

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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY THE PRESBYTERIAN HOSPITAL) DECLARATORY RULING
AND CAROLINAS INTEGRATED)
HEALTHCARE, LLC)**

I, Robert J. Fitzgerald, as Director of the Division of Facility Services, hereby issue this Declaratory Ruling to The Presbyterian Hospital (“Presbyterian Hospital”), and Carolinas Integrated Healthcare, LLC (“CIH”) (collectively, “Petitioners”), pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0108, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services (the “Department”).

Petitioners have requested a declaratory ruling (the “Request”) that:

(1) Presbyterian may acquire CIH, a diagnostic center that owns one open bore fixed MRI scanner (“the CIH Scanner”) pursuant to N.C.G.S. § 131E-184(8); (2) Presbyterian may replace the CIH Scanner with a closed bore fixed MRI scanner (the “Replacement Scanner”) pursuant to N.C.G.S. § 131E-184(a)(7); and (3) Presbyterian may relocate the Replacement Scanner to the Huntersville Campus of Presbyterian Hospital (“PHH”). For the reasons stated below, I have concluded that the transaction proposed by Petitioners may be conducted without a certificate of need (“CON”) review.

This ruling will be binding on the Department and the person requesting it if the material facts stated herein are accurate and no material facts have been omitted from the request. 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 statutes and regulations at issue in this Declaratory Ruling. Denise M. Gunter of Nelson Mullins Riley &

Scarborough LLP has requested this ruling on behalf of Petitioners and has provided the material facts upon which this ruling is based. Petitioners submitted information in the original request dated 14 September 2006; in a response to a request for additional information dated 6 November 2006; and in another response dated 9 November 2006. Susan M. Fradenburg of Smith Moore LLP submitted comments by letter dated 24 October 2006 on behalf of Mooresville Hospital Management Associates, Inc. d/b/a Lake Norman Regional Medical Center (“Lake Norman”), requesting that the declaratory ruling be denied.

STATEMENT OF THE FACTS

In 1999, CIH installed an open bore fixed MRI scanner at Midtown Medical Plaza (“MMP”) located at 1918 Randolph Road in downtown Charlotte, on the main Presbyterian Hospital campus. Petitioners state that the MRI scanner was installed pursuant to a CON issued April 23, 1998 to CIH for Project I.D. # F-5580-97.

Petitioners now seek approval for Presbyterian to acquire CIH, to replace the CIH Scanner with the Replacement Scanner pursuant to N.C.G.S. § 131E-184(a)(7), and to relocate the Replacement Scanner to PHH.

1. Acquisition of CIH

Petitioners provide no details on the proposed acquisition of CIH by Presbyterian. The then-current relationship between CIH, Presbyterian, and PHH is described in the Declaratory Ruling issued on 24 April 2006 to Novant Health, Inc. (“Novant”), Novant Health Southern Piedmont Region, LLC (“NHSPR”), The Presbyterian Hospital (“Presbyterian Hospital”), The Presbyterian Hospital d/b/a Presbyterian Hospital Huntersville (“PHH”), Presbyterian Regional Healthcare Corp. (“PRHC”), and Carolinas Integrated Healthcare, LLC (“CIH”). That Declaratory Ruling is referred to hereinafter as the “Novant Ruling.”

2. Replacement of CIH Scanner

Petitioners seek to replace the CIH Scanner with the Replacement Scanner. The CIH Scanner is described in Attachment C to the Request as an Hitachi .3T Open MRI Scanner. The proposed Replacement Scanner is a Siemens 1.4T MAGNETOM Avanto MRI Scanner. Petitioners state that the total capital cost of the project (including replacement and relocation) is \$1,985,769. Petitioners further state that this cost includes all activities essential to acquiring the equipment and making it operational. On the Architect's Certification proffered as Exhibit E to the Request, the Proposed Capital Costs are stated as:

Cost of Materials:	\$ 177,948.40
Cost of Labor:	\$ 266,922.60
Subtotal Construction Contract:	\$ 444,871
Fixed Equipment Purchase/Lease:	\$1,505,898
Architect and Engineering Fees:	\$ 35,000
Subtotal Miscellaneous Project Costs:	\$1,540,898
Total Capital Cost of Project:	\$1,985,769

Petitioners state that Siemens has agreed to honor the total price of the Replacement Scanner (\$1,505,898) until 29 December 2006.

