



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

October 8, 2020

Catharine Cummer
3100 Tower Boulevard
Suite 1300
Durham, NC 27707

Conditional Approval

Project ID #: J-11913-20
Facility: Duke Health Arrington Radiology
Project Description: Acquire a fixed MRI scanner pursuant to the need determination in the 2020 SMFP which is a change of scope for Project ID#J-11718-19 (develop a new diagnostic center with one MRI scanner relocated from Page Road)
County: Durham
FID #: 190274

Approved Capital Expenditure: \$2,847,000
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: November 9, 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 attached to emails addressed to the Project Analyst and the Co-signer no later than 35 days from the date of the decision. Failure to respond within this time period may result in the Agency determining 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).

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



Fatimah Wilson
Team Leader
fatimah.wilson@dhhs.nc.gov

Enclosures:

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

Attachment A
Conditions of Approval

1. Duke University Health Systems, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application, the representations in Project I.D. #J-11718-19 and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.
2. The certificate holder shall acquire a fixed MRI scanner pursuant to the need determination in the 2020 SMFP which is a change of scope for Project ID#J-11718-19 (which authorized the development of a new diagnostic center with CT, mammography, ultrasound, X-ray and DEXA equipment and replacement and relocation of one existing MRI scanner from Page Road.).
3. Upon completion of the project, Duke Health Arrington Radiology shall be licensed for no more than two fixed MRI scanners.
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 January 1, 2021. The second progress report shall be due on April 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. 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, 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.
7. 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 mm/dd/yyyy
4	Construction / Renovation Contract(s) Executed	07/23/2021
9	Equipment Ordered	02/02/2021
10	Equipment Installed	08/01/2021
11	Equipment Operational	08/22/2021
14	Services Offered	09/01/2021
17	First Annual Report Due*	09/30/2023