



North Carolina Department of Health and Human Services  
Division of Health Service Regulation

Pat McCrory  
Governor

Aldona Z. Vos, M.D.  
Ambassador (Ret.)  
Secretary DHHS

Drexdal Pratt  
Division Director

August 12, 2015

Gary S. Qualls  
K&L Gates, LLP  
Post Office Box 14210  
Research Triangle Park, North Carolina 27709-4210

William R. Shenton  
Poyner Spruill  
Post Office Box 1801  
Raleigh, North Carolina 27602-1801

**No Review**

**Record #:** 1683  
**Business Name:** Vidant Radiation Oncology  
**Business #:** 2249  
**Project Description:** Vidant Medical Center becoming 100% owner of NewCo Cancer Services, LLC  
**County:** Pitt

Dear Messrs. Qualls and Shenton:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of July 31, 2015 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.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Section, DHSR Sections to determine if they have any requirements for development of the proposed project.



**Healthcare Planning and Certificate of Need Section**

[www.ncdhhs.gov](http://www.ncdhhs.gov)

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

An Equal Opportunity/ Affirmative Action Employer



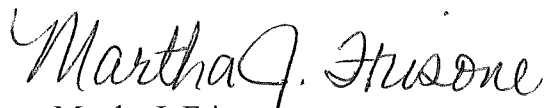
It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. 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 this office if you have any questions. Also, in all future correspondence you should reference the Business # if the facility is licensed.

Sincerely,



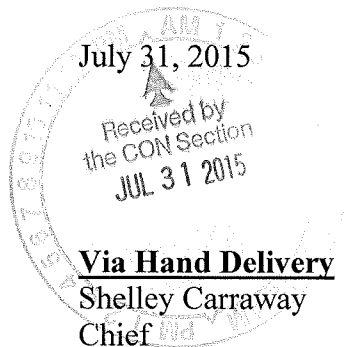
Jane Rhoe-Jones  
Project Analyst



Martha J. Frisone  
Assistant Chief, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR  
Construction Section, DHSR  
Assistant Chief, Healthcare Planning

K&L Gates LLP  
Post Office Box 14210  
Research Triangle Park, NC 27709-4210  
430 Davis Drive, Suite 400  
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T 919.466.1190      www.klgates.com



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

**Via Hand Delivery**

Shelley Carraway  
Chief  
Department of Health and Human Services  
Division of Health Service Regulation  
Health Planning and Certificate of Need  
Section  
809 Ruggles Drive  
Raleigh, North Carolina 27603

Martha Frisone  
Assistant Chief, Certificate of Need  
Department of Health and Human Services  
Division of Health Service Regulation  
Health Planning and Certificate of Need  
Section  
809 Ruggles Drive  
Raleigh, North Carolina 27603

RE: No Review Request - Joint Venture between Vidant and 21st Century Oncology Affiliate

Dear Ms. Carraway and Ms. Frisone:

On behalf of our client, Pitt County Memorial Hospital, Incorporated, d/b/a Vidant Medical Center ("Vidant"), along with William Shenton, who is counsel for 21st Century Oncology and its North Carolina affiliate, North Carolina Radiation Therapy Management Services, LLC ("NCRT"), enclosed please find an attachment describing a No Review Request for a potential joint venture between Vidant and NCRT.

As indicated in the No Review Request, we do not believe that this joint venture is subject to certificate of need review. Thank you in advance for your attention, and please let me know if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Gary S. Qualls".

Gary S. Qualls

cc: William Shenton

Attachments

July 31, 2015

William R. Shenton  
*Partner*  
D: 919.783.2947  
F: 919.783.1075  
wshenton@poynerspruill.com

Shelley Carraway  
Chief  
Healthcare Planning and Certificate of Need Section  
NC Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Martha Frisone  
Asst. Chief  
Certificate of Need  
NC Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, NC 27699-2704

RE: No Review Request – Joint Venture between Vidant and 21<sup>st</sup> Century Oncology Affiliate

Dear Ms. Carraway and Ms. Frisone:

I am writing as counsel for 21<sup>st</sup> Century Oncology and its North Carolina affiliate, North Carolina Radiation Therapy Management Services, LLC ("NCRT"), to transmit, along with Gary Qualls and Colleen Crowley, who are counsel for Vidant Medical Center, a No-Review request for your consideration. Vidant and NCRT are planning to implement a joint venture which will entail the combination of their respective freestanding radiation equipment and services in the Greenville area into a new limited liability company, called Vidant Radiation Oncology.

The enclosed document describes the steps in the transaction, and as we indicate this joint venture should not be subject to certificate of need review. We appreciate your attention to this request and please feel free to contact counsel for either of the parties if you should have any questions or need further clarification.

Very truly yours,



**William R. Shenton**  
*Partner*

**No Review Request for Joint Venture between  
Vidant Health and 21st Century Oncology**

The purpose of this request is to inform the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the “Agency”) of a planned joint venture between Pitt County Memorial Hospital, Incorporated, d/b/a Vidant Medical Center (“Vidant”) and North Carolina Radiation Therapy Management Services, LLC (“NCRT”),<sup>1</sup> involving the combination of their existing, freestanding radiation oncology equipment and services into a single joint venture limited liability company to be named Vidant Radiation Oncology (“VRO”). We ask that the Agency confirm that this joint venture is not reviewable as a new institutional health service under the North Carolina Certificate of Need (“CON”) law.

**STATEMENT OF FACTS**

By way of background, NewCo Cancer Services LLC (“NewCo”), d/b/a Leo Jenkins Cancer Center (“Cancer Center”), a 50/50 joint venture between East Carolina University Brody School of Medicine (“ECU”) and Vidant, owns and operates two existing linear accelerators (“linacs”) and CT simulators, pursuant to CON Project I.D. Q-8562-10. See Certificate of Need attached as Exhibit 1 and Exemption Request and Approval to Replace a CT Simulator attached as Exhibit 2. Vidant also owns and operates a Cyberknife linac, which is operated as a freestanding radiation treatment service at the Cancer Center, pursuant to CON Project I.D. Q-8558-10 and Material Compliance letter dated May 19, 2011. See Certificate of Need attached as Exhibit 3 and Material Compliance Letter attached as Exhibit 4.

NCRT owns and operates two existing linacs as part of NC Radiation Therapy-Greenville. See Declaratory Ruling and Exemption attached as Exhibits 5 and 6.

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<sup>1</sup> NCRT is a controlled affiliate of 21st Century Oncology.

First, Vidant seeks to obtain full ownership of the two linacs and CT simulators currently owned by NewCo and located at the Cancer Center. NewCo will continue to exist after Vidant obtains 100% ownership of the linacs and simulators. Once Vidant obtains full ownership, the same equipment will be used to provide the same radiation oncology services, in the same location.

Second, as part of a joint venture, Vidant and NCRT will be combining and contributing their existing freestanding radiation oncology services, medical equipment (including the 5 linacs, one of which is a Cyberknife linac) and related assets to the newly created VRO. After the joint venture transaction occurs, all of the equipment will continue to be operated in the same two locations as described above.<sup>2</sup> Therefore, as a result of these two steps (collectively, the “Transaction”), no linacs will be relocated or added to Linear Accelerator Service Area 27, as defined by the 2015 State Medical Facilities Plan (“SMFP”).

## **DISCUSSION**

### **I. Obtaining NewCo’s Interest in the Equipment Does Not Require a CON.**

As Step #1 to the Transaction, Vidant seeks to acquire 100% ownership of the two linacs and simulators currently owned by NewCo. A separate, third party will not be obtaining ownership of the linacs and simulators. Instead, Vidant, the 50% owner of the equipment, will now become the 100% owner. The linacs and simulators will continue to be operated at the Cancer Center in the same manner they are currently being operated.

