



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
July 9, 2012

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

S. Todd Hemphill
Bode, Call & Stroupe, L.L.P.
P. O. Box 6338
Raleigh, NC 27628-6338

RE: No Review / Cancer Center of Davidson County, LLC and its members Lexington Memorial Hospital, Inc., North Carolina Baptist Hospital and Wake Forest University Health Sciences/ North Carolina Baptist Hospital and Wake Forest University Health Sciences transfer their membership interests in Cancer Center of Davidson County, LLC to Lexington Memorial Hospital, Inc., and Cancer Center of Davidson County, LLC merges into Lexington Memorial Hospital, Inc. and ceases to exist

FID #: 060614

Dear Mr. Hemphill:

The Certificate of Need (CON) Section received your letter of June 5, 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.

In addition, you should contact the Acute and Home Care Licensure and Certification Section, DHHS to determine if they have any requirements for the proposed reorganization. Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# s (FID) if the facility(s) is licensed.

Sincerely,

Lisa Pittman
Team Leader

Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHHS



Location: 809 Ruggles Drive, Dorothea Dix Hospital Campus, Raleigh, N.C. 27603
An Equal Opportunity/Affirmative Action Employer



BODE, CALL & STROUPE, L.L.P.

ATTORNEYS AT LAW

3105 GLENWOOD AVENUE, SUITE 300
RALEIGH, NORTH CAROLINA 27612

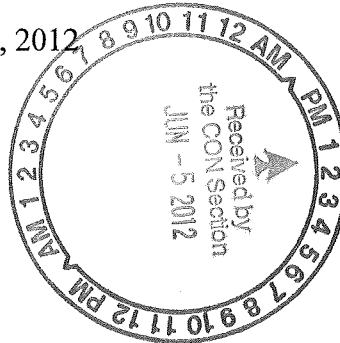
TELEPHONE (919) 881-0338
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JOHN T. BODE
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JOHN V. HUNTER III
RETIRED

MAILING ADDRESS
POST OFFICE BOX 6338
RALEIGH, NORTH CAROLINA
27628-6338

June 5, 2012



HAND DELIVERY

Craig R. Smith, Chief
Martha J. Frisone, Assistant Chief
Certificate of Need Section
N.C. Department of Health and Human Services
Division of Facility Services
809 Ruggles Drive
Raleigh, NC 27603

Re: Cancer Center of Davidson County, LLC / Project I.D. No. G-7598-06

Dear Mr. Smith and Ms. Frisone:

Cancer Center of Davidson County, LLC (“CCDC”) owns and operates a linear accelerator and simulator on the campus of Lexington Memorial Hospital in Lexington, Davidson County, pursuant to a certificate of need issued by the CON Section effective July 26, 2007. See CON issued to CCDC, Exhibit 1 hereto. The facility is operated as a free-standing radiation oncology center. The members of CCDC are three non-profit corporations, Lexington Memorial Hospital, Inc. (“LMH”), North Carolina Baptist Hospital (“NCBH”), and Wake Forest University Health Sciences (“WFUHS”). See CON application, Exhibit 2 hereto, pp. 1, 6. LMH, NCBH and WFUHS are “related entities” within the meaning of the Agency’s rules, because they are engaged in a joint venture with regard to health services. See, e.g., 10A N.C.A.C. 14C. 2101, .2301, .2701. Specifically, each of these entities operates as a part of and under the control of Wake Forest Baptist Medical Center.

The owners of CCDC now believe that it would be more appropriate to operate the radiation oncology center as provider-based, rather than as a freestanding facility. To that end, they propose that NCBH and WFUHS would transfer their membership interests in CCDC to LMH, such that LMH would be the sole member of CCDC. Thereafter, LMH and CCDC would merge, so that LMH will be the surviving entity.

This letter is to request that you confirm that the above transactions would not constitute a new institutional health service, and would not require a CON. Each transaction is discussed below.

Mr. Smith
Ms. Frisone
June 5, 2012
Page 2

Transfer of CCDC Membership Interests to LMH

In a Declaratory Ruling issued in 2007 (copy attached as *Exhibit 3*), the Agency described one method of addressing this issue, permitting providers to sell the equity (rather than the assets) of an existing radiation oncology facility without a CON. The Agency has determined that this type of transfer does not violate the CON law, because the entity which owned the facility will not change: rather, the persons owning that entity will change.

