

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

RESPONSE REQUIRED

June 3, 2020

Kimberly Clark PO Box 7710 Tifton, GA 31793

Conditional Approval

Project ID #: G-11868-20

Facility: Piedmont Dialysis Center of Wake Forest University

Project Description: Add no more than 10 dialysis stations pursuant to facility need for a total of no

more than 64 in-center stations upon project completion

County: Forsyth FID #: 944661

Approved Capital Expenditure: \$168,000

Conditions of Approval:

Approved Timetable:

Last Date to Appeal:

Required State Agency Findings:

See Attachment A
See Attachment B
July 6, 2020
Enclosed

Dear Ms. Clark:

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. 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.

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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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,

Gregory F. Yakaboski

Project Analyst

greg.yakaboski@dhhs.nc.gov

Gloria C. Hale

Gloria C. Hale

Team Leader

gloria.hale@dhhs.nc.gov

Enclosures:

cc:

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

Acute & Home Care Licensure & Certification Section, DHSR

Attachment A Conditions of Approval

- 1. Wake Forest University Health Sciences and Piedmont Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Wake Forest University Health Sciences and Piedmont Dialysis Center of Wake Forest University shall materially comply with the last made representation.
- 2. Pursuant to the facility need determination in the 2020 SMFP, Wake Forest University Health Sciences and Piedmont Dialysis Center of Wake Forest University shall develop no more than ten additional dialysis stations for a total of no more than sixty-four certified stations at Piedmont Dialysis Center which shall include any home hemodialysis training or isolation stations.
- 3. Wake Forest University Health Sciences and Piedmont Dialysis Center of Wake Forest University 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

1.	Financing Obtained	January 1, 2020
2.	Equipment Ordered	November 17, 2020
3.	Equipment Installed	December 15, 2020
4.	Equipment Operational	December 31, 2020
5.	Licensure Obtained	October 3, 2020
6.	Services Offered (required)	December 31, 2020
7.	Medicare and / or Medicaid Certification Obtained	December 31, 2020