



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**

November 23, 2021

Catharine Cummer  
3100 Tower Boulevard  
Suite 1300  
Durham, NC 27707

**Conditional Approval**

Project ID #: J-12083-21  
Facility: Duke University Hospital  
Project Description: Acquire 1 fixed PET/CT scanner pursuant to the need determination in the 2021 SMFP for a total of no more than 3 fixed PET/CT scanners upon project completion  
County: Durham  
FID #: 943138

Approved Capital Expenditure: \$4,606,000  
Conditions of Approval: See Attachment A  
Approved Timetable: See Attachment B  
Last Date to Appeal: December 28, 2021  
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. 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

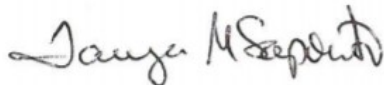
It is requested that a copy of the petition also be served on the Agency.

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,



Tanya M. Saporito  
Project Analyst  
[Tanya.saporito@dhhs.nc.gov](mailto:Tanya.saporito@dhhs.nc.gov)



Lisa Pittman  
Assistant Chief  
[Lisa.pittman@dhhs.nc.gov](mailto:Lisa.pittman@dhhs.nc.gov)

Enclosures:

Attachment A: Conditions of Approval  
Attachment B: Approved Timetable

cc: Acute & Home Care Licensure & Certification Section, DHSR  
Construction Section, DHSR  
Radiation Protection 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 one fixed PET scanner pursuant to the need determination in the 2021 SMFP, to be located at Duke University Hospital, for a total of three fixed PET scanners.
3. Upon completion of the project, Duke University Health System, Inc. shall be licensed for no more than three fixed PET 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 fourth month. The first progress report shall be due on March 1, 2022. The second progress report shall be due on July 1, 2022 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 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.
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**

	<b>Milestone</b>	<b>Date</b> <i>mm/dd/yyyy</i>
2	Drawings Completed	04/01/2022
4	Construction / Renovation Contract(s) Executed	05/01/2022
8	Construction / Renovation Completed	08/12/2022
9	Equipment Ordered	05/01/2022
10	Equipment Installed	08/01/2022
11	Equipment Operational	08/15/2022
12	Building / Space Occupied	08/15/2022
<b>14</b>	<b>Services Offered</b>	09/01/2022
17	First Annual Report Due*	10/01/2024