



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 26, 2019

Jim Swann
3390 Dunn Road
Eastover, NC 28312

Conditional Approval

Project ID #: J-11773-19
Facility: Zebulon Kidney Center
Project Description: Add no more than 2 dialysis stations and relocate no more than 2 stations from Fresenius Medical Care Eastern Wake pursuant to Policy ESRD 2, for a total of no more than 30 stations upon completion of this project and Project ID #J-11540-18 (relocate 4 stations to Johnston Dialysis Center)
County: Wake
FID #: 970505

Approved Capital Expenditure: \$0
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: December 27, 2019
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.

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

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.

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,



Celia C. Inman
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, DHR

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 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than two additional dialysis stations and relocate no more than two stations from Fresenius Medical Care Eastern Wake for a total of no more than 30 certified stations upon completion of this project and Project ID #J-11540-18 (relocate four stations to Johnston Dialysis Center), which shall include any home hemodialysis training or isolation stations.**
- 3. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify two dialysis stations at Fresenius Medical Care Eastern Wake for a total of no more than 15 dialysis stations upon completion of this project.**
- 4. 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** _____ **September 29, 2020**
2. **Equipment Installed** _____ **December 13, 2020**
3. **Equipment Operational** _____ **December 27, 2020**
4. **Building / Space Occupied** _____ **December 27, 2020**
5. **Services Offered (required)** _____ **December 31, 2020**
6. **Medicare and / or Medicaid Certification Obtained** _____ **December 31, 2020**