The purchase of NewCo’s interest in the two linacs and simulators does not involve the offering or expansion of any new facility, service or equipment, and the State’s inventory of linacs will not change. No new or additional linacs will be acquired or placed in operation in the

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<sup>2</sup> While at some point in the future VRO may seek to relocate equipment, it would not do so unless and until all necessary approvals are obtained from the Agency.

State. As detailed below in Section II, this is similar to membership change in the ownership of regulated equipment and a CON is not required.

## **II. Creating VRO as a Conduit for Ownership is Not Regulated Under CON Law.**

Likewise, Step 2 in the Transaction -- Vidant and NCRT contributing their respective linacs to VRO -- does not require a CON. The CON statute provides a lengthy and exclusive list of activities that constitute development of a new institutional health service, requiring a CON. The joint venture of two existing entities that already actively provide health services is not included on that list. Pursuant to a well-established maxim of statutory construction, *expressio unius est exclusio alterius*, those transactions not included in N.C. Gen. Stat. § 131E-176(16) do not require a CON. *See, e.g., In re Miller*, 357 N.C. 316, 325, 584 S.E.2d 772, 780 (2003) (stating that “[u]nder the doctrine of *expressio unius est exclusio alterius*, when a statute lists the situations to which it applies, it implies the exclusion of situations not contained in the list”); *see also Jackson v. A Woman’s Choice, Inc.*, 130 N.C. App. 590, 594, 503 S.E.2d 422, 425 (1998) (internal citations omitted) (“Where a statute is explicit on its face, the courts have no authority to impose restrictions that the statute does not expressly contain.”).

Here, Vidant and NCRT will place the ownership rights of all five linacs into the joint venture, VRO. NCRT will own 50% of VRO and Vidant will own 50% of VRO. Therefore, both Vidant and NCRT will continue to own the linacs through their respective ownership of VRO.

Previous Declaratory Rulings and No Review Decisions demonstrate that the Agency and the Division of Health Service Regulation have already determined that a CON is not required for similar membership interest changes pertaining to CON regulated equipment. *See Id.*, attached as Exhibit 7; *In re: Request for Declaratory Ruling by Wake Radiology Oncology*

*Services, PLLC, et al.*, attached as Exhibit 8; *In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. et. al.*, attached as Exhibit 9; *No Review/WakeMed/Acquisition of Ownership Interest of CSA-1, Owners of Five Heart-Lung Bypass Machines Located in WakeMed/Wake County* attached as Exhibit 10; and *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* attached as Exhibit 11.

Likewise, here, Vidant and NCRT's joint venture does not constitute the acquisition of a linac. In fact, the underlying linac ownership will be essentially the same. Unlike some of the prior situations referenced above that were determined not to be subject to CON review, Vidant and NCRT will still retain an ownership interest in the linacs. No separate third party will be acquiring any ownership interest in the equipment. The same parties will retain ownership of all five linacs (now through the joint conduit of VRO); and the linacs will remain in the same location, and will still be used to serve patients in the same manner.

A "new institutional health service" includes "the acquisition by purchase, donation, lease, transfer, or comparable arrangement . . . by or on behalf of any person" a linear accelerator and simulator. N.C. Gen. Stat. § 131E-176(16)(f1)(5a) and (f1)(9). However, the transaction contemplated here will not constitute the acquisition of a linear accelerator as defined by N.C. Gen. Stat. § 131E-176(16). Ownership of the radiation therapy equipment will largely be unaffected by this transaction. That equipment will continue to be owned, in part, by the same entities both before and after this transaction. VRO will be owned by Vidant and NCRT. VRO will merely be the new ownership conduit through which NCRT and Vidant continue to own the radiation oncology treatment equipment.



A fundamental concept of corporate law is that the owners of corporate stock are distinct from the corporation itself. *See* Robinson on North Carolina Corporate Law, § 2.08 (“A corporation is a legal entity separate and distinct from its shareholders.”) By design, LLC members also stand in a position similar to corporate shareholders. *Id.* at § 34.03[3]. Consequently, under the general principles of business organizations law governing LLC membership interests, the members of an LLC are legally distinct from the LLC itself. *Id.* at § 34.05[1] (“A membership interest may be acquired directly from the LLC or by assignment from another holder”).

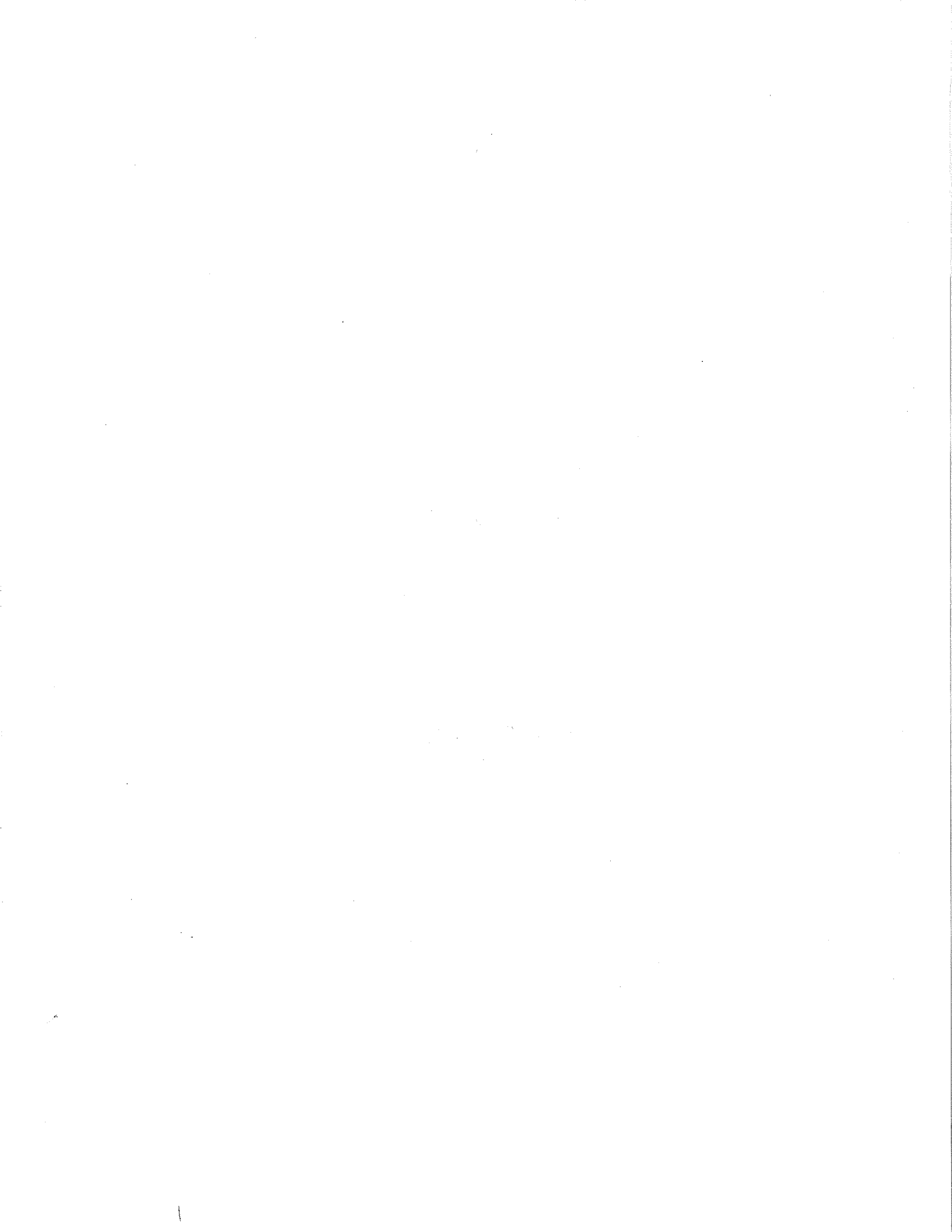
Vidant and NCRT are merely placing their collective ownership interests into one joint venture and will then each retain a percentage share of the ownership of the joint venture. Therefore, this transaction cannot constitute the acquisition of a linear accelerator because Vidant and NCRT will retain ownership of their respective equipment through the VRO.

