

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 7, 2022

Gary S. Qualls, K & L Gates Gary.qualls@klgates.com

No Review

Record #: 4018

Date of Request: August 16, 2022

Facility Name: UNC REX Holly Springs Hospital

FID #: 070823

Business Name: Rex Hospital, Inc.

Business #: 1554

Project Description: The use, in emergency situations, of the two dedicated C-section operating rooms

as general procedure rooms in handling emergent birthing cases

County: Wake

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law in effect on the date of this response to your request, the project as described 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.

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. McKillip

Micheala Mitaell

Team Leader

Micheala Mitchell

Chief

cc: 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



August 16, 2022

Gary S. Qualls D 919.466.1182 F 919.516.2072 Gary.qualls@klgates.com

Via E-Mail Delivery

Micheala Mitchell, Chief Mike McKillip, Project Analyst Healthcare Planning and Certificate of Need Section Division of Health Service Regulation N.C. Department of Health and Human Services 809 Ruggles Drive Raleigh, NC 27603

RE: Rex Hospital, Inc.'s Material Compliance and No Review Request Regarding C-Section Room and Procedure Room Usage at Rex Hospital's Holly Springs Campus

Dear Ms. Mitchell and Mr. McKillip:

On behalf of our client, Rex Hospital, Inc. ("UNC Rex") we request a determination by the Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") that UNC Rex be permitted to slightly modify its plans for certain surgical services offered at its Holly Springs Hospital Campus (the "Holly Springs Campus"). The Holly Springs Campus has been operational since November 1, 2021. That campus is operated under Rex Hospital's single license.

With respect to surgical capacity, the Holly Springs Campus has operated with:

- 1. three (3) shared operating rooms;
- 2. one (1) dedicated C-Section room ("C-Section Room #1"); and
- 3. one (1) procedure room.

A CON was issued on October 28, 2021, approving a second C-Section room ("C-Section Room #2), which is scheduled to become operational in early 2023.

Those surgical assets were approved as part of:

- a. the original CON for the Holly Springs Campus (Project ID #J-8669-11), issued on January 22, 2014;
- b. a material compliance approval dated January 11, 2019 (Exhibit 1A is the Approval and Exhibit 1B is the Request); and

c. a CON issued on October 28, 2021, approving C-Section Room #2. See Exhibit 2 (CON) and Exhibit 3 (Findings).

UNC Rex now asks the Agency to verify that the slight usage changes described below:

- 1. do not require additional CON review; and
- would not be a material change in scope for purposes of N.C. Gen. Stat. §131E-181(a), and are otherwise permissible.

I. Proposed Slight Usage Changes.

UNC Rex is now confronting important challenges in handling emergent, unscheduled minor surgeries that are related to birthing issues (the "Emergent Birthing Cases") that are not technically covered as procedures explicitly permissible to be performed in dedicated C-Section rooms in light of the CON limits on such rooms. See Exhibit 4 (SMFP Limitations on New Dedicated C-Section Rooms). These Emergent Birthing Cases all require a very quick response by surgical birthing staff to provide necessary care for patients. In one recent example, a patient was losing significant amounts of blood when an Emergent Birthing Case was required to address the patient's immediate needs as a result of an issue related to her delivery.

By way of example, the following categories of cases constitute Emergent Birthing Cases:

- a. Dilation And Curettage, Diagnostic And/Or Therapeutic (Non Obstetrical) [CPT Code 58120]
- b. Episiotomy Or Vaginal Repair, By Other Than Attending Physician [CPT Code 59300]
- c. Standby Service, Requiring Prolonged Attendance, Each 30 Min [CPT Code 99360]
- d. Vaginal Repair [CPT Code 59300]
- e. Vaginal Repair, By Other Than Attending Physician [CPT Code 59300]
- f. Total Abdominal Hysterectomy (Corpus & Cervix), W/Wo Removal Of Tube(S), W/Wo Removal Of Ovary(s) [CPT Code 58150]

To address these emergent issues and create a safety net for Emergent Birthing Cases, UNC Rex proposes the following:

1. For the vast majority of the time, UNC Rex would plan to use both of its C-Section Rooms exclusively as C-Section rooms; and

2. For a very small fraction of the time in any given week or month, UNC Rex would use one of the C-Section Rooms at a time¹ as a temporary procedure room (the "Procedure Room Usage") for Emergent Birthing Cases.

Based on historical experience, UNC Rex estimates that the Procedure Room Usage for Emergent Birthing Cases would total around 20 cases per year.

Therefore, this request seeks confirmation that UNC Rex can, in these emergent situations, utilize each of its two rooms that are already approved as C-Section rooms as an unregulated general procedure room a small fraction of the time. Once UNC Rex implements C-Section Room #2, UNC Rex projects this Procedure Room Usage to occur in only one C-Section room at a time. During those small increments of time when UNC Rex is handling an Emergent Birthing Case in one of those rooms, that room will be treated as an unregulated procedure room and will not be treated (i.e., not billed or counted for utilization purposes) as a C-Section room.

II. Applicable Law.

A. No Review Component.

Even if the Agency treats this occasional use of the C-Section rooms as the addition of a procedure room,² the Procedure Room Usage proposed here does not constitute a CON reviewable event because adding a procedure room for less than \$4 Million is not covered by any of the new institutional health service "CON triggers" in N.C. Gen. Stat. § 131E-176(16). Moreover, unlike operating rooms, a procedure room addition is not reviewable *per se. Id.*

Pursuant to the maxim of statutory construction expressio unius est exclusio alterius, those events not included in Section 131E-176(16) -- such as this Procedure Room Usage – 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 situation 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) ("[W]here a statute is explicit on its face, the courts have no authority to impose restrictions that the statute does not expressly contain.").

¹ For the coming months, UNC Rex will operate only C-Section Room #1. However, this projection becomes relevant once C-Section Room #2 is also made operational.

² The term "procedure room" is used here in the singular because, as stated above, UNC Rex would use only one of these C-Section rooms at a time in that manner.

B. Material Compliance Component.

Moreover, because the Procedure Room Usage is proposed during the first year of the Holly Springs Campus' operation and prior to C-Section Room #2 being operationalized, we also ask the Agency to confirm that such occasional, emergent usage as described herein materially complies with the CONs for the Holly Springs Campus and C-Section Room #2 under N.C. Gen. Stat. §131E-181(a), and would otherwise be permissible without further CON review. The Procedure Room Usage is not a change in scope because each C-Section room will still be used as a C-Section room except when occasionally used as an unregulated procedure room for Emergent Birthing Cases.

Even where recently approved or recently operational CON project owners have sought approval for the <u>physical addition</u> (via new construction or renovation) of one or more new procedure rooms, the Agency has approved such procedure room additions as being materially compliant on a number of occasions. <u>See e.g.</u>, Exhibits 5A and 5B (Agency Material Compliance Approval [Ex. 5A] and Request [Ex. 5B] for Henderson County ASC to Add Four [4] Procedure Rooms Before Opening).

This is a much more modest request than the approved Henderson County request. Here, UNC Rex's request does not propose any additional physical space for a procedure room. Rather, we merely ask the Agency to approve this occasional and infrequent Procedure Room Usage for already approved rooms to allow for optimal patient care. In fact, since procedure rooms are not CON regulated as such, this proposed Procedure Room Usage is the CON-equivalent of simply not using these C-Section rooms for the small period of time at issue.

III. Conclusion.

UNC Rex will continue to deliver the highest quality care to its patients, and the proposed Procedure Room Usage will enhance UNC Rex's ability to do so. As described above, no new institutional health service triggers are implicated.

Moreover, approval of this proposed change will not result in: (a) any additional capital or operating costs, (b) higher patient charges, or (c) any new health services being performed. The slight usage revisions to the Holly Springs Hospital Project and C-Section Room #2 Project do not constitute a material change to either project, and thus do not require a new CON.

UNC Rex therefore asks the Agency to verify that the proposed Procedure Room Usage described above:

- 1. does not require additional CON review; and
- 2. would not be a material change in scope for purposes of N.C. Gen. Stat. §131E-181(a), and is otherwise permissible.

Thank you for your assistance. If you have any questions, please give me a call.

Sincerely,

Lary S. Qualls Gary S. Qualls

312822651.2

Exhibits

- 1. Material Compliance Request and Approval For Holly Springs Campus Modifications
 - a. Exhibit 1A is January 11, 2019 Material Compliance Approval Letter
 - b. Exhibit 1B is December 13, 2018 Material Compliance Request and January 9, 2019 e-mail clarification
- 2. CON issued on October 28, 2021 for C-Section Room #2 at Holly Springs Campus
- 3. Agency Findings issued on September 27, 2021 approving a second C-Section room
- 4. 2021 SMFP Excerpt Containing Dedicated C-Section Room Limitations
- 5. Material Compliance Request and Approval for Henderson County ASC to Add Four (4) Procedure Rooms Before Opening
 - a. Exhibit 5A is Approval
 - b. Exhibit 5B is Request

Exhibit 1A



ROY COOPER . Governor

MANDY COHEN, MD, MPH . Secretary

MARK PAYNE . Director, Division of Health Service Regulation

January 11, 2019

Gary S. Qualls K&L Gates, LLP P.O. Box 14210 Research Triangle Park NC 27709-4210

Material Compliance Approval

Project ID #:

J-8669-11

Facility:

Rex Hospital Holly Springs

Project Description:

Develop a separately licensed hospital in Holly Springs with 50 acute care beds,

three shared operating rooms, one dedicated C-section operating room and five

unlicensed observation beds

County:

Wake

FID#:

070823

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the changes proposed in your letter of December 13, 2018 and the January 9, 2019 email are in material compliance with representations made in the application. These changes include construction of a 7-story facility on a smaller footprint rather than a 3-story structure, increasing the general medical/surgical beds from 38 to 44, increasing the number of intensive care beds from four to six, developing 7 LDR beds rather than 8 LDRP beds, increasing the unlicensed observation beds from five to ten, increasing emergency department treatment bays from 10 to 24, licensing the hospital under the UNC REX Hospital license rather than licensing it separately, changes to the floor plan, and other changes as detailed in your letter of December 13, 2018 and the January 9, 2019 email. However, you should contact the Agency's Acute and Home Care Licensure and Certification and Construction Sections to determine if they have any requirements pertinent to the proposed change.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Project Analyst

Chief, Healthcare Planning and Certificate of Need Section

cc:

Construction Section, DHSR

Acute and Home Care Licensure and Certification Section, DHSR Melinda Boyette, Administrative Assistant, Healthcare Planning, DHSR

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

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

Exhibit 1B

Qualls, Gary

From:

Qualls, Gary

Sent:

Wednesday, January 9, 2019 12:03 PM

To:

Frisone, Martha (martha.frisone@dhhs.nc.gov); Mckillip, Mike

Subject:

Modification to Rex Holly Springs Material Compliance Request

Attachments:

20181214121833580new.pdf

Martha and Mike:

Yesterday, you had a question about the C-Section Room component of the attached Holly Springs Material Compliance Request that we filed in December. See p. 2. To clarify, Rex only proposes to develop the one C-Section Room already approved rather than two C-Section Rooms. Please accept this e-mail as a modification and clarification of Rex's request in that respect. Let me know if you have any further questions.

Thanks

Gary

Gary S. Qualls Partner K&L Gates LLP 430 Davis Drive, Suite 400 Morrisville, NC 27560 Phone: 919-466-1182 Fax: 919-516-2072 gary.qualls@klgates.com www.klgates.com



December 13, 2018



Gary S. Qualls gary.qualls@klgates.com

T +1 919 466 1182 F +1 919 516.2072

Via Hand Delivery

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

RE: Rex Hospital, Inc. d/b/a Rex Hospital Holly Springs Material Compliance regarding Project ID J-8669-11, Wake County

Dear Ms. Frisone:

On behalf of our client, Rex Hospital, Inc. ("Rex") we request a determination by the Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") that Rex be permitted to modify its plans for its hospital in Holly Springs, Project ID #J-8669-11 (the "Holly Springs Hospital Project"), the CON for which was originally issued on January 22, 2014. Rex is planning some design changes and minor programmatic modifications. Rex therefore asks the Agency to verify that such changes -- described below -- would not be a material change in scope for purposes of N.C.G.S. §131E-181(a), and is otherwise permissible.

As background, Rex was approved to develop a new separately licensed hospital in Holly Springs with no more than fifty (50) licensed general acute care beds, three (3) licensed shared operating rooms ("ORs"), one (1) dedicated C-Section OR and five (5) unlicensed observation beds. Since the approval of the Holly Springs Hospital Project, Rex has determined that it would be more efficient to build a taller building on a smaller footprint to allow for future expansion on the campus and diminish the risk of being landlocked. Rex does not intend to change the number of acute care beds or operating rooms approved in the CON. Furthermore, this will not generate a cost-overrun.

K&L GATES LLP
POST OFFICE BOX 14210 RESEARCH TRIANGLE PARK NC 27709-4210 430 DAVIS DRIVE SUITE 400 MORRISVILLE NC 27560 T+1 919 466 1190 F+1 919 831 7040 klgates.com

I. Proposed Changes

As mentioned above, the structural changes to the facility would be to build a seven (7) story community hospital on a smaller foot print rather than the originally proposed three (3) story community hospital. Compare Exhibit 1 (original floor plans from CON Application) to Exhibit 2 (revised floor plans). See additional discussion in Part II below.

Below is a summary chart describing the proposed changes to the Holly Spring Hospital Project:

SUMMARY	
APPROVED CON PROJECT FOR UNC REX HOLLY SPRINGS	CURRENTLY PROPOSED UNC REX HOLLY SPRINGS
3 story community hospital	7 story community hospital
38 general medical/surgical beds	44 general medical/surgical beds
4 ICU beds	6 ICU Beds
8 LDRP beds	7 LDR beds
5 Observation beds	10 Observation beds
ED - 10 general treatment rooms, including an isolation room	ED 24 General treatment rooms, including an isolation room, triage room, and 2 resuscitation rooms
One C-Section room and 15 pre/post bays	2 C-Section rooms, and 7 pre/post bays
No Procedure rooms.	1 General Procedure Room
15 pre/post recovery rooms	18 pre/post recovery rooms + 1 isolation room
No MRI in building	Space for future MRI within building ¹

¹ In a Settlement Agreement dated October 22, 2018, involving Rex and the Agency, The Agency agreed that Rex could later place the current Cary MRI scanner at the Rex Holly Springs Campus after that scanner is used as a mobile scanner. See Exhibit 4.

