

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

IN RE: REQUEST FOR)	
DECLARATORY RULING BY)	DECLARATORY RULING
MECKLENBURG DIAGNOSTIC)	
IMAGING, INC.)	
Project I.D. No. F-7728-06)	

I, Jeff Horton, Acting Director of the Division of Health Service Regulation (the “Department”), hereby issue this declaratory ruling to Mecklenburg Diagnostic Imaging, Inc. (“MDI”) pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. MDI has filed a Declaratory Ruling Request (the “Request”) asking the Department to issue a ruling as to the applicability of Article 9 of N.C.G.S. Chapter 131E to the facts described below. For the reasons set forth below, I conclude that MDI may change the location of the Magnetic Resonance guided Focused Ultrasound unit (the “MRgFUS Unit”) that was approved in Project I.D. No. F-7728-06 from 6324 Fairview Road, Suite 120A, Charlotte, North Carolina 28210 to Presbyterian Imaging Center-Museum (“PIC Museum”), located at 2900 Randolph Road, Charlotte, North Carolina 28211.

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. Denise M. Gunter of Nelson Mullins Riley & Scarborough LLP has requested this ruling on behalf of MDI and has provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for MDI are set out below.

STATEMENT OF THE FACTS

Effective 24 April 2007, the Department issued a CON to MDI for Project I.D. No. F-7728-06. The CON authorized the development of the MRgFUS Unit at MDI's location at 6324 Fairview Road, Suite 120A, Charlotte. MDI states that the MRgFUS procedure combines magnetic resonance imaging and focused ultrasound for non-invasive treatment of tumors inside the body. It is FDA-approved for the treatment of uterine fibroids. MRgFUS uses ultrasound energy to treat a small volume of tissue inside the body to the point of thermal ablation.

The Request describes MDI as an affiliate of MedQuest Associates, Inc. ("MedQuest"). It states that at the time of the CON application, MedQuest was not affiliated with Novant Health, Inc. ("Novant"). MedQuest was acquired by Novant in November 2007.

The Request states that following the acquisition, Novant and MedQuest began evaluating how best to use MedQuest's assets to serve the greatest number of patients. They concluded that the MRgFUS Unit should be located at PIC Museum, a diagnostic center that offers MRI, CT, ultrasound, X-Ray, and screening mammography. MDI contends that a variety of factors, including the proximity of a number of OB/GYN practices and the other services available at PIC Museum, are likely to increase the physician awareness of the technology and prove convenient for many patients. PIC Museum is located slightly over four miles from the Fairview Road location approved in the CON.

MDI states that the proposed relocation will not increase the capital costs of the project in any way. The MRgFUS unit essentially attaches to an MRI scanner, of which there is already one at PIC Museum. In response to a request for clarification from the Agency after receiving the Request, MDI represented that the equipment and installation costs for the Project Unit will be unchanged from those included in its CON application. MDI states that it will continue to

own the MRgFUS Unit, and MDI will bill for the MRgFUS procedure.

ANALYSIS

The CON law would require a full review of MDI's 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 MDI's project does not constitute a material change in the physical location or the scope of the proposed project because locating the MRgFUS Unit at the PIC Museum Site will not affect the scope of services offered or the costs and charges to MDI or to the public. Because of the close proximity of the PIC Museum location to the original Fairview Road location, 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. Ownership of the MRgFUS Unit will remain with MDI, and MDI will bill for the MRgFUS procedures.

N.C.G.S. § 131E-189(b) allows the Agency to withdraw MDI's CON if MDI 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. MDI 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 the foregoing reasons, assuming the statements of fact in the Request and subsequent clarifications to be true, I conclude changing the location of the MRgFUS Unit from 6324 Fairview Road, Suite 120A, Charlotte, North Carolina 28210 to Presbyterian Imaging Center-Museum, located at 2900 Randolph Road, Charlotte, North Carolina 28211 will not constitute a

material change in the physical location or scope of the project (Project I.D. No. F-7728-06), 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 conditioned on MDI continuing to own the MRgFUS Unit and on MDI billing for the MRgFUS procedures performed by that unit.

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 ____ day of _____, 2008.

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 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

Denise M. Gunter
Nelson Mullins Riley & Scarborough LLP
380 Knollwood Street
Winston-Salem, NC 27103

This _____ day of _____, 2008.

Jesse Goodman
Acting Chief Operating Officer