

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

January 14, 2019

Esther Fleming
2321 W. Morehead Street
Charlotte, NC 28208

Conditional Approval

Project ID #: O-11593-18
Facility: Leland Dialysis
Project Description: Add one dialysis station for a total of 11 stations
County: Brunswick
FID #: 140237

Approved Capital Expenditure: \$18,470
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: February 13, 2019
Required State Agency Findings: Enclosed

Dear Ms. Fleming

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 a cost overrun occurs that exceeds the approved capital expenditure amount, a new certificate of need may be required based on N.C. Gen. Stat. §131E-176(16)(e).

The applicant shall not proceed with the construction, offering or development of this project until the certificate of need is issued. Furthermore, the Agency shall not issue the certificate of need until all applicable conditions of approval have been met pursuant to N.C. Gen. Stat. §131E-187(a). **Response to the conditions in Attachment A should be submitted to the Agency no later than 35 days from the date of the decision. Failure to respond within this time period may result in the Agency making a determination 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.

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
www.ncdhhs.gov/dhsr • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

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.

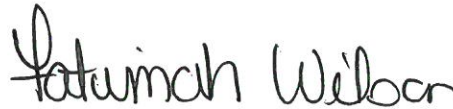
If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the certificate of need is issued. Please contact this office if any clarification of this decision is required.

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

Sincerely,



Tanya M. Saporito
Project Analyst



Fatimah Wilson
Team Leader

Enclosures:

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

cc: Acute & Home Care Licensure & Certification Section, DHSR (not for Diagnostic Centers)
Melinda Boyette, Administrative Assistant, Healthcare Planning, DHSR

Attachment A
Conditions of Approval

- 1. Total Renal Care of North Carolina, LLC d/b/a Leland Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the July 2018 SDR, Total Renal Care of North Carolina, LLC shall develop no more than one additional dialysis station for a total of no more than 11 certified stations at Leland Dialysis upon project completion, which shall include any home hemodialysis training or isolation stations.**
- 3. Total Renal Care of North Carolina, LLC shall install plumbing and electrical wiring through the walls for no more than one dialysis station which shall include any isolation stations.**
- 4. Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the issuance of the certificate of need.**

Attachment B
Approved Timetable

1. Equipment Ordered _____ July 15, 2019
2. Equipment Installed _____ November 15, 2019
3. Equipment Operational _____ December 1, 2019
4. Services Offered _____ January 1, 2020
5. Medicare and/or Medicaid Certification Obtained _____ January 1, 2020