#### **CONCLUSION**

Based on the discussion herein, Vidant and NCRT request that the Agency provide confirmation that no CON is required for the proposed Transaction described above.

## EXHIBITS

1. Certificate of Need CON Project I.D. Q-8562-10
2. Exemption Request (without exhibits) and Approval to Replace CT Simulator
3. Certificate of Need CON Project I.D. Q-8558-10
4. Material Compliance Letter dated May 19, 2011
5. NC Radiation Therapy-Greenville 2007 Declaratory Ruling
6. NC Radiation Therapy-Greenville's 2009 Certificate of Need Exemption
7. *Declaratory Ruling for the Charlotte-Mecklenburg Hospital Authority d/b/a/Carolinas Healthcare System, November 4, 2011*
8. *In re: Request for Declaratory Ruling by Wake Radiology Oncology Services, PLLC, et al.*
9. *In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. et. al.*
10. *No Review/WakeMed/Acquisition of Ownership Interest of CSA-1, Owners of Five Heart-Lung Bypass Machines Located in WakeMed/Wake County*
11. *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*



# STATE OF NORTH CAROLINA

*Department of Health and Human Services  
Division of Health Service Regulation*

## **CERTIFICATE OF NEED**

for

Project Identification Number #Q-8562-10

FID #100878

**ISSUED TO:** NewCo Cancer Services, LLC  
P.O. Box 6028  
Greenville, NC 27835

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-176(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:** NewCo Cancer Services shall acquire two existing linear accelerators, CT simulator, and related equipment, and multispecialty oncology physician practices from East Carolina University Brody School of Medicine/ Pitt County

**CONDITIONS:** See Reverse Side

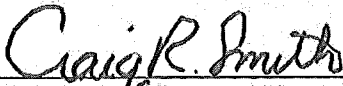
**PHYSICAL LOCATION:** Pitt County Memorial Hospital  
600 Moye Boulevard  
Greenville, NC 27834

**MAXIMUM CAPITAL EXPENDITURE:** \$9,700,000

**TIMETABLE:** See Reverse Side

**FIRST PROGRESS REPORT DUE:** May 1, 2011

This certificate is effective as of the 30<sup>th</sup> day of December, 2010

  
\_\_\_\_\_  
Chief, Certificate of Need Section  
Division of Health Service Regulation

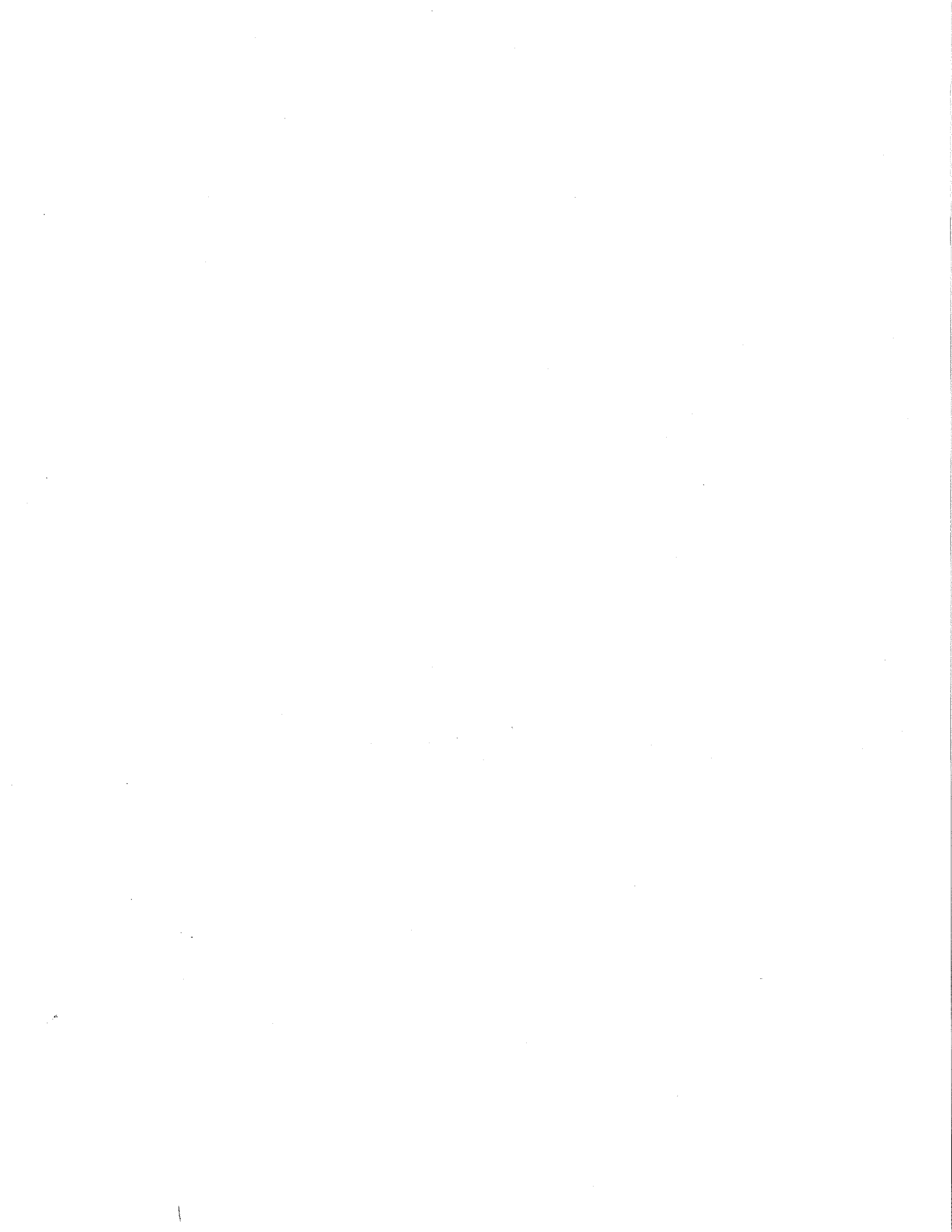
**CONDITIONS:**

1. NewCo Cancer Services, LLC shall materially comply with all representations made in its application.
2. NewCo Cancer Services, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or which would otherwise require a certificate of need.
3. NewCo Cancer Services, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on December 6, 2010.

**TIMETABLE:**

Occupancy/Offering of service(s) \_\_\_\_\_ April 1, 2011





North Carolina Department of Health and Human Services  
Division of Health Service Regulation

Pat McCrory  
Governor

Aldona Z. Wos, M.D.  
Ambassador (Ret.)  
Secretary DHHS

Drexdal Pratt  
Division Director

September 13, 2013

Jeffrey Shovelin, Director of Corporate Planning  
Vidant Health  
Post Office Box 2068  
Greenville, North Carolina 27835-6028

**Exempt from Review - Replacement Equipment**

Facility or Business: Vidant Medical Center  
Project Description: Replace CT Scanner and CT Simulator at the Leo Jenkins Cancer Center  
County: Pitt  
FID #: 933410

Dear Mr. Shovelin:

In response to your letter of August 14, 2013, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the GE Optima CT580 16 Slice CT Simulator to replace the existing Siemens SimView CT Scanner. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

Moreover, you need to contact the Acute and Home Care Licensure and Certification Section and the Construction Section to determine if they have any requirements for development of the proposed project.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.