In response to a request for additional information by counsel for the Department, Petitioners provided the following additional representations as to costs.

a. The project will go into existing space that was designed and built for a future MRI scanner when PHH was built. The space where the MRI scanner is to be located is 1602 square feet, and it will require very little structural renovation. It is currently used as a

conference room. Most of the construction cost is for electrical work required to install the equipment.

b. The CIH Scanner will be sold to a third party, which will be responsible for removal costs.

c. Freight costs for the Replacement Scanner are included in the total price quoted by Siemens.

d. The construction cost estimates include 5% contingency costs.

e. There are no Group Purchasing Organization fees to be paid for the purchase of the Replacement Scanner.

f. The electrical room exists at PHH. “Provisions were made” in the original design of the hospital to have the power requirements “for an MRI available in this electric room.” The electrical room also feeds existing radiology equipment in the existing Radiology Department.

g. The subwait area and access corridors/vestibules are existing areas that will require no additional cost beyond that included in the construction cost submitted.

h. Travel, lodging, meals and other expenses for training will not exceed \$750.

i. As part of a nonprofit, tax-exempt organization, Presbyterian will receive a refund on any sales taxes, and therefore taxes are not included as part of the purchase price.

Lake Norman has submitted several additional facts in connection with the Request. It points out that Petitioners previously sought to replace and relocate the CIH Scanner, and their request was denied by the Novant Ruling. In the Request for the Novant Ruling (“the “Novant Ruling Request”), Petitioners stated that the price of the replacement MRI scanner in that case was \$1,504,869. The Novant Ruling noted that the replacement price did not include a \$135,000 Trade-In amount, and that when the Trade-In amount was added to the price, it increased the

total cost of the project beyond \$2,000,000. The equipment to be purchased for the Novant Ruling Request was a GE 1.5T EXCITE Echospeed+ fixed MRI scanner, to be purchased from GE Healthcare Technologies. Lake Norman also notes that the price quotation provided by Petitioners in this Request describes the price as “a special offer.” The quote by Siemens is described on page 2 of Exhibit D to the Request as “a confidential special offer extended to Novation Sole Source MR Group Buy Customers.” The quote is addressed to “Novant Health Inc.” Lake Norman argues that these facts show that the quote presented by Petitioners does not reflect the fair market value of the equipment.

Lake Norman also argues that the total capital cost figure presented by Petitioners does not include the requisite connectivity equipment, supplies or software. It points to a statement in the quote (Exhibit D to the Request, p. 49) regarding 10/100 Mbit Ethernet connectivity for the implication that some items are not included in the price.

Lake Norman argues that Petitioners failed to show that the Replacement Scanner and the CIH Scanner are “comparable” for purposes of the definition of replacement equipment in N.C.G.S. § 131E-179(22a) and 10A NCAC 14C .0303(d)(3). Lake Norman contends that the Petitioners had not sufficiently established that the increase in patient charges or per procedure operating expenses would not exceed 10% within the first 12 months after acquisition.

In response to a request for additional information from counsel for the Department, and to points raised by Lake Norman, Petitioners through counsel made several representations in materials submitted 9 November 2006. Petitioners provided a list of current patient charges on the CIH Scanner at MMP and the proposed patient charges on the Replacement Scanner at PHH for the fifteen most commonly performed scans at the CIH Scanner. The increase for the

proposed charges did not exceed 10% for any procedure, and exceeded 5% for only one procedure.

With respect to connectivity costs, Petitioners represented in their 9 November 2006 response that 10/100 Mbit Ethernet connectivity is the basic connectivity that exists at all Novant facilities, including PHH, and that there is no additional cost to this project for this connectivity.

In the Novant Ruling Request, Petitioners submitted as Attachment E a project capital cost estimate by McCulloch England Associates Architects and signed by Jerry W. Currie, AIA, Executive Vice President. The cover page estimated the total cost of construction to be \$444,871.00, which did “not include the MRI Unit, medical equipment, furniture, artwork, telecommunication equipment & reconnection of equipment.”

As Exhibit E to this Request, Petitioners also have submitted a project capital cost estimate by McCulloch England Associates Architects and again signed by Jerry W. Currie, AIA, Executive Vice President. The cover page for this estimate estimated the total cost of construction to be \$444,871.00 (the same total amount as for the Novant Ruling Request), but it did not contain an exclusion for “the MRI Unit, medical equipment, furniture, artwork, telecommunication equipment & reconnection of equipment.”

In response to a request for additional information on this point, Petitioners represented in their 9 November 2006 response that everything needed for this project is either included in the equipment quote, is already existing, or is covered in the construction quote. For example, Petitioners state that the equipment quote includes the MRI scanner, the contrast injector, the various coils, the computer, all the necessary software, the furniture, the rigging, and the installation. They represent that there is no artwork associated with this project, and there is no other medical equipment involved besides the MRI scanner.