Two radiographic/fluoroscopy rooms staffed and operational for scheduled procedures 14 hours a day, M-F. Available 24/7 for unscheduled emergency procedures	1 X-ray room and 1 R/F room
Cardiopulmonary services will include arterial flow studies, electrocardiograms, stress testing, echo cardiography,	Cardiopulmonary services will include arterial flow studies, electrocardiograms, stress testing, echocardiography and respiratory therapy
8,300 square foot central energy plant at rear of hospital	11,500 square foot central energy plant at rear of hospital

- * The ED triage rooms will double as treatment rooms.
- * The prep/post bays for C-Section are also the OB ED bays. These are shared use.
- * Procedure room on OR floor.

II. Revised Floor Plan.

The Holly Springs Project CON approved a capital cost of \$171,616,236 for a proposal projected to be 213,000 square feet on three (3) floors. Three fully constructed road systems surround the Holly Springs Hospital Campus, setting the parameters of future Holly Springs Hospital expansion. Thus, so as to avoid being landlocked upon future expansion, Rex has decided that the more prudent long-term strategy is to build essentially the same hospital more vertically, with seven (7) floors.

Exhibit 1 shows the original square footage as proposed in the application (total square and square feet by department). In comparison, Exhibit 2 reflects the revised, proposed square footage (total square feet and square feet by area). Rex expects the capital costs for the Holly Springs Hospital Project to remain roughly the same. Rex currently plans to complete construction and offer services by June 1, 2020. See Exhibit 5 (Progress Report with Revised Timetable).

III. CT Scanner

In addition to the changes described in Parts I and II above, Rex also requests that the Agency confirm that it is materially compliant for Rex to acquire a CT scanner for under \$750,000, which would begin operating upon completion of the Project. See Exhibit 6 (CT Scanner Quote).

Martha J. Frisone, Chief December 13, 2018 Page 4

IV. Change to Single Rex License

The Holly Springs Project CON originally contemplated that Rex would operate the Holly Springs Hospital as a separately licensed hospital from Rex Hospital in Raleigh. Now, Rex has identified some operational efficiencies associated with operating the Holly Springs Hospital under the same license as Rex Hospital in Raleigh. This change will not detrimentally impact Rex's ability to comply with all of the material representations in the Holly Springs Hospital Project Application. Moreover, the Holly Springs Project CON Application touted no specific advantages associated with operating under a separate license.

V. Conclusion

Rex will continue to deliver the highest quality acute inpatient care to its patients. Approval of this proposed change will not result in a cost overrun, additional health services, or higher patient charges. Rex believes that the revisions to the Holly Springs Hospital Project do not constitute a material change to that project, and thus do not require a new CON. In the event that the Agency has any concerns about specific components of this Request, we ask the Agency to treat components of the Request as severable.

We therefore ask the Agency to verify that the proposed changes in the Holly Springs Hospital Project described above are in material compliance with the Holly Springs Hospital CON, and that Rex need not obtain an additional CON to make these foregoing changes. Thank you for your assistance. If you have any questions, please give me a call.

Sincerely,

Gary S. Qualls

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Martha J. Frisone, Chief December 13, 2018 Page 5

Exhibits

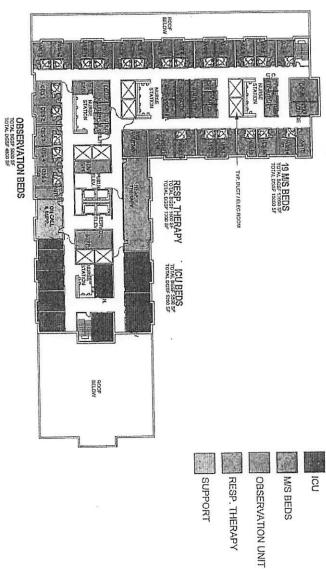
- 1. CON Application Excerpts, including: original floor plan and square footage.
- 2. Site Plan
- 3. Revised Floor Plan with revised square footage
- 4. Settlement Agreement dated October 22, 2018.
- 5. Current Progress Report with Revised Timetable
- 6. CT Scanner Quote



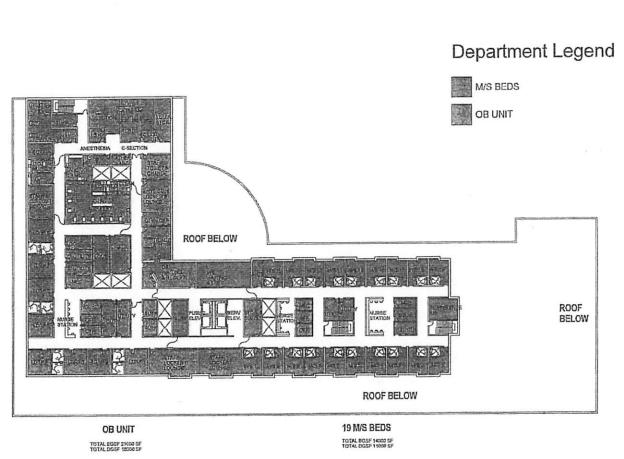
EXHIBIT \

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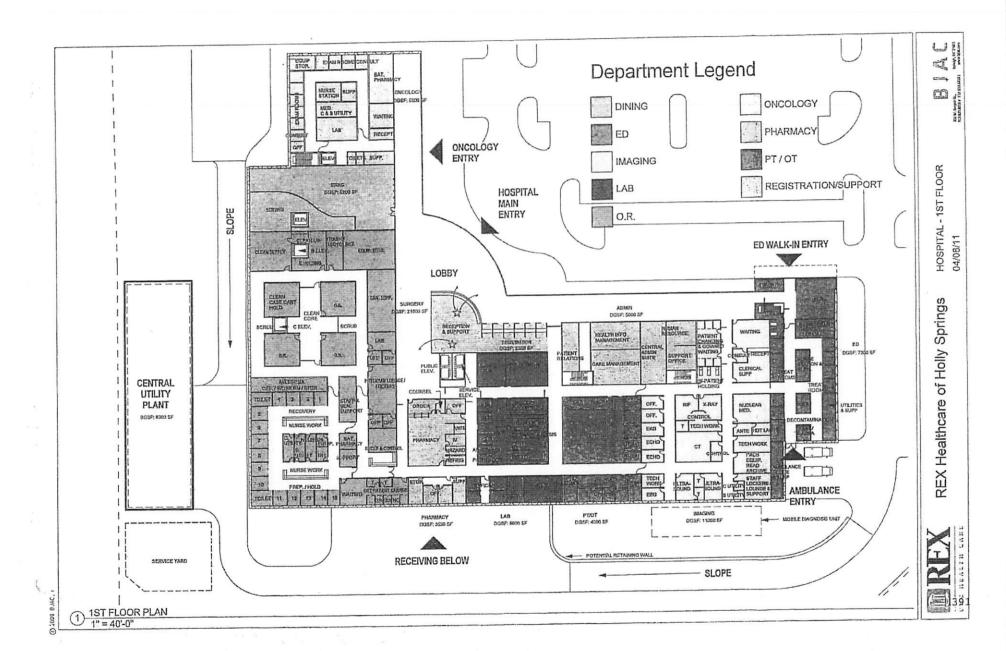


Department Legend



1 2ND FLOOR PLAN 1" = 40'-0"

1.5000 R.L.



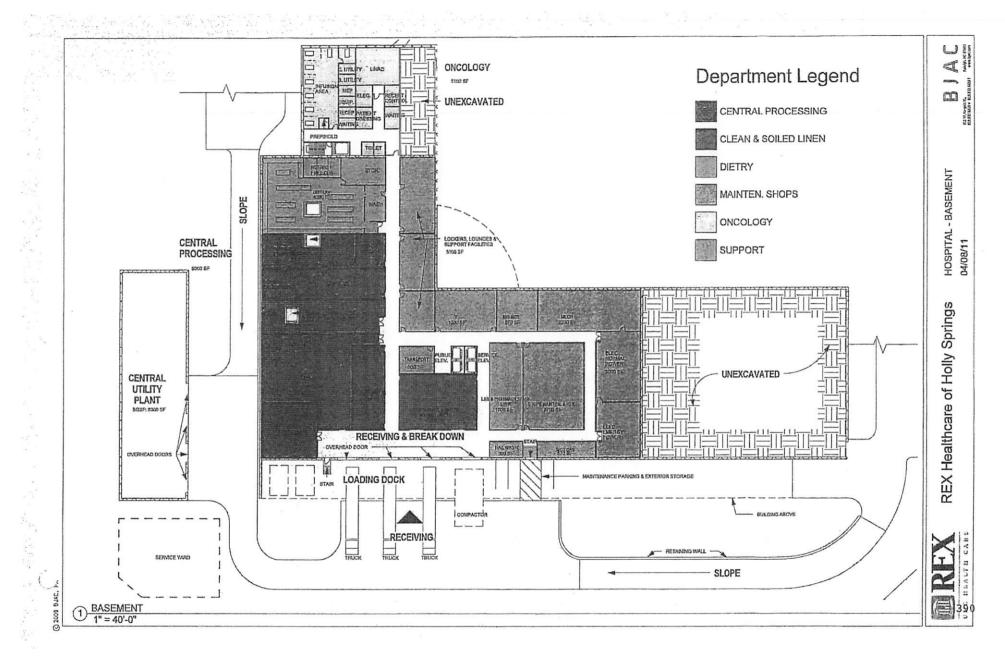
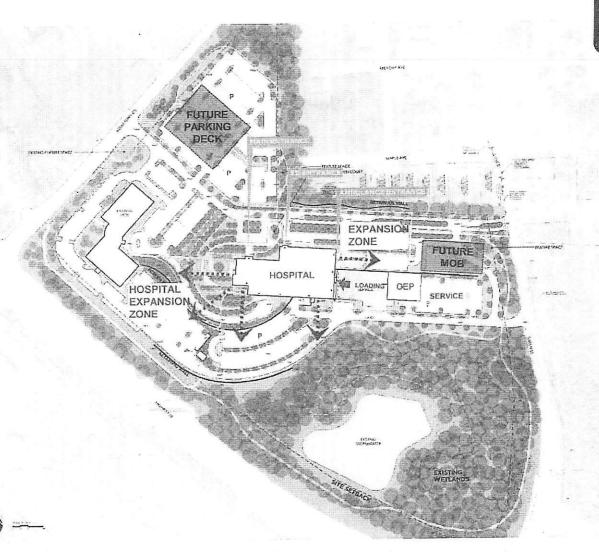


EXHIBIT (A)

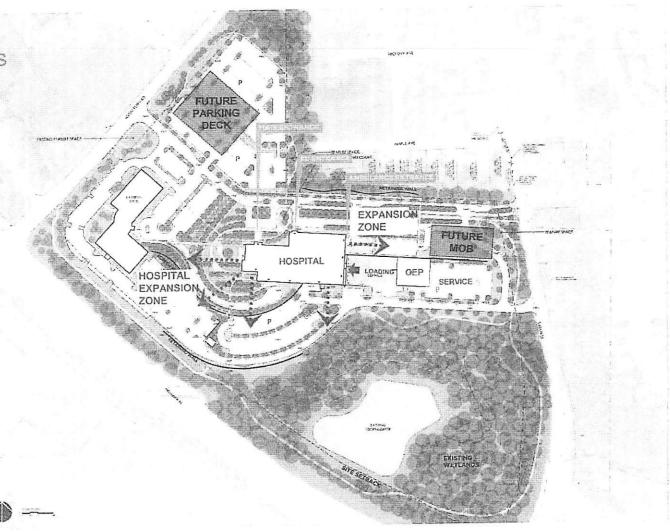
UNC REX Holly Springs Site Positioning

- · Creates shared outdoor areas
- Allows existing main entry points to service hospital additions.



