

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

IN RE: REQUEST FOR DECLARATORY)	
RULING BY BIO-MEDICAL)	
APPLICATIONS OF NORTH CAROLINA,)	DECLARATORY RULING
INC. d/b/a FRESENIUS MEDICAL CARE)	
OF BRUNSWICK COUNTY)	
Project I.D. No. O-7965-07)	

I, Drexdal Pratt, as 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 Fresenius Medical Care of Brunswick County (“BMA”) has requested a declaratory ruling allowing for a change in the site for Project I.D. No. O-7965-07 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 19 March 2009, the CON Section issued a CON to BMA to develop a new 10-station dialysis facility to be located at 294 Ocean Highway (US 17 South) in Supply, North Carolina (the “Original Site”). BMA represents that subsequent to obtaining the CON, it determined that the Original Site is unsuitable because of drainage issues. BMA now proposes to develop the project at an alternative site (the “Proposed Site”).

The Proposed Site is identified as a 2.68 acre tract of land located at 112 Stone Chimney Road in Supply. The Proposed Site is less than one mile from the Original Site. BMA states that the Proposed Site is properly zoned, has power, sewer and water capabilities, and is not in a floodplain. BMA further represents that the Proposed Site “will be as convenient for patients as the originally proposed site and will be beneficial to the same patient population” as proposed in its CON application. BMA further represents that it does not contemplate any change to the scope or scale of the services proposed in its original application.

ANALYSIS

The CON law would require a full review of BMA’s proposed change of site if that change were to represent a material change in the physical location or scope of the project. N.C.G.S. § 131E-181(a). The proposed change of the site for BMA’s project does not constitute a material change in the physical location because of the close proximity of the Proposed Site to the Original Site. The change 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.

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 for BMA's 10-station dialysis facility (Project I.D. No. O-7965-07) 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 January, 2011.

Drexdal Pratt, 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 Certificate of Need
Fresenius Medical Care
3725 National Drive, Suite 130
Raleigh, NC 27612

This the _____ day of January, 2011.

Jeff Horton
Chief Operating Officer