**Certificate of Need Section**

[www.ncdhhs.gov](http://www.ncdhhs.gov)

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

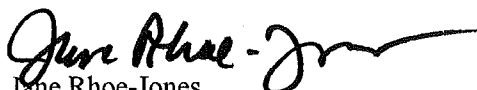
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

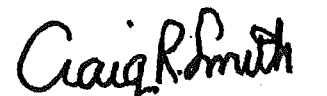
An Equal Opportunity/ Affirmative Action Employer



Jeffrey Shovelin  
September 13, 2013  
Page 2

Sincerely,

  
Jane Rhoe-Jones  
Project Analyst

  
Craig R. Smith, Chief  
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification, DHSR  
Construction Section, DHSR  
Medical Facilities Planning Branch, DSHR



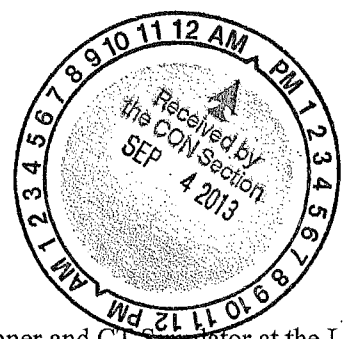
*Jane*



**VIDANT HEALTH™**

August 29, 2013

Ms. Jane Rhoe-Jones  
Certificate of Need Section  
Division of Health Service Regulation  
NC Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, NC 27699-2704



RE: Request for "No Review" for Replacement CT Scanner and CT Simulator at the Leo Jenkins Cancer Center

Dear Ms. Rhoe-Jones:

NewCo Cancer Services, LLC (NewCo), a joint venture between Vidant Medical Center and ECU's Leo Jenkins Cancer Center, plans to replace an existing CT simulator with new equipment. NewCo believes that the proposed equipment replacement is not subject to review under North Carolina's Certificate of Need (CON) laws.

The proposed project includes the replacement of a Siemens SimView CT scanner with a GE Optima CT580 16 slice CT simulator (see Appendix A for vendor quotes and Appendix B for equipment comparison table and brochure). The equipment will be secured through accumulated reserves. The reason for this replacement is due to age and the need for upgraded technology to provide optimal care. Only minor renovations are needed for the existing CT simulator suite (See Appendix C for drawings and construction estimate). The total capital costs for the proposed replacement is estimated to be \$ 1,147,781 (see Appendix D for the Capital Cost Sheet). These costs include all expenses associated with the equipment and minor renovations. After the new scanner is operational, the existing equipment will be permanently removed from the facility and will no longer be exempt from CON law (see Appendix E for required documentation of equipment removal).

NewCo's proposed project meets the definition of replacement equipment found in G.S. 131E-176(22a). The total capital expenditure for the equipment is less than \$2,000,000 and the equipment being purchased is for the sole purpose of replacing comparable medical equipment. Since NewCo's proposal meets the definition of "replacement equipment", G.S. 131E-184(a)(7) exempts this project from review. Therefore, NewCo requests approval of a no review status for the proposed project.

If you require additional information or clarification, please contact me at (252)-847-3631.

Jeffrey Shovelin  
Director of Corporate Planning  
Vidant Health



# STATE OF NORTH CAROLINA

*Department of Health and Human Services  
Division of Health Service Regulation*

## **CERTIFICATE OF NEED**

for

**Project Identification Number #Q-8558-10**

**FID #933410**

**ISSUED TO: Pitt County Memorial Hospital, Inc.  
P.O. Box 6028  
Greenville, NC 27835**

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-176(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: Pitt County Memorial Hospital shall acquire a CyberKnife radiosurgery system and related equipment from East Carolina University Brody School of Medicine/ Pitt County**

**CONDITIONS: See Reverse Side**


**PHYSICAL LOCATION: Pitt County Memorial Hospital  
600 Moye Boulevard  
Greenville, NC 27834**

**MAXIMUM CAPITAL EXPENDITURE: \$4,750,000**

**TIMETABLE: See Reverse Side**

**FIRST PROGRESS REPORT DUE: May 1, 2011**

This certificate is effective as of the 30<sup>th</sup> day of December, 2010

  
\_\_\_\_\_  
Chief, Certificate of Need Section  
Division of Health Service Regulation

# STATE OF NORTH CAROLINA

*Department of Health and Human Services  
Division of Health Service Regulation*

## **CERTIFICATE OF NEED**

for

**Project Identification Number #Q-8558-10**

**FID #933410**

**ISSUED TO: Pitt County Memorial Hospital, Inc.  
P.O. Box 6028  
Greenville, NC 27835**

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-176(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: Pitt County Memorial Hospital shall acquire a CyberKnife radiosurgery system and related equipment from East Carolina University Brody School of Medicine/ Pitt County**

**CONDITIONS: See Reverse Side**


**PHYSICAL LOCATION: Pitt County Memorial Hospital  
600 Moye Boulevard  
Greenville, NC 27834**

**MAXIMUM CAPITAL EXPENDITURE: \$4,750,000**

**TIMETABLE: See Reverse Side**

**FIRST PROGRESS REPORT DUE: May 1, 2011**

This certificate is effective as of the 30<sup>th</sup> day of December, 2010

  
\_\_\_\_\_  
Chief, Certificate of Need Section  
Division of Health Service Regulation

**CONDITIONS:**

1. Pitt County Memorial Hospital, Incorporated shall materially comply with all representations made in its application.
2. Pitt County Memorial Hospital, Incorporated shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or which would otherwise require a certificate of need.
3. Pitt County Memorial Hospital, Incorporated shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on December 6, 2010.

**TIMETABLE:**

Occupancy/Offering of service(s) \_\_\_\_\_ January 1, 2011





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

Beverly Eaves Perdue, Governor  
Lanier M. Cansler, Secretary

[www.ncdhhs.gov/dhsr](http://www.ncdhhs.gov/dhsr)

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

May 19, 2011

Mr. Jeff Shovelin, Director of Corporate Planning  
Pitt County Memorial Hospital  
2100 Stantonsburg Road  
Greenville, NC 27835

RE: Material Compliance/ Project I.D. # Q-8558-10 Pitt County Memorial Hospital shall acquire a CyberKnife radiosurgery system and related equipment from East Carolina University Brody School of Medicine/ Change from operating the CyberKnife as a hospital-based service to a freestanding radiation treatment center/ Pitt County  
FID # 933410

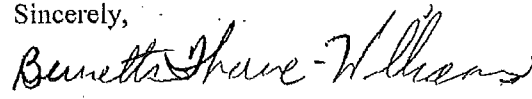
Dear Mr. Shovelin:

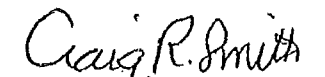
In response to your correspondence dated April 18, 2011 regarding the above referenced project, the Certificate of Need Section has determined that the proposed change is in material compliance with representations made in the application. These changes include obtaining an additional NPI number and new Medicare and Medicaid identification numbers to operate the CyberKnife service as a freestanding radiation treatment center at the same location in the Leo W. Jenkins Cancer Center. This change in operating status does not constitute a change in the equipment to be acquired from East Carolina University Brody School of Medicine. However, you should contact the Construction Section of the Division of Health Service Regulation to determine if they have any requirements pertinent to the proposed change.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination.

