

**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  
DUKE UNIVERSITY HEALTH SYSTEM )  
d/b/a DUKE UNIVERSITY HOSPITAL )**

I, Jeff Horton, Acting Director of the Division of Health Service Regulation (the “Department”), hereby issue this declaratory ruling to Duke University Health System d/b/a/ Duke University Hospital (“Duke”) 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. Duke has filed a Declaratory Ruling Request (the “Request”) asking the Department to issue a ruling as to the applicability of N.C.G.S. Chapter 131E, Article 9 to the facts described below.

In the Request, Duke seeks a determination that the acquisition of medical equipment that would combine PET scanning capabilities for research purposes and CT capabilities to replace an existing CT simulator is exempt from certificate of need (“CON”) review or is otherwise not subject to such review. For the reasons stated below, I conclude that Duke may proceed with its proposed acquisition, subject to the conditions and limitations set out herein.

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. Catherine W. Cummer, as counsel for Duke, has requested this ruling on behalf of Duke and has provided the

statement of facts upon which this ruling is based. The material facts as provided by counsel for Duke are set out below.

### **STATEMENT OF THE FACTS**

Duke is a health service facility as defined in N.C.G.S. § 131E-176(9b). In the Request, Duke states that its Department of Radiation Oncology currently operates a CT simulator (the “Existing Simulator”) that is used in treatment planning for radiation therapy patients. The Existing Simulator is a CT scanner that was acquired in 1994 and upgraded to a CT simulator for treatment planning in 2000. According to Duke, the Existing Simulator is now at the end of its useful life and is in need of replacement. Duke calculates that the total cost for equipment and renovations of replacing the Existing Simulator with a new CT simulator would be \$890,673.

Duke also states that the Department of Radiation Oncology separately needs a PET/CT scanner to be used for research purposes. It calculates the total project cost of acquiring and installing a dedicated research PET/CT scanner separately from the Existing Simulator in the Department of Radiation Oncology as \$2,592,165. The total cost of separately replacing the Existing Simulator and acquiring a research PET/CT would therefore be \$3,482,838.

Duke seeks through the Request to combine these two projects by acquiring a single PET/CT scanner and upgrading the CT scanner component to a CT simulator. It would then use the PET/CT scanner for both the research needed by the Department of Radiation Oncology and the clinical treatment planning now performed with the Existing Simulator. Duke contends this approach would result in significant savings through lower equipment and renovation costs. It represents the total cost to acquire and install the PET/CT scanner would be \$2,592,165. This would reduce the total project cost for both components by \$890,673.

Duke states that it currently operates two clinical PET scanners, and represents that it would not use the proposed PET/CT scanner for any clinical PET scans but would use the equipment for clinical treatment planning procedures (i.e. use it as a CT simulator). Duke represents that the proposed acquisition will not affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research, change the bed capacity of the facility, or change the medical or other patient care services of the facility. Duke also represents that after the project is completed, it will dispose of the Existing Simulator out-of-state.

### **ANALYSIS**

Duke seeks a ruling that it may proceed with the proposed acquisition without first obtaining a certificate of need (“CON”).

While the acquisition of a Simulator is a “new institutional health service,” N.C.G.S. § 131E-167(16)f1.9, Duke’s acquisition of a CT simulator to replace the Existing Simulator would, on the facts given in the Request, be exempt from CON review pursuant to N.G.C.S. § 131E-184(a)(7), which exempts replacement equipment from CON review if the entity proposing the new institutional health service provides a written explanation of why it is needed. The acquisition of a replacement stand-alone CT simulator as described by Duke in the Request would fall within the definition of “replacement equipment” in N.C.G.S. § 131E-176(22a): “equipment that costs less than two million dollars (\$ 2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.” The same acquisition also would fall within the terms of 10A NCAC 14C .0303, which states in part:

(d) Replacement equipment is comparable to the equipment being replaced if:

(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and

(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and

(3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

Similarly, the acquisition of a PET/CT scanner is a new institutional health service pursuant to N.C.G.S. § 131E-176(16)f1.8, (and, in this case, N.C.G.S. § 131E-176(16)(p)). Duke's proposed acquisition of a PET/CT scanner for research purposes would be eligible for an exemption from the requirement for a CON if it meets the conditions specified in N.C.G.S. § 131E-179. That statute reads:

(a) Notwithstanding any other provisions of this Article, a health service facility may offer new institutional health services to be used solely for research, or incur the obligation of a capital expenditure solely for research, without a certificate of need, if the Department grants an exemption. The Department shall grant an exemption if the health service facility files a notice of intent with the Department in accordance with rules promulgated by the Department and if the Department finds that the offering or obligation will not:

(1) Affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research;

(2) Substantially change the bed capacity of the facility; or

(3) Substantially change the medical or other patient care services of the facility.

(b) After a health service facility has received an exemption pursuant to subsection (a) of this section, it shall not offer the new institutional health services, or use a facility acquired through the capital expenditure, in a manner which affects the charges of the facility for the provision of medical or other patient care services, other than the services which are included in the research and shall not charge patients for the use of the service for which an exemption has been granted, without first obtaining a certificate of need from the Department; provided, however, that any

facility or service acquired or developed under the exemption provided by this section shall not be subject to the foregoing restrictions on its use if the facility or service could otherwise be offered or developed without a certificate of need.

(c) Any of the activities described in subsection (a) of this section shall be deemed to be solely for research even if they include patient care provided on an occasional and irregular basis and not as a part of the research program.

The General Assembly in enacting the CON law found that “the financing of health care, particularly the reimbursement of health services rendered by health service facilities, limits the effect of free market competition and government regulation is therefore necessary to control costs, utilization, and distribution of new health service facilities and the bed complements of these health service facilities.” N.C.G.S. § 131E-175(1).

Taking all of this authority together, I find that on the specific facts of this case, the appropriate interpretation of the CON law to accomplish the intent of the General Assembly is to allow Duke to implement its proposed project subject to certain conditions. First, as required in N.C.G.S. § 131E-179(b), Duke cannot charge any patients for any procedures performed on the PET/CT scanner, with the exception of CT treatment planning procedures which are allowed strictly on the basis of the replacement equipment exemption for the CT simulator. Second, the patient charges or per procedure operating expenses for CT treatment planning procedures performed on the PET/CT scanner shall not increase more than 10% within the first twelve months after the replacement equipment is acquired, as required in 10A NCAC 14C .0303(d)(3). Further, the CT Simulator component of the PET/CT scanner is appropriately valued at the replacement cost of the Existing Simulator, which is within the \$2,000,000 limit for replacement equipment as defined by N.C.G.S. § 131E-176(22a).

## CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the replacement of the Existing Simulator with the CT Simulator component of the PET/CT scanner is exempt from certificate of need review pursuant to N.C.G.S. § 131E-184(a)(7) and the acquisition of the PET/CT scanner is exempt from certificate of need review pursuant to N.C.G.S. § 131E-179, subject to the conditions that: (1) Duke shall not charge any patients for any procedures performed on the PET/CT scanner with the exception of CT treatment planning procedures, (2) Duke shall not increase the patient charges or per procedure operating expenses for CT treatment planning procedures performed on the PET/CT scanner more than 10% within the first twelve months after the replacement equipment is acquired, and (3) Duke shall comply with all other representations made in the Request.

This the 27<sup>th</sup> day of May, 2008.

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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**

Catherine W. Cummer  
149 Cedar Hills Cir.  
Chapel Hill, NC 27514

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This \_\_\_\_\_ day of May, 2008.

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Jeff Horton  
Acting Director