemens Quote to De-install and Re-install Existing Rex PET Scanner
3. CON for Newly Approved Rex PET Scanner

STATE OF NORTH CAROLINA

Department of Health and Human Services
Division of Facility Services



CERTIFICATE OF NEED
for
Project Identification Number J-6428-01
FID #953429

ISSUED TO: Rex Hospital, Inc.
4420 Lake Boone Train
Raleigh, NC 27607

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Rex Hospital, Inc. shall acquire one position emission tomography (PET) scanner/Wake County

CONDITIONS: See Reverse Side

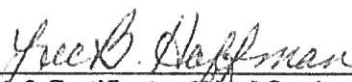
PHYSICAL LOCATION: Rex Hospital, Inc.
4420 Lake Boone Trail
Raleigh, NC 27607

MAXIMUM CAPITAL EXPENDITURE: \$3,366,374

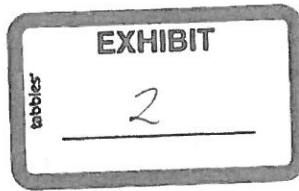
TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: January 2, 2003

This certificate is effective as of the 17th day of September, 2002.



Chief, Certificate of Need Section
Division of Facility Services



District/Sales Office

Siemens Medical Solutions USA, Inc.
 221 Gregson Drive
 Cary, NC 27511
 Attn: Lee Propst, RSM
 Phone: 919-612-4517
 Email: lee.propst@siemens.com

Proposal # 1-R85NW1

Inquiries regarding this proposal should refer to proposal number, indicate services purchased, and be directed to the District/Sales Office.

Customer

Rex Hospital
 4420 LAKE BOONE TRAIL
 Raleigh, NC 27607
 Attn: Diana Massa

Functional Location: 400-412632

Siemens Medical Solutions USA, Inc. is pleased to submit the following two-page quotation for the products and services described herein at the stated prices and terms, subject to Customer's acceptance of the terms and conditions on all pages hereof.

Item	Qty	Catalog No.	Description of Products and/or Services	Price
1	1	RELO	<p>De-install, remove, relocate, and re-install the following equipment: Biograph mCT</p> <p>Includes the de-installation, removal, transport, and re-installation of the Equipment from Rex Hospital, 4420 Lake Boone Trail, Raleigh, NC 27607 to Wake Radiology, 300 Ashville Ave, Cary NC 27518</p> <p>Includes the materials and parts necessary to install the equipment in the new location, as well as set-up and calibration of the equipment as required.</p> <p>Original interconnecting cable and high tension cable will be used for the re-installation to the extent possible. Should additional cables be required, Siemens will supply the cables at the customer's expense.</p> <p>Power supplied to the new room, as well as all site preparations, is the responsibility of the customer and should be identical to the original room power supply and site specifications.</p>	<p>\$72,974.50</p> <p>Total: \$72,974.50</p>

F.O.B.: US Shipping Point Only. Freight charges and taxes, if any, are payable upon receipt of invoice.
 Terms of payment: Net 30 days from invoice date. Past due payment is subject to 1.5 % interest charge per month.

Siemens Medical Solutions USA, Inc.

By _____
 (Signature)

Jason Every, Order Fulfillment - SI

 Name and Title

Date _____

Customer's Acceptance

By _____
 (Signature)

 Name and Title

Customer P.O. # (Initial if not applicable) _____

Acceptance Date: _____

This proposal is valid for 30 days. Agreement becomes effective upon Customer signature and Siemens acceptance.

CONDITIONS

1. Rex Hospital, Inc. shall not acquire, as part of this project, any equipment that is not included in the capital expenditure in Section VIII of the application.
2. Rex Hospital, Inc. shall materially comply with all the representations in its certificate of need application and the representations in the supplemental documents it filed with the agency on August 23, 2002. In those instances in which the representations in these documents conflict, Rex Hospital, Inc. shall materially comply with the last-made representation.

Financing

Obtaining funds necessary to undertake project _____ October 1, 2002

Design

Completion of preliminary drawings _____ October 1, 2002

Completion of final drawings and specifications _____ January 1, 2003

Approval of final drawings and specifications by DFS Construction Section _____ April 1, 2003

Construction

Contract award _____ June 1, 2003

25% completion of construction _____ July 1, 2003

50% completion of construction _____ August 1, 2003

75% completion of construction _____ September 1, 2003

Completion of construction _____ October 1, 2003

Occupancy offering of service(s) _____ November 1, 2003

Acquisition of Medical Equipment

Ordering equipment _____ January 1, 2003

Arrival of equipment _____ September 1, 2003

Operation of equipment _____ November 1, 2003

Siemens Medical Solutions USA, Inc.

