



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**

April 29, 2021

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

**Conditional Approval**

Project ID #: F-12019-21  
Facility: Metrolina Vascular Access Care, LLC  
Project Description: Cost overrun and change of scope for Project ID #F-11612-18 (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: \$1,200,000  
Conditions of Approval: See Attachment A  
Approved Timetable: See Attachment B  
Last Date to Appeal: June 1, 2021  
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. 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.

**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

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 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

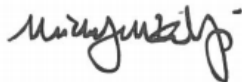
It is requested that a copy of the petition also be served on the Agency.

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,



Michael J. McKillip  
Project Analyst  
[mike.mckillip@dhhs.nc.gov](mailto:mike.mckillip@dhhs.nc.gov)



Fatimah Wilson  
Team Leader  
[Fatimah.wilson@dhhs.nc.gov](mailto:Fatimah.wilson@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  
Construction Section,

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

1. Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC (hereinafter certificate holder) shall materially comply with the representations in this application and the representations in Project I.D. # F-11612-18. Where representations conflict, the certificate holder shall materially comply with the last made representation.
2. The total combined capital expenditure for both projects is \$4,100,000, an increase of \$1,200,000 over the capital expenditure of \$2,900,000 previously approved in Project I.D. # F-11612-18.
3. Upon completion of the project and Project I.D. # F-11612-18, Metrolina Vascular Access Care shall be licensed for no more than one operating room and one procedure room.
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. Progress reports shall be due on the first day of every third month. The first progress report shall be due on September 1, 2021. The second progress report shall be due on December 1, 2021 and so forth.
5. The certificate holder shall not acquire as part of this project any equipment that is not included in this project's and Project I.D. # F-11612-18's combined proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
6. The certificate holder 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, the certificate holder shall not increase charges more than 5% of the charges projected in this application, in Project I.D. # F-11612-18, 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. The certificate holder 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.

11. 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, the certificate holder 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.
  
12. 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>
4	Construction / Renovation Contract(s) Executed	7/1/2021
6	50% of Construction / Renovation Completed	11/8/2021
8	Construction / Renovation Completed	1/15/2022
13	Licensure Obtained	4/15/2022
<b>14</b>	<b>Services Offered</b>	6/8/2022
17	First Annual Report Due*	8/1/2023