



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

January 28, 2020

Rhonda Palumbo
52 East Swedesford Road
Suite 110
Malvern, PA 19355

Conditional Approval

Project ID #: J-11804-19
Facility: RAC Surgery Center, LLC
Project Description: Cost overrun and change of scope for Project ID# J-11551-18 (Develop a new ASC with 1 OR and 2 procedure rooms for vascular access procedures for ESRD patients)
County: Wake
FID #: 180414

Approved Capital Expenditure: \$1,792,511
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: February 27, 2020
Required State Agency Findings: Enclosed

Dear Ms. Palumbo:

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.

**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.

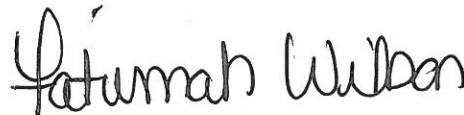
If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the certificate of need is issued. Please contact this office if any clarification of this decision is required.

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

Sincerely,



Ena Lightbourne  
Project Analyst



Fatimah Wilson  
Team Leader

Enclosures:

- Attachment A: Conditions of Approval
- Attachment B: Approved Timetable
- Required State Agency Findings

cc: Radiation Protection Section, DHSR

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

- 1. RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall materially comply with the representations in this application and the representations in Project ID#J-11551-18. Where representations conflict, RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall materially comply with the last made representation.**
- 2. RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall develop no more than one operating room and three procedure rooms upon completion of this project and Project J-11551-18 (Develop a new ambulatory surgical facility in Raleigh with one operating room and two procedure rooms focused on vascular access procedures for patients with end stage renal disease).**
- 3. Upon completion of the project, RAC Surgery Center, LLC shall be licensed for no more than three procedure rooms.**
- 4. The total combined capital expenditure for both projects is \$3,792,511, an increase of \$1,792,511 over the capital expenditure of \$2,000,000 previously approved in Project ID# J-11551-18.**
- 5. RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
- 7. For the first three years of operation following completion of the project, RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 8. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
- 9. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**

- 10. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
  - a. Payor mix for the services authorized in this certificate of need.**
  - b. Utilization of the services authorized in this certificate of need.**
  - c. Revenues and operating costs for the services authorized in this certificate of need.**
  - d. Average gross revenue per unit of service.**
  - e. Average net revenue per unit of service.**
  - f. Average operating cost per unit of service.**
  
- 11. RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC 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 30, 2020
2. Drawings Completed \_\_\_\_\_ August 28, 2019
3. Construction / Renovation Contract(s) Executed \_\_\_\_\_ March 1, 2020
4. 25% of Construction / Renovation Completed  
(25% of the cost is in place) \_\_\_\_\_ April 15, 2020
5. 50% of Construction / Renovation Completed \_\_\_\_\_ May 15, 2020
6. 75% of Construction / Renovation Completed \_\_\_\_\_ June 15, 2020
7. Construction / Renovation Completed \_\_\_\_\_ August 1, 2020
8. Equipment Ordered \_\_\_\_\_ June 1, 2020
9. Equipment Installed \_\_\_\_\_ August 1, 2020
10. Equipment Operational \_\_\_\_\_ August 31, 2020
11. Building / Space Occupied \_\_\_\_\_ September 1, 2020
12. Licensure Obtained \_\_\_\_\_ September 30, 2020
13. Services Offered (required) \_\_\_\_\_ October 1, 2020
14. Medicare and / or Medicaid Certification Obtained \_\_\_\_\_ January 1, 2023
15. Facility or Service Accredited \_\_\_\_\_ December 21, 2020