



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

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

RESPONSE REQUIRED

January 16, 2015

Jim Swann
3717 National Drive, Suite 206
Raleigh, NC 27612

Conditional Approval

Project I.D. #: J-10343-14
Facility: Fresenius Medical Care Eastern Wake
Project Description: Add three dialysis stations for a total of 14 certified stations upon completion of this project and Project I.D. #K-10099-13
County: Wake
FID #: 0611335

Dear Mr. Swann:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), Department of Health and Human Services 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 that can be satisfied before issuance of the certificate of need have been met pursuant to G.S. 131E-187(a). The conditions are as follows:

1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Eastern Wake shall materially comply with all representations made in the certificate of need application.
2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Eastern Wake shall develop and operate no more than three additional dialysis stations for a total of no more than 14 certified stations upon completion of this project, which shall include any isolation or home hemodialysis stations.

Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone 919-855-3873 • Fax 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Eastern Wake shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 14 dialysis stations, which shall include any isolation or home hemodialysis stations.
4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Eastern Wake 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 **\$0**. 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

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 **February 16, 2015**. 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:

Ordering Equipment _____ October 2, 2016
Certification of Stations _____ December 31, 2016

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 us if any clarification of this decision is required.

Please refer to the Project I.D. # and Facility I.D. # (FID) in all correspondence.

Sincerely,

Michael J. McKillip, Project Analyst

Lisa Pittman, Team Leader
Certificate of Need

MJM:LP:ar

Attachment

cc: Assistant Chief, Healthcare Planning
Acute & Home Care Licensure & Certification 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
3717 National Drive, Suite 206
Raleigh, NC 27612

Project I.D. # J-10343-14
FID #061335

This the 16th day of January, 2015.

Michael J. McKillip, Project Analyst