



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

March 27, 2015

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

Conditional Approval

Project ID #: F-10369-15
Facility: FMC Regal Oaks
Project Description: Develop a new 12-station dialysis facility by relocating eight dialysis stations from FMC Matthews and four dialysis stations from BMA East Charlotte
County: Mecklenburg
FID #: 150024

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. d/b/a FMC Regal Oaks 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 Regal Oaks shall relocate no more than 8 dialysis stations from FMC Matthews and no more than 4 dialysis stations from BMA East Charlotte.



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 Regal Oaks shall install plumbing and electrical wiring through the walls for no more than 12 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 8 dialysis stations at FMC Matthews for a total of no more than 13 dialysis stations at FMC Matthews upon project completion.
5. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 4 dialysis stations at BMA East Charlotte for a total of no more than 21 dialysis stations at BMA East Charlotte upon project completion.
6. Prior to issuance of the certificate of need, Bio-Medical Applications of North Carolina, Inc. shall provide the Agency with a letter of intent to sign a written agreement with a transplantation center describing the relationship with the facility and the specific services that will be provided by the transplantation center.
7. Prior to issuance of the certificate of need, Bio-Medical Applications of North Carolina, Inc. shall provide the Agency with documentation to demonstrate the availability of power at the proposed primary FMC Regal Oaks site.
8. Prior to issuance of the certificate of need, Bio-Medical Applications of North Carolina, Inc. shall provide the Agency with documentation that the primary site is owned or under option by the applicant or provide documentation to demonstrate the availability of power and water at the proposed secondary site.
9. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Regal Oaks 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 \$1,932,692. 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 April 27, 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:

Completion of Final Drawings _____	August 20, 2015
Contract Award _____	October 4, 2015
25% Completion of Construction _____	December 3, 2015
50% Completion of Construction _____	February 1, 2016
75% Completion of Construction _____	March 17, 2016
Completion of Construction _____	May 16, 2016
Occupancy/Offering Service/ Certification of Stations _____	June 30, 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 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
Assistant Chief, Healthcare Planning
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
3717 National Drive, Suite 206
Raleigh, NC 27612

Project ID #: F-10369-15
FID #: 150024

This the 27th day of March, 2015.

Celia C. Inman
Project Analyst, Certificate of Need