

**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**
JOHNSTON MEMORIAL HOSPITAL)
AUTHORITY)**

I, Jeff Horton, Acting Director of the Division of Health Service Regulation (the “Department” or the “Agency”), hereby issue this declaratory ruling to Johnston Memorial Hospital Authority (“JMHA”) 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. JMHA has filed a Declaratory Ruling Request (the “Request”) asking the Department to issue a ruling as to the applicability of Chapter 131E, Article 9 of the North Carolina General Statutes to the facts described below. For the reasons given below, I conclude that I must deny JMHA’s requested ruling.

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. Lee M. Whitman and Sarah M. Johnson of Wyrick Robbins Yates & Ponton LLP have requested this ruling on behalf of JMHA and have provided the statement of facts upon which this ruling is based. Certain other facts are based on the Department’s files. The material facts are set out below.

STATEMENT OF THE FACTS

The Request involves several projects. Effective 27 February 2007, JMHA received a certificate of need (“CON”) to acquire a linear accelerator and upgrades for an existing CT scanner to develop a simulator in Smithfield, Johnston County (Project I.D. Number J-7669-06) (the “Smithfield Project”). The Smithfield Project, which was to be licensed as part of Johnston Memorial Hospital, was to be located at the Medical Mall building at 509 N. Brightleaf Boulevard, across the street from the main hospital. To the Department’s knowledge, the Smithfield Project has not yet been developed.

Effective 25 May 2007, the Agency issued another CON to JMHA to build a new medical center in Clayton, Johnston County (Project I.D. Number J-7773-06) (the “Clayton Project”). JMHA describes the Clayton Project as an approximately 40,000 square foot medical center, to be known as Clayton Medical Center (“CMC”), that will be located at 1866 NC Highway 42 West. According to the CON application, CMC will be licensed as part of Johnston Memorial Hospital and will include a 24-hour emergency room, diagnostic imaging services (including a CT scanner), a laboratory, and two relocated outpatient surgery rooms. A medical office building (the “MOB”) is also proposed for the same site but was not included as a component of the CON application for the Clayton Project because it was not proposed to be licensed as part of the hospital. The Agency determined the MOB was exempt from CON review on 4 December 2006.

JMHA now seeks a declaratory ruling approving the relocation of the linear accelerator and the CT scanner upgrades to Clayton rather than install them at the site approved in the Smithfield Project. The Request indicates that the approved new CT scanner to be located in CMC would be equipped with the simulation software that is necessary for use of the CT scanner

upgrades as a simulator. In contrast, JMHA plans to locate the linear accelerator in the MOB. In the Request, JMHA offers various reasons why it believes that leased space within the MOB would be a more cost-effective alternative for placement of the linear accelerator.

According to Google Maps, the distance between the Smithfield Project location and the Clayton Project location is 15.1 miles, or about 22 minutes driving time. As noted in the Request, Smithfield is centrally located in Johnston County and Clayton is not.

In the Request, JMHA also seeks a declaratory ruling approving a transfer of the linear accelerator portion of the Smithfield Project to a newly created entity, Johnston Radiation Oncology, LLC (“Johnston Radiation”). It states that Johnston Radiology is a wholly owned subsidiary of another newly formed entity, Johnston Health Enterprises, Inc. (“JHE”). JHE is described as a wholly owned subsidiary of JMHA, subject to JMHA’s control through the appointment of the JHE governing board, the ability to dissolve JHE, and the right to receive the assets of JHE upon liquidation. The Articles of Incorporation for JHE show that it is a North Carolina non-profit corporation with no members.

JMHA does not seek in the Request to authorize any transfer of ownership of any portion of the Clayton Project, including the approved new CT scanner. JMHA also does not seek transfer of the CT scanner upgrades and resulting development of a simulator that are approved for the Smithfield Project.

ANALYSIS

N.C.G.S. § 131E-181 provides in part:

(a) A certificate of need shall be valid only for the defined scope, physical location, and person named in the application. A certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c).

(b) A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the

service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.

N.C.G.S. § 131E-189(c) states:

The Department may immediately withdraw any certificate of need if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need. Any transfer after that time will be subject to the requirement that the service be provided consistent with the representations made in the application and any applicable conditions the Department placed on the certificate of need. Transfers resulting from death or personal illness or other good cause, as determined by the Department, shall not result in withdrawal if the Department receives prior written notice of the transfer and finds good cause. Transfers resulting from death shall not result in withdrawal.