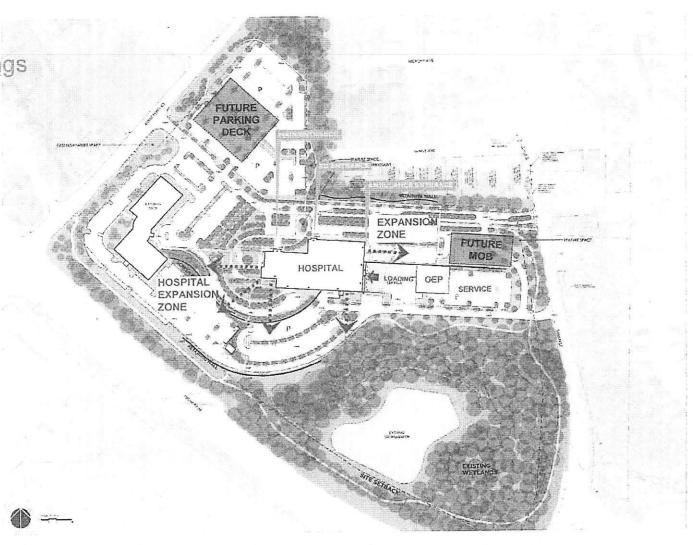
UNC REX Holly Springs Site Positioning

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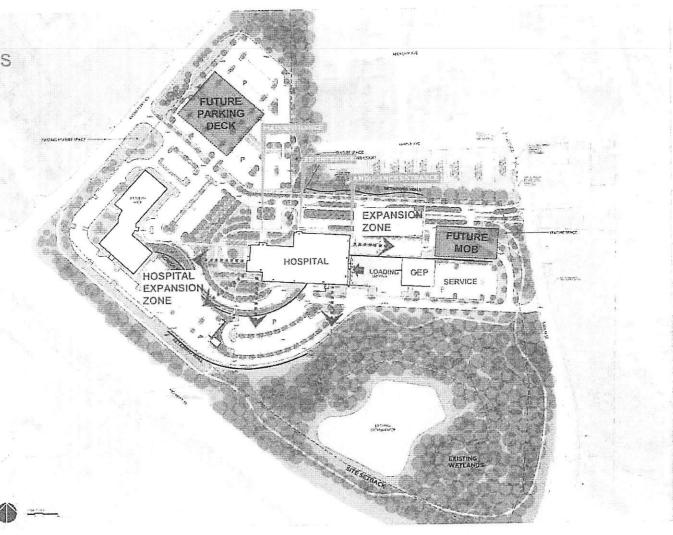
UNC REX Holly Springs
Site Positioning

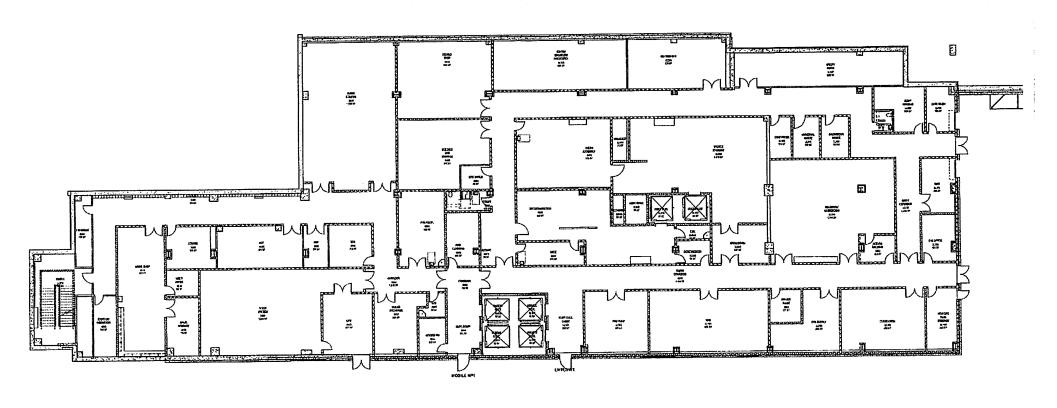
- · Creates shared outdoor areas
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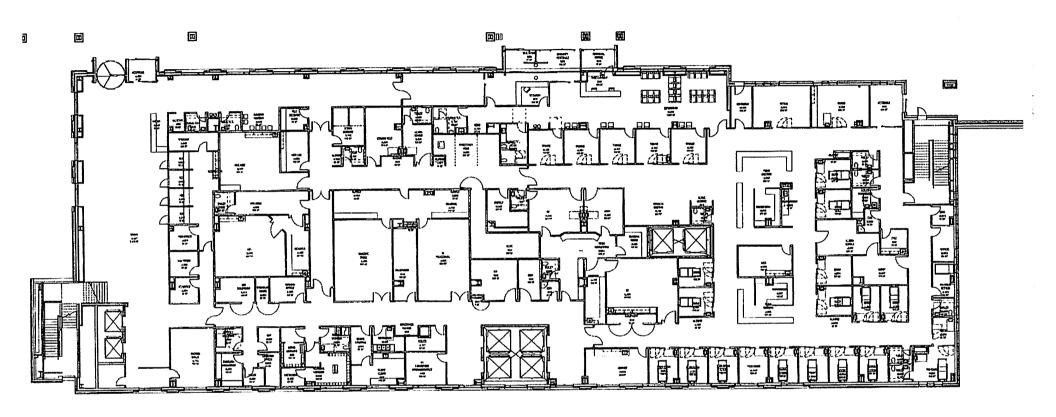


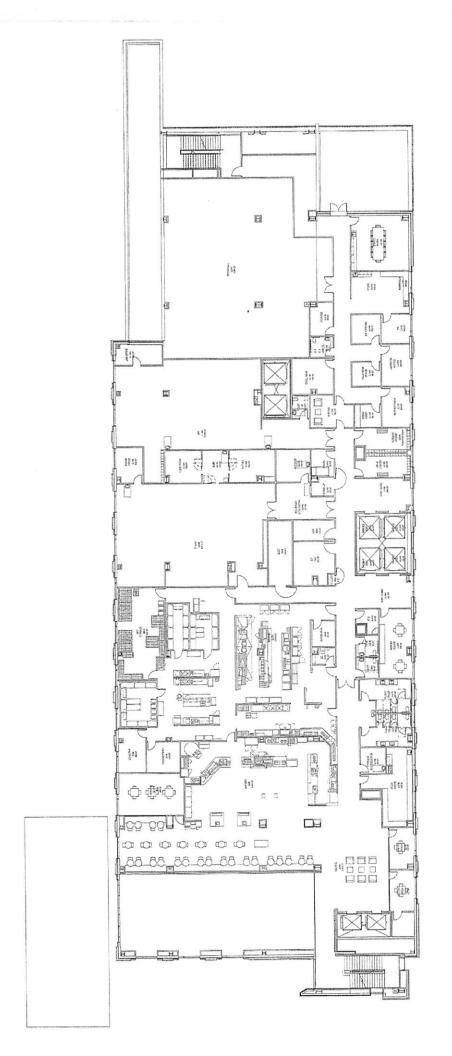
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- Allows existing main entry points to service hospital additions.

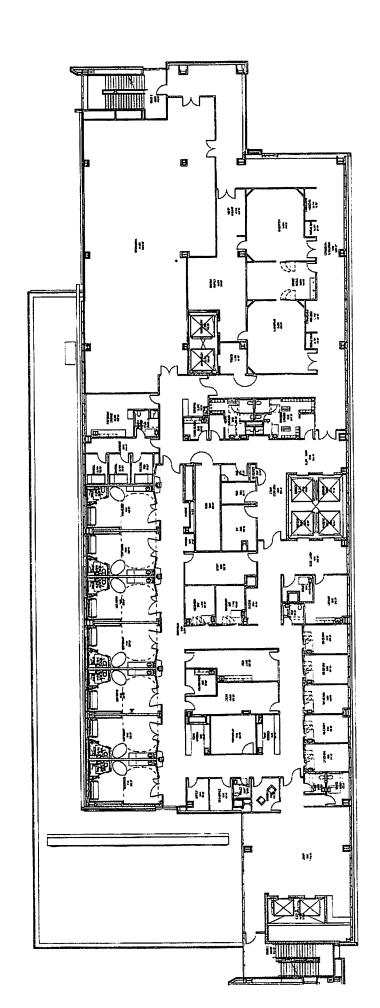


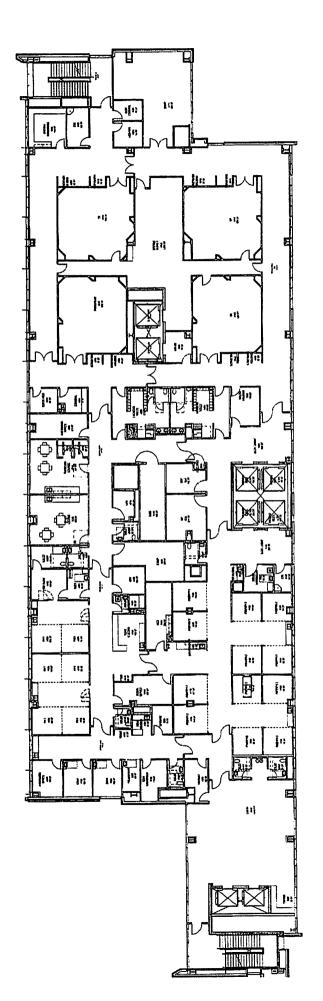


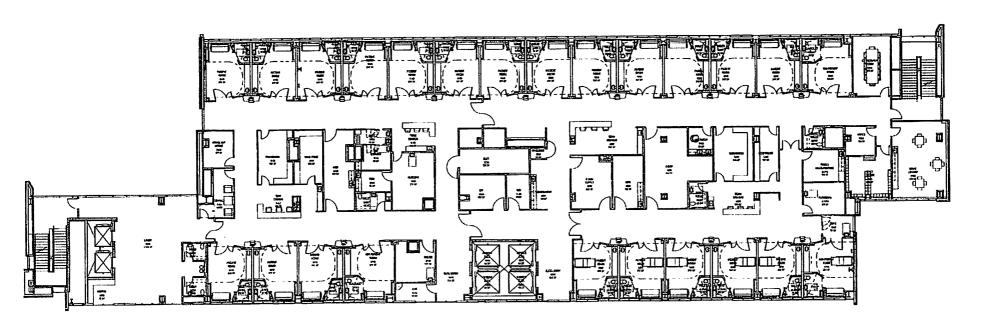
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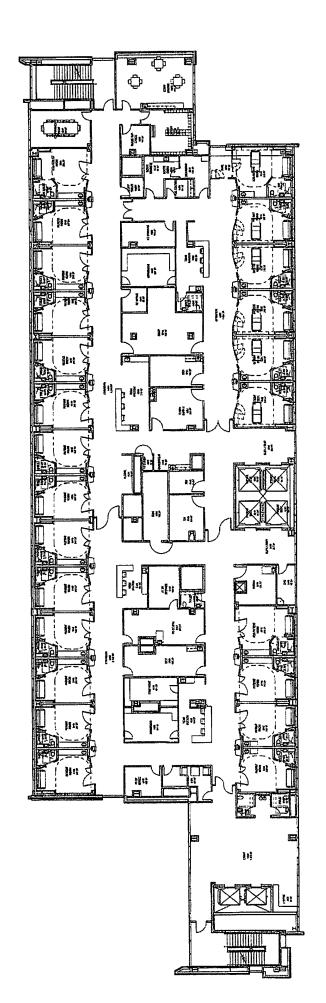


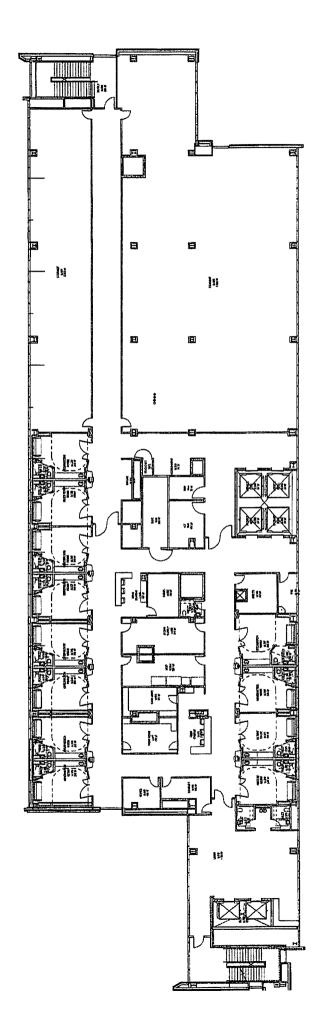












STATE OF NORTH CAROLINA	IN THE OFFICE OF ADMINISTRATIVE HEARINGS
COUNTY OF WAKE	18 DHR 2445
REX HOSPITAL, INC., d/b/a UNC REX HEALTHCARE,	
Petitioner,	
٧.	
N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION,	
Respondent,))
and))
WAKEMED,))
Respondent-Intervenor.)

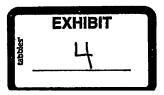
IN THE OFFICE OF

AGENCY SETTLEMENT AGREEMENT

This Agency Settlement Agreement ("Agency Settlement Agreement") is entered into by and among Petitioner Rex Hospital, Inc., d/b/a UNC Rex Healthcare ("Rex"), Respondent North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("Agency"), and Respondent-Intervenor WakeMed, (collectively referred to hereinafter the "Parties" and individually referred to hereinafter as a "Party").

WITNESSETH

WHEREAS, on October 16, 2017, WakeMed filed a Certificate of Need ("CON") application to construct an addition at WakeMed Cary Hospital and relocate 30 approved, but



undeveloped acute care beds and one shared operating room from WakeMed's Raleigh campus to WakeMed Cary Hospital, and its application was designated Project I.D. No. J-11428-17 (the "WakeMed Application").

WHEREAS, the Agency began its review of the WakeMed Application on November 1, 2017;

WHEREAS, in a written decision and findings dated March 29, 2018 ("the Agency Decision"), the Agency conditionally approved the WakeMed Application;

WHEREAS, on April 23, 2018, Rex filed a petition for contested case hearing with the Office of Administrative Hearings to challenge the Agency Decision. The contested case has been assigned OAH case number 18 DHR 2445 and remains pending;

WHEREAS, WakeMed was allowed to intervene as respondent-intervenor with all the rights of a party;

WHEREAS, no other person or entity sought to intervene in Contested Case No. 18 DHR 2445;

WHEREAS, all Parties participated in a mediated settlement conference on September 5, 2018 and later reached a mutually agreeable settlement;

WHEREAS, pursuant to N.C. Gen. Stat. § 150B-22, it is the policy of the State to settle disputes between State agencies and other persons whenever possible;

WHEREAS, in addition to this Agency Settlement Agreement, Rex and WakeMed (the "Private Parties") will enter into a Private Party Settlement Agreement ("Private Party Settlement Agreement"), to which the Agency is not a party; and

WHEREAS, the execution of this Agency Settlement Agreement does not constitute an admission of error by any Party, including, without limitation, an admission of error or an

admission concerning any aspect of the contents of the WakeMed Application or its review by the Agency;

NOW, THEREFORE, pursuant to N.C. Gen. Stat. §§ 150B-22 and 31(b), and subject to the approval of Mark Payne, Director of the Division of Health Service Regulation ("Director"), the Parties have decided to resolve this contested case in the manner set forth below.