The transfer of NCBH's and WFUHS' membership interests in CCDC to LMH is the same type of transaction as the one described in *Exhibit 3*, and therefore, this transaction does not violate the CON law and does not require a CON.

Merger of CCDC into LMH

The CON law provides that transfer of ownership or control of a CON constitute grounds for withdrawal of the CON. G.S. 131E-189. However, Agency rules provide that neither ownership nor control of a certificate of need is transferred when the holder of the certificate is a corporation and the identity of the holder changes because of a corporate reorganization, such as a corporate merger. 10A. N.C.A.C. 14C.0502(b)(1) and (c).

If the CON law permits the transfer of a CON for a project in a corporate merger without a new CON or other sanction, then it would make no sense to interpret the law to prevent an existing owner from merging a wholly-owned subsidiary which operates the facility into the parent company after the project has been developed.

For these reasons, we believe that the CON law allows the transfer of an entire facility (including new institutional health services within that facility) to a wholly-owned subsidiary of the existing provider, without the requirement of a CON, because such a transfer does not constitute the acquisition of such facility or services by the subsidiary, within the meaning of G.S. 131E-176(16)f1.¹ The subsidiary has no control over those services independent of its parent entity. Nothing is "acquired" by the subsidiary, and the ultimate ownership and control of the service does not change. Thus, there has been no action which constitutes the offering or development of a new institutional health service within the meaning of G.S. 131E-178(a), and no CON is required.

The Department addressed this issue in a similar context in a Declaratory Ruling issued on August 18, 2011. In that Declaratory Ruling, a copy of which is attached as *Exhibit 4*, the Director addressed the issue of whether Radiation Oncology Centers of the Carolinas, Inc. ("ROCC"), could transfer its interest in two radiation oncology facilities (each of which owned and operated a linear accelerator and simulator) to two separate subsidiary entities. The Director concluded that this transaction would not constitute a new institutional health service, because the entity that owned the linear accelerator and simulator would

¹ This would be the case whether or not the facility is a health service facility within the meaning of G.S. 131E-176(9b).

Mr. Smith
Ms. Frisone
June 5, 2012
Page 3

not change, and the same equipment would be used to provide the same radiation oncology services, in the same location. See Exhibit 4, p. 3.²

All of that is true here, as well. As the sole member of CCDC, Lexington Memorial Hospital would be the entity which ultimately owns the linear accelerator and simulator. By merging CCDC and Lexington Memorial Hospital into one legal entity, the ownership of the equipment would not change, and the same equipment would be providing the same radiation oncology services at the same location.

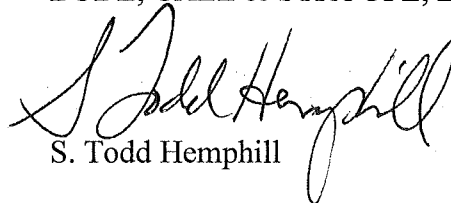
Conclusion

For the foregoing reasons, we believe that based on the above facts, our interpretation of the CON law and applicable rules is correct, and that neither (1) the transfer of NCBH's and WFUHS' membership interests in CCDC to LMH, nor (2) the subsequent merger of CCDC and LMH, such that LMH is the surviving entity, constitutes a new institutional health service, and that neither transaction is subject to certificate of need review. We would appreciate your confirming our understanding at your earliest convenience.

Please let us know if you need further information or if there are questions we can answer.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.



