



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

January 30, 2020

Allyson Jones Labban, Associate General Counsel
WakeMed Health & Hospitals
300 New Bern Avenue
Raleigh NC 27610

No Review

Record #: 3193
Facility Name: Wake PET, LLC
FID #: 041002
Business Name: Wake PET, LLC
Business #: 3173
Project Description: Relocate an existing PET scanner from 300 Ashville Avenue to 210 Ashville Avenue in Cary
County: Wake

Dear Ms. Labban:

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,

Handwritten signature of Michael J. McKillop
Michael J. McKillop
Project Analyst

Handwritten signature of Martha J. Frisone
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



WakeMed Health & Hospitals
 3000 New Bern Avenue
 Raleigh, NC 27610
 919-350-8000

January 17, 2020



Via electronic mail to martha.waller@dhhs.nc.gov

Martha Frisone, Chief
 DHHS, Division of Health Service Regulation,
 Healthcare Planning and Certificate of Need Section
 809 Ruggles Drive
 Raleigh, NC 27603

Re: No Review Request to Relocate Wake PET, LLC's Existing PET Scanner

Dear Ms. Frisone:

Wake PET, LLC ("Wake PET") requests a no review determination that the relocation of its existing PET Scanner from its existing location in Cary, Wake County to a new location in Cary (the "Relocation") does not require a CON.

As you know, the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") recently issued a no review determination to Rex Hospital ("Rex"), authorizing the relocation of one existing PET scanner from its licensed hospital space in Raleigh to unlicensed outpatient space in Cary at Suite 180, 300 Asheville Avenue, Cary. This space, which is operated by Wake Radiology Services, LLC ("WRS"), is currently occupied by the PET scanner owned by Wake PET, with whom WRS has a services agreement¹. See Exhibit 1 (Wake Radiology Services & Hours by Office Location). Given Rex's proposal to relocate its hospital-based PET scanner to 300 Asheville Avenue, Suite 180 and enter into a services agreement with WRS, Wake PET anticipates receiving a notice of termination from WRS that will force it to relocate the existing PET scanner from the location.

We ask that the Agency determine that the 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" is defined to include the acquisition of a PET scanner. See N.C. Gen. Stat. § 131E-176(16)(f1)(8). However, the proposed Relocation involves only the relocation of Wake PET's existing regulated health service within its existing service area, from one location in Cary to another. Wake PET will retain ownership of the PET scanner following the relocation, and will enter into a services agreement with one or more radiologists to operate the PET scanner, similar to the arrangement Wake PET currently has, and Rex proposes to have, with WRS.

¹ Wake PET, LLC was authorized to acquire a fixed PET scanner through settlement after the Agency initially denied Project I.D. No. J-7103-04 (acquire a fixed PET scanner and develop a diagnostic center). The Agency approved the development of the project at the Asheville Avenue location, rather than at WakeMed Cary Hospital, through a 2006 settlement agreement, and the unit has been operated by WRS since 2008. Recently, WRS sold its ownership shares in Wake PET, LLC to WakeMed.

Wake PET Service, LLC

Bus # ~~2010~~ 3173

CID # ~~041002~~
 041022

PAC 1492

As stressed by Rex in its December 19, 2019 letter of no review, the statutory list of activities that require a CON does not include the relocation of existing equipment within the same service area and under the same ownership. Rex also summed up the rule of statutory construction, "*expressio unius est exclusio alterius*," meaning "the explicit mention of one is the exclusion of another," which courts apply to hold that anything not included in a list of items set forth in a statute is not covered by the statute. Because the relocation of an existing unit in the same service area is not included in the list of items and services that qualify as a "new institutional health service," such relocation is exempt from CON review.

Wake PET anticipates relocating from 300 Asheville Avenue, Cary to space in the medical office building that is currently under construction at 210 Asheville Avenue, Cary. The anticipated cost of relocation is \$82,873.00. See Exhibit 2 (Quotation from Siemens). Unfortunately, Rex did not provide the Agency with a timeline for its proposed relocation, nor was Wake PET given advance notice, and Wake PET does not know at what point it will be forced to vacate Suite 180 at 300 Asheville Avenue. Therefore, in an abundance of caution, the quotation obtained from Siemens and attached as Exhibit 2 also includes costs for temporary storage of the unit, should Wake PET be forced to relocate the unit prior to completion of the medical office building at 210 Asheville Avenue, Cary. Even if temporary storage is required, the cost is well under the two million dollar threshold for new institutional health services at N.C. Gen. Stat. § 131E-176(16)(b).

