



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

April 23, 2021

Catharine Cumber
3100 Tower Boulevard
Suite 1300
Durham, NC 27707

Conditional Approval

Project ID #: J-12000-20
Facility: Duke Cancer Center Green Level Radiation Oncology
Project Description: Acquire, replace, and relocate a linear accelerator from Franklin County Cancer Center and acquire a simulator
County: Wake
FID #: 200892

Approved Capital Expenditure: \$10,710,000
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: May 25, 2021
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,



Gregory F. Yakaboski
Project Analyst
Greg.yakaboski@dhhs.nc.gov



Gloria C. Hale
Team Leader
Gloria.hale@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. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
2. The certificate holder shall acquire, replace, and relocate a linear accelerator from Franklin County Cancer Center and acquire a simulator.
3. Upon completion of the project, Duke Cancer Center Green Level Radiation Oncology shall be licensed for no more than one linear accelerator and one simulator.
4. 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 July 1, 2021. The second progress report shall be due on October 1, 2021 and so forth.
5. 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.
6. The certificate holder 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.
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.

Attachment B
Approved Timetable

Milestone		Date <i>mm/dd/yyyy</i>
2	Drawings Completed	11/01/2021
4	Construction / Renovation Contract(s) Executed	2/01/2022
8	Construction / Renovation Completed	5/01/2023
9	Equipment Ordered	2/01/2023
10	Equipment Installed	6/01/2023
11	Equipment Operational	7/01/2023
12	Building / Space Occupied	7/01/2023
14	Services Offered	7/01/2023
15	Medicare and / or Medicaid Certification Obtained	10/01/2023
16	Facility or Service Accredited	10/01/2023
17	First Annual Report Due*	10/01/2024