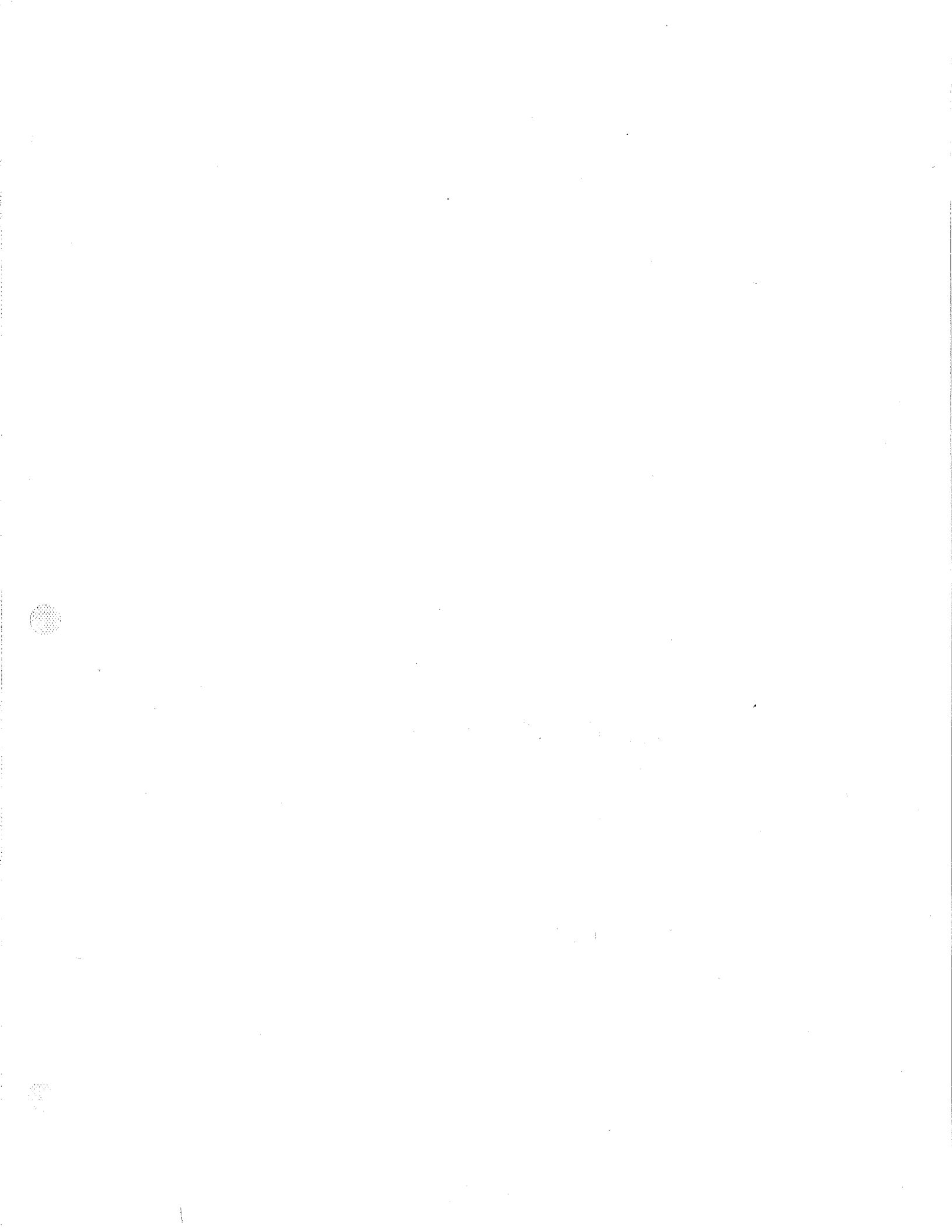
S. Todd Hemphill

STH:sh

Enclosures

cc w/enc.: J. McLain Wallace, Jr., Vice President and General Counsel

² That Declaratory Ruling also confirmed prior Declaratory Rulings (such as Exhibit 3) finding that an entity is not required to obtain a CON to acquire membership interests in an existing legal entity which owns and operates a linear accelerator or simulator. See Exhibit 4, p. 2.





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

Michael F. Easley, Governor
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

July 31, 2007

John A. Cashion
Cancer Center of Davidson County, LLC
250 Hospital Drive
Lexington, NC 27292

RE: Transmittal of CON/ Project I.D. #G-7598-06/ Cancer Center of Davidson County, LLC/
Acquire a linear accelerator and a treatment simulator and establish a new radiation oncology
center / Davidson County
FID #060614

Dear Mr. Cashion:

We are happy to transmit your certificate of need for the above referenced project. At this time, you should contact the Construction Section and the Licensure and Certification Section, regarding their procedures and requirements for the development of this project. The Certificate of Need Section will notify the other Sections that the certificate of need has been issued. However, please note that it is the responsibility of the holder of the certificate of need to contact these Sections concerning the next steps to follow in the development of the approved project.

Please be aware that pursuant to General Statute 131E-181(b), you are required to materially comply with the representations made in your application for a certificate of need, or with any conditions the department placed on the certificate of need. If you operate a service which materially differs from the representations made in your application for a certificate of need, or with any conditions the department placed on the certificate of need, including any increase in per diem reimbursement rates/charges, the department may bring remedial action against the holder of the certificate of need pursuant to General Statutes 131E-189 and 131E-190.

