

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

<b>IN RE: REQUEST FOR DECLARATORY</b>	)	
<b>RULING BY BIO-MEDICAL</b>	)	
<b>APPLICATIONS OF NORTH CAROLINA,</b>	)	<b>DECLARATORY RULING</b>
<b>INC. d/b/a FRESENIUS MEDICAL CARE</b>	)	
<b>OF SOUTH GASTON</b>	)	
<b>Project I.D. No. F-7913-07</b>	)	

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 Fresenius Medical Care of South Gaston (“BMA”) has requested a declaratory ruling allowing for a change in the site for Project I.D. No. F-7913-07 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, Regional Director of Health Planning 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 8 May 2008, the CON Section issued a CON to BMA develop a 12 station dialysis facility to be located at the northwest corner of Claudette Drive and York Highway in Gastonia, North Carolina (the “Original Site”). BMA represents that subsequent to obtaining the CON, it determined that developing the project at the secondary site identified in the CON application (the “Proposed Site”) is “more suitable to its needs.”

The Proposed Site is identified as the northwest corner of West Hudson Boulevard and Clyde Street in Gastonia and is approximately 1.1 miles from the Original Site. BMA states that the Proposed Site “will be equally as convenient for BMA’s patients” 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 12 station dialysis facility (Project I.D. No. F-7913-07) 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 \_\_\_\_\_, 2008.

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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  
Regional Director of Health Planning  
Fresenius Medical Care  
3867 Dunn Road  
Eastover, NC 28312

This the \_\_\_\_\_ day of \_\_\_\_\_, 2008.

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Jeff Horton  
Acting Director