



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 12, 2021

Jim Swann
2800 Breezewood Avenue
Suite 200
Fayetteville, NC 28303-5282

Conditional Approval

Project ID #: F-12136-21
Facility: Fresenius Kidney Care Regal Oaks
Project Description: Relocate the home training program and no more than two dialysis stations from FMC Charlotte for a total of no more than 19 stations upon project completion
County: Mecklenburg
FID #: 150024

Approved Capital Expenditure: \$18,750
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: December 13, 2021
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. 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 an email addressed to the Project Analyst and the Co-signer no later than 35 days from the date of the decision. The certificate of need will not be issued if the response to the conditions in Attachment A has not been received by the Agency.

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.

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.

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 G.S.150B, Article 3.

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

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).

G.S. 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
Julie.Faenza@dhhs.nc.gov



Micheala Mitchell
Team Leader
Micheala.Mitchell@dhhs.nc.gov

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. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall relocate the home training program at FMC Charlotte, along with the two dedicated home hemodialysis training stations at FMC Charlotte, to Fresenius Kidney Care Regal Oaks.**
- 3. Fresenius Kidney Care Regal Oaks shall be certified for no more than 19 stations, including any home hemodialysis training stations, upon project completion.**
- 4. Upon completion of this project, Fresenius Medical Care Holdings, Inc. shall take the necessary steps to decertify two home hemodialysis training stations at FMC Charlotte for a total of no more than 43 in-center stations and no home hemodialysis training stations upon project completion.**
- 5. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on March 1, 2022. The second progress report shall be due on June 1, 2022 and so forth.**
- 6. The certificate holder 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

	Milestone	Date
1	Equipment Installed	11/29/2022
2	Equipment Operational	12/6/2022
3	Services Offered (required)	12/31/2022
4	Medicare and / or Medicaid Certification Obtained	12/31/2022