



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

August 17, 2018

Jim Swann
3390 Dunn Road
Eastover, NC 28312

Conditional Approval

Project ID #: J-11510-18
Facility: Fresenius Kidney Care Holly Springs
Project Description: Develop a new 10-station dialysis facility by relocating 4 stations from BMA of Raleigh Dialysis, 4 stations from FMC New Hope Dialysis and 2 stations from Southwest Wake County Dialysis
County: Wake
FID #: 180261

Dear Mr. Swann:

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 a review of the applications submitted for this cycle and after consideration of the Certificate of Need Law, N.C. Gen. Stat. §131E-175 et. seq. and regulations promulgated there under, the State Medical Facilities Plan, and other applicable information. Attached to this letter are the required findings made with respect to your application. The applicant shall not proceed with the construction, offering or development of this project until the certificate of need is issued. Further, 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). The conditions are as follows:

- 1. The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a/ Fresenius Kidney Care Holly Springs shall materially comply with the representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. d/b/a/ Fresenius Kidney Care Holly Springs shall develop a new kidney disease treatment center to be known as Fresenius Kidney Care Holly Springs by relocating four existing certified dialysis stations from BMA of Raleigh Dialysis, four existing**

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: 2701 Mail Service Center, Raleigh, NC 27699-2701
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3750 • FAX: 919-733-2757

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

certified dialysis stations from FMC New Hope Dialysis, and two existing certified dialysis stations from Southwest Wake County Dialysis.

- 3. The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a/ Fresenius Kidney Care Holly Springs shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include isolation stations.**
- 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 4 dialysis stations at BMA Raleigh for a total of no more than 46 dialysis stations at BMA Raleigh, 4 dialysis stations at FMC New Hope for a total of no more than 28 dialysis stations at FMC New Hope, and 2 dialysis stations at Southwest Wake County for a total of no more than 28 dialysis stations at Southwest Wake County.**
- 5. The applicant, Bio-Medical of Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care of Holly Springs 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.**

Response to the above conditions 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 conditional approval is valid only for a capital expenditure of **\$1,783,044**. If a cost overrun occurs that exceeds the approved capital expenditure amount, a new certificate of need may be required as determined by N.C. Gen. Stat. §131E-176(16)(e).

The applicant should be aware that according to the Certificate of Need law any affected person shall have thirty (30) days after the date of decision to file a petition for a contested case on this approval. Further, if you are aggrieved by the conditions of the decision you may file a petition for a contested case hearing in accordance with N.C. Gen. Stat. §150B, Article 3, as amended. 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. [Note: Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to 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 this 30 day period ending **September 17, 2018**. If a contested case request is received within the thirty (30) day period, the certificate will not be issued until the appeal is resolved (10A NCAC 14C .0208).

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 timetable for this project is as follows:

1. Construction/Renovation Contract(s) Executed _____ March 3, 2019
2. 25% of Construction/Renovation Completed (25% of the cost is in place) __ May 17, 2019
3. 50% of Construction/Renovation Completed _____ July 16, 2019
4. 75% of Construction/Renovation Completed _____ September 14, 2019
5. Construction/Renovation Completed _____ November 13, 2019
6. Equipment Ordered _____ October 17, 2019
7. Equipment Operational _____ December 15, 2019
8. Services Offered _____ December 31, 2019
9. Medicare and/or Medicaid Certification Obtained _____ December 31, 2019

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

Gloria C. Hale
Team Leader (West Team)

Attachment

cc: Acute and Home Care Licensure and Certification Section, DHSR
Melinda Boyette, Administrative Assistant, Healthcare Planning, DHSR

CERTIFICATE OF SERVICE

I hereby certify that I have served the foregoing notice of **conditional approval** on the following person by placing a copy in an official depository of the United States Postal Service in a postage-paid, first class envelope addressed as follows:

Jim Swann
3390 Dunn Road
Eastover, NC 28312

This the 17th day of August, 2018.

Ena Lightbourne
Project Analyst, Certificate of Need