



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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

RESPONSE REQUIRED

September 25, 2019

Catharine Cummer
3100 Tower Boulevard, Suite 1300
Durham, NC 27707

Conditional Approval

Project ID #: J-11692-19
Facility: Duke Health Orange Ambulatory Surgical Center
Project Description: Develop a new ambulatory surgical center in Chapel Hill with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2019 SMFP
County: Orange
FID #: 190164

Approved Capital Expenditure: \$12,084,000
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: October 25, 2019
Required State Agency Findings: Will be mailed within five business days after the date of this letter

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has conditionally approved the above referenced certificate of need application. This decision was made after review of the application or applications if the review was competitive, consideration of the Certificate of Need Law and regulations promulgated thereunder, the State Medical Facilities Plan, written comments if any, responses to comments if any, and other publicly applicable information.

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 submitted to the Agency no later than 35 days from the date of the decision. Failure to respond within this time period may result in the Agency making a determination not to issue a certificate of need for the project referenced above.

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.

Note: 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

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 that must be met prior to issuance of the certificate of need have been met. Furthermore, if the project requires that plans be submitted to the Construction Section, those plans will not be reviewed or approved until after the certificate of need has been issued.

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 conditions you may file a petition for a contested case hearing in accordance with N.C. Gen. Stat. §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).

N.C. Gen. Stat. §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.

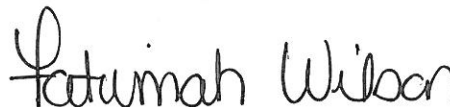
If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the certificate of need is issued. Please contact this office if any clarification of this decision is required.

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

Sincerely,



Gregory F. Yakaboski
Project Analyst



Fatimah Wilson
Team Leader

Enclosures:

Attachment A: Conditions of Approval

Attachment B: Approved Timetable

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

Attachment A
Conditions of Approval

1. Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application.
2. Duke University Health System, Inc. shall develop a new multi-specialty ambulatory surgical facility by developing no more than two operating rooms and two procedure rooms.
3. Upon project completion, Duke Health Orange Ambulatory Surgery Center shall be licensed for no more than two operating rooms and two procedure rooms.
4. Duke University Health System, Inc. 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. Duke University Health System, Inc. 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.
6. For the first three years of operation following completion of the project, Duke University Health System, Inc. 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.
7. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
8. 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.
9. Duke University Health System, Inc. 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.
10. Prior to issuing a certificate of need for this project (Project I.D.#J-11692-19), Duke University Health System, Inc. shall either:
 - a. surrender the certificate of need issued for Project I.D.#J-11632-18, if one has been issued, by submitting a letter to the Healthcare Planning and Certificate of Need Section which states that the certificate of need is being surrendered and returning the certificate of need; or
 - b. withdraw the application identified as Project I.D. #J-11632-18, if no certificate of need has been issued for that project, by submitting a letter to the Healthcare Planning and Certificate of Need Section which states that the application identified as Project I.D. #J-11632-18 is being withdrawn.
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, Duke University Health System, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
12. Duke University Health System, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

Attachment B
Approved Timetable

1. Drawings Completed _____ March 1, 2020
2. Construction / Renovation Contract(s) Executed _____ April 1, 2020
3. 25% of Construction / Renovation Completed
(25% of the cost is in place) _____ June 1, 2020
4. 50% of Construction / Renovation Completed _____ September 1, 2020
5. 75% of Construction / Renovation Completed _____ December 1, 2020
6. Construction / Renovation Completed _____ February 1, 2021
7. Equipment Ordered _____ February 1, 2020
8. Equipment Installed _____ February 1, 2021
9. Equipment Operational _____ February 15, 2021
10. Building / Space Occupied _____ February 1, 2021
11. Licensure Obtained _____ February 15, 2021
12. Services Offered (required) _____ March 1, 2021
13. Medicare and / or Medicaid Certification Obtained _____ June 1, 2021
14. Facility or Service Accredited _____ January 1, 2022
15. First Annual Report Due _____ September 30, 2024