TERMS OF AGREEMENT

- 1. <u>Voluntary Dismissal with Prejudice</u>. Rex shall dismiss with prejudice its appeal of the approval of the WakeMed Application within five (5) business days of complete execution of this Agency Settlement Agreement.
- 2. <u>Issuance of CON to WakeMed</u>. Within five (5) business days after it receives a file-stamped copy of Rex's Notice of Dismissal, the Agency shall issue a CON to WakeMed for Project I.D. No. J-11428-17 to construct an addition at WakeMed Cary Hospital and relocate 30 acute care beds and one shared operating room from WakeMed Raleigh Hospital to WakeMed Cary Hospital.
- 3. <u>WakeMed's Acceptance of Conditions</u>. By executing this Agreement, WakeMed accepts and agrees to comply with the conditions and timetable which have been imposed upon its certificate of need as set forth in <u>Exhibit A</u> to this Agreement.
- 4. Rex Healthcare of Cary's MRI Scanner. The Agency approves Rex to (a) replace Rex Healthcare of Cary's fixed MRI scanner with a mobile MRI scanner; and (b) convert that mobile MRI scanner back to a fixed scanner at Rex's Holly Springs Hospital at any time, at Rex's election, following one year of Rex's Holly Springs Hospital being licensed. That mobile MRI scanner would be limited to serving only UNC Rex Hospital's Main Campus, Rex's Holly Springs medical office building located at 781 Avent Ferry Road in Holly Springs, and/or Rex's

Holly Springs Hospital once licensed, for the duration that it operates as a mobile MRI scanner.

After execution of the Agency Settlement Agreement, the Agency will reissue the certificate of need for Rex Healthcare of Cary's MRI scanner to reflect the new scope as follows:

Replace the fixed MRI scanner located in Cary with a mobile MRI scanner to be used only at Rex's Main Campus, Rex's Holly Spring's medical office building located at 781 Avent Ferry Road and Rex's Holly Springs Hospital once licensed for the duration that it operates as a mobile MRI scanner. The mobile MRI scanner may be replaced with a fixed MRI scanner at any time, at Rex's election, following one year of Rex's Holly Springs Hospital being licensed. If and when Rex elects to replace the mobile MRI scanner with a fixed MRI scanner, the fixed MRI scanner will be located at Rex's Holly Springs Hospital.

The conditions on the certificate of need for Rex Healthcare of Cary's MRI scanner will not change.

- 5. Release. The Parties hereby release each other and their respective officials, employees, and representatives, from any and all liability that has arisen or that might arise out of the CON Section's review of the WakeMed Application or this contested case, specifically excepting any claims and obligations that may arise out of this Agreement.
- 6. No Claim for Attorneys' Fees or Costs. The Parties agree that each Party shall bear its own expenses, including attorneys' fees and costs incurred in this contested case. No Party shall make any claim against any other Party for attorneys' fees and costs incurred in this contested case.
- 7. <u>Effect of Approval</u>. By executing this Agency Settlement Agreement, the Parties acknowledge that, if approved by the Director, this Agreement shall resolve all issues involved in this contested case, subject to any issues that are separately addressed in the Private Party Settlement Agreement.

- 8. <u>Effect of Disapproval</u>. In the event that this Agency Settlement Agreement is not approved by the Director, the Parties acknowledge that this Agency Settlement Agreement shall be null and void and the Parties shall be entitled to proceed with this contested case. In addition, if this Agency Settlement Agreement is not approved by the Director, the Parties agree that it shall be inadmissible for any purpose in this contested case.
- 9. <u>Waiver of Right to Appeal Agreement</u>. If this Agency Settlement Agreement is approved by the Director, the Parties irrevocably waive any right to initiate an appeal from this Agency Settlement Agreement, if any such right of appeal exists. However, nothing in this Agreement shall be construed to waive any claim for enforcement or breach of this Agency Settlement Agreement. The Parties reserve the right to intervene in any appeal of this Agency Settlement Agreement that might be filed by any third party.
- 10. Merger. The Parties agree and acknowledge that this Agency Settlement Agreement sets forth all of the terms and conditions among them concerning the subject matter of this Agency Settlement Agreement, superseding all prior oral and written drafts, statements and representations, and that there are no terms or conditions among the Parties except as specifically set forth in this Agency Settlement Agreement and/or the Private Party Settlement Agreement.
- 11. <u>Modification or Waiver</u>. No modification or waiver of any provision of this Agency Settlement Agreement shall be effective unless it is in writing. Any modification or waiver must be signed by authorized representatives of the Parties and must be approved and adopted by the Director of the Division of Health Service Regulation.
- 12. <u>No Strict Interpretation Against Drafter</u>. Each Party has participated in the drafting of this Agency Settlement Agreement and has had the opportunity to consult with

counsel concerning its terms. This Agency Settlement Agreement shall not be interpreted strictly against any one Party on the grounds that it drafted the Agreement.

- 13. Recitals and Headings. All parts and provisions of this Agency Settlement Agreement, including the recitals and paragraph headings, are intended to be material parts of the Agency Settlement Agreement.
- 14. <u>Authority to Settle</u>. The undersigned represent and warrant that they are authorized to enter into this Agency Settlement Agreement on behalf of the Parties to this Agency Settlement Agreement.
- 15. <u>Ex Parte Presentation</u>. Rex and WakeMed authorize counsel for the Agency to present this Agency Settlement Agreement to the Director *ex parte*. The Agency's counsel shall exercise due diligence to have the Director review and act upon this Agreement without undue delay.
- 16. <u>Effective Date</u>. This Agency Settlement Agreement shall be effective as of the day and year on which it is adopted and approved by the Director.
- 17. <u>Binding Effect</u>. This Agency Settlement Agreement is binding on the Parties and the Parties' parents, subsidiaries, predecessors, successors, affiliates, assigns, shareholders, officers, officials, directors, trustees, managers, members, employees, agents, representatives and attorneys.
- 18. Governing Law. This Agency Settlement Agreement shall be construed and governed according to the laws of the State of North Carolina. If any provisions of this Agency Settlement Agreement are held to be invalid or unenforceable, all other provisions shall nevertheless continue in full force and effect.

-DocuSigned by:

- 19. <u>Counterparts</u>. This Agency Settlement Agreement may be executed in multiple counterparts, all of which shall be considered one and the same agreement, it being understood that all Parties need not sign the same counterpart.
- 20. <u>E-mailed Signature Pages</u>. In order to expedite the signing of this Agency Settlement Agreement, the Parties stipulate and agree that the delivery of an executed signature page by each Party to the other via electronic (e-mail) transmission shall bind the transmitting Party.

IN WITNESS WHEREOF, the Parties sign below in acknowledgement of their agreement to the foregoing.

PETITIONER REX HOSPITAL, INC. d/b/a UNC REX HEALTHCARE

— 1 ·	teu Burniss 080549344487445			
	ve Burriss			
	ident			
	/22/2018			
Date:				
CONSENT	ED TO:			
K&L GAT	ES LLP			
DocuSigned by				
Susan te	. Hackney		10/18/2018	
628707400D80	•	Date:	10/10/2010	
Gary S. Qu	alls			
Susan K. H	ackney			
Steven G. I	Pine			
	Drive, Suite 400			
Morrisville	, North Carolina 27560			

Counsel for Rex Hospital, Inc. d/b/a UNC Rex Healthcare

RESPONDENT NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

By: CFBD2033C93B4BB	10/18/2018 Date:
Martha J. Frisone, Chief	
CONSENTED TO:	
JOSH STEIN Attorney General	
By: June S. Ferrell June S. Ferrell	10/18/2018 Date:
Special Deputy Attorney General N.C. Department of Justice	
Post Office Box 629 Raleigh, NC 27602-0629	

COUNSEL FOR THE DIVISION OF HEALTH SERVICE REGULATION

RESPONDENT-INTERVENOR WAKEMED

	DocuSigned by:
_	Dag-
By:	—582342F2DC194BA
	Donald R. Gintzig
	President and Chief Executive Officer
	10/18/2018
Date:	

CONSENTED TO:

SMITH MOORE LEATHERWOOD LLP

Marcus C. Hewitt
Elizabeth Sims Hedrick
Terrill Johnson Harris
Post Office Box 27525
Raleigh, North Carolina 27611

Counsel for WakeMed

10/18/2018

Date:

APPROVAL AND ADOPTION

The foregoing Agency Settlement Agreement is hereby APPROVED AND ADOPTED this the 22nd day of October, 2018.

Mark Payue

16BE3E02F308417...

Mark Payne, Director

Division of Health Service Regulation

NC Department of Health and Human Services

EXHIBIT A

CONDITIONS

The WakeMed Application is approved subject to the following conditions:

- 1. WakeMed shall materially comply with all representations made in the certificate of need application.
- 2. WakeMed shall relocate no more than 30 approved acute care beds from WakeMed Raleigh Campus to WakeMed Cary Hospital. Upon completion of the proposed project, WakeMed Cary Hospital will be licensed for no more than 208 acute care beds.
- 3. WakeMed shall relocate no more than one shared surgical operating room from WakeMed Raleigh Campus to WakeMed Cary Hospital. Upon completion of the proposed project, WakeMed Cary Hospital will be licensed for no more than ten shared surgical operating rooms and two dedicated C-section operating rooms.
- 4. WakeMed shall not acquire as part of this project 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.
- 5. WakeMed shall develop and implement an energy efficiency and sustainability plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
- 6. 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, WakeMed 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.
- 7. WakeMed 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.

TIMETABLE

1.	Construction/Renovation Contract(s) Executed	December 1, 2018
2.	25% of Construction/Renovation Completed	
	(25% of the cost is in place)	March 1, 2019
3.	50% of Construction/Renovation Completed	
4.	Construction/Renovation Completed	February 1, 2020
5.	Services Offered	April 1, 2020
	Final Annual Report Due	



James T. Hedrick Building 211 Friday Center Drive, Suite G015 Chapel Hill, NC 27517

December 7, 2018

Michael J. McKillip, Project Analyst Certificate of Need Section Division of Health Service Regulation, DHHS 2704 Mail Service Center Raleigh, NC 27699-2704

Dear Mr. McKillip:

Attached you will find the Progress Report for CON Project I.D. # J-8669-11 and Facility I.D. # 070823. This project involves the development of a new hospital in Holly Springs.

Please call me at 984-215-3622 if you have any questions or require any additional information at this time.

Sincerely,

Elizabeth Runyon, System Director of Regulatory Affairs

Strategic Planning UNC Health Care

CERTIFICATE OF NEED PROGRESS REPORT FORM

County: Wake County
Facility: Rex Hospital Inc.

Date of Progress Report: 12/5/2018

Facility I.D. #: 070823

Effective Date of Certificate: 1/22/2014

Project I.D. #: 1-8669-11

Project Description: Develop a new separately licensed hospital in Holly Springs with no more than 50 licensed general acute care

beds, 3 licensed shared ORs, 1 dedicated C-Section OR and 5 unlicensed observation beds

A. Status of the Project

1. Describe in detail the steps taken to complete the project since the CON was issued or since the last progress report was submitted.

Response: The project was initially delayed due to opposition from another organization, thus the actual certificate of need was not issued until 2014. This lengthy legal delay caused us to proceed first with the Rex heart hospital project. In order to ensure we did not take on too much debt at one time, as well as having the internal staff needed to manage a second large project, we held off beginning the Holly Springs project until the completion and opening of the heart hospital project. Now that the heart hospital is operational, we have hired an architect and begun planning for the Holly Springs hospital, with an expected opening in early 2021.

In 2017, Rex engaged the services of a new design team, and held community forums to discuss the desire and needs for the community hospital. A comprehensive Progress Report was submitted on 7/15/2017 and a Timetable Extension was granted on 10/2/2017. The design team and Rex staff have taken site visits to other similar sized hospital (in NC and CO), and participated in additional benchmarking tours. Additionally, Holly Springs Community Forums were hosted to collect ideas and feedback from residents. The hospital design efforts have been progressing and are very close to completion. A package of drawing documents will be submitted in a few weeks for approval. The municipal approval process with the Town has already begun.

Given the rising cost of construction (both in materials and labor), project coordination is a very important factor that when applicable will drive us to consolidate projects whenever possible. By designing, and constructing as a whole versus in parts, will not only reduce our overall spend, it will result in a more cohesive and efficient project. Due to market escalation in construction costs the team has launched more design time to reduce the costs of the project and maximize the project. Drawings should be completed very shortly, and after town approvals are secured, site work construction is anticipated to begin in the first quarter of 2019.

- 2. Describe any of the previously approved changes which will impact this project:
 - 1. Cost Overruns and/or Changes of Scope (Include the Project I.D. numbers);
 - 2. Material Compliance determinations; and
 - 3. Declaratory Rulings

Response: Not applicable.

- 3. If the project is not going to be developed exactly as approved, describe all differences between the project as approved and the project as currently proposed. Such changes include, but are not limited to, changes in the:
 - a, Sito;

- b. Design of the facility;
- o. Number or type of beds to be developed;
- d. Medical equipment to be acquired;

e. Proposed charges; and

f. Capital cost of the project.

Response: Not applicable,

4. Pursuant to G.S. 131E-181(d), the Certificate of Need (CON) Section cannot determine that a project is complete until "the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application." To document that new or replacement facilities, new or additional beds or dialysis stations, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

Response: Not applicable.

B. Timetable

1. Complete the following table. The first column must include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

DHHS/DHSR/(CON) FORM NO. 9001 Date of Last Revision: 1/20/15

Project Milestone	Original projected completion date from certificate	Projected completion date from most recently approved timetable extension	Actual completion date	Proposed completion date
	1/22/2014	10/2/2017	mm/dd/yy	mm/dd/yy
Obtained Funds for Project	NA	NA	NA	NA
Final Drawings and Specifications Sent to Construction Section, DHSR	NA	NA	NA	NA
Completion of Final Drawings	12/1/2014	6/29/2018		12/17/2018
Acquisition of Land/Pacility	NA	NA	NA	NA
Construction Contract Executed	NA	· NA	NA	NA
25% Completion of Construction	10/1/2015	12/10/2018		7/8/2019
50% Completion of Construction	2/1/2016	5/20/2019		12/20/2019
75% Completion of Construction	8/1/2016	10/21/2019		6/19/2020
Completion of Construction	12/1/2016	3/21/2019		12/21/2020
Ordering of Medical Equipment	NA	NA	NA	NA
Operation of Medical Equipment	NA	NA	NΛ	NA
Occupancy/Offering of Services	2/1/2017	6/1/2020		4/5/2021
Licensure	NA	NA	NA	NA
Certification	NA	NA	ÑΑ	NA

^{*}Proposed completion dates are contingent upon CON approval

<u>Please note</u>: All dates in the "Proposed completion date" column are tentative and subject to change, but are provided in an effort to keep the CON Section informed about the current status of the project. The proposed date of 12/17/2018 for completion of drawings represents the date a package of documents will be submitted for approval, but will not be the "for permit" set of documents.

