



North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Certificate of Need Section

2704 Mail Service Center • Raleigh, North Carolina 27699-2704  
<http://www.ncdhhs.gov/dhsr/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor  
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief  
Phone: (919) 855-3873  
Fax: (919) 733-8139

February 27, 2012

Gary S. Qualls  
K & L Gates, LLP  
P.O. Box 14210  
Research Triangle Park NC 27709-4210

RE: No Review / Rex Hospital, Inc. / Acquisition of ownership interests of CSAMS Lake Boone, LLC, owners of three heart-lung bypass machines located at Rex Hospital / Wake County  
FID #: 953429

Dear Mr. Qualls:

The Certificate of Need (CON) Section received your letter of February 9, 2012 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact the CON Section if you have any questions.

Sincerely,

Michael J. McKillop  
Project Analyst

Craig R. Smith, Chief  
Certificate of Need Section





K&L Gates LLP  
Post Office Box 14210  
Research Triangle Park, NC 27709-4210

430 Davis Drive, Suite 400  
Morrisville, NC 27560

T 919.466.1190 www.klgates.com

*Mike*

February 9, 2012

Mr. Craig R. Smith, Chief  
Ms. Martha Frisone, Assistant Chief  
North Carolina Department of Health  
Service Regulation  
Certificate of Need Section  
2704 Mail Service Center  
Raleigh, North Carolina 27696-2704

Gary S. Qualls  
D 919.466.1182  
F 919.516.2072  
gary.qualls@klgates.com

Re: Rex Acquisition of Ownership Interests in CSAMS Lake Boone Trail, LLC

Dear Mr. Smith and Ms. Frisone:

We represent Rex Hospital, Inc. ("Rex"). The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency") and confirm that Rex's acquisition of the ownership interests of CSAMS Lake Boone Trail, LLC ("CSA Lake Boone") is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law. CSA Lake Boone is a wholly owned sub of CSA Medical, LLC ("CSA") and owns three (3) heart-lung bypass ("HLB") machines that have been and are operated at Rex. Rex would acquire the membership interests in CSA Lake Boone, which would continue to exist as a legal entity and to own the three (3) HLB machines that would remain located and operated at Rex.

The Agency has issued numerous declaratory rulings and no review letters that acknowledge that acquisition of ownership interest in a legal entity does not constitute a reviewable acquisition of the medical equipment owned by that legal entity. For example, in a declaratory ruling issued to New Hanover Perfusionists, Inc., the Agency determined that the purchase of stock did not constitute the acquisition of a heart-lung bypass machine because ownership of the regulated heart-lung bypass equipment would not change. The Agency also determined that the transaction was not an obligation to develop or expand a health service or health service facility because the equipment company was not a health service facility. The stock purchase transaction proposed also was not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C. Gen. Stat. § 131E-176(16)(b). The

Mr. Craig R. Smith, Chief  
Martha Frisone, Assistant Chief  
February 9, 2012  
Page 2

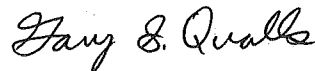
definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Stock or membership interest ownership is not integral to clinical management. *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc., January 24, 2008.*

Similarly, the Department has recently approved the sale of 100% of the membership interests in a company that owned a linear accelerator to another entity. Linear accelerators are regulated in the same manner as heart-lung bypass equipment. The Department held that certificate of need review was not required for the LLC membership purchase transaction. *See Declaratory Ruling, In re: Request for Declaratory Ruling by The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare, November 4, 2011 (attached as Exhibit 1).*

We would appreciate written confirmation from you that the anticipated transaction does not require CON review. If you require additional information to consider this request, please contact us. We appreciate your consideration.