If you have any questions concerning this matter, please feel free to contact this office. Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

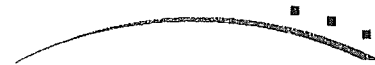
Sincerely,

  
Bernetta Thorne-Williams, Project Analyst

  
Craig R. Smith, Chief  
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR  
Construction Section, DHSR  
Acute Care Licensure and Certification Section, DHSR



  
**PITT COUNTY MEMORIAL HOSPITAL**  
*University Health Systems of Eastern Carolina<sup>SM</sup>*

April 18, 2010

Mr. Craig Smith, Chief  
Certificate of Need Section, Division of Health Service Regulation  
North Carolina Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Re: Notification of a minor project change to Project ID #Q-8558-10 / Pitt County Memorial Hospital, Inc. / Acquire CyperKnife (linear accelerator) from Brody School of Medicine / Pitt County FID#933410

Dear Mr. Smith:

This letter serves as notification of a minor project change in approved Project ID #Q-8558-10 / Pitt County Memorial Hospital, Inc. / Acquire CyperKnife (linear accelerator) from Brody School of Medicine / Pitt County. We believe the change outlined below does not constitute a material difference in the representations made in the original CON. The change was necessary to comply with the new CMS Life Safety Code Requirements effective February, 2011.

Specifically, in the original application, Pitt County Memorial Hospital, Inc. (PCMH) stated the CyberKnife would be operated in its existing location in the existing Leo W. Jenkins Cancer Center (LWJCC) as a hospital-based service under the hospital's existing provider numbers. As a result of new CMS Life Safety Code Requirements effective February, 2011, the LWJCC does not meet the requirements for institutional space. Therefore, in its existing location, the CyberKnife cannot be operated as a hospital-based service without first incurring significant capital improvements.

To address this issue, PCMH will operate the CyberKnife in its current location, but instead of operating as a hospital-based service, PCMH will obtain an additional NPI number and new Medicare and Medicaid identification numbers to operate CyberKnife services as a freestanding radiation treatment center, doing business as "UHS CyberKnife". PCMH believes this change has not materially altered the approved CON as these changes do not require modifications to ownership, need, services to be provided, patients to be served, capital costs, staffing, time lines, or financial projections.

If you need additional information or have any questions, please do not hesitate to call me at (252) 847-3631 or email me directly at [jshoveli@uhseast.com](mailto:jshoveli@uhseast.com).

Sincerely,



Jeff Shovelin  
Director of Corporate Planning,  
University Health System of Eastern Carolina







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

Michael F. Easley, Governor  
Dempsey Benton, Secretary

Robert J. Fitzgerald, Director  
Phone: 919-855-3750  
Fax: 919-733-2757

September 18, 2007

**CERTIFIED MAIL**

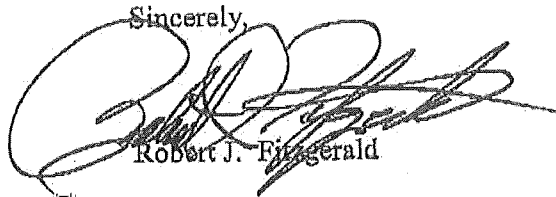
Susan H. Hargrove, Esquire  
Smith, Anderson, Blount, Dorsett  
Mitchell & Jernigan, L.L.P.  
P.O. Box 2611  
Raleigh, NC 27602-2611

RE: Declaratory Ruling for Radiation Therapy Services, Inc. and North Carolina Radiation  
Therapy Management Services, Inc.

Dear Ms. Hargrove:

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

Sincerely,



Robert J. Fitzgerald

RJF:JH:peb

Enclosure

cc: Jeff Horton, Chief Operating Officer, DHSR  
Lee Hoffman, Chief, Certificate of Need Section, DHSR  
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section, DHSR  
Marc Lodge, Special Deputy Attorney General, DOJ



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



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

**IN RE: REQUEST FOR )  
DECLARATORY RULING BY RADIATION )  
THERAPY SERVICES, INC. AND NORTH )     DECLARATORY RULING  
CAROLINA RADIATION THERAPY )  
MANAGEMENT SERVICES, INC. )**

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Radiation Therapy Services, Inc. d/b/a/ 21<sup>st</sup> Century Oncology ("RTS") and North Carolina Radiation Therapy Management Services, Inc. ("NC Radiation") (collectively "Petitioners") 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. Petitioners have filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that they may acquire all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTC") without certificate of need ("CON") review.

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. Susan H. Hargrove, Sean A. Timmons, and Jennifer B. Markhan of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., counsel for Petitioners, have requested this ruling on behalf of Petitioners and have provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for Petitioners are set out below.

### STATEMENT OF THE FACTS

Except as noted, the following statement of the facts is based on the representations of Petitioners in the Request.

Petitioner RTS is a Florida corporation. NC Radiation is a North Carolina corporation that is a wholly-owned subsidiary of RTS. Both have their principal business address in Fort Myers, Florida.

Petitioners wish to acquire 100% of the issued and outstanding stock of CRTC, which they state is a North Carolina corporation owned by Dr. Gordon Koltis that operates a radiation therapy facility for cancer patients. Petitioners describe CRTC as an oncology treatment center that, prior to 26 August 2005, would have been a "health service facility" as defined in N.C.G.S. § 131E-176(9b). S.L. 2005-325 eliminated oncology treatment centers from the category of "health service facilities," effective 26 August 2005.

Petitioners also state that CRTC "owns and operates two linear accelerators" and "one simulator." Request, p. 3. Footnote 1 to the Request states:

CRTC has represented to Petitioners that it entered into binding obligations to acquire the second linear accelerator prior to August 26, 2005, and that the acquisition of the second linear accelerator cost less than \$750,000, including the cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the second linear accelerator.

I note from the files of the Department that the inventory report of linear accelerator equipment submitted by Carolina Radiation Medicine, P.A., certified and dated by Gordon G. Koltis on April 6, 2007, identifies only one linear accelerator owned by CRTC. The Department files do not contain any information concerning the purported second linear accelerator.

Petitioners represent that they have executed a stock purchase agreement by which NC Radiation will acquire 100% of the issued and outstanding capital stock of CRTC from Dr. Koltis. After closing the transaction, Petitioners state that CRTC will remain a separate corporate entity that is a wholly-owned subsidiary of NC Radiation. They state that CRTC will continue to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways. Petitioners will pay more than two million dollars to purchase the CRTC stock. The closing of the transaction is conditioned on receiving confirmation from the Department that acquisition of the stock will not require a certificate of need.

#### ANALYSIS

N.C.G.S. § 131E-178 provides that no person shall offer or develop "a new institutional health service" without first obtaining a CON. N.G.C.S. § 131E-176(16) defines "new institutional health service" to include: (1) "The acquisition by purchase, donation, lease, transfer, or comparable arrangement" of a linear accelerator "by or on behalf of any person," N.G.C.S. § 131E-176(16)f1.5a, and (2) "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.G.S. § 131E-176(16)b.

The transaction described by Petitioners does not constitute the acquisition of a linear accelerator or a simulator by any person because ownership of the one reported linear accelerator and one reported simulator here will not change. CRTC will continue to be the owner of these two pieces of equipment, and CRTC's legal status as a corporate entity will not change.

Similarly, the transaction is not an obligation to develop or expand a health service or a health service facility, since Petitioners represent that CRTC will continue to operate at the same

location in a manner that is the same in all material respects as it operated prior to the transaction. In addition, pursuant to S.L. 2005-325, oncology treatment centers are not "health service facilities" for purposes of the CON law.