Because the Relocation does not qualify as a "new institutional health service," please confirm that the Relocation is not CON reviewable. If you need additional information, please feel free to contact me.

Sincerely,

DocuSigned by:

0992F5EC848C4EC...
ALLYSON JONES LATTAN

Wake Radiology Services & Hours by Office Location[†]

For directions, maps and exam preparations, please visit wakerad.com

| Raleigh - North Hills Offices | | | Cary Offices | | | |
|---|---|---|---|--|---|---|
| WR North Hills* 3821 Merton Dr Raleigh, NC 27609 Mon-Fri 8am-5pm Adult & pediatric imaging General X-ray Fluoroscopy IVP* Ultrasound Venous Doppler CT* Bone density screenings (DXA) | WR North Hills Breast Center 3821 Merton Dr Raleigh, NC 27609 Mon-Fri 7am-5pm 1 st & 3 rd Thursday 7am-7pm 2 nd Saturday 8am-12pm 3D Digital screening mammography Digital screening mammography 3D Digital diagnostic mammography Digital diagnostic mammography Breast ultrasound Ultrasound-guided core biopsy Ultrasound-guided cyst aspiration Fine needle aspiration | WR Raleigh MRI Center* 3811 Merton Dr Raleigh, NC 27609 Mon-Fri 7am-9pm Saturday 6am-7:30pm Adult & pediatric imaging MRI* and Breast MRI* MRA*, MRE* and MR Arthrography* MRI-guided breast biopsy | WR Cary Diagnostic Imaging* 300 Ashville Ave, #100 Cary, NC 27518 Mon-Fri 8am-5pm Saturday 8am-1pm Adult & pediatric imaging General X-ray Fluoroscopy IVP* Ultrasound Venous Doppler CT* Nuclear medicine Bone density screenings (DXA) | WR Cary Breast Center 300 Ashville Ave, #260 Cary, NC 27518 Mon-Fri 7:45am-5pm Tuesday 7:45am-6pm Saturday 8am-1pm Digital screening mammography Digital diagnostic mammography Breast ultrasound Stereotactic breast biopsy Ultrasound-guided core biopsy Ultrasound-guided cyst aspiration Fine needle aspiration Bone density screenings (DXA) | WR Interventional Services & Vein Center 300 Ashville Ave, #160 Cary, NC 27518 Mon-Fri 8am-12:30pm Endovenous laser treatment (EVLT) for varicose veins Sclerotherapy Thyroid biopsy Paracentesis/Thoracentesis PORT/PICC procedures Consultations include: - Kyphoplasty, vertebroplasty & sacroplasty, Uterine fibroid embolization (UFE) | WR PET-CT* 300 Ashville Ave, #180 Cary, NC 27518 Mon-Fri 8am-5pm PET CT scans* WR Cary MRI* 300 Ashville Ave, #180 Cary, NC 27518 Mon-Fri 7am-8pm Sat 7am-8pm Sun 8am-6pm Adult & pediatric imaging MRI* and Breast MRI* MRA* and MR Arthrography* |
| West Raleigh Offices | | North Raleigh Office | Garner Office | Fuquay-Varina Office | Wake Forest Offices | Chapel Hill Office |
| WR West Raleigh Diagnostic & Sports Imaging* 4301 Lake Boone Trail, #103 Raleigh, NC 27607 Mon-Fri 8am-5pm Adult & pediatric imaging General X-ray Fluoroscopy (low-dose pulsed) IVP* Ultrasound Venous Doppler Nuclear medicine CT* Bone density screenings (DXA) | WR Pediatric Imaging 4301 Lake Boone Trail, #100 Raleigh, NC 27607 Mon-Fri 8am-5pm Newborns to age 18 General X-ray Fluoroscopy (low-dose pulsed) Ultrasound CT* Nuclear medicine WR Breast Center West 2301 Rexwoods Drive, #116B Raleigh, NC 27607 Mon-Fri 8am-5pm Digital screening mammography Digital diagnostic mammography Breast ultrasound | WR North Raleigh at American Institute of Healthcare & Fitness 8300 Health Park, #221 Use AIHF building entrance D Raleigh, NC 27615 Mon-Fri 8am-4:30pm Adult & pediatric imaging General X-ray Ultrasound Bone density screenings (DXA) Digital screening mammography | WR Garner* 300 Health Park Dr, #100 Garner, NC 27529 Mon-Fri 7:45am-5pm Saturday 8am-1pm MRI Mon-Fri 7am-7pm MRI Saturday 7am-7pm Adult & pediatric imaging General X-ray Fluoroscopy IVP* Ultrasound Venous Doppler CT* Bone density screenings (DXA) Digital screening mammography MRI* and Breast MRI* MRA* and MR Arthrography* | WR Fuquay-Varina 7636 Purfoy Road, #200 Fuquay-Varina, NC 27526 Mon-Fri 8am-5pm Adult & pediatric imaging General X-ray Ultrasound Venous Doppler Bone density screenings (DXA) Digital screening mammography MRI and MRA Morrisville Office WR Morrisville Women's Imaging 1101 Grace Park Drive Morrisville, NC 27560 Mon 8:30am-7pm Tues-Fri 7:00am-3:00pm Digital screening mammography Bone density screenings (DXA) | WR Wake Forest* 3150 Rogers Rd, #115 Wake Forest, NC 27587 Mon-Fri 8am-5pm Adult & pediatric imaging General X-ray Ultrasound Venous Doppler Bone density screenings (DXA) CT* MRI* and MRA* WR Wake Forest Mammography 3309 Rogers Road, #209 Wake Forest, NC 27587 Mon, Wed, Fri 8am-4:30pm Tues 7:15am-3:45pm Thurs 7:15am-7pm 3 rd Saturday 8am-12pm Digital screening mammography | WR Chapel Hill* 110 S. Estes Dr Chapel Hill, NC 27514 Mon-Fri 7:30am-5pm Saturday hours 8am-1pm Adult & pediatric imaging General X-ray Fluoroscopy Ultrasound Venous Doppler CT* Bone density screenings (DXA) Digital screening mammography Digital diagnostic mammography MRI* and Breast MRI* MRA* and MR Arthrography* |

