



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

**ROY COOPER** • Governor

**KODY H. KINSLEY** • Secretary

**MARK PAYNE** • Director, Division of Health Service Regulation

**RESPONSE REQUIRED**

January 20, 2023

Fatimah Wilson  
3943 New Bern Avenue  
Raleigh, NC 27610

**Conditional Approval**

Project ID #: F-12278-22  
Facility: Fresenius Kidney Care Regal Oaks  
Project Description: Cost overrun for Project ID# F-12162-21 (add 2 dialysis stations for a total of 21 stations upon completion of this project and Project ID #F-12136-21)  
County: Mecklenburg  
FID #: 150024

Approved Capital Expenditure: \$1,148,730  
Conditions of Approval: See Attachment A  
Approved Timetable: See Attachment B  
Last Date to Appeal: February 20, 2023  
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. This petition must be filed with the Office of Administrative Hearings, 6714 Mail Service

**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

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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:

Julie Cronin  
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.

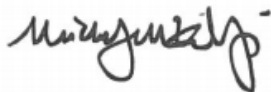
If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the certificate of need is issued. Please contact this office if any clarification of this decision is required.

Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,



Gregory F. Yakaboski  
Project Analyst  
[Greg.yakaboski@dhhs.nc.gov](mailto:Greg.yakaboski@dhhs.nc.gov)



Michael J. McKillip  
Team Leader  
[Mike.mckillip@dhhs.nc.gov](mailto:Mike.mckillip@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 dialysis stations for a total of no more than 21 in-center (and home hemodialysis) 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. The approved combined capital expenditure for both Project ID# F-12162-21 and this project is 2,281,258, an increase of \$1,148,730 over the capital expenditure of \$1,132,526 previously approved in Project ID #F-12162-21.
4. 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. The first progress report shall be due on July 1, 2023.
5. 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**

<b>Milestone</b>		<b>Date</b> <i>mm/dd/yyyy</i>
2	Drawings Completed	8/18/2023
4	Construction / Renovation Contract(s) Executed	12/1/2023
5	25% of Construction / Renovation Completed (25% of the cost is in place)	2/29/2024
6	50% of Construction / Renovation Completed	5/14/2024
7	75% of Construction / Renovation Completed	7/28/2024
8	Construction / Renovation Completed	9/26/2024
9	Equipment Ordered	9/17/2024
10	Equipment Installed	11/5/2024
11	Equipment Operational	11/26/2024
<b>14</b>	<b>Services Offered</b>	12/31/2024
15	Medicare and / or Medicaid Certification Obtained	12/31/2024