



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

December 6, 2019

Jim Swann
3390 Dunn Road
Eastover, NC 28312

Conditional Approval

Project ID #: F-11775-19
Facility: Fresenius Kidney Care Regal Oaks
Project Description: Add no more than 2 dialysis stations for a total of no more than 17 stations upon project completion
County: Mecklenburg
FID #: 150024

Approved Capital Expenditure: \$7,500
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: January 6, 2020
Required State Agency Findings: Enclosed

Dear Mr. Swann:

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 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.

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/dhstr/> • 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).

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,


Julie M. Faenza
Project Analyst


Gloria C. Hale
Team Leader

Enclosures:

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

cc: Acute & Home Care Licensure & Certification Section, DHSR

Attachment A
Conditions of Approval

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the July 2019 Semiannual Dialysis Report, Bio-Medical Applications of North Carolina, Inc. shall develop no more than two additional dialysis stations at Fresenius Kidney Care Regal Oaks for a total of no more than 17 certified stations at Fresenius Kidney Care Regal Oaks upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. 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. Equipment Ordered _____ October 30, 2020
2. Equipment Installed _____ December 9, 2020
3. Equipment Operational _____ December 23, 2020
4. Building / Space Occupied _____ December 23, 2020
5. Services Offered (required) _____ December 31, 2020
6. Medicare and / or Medicaid Certification Obtained _____ December 31, 2020