

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**

January 24, 2020

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

**Conditional Approval**

Project ID #: J-11799-19  
Facility: Duke University Hospital  
Project Description: Acquire two units of heart-lung bypass equipment for a total of eleven units upon project completion  
County: Durham  
FID #: 943138

Approved Capital Expenditure: \$750,000  
Conditions of Approval: See Attachment A  
Approved Timetable: See Attachment B  
Last Date to Appeal: February 24, 2020  
Required State Agency Findings: Enclosed

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 conditions that must be met prior to issuance of the certificate of need have been met.**

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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**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

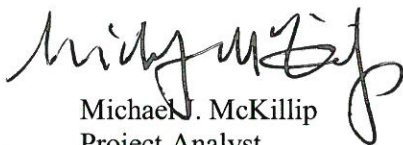
It is requested that a copy of the petition also be served on the Agency.

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.

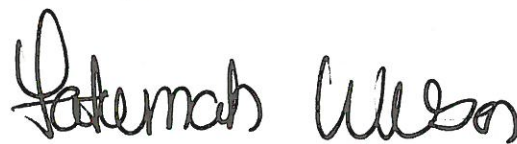
If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the certificate of need is issued. Please contact this office if any clarification of this decision is required.

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

Sincerely,



Michael J. McKillip  
Project Analyst



Fatimah Wilson  
Team Leader

Enclosures:

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

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

**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 acquire no more than two additional heart-lung bypass machines for a total of no more than eleven heart-lung bypass machines at Duke University Hospital.
3. 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 F of the application and that would otherwise require a certificate of need.
4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, 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
5. Duke University Health System, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the issuance of the certificate of need.

**Attachment B**  
**Approved Timetable**

1. Equipment Ordered \_\_\_\_\_ July 1, 2020
2. Equipment Operational \_\_\_\_\_ January 1, 2021
3. Services Offered (required) \_\_\_\_\_ January 1, 2021
4. First Annual Report Due \_\_\_\_\_ September 30, 2022