

**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 ) DECLARATORY RULING  
OF NORTH CAROLINA )  
Project I.D. No. H-7687-06 )**

I, Robert J. Fitzgerald, 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 N.C.A.C. 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 Anson County (FMC Anson County) has requested a declaratory ruling allowing for a change of site for Project I.D. No. H-7687-06 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 FMC Anson County 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 at Fresenius Medical Care, has requested this ruling on behalf of FMC Anson County and has provided the material facts upon which this ruling is based.

## STATEMENT OF THE FACTS

Effective 11 July 2007, the CON Section issued a CON to FMC Anson County for Project H-7687-06 to develop a 10-station ESRD facility in Anson County, North Carolina. FMC Anson County represented in its CON application that its proposed primary site was the 2600 Block of US Highway 74 West (the "Original Site"). In preparation of construction for the proposed project on the primary site, FMC Anson County conducted a subsoil test. The results of that test show that "the soft clay soils strata encountered at the Test Borings at this time are not suitable for adequately supporting the proposed construction." FMC Anson County's secondary site is no longer an option due to the likelihood of subsoil contamination. At the time the CON application was prepared, FMC Anson County states it had no way of knowing the subsoil conditions at either site. FMC Anson County now requests a declaratory ruling approving an alternate site (the "Alternate Site") for the facility in a location on US Highway 74 approximately one quarter mile from the Original Site. (Anson County Tax Parcel I.D. #646.02-78 0786).

FMC Anson County states that the property it proposes to purchase for the Alternate Site is appropriately zoned for dialysis, and is not located in a flood plain. According to FMC Anson County, the change in site will not affect the development of the 10-station ESRD facility as approved in the CON. Further, the Alternate Site will be as convenient to existing and proposed patients since it is only one-quarter mile away from the original and secondary sites. In addition, the timeline for development approved in the CON will not be affected by the proposed site change.

## **ANALYSIS**

The CON law would require a full review of FMC Anson County'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 FMC Anson County's project does not constitute a material change in the physical location or the scope of the proposed project because locating the project at the Alternate Site will not affect the scope of services offered or the costs and charges to Community Alternatives or to the public. Because of the close proximity of the Alternate Site to the Original Site, the change will not affect the population to be served. 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 FMC Anson County's CON if FMC Anson County 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. FMC Anson County will not develop its project in a manner that is materially different from the representations made in its application, nor will it develop 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 change of site from the Original Site to the Alternate Site for FMC Anson County's 10-station ESRD facility (Project I.D. No. H-7687-06) 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 ruling is not intended, and should not be interpreted, to authorize any increases in the approved capital expenditure for this project, a change in the approved timetable, a change in the conditions placed on the certificate of need, or any other change in the approved project.

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

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Robert J. Fitzgerald, 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 non-agency 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**

Mr. Jim Swann  
Fresenius Medical Care  
3867 Dunn Road  
Fayetteville, NC 28312

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

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Jeff Horton  
Chief Operating Officer