2. If the project is experiencing delays in development, explain in detail the reasons for the delay.

Response: As noted above in response to question A.1, given the rising cost of construction (both in materials and labor), project coordination is a very important factor that when applicable will drive us to consolidate projects whenever possible. By designing, and constructing as a whole versus in parts, will not only reduce our overall spend, it will result in a more cohesive and efficient project. Due to market escalation in construction costs the team has launched more design time to reduce the costs of the project and maximize the project. Revised drawings should be completed shortly, and after town approval has been secured, a more reliable timetable can be developed. Site work construction is anticipated to begin in the first quarter of 2019.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(140); 2) the specific equipment listed in NCGS §131-176(16); or 3) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

Response: Not applicable.

D. Capital Expenditure

- 1. What is the total approved capital cost of the project indicated on the certificate of need? \$171.616.236
- 2. Complete the table on the following page.
 - a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
 - b. If you have not already done so, provide copies of all executed contracts, including architect and engineering services (as applicable) and all final purchase orders for medical equipment costing more than \$10,000 per unit.
 - p. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703]. Capital Expense Total Cumulative

Since Last Capital
Report Expenditure

Sita Costs

Purchase price of land
Closing costs
Site Inspection and Survey
Legal fees
Site preparation costs

DHHS/DHSR/(CON) FORM NO. 9001 Date of Last Revision: 1/20/15

Other site costs (identify) Subtotal Site Costs	<u> </u>	
Construction Contract Cost of materials Cost of Labor Other (Specify) Subtotal Construction Contract		
Miscellaneous Costs Building purchase Fixed equipment purchase/lease Moveable equipment purchase/lease Furniture Landscaping Consultant fees (Architect & Engineering) Financing costs Interest during construction Other miscellaneous costs (Legal fees) Subtotal Miscellaneous Costs	\$1,314,921.83: \$1,314,921.83	\$3,589,501.26 *Note \$3,389,501.26
Total	\$1,314,921.83	\$ <u>3,589,501.26</u>
Note: Legal fees incurred as a result of litigation were eand does not include those fees as a cost subject to the C	erroneously included in a previous progress rep CON-approved capital cost for the project.	ort. This report has corrected that error
What is the projected remaining capital expenditur	e required to complete the project? \$168.	026,734.74
Will the total <u>actual</u> capital cost of the project exceptain the reasons for the difference.	eed 115% of the approved capital expendi	iture on the certificate of need? If yes,
Response: Capital costs are not anticipated to exc	eed 115% of the approved capital expend	ture amount.
CERTIFICATION – The undersigned hereby condocuments are correct to the best of his or her kn forms will not be accepted and must be resubmited. Signature of Officer: Name and Title of Responsible Officer Telephone Number of Responsible Officer	towledge and belief. In addition, I acknowled upon notification from an Agency Projection	Miedge that incombiete brogress rebor

3.4.

E.



Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard, Malvern, PA 19355

Fax: (336) 856-9995

SIEMENS REPRESENTATIVE Edwin Winicki - (336) 688-0978

Customer Number: 0000010805

Date: 12/8/2018

UNIVERSITY OF NORTH CAROLINA 101 MANNING DR **CHAPEL HILL, NC 27514**

Siemens Medical Solutions, USA, Inc. is pleased to submit the following quotation for the products and services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions on the face and back hereof, and on any attachment hereto.

Quote Nr:

1-OG4RS5 Rev. 0

Trade:

N/A - no trade

Terms of Payment

00% Down, 80% Delivery, 20% Installation

Free On Board: Destination

Purchasing Agreement

Vizient

Terms and Conditions

Vizient terms and conditions apply

Proposal Valid Until

9/30/2019

Slemens Somatom go. Top for UNC Rex Holly Springs

Part No. Qty

Item Description

14460603

SOMATOM go.Top

As a member of the SOMATOM go, platform, the SOMATOM go, Top supports all users to provide the best scan for every type of patient - no matter the clinical demands and challenges. The scanner features a unique tablet-based mobile workflow, user guidance with our GO technologies, and exclusive innovations such as Tin Filter low-dose technology. SOMATOM go.Top is built for personalization of processes and care, allowing every operator to optimally adapt to the individual patient and indication while interacting with patients in a more personalized way than ever before. Produce excellent results for the full clinical spectrum including Dual Energy imaging, and offer what others cannot - for a successful CT business.

14460622

High Performance Package

High Power 70 Mode for exceptionally high currents at low kV selectable in 10kV steps for enhanced lodine contrast, which is especially useful for very small vessels. High Power 70 and the all new Athlon X-ray tube allow you to scan at 70 kV with the highest tube current of this CT class, up to 825 mA.

High-speed 0.33 s rotation time for outstanding image quality and very high scan speeds. Delivering a temporal resolution of 165 ms, which is ideally suited for cardiac exams.

Created: 12/8/2018 4:27:00 PM PRO 1-OG8WBU

Siemens Medical Solutions USA, Inc. Confidentia

age 1 of 6



Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard, Malvern, PA 19355 Fax: (336) 856-9995

SIEMENS REPRESENTATIVE Edwin Winicki - (336) 688-0978

Part No. Qtv

Item Description

included Cardio Spiral for adaptive retrospective ECG-gated spiral scanning to obtain CT images of the heart in defined phased of the cardiac cycle.

Physiological Measurement Module and ECG cables included.

The iMAR metal artifact reduction algorithm makes it possible to reduce metal artifacts caused by metal implants. IMAR can be combined with Iterative reconstruction methods.

Inline Spine Ranges for Zero-click reconstruction of anatomically aligned spine reconstructions. This delivers time savings, while reducing the risk of mislabeling associated with manual preparation.

Inline Rib Ranges for Zero-click reconstruction of radial and parallel rib specific visualization that adapts the rib cage anatomy according to the radiologist's reading needs - displaying all ribs spread out in one plane. Automated rib labelling and numbering.

Spine Ranges @ CT View&GO

Guided reconstruction of anatomically aligned spine Curved Planar Reconstructions. Automatic detection/labeling of vertebrae.

Lung CAD for fully automated, computer-assisted second reader tool designed to assist radiologist in the detection of pulmonary nodules during review of CT examinations of the chest.

syngo.CT Calcium Scoring supports all common quantification algorithms: Agatston scoring, volumetric scoring and calcium mass quantification.

14460605

SW Base Package

SW Base Package

Scan&GO mobile workflow, including tablet, remote control, camera, and a new workplace design

Check&GO flags problems with scan coverage or contrast distribution as they occur

Recon&GO reduces post-processing to just one click, with: Inline Anatomical Ranges, Inline Table and Bone Removal, Inline Vessel Ranges and Multi Recon-performing multiple reconstructions in one step

CT View&GO provides a variety of clinical applications and tools for smooth reading in just one workflow

SAFIRE

SOMATOM go. scanners achieve higher efficiency with in dose reduction with Sinogram Affirmed Iterative Reconstruction while maintaining excellent image quality

Interleaved Volume Reconstruction

Enhances spatial sampling in z-direction, independent of pitch

CARE Dose4D, CARE kV, 10 kV Steps, CARE Child

Personalized dose control tools that allow you to increase consistency of low dose CT scanning techniques across all technologists

Endoscopic View

Simulated views of e.g. the Inside of bronchi, colon and any other hollow structures

Dual Spiral Dual Energy and Dual Energy ROI

syngo Single Source Dual Energy Scan mode option offers the possibility to acquire two spiral data sets in sequence at different energies

HD FoV**

Enables a field of view up to 70 cm, which is optimal for visualization of obese patients and those that are positioned outside the CT isocenter



Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard, Malvern, PA 19355

Fax: (336) 856-9995

SIEMENS REPRESENTATIVE Edwin Winicki - (336) 688-0978

Qty	Part No.	Item Description
		*In clinical practice, the use of SAFIRE may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task
		** The image quality for the area outside the standard 50 cm scan field does not meet the image quality specifications shown in the technical data sheet and Image artifacts may appear, depending on the anatomy scanned
1	14460659	Advanced Cardio Package
		The Advanced Cardio Package allows for comprehensive cardiac assessment and clinical consistency in cardiac CT with ease. This option delivers an optimized, fully tablet-operated scan preparation, fast scanning, and standardized results in every cardiac case enabled by the Integrated GO technologies that allow you to devote more time to your patient.
		During the scan, Check&GO monitors coverage and contrast in real time, allowing you to correct problems as you work and thus potentially avoiding repeat scans. Quality-control images are sent wirelessly to the tablet, so you can review them directly at the scanner.
		Adapt Cardio Sequence for adaptive prospective ECG-triggered sequence scanning.
		Inline Cardio Ranges for zero-click curved planar reformats (CPRs) of the main coronaries and radial VRT ranges of the coronary tree help you quickly rule out coronary artery disease.
		Cardio Ranges @ CT View&GO: CT View&GO supports you in challenging cases where you need to manually interact with the images. Its intuitive and customizable tools enable smooth, straightforward reading.
1	14460606	Scan&GO wireless edition
		Includes Scan&GO Tablet and Remote Scan Control. Built around a new mobile workflow, the SOMATOM go. platform features a line-up of innovative solutions - tablet, remote control, camera, and a new workplace design - that bring an unparalleled level of flexibility and mobility to daily CT routines. The solutions also enhance patient comfort for potentially higher levels of patient satisfaction.
		The lightweight, high-resolution tablet gives our customers total freedom over how they work: only a few steps for the entire scan.
1	14460608	HP Care Pack HP Tablet Care Pack for 3 years duration.
1	14460885	307 kg Patient Table
ř		Pattent table with 676 lb / 300 kg weight limit designed to accommodate virtually all patients with a long scan range of 2000 mm.
1	14460613	Foot Switch for Pat.Table control
		Additional flexibility with a foot switch that controls patient table movements only.
1	14460643	Table Accessories Set More table accessories for further flexibility based on the clinical needs. Includes table side rails, storage box and infusion holder.
1	14460615	Positioning & Fixation Set Including Pediatric Cradle, Arm support, Patient fixation with silder
1	14460614	Table Extension Table extension
1	14460647	UPS
•		UPS. An uninterrupted power supply, for the syngo Acquisition Workplace in the event of network fluctuations and brief power failures.
1	14460793	Computer Desk 1200 mm CT desk designed to accommodate the control components and color monitor(s).



Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard, Malvern, PA 19355 Fax: (336) 856-9995

SIEMENS REPRESENTATIVE Edwin Winicki - (336) 688-0978

Qty	Part No.	Item Description
1	14460628	CARE Contrast II CARE Contrast is an integrated solution for a simplified bolus injector coupling due to synchronized scanning and contrast injection.
1	B2ISI900SN	Medrad ISI900 interface, POS
1	BSCT322	Stellant D Dual Ceiling w/Certegra WS Stellant D Dual Ceiling mounted with Certegra Workstation NO Informatics. Short ceiling post - 580 mm.
		Other ceiling post lengths are available (different part numbers): 850 mm and 1000 mm.
	CT CO STELL	Includes Stellant D, Dual Head, ceiling mounted injector; Certegra workstation; installation and warranty through Medrad.
1	CT_GO_STELL AR	Stellar Low Noise Technology Detector The Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detector technology keeps electronic noise low, increases dose efficiency and improves spatial resolution. The smart configuration of the detector elements simplifies access, eases maintenance, and increases scanner uptime. For SOMATOM go scanners, the Stellar detector features a 3D anti-scatter collimator for even more efficient optimization of X-ray energy.
1	SURE_VIEW	SureView Provides exceptional image quality at any pitch setting, enabling you to scan faster because you can scan at any pitch without degrading image quality
4	CARE_DOSE4	CARE Dose4D
1	D	CARE Dose4D CARE Dose4D delivers the highest possible image quality at the lowest possible dose for patients - maximum detail, minimum dose. Adaptive dose modulation for up to 60% dose reduction
1	CT_LUNGIMA GINGGO	Lung Imaging
·		Lung Imaging Go: For well over a decade, CT has been recognized and used as the standard of care for lung nodule visualization and sizing. This is due to CT's spatial resolution, geometric accuracy, and ability to create various reconstructions and 3D views. The high contrast environment in the chest between the lungs and the nodules makes for a relatively easy visualization task for clinicians using CT images. Recent advances in CT technology have allowed these scans to be effectively performed at lower doses, higher resolutions, and faster scan times. The SOMATOM go.Platform leverages Tin Filter Technology to further enhance the delivery of low dose lung cancer screening for high risk populations*. The SOMATOM go scanners are delivered with specific scan protocols to provide low dose lung cancer screening exams that use Siemens-exclusive Tin Filter Technology to reduce unnecessary radiation. These default protocols also utilize Siemens proprietary dose reducing features such as CARE Dose4D(tm), automatic exposure control technology, that further modulates and adapts dose for every patient, for high image quality at low dose. The SOMATOM go scanners come with default low dose lung imaging protocols below 1 mSv. *As defined by professional medical societies.
1	DOSE_ALERT	Dose Alert
		Dose Alert: Dose Alert automatically adds CTDIvol and DLP values depending on z-position (scan axis). The Dose Alert window appears, if either of these cumulative values exceeds a user-defined threshold.
1	DOSE_NOTIFI CATION	Dose Notification
		Dose Notification: Dose Notification provides the ability to set dose reference values (CTDIvol, DLP) for each scan range, if these reference values are exceeded the Dose Notification window informs the user.
1	ACCESS_PRO TECT	Access Protection Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols
1	NEMA_XR-29	NEMA_XR-29 Standard This system is in compliance with NEMA XR-29 Standard Attributes on CT Equipment Related to Dose Optimization and Management, also known as Smart Dose.
1 Croat	CT_UPS_DEF_ AS	Standard UPS for Definition AS The standard partial system uninterruptible power system (UPS) is built directly into the power distribution cabinet (PDC) and supports the critical circuits for table and gantry electronics, console computer, image reconstruction Stemens Medical Solutions USA Inc. Confidential Page 4 of 6



Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard, Malvern, PA 19355

Fax: (336) 856-9995

SIEMENS REPRESENTATIVE Edwin Winicki - (336) 688-0978

Qty Part No.

