

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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY WAKE PET SERVICES, LLC,)
WAKEMED, WAKE RADIOLOGY) **DECLARATORY RULING**
ONCOLOGY SERVICES, PLLC, WAKE)
RADIOLOGY SERVICES, LLC.)**

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.

Wake PET Services, LLC, WakeMed, Wake Radiology Oncology Services, PLLC, and Wake Radiology Services, LLC (collectively “Wake”) have requested a declaratory ruling to allow Wake PET Services, LLC to lease its PET/CT scanner at 300 Ashville Avenue, Cary, North Carolina, to Wake Radiology Services, LLC rather than to Wake Radiology Oncology Services; also to allow Wake Radiology Oncology Services, PLLC to transfer its ownership interests in Wake PET Services, LLC to Wake Radiology Services, LLC for Project I.D. #J-7103-04. This ruling will be binding upon the Department and the entities 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. Attorneys for the Petitioners have requested this ruling on their behalf and have provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

On November 18, 2005, Wake was issued a certificate of need (“CON”) for Project I.D. #J-7103-04, which enabled Wake to operate a combined positron emission tomography/computed tomography scanner (“PET/CT”) at a facility located at 1900 Kildaire Farm Road, Cary, North Carolina.

On July 14, 2006, Wake and the Department executed a Settlement Agreement that permitted Wake to change the site for the PET/CT scanner to 300 Ashville Avenue in Cary, North Carolina, which is space leased by Wake Radiology Oncology Services, PLLC (“WROS”).

On July 30, 2008, Wake and the Department entered into an Amended and Restated Settlement Agreement (the “Agreement”) whereby it was agreed that Wake PET Services, LLC would lease the PET/CT scanner to WROS rather than to WakeMed as approved by the issuance of the CON.

Through this declaratory ruling request, Wake seeks approval for Wake PET Services, LLC (“Wake PET”) to lease, at fair market value, the PET/CT scanner to Wake Radiology Services, LLC (“WRS”), rather than to WROS, as approved by the Agreement, and to transfer WROS’s ownership rights and interests in Wake PET to WRS.

As outlined in the Request for Declaratory Ruling filed with the Department on August 10, 2010 by WROS, Cancer Centers of North Carolina, P.C., US Oncology, Inc., AOR Management Company of Virginia, LLC (“AOR”), and WakeMed (the “August Request”), the physician owners of WROS have entered into a letter of intent to sell all of their individual membership interests in WROS to AOR. The August Request was approved, and a Declaratory Ruling was issued on September 27, 2010.

WRS and WROS are each approved applicants for the CON. Wake intends to comply with all terms and conditions associated with its CON and the Agreement other than this change in lessee and ownership of Wake PET.

ANALYSIS

N.C. Gen. Stat. § 131E-181(a) states that a CON is “valid only for the defined scope, physical location and person in the named application.” Because both WROS and WRS are approved applicants for the CON, this request to change the lessee of the PET/CT scanner to WRS and to transfer ownership interest in Wake PET from WROS to WRS does not constitute a material change in the project.

The CON law provides that no person shall offer or develop a “new institutional health service” without first obtaining a CON. N.C. Gen. Stat. § 131E-178. The acquisition by lease of a PET scanner would ordinarily constitute a “new institutional health service,” triggering the need for WRS to obtain a certificate of need. However, the Department has previously allowed Wake PET to lease the PET/CT scanner to co-applicant WakeMed and also to co-applicant WROS. Because WRS is a co-applicant as well, the requested change is similar to those previous arrangements, and therefore WRS is not required to obtain a new CON.

With WRS as the lessee in place of WROS, Wake will remain able to operate its PET/CT scanner in a manner consistent with the conditions placed upon its CON and in accordance with the remaining terms of the Agreement.

The approval of this request will not result in a change in the physical location of the PET/CT scanner, and will not result in a interruption of service or a change in the costs or charges to the public.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the Petitioners do not require a certificate of need in order to proceed with the proposed transaction.

This the _____ day of December, 2010.

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 a first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

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This the _____ day of December, 2010.

Jeff Horton
Chief Operating Officer