



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Vos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

RESPONSE REQUIRED

April 10, 2013

Catherine W. Cummer
3100 Tower Boulevard, Suite 1300
Durham, NC 27707

Conditional Approval

Project I.D. #: J-10077-13
Facility: Duke University Hospital
Project Description: Acquisition of two heart-lung bypass machines for a total of 9 upon project completion
County: Durham
FID #: 943138

Dear Ms. Cummer:

The Certificate of Need (CON) Section, Division of Health Service Regulation, Department of Health and Human Services has conditionally approved the above referenced certificate of need application. This decision was made after a review of the applications submitted for this cycle and after consideration of the Certificate of Need Law, G.S. 131E-175 et. seq. and regulations promulgated thereunder, the State Medical Facilities Plan, and other applicable information. Attached to this letter are the required findings made with respect to your application. The applicant shall not proceed with the construction, offering or development of this project until the certificate of need is issued. Further, the Department shall not issue the certificate of need until all applicable conditions of approval that can be satisfied before issuance of the certificate of need have been met pursuant to G.S. 131E-187(a). The conditions are as follows:

1. Duke University Health System d/b/a Duke University Hospital shall materially comply with all representations made in the certificate of need application.
2. Duke University Health System d/b/a Duke University Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.



Certificate of Need Section

www.ncdhhs.gov

Telephone 919-855-3873 • Fax 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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3. Duke University Health System d/b/a Duke University Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section, in writing prior to issuance of the certificate of need.

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

The conditional approval is valid only for a capital expenditure of \$444,979. If a cost overrun occurs that exceeds the approved capital expenditure amount, a new certificate of need may be required as determined by G.S. 131E-176(16)(e).

The applicant should be aware that according to the Certificate of Need Law any affected person shall have thirty (30) days after the date of decision to file a petition for a contested case on this approval. Further, if you are aggrieved by the conditions of the decision you may file a petition for a contested case hearing in accordance with G.S. 150B, Article 3, as amended. 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. [Note: Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to 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:

Emery Milliken
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 Certificate of Need Section. The certificate of need will not be issued before the completion of this 30 day period ending May 10, 2013. If a contested case request is received within the thirty (30) day period, the certificate will not be issued until the appeal is resolved (10A NCAC 14C .0208)

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 CON Section because the review period was extended. The timetable for this project is as follows:

Acquisition of Medical Equipment (first bypass machine)

Ordering Equipment _____ September 1, 2013

Operation of Equipment _____ October 15, 2013

Acquisition of Medical Equipment (second bypass machine)

Ordering Equipment _____ June 1, 2014

Operation of Equipment _____ July 1, 2014

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 us if any clarification of this decision is required.

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

Sincerely,

Michael J. McKillip, Project Analyst

Martha J. Frisone, Assistant Chief
Certificate of Need Section

MJM:MJF:llp

Attachment

cc: Acute & Home Care Licensure & Certification Section, DHSR
Medical Facilities Planning Section, DHSR

CERTIFICATE OF SERVICE

I hereby certify that I have served the foregoing notice of **conditional approval** on the following person by placing a copy in an official depository of the United States Postal Service in a postage-paid, first class envelope addressed as follows:

Catherine W. Cummer
3100 Tower Boulevard, Suite 3100
Durham, NC 27707

Project I.D. #J-10077-13

FID #943138

This the 10th day of April, 2013

Michael J. McKillip, Project Analyst