Item Description

system, and the internal Ethernet switch (to ensure connectivity). This enables safe removal of patient if outage occurs during scanning.

The UPS allows for a safe shutdown of the CT scanner in the event of power interruption. The UPS provides 5-7 minutes of power, during which the user is prompted and guided through the process to perform a safe shutdown of the system. This safe shutdown ensures that no data is lost.

CT_PM

CT Project Management

A Siemens Project Manager (PM) will be the single point of contact for the Implementation of your Siemen's equipment. The assigned PM will work with the customer's facilities management, architect or building contractor to assist you in ensuring that your site is ready for installation. Your PM will provide initial and final drawings and will coordinate the scheduling of the equipment, installation, and rigging, as well as the initiation of on-site clinical education.

CT BUDG AD DL_RIG CT_STD_RIG_I NST

Add'I/Out of Scope Rigging

CT Standard Rigging and Installation

This quotation includes standard rigging and installation of your CT new system.

Standard rigging into a room with reasonable access, as determined by Slemens Project Management, during standard working hours (Mon. - Fri./ 8 a.m. to 5 p.m.)

It remains the responsibility of the Customer to prepare the room in accordance with the SIEMENS planning

Any special rigging requirements (Crane, stairs, etc.) and/or special site requirements (e.g. removal of existing systems, etc.) is an incremental cost and the responsibility of the Customer.

All other "out of scope" charges (not covered by the standard rigging and installation) will be identified during the site assessment and remain the responsibility of the Customer.

4SPAS014 PSPD250480Y

CT EDUOPTIO

Low Contrast CT Phantom & Holder

Surge Protective Device (SPD)

Clinical Education & Training: Option 3

Siemens offers multiple options for clinical education and training on your new system. These options enable a more personalized approach to the introduction to system operation, features, and benefits and will help ensure that your technologists and physicians have the opportunity to engage in the level of training that best meets your current clinical needs and business objectives.

The following items are the education and training modules are highly recommended for the operation of your new Slemens system and are most effective for sites where technologists and/or physicians have limited experience on Stemens' systems. With a focus on routine procedures, this option also provides additional opportunities to further increase efficiencies.

CT_CONVERP

Education Pkg for Conversion Customers

This educational package is designed to assist customers in the transition to Siemens CT scanning systems. The package offering consists of two 4 hour customized workshop sessions at the customer's facility-both sessions must be scheduled for and subsequently completed within a 24 hour window, access to Siemens Learning Center for 12 months and up to a total of 100 CE's. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

CT_INITIAL_32

Initial onsite training 32 hrs

Up to (32) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) Imaging professionals. Training will cover agenda items on the ASRT approved checklist. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Slemens obligation to provide the training will expire without refund.

CT FOLLOWU 1 P_16

Follow-up training 16 hrs

Up to (16) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12)



Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard, Malvern, PA 19355

Fax: (336) 856-9995

SIEMENS REPRESENTATIVE Edwin Winicki - (336) 688-0978

Qty Part No.

Item Description

months from install end date. If training is not completed within the applicable time period, Slemens obligation to provide the training will expire without refund.

SY_PR_TEAM PLAY

teamplay Welcome & Registration Package

teamplay is a cloud-based network that brings together your imaging modality users, the systems' dose and utilization data, and the users' expertise to help you improve the delivery of care to your patients. Basic features are provided free of charge. Premium features (benchmarking, non-Siemens devices) are provided on a trial basis for three months at no charge, and may be used thereafter on a subscription fee basis.

To register: http://teamplay.siemens.com/#/institutionRegistration/1

System Total:

\$714,000

Created: 12/8/2018 4:27:00 PM PRO 1-OG8WBU

Siemens Medical Solutions USA, Inc. Confidential

Page 6 of 6

State of North Carolina

Department of Health and Human Services Division of Health Service Regulation

Certificate of Need



for

Project ID #: J-12087-21

FID #: 070823

ISSUED TO: Rex Hospital, Inc.

Pursuant to G.S. 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 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 G.S. 131E-189(a). The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by G.S. 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in G.S. 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 G.S. 131E-189 for any of the reasons provided in that section.

SCOPE:

Develop a 2nd dedicated C-Section OR which is a change in scope for

Project ID# J-8669-11 (develop a separately licensed 50-bed hospital)/

Wake County

CONDITIONS:

See Reverse Side

PHYSICAL LOCATION:

UNC REX Holly Springs Hospital

850 South Main Street Holly Springs NC 27540

CAPITAL EXPENDITURE:

\$0

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE:

March 1, 2022

This certificate is effective as of October 28, 2021

Micheala Mitchell

CONDITIONS:

- 1. Rex Hospital, Inc. (hereinafter certificate holder) shall materially comply with the representations in this application and the representations in Project I.D. # J-8669-11. Where representations conflict, the certificate holder shall materially comply with the last made representation.
- 2. Upon completion of this project and Project I.D. # J-8669-11, UNC REX Hospital shall be licensed for no more than 32 operating rooms, including no more than 24 shared operating rooms and 3 dedicated C-section operating rooms on the UNC REX Hospital main campus, and no more than three shared operating rooms and two dedicated C-section operating rooms on the UNC REX Holly Springs Hospital campus.

3. Progress Reports:

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
- b. The certificate holder shall complete all sections of the Progress Report form.
- c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
- d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on March 1, 2022. The second progress report shall be due on July 1, 2022 and so forth.
- 4. The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations or a comparable accreditation authority within two years following licensure of the facility.
- 5. For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in this application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.
- 6. The certificate holder shall not acquire as part of this project 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.
- 7. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Pavor 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.

(J-12087-21 Con't)

- d. Average gross revenue per unit of service.
- e. Average net revenue per unit of service.
- f. Average operating cost per unit of service.
- 8. The certificate holder 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 of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on September 29, 2021.

Timetable

Milestone		Date mm/dd/yyyy
4	Construction / Renovation Contract(s) Executed	1/3/2022
8	Construction / Renovation Completed	2/28/2022
13	Licensure Obtained	5/1/2022
14	Services Offered	7/1/2022
17	First Annual Report Due*	10/1/2023

Exhibit 3

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date:

September 27, 2021

Findings Date:

September 27, 2021

Project Analyst:

Mike McKillip Fatimah Wilson

Project ID #:

Co-Signer:

J-12087-21

Facility:

UNC REX Holly Springs Hospital

FID #:

070823

County:

Wake

Applicant:

Rex Hospital, Inc.

Project:

Develop a 2nd dedicated C-Section OR which is a change in scope for Project ID#

J-8669-11 (develop a separately licensed 50-bed hospital)

REVIEW CRITERIA

G.S. §131E-183(a): The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Rex Hospital, Inc. (hereinafter referred to as "the applicant") proposes a change of scope (COS) for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds.

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

The applicant does not propose to develop any beds or services or acquire any medical equipment for which there is a need determination in the 2021 SMFP, nor offer a new

institutional health service for which there are any policies in the 2021 SMFP. Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes a change of scope (COS) for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds.

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. On January 11, 2019, the applicant received a material compliance determination from the Agency for proposed changes to the project, including construction of a 7-story facility on a smaller footprint rather than a 3-story structure, increasing the general medical/surgical beds from 38 to 44, increasing the number of intensive care beds from four to six, developing 7 labor-delivery-recovery (LDR) beds rather than 8 labor-delivery-recovery-postpartum (LDRP) beds, increasing the unlicensed observation beds from five to ten, increasing emergency department treatment bays from 10 to 24, licensing the hospital under the UNC REX Hospital license rather than licensing it separately, changes to the floor plan, and other minor changes.

This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

In Section C.8, page 34, the applicant describes the project as follows:

"The proposed project is a change of scope to Project ID # J-8669-11, which was originally approved as the development of a new separately licensed hospital in Holly Springs with no more than 50 licensed general acute care beds, three licensed shared ORs, and one dedicated C-Section operating room. Since the original Certificate of Need (CON) was issued, UNC REX requested several modifications from the Healthcare Planning and Certificate of Need Section (the Agency), which were determined to be in material compliance with the CON on January 11, 2019. As part of the material compliance request, UNC REX asked for approval to develop a second dedicated C-Section operating room; however, this portion of the request was not approved. The Agency stated that a CON would be needed to add a second C-Section room. Thus, the sole change proposed in this project is the addition of a second dedicated C-Section operating room. [Underline in original]. The proposed dedicated

C-Section operating room will be co-located with the approved dedicated C-Section operating room on Floor 3 of the hospital, adjacent to the obstetrics unit."

Patient Origin

On page 49, the 2021 SMFP states, "An OR's service area is the single or multicounty grouping shown in Figure 6.1." In Figure 6.1, page 55 of the 2021 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately identified the population to be served by the proposed project at that time. The applicant proposes no changes in the current application which would change the projected patient origin from the previous project, or which would otherwise affect the Agency's determination in that project.

Analysis of Need

In Section C.8, pages 34-37, the applicant states the need for the additional dedicated C-section operating room is based on the need to have the operating room for emergency standby capacity. The applicant states,

"The need for the proposed second C-Section room is based on qualitative, not quantitative factors. UNC REX believes that two C-Section rooms are needed to ensure optimal patient safety and quality of care at the approved hospital. Specifically, UNC REX will follow the recommendations from the American College of Obstetricians and Gynecologists (ACOG), as noted in the most recent edition of Guidelines for Perinatal Care, which suggest that while a 30-minute "decision-to-incision" time for emergency C-Sections has been the general consensus among providers historically, some conditions may warrant even shorter intervals necessitating the short-term availability of a sterile operating room for the procedure. As such, UNC REX will maintain this standard by holding an operating room open (unscheduled) any time a C-Section is scheduled in the already approved C-Section room to ensure that an operating room is available for emergency cases. Since the approved hospital will have only three operating rooms which are expected to be well-utilized, UNC REX believes that the most effective approach is to develop a second dedicated C-Section room that can remain unscheduled when the other C-Section room is scheduled, allowing the second room to be on standby in the event an emergency arises. Thus, the need to develop a second dedicated C-Section room is not driven by the expected utilization of the room, but by the need to mitigate the risk of a lack of timely surgical availability for emergency cases. Although the proposed labor and delivery services at UNC REX will involve mostly lower risk patients, the potential for fetal distress or other complications still exists and must be considered in the development of the proposed project. Thus, the proposed development of the second C-Section room is driven by UNC REX's dedication to patient safety and is reflective of its commitment to achieving optimal outcomes for women and their newborn children. ... As noted in the response below, the proposed project will not require a cost overrun to the already approved project.

The space for the proposed additional dedicated C-Section operating room will require only minor upgrades, including the necessary gasses and electrical connections, as well as some minor equipment, such as booms and lights required for the surgical cases. Given the ability to develop the project within the CON approved budget without requiring a cost overrun, or without additional construction apart from minor renovations, the proposed project presents a reasonable and effective method of maintaining the standard of care provided currently at UNC REX Hospital and ensuring optimal safety for obstetrics patients at UNC REX Holly Springs Hospital.

The information is reasonable and adequately supported based on the following:

- The applicant adequately explains the reasons the additional dedicated C-section operating rooms is necessary as part of the new hospital.
- The applicant provides supporting documentation for its statements in Section C.8, pages 34-37.
- The applicant does not propose to change the scope of services offered, other than the addition of a second C-section operating room, or to change the patients projected to be served by the proposed project.

Projected Utilization

In Project I.D. # J-8669-11, the Agency determined the applicant had demonstrated its projected utilization was based on reasonable and adequately supported assumptions. On page 38, the applicant states,

"As noted above, the proposed project is not based on any expected change in utilization, nor is the proposed development of a second C-Section operating room expected to impact utilization. While either of the C-Section rooms may be scheduled for a case, the other room will be kept unscheduled and available for an emergency case any time one room has a scheduled C-Section. As such, UNC REX does not anticipate the two rooms to be used simultaneously, except in case of an emergency, and thus, the proposed project will not increase the capacity of scheduled C-Section cases or projected C-Section utilization."

Therefore, the applicant proposes no changes in the current application which would change the projected utilization from the previous project, or which would otherwise affect the Agency's determination in that project.

Access

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated the extent to which all residents of the area, including underserved groups, were likely to have access to the proposed services. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The application for Project I.D. # J-8669-11 adequately identified the population to be served and there are no changes proposed in this application which would affect that determination.
- The applicant adequately explains why the additional dedicated C-section operation room is necessary to provide the population to be served with the services proposed in this application.
- Projected utilization was deemed reasonable and adequately supported in Project I.D. # J-8669-11 and there are no changes proposed in this application which would affect that determination.
- The application for Project I.D. # J-8669-11 adequately identified the extent to which all residents, including underserved groups, were likely to have access to the proposed services, and there are no changes proposed in this application which would affect that determination.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care

beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds.

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. On January 11, 2019, the applicant received a material compliance determination from the Agency for proposed changes to the project, including construction of a 7-story facility on a smaller footprint rather than a 3-story structure, increasing the general medical/surgical beds from 38 to 44, increasing the number of intensive care beds from four to six, developing 7 labor-delivery-recovery (LDR) beds rather than 8 labor-delivery-recovery-postpartum (LDRP) beds, increasing the unlicensed observation beds from five to ten, increasing emergency department treatment bays from 10 to 24, licensing the hospital under the UNC REX Hospital license rather than licensing it separately, changes to the floor plan, and other minor changes.

This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

In Section E, page 44, the applicant states there are no alternatives other than the alternative proposed in this application to meet the need. The applicant states,

"As described in Section C.8, the need for the proposed project is to ensure the availability of an appropriate surgical setting in case an emergency arises requiring an immediate C-Section while the one approved dedicated C-Section operating room is occupied. The Agency previously determined that the development of a second dedicated C-Section operating room would not be in material compliance with the conditions of the original application and would thus require a Certificate of Need. As such, there is no other alternative for developing timely surgical availability for emergency C-Section cases in an appropriate operating room setting than the proposed project."

