

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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY TOTAL RENAL CARE OF)
NORTH CAROLINA, LLC CONCERNING THE) DECLARATORY RULING
DEVELOPMENT AND OPERATION OF THE)
ST. PAULS DIALYSIS CENTER)**

I, Robert J. Fitzgerald, Director of the Division of Facility Services of the North Carolina Department of Health and Human Services (the “Department”), do hereby issue this Declaratory Ruling to Total Renal Care of North Carolina, LLC (“TRC”) pursuant to N.C.G.S. § 150B-4 and 10A NCAC 14A .0310, and the authority granted to me by the Secretary of the Department of Health and Human Services. TRC seeks a declaratory ruling to allow it to develop and operate the St. Pauls Dialysis Center, for which it has previously received a certificate of need (“CON”), at a location other than the primary or secondary sites described in its CON application. For the reasons set out below, I conclude that TRC’s change of site for this facility does not constitute a material change in the implementation of the project under N.C.G.S. § 131E-189(b) and is not subject to further CON review as a new institutional health service under N.C.G.S. § 131E-176(16).

This ruling is binding on the Department and the person requesting it if the material facts stated in the request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department reserves the right to change the conclusions which are contained in this ruling. William R. Shenton, of Poyner & Spruill LLP, has requested this ruling on behalf of TRC and has provided the material facts set out below. Joy H. Thomas, on behalf of Bio-Medical

Applications of North Carolina, Inc. (“BMA”) has submitted comments urging denial of the requested ruling.

STATEMENT OF THE FACTS

TRC applied for and received a CON to develop and operate a 10-station dialysis center in St. Pauls, Robeson County, to be known as the St. Pauls Dialysis Center. TRC represented in its original request submitted February 20, 2006, that the primary site that was identified in its CON application (the “Original Site”) is no longer available and that the secondary site identified in the application has been determined to be not suitable. The Original Site was at the intersection of Clark Street and Fourth Street in St. Pauls.

TRC represents that it has located a new site at the intersection of Blue Street and Old Stage Road in St. Pauls, about one-half mile from the primary site identified in the application. It states that distances to key support services identified in the application are very similar. It represents that, if approved, it will develop the same size facility and offer the same services as proposed in the application, and that costs for the facility will not exceed 115% of the amount shown on the certificate of need.

BMA has submitted an statement dated February 23, 2006, from John E. Odom, Jr., who BMA represents to be the owner of the tract where the Original Site is located, stating that the property is available for sale “at the present time.” BMA argues that TRC has failed to fulfill its commitment in the CON application to “pursue acquiring the [primary] site” as set forth in 10 NCAC 14C.2202(b)(4).

TRC in response submitted an affidavit from William L. Hyland, Director of Healthcare Planning for TRC. Mr. Hyland states that the CON application for the St. Pauls Dialysis Center was submitted on March 17, 2003, and the CON was issued in August 2004. The project remained in litigation until the Court of Appeals issued a decision on October 4, 2005. Thereafter, TRC determined that the primary site was no longer available. Mr. Hyland recounts attending a zoning board meeting in December, 2005, during which he came to believe that the owner of the Original Site had planned to sell the site to "O&G," a company owned by John E. Odum, Jr., and that the new owner intended to build a mini-storage business on the site. He further states that it would be impossible to build both a mini-storage facility and a dialysis clinic on the property.

By letter dated April 13, 2006, TRC submitted a letter from R. Gregg Hill, who states that he assisted TRC in identifying sites for new facilities. Mr. Hill states that in October or November, 2005, he contacted Mr. John Odum, Jr. and asked him about the availability of the Original Site. He states that at that time, Mr. Odum informed him that the property was under option to another purchaser and was no longer available. Mr. Hill states that he passed this information along to Mr. Hyland and assisted Mr. Hyland in identifying an alternative site.

ANALYSIS

The CON law would require a full review of TRC's proposed change of site if that change were to represent a material change in the physical location of the project according to N.C.G.S. § 131E-181(a). N.C.G.S. § 131E-189(b) allows the Department to withdraw TRC's CON if TRC fails to develop the service in a manner consistent with the representations made in its application or with any of the conditions that were placed on the CON. If during development or within one year of completion, a change in a project for which a CON was

issued is more than 15% of the approved capital expenditure amount, it is a “new institutional health service” and a new CON may be required unless otherwise exempt. N.C.G.S. § 131E-176(16)(e).

The relocation of the site for TRC’s new dialysis center does not constitute a material change in either the physical location or in the scope of the proposed project because TRC will be developing its project in a manner which is not materially different from the representations made in its application and not inconsistent with any conditions that were placed on its CON. The new site is located in close proximity to the primary site identified in TRC’s application. The change of site will not materially impact the project’s original capital costs. Neither the fact that the Original Site may still be available for purchase nor the validity of TRC’s conclusion that the Original Site is no longer available for the project is material to the issue of determining if the new site is a material change in the implementation of the project under N.C.G.S. 131E-189(b).

CONCLUSION

For the foregoing reasons, and assuming the statements of material fact in the request to be true, I conclude that the change in the site for the development of the St. Pauls Dialysis Center will not violate N.C.G.S. § 131E-181, because it will not constitute a material change in the physical location of the proposed facility, will not constitute a failure to satisfy a condition of the CON in violation of N.C.G.S. § 131E-189(b), and is not subject to additional certificate of need review as a new institutional health service under N.C.G.S. § 131E-176(16).

This ruling is not intended, and should not be interpreted to authorize any increase in the approved capital expenditure for this project, a change in the approved timetable, a change in the conditions placed on the CON, or any other change in the approved project.

This _____ day of April, 2006.

Robert J. Fitzgerald, Director
Division of Facility 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 a first class, postage prepaid envelope addressed as follows:

CERTIFIED MAIL

William R. Shenton
Poyner & Spruill, LLP
3600 Glenwood Avenue
Post Office Box 10096
Raleigh, NC 27605-0096

Joy H. Thomas
Law Office of Joy H. Thomas
514 Daniels Street # 182
Raleigh, NC 27605

This the 19th day of April, 2006.

Jeff Horton
Chief Operating Officer