



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

RESPONSE REQUIRED

July 21, 2022

Catharine Cumber
3100 Tower Boulevard
Suite 1300
Durham, NC 27707

Conditional Approval

Project ID #: J-12212-22
Facility: Duke Health Raleigh Ambulatory Surgical Center
Project Description: Develop a new, separately licensed freestanding ASF on the Duke Raleigh Hospital campus by re-licensing one existing hospital-based OR from the Duke Raleigh Hospital license
County: Wake
FID #: 220335

Approved Capital Expenditure: \$1,000,000
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: August 22, 2022
Required State Agency Findings: Enclosed

Dear Ms. Cumber:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has conditionally approved the above referenced certificate of need application. The conditional approval is valid only for the approved capital expenditure shown above. If the capital cost will exceed the approved capital expenditure amount by more than 115%, the applicant must first obtain a new certificate of need.

Response to the conditions in Attachment A should be attached to an email addressed to the Project Analyst and the Co-signer no later than 35 days from the date of the decision. The certificate of need will not be issued if the response to the conditions in Attachment A has not been received by the Agency.

The timetable for completion of the project is the timetable outlined in the certificate of need application, unless an adjustment has been made by the Agency because the review period was extended. The approved timetable for this project is found in Attachment B.

The applicant shall not begin developing this project until after the certificate of need has been issued and the certificate of need will not be issued until the applicant has documented that all conditions that must be met prior to issuance of the certificate of need have been met.

The Certificate of Need law provides that any affected person has thirty (30) days after the date of the decision to file a petition for a contested case on this approval. Further, if you are aggrieved by any of the

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: 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

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conditions you may file a petition for a contested case hearing in accordance with G.S.150B, Article 3. This petition must be filed with the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, North Carolina 27699-6714 within thirty (30) days of the date of this decision. Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to the OAH Clerk's Office (919-431-3000).

G.S. 150B-23 provides that a party filing a petition must also serve a copy of the petition on all parties to the petition. Therefore, if you file a petition for a contested case hearing, you must serve a copy of the petition on the Department of Health and Human Services by mailing a copy of your petition to:

Lisa G. Corbett
Department of Health and Human Services,
Office of Legal Affairs,
Adams Building – Room 154
2001 Mail Service Center
Raleigh, North Carolina, 27699-2001

It is requested that a copy of the petition also be served on the Agency.

The certificate of need will not be issued before the completion of thirty-day appeal period which ends on the date shown above. If a contested case petition is filed with OAH within the thirty-day appeal period, the certificate will not be issued until the appeal is resolved.

If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the certificate of need is issued. Please contact this office if any clarification of this decision is required.

Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,



Kim Meymandi
Project Analyst
Kim.meymandi@dhhs.nc.gov



Micheala Mitchell
Chief
Micheala.mitchell@dhhs.nc.gov

Enclosures:

- Attachment A: Conditions of Approval
- Attachment B: Approved Timetable
- Required State Agency Findings

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

Attachment A
Conditions of Approval

1. Duke University Health System, Inc. and Associated Health Services, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
2. The certificate holder shall develop a freestanding multispecialty ambulatory surgical facility on the Duke Raleigh Hospital campus by relicensing no more than one existing hospital-based operating room from the Duke Raleigh Hospital license and reallocating three procedure rooms.
3. Upon project completion, Duke Health Raleigh Ambulatory Surgical Center shall be licensed for no more than one operating room and three procedure rooms.
4. The Duke University Health System shall take the necessary steps to delicense one operating room on the Duke Raleigh Hospital License #H0238. The Duke Raleigh Hospital License #H0238 shall have a total of 12 operating rooms upon completion of this project and Project ID #J-12029-21 (relocate two shared operating rooms from Duke Raleigh Hospital).
5. 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. The first progress report shall be due on February 1, 2023.
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. The certificate holder 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.
8. 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 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.

9. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
10. 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.
11. 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.
12. 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.

Attachment B
Approved Timetable

Milestone		Date <i>mm/dd/yyyy</i>
9	Equipment Ordered	12/01/2022
10	Equipment Installed	05/01/2023
11	Equipment Operational	05/15/2023
13	Licensure Obtained	06/01/2023
14	Services Offered	06/01/2023
15	Medicare and / or Medicaid Certification Obtained	07/01/2023
16	Facility or Service Accredited	07/01/2023
17	First Annual Report Due*	10/01/2025