General Terms and Conditions for Relocation Services

1. Scope

Siemens will provide the services described on the first page hereof. Siemens will commence such services at the time set forth on the first page hereof or, if a date is not specified, then on a date mutually agreed to by Siemens and the Customer. Siemens personnel will be given full and free access to the Equipment and the facilities of the Customer in order to perform the services described herein. If the Equipment and the facilities are not made available at the appointed time, waiting time beyond a reasonable allowance will be charged at Siemens' prevailing rates. Customer shall provide a suitable environment for the Equipment and shall ensure, at its sole cost and expense, that its premises are free of asbestos, hazardous conditions and any concealed dangerous conditions and that all site requirements for the installation of the Equipment are met.

2. Causes for Exclusion/Separate Charges

This Agreement specifically excludes labor, parts and expenses resulting from (i) any force majeure occurrence as defined in Section 11 hereof or other unforeseen circumstances, (ii) any hidden or concealed condition or defect, (iii) any attempt by the Customer or other third party to relocate the Equipment, or (iv) the negligence or intentional misconduct of the Customer or any other party not under the control and supervision of Siemens.

3. Default

Siemens reserves the right to suspend services hereunder and/or cancel this Agreement if the Customer is in default. An event of default shall include, but is not limited to, a failure by Customer to make any payment due Siemens under this Agreement, failure to grant Siemens access to the Customer's facility or to perform any other obligation hereunder, the filing of any notice under Federal Bankruptcy laws, or a default by Customer under any other obligation to or agreement with Siemens or any affiliate or assignee of Siemens (including but not limited to, a promissory note, lease, rental agreement, license agreement or purchase contract).

4. Limitation of Liability

Siemens' entire liability and Customer's exclusive remedy for any direct damages incurred by the Customer from any cause whatsoever, and regardless of the form of action, whether liability in contract or in tort, arising under the Agreement or related hereto, shall not exceed the amount paid by Customer to Siemens hereunder. The foregoing limitation of liability shall not apply to claims by Customer for personal injury or damage to real property or tangible personal property to the extent caused by Siemens' negligence or willful misconduct. In addition, Siemens shall have no liability hereunder to Customer to the extent that Customer's or any third party's acts or omissions contributed in any way to any loss it sustained or to the extent that the loss or damage is due a force majeure occurrence as described in paragraph 11 hereof or other causes beyond the reasonable control of Siemens.

THIS IS AN AGREEMENT FOR SERVICES. THERE ARE NO SIEMENS WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL SIEMENS BE LIABLE FOR ANY LOST PROFITS, LOST SAVINGS, LOST DATA, LOST REVENUES, LOSS OF USE OR DOWNTIME, OR FOR ANY SPECIAL, INDIRECT, INCIDENTAL, UNFORESEEN, PUNITIVE OR CONSEQUENTIAL DAMAGES WHETHER BASED ON CONTRACT TORT (INCLUDING NEGLIGENCE) STRICT LIABILITY OR ANY OTHER THEORY OR FORM OF ACTION, EVEN IF SIEMENS HAS BEEN ADVISED OF THE POSSIBILITY THEREOF, ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR THE SERVICES PROVIDED HEREUNDER.

5. Notices; Non-Assignment

All notices and changes to this Agreement must be in writing. The Agreement is not assignable except that Siemens may assign without Customer approval to any subsidiary or affiliated company or to any of its authorized subcontractors.

6. Governing Law

This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania.

7. Government Access Clause

Until the expiration of four (4) years after the furnishing of any services under this Agreement, Siemens shall make available upon written request of the Secretary of the Department of Health and Human Services or upon the written request of the Comptroller General or any of their duly authorized representatives, this Agreement and the books, documents and records of Siemens which are necessary to certify the nature and extent of costs incurred under this Agreement. If Siemens carries out any of the duties of this Agreement through a subcontract with a value of \$10,000 or more over a 12 month period with a related organization, such subcontract

shall include a clause to the effect that until the expiration of four (4) years after the furnishing of any services under the subcontract, the related organization shall make available upon written request of the Secretary of Health and Human Services, the Comptroller General, or any of their duly authorized representatives, the subcontract and the books, documents and records of the related organization that are necessary to certify the nature and extent of costs incurred under that subcontract. This provision shall apply if and solely to the extent that Section 1861 (v) (1) (I) of the Social Security Act applies to this Agreement.

8. Attorney's Fees

In the event that any dispute or difference is brought arising from or relating to this Agreement or the breach, termination, or validity thereof, the prevailing party shall be entitled to recover from the other party all reasonable attorney's fees incurred, together with such other expenses, costs and disbursements as may be allowed by law.

