

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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY CAROLINA DIALYSIS, LLC)
d/b/a CAROLINA DIALYSIS – SILER CITY) **DECLARATORY RULING**
Project I.D. No. J-7963-07)**

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 N.C.A.C. 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

Carolina Dialysis, LLC d/b/a Carolina Dialysis – Siler City (“Carolina Dialysis”) has requested a declaratory ruling allowing for a change of site for Project I.D. No. J-7963-07 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 Carolina Dialysis 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 Carolina Dialysis and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

Carolina Dialysis filed a Certificate of Need application to relocate its existing nine station dialysis facility and to add six additional dialysis stations at the time of relocation. On 27 February 2008, the CON application was conditionally approved by the Certificate of Need Section. After appealing a condition of the approval, on 22 April 2008 Carolina Dialysis entered into a settlement agreement with the Division of Health Service Regulation which resolved the appeal. A CON was issued to Carolina Dialysis for Project No. J-7963-07, effective 28 April 2008, to relocate its existing facility and expand the facility from nine dialysis stations to fifteen dialysis stations at the time of relocation.

Carolina Dialysis represented in its CON application that its proposed primary site was 120 Elm Street in Siler City, North Carolina (the “original site”). However, since the CON was issued, Carolina Dialysis determined that a more suitable site for the facility would be the property identified as Site B (the “new site”), a 2.32 acre site located on the Chatham Hospital Campus. The new site was not available during the development of the CON application or during the pendency of the appeal and settlement. According to Carolina Dialysis, developing the facility at the new site puts it in closer proximity to the hospital where it will be more convenient for patients who may have need of hospital services on the day of their dialysis treatment.

Carolina Dialysis represents in its request that the new site is only 2.9 miles from the currently approved location. According to Carolina Dialysis, the new site is equally as convenient for Carolina Dialysis patients and serves the same patient population as proposed in the Certificate of Need application. Further, the change of site will not affect the ability of Carolina Dialysis to develop the project in a manner consistent with the representations in the

CON application and with the conditions placed on the CON. Carolina Dialysis asserts that development of the project at the new site will not represent a material change to the capital expenditure for the project.

In addition to the change in location, Carolina Dialysis requests approval of an amended timeline, attached to its request.

ANALYSIS

The CON law would require a full review of Carolina Dialysis' 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 Carolina Dialysis' project does not constitute a material change in the physical location or the scope of the proposed project because locating the project at the new site will not affect the scope of services offered or the costs and charges to the public. Because of the close proximity of the new 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 Carolina Dialysis' CON if Carolina Dialysis 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. Carolina Dialysis 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.

Because modification of the project's timeline does not involve statutory interpretation, I decline to rule on this portion of Petitioner's request. However, changes in the project's timeline can be addressed directly with the CON Section.

CONCLUSION

For 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 new site for Carolina Dialysis fifteen-station dialysis facility (Project I.D. No. J-7963-07) 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 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 conditions placed on the certificate of need, or any other change in the approved project.

This the _____ day of June, 2009.

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 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
Eastover, NC 28312

This the _____ day of June, 2009.

Jesse Goodman
Chief Operating Officer