N.C.G.S. § 131E-176(16)(e) includes in the definition of “new institutional health service” the following:

A change in a project that was subject to certificate of need review and for which a certificate of need was issued, if the change is proposed during the development of the project or within one year after the project was completed. For purposes of this subdivision, a change in a project is a change of more than fifteen percent (15%) of the approved capital expenditure amount or *the addition of a health service that is to be located in the facility, or portion thereof, that was constructed or developed in the project.*

(emphasis added).

N.C.G.S. 131E-176(9)(a) defines “health service:”

"Health service" means an organized, interrelated medical, diagnostic, therapeutic, and/or rehabilitative activity that is integral to the prevention of disease or the clinical management of a sick, injured, or disabled person. "Health service" does not include administrative and other activities that are not integral to clinical management.

The consequence of the above statutory provisions is that the Request must be denied, because the changes it proposes are material changes to the scope, location and person named in the CONs for the Smithfield Project and for the Clayton Project.

Scope

The Smithfield Project CON was issued to JMHA for the acquisition of a linear accelerator and upgrades for an existing CT scanner to develop a simulator to provide services at JMHA's hospital in Smithfield. In the application for the Smithfield Project, JMHA stated: "The proposed service will be hospital-based and licensed to JMHA; JMHA will contract with Duke University Health System for the management of the radiation therapy portion of the Johnston Cancer Center." (App., p. 22) JMHA stated that it was submitting the application to "meet the need for radiation therapy services" in Johnston County identified in the 2006 State Medical Facilities plan. (App., p. 17) In the application, it claimed various advantages of its proposed project, including: "Having chemotherapy and radiation oncology treatment services in one location will make the process much easier for the patient and will ensure physician involvement and oversight in the process." (App., p. 19)

The changes proposed in the Request are materially different in scope than either the Smithfield or Clayton Projects. Instead of providing radiation oncology treatment as a hospital-based service in a facility that is licensed as part of JMHA's Smithfield hospital, the Request proposes radiation oncology treatment services to be provided in an unlicensed medical office building. Also, the Request does not address chemotherapy services in Clayton.

Further, the CT upgrade would be applied to a new CT scanner that was approved as part of the Clayton Project, thus resulting in the development of a simulator to be located in the CMC. The Request therefore falls within the definition in N.C.G.S. § 131E-176(16)(e) above as

an addition of a health service that is to be located in the facility, or portion thereof, that was constructed or developed in a project that was subject to certificate of need review and for which a certificate of need was issued, if the change is proposed during the development of the project or within one year after the project was completed.

Moreover, the application for the Clayton Project described that CT scanner as being available for scheduled scans 66 hours a week, with 24/7 availability for emergency scans if needed. The application has no discussion of plans to provide simulation services in the CMC. The Request provides no information to allow analysis of the usage of the proposed new CT scanner for the dual purposes of diagnostics and simulation.

Location

Under the circumstances of this Request, the change in proposed location for Smithfield project is material. The services to be offered as a result of the Smithfield Project would, in part, reduce travel requirements for Johnston County residents, including inpatients at JMHA. Changing the location of the radiation treatment capability to Clayton could affect a significant number of prospective patients. The effect of this potential impact cannot be deemed immaterial, and it should be considered as a part of a CON review.

Person Named

JMHA seeks in the Request to transfer ownership of only the linear accelerator to Johnston Radiation, characterizing this transfer as “a change in name only.” JMHA does not seek to transfer ownership of the CT scanner upgrades or development of a simulator to Johnston Radiation. JMHA describes Johnston Radiation as a wholly-owned subsidiary of JHE, which is in turn effectively a corporation controlled by JMHA. However, the organization chart submitted by JMHA refers to JHE as “Joint Ventures.”

Regardless of the status of Johnston Radiation and JHE, the change in person named proposed in the Request is a material change in the Smithfield Project. First, the change in ownership of the linear accelerator is from an entity licensed as a hospital to a non-hospital entity operating in an unlicensed medical office building. In addition, as noted, the Request does not seek an ownership change for the CT upgrade or simulator. JMHA apparently seeks to bifurcate the Smithfield Project CON between two persons, which would effectively result in two different CONs issuing to two different entities from the same CON application. That alone would be a material change because it would constitute two different projects rather than a single project.

In suumary, the proposal in the Request would constitute material changes in the scope, location and person named in the Smithfield Project, and in the scope of the Clayton Project.

CONCLUSION

For the foregoing reasons, I conclude that JMHA's request for a declaratory ruling must be denied.

This the ____ day of May, 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

Lee M. Whitman
Sarah M. Johnson
Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail
Raleigh, NC 27607

This _____ day of May, 2008.

Jeff Horton
Acting Director