

North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Richard O. Brajer Secretary DHHS

Mark Payne Assistant Secretary for Audit and Health Service Regulation

RESPONSE REQUIRED

April 22, 2016

Jim Swann 2800 Breezewood Avenue, Suite 200 Fayetteville, NC 28303

Conditional Approval

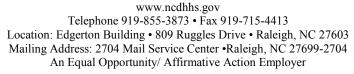
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Project ID #:	J-11133-16
Facility:	Fresenius Medical Care Morrisville
Project Description:	Develop a new 10-station dialysis facility by relocating four stations from
	Cary Kidney Center and six stations from Southwest Wake County
	Dialysis
County:	Wake
FID #:	160069

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, G.S. 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 G.S. 131E-187(a). The conditions are as follows:

- 1. Bio-Medical Applications of North Carolina, Inc. and Carolina Dialysis, LLC shall materially comply with all representations made in the certificate of need application.
- 2. Bio-Medical Applications of North Carolina, Inc. and Carolina Dialysis, LLC shall relocate no more than 4 dialysis stations from Cary Kidney Center and no more than 6 dialysis stations from Southwest Wake County Dialysis.

Healthcare Planning and Certificate of Need Section



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- 3. Bio-Medical Applications of North Carolina, Inc. and Carolina Dialysis, LLC shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.
- 4. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 4 dialysis stations at Cary Kidney Center for a total of no more than 24 dialysis stations at Cary Kidney Center upon project completion.
- 5. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 6 dialysis stations at Southwest Wake County Dialysis for a total of no more than 24 dialysis stations at Southwest Wake County Dialysis upon project completion.
- 6. Bio-Medical Applications of North Carolina, Inc. and Carolina Dialysis, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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 1,607,166. If a cost overrun occurs that exceeds the approved capital expenditure amount, a new certificate of need may be required as determined by G.S. 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 G.S. 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).]

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:

Emery Milliken Department of Health and Human Services, Office of Legal Affairs, Adams Building – Room 154 2001 Mail Service Center Raleigh, North Carolina, 27699-2001 Jim Swann April 22, 2016 Page 3

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 May 23, 2016. 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:

Contract Award	March 31, 2017
25% Completion of Construction	June 14, 2017
50% Completion of Construction	August 13, 2017
75% Completion of Construction	September 27, 2017
Completion of Construction	October 27, 2017
Occupancy/Offering of Service/Certification	December 31, 2017

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,

Celia C. Inman Project Analyst Martha J. Frisone Assistant Chief, Certificate of Need

Attachment

cc: Acute & Home Care Licensure & Certification Section, DHSR Kelli Fisk, Program Assistant, Healthcare Planning, DHSR Construction Section, 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 2800 Breezewood Avenue, Suite 200 Fayetteville, NC 28303 Project ID #: J-11133-16 FID #: 160069

This the 22nd day of April, 2016.

Celia C. Inman Project Analyst, Certificate of Need