The holder of a certificate of need is obligated to submit progress reports to this Agency as required by 10A NCAC 14C .0209. The applicant shall notify the Agency of any variations from the schedule or the projected capital cost of the project. During the development of the project, the Agency may request any additional information pertinent to the project, including additional progress reports, to determine: 1) if the timetable specified on the certificate is being met; 2) if the amount of the capital expenditure obligated under the certificate has exceeded or can be expected to exceed the maximum amount under the certificate; 3) if the terms and conditions of the approval are being met; and 4) if the



Location: 701 Barbour Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
An Equal Opportunity / Affirmative Action Employer



John A. Cashion
Page 2
July 31, 2007

November 16, 2007. Forms for the submittal of these reports are enclosed. Failure to submit any scheduled or requested progress report in a timely manner may result in the agency withdrawing the certificate pursuant to G.S.131E-189 (a). If after reviewing the status of the project, the Certificate of Need Section determines that the holder of the certificate is not meeting the timetable and is not making a good faith effort to meet it, the Agency may withdraw the certificate in accordance with G.S. 131E-189.

Moreover, please be advised that this Agency may assess a civil penalty not to exceed \$20,000 against any person who violates the terms of a certificate of need which has been issued each time the service provided is in violation of this provision (G.S. 131E-190(f)). If for some reason, the holder of a certificate of need determines it necessary to request an increase in a per diem charge or reimbursement rate over that which was stated in the application for the certificate of need, then the holder must first contact the Certificate of Need Section to obtain proper instructions for initiating such a request. The request for the increase will be considered by the department pursuant to G.S. 131E-181(b).

Please keep us informed of the progress in the development of this project. Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

Sincerely,



Helen E. Alexander, Project Analyst



Lee B. Hoffman, Chief
Certificate of Need Section

HEA:LBH: mhb

Enclosures

cc: Medical Facilities Planning Section, DHSR

STATE OF NORTH CAROLINA
Department of Health and Human Services
Division of Health Service Regulation

CERTIFICATE OF NEED
for
Project Identification Number G-7598-06
FID #: 060614

ISSUED TO: **John A. Cashion**
Cancer Center of Davidson County, LLC
250 Hospital Drive
Lexington, NC 27292

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-175(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Acquire a linear accelerator and a treatment simulator and establish a new radiation oncology center / Davidson County

CONDITIONS: See Reverse Side

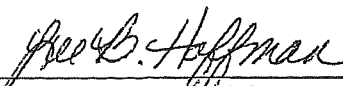
PHYSICAL LOCATION: Cancer Center of Davidson County
250 Hospital Drive, Lexington, NC 27292

MAXIMUM CAPITAL EXPENDITURE: \$3,200,757

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: November 16, 2007

This certificate is effective as of the 26th day of July, 2007



Chief, Certificate of Need Section
Division of Health Service Regulation

Conditions:

1. Cancer Center of Davidson County, LLC shall materially comply with all representations made in the certificate of need application.
2. Cancer Center of Davidson County, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application or that would otherwise require a certificate of need.
3. Prior to issuance of the certificate of need, Cancer Center of Davidson County, LLC shall submit to the Certificate of Need Section documentation of the commitment of \$230,000 for initial start-up and working capital.
4. Prior to issuance of the certificate of need, Cancer Center of Davidson County, LLC shall submit to the Certificate of Need Section documentation of the availability of sufficient funds for the projected capital cost of \$3,023,246 to develop the proposed project.
5. Prior to issuance of the certificate of need, Cancer Center of Davidson County, LLC shall submit to the Certificate of Need Section documentation of the radiation therapy continuing education program.
6. Cancer Center of Davidson County's charges for the technical and professional components for the first three years of operation following completion of the this project shall not exceed the following charges for the listed procedures:

