

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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY WACCAMAW ULTRASOUND)
& DIAGNOSTICS, INC.) DECLARATORY RULING
Project I.D. No. O-7340-05)**

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

Waccamaw Ultrasound & Diagnostics, Inc. (“Waccamaw”) has requested a declaratory ruling allowing for an additional host site for Project I.D. No. O-7340-05 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 Waccamaw 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. Renee J. Montgomery and Robert A. Leandro of Parker Poe Adams & Bernstein, LLP, counsel for Waccamaw, have requested this ruling on behalf of Waccamaw and have provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

Effective 30 November 2006, the CON Section issued a CON to Waccamaw for Project I.D. No. O-7340-05 to acquire a mobile MRI scanner and trailer (the “Project Unit”) to provide MRI services at two host sites. The proposed host sites were 619 Jefferson Street, Whiteville, NC and 604 North Madison Street, Whiteville, NC (the “Original Sites”). Both sites are in Columbus County and HSA V.

Waccamaw proposes to serve an additional host site one day per week. The proposed site is Allen Orthopedics at 404 Hatfield Court, Lumberton, Robeson County, NC. (the “Proposed Site”). Waccamaw represents that the time it proposes to serve the Proposed Site is currently unused time on the schedule of the Project Unit. Waccamaw states that the Proposed Site currently contains a mobile MRI docking pad, and that there are no capital costs associated with the addition of the Proposed Site. It represents that it will comply with all conditions of its CON and of applicable regulations.

ANALYSIS

The CON law would require a full review of Waccamaw’s proposed change of 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 the Proposed Site for Waccamaw’s Project Unit does not constitute a material change in the physical location or the scope of the proposed project because the use of the Proposed Site as a host site will not affect the scope of services offered or the costs and charges to Waccamaw or to the public for the provision of mobile MRI services. The Proposed Site is in a county adjacent to the county of the Original Sites, and it is in the same HSA as the original sites. In addition, there is no proposed change in the person named in the application that would result in a violation of N.C.G.S. § 131E-181(a).

N.C.G.S. § 131E-189(b) allows the Agency to withdraw Waccamaw's CON if Waccamaw 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. Waccamaw 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 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 subject to the conditions set out herein, the addition of the Proposed Site as a host site for Waccamaw's mobile MRI scanner, Project I.D. No. O-7430-05 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) Waccamaw shall enter into a service agreement with Allen Orthopedics that is substantially similar to the agreement signed by its other host sites.
- (2) Waccamaw shall satisfy all the requirements and representations regarding the host sites in its original CON application.

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 _____, 2007.

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 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

Renee J. Montgomery
Robert A. Leandro
Parker Poe Adams & Bernstein, LLP
150 Fayetteville Street
Suite 1400
Raleigh, NC 27602-0389

This the _____ day of _____, 2007.

Jeff Horton
Chief Operating Officer