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant does not propose to change the scope services, other than the addition of a second C-section operating room, or patients to be served from the previously approved Project I.D. # J-8669-11.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Rex Hospital, Inc. (hereinafter certificate holder) shall materially comply with the representations in this application and the representations in Project I.D. # J-8669-11. Where representations conflict, the certificate holder shall materially comply with the last made representation.
- 2. Upon completion of this project and Project I.D. # J-8669-11, UNC REX Hospital shall be licensed for no more than 32 operating rooms, including no more than 24 shared operating rooms and 3 dedicated C-section operating rooms on the UNC REX Hospital main campus, and no more than three shared operating rooms and two dedicated C-section operating rooms on the UNC REX Holly Springs Hospital campus.

3. Progress Reports:

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
- b. The certificate holder shall complete all sections of the Progress Report form.
- c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
- d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on March 1, 2022. The second progress report shall be due on July 1, 2022 and so forth.
- 4. The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations or a comparable accreditation authority within two years following licensure of the facility.
- 5. For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in this application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.

- 6. The certificate holder shall not acquire as part of this project 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.
- 7. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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.
- 8. The certificate holder 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.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds. This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

Capital and Working Capital Costs

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. In Section F.5, page 51, the applicant states the proposed project does not require a cost overrun, and that no additional working capital will be required for the proposed project. In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated the availability of the capital and working capital necessary to develop the proposed services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

Financial Feasibility

The applicant provided pro forma financial statements for the dedicated C-section operating rooms for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

	1 st Full FY SFY2023	2 nd Full FY SFY2024	3 rd Full FY SFY2025
Total Patients	190	257	261
Total Gross Revenues (Charges)	\$3,473,782	\$4,839,710	\$5,054,603
Total Net Revenue	\$2,004,500	\$2,792,691	\$2,916,692
Average Net Revenue per Patient Day	\$10,550	\$10,867	\$11,175
Total Operating Expenses (Costs)	\$1,669,335	\$1,939,377	\$2,009,710
Average Operating Expense per Patient Day	\$8,786	\$7,546	\$7,700
Net Income	\$335,165	\$853,314	\$906,982

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant demonstrated sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal was based upon reasonable projections of costs and charges.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds. This COS application is necessary because the applicant proposes

to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

On page 49, the 2021 SMFP states, "An OR's service area is the single or multicounty grouping shown in Figure 6.1." In Figure 6.1, page 55 of the 2021 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrate that the project would not result in unnecessary duplication of existing or approved services in the service area. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds. This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed services through the first three full fiscal years of operation, as summarized below:

Position	FTE Positions SFY2023	FTE Positions SFY2024	FTE Positions SFY2025
Patient Services Manager	0.37	0.37	0.37
Supervisor Clinical Nurse IV LDOR	0.73	0.73	0.73
Clinical Nurse III LDOR	0.99	0.99	0.99
Clinical Nurse II LDOR	4.58	4.58	4.58
Surgical Technician	3.84	3.84	3.84
Health Unit Coordinator	1.54	1.54	1.54
Total	12.00	12.00	12.00

Source: Section Q. Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, page 55, and in Section Q, Form H, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds. This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the

existing healthcare system. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds.

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. On January 11, 2019, the applicant received a material compliance determination from the Agency for proposed changes to the project, including construction of a 7-story facility on a smaller footprint rather than a 3-story structure, increasing the general medical/surgical beds from 38 to 44, increasing the number of intensive care beds from four to six, developing 7 labor-delivery-recovery (LDR) beds rather than 8 labor-delivery-recovery-postpartum (LDRP) beds, increasing the unlicensed observation beds from five to ten, increasing emergency department treatment bays from 10 to 24, licensing the hospital under the UNC REX Hospital license rather than licensing it separately, changes to the floor plan, and other minor changes.

This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

In Section K.5, page 61, the applicant states that the project involves renovation of 520 square feet of space. Line drawings are provided in Exhibit K.5.

In Section K.5, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information and representations made by the applicant on page 61.

In Section K.5, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the information and representations made by the applicant on page 62 of the application.

In Section K.5, page 62, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

UNC REX Holly Springs Hospital Project I.D. # J-12087-21 Page 15

In Project I.D. # J-8669-11, the Agency determined the application was conforming to this criterion. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

 \mathbf{C}

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated the elderly and the medically underserved groups identified in this subdivision would be served by the applicant's proposed services and the extent to which each of these groups would be expected to utilize the proposed services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

 \mathbf{C}

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated it would offer a range of means by which a person would have access to

UNC REX Holly Springs Hospital Project I.D. # J-12087-21 Page 16

its services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated that the proposed health services would accommodate the clinical needs of health professional training programs in the area. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds.

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. On January 11, 2019, the applicant received a material compliance determination from the Agency for proposed changes to the project, including construction of a 7-story facility on a smaller footprint rather than a 3-story structure, increasing the general medical/surgical beds from 38 to 44, increasing the number of intensive care beds from four to six, developing 7 labor-delivery-recovery (LDR) beds rather than 8 labor-delivery-recovery-postpartum (LDRP) beds, increasing the unlicensed observation beds from five to ten, increasing emergency department treatment bays from 10 to 24, licensing the hospital under the UNC REX Hospital license rather than licensing it separately, changes to the floor plan, and other minor changes.

This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

On page 49, the 2021 SMFP states, "An OR's service area is the single or multicounty grouping shown in Figure 6.1." In Figure 6.1, page 55 of the 2021 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition would have a positive impact upon the cost effectiveness, quality, and access to the services proposed. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form O, the applicant identifies hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identified 12 hospitals.

In Section O.4, pages 72-73, the applicant states that during the 18 months immediately preceding the submittal of the application, there were incidents related to quality of care at two facilities: UNC REX Hospital and Onslow Memorial Hospital.

On October 6, 2020, UNC REX Hospital received notification that CMS determined, based on a survey visit completed by DHSR surveyors on October 17, 2019 that UNC REX Hospital was not in compliance with requirements of Responsibilities of Medicare Participating Hospitals in Emergency Cases based on 42 CFR 489.24 (Special Responsibilities of Medicare Hospitals in Emergency Cases). Further, the October 6, 2020 letter indicated that UNC REX Hospital was subject to termination of its provider agreement if compliance was not demonstrated by October 16, 2020. UNC REX Hospital timely submitted a plan of correction on October 13, 2020, which was subsequently accepted on October 21, 2020 as documented in the CMS correspondence letter dated October 21, 2020, which is included in Exhibit O.4. A follow-up desk review was completed, at which time it was determined that actions had been taken to correct the deficiency that was cited, and that procedural changes had been made giving reasonable assurance that a similar violation will not recur and the termination action was withdrawn as documented in the CMS correspondence letter dated October 21, 2020, which is included in Exhibit O.4.

On November 30, 2020, Onslow Memorial Hospital received notification that CMS determined, based on a survey visit completed by the North Carolina Division of Health Service Regulation (DHSR) surveyors on October 13 and 14, 2020 that a potential violation pertaining to the Federal Emergency Medical Treatment and Labor Act (EMTALA) was identified. Further, the letter indicated that Onslow Memorial Hospital was subject to termination of its provider agreement if compliance was not demonstrated by December 23, 2020. Onslow Memorial Hospital timely submitted a plan of correction on December 9, 2020, which was subsequently accepted on December 14, 2020 as documented in the CMS correspondence letter dated December 14, 2020, which is included in Exhibit O.4. A follow-up review was completed by DHSR on December 21, 2020 and information gathered during the survey was forwarded to CMS as documented in the DHSR correspondence letter dated December 23, 2020, which is included in Exhibit O.4.

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care that occurred in any of the applicant's other facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the hospitals, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

UNC REX Holly Springs Hospital Project I.D. # J-12087-21 Page 19

(21) Repealed effective July 1, 1987.

G.S. 131E-183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes a COS for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds. This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two. There are no administrative rules that are applicable to proposals to add a dedicated C-section operating room.

Exhibit 4

STATE HEALTH COORDINATING COUNCIL

EXHIBIT

Lipping

Lipping

STATE MEDICAL FACILITIES PLAN



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Division of Health Service Regulation

Step 6: Determination of Service Area Operating Room Need (Table 6B, Column N)

a. Round the health system deficits according to the rounding rules, below:

If a health system located in an OR service area with more than 10 ORs in the Adjusted Planning Inventory has a projected fractional deficit of 0.50 or greater, round the deficit to the next highest whole number. For each health system in an OR service area with more than 10 ORs and a projected deficit less than 0.50 or in which there is a projected surplus, there is no need.

If a health system located in an OR service area with six to 10 ORs in the Adjusted Planning Inventory has a projected fractional deficit of 0.30 or greater, round the deficit to the next highest whole number. For each health system in an OR service area with six to 10 ORs and a projected deficit less than 0.30 or in which there is a projected surplus, there is no need.

If a health system located in an OR service area with five or fewer ORs in the Adjusted Planning Inventory has a projected fractional deficit of 0.20 or greater, round the deficit to the next highest whole number. For each health system in an OR service area with five or fewer ORs and a projected deficit less than 0.20 or in which there is a projected surplus, there is no need.

- b. Add all rounded health systems deficits. Then adjust for any placeholders for need determinations in previous SMFPs to calculate the Service Area Need (Column N).
- c. For the current plan, the Service Area Need must be at least two to show an OR Need Determination in Table 6C.

<u>NOTE</u>: The need methodology excludes Dedicated C-Section ORs and associated cases from the calculation of need determinations.

A dedicated C-section OR shall only be used to perform C-sections and other procedures performed on the patient in the same visit to the C-section operating room, such that a patient receiving another procedure at the same time as the C-section would not need to be moved to a different OR for the second procedure.

Hospitals proposing to add a new OR for use as a dedicated C-section OR must obtain a CON but may apply for a CON without regard to the need determinations in this chapter.

Exhibit 5A



ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

EXHIBIT

5 A

March 9, 2020

Denise Gunter

Denise.gunter@nelsonmullins.com

Material Compliance Approval

Project ID #:

B-11520-18

Facility:

Western Carolina Surgery Center

Project Description:

Develop a new multispecialty ambulatory surgical facility with one operating room and three procedure rooms by relocating one operating room from Fletcher Hospital,

Incorporated d/b/a AdventHealth Hendersonville

County:

Henderson

FID #:

180265

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of February 26, 2020 is in material compliance with representations made in the application. These changes include change in the site location and add four additional procedure rooms for a total of seven procedure rooms. However, you should contact the Agency's Construction, and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements pertinent to the proposed change.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination.

If you have any questions concerning this matter, please feel free to contact this office. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Ena Lightbourne Project Analyst Martha J. Frison

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

Exhibit 5B



Denise M. Gunter T 336.774.3322 F 336.774.3372 denise.aunter@nelsonmullins.com NELSON MULLINS RILEY & SCARBOROUSH LL ATTORNEYS AND COUNSELORS AT LAW

380 Knollwood Street | Suite 530 Winston-Salem, NC 27103 T 336.774.3300 F 336.774.3299 nelsonmullins.com

February 26, 2020

Via Electronic Mail

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

Material Compliance Request Summit Health Partners, LLC Henderson County

HSA I

Project I.D. # B-11520-18

FID # 180265

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. §§ 131E-181 and 189, I am writing on behalf of Summit Health Partners, LLC ("Summit") to request a material compliance determination. In this request, Summit seeks to relocate its ambulatory surgery center ("ASC") to a different site in Henderson County and to add four additional procedure rooms, for a total of seven procedure rooms.

On June 5, 2019, the Agency issued a CON to Summit to develop an ASC with one OR and three procedure rooms by relocating one OR from Fletcher Hospital, Incorporated d/b/a AdventHealth Hendersonville "AHH"). The location identified in the CON is 1151 Naples Road, Hendersonville, North Carolina 28792 (the "Original Site"). The maximum capital expenditure for the CON is \$9,732,464. The CON is attached to this letter as Exhibit A.

Since the time the CON was issued, Summit has found a new site for the ASC in Henderson County. The new site is 30 Airport Park Road, Fletcher, NC 28732 (the "New Site"). Like the Original Site, the New Site is also located in Henderson County. As Martha J. Frisone February 26, 2020 Page 2

shown in **Exhibit B** to this letter, the New Site is 5.4 miles from the Original Site. The New Site offers a number of advantages for patients and providers as compared to the Original Site:

- The New Site will accommodate options for providers to co-locate services such as clinic and physical therapy space.
- The New Site is more visible and more accessible off the main highway in the area, I-26.
- The New Site is also more accessible to the growing population in the northern part of Henderson County.
- The New Site's easy access from I-26 is more convenient for many of the providers who are expected to use the ASC. Many of these providers maintain multiple practice locations and live in Buncombe County.

As such, a site that affords better access for both patients and providers is ideal, and consistent with the purposes of the CON Law and the SMFP. See N.C. Gen. Stat. § 131E-175(3a); see also N.C. Gen. Stat. § 131E-183(a)(1) and Policy GEN-3 in the SMFP. The Department has previously approved location changes of similar or greater distances. See, e.g., Exhibit C (approving relocation of dialysis facility 7.8 miles from original site) and Exhibit D (approving relocation of adult care home 19 miles from original site).

Physicians have enthusiastically supported Summit's project, and for that reason, Summit believes four additional procedure rooms, for a total of seven procedure rooms, are needed to accommodate expected volumes. Developing the additional procedure rooms concurrently with the OR and the originally-approved procedure rooms instead of waiting until after the facility opens is more efficient and less disruptive to the ongoing operations of the ASC. Thus, if this material compliance letter is approved, the ASC will consist of one OR relocated from AHH and seven procedure rooms.