Finally, on the specific facts of this case, the transaction proposed by Petitioners is not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C.G.S. § 131B-176(16)b. The definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Petitioners' representations indicate that stock ownership of CRTC is not integral to the clinical management of CRTC, because in all material respects the operations of CRTC will not change.

I specifically except from this Ruling any conclusions as to the status or legality of the ownership of a purported second linear accelerator by CRTC. The Department has no notice of the existence or ownership of the second linear accelerator, and I make no finding that CRTC may acquire or operate, or has properly acquired and operated, a second linear accelerator without CON review.

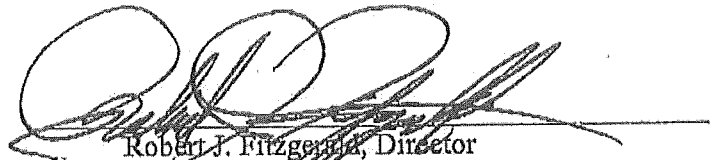
### CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Petitioners of 100% of the outstanding and issued stock of CRTC, in the manner represented by Petitioners in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, CRTC continues to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of CRTC with respect to the requirements of the CON law as it relates to CRTC. The ruling is limited to the specific facts presented in the Request. It specifically does not address the status of any linear accelerator that CRTC may own or claim to own.

This 14<sup>th</sup> day of September 2007.



Robert J. Fitzgerald, 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 pre-paid envelope addressed as follows:

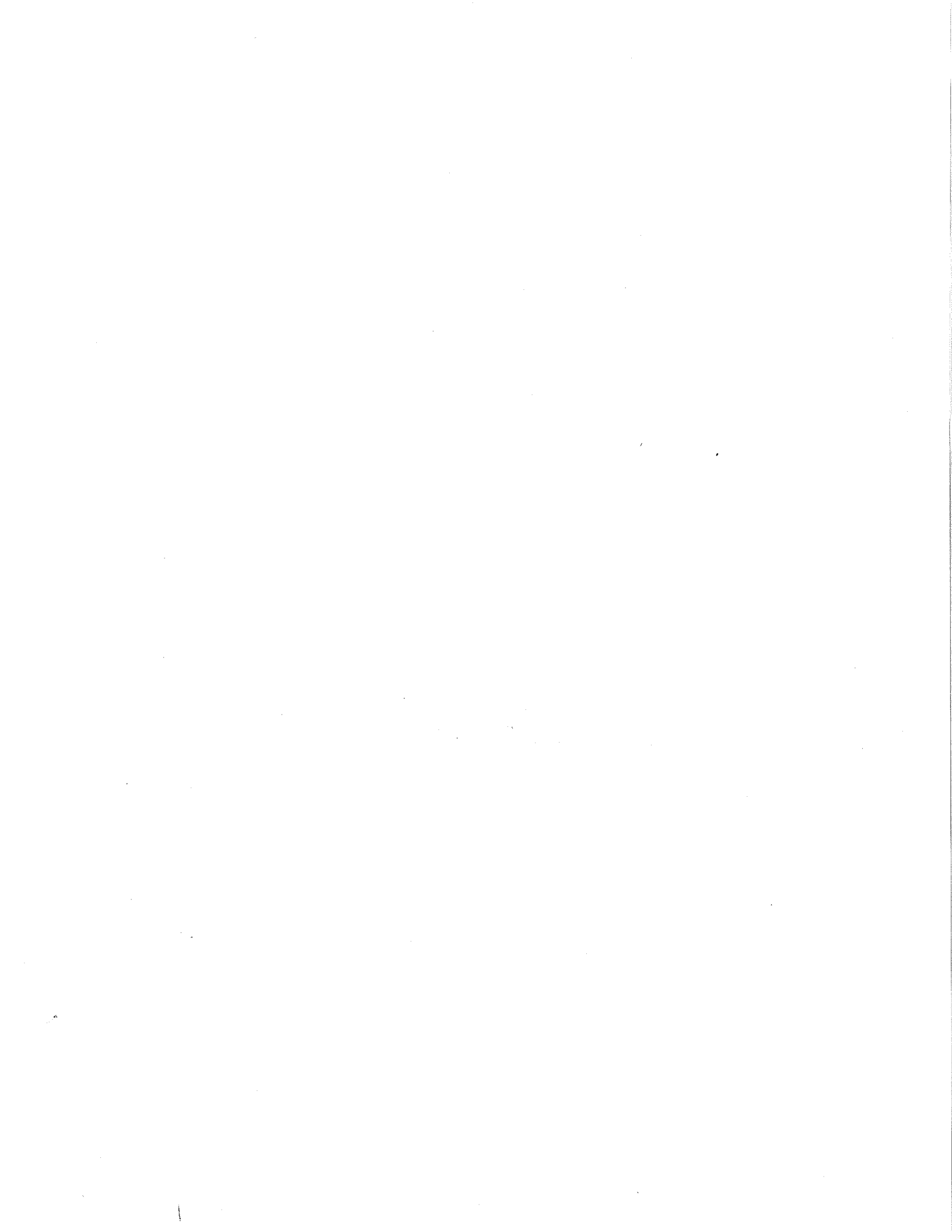
**CERTIFIED MAIL**

Susan H. Hargrove, Esq.  
Smith, Anderson, Blount, Dorsett  
Mitchell & Jernigan, L.L.P.  
P.O. Box 2611  
Raleigh, NC 27602-2611

This the 14<sup>th</sup> day of September, 2007.

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







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

Beverly Eaves Perdue, Governor  
Lanier M. Cansler, Secretary

[www.ncdhhs.gov/dhsr](http://www.ncdhhs.gov/dhsr)

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

June 29, 2009

Renee J. Montgomery, Partner  
Parker Poe Adams and Bernstein LLP  
Post Office Box 389  
Raleigh, NC 27602-0389

RE: Exempt from Review - Replacement Equipment/ Radiation Therapy Services, Inc. d/b/a 21<sup>st</sup> Century Oncology, North Carolina Radiation Therapy Management Services, Inc. and Carolina Radiation and Cancer Treatment Center, Inc./ Acquire a replacement linear accelerator for the second linear accelerator located at CRCTC in Greenville/ Pitt County

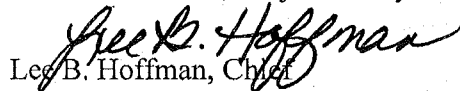
Dear Ms. Montgomery:

In response to your letters of June 23, 2009, November 18, 2008, and July 29, 2008, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Varian 2100C, s/n 1167, to replace the existing Varian 2100C, s/n 527. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

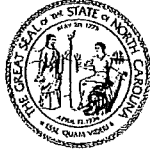
  
F. Gene DePorter, Project Analyst

  
Lee B. Hoffman, Chief  
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR







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 Haves 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,

A handwritten signature in black ink, appearing to read "Drexdal Pratt", with a long horizontal line extending to the right.