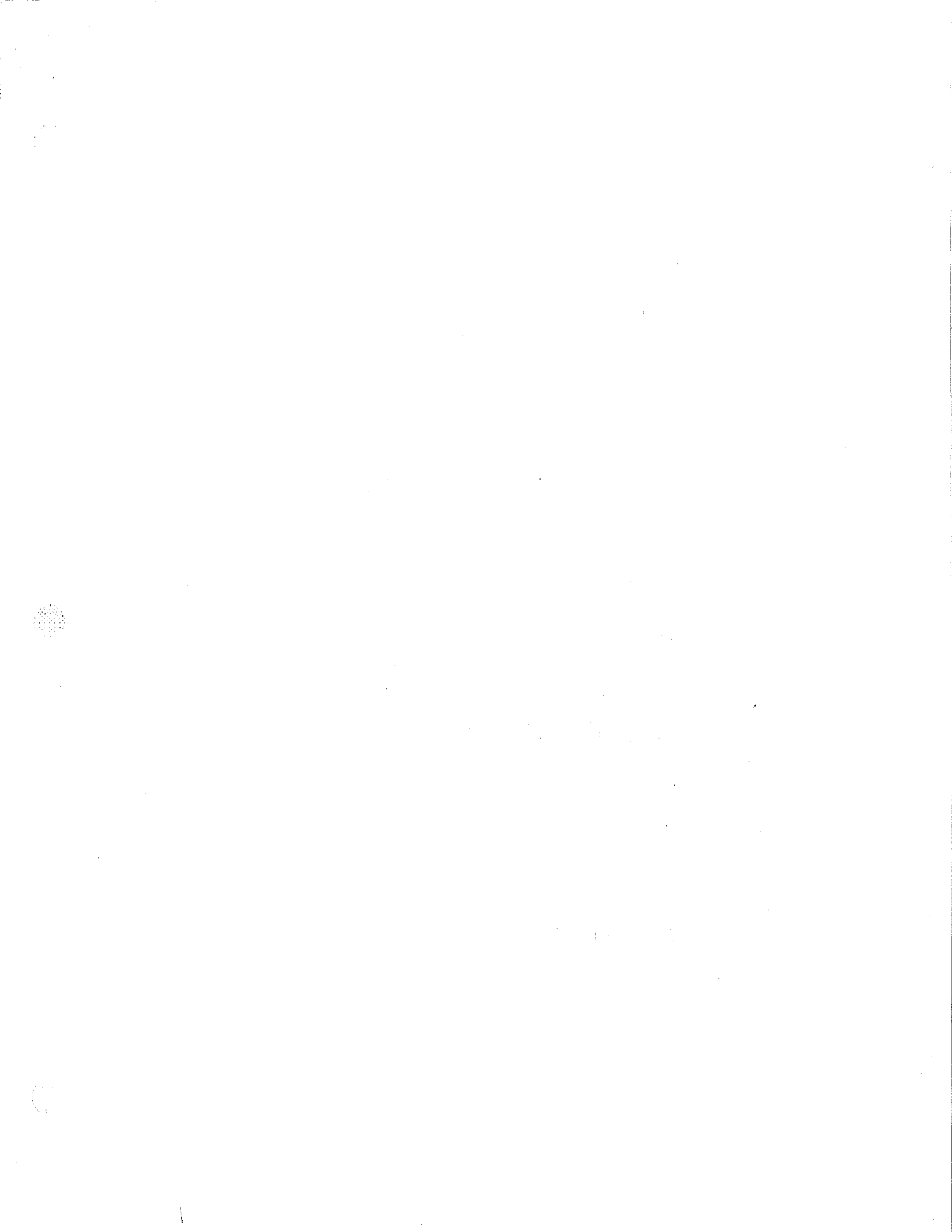
CPT Code	Charge
77413	\$211.85
77417	\$53.85
77414	\$211.85
77418	\$1,582.95
77336	\$603.75
77427	\$416.30
77300	\$199.05
77334	\$450.45
77403	\$161.83
77290	\$786.65
99213	\$125.45
99243	\$292.00
77263	\$403.95
77280	\$402.18
76370	\$267.70
77315	\$437.45
77295	\$3,104.45
77370	\$790.00
77301	\$3,536.48
77332	\$188.85

7. Cancer Center of Davidson County, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

The CON Section received a letter acknowledging and accepting conditions on November 28, 2006.

Timetable:

Contract award _____ November 1, 2007
 50% completion of construction _____ January 15, 2008
 Order equipment _____ March 15, 2008
 Occupancy / offering of services _____ May 15, 2008



Certificate of Need Application
**ACUTE CARE FACILITY/
 MEDICAL EQUIPMENT PROJECT**
State of North Carolina
Department of Human Resources

OFFICE USE ONLY

Project I. D. Number: _____ **Batch Category:** _____
Proposal Type: _____ **Beginning of Review:** _____

I. IDENTIFICATION

- 1. Legal Name of the Applicant:** The applicant is the existing legal entity (i. e., person or organization) that will own the facility. If the facility will be leased, complete two copies of Section VIII for the project; one with the lessor as the applicant and the other with the lessee as the applicant.