[†]Please call our scheduling numbers if you have questions about a radiology service not listed.

*iStat for creatinine levels available at these locations.





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-RSKL8Y

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

Customer

Wake PET, LLC
 3000 New Bern Ave
 Raleigh, NC 27610

Functional Location: 400-412632

Siemens Medical Solutions USA, Inc. is pleased to submit the following three-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 6 TruePoint</p> <p>Includes the de-installation, removal, transport, and re-installation of the Equipment from 300 Ashville Ave, Cary, NC 27518 to 210 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. This price includes room specific drawings and Project Management.</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><u>If Needed Cost (Optional)</u> Storage of Pet/CT in a climate-controlled environment for 6 months. If storage is less than six months then the price will be prorated.</p> | <p>\$82,873.00</p> <p>Total: \$82,873.00</p> <p>Optional \$10,850.00</p> <p>Total w/ Optional \$93,723.00</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.

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

Waller, Martha K

From: ALLYSON LABBAN <alabban@wakemed.org>
Sent: Friday, January 17, 2020 3:54 PM
To: Waller, Martha K
Cc: ROBBIE ROBERTS
Subject: [External] No Review Request - Wake PET, LLC Relocation
Attachments: Letter to Martha Frisone - 1.17.2020 signed.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

Dear Ms. Waller:

Please find attached a no review request for Ms. Frisone's review. Should you or Ms. Frisone have any questions, please do not hesitate to contact me.

Thank you,

Allyson Jones Labban
Associate General Counsel
WakeMed Health & Hospitals
3000 New Bern Avenue
Raleigh, NC 27610

Office: 919-350-6130
alabban@wakemed.org

