

DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR MANDY COHEN, MD, MPH SECRETARY

> MARK PAYNE DIRECTOR

RESPONSE REQUIRED

October 13, 2017

Jim Swann 3390 Dunn Road Eastover, NC 28312

Conditional Approval

Project ID #: F-11375-17

Facility: Fresenius Kidney Care Mallard Creek

Project Description: Develop a new 12-station dialysis facility by relocating 12 stations from

BMA North Charlotte

County: Mecklenburg

FID #: 170326

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. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Mallard Creek shall materially comply with all 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 Mallard Creek shall develop a new kidney disease treatment center

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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to be known as FKC Mallard Creek by relocating 12 dialysis stations from BMA North Charlotte.

- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Mallard Creek shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations, which shall include any isolation stations.
- 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 12 dialysis stations at BMA North Charlotte for a total of no more than 28 dialysis stations at BMA North Charlotte upon completion of this project and Project I.D. #F-11243-16 (add 4 stations).
- 5. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Mallard Creek 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 \$1,850,220. 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

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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 **November 13, 2017.** 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	May 18, 2018
2.	25% of Construction/Renovation Completed (25% of the cost is in pla	(ce) July 2, 2018
3.	50% of Construction/Renovation Completed	June 1, 2018
4.	75% of Construction/Renovation Completed	September 30, 2018
5.	Construction/Renovation Completed	November 14, 2018
6.	Services Offered	December 31, 2018
7.	Medicare and/or Medicaid Certification Obtained	December 31, 2018
8.	Final Annual Report Due	March 31, 2022

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,

Gloria C. Hale Project Analyst Fatimah Wilson

Team Leader, Certificate of Need

Attachment

cc: Construction Section, DHSR

Acute & Home Care Licensure & Certification Section, DHSR Sharetta Blackwell, Program 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 13th day of October, 2017.

Gloria C. Hale Project Analyst, Certificate of Need