Cancer Center of Davidson County, LLC
 (Name of Applicant)

250 Hospital Drive
 (Street & Number)

<u>Lexington</u>	<u>NC</u>	<u>27292</u>	<u>Davidson</u>
(City)	(State)	(Zip)	(County)

- 2. Name of Parent Company (if applicable):**

Lexington Memorial Hospital, 250 Hospital Dr., Lexington, NC 27292

North Carolina Baptist Hospital, Medical Center Blvd., Winston Salem, NC 27157

Wake Forest University Health Sciences, Medical Center Blvd., Winston Salem, NC 27157



Note: The three aforementioned parties have an ownership interest in the LLC, though none are a "parent company" in the strict sense of the definition.

3. **Person to whom all correspondence and questions regarding this application should be directed:**

John A. Cashion President and CEO
(Name) (Title)

250 Hospital Drive
(Street & Number)

Lexington NC 27292 (336) 249-1250
(City) (State) (Zip) (Area Code & Phone Number)

4. **Name of Lessor (If applicable):**

Not applicable.

(Street & Number)

(City) (State) (Zip)

5. **Name of Lessee: (If applicable) (Attach copy of lease agreement)**

Not applicable.

(Street & Number)

(City) (State) (Zip)

6. **Name of Management Company: (If applicable) (Attach copy of management contract)**

Wake Forest University Health Sciences

Medical Center Blvd
 (Street & Number)

Winston Salem NC 27157
 (City) (State) (Zip)

7. **Name of existing/proposed facility as it will appear on a certificate of need. (i.e. Jones Health Care d/b/a Jones of Smithburg):**

Cancer Center of Davidson County, LLC Davidson
 (Name of Facility) (County)

107 Medical Park Drive Lexington NC 27292
 (Street & Number) (City) (State) (Zip)

8. **Provide a brief project description to identify the basic components of the project including the bed complement and proposed levels of care. This should be a one sentence description for identification purposes only.**

The Cancer Center of Davidson County proposes to acquire one linear accelerator to meet the need for a linear accelerator identified in the *2006 State Medical Facilities Plan* for Service Area 11 – Davidson County.

9. **Indicate the type of Construction or Change in Service:
 (Check the appropriate boxes)**

(a)	<input checked="" type="checkbox"/>	New Facility or Service
(b)	<input type="checkbox"/>	Total Replacement of Existing Facility
(c)	<input type="checkbox"/>	Renovation or Modernization
(d)	<input type="checkbox"/>	Expansion or Reduction of Services
(e)	<input checked="" type="checkbox"/>	Medical Equipment
(f)	<input type="checkbox"/>	Change in Bed Capacity

1.	<input type="checkbox"/>	Number of Beds to be Added
2.	<input type="checkbox"/>	Number of Beds to be Deleted
3.	<input type="checkbox"/>	<u>Total Number of Beds Currently Licensed (by licensure category)</u>
4.	<input type="checkbox"/>	Total Numbers of Beds to Be Licensed After Project Completion
5.	<input type="checkbox"/>	Total Beds Currently Operational

10. **Type of Ownership:** Check one of the following line items to describe the "ownership" of the applicant that is identified in Section I.1 of this application. Attach any documentation that will clearly identify the owner or lessee of the facility even if specific documents are not indicated below.

PROPRIETARY	
<input type="checkbox"/>	Individual
<input type="checkbox"/>	Partnership-Attach copy of Partnership Agreement and receipt showing the agreement is recorded with the Secretary of State
<input type="checkbox"/>	In-State Corp.-Attach a copy of the Articles of Incorporation and Certificate of Incorporation

	Out-of-State Corp-Attach evidence of registration with the Secretary of State
	Other (Specify)
NON-PROFIT	
	Corporation-Attach a copy of Articles of Incorporation and Certificate of Incorporation.
	Church
X	Other- (Specify) <u>Limited Liability Company</u> . See Exhibit 1, Articles of Organization. Tax status of this LLC is non-specified, but all organizations with an ownership interest are 501(c)(3) non-profit corporations.
GOVERNMENTAL	
	State
	County-Attach documentation that the county commissioners have endorsed this project if prior approval is required.
	City
	City/Council
	District
	Hospital Authority or Commission
	Other- (Specify)

11. Attach a list of the names of all owners, partners or persons having a financial interest of five percent (5%) or more in the facility. If the facility is leased, provide the same information for persons having an interest of five percent (5%) or more in the company leasing the facility.

