



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**

March 27, 2019

Jim Swann  
3390 Dunn Road  
Eastover, NC 28312

**Conditional Approval**

Project ID #: E-11649-19  
Facility: Fresenius Kidney Care Newton  
Project Description: Relocate three stations from FMC of Catawba Valley to FKC Newton for a total of 15 stations at FKC Newton  
County: Catawba  
FID #: 160340

Approved Capital Expenditure: \$11,250  
Conditions of Approval: See Attachment A  
Approved Timetable: See Attachment B  
Last Date to Appeal: April 26, 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 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,



Ena Lightbourne  
Project Analyst



Lisa Pittman  
Assistant Chief

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)

**Attachment A**  
**Conditions of Approval**

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with the representations in this application and the representations made in Project ID# E-11209-16. Where representations conflict, Bio-Medical Applications of North Carolina, Inc. shall materially comply with the last made representation.**
- 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than three dialysis stations from FMC of Catawba Valley to FKC Newton for a total of no more than 15 certified stations upon completion of this project and Project ID# E-11209-16 which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than three dialysis stations, which shall include any isolation stations.**
- 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify three dialysis stations at FMC of Catawba Valley for a total of no more than 22 dialysis stations at FMC of Catawba Valley.**
- 5. 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. Financing Obtained \_\_\_\_\_ January 15, 2019
2. Drawings Completed \_\_\_\_\_ September 4, 2019
3. Construction/Renovation Contract(s) Executed \_\_\_\_\_ October 4, 2019
4. 25% of Construction/Renovation Completed  
(25% of the cost is in place) \_\_\_\_\_ October 25, 2019
5. 50% of Construction/Renovation Completed \_\_\_\_\_ November 15, 2019
6. 75% of Construction/Renovation Completed \_\_\_\_\_ November 29, 2019
7. Construction/Renovation Completed \_\_\_\_\_ December 6, 2019
8. Equipment Ordered \_\_\_\_\_ October 17, 2019
9. Equipment Installed \_\_\_\_\_ December 16, 2019
10. Equipment Operational \_\_\_\_\_ December 23, 2019
11. Building/Space Occupied \_\_\_\_\_ December 23, 2019
12. Services Offered \_\_\_\_\_ December 31, 2019
13. Medicare and/or Medicaid Certification Obtained \_\_\_\_\_ December 31, 2019