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

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

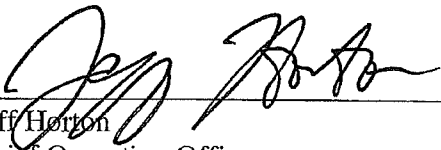
**CERTIFICATE OF SERVICE**

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:

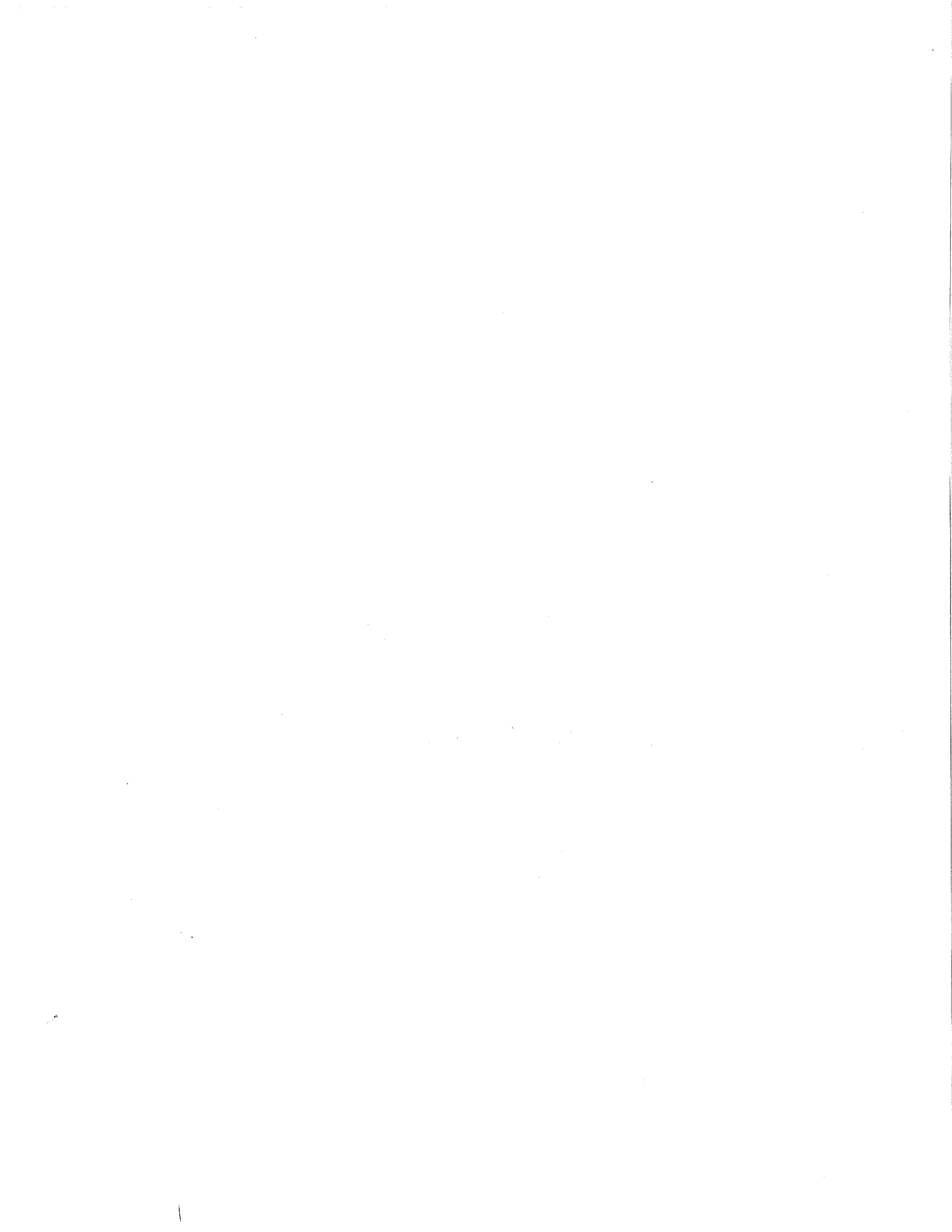
**CERTIFIED MAIL**

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





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

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

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**

Ronald I. Kirschbaum  
KIRSCHBAUM, NANNEY, KEENAN & GRIFFIN, P.A.  
P.O. Box 19766  
Raleigh, North Carolina 27607  
Attorneys for Wake Radiology Oncology, PLLC

William R. Shenton  
POYNER SPRUILL LLP  
301 Fayetteville Street, Suite 1900  
Raleigh, North Carolina 27601  
Attorneys for U.S. Oncology, Inc. and AOR Management  
Company of Virginia, LLC

Larry E. Robbins  
WYRICK ROBBINS YATES & PONTON, LLP  
P.O. Drawer 17803  
Raleigh, North Carolina 27607  
Attorneys for Cancer Centers of North Carolina, P.C.

Maureen Demarest Murray  
SMITH MOORE LEATHERWOOD LLP  
P.O. Box 21927  
Greensboro, North Carolina 27420  
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  
RALEIGH, NORTH CAROLINA**

<b>IN RE: REQUEST FOR</b>	)	
<b>DECLARATORY RULING BY RADIATION</b>	)	
<b>THERAPY SERVICES, INC. AND NORTH</b>	)	<b>DECLARATORY RULING</b>
<b>CAROLINA RADIATION THERAPY</b>	)	
<b>MANAGEMENT SERVICES, INC.</b>	)	

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Radiation Therapy Services, Inc. d/b/a/ 21<sup>st</sup> Century Oncology ("RTS") and North Carolina Radiation Therapy Management Services, Inc. ("NC Radiation") (collectively "Petitioners") 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. Petitioners have filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that they may acquire all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTCC") without certificate of need ("CON") review.

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. Susan H. Hargrove, Sean A. Timmons, and Jennifer B. Markhan of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., counsel for Petitioners, have requested this ruling on behalf of Petitioners and have provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for Petitioners are set out below.

## STATEMENT OF THE FACTS

Except as noted, the following statement of the facts is based on the representations of Petitioners in the Request.

Petitioner RTS is a Florida corporation. NC Radiation is a North Carolina corporation that is a wholly-owned subsidiary of RTS. Both have their principal business address in Fort Myers, Florida.

Petitioners wish to acquire 100% of the issued and outstanding stock of CRTC, which they state is a North Carolina corporation owned by Dr. Gordon Koltis that operates a radiation therapy facility for cancer patients. Petitioners describe CRTC as an oncology treatment center that, prior to 26 August 2005, would have been a "health service facility" as defined in N.C.G.S. § 131E-176(9b). S.L. 2005-325 eliminated oncology treatment centers from the category of "health service facilities," effective 26 August 2005.

Petitioners also state that CRTC "owns and operates two linear accelerators" and "one simulator." Request, p. 3. Footnote 1 to the Request states:

CRTC has represented to Petitioners that it entered into binding obligations to acquire the second linear accelerator prior to August 26, 2005, and that the acquisition of the second linear accelerator cost less than \$750,000, including the cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the second linear accelerator.

I note from the files of the Department that the inventory report of linear accelerator equipment submitted by Carolina Radiation Medicine, P.A., certified and dated by Gordon G. Koltis on April 6, 2007, identifies only one linear accelerator owned by CRTC. The Department files do not contain any information concerning the purported second linear accelerator.

Petitioners represent that they have executed a stock purchase agreement by which NC Radiation will acquire 100% of the issued and outstanding capital stock of CRTC from Dr. Koltis. After closing the transaction, Petitioners state that CRTC will remain a separate corporate entity that is a wholly-owned subsidiary of NC Radiation. They state that CRTC will continue to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways. Petitioners will pay more than two million dollars to purchase the CRTC stock. The closing of the transaction is conditioned on receiving confirmation from the Department that acquisition of the stock will not require a certificate of need.

#### ANALYSIS

N.C.G.S. § 131E-178 provides that no person shall offer or develop “a new institutional health service” without first obtaining a CON. N.G.C.S. § 131E-176(16) defines “new institutional health service” to include: (1) “The acquisition by purchase, donation, lease, transfer, or comparable arrangement” of a linear accelerator “by or on behalf of any person,” N.G.C.S. § 131E-176(16)f1.5a, and (2) “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.G.S. § 131E-176(16)b.