At the New Site, Summit will be a tenant in a building owned by a third party. Summit will renovate space in the building. The capital costs to develop the ASC at the New Site, as shown on **Exhibit E**, are \$8,833,875 and therefore significantly lower than the maximum capital expenditure of \$9,732,464 shown in **Exhibit A**.

Summit further represents that there will be no increase in patient charges as a result of changing locations and adding four additional procedure rooms. Summit also represents that there will be no change in the scope of services approved for the ASC. While the New Site affords greater access for patients, the patient population that is likely to use the ASC is not expected to change.

N.C. Gen. Stat. § 131E-189(b) allows the Agency to withdraw the CON if Summit fails to develop the service in a manner consistent with the representations made in the

Martha J. Frisone February 26, 2020 Page 3

application or with any conditions that were placed on the CON. Summit will not be operating the project in a manner that is materially different from the representations made in the application, nor in a manner that is inconsistent with any of the conditions that were placed on the CON.

Accordingly, Summit respectfully requests that the CON Section issue a material compliance determination that it be allowed to relocate the project to the New Site and add four additional procedure rooms, for a total of seven procedure rooms.

Thank you for your time and consideration. Please let me know if you have any questions or need any other information.

Sincerely,

Denise M. Gunter

Enclosures



CERTIFICATE OF NEED

for Project ID #: B-11520-18 FID #: 180265

ISSUED TO: Summit Health Partners, LLC

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:

Develop a new multispecialty ambulatory surgical facility with one operating room and three procedure rooms by relocating one operating room from Fletcher Hospital, Incorporated d/b/a AdventHealth Hendersonville / Henderson County

CONDITIONS:

See Reverse Side

PHYSICAL LOCATION:

Western Carolina Surgery Center

1151 Naples Road

Hendersonville, NC 28792

MAXIMUM CAPITAL EXPENDITURE:

\$9,732,464

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE:

November 1, 2019

This certificate is effective as of June 5, 2019

Martha J. Frisone, Chief

CONDITIONS:

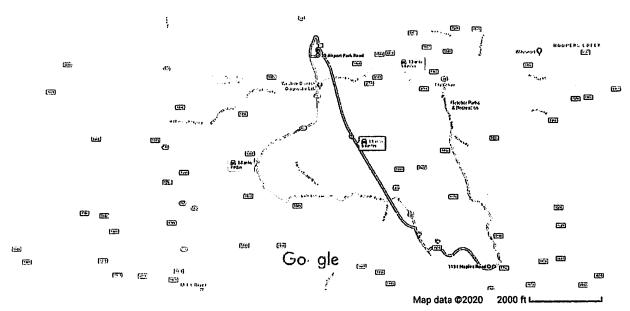
- 1. Summit Health Partners, LLC shall materially comply with all representations made in the certificate of need application, except as specifically amended by the conditions of approval and as modified by additional information submitted to the CON Section. In those instances, in which any of these representations conflict, Summit Health Partners, LLC shall materially comply with the last-made representation.
- 2. Summit Health Partners, LLC shall develop a multi-specialty ambulatory surgical facility in Henderson County with one shared OR relocated from Fletcher Hospital, Incorporated d/b/a AdventHealth Hendersonville and three procedure rooms.
- 3. Summit Health Partners, LLC shall not begin offering services before June 1, 2021.
- 4. Upon completion of the project, Fletcher Hospital, Incorporated d/b/a AdventHealth Hendersonville shall be licensed for no more than six operating rooms, including five shared ORs and one dedicated C-Section OR.
- 5. Summit Health Partners, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.
- 6. Summit Health Partners, LLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.
- 7. For the first three years of operation following completion of the project, Summit Health Partners, LLC shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.
- 8. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
- 9. Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.
- 10. Summit Health Partners, LLC shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
- 11. 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, Summit Health Partners, LLC 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; and
 - f. Average operating cost per unit of service.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on June 5, 2019.

TIMETABLE:

1.	Drawings Completed	October 1, 2019
2.	Land Acquired	October 1, 2019
3.	Construction/Renovation Contract(s) Executed	November 1, 2019
4.	25% of Construction/Renovation Completed	•
	(25% of the cost is in place)	January 1, 2020
5.	50% of Construction/Renovation Completed	March 1, 2020
6.	75% of Construction/Renovation Completed	May 1, 2020
7.	Construction/Renovation Completed	July 1, 2020
8.	Building/Space Occupied	September 1, 2020
9.	Licensure Obtained	June 1, 2021
10.	Services Offered	June 1, 2021
11.	Medicare and/or Medicaid Certification Obtained	October 1, 2021
12.	Facility or Service Accredited	June 1, 2023
13.	Final Annual Report Duc	September 1, 2024

Go-gle Maps 1151 Naples Rd, Hendersonville, NC 28792 Drive 5.4 miles, 11 min to 30 Airport Park Road, Fletcher, NC



1151 Naples Rd

Hendersonville, NC 28792

Get on I-26 W/US-74 W from Naples Rd and Asheville Hwy

		5 min (1.8 mi)
Î	1.	Head northeast toward Homestead Farm Cir
		157 ft
4	2.	Turn left toward Homestead Farm Cir
		243 ft
(>	3.	Turn right onto Homestead Farm Cir
		85 ft
(*)	4.	Turn right onto Naples Rd
		1.2 mi
L >	5.	Turn right onto Asheville Hwy
		0.4 mi
Â	6.	Turn left to merge onto I-26 W/US-74 W
		0.2 mi

Follow I-26 W/US-74 W to NC-280 W/New Airport Rd. Take exit 40 from I-26 W/US-74 W

3 min (3.1 mi)

7. Merge onto I-26 W/US-74 W

2.9 mi

8. Use the right 2 lanes to take exit 40 for NC-280 toward Asheville/Arden

0.2 mi

Keep left at the fork, follow signs for Brevard and merge onto NC-280 W/New Airport Rd

180 ft

Continue on NC-280 W/New Airport Rd to your destination in Fletcher

2	min (0.4	mi)
---	-------	-----	-----

10. Merge onto NC-280 W/New Airport Rd

0.3 mi

11. Turn left onto Airport Park Rd

0.1 mi

↑ 12. Turn left

33 ft

13. Turn right

Destination will be on the left

69 ft

30 Airport Park Rd

Fletcher, NC 28732

These directions are for planning purposes only. You may find that construction projects, traffic, weather, or other events may cause conditions to differ from the map results, and you should plan your route accordingly. You must obey all signs or notices regarding your route.

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION RALEIGH, NORTH CAROLINA

IN RE REQUEST FOR DECLARATORY)	
RULING BY TOTAL RENAL CARE OF)	
NORTH CAROLINA, LLC CONCERNING)	DECLARATORY RULING
THE DEVELOPMENT AND OPERATION)	
OF HAMPSTEAD DIALYSIS)	
Project I.D. No. O-10125-13)	
OF HAMPSTEAD DIALYSIS)))	

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency") do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10 NCAC 14A .0103 under the authority granted me by the Secretary of the Department.

Total Renal Care of North Carolina, LLC ("TRC") has requested a declaratory ruling allowing a change in site and name for Project I.D. No. O-10125-13 ("Project") on the grounds that the changes do not constitute a material change in scope or physical location or a failure to materially comply with the representations made by TRC in its Certificate of Need ("CON") application for the Project. This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C. Gen. Stat. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. William R. Shenton of Poyner Spruill LLP as counsel for TRC has requested this ruling and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

Effective 23 August 2013, the CON Section issued a CON for the Project to TRC to develop a new ten-station dialysis center to be located in Hampstead, Pender County, North

Carolina and to be known as Hampstead Dialysis. In its CON application, TRC identified the primary site for the Project as 17160 US Highway 17 North ("Original Site"). TRC now seeks to change the site of the Project to a location along US Highway 17 near Longson Drive in Surf City, Pender County ("New Site"). The New Site is identified as Pender County PIN #4215-7875-86-0000 in an attachment to TRC's request for this ruling. TRC states that it wants to change the sites because of an issue related to the cost of maintenance of a private sewer system.

TRC represents that the New Site is 7.8 miles from the Original Site. It states that the construction costs for the New Site will not exceed 115% of the capital expenditure authorized by the CON for the Project. TRC states that it will offer the same services at the New Site as it proposed at the Original Site.

TRC also wants to change the name of the Project facility from Total Renal Care of North Carolina, LLC d/b/a Hampstead Dialysis to Total Renal Care of North Carolina, LLC d/b/a Surf City Dialysis to more accurately identify the area where the facility will be located.

ANALYSIS

The CON law would require a full review of TRC's change in site if that change were to represent a material change in the physical location or scope of the Project. N.C. Gen. Stat. § 131E-181(a). The proposed site change does not constitute a material change in the physical location or scope of the Project for the following reasons:

The two locations are approximately 7.8 miles apart and are both located within Pender County.

TRC has identified the new location as the more cost effective alternative because of the availability of water and sewer from the Town of Surf City.

The change in name will not affect services or the scope of the Project and will more accurately reflect the facility's location.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that TRC's proposal to change the approved site for the Project from the Original Site to the New Site, and the change in name from Hampstead Dialysis to Surf City Dialysis, does not constitute a material change in the physical location or scope of the Project, does not violate N.C. Gen. Stat. § 131E-181, and does not constitute a failure to satisfy a condition of the CON in violation of N.C. Gen. Stat. § 131E-189(b).

This ____ day of June, 2014.

Drexdal Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this day served the foregoing Declaratory Ruling upon the PETITIONER by causing a copy of same to be placed in the United States mail, postage prepaid envelope, certified mail, return receipt requested, addressed as follows:

CERTIFIED MAIL

William R. Shenton Poyner Spruill LLP 301 Fayetteville Street, Suite 1900 (27601) Post Office Box 1801 Raleigh, NC 27602-1801

This the day of June, 2014	
	Cheryl Ouimet Chief Operating Officer

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION RALEIGH, NORTH CAROLINA

IN RE REQUEST FOR DECLARATORY)	
RULING BY CHEROKEE VALLEY, LLC)	
AND PEACHTREE MANOR, INC.)	DECLARATORY RULING
Project I.D. No. A-8701-11	j	

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency") do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10 NCAC 14A .0103 under the authority granted me by the Secretary of the Department.

Cherokee Valley, LLC and Peachtree Manor, Inc. ("Petitioners") have requested a declaratory ruling allowing a change in site for Project I.D. No. A-8701-11 ("Project") on the grounds that the changes do not constitute a material change in scope or physical location or a failure to materially comply with the representations made by Petitioners in their Certificate of Need ("CON") application for the Project. This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C. Gen. Stat. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Renee J. Montgomery and Robert A. Leandro of Parker Poe Adams & Bernstein Spruill LLP as counsel for Petitioners have requested this ruling and have provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

Effective 20 December 2011, the CON Section issued a CON for the Project to Petitioners to develop an 80-bed adult care home, with a 32-bed special care unit, in Cherokee County. Petitioners now seek to change the site for the Project from 55 Glenn Drive, Andrews, Cherokee

County (the "Original Site") to 4443 East US Highway 64 Alternate, Murphy, Cherokee County (the "New Site").

Petitioners state that the New Site, which was listed as the secondary site in the Project Application, has water and sewer hookups available, while the Original Site would require construction of a septic tank type system. They assert that the capital costs of the Project will be approximately \$100,000.00 less at the New Site.

According to Petitioners, the New Site is appropriately zoned and changes in zoning will not be required. They can develop the Project in a manner consistent with the representations made in their CON application. The New Site is 19 miles from the Original Site. It is 0.1 miles from the nearest hospital and within one mile of a community college. Petitioners do not anticipate that the change in sites will affect the population served by the Project.

ANALYSIS

The CON law would require a full review of Petitioners' change in site if that change were to represent a material change in the physical location or scope of the Project. N.C. Gen. Stat. § 131E-181(a). The proposed site change does not constitute a material change in the physical location or scope of the Project for the following reasons:

The two locations are approximately 19 miles apart and are both located within Cherokee County.

Petitioners have identified the new location as the more cost effective alternative because of the availability of water and sewer.

The change does not affect the scope of the services offered or the population to be served by the Project.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that Petitioners' proposal to change the approved site for the Project from the Original Site to the New Site does not constitute a material change in the physical location or scope of the Project, does not violate N.C. Gen. Stat. § 131E-181, and does not constitute a failure to satisfy a condition of the CON in violation of N.C. Gen. Stat. § 131E-189(b).

This ____ day of July, 2014.

Drexdal Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this day served the foregoing Declaratory Ruling upon the PETITIONER by causing a copy of same to be placed in the United States mail, postage prepaid envelope, certified mail, return receipt requested, addressed as follows:

CERTIFIED MAIL

Renee J. Montgomery Robert A. Leandro Parker Poe Adams & Bernstein, L.L.P. 150 Fayetteville Street, Suite 1400 Post Office Box 389 Raleigh, N.C. 27602-0389

This the day of July, 2014.		
	Cheryl Ouimet	
	Chief Operating Officer	

Projected Capital Cost Form

	
Building Purchase Price	\$0
Purchase Price of Land	\$0
Closing Costs	\$0
Site Preparation	\$0
Construction/Renovation Contract(s)	\$4,759,425
Landscaping	\$0
Architect / Engineering Fees	\$370,000
Medical Equipment	\$2,400,000
Non-Medical Equipment	\$0
Furniture	\$250,000
Consultant Fees (related to ASC buildout)	\$200,000
Financing Costs	\$0 ⁻
Interest during Construction	\$0
Other (CON related, permits, contingency)	\$854,450
Total Capital Cost	\$8,833,875

Interest during Construction	\$0	
Other (CON related, permits, contingency)	\$854,450	
Total Capital Cost	\$8,833,875	
CERTIFICATION BY A LICENSED ARCHITECT I certify that, to the best of my knowledge, complete and correct. Signature of Licensed Architect or Engineer	the projected capital cost for the proposed pate Signed: 7	
CERTIFICATION BY AN OFFICER OR AGENT I certify that, to the best of my knowledg project is complete and correct and that it described,	e, the projected total capital cost for	the proposed ed project as
Ella Stantal Signature of Officer/Agent	Date Signed; 요,	125/20
Date of Last Revision: 5.17.19		