The Cancer Center of Davidson County, LLC (herein referred to as the Cancer Center of Davidson County) is a North Carolina limited liability company. The three non-profit organizations that have an interest of five percent or more in the Cancer Center of Davidson County include Lexington Memorial Hospital, North Carolina Baptist Hospital, and Wake Forest University Health Sciences.

The registered agent for the Cancer Center of Davidson County, LLC is John A. Cashion.

(a) In the case of a proprietary or non-profit corporation, also attach:

(1) A list of the officers of the corporation, and

(2) The name and address of the registered agent for the corporation.

Not applicable. The Cancer Center of Davidson County is not a proprietary or non-profit corporation. The Cancer Center of Davidson County is a limited liability company.

(b) In the case of a partnership, also attach the name and address of the general or managing partner.

Not applicable. The Cancer Center of Davidson County is not a partnership. The Cancer Center of Davidson County is a limited liability company.

For Facility and Service Related Projects

12. Describe the experience and expertise of the applicant and/or facility's management in the planning, development, financing, construction, and management of health care facilities. At a minimum, provide responses to the following:

(a) If this project is for the construction of a new facility, please list by name and location all health care facilities that you have constructed in

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

IN RE: REQUEST FOR DECLARATORY)
RULING BY WAKE RADIOLOGY)
ONCOLOGY SERVICES, PLLC, CANCER) DECLARATORY RULING
CENTERS OF NORTH CAROLINA, P.C.,)
US ONCOLOGY, INC., AOR)
MANAGEMENT COMPANY OF VIRGINIA,)
LLC AND WAKEMED)

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.

Wake Radiology Oncology Services, PLLC (hereinafter “WROS”); Cancer Centers of North Carolina, P.C. (“CCNC”); US Oncology, Inc. (“USON”) and its subsidiary AOR Management Company of Virginia, LLC (“AOR”); and WakeMed have requested a declaratory ruling to confirm that the acquisition of the membership interests in WROS and the continued operation of the oncology treatment center may proceed without first obtaining a certificate of need. 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. Attorneys for the Petitioners have requested this ruling on their behalf and have provided the material facts upon which this ruling is based.



STATEMENT OF THE FACTS

WROS is a North Carolina professional limited liability company presently owned by certain physician-members, each of whom owns a specific percentage of the total membership interests in WROS. WROS provides radiation oncology treatment services at 300 Ashville Avenue, Suite 110, Cary, North Carolina, based on a certificate of need that was issued in 1997 to own an oncology treatment center and to operate a linear accelerator and simulator and other equipment used in furnishing radiation oncology services.

CCNC is a professional corporation organized under the laws of the State of North Carolina. CCNC employs physicians licensed to practice medicine in the State of North Carolina, who provide oncology treatment services, including radiation oncology services through the use of a linear accelerator.

USON is a business corporation organized under the laws of the State of Delaware. Through its subsidiaries, US Oncology provides administrative support for, and furnishes medical equipment used by, oncology practices throughout the United States.

AOR is a limited liability company, a subsidiary of USON and was organized under the laws of the State of Delaware and authorized to do business in North Carolina. AOR provides administrative and other support services to CCNC under a Management Services Agreement with CCNC.

WakeMed is a North Carolina nonprofit corporation engaged in the provision of acute care services and other health care services in Wake County.

WROS established its oncology treatment center on or about July 17, 1998. Since the establishment of its oncology treatment center, WROS has continuously operated the oncology treatment center established pursuant to the CON it received in 1997.

When the CON Law was amended in 2005, WROS already was operating an existing oncology treatment center pursuant to the CON that it had obtained in 1997 and using a linear accelerator and simulator that had been recognized in the SMFP inventory for seven years. Since it already owned the equipment, it was not required to obtain a second CON to be able to continue to operate its linear accelerator and simulator.

