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

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IN RE: REQUEST FOR DECLARATORY RULING BY WAKEMED Project I.D. No. J-7013-04

DECLARATORY RULING

I, Jeff Horton, 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.

WakeMed has requested a declaratory ruling allowing for an additional host site for Project I.D. No. J-7013-04 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 WakeMed 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. Kathleen K. Gormley, Executive Vice President of Operations and Ambulatory Services of WakeMed, has requested this ruling on behalf of WakeMed and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

Effective February 28, 2005, the CON Section issued a CON to WakeMed for Project I.D. No. J-7013-04 to acquire a mobile magnetic resonance imaging ("MRI") scanner (the

"Project Unit") to provide MRI services, initially at the following sites: Community Family Medicine and Obstetrics (Pittsboro); Sampson Regional Medical Center; Carteret General Hospital; Bladen County Hospital and Lillington Family Medical Center. A condition of the CON is that the equipment "shall not, at any time, serve less than two host sites each week." Another condition of the CON is that "WakeMed shall not change or add host sites unless it first obtains a declaratory ruling authorizing the change in location of the equipment pursuant to [N.C.G.S.] 150B-4 and the rules of the Department of Health and Human Services, Division of Health Service Regulation."

In a declaratory ruling dated September 26, 2005, WakeMed was allowed to add a host site at WakeMed North Healthplex, located in Wake County, increasing the number of host sites from five to six.

In correspondence dated March 13, 2006, WakeMed informed the agency that it would no longer provide mobile MRI services at Community Family Medicine and Obstetrics (Pittsboro) and Lillington Family Medical Center.

In a declaratory ruling dated January 10, 2007, WakeMed was allowed to add a host site at Dorothea Dix Hospital, located in Wake County.

WakeMed represents that it currently provides mobile MRI services to three approved locations: Bladen County Hospital, Dorothea Dix Hospital, and WakeMed North Healthplex. In this request, WakeMed seeks to add an additional site at Central Regional Hospital, 300 Veazey Road, Butner, North Carolina in Granville County. WakeMed states that it is able to add an additional host site due to schedule availability for its mobile MRI scanner.

WakeMed represents that it can provide mobile MRI services to the previously approved sites as well as to Central Regional Hospital without any compromise in services, changes in cost

or charges, or compromise compliance with the representations WakeMed made in its application regarding its proposed host sites.

ANALYSIS

The CON law would require a full review of WakeMed's proposed addition of a host 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 addition of Central Regional Hospital as a host site for WakeMed's project does not constitute a material change in the physical location or the scope of the proposed project because the use of Central Regional Hospital as a host site will not affect the scope of services offered or the costs and charges to WakeMed or to the public for the provision of MRI scanner services. 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 WakeMed's CON if WakeMed either 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. WakeMed 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 materially different from the representations made in its 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 subject to the conditions set out herein, the addition of Central Regional Hospital as a host site for WakeMed's mobile MRI scanner (Project I.D. No. J-7013-04) 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 subject to the following conditions:

- (1) WakeMed shall enter into a service agreement with Central Regional Hospital that is substantially similar to the agreement signed by its other host sites.
- (2) WakeMed shall satisfy all the requirements and representations regarding the host sites in its original CON application.

This the _____ day of _____, 2010.

Jeff Horton, 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

Kathleen K. Gormley Executive Vice President-Operations & Ambulatory Services WakeMed 3000 New Bern Avenue Raleigh, NC 27610

This the _____ day of _____, 2010.

Jesse Goodman Chief Operating Officer