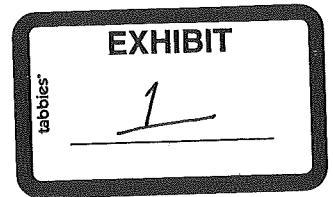
Sincerely yours,

K&L GATES LLP



Gary S. Qualls





North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Office of the Director  
2701 Mail Service Center • Raleigh, North Carolina 27699-2701  
<http://www.ncdhhs.gov/dhsr>

Beverly Eaves Perdue, Governor  
Lanier M. Cansler, Secretary

Drexdal Pratt, Director  
Phone: 919-855-3750  
Fax: 919-733-2757

November 4, 2011

**CERTIFIED MAIL & FACSIMILE**

William W. Stewart, Esq.  
K&L Gates LLP  
430 Davis Drive, Suite 400  
Morrisville, NC 27560

RE: Declaratory Ruling for The Charlotte-Mecklenburg Hospital Authority  
d/b/a Carolinas Healthcare System

Dear Mr. Stewart:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

cc: Jeff Horton, Chief Operating Officer, DHSR  
Craig Smith, Chief, Certificate of Need Section  
Steven Lewis, Chief, Construction Section  
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section  
DHSR Medical Facilities Planning Section  
Marc Lodge, Special Deputy Attorney General, DOJ



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

<b>IN RE: REQUEST FOR</b>	)	
<b>DECLARATORY RULING BY</b>	)	
<b>THE CHARLOTTE-MECKLENBURG</b>	)	<b>DECLARATORY RULING</b>
<b>HOSPITAL AUTHORITY D/B/A</b>	)	
<b>CAROLINAS HEALTHCARE SYSTEM</b>	)	

I, Drexdal Pratt, 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.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System (“CMHA”) has requested a declaratory ruling to confirm that its acquisition of the membership interests of University Radiation Oncology Center, LLC (“UROC”) and its continued operation of that facility may proceed without first obtaining a Certificate of Need (“CON”). This ruling will be binding upon the Department and the entities 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. William W. Stewart of K&L Gates LLP has requested this ruling on CMHA’s behalf and has provided the material facts upon which this ruling is based.

**STATEMENT OF THE FACTS**

UROC, which is located at 8310 University Executive Park, Suite 500, Charlotte, NC 28262, is a limited liability company which provides radiation therapy treatment. UROC was

acquired by Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") pursuant to an exemption in August 1997. Currently, UROC operates a Varian 2100C linear accelerator and a GE Highspeed Advantage CT simulator, which the CON Section previously approved.

On August 18, 2011, the Department issued a Declaratory Ruling determining that ROCC could transfer, without a CON, its interest in UROC and Matthews Radiation Oncology Center ("MROC") to two wholly owned subsidiaries of ROCC. Once that transaction is consummated, ROCC will be the sole member of UROC. ROCC will then transfer its entire membership interest in UROC to CMHA and CMHA will become UROC's sole member. Thus, UROC will remain intact as the same LLC, but with a different membership composition.

#### ANALYSIS

The CON law provides that no person shall offer or develop a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178. The list of new institutional health services includes "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of a linear accelerator or simulator "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9, and "the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C. Gen. Stat. § 131E-176(16)(b).

Prior declaratory rulings show that the Department has already determined that these definitions do not require an entity to obtain a CON to acquire membership interests in an existing legal entity like UROC which owns and operates a linear accelerator or simulator. The declaratory ruling requested by CMHA is consistent with the Department's prior rulings that

have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations, for the following reasons:


CMHA's acquisition of the membership interests in UROC does not constitute the acquisition of a linear accelerator or a simulator because the ownership of the equipment will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. UROC will continue to own the two pieces of equipment and UROC's legal status as a corporate entity will not change.

The purchase of ROCC's membership interests in UROC does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change. No new or additional equipment will be acquired or placed in operation in the State.

#### CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that CMHA does not require a certificate of need in order to proceed with the purchase of ROCC's membership interests in UROC.

This the 4th day of November, 2011.

  
Drexdal Pratt, Director  
Division of Health Service Regulation  
N.C. Department of Health and Human Services



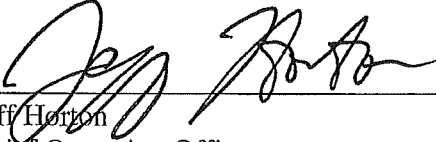
**CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by facsimile and certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

**CERTIFIED MAIL**

William W. Stewart  
K&L Gates LLP  
430 Davis Drive, Suite 400  
Morrisville, NC 27560

This the 4<sup>th</sup> day of November, 2011.

  
\_\_\_\_\_  
Jeff Horton  
Chief Operating Officer