

**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

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| IN RE: REQUEST FOR DECLARATORY |) | |
| RULING BY BIO-MEDICAL APPLICATIONS |) | |
| OF NORTH CAROLINA, INC. D/B/A |) | DECLARATORY RULING |
| FMC ST. AGNES |) | |
| Project I.D. No. J-8259-08 |) | |

I, Jeff Horton, as Acting Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services (“Department” or “Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Agnes (“BMA”) has requested a declaratory ruling allowing for a change in the site and name for Project I.D. No. J-8259-08 on the grounds that the change does not constitute a material change in physical location or a failure to materially comply with the representations made by BMA in its Certificate of Need (“CON”) application for its project. N.C.G.S. §§ 131E-181(a) and (b). This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Jim Swann, Director of Market Development and Certificate of Need for BMA, has requested this ruling on behalf of BMA and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

Effective 7 May 2009, the CON Section issued a CON to BMA to relocate nine dialysis stations from BMA Raleigh and four dialysis stations from Fresenius Medical Care (“FMC”) New Hope to develop a new 13-station facility, FMC St. Agnes, to be located at 311 North Tarboro Street in Raleigh, Wake County (the “Original Site”). BMA represents that, subsequent to the issuance of the CON, it determined that the Original Site was not suitable for development and has identified an alternate site for development of its project (the “Proposed Site”).

The Proposed Site is identified as existing space at Seaboard Station, Building II at 802 Semart Drive in Raleigh, Wake County. The Proposed Site is approximately 1.5 miles and 5 minutes driving time from the Original Site. BMA states that the property developer at Seaboard Station has provided assurances to BMA that the Proposed Site is suitably zoned to allow development of a dialysis facility. BMA represents that it does not contemplate any change to the scope or scale of the services proposed in its original application.

BMA anticipates that the CON approved capital expenditure for its project will not be sufficient to cover the total costs of development at the Proposed Site. Therefore, BMA filed a Cost Overrun CON application on 15 April 2010 seeking approval for an additional \$303,211 capital expenditure for a total capital expenditure of \$1,023,641.

As part of its Request, BMA also proposes to change the name of its facility because it will no longer be located in the historical St. Agnes Hospital building on the campus of Saint Augustine College. BMA seeks to change the name of its facility to “FMC Central Raleigh” as a more appropriate reflection of its new location at the Proposed Site.

ANALYSIS

The CON law would require a full review of BMA's proposed changes of site and name if those changes were to represent a material change in the physical location or scope of the project. N.C.G.S. § 131E-181(a). The proposed changes of the site and name for BMA's project do not constitute a material change in the physical location because of the close proximity of the Proposed Site to the Original Site. The changes will not affect the scope of services offered or the costs and charges to the public. In addition, there is no proposed change in the person named in the application such that a violation of N.C.G.S. § 131E-181(a) would result.

N.C.G.S. § 131E-189(b) allows the Agency to withdraw BMA's CON if BMA fails to develop the service in a manner consistent with the representations made in the application or with any conditions that were placed on the CON. BMA will not be developing its project in a manner that is materially different from the representations made in its application, nor will it be developing its project in a manner that is inconsistent with any of the conditions that were placed on its CON. Further, BMA has filed a Cost Overrun CON application to address the additional capital expenditures caused by the site change.

CONCLUSION

For all the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the substitution of the Proposed Site for the Original Site and a change of name to "FMC Central Raleigh" for BMA's 13-station dialysis facility (Project I.D. No. J-8259-08) will not constitute a material change in the physical location or scope of the project, will not violate N.C.G.S. § 131E-181, and will not constitute a failure to satisfy a condition of the CON in violation of N.C.G.S. § 131E-189(b).

This the _____ day of _____, 2010.

Jeff Horton, Acting Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Jim Swann
Director of Market Development and CON
Fresenius Medical Care
3867 Dunn Road
Eastover, NC 28312

This the _____ day of _____, 2010.

Jesse Goodman
Chief Operating Officer