Recently, WROS physician owners approved a conversion of WROS from a professional limited liability company to a limited liability company, to occur simultaneously with the sale of ownership interests to CCNC. It is likely that WROS will change its name after the sale. Subsequently, in a separate transaction, WakeMed anticipates purchasing a minority membership interest in the renamed WROS ("the LLC").

This change in the business form of WROS that has been approved by its physician owners will not constitute a change in or dissolution of WROS, the legal entity that received the CON in 1997 and has continuously operated the oncology treatment center and the linear accelerator and simulator since they became operational.

After these two transactions, the LLC will continue to exist as a legal and business entity, and will continue to own the oncology treatment center and the equipment that was authorized under the 1997 CON, including the linear accelerator and simulator. The oncology treatment center and its equipment will remain at the same location at 300 Ashville Avenue in Cary.

The LLC will not offer any medical services. Oncology treatment services will be furnished by physicians associated with CCNC.

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 WROS which owns and operates a linear accelerator or simulator. The declaratory ruling requested by Petitioners 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:

The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. The LLC will continue to own the linear accelerator, the simulator, and all the oncology treatment center assets that were authorized under the 1997 CON and have been used to furnish oncology treatments to patients. Its membership composition initially will change from the present physician members to a single member, CCNC, with the subsequent purchase of a minority interest by WakeMed.

The Proposed Transaction will involve expenditures by CCNC, and later by WakeMed, but these will be purchases of ownership interests in an existing limited liability company that owns the oncology treatment center. There will be no capital expenditure to develop or expand a

health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed.

The Proposed Transaction 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 the Petitioners do not require a certificate of need in order to proceed with the Proposed Transaction.

This the _____ day of September, 2010.

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 certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

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P.O. Box 21927
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Attorneys for WakeMed

This the _____ day of September, 2010.

Jeff Horton
Chief Operating Officer



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. Canales, Secretary

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

August 18, 2011

CERTIFIED MAIL

Bode Call & Stroupe, L.L.P.
S. Todd Hemphill, Esquire
Post Office Box 6338
Raleigh, NC 27628-6338

RE: Declaratory Ruling for Radiation Oncology Centers of the Carolinas, Inc.

Dear Mr. Hemphill:

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



Location: 809 Ruggles Drive • Dorothea Dix Hospital Campus • Raleigh, N.C. 27603
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**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

**IN RE: REQUEST FOR DECLARATORY)
RULING BY RADIATION ONCOLOGY) DECLARATORY RULING
CENTERS OF THE CAROLINAS, INC.)**

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.

Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") has requested a declaratory ruling to confirm that the transfer of two CON-approved radiation oncology facilities to two wholly owned subsidiaries (the "Proposed Transaction") will not constitute a new institutional health service or require a 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. S. Todd Hemphill of Bode, Call & Stroupe, L.L.P. has requested this ruling on ROCC's behalf and have provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

ROCC directly owns and operates two CON-approved radiation oncology facilities. University Radiation Oncology Center ("UROC"), located at 8310 University Executive Park, Suite 500, Charlotte, NC 28262, was acquired by ROCC in 1997 pursuant to an exemption.

Matthews Radiation Oncology Center ("MROC"), located at 1400 Matthews Township Parkway, Matthews, NC 28105, is a "grandfathered" facility, because it became operational in 1990, prior to the application of the CON law to oncology treatment centers or major medical equipment.

The radiation oncology equipment located at UROC includes a Varian 2100C linear accelerator and a GE Highspeed Advantage CT simulator. The radiation oncology equipment located at MROC includes a Varian 21Ex-d linear accelerator and a GE Brightspeed CT simulator. Acquisition of the linear accelerator and CT simulator equipment at each facility has been previously approved by the agency.

ROCC would like to transfer its interest in UROC and MROC to two wholly owned subsidiaries of ROCC.

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 ROCC which owns and operates a linear accelerator or simulator. The declaratory ruling requested by Petitioner 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:


The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. The LLC will continue to own the linear accelerator, the simulator, and all the oncology treatment center assets that were authorized under the CON and have been used to furnish oncology treatments to patients.

The Proposed Transaction 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 the Petitioner does not require a certificate of need in order to proceed with the Proposed Transaction:

This the 18th day of August, 2011.


Drexel 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

Bode Call & Stroupe, L.L.P.
S. Todd Hemphill, Esquire
Post Office Box 6338
Raleigh, NC 27628-6338

This the 18th day of August, 2011.



Jeff Horton
Chief Operating Officer