



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • GOVERNOR
KODY H. KINSLEY • SECRETARY
MARK PAYNE • DIRECTOR, DIVISION OF HEALTH SERVICE
REGULATION

RESPONSE REQUIRED

April 26, 2022

Fatimah Wilson
3943 New Bern Avenue
Raleigh, NC 27610

Conditional Approval

Project ID #: F-12162-21
Facility: Fresenius Kidney Care Regal Oaks
Project Description: Add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 21 stations upon completion of this project and Project ID #F-12136-21 (relocate home therapies program and two stations)
County: Mecklenburg
FID #: 150024
Approved Capital Expenditure: \$1,132,516
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: May 26, 2022
Required State Agency Findings: Enclosed

Dear Ms. Wilson:

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.

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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.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2021 SMFP, the certificate holder shall develop no more than 2 additional in-center (and home hemodialysis) dialysis stations for a total of no more than 21 in-center (and home hemodialysis) dialysis stations at Fresenius Kidney Care Regal Oaks upon completion of this project and Project ID #F-12136-21 (relocate home therapies program and 2 stations).**
- 3. 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 November 1, 2022. The second progress report shall be due on February 1, 2023 and so forth.**
- 4. 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	Drawings Completed	9/17/2022
2	Construction / Renovation Contract(s) Executed	12/31/2022
3	25% of Construction / Renovation Completed (25% of the cost is in place)	3/31/2023
4	50% of Construction / Renovation Completed	6/14/2023
5	75% of Construction / Renovation Completed	8/28/2023
6	Construction / Renovation Completed	10/27/2023
7	Equipment Ordered	9/17/2023
8	Equipment Installed	11/5/2023
9	Equipment Operational	11/26/2023
10	Services Offered (required)	12/31/2023
11	Medicare and / or Medicaid Certification Obtained	12/31/2023