



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 29, 2019

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

Conditional Approval

Project ID #: F-11612-18
Facility: Metrolina Vascular Access Care
Project Description: Develop a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease
County: Mecklenburg
FID #: 180517

Approved Capital Expenditure: \$2,900,000
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: April 29, 2019
Required State Agency Findings: Will be mailed within five business days after the date of this letter

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 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,


Julie M. Faenza
Project Analyst


Fatimah Wilson
Team Leader


Martha J. Frisone
Chief, Healthcare
Planning and Certificate
of Need Section

Enclosures:

Attachment A: Conditions of Approval
Attachment B: Approved Timetable

cc: Acute & Home Care Licensure & Certification Section, DHSR

Attachment A
Conditions of Approval

1. **Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC shall materially comply with all representations made in the certificate of need application.**
2. **Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC shall develop Metrolina Vascular Access Care, a new ambulatory surgical facility, with one operating room and one procedure room, to be focused on vascular access procedures for patients with end stage renal disease.**
3. **Upon completion of the project, Metrolina Vascular Access Care shall be licensed for no more than one operating room.**
4. **Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte 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.**
5. **Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte 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.**
6. **For the first three years of operation following completion of the project, Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC shall not increase charges more than 5 percent 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.**
7. **The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
8. **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.**
9. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte 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.**

Project F-11612-18 Cont.

- 10. Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte 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. Drawings Completed _____ May 1, 2019
2. Construction/Renovation Contract(s) Executed _____ July 15, 2019
3. 25% of Construction/Renovation Completed _____
(25% of the cost is in place) _____ August 2, 2019
4. 50% of Construction/Renovation Completed _____ September 2, 2019
5. 75% of Construction/Renovation Completed _____ October 31, 2019
6. Construction/Renovation Completed _____ December 31, 2019
7. Equipment Ordered _____ December 1, 2019
8. Equipment Installed _____ January 15, 2020
9. Equipment Operational _____ February 1, 2020
10. Building/Space Occupied _____ February 1, 2020
11. Licensure Obtained _____ March 2, 2020
12. Services Offered _____ May 1, 2020
13. Medicare and/or Medicaid Certification Obtained _____ April 22, 2020
14. Facility or Service Accredited _____ April 30, 2020
15. Final Annual Report Due _____ July 31, 2023