9. Severability; Headings

No provision of this Agreement which may be deemed unenforceable will in any way invalidate any other portion or provision of this Agreement. Section headings are for convenience only and will have no substantive effect.

10. Waiver

No failure, and no delay in exercising, on the part of any party, any right under this Agreement will operate as a waiver thereof, nor will any single or partial exercise of any right preclude the further exercise of any other right.

11. Force Majeure

Siemens will not be liable to Customer for any failure to fulfill its obligations under this Agreement due to causes beyond its reasonable control and without its fault or negligence including, but not limited to, governmental laws and regulations, acts of God or the public, war or other violence, civil commotion, blockades, embargoes, calamities, floods, fires, earthquakes, explosions, accidents, storms, strikes, lockouts, work stoppages, labor disputes, or unavailability of labor, raw materials, power or supplies. In addition, in the event of any determination pursuant to the provisions of a collective bargaining agreement between the Customer and any labor union representing any employees of the Customer preventing or hindering the performance of any of the obligations of Siemens under this Agreement, or determining that the performance of any such obligations violates provisions of that collective bargaining agreement, or in the event a trade union, or unions, representing any of the employees of the Customer otherwise prevents Siemens from performing any such obligations, then Siemens shall be excused from the performance of such obligations unless the Customer makes all required arrangements with the trade union, or unions, to permit Siemens to perform the work. The Customer shall pay any additional costs incurred by Siemens that are related to any labor dispute(s) that involve the Customer.

12. Execution

If Customer is a corporation or partnership, the person signing this Agreement on its behalf certifies that such person is an officer or partner thereof, that his or her action was duly authorized by appropriate corporate or partnership action, that such action does not conflict with the corporate charter or bylaws or the partnership agreement, as the case may be, or any contractual provision binding on such corporation or partnership, and that no consent of any stockholders to his or her action is required.

13. Entire Agreement

This Agreement constitutes the entire agreement between the parties relating to the subject matter hereof, and it may not be modified or amended, except in writing executed by the appropriate designated officers of the parties hereto. Any variation in the terms of this Agreement (including, but not limited to, the inclusion of terms and conditions in any Purchase Order or other document issued by the Customer) shall not be deemed to be a part hereof and shall not be binding upon Siemens unless set forth in writing and executed by the appropriate designated officer of Siemens. Subject to the limitations expressed herein, this Agreement will be binding upon and inure to the benefit of the parties hereto, their successors, legal representatives, and permitted assigns. Notwithstanding anything to the contrary contained herein, the provisions of Sections 4, 6, 7, 8, 9 and 10 shall survive the expiration or termination of this Agreement.

Rev. 06-14

SPECIAL NOTES:

Lead Time :

14 days 21 days 28 days ___ days

STATE OF NORTH CAROLINA

*Department of Health and Human Services
Division of Health Service Regulation*

CERTIFICATE OF NEED

for

Project ID #: J-11659-19

FID #: 953429

ISSUED TO: Rex Hospital, Inc.

Pursuant to N.C. Gen. Stat. § 131E-177(6), the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project described below. The certificate holder shall develop the project in a manner consistent with the representations in the application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein, as documented by the periodic progress reports required by 10A NCAC 14C .0209. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that section.

SCOPE: Acquire a second fixed dedicated PET scanner pursuant to the need determination in the 2019 SMFP/ Wake County

CONDITIONS: See Reverse Side

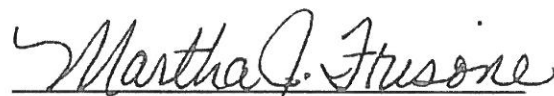
PHYSICAL LOCATION: Rex Hospital
4420 Lake Boone Trail
Raleigh, NC 27607

MAXIMUM CAPITAL EXPENDITURE: \$4,206,352

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: November 1, 2019

This certificate is effective as of June 1, 2019


Martha J. Frisone, Chief

CONDITIONS:

1. Rex Hospital, Inc. shall materially comply with all representations made in the certificate of need application.
2. Rex Hospital, Inc. shall acquire no more than one additional fixed PET scanner for a total of no more than two fixed PET scanners at the hospital.
3. Rex Hospital, Inc., as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Rex Hospital, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
5. Rex Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on May 3, 2019.

TIMETABLE:

- | | |
|--|------------------|
| 1. Drawings Completed | October 25, 2019 |
| 2. 25% of Construction/Renovation Completed
(25% of the cost is in place) | January 13, 2020 |
| 3. Construction/Renovation Completed | June 1, 2020 |
| 4. Services Offered | July 1, 2020 |
| 5. Final Annual Report Due | October 1, 2023 |