3. Relocation of Replacement Scanner.

Petitioners assert that the primary rationale for relocating the Replacement Scanner is to improve access to MRI diagnostic services for residents of the rapidly-growing Huntersville area. In support of their request, they provide a series of statistics that purport to show: (1) a substantial demand for MRI scanner services at PHH; (2) an overlap of service areas for the CIH Scanner and the Replacement Scanner at PHH; (3) population growth in North Mecklenburg County; (4) a disparity in the Fixed MRI Scanner to Population Ratio between the Huntersville area and central Charlotte; and (5) the availability of open MRI scanner services at other sites in what they describe as the Charlotte area. They also contend that in the approval of Project I.D. No. F-7062-04, the Agency acknowledged the need for MRI scanner services at PHH. Project I.D. No. F-7062-04 proposed to replace the CIH Scanner with a mobile MRI scanner that would provide four days of MRI scanner service per week at PHH.

ANALYSIS

1. Presbyterian's Acquisition Of CIH Does Not Require CON Review.

N.C.G.S. § 131E-184(a) provides that the Department shall exempt from CON review certain new institutional health services if it receives in advance notice of the proposed project and explanation of why it is required for certain enumerated circumstances, including "(8) to acquire an existing health service facility, including equipment owned by the health service facility at the time of the acquisition." Presbyterian has provided the required notice of the acquisition of CIH and the CIH Scanner. Therefore, Presbyterian may acquire CIH, and the CIH Scanner, without a CON review.

2. The Replacement Of The CIH Scanner With The Replacement Scanner Does Not Require CON Review.

The next part of the transaction proposed by Petitioners, assuming that Presbyterian acquires ownership of the CIH Scanner as part of its acquisition of CIH, is to replace it with the Replacement Scanner to be operated at PHH. Petitioners contend that the proposed change in the equipment to be operated qualifies for an exemption from CON review as replacement equipment. N.C.G.S. § 131E-184(a)(7).

“Replacement equipment” is a specifically defined term in the CON law:

"Replacement equipment" means 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. In determining whether the replacement equipment costs less than two million dollars (\$ 2,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

N.C.G.S. § 131E-176(22a).

The Department has adopted rules providing additional precision to the definition in the statute:

10A NCAC 14C .0303 REPLACEMENT EQUIPMENT

- (a) The purpose of this Rule is to define the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a).
- (b) "Activities essential to acquiring and making operational the replacement equipment" means those activities which are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.
- (c) "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.
- (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.

(e) Replacement equipment is not comparable to the equipment being replaced if:

(1) the replacement equipment is new or reconditioned, the existing equipment was purchased second-hand, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or

(2) the replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or

(3) the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment; or

(4) the replacement equipment is purchased and the existing equipment is leased, unless the lease is a capital lease; or

(5) the replacement equipment is a dedicated PET scanner and the existing equipment is:

(A) a gamma camera with coincidence capability; or

(B) nuclear medicine equipment that was designed, built, or modified to detect only the single photon emitted from nuclear events other than positron annihilation.

Petitioners represent that the total capital cost of the replacement equipment is \$1,985,769, and, as set out in the Statement of Facts, have addressed questions as to various components of those costs by representing that each of the components is either included in the cost calculations or is already existing. Petitioners have addressed the factual questions raised by Lake Norman in its comments and, assuming their representations to be accurate, have shown that the total capital expenditure for this project will be less than \$2,000,000. Petitioners also have demonstrated that the proposed equipment is to replace equipment currently in use and conforms to 10A NCAC 14C .0303. Although Lake Norman argues that the cost of the equipment shown by Petitioners is not the fair market value, Petitioners have explained the items of cost raised by Lake Norman, and the representations of Petitioners do not support a conclusion

that the cost shown is less than fair market value. The replacement equipment, therefore, is exempt from CON review.

3. The Change in Location is Not a Material Change.

N.C.G.S. § 131E-181(a) provides: “A certificate of need shall be valid only for the defined scope, physical location, and person named in the application.”

Petitioners propose to relocate the MRI scanner services from downtown Charlotte to Huntersville. Charlotte and Huntersville are in the same single-county MRI scanner service area. The CIH Scanner will be taken out of service, and therefore the Replacement Scanner will not result in an increase in the MRI scanner inventory in Mecklenburg County.

Petitioners have provided data tending to demonstrate that the relocation will provide greater access to MRI scanner services in northern Mecklenburg County without adversely impacting patients by the elimination of the CIH Scanner.

The relocation of the site for the Replacement Scanner does not represent a material change in the physical location of the service.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that:

- (1) Presbyterian may acquire CIH without a CON review;
- (2) The Replacement Scanner is replacement equipment as defined by N.C.G.S. § 131E-176(22a) and therefore is exempt from CON review pursuant to N.C.G.S. § 131E-184(a)(7);
- (3) The relocation of the Replacement Scanner to PHH does not constitute a material change in the location of the project, and therefore does not require CON review.

This ruling is only applicable to the facts as represented by the party requesting this declaratory ruling.

This the 13th day of November 2006.

Robert J. Fitzgerald, Director
Division of Facility Services
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
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With a courtesy copy to:

Susan M. Fradenburg
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This 13th day of November, 2006.

Jeff Horton
Chief Operating Officer