The transaction described by Petitioners does not constitute the acquisition of a linear accelerator or a simulator by any person because ownership of the one reported linear accelerator and one reported simulator here will not change. CRTC will continue to be the owner of these two pieces of equipment, and CRTC’s legal status as a corporate entity will not change.

Similarly, the transaction is not an obligation to develop or expand a health service or a health service facility, since Petitioners represent that CRTC will continue to operate at the same

location in a manner that is the same in all material respects as it operated prior to the transaction. In addition, pursuant to S.L. 2005-325, oncology treatment centers are not “health service facilities” for purposes of the CON law.

Finally, on the specific facts of this case, the transaction proposed by Petitioners is not “a capital expenditure . . . which relates to the provision of a health service” within the meaning of N.C.G.S. § 131E-176(16)b. The definition of “health service” specifically “does not include administrative and other activities that are not integral to clinical management.” Petitioners’ representations indicate that stock ownership of CRTC is not integral to the clinical management of CRTC, because in all material respects the operations of CRTC will not change.

I specifically except from this Ruling any conclusions as to the status or legality of the ownership of a purported second linear accelerator by CRTC. The Department has no notice of the existence or ownership of the second linear accelerator, and I make no finding that CRTC may acquire or operate, or has properly acquired and operated, a second linear accelerator without CON review.

### **CONCLUSION**

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Petitioners of 100% of the outstanding and issued stock of CRTC, in the manner represented by Petitioners in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, CRTC continues to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of CRTC with respect to the requirements of the CON law as it relates to CRTC. The ruling is limited to the specific facts presented in the Request. It specifically does not address the status of any linear accelerator that CRTC may own or claim to own.

This \_\_\_\_ day of \_\_\_\_\_, 2007.

---

Robert J. Fitzgerald, 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:

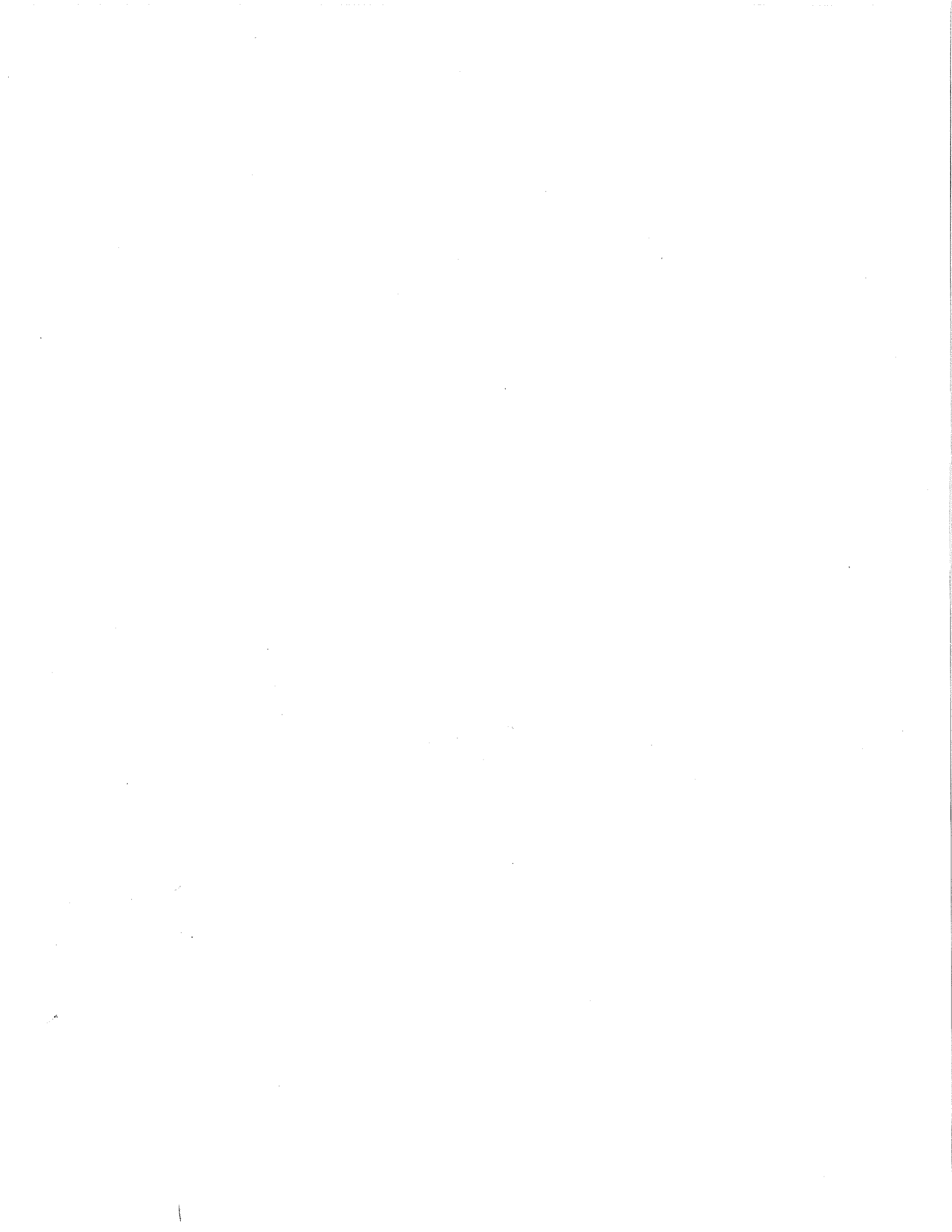
**CERTIFIED MAIL**

Susan H. Hargrove  
Smith, Anderson, Blount, Dorsett,  
Mitchell & Jernigan, L.L. P  
P.O. Box 2611  
Raleigh, NC 27602-2611

This \_\_\_\_\_ day of \_\_\_\_\_, 2007.

---

Jeff Horton  
Chief Operating Officer





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

Maureen Demarest Murray  
 Smith, Moore, Leatherwood  
 300 N. Greene Street, Suite 1400  
 Greensboro, NC 27401

RE: No Review / WakeMed / Acquisition of ownership interests of CSA-1, owners of five heart-lung bypass machines located at WakeMed / Wake County  
 FID #: 943528

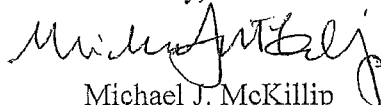
Dear Ms. Murray:


The Certificate of Need (CON) Section received your letter of February 8, 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. McKillip  
 Project Analyst

  
 Craig R. Smith, Chief  
 Certificate of Need Section

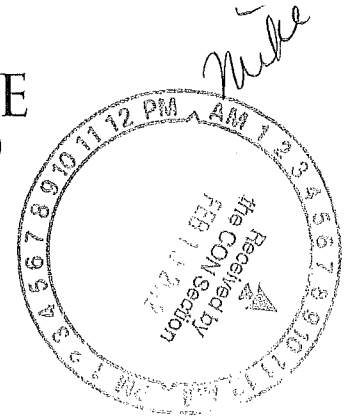






# SMITH MOORE LEATHERWOOD

February 8, 2012



*Via E-Mail and U.S. Mail*

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

Re: WakeMed Acquisition of Ownership Interests in CSA-1

Dear Mr. Smith and Ms. Frisone:

We represent WakeMed. 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 WakeMed's acquisition of the ownership interests of CSA-1 is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law. CSA-1 is a wholly owned sub of CSA Medical, LLC ("CSA") and owns five (5) heart lung bypass ("HLB") machines that have been and are operated at WakeMed. WakeMed would acquire the membership interests in CSA-1, which would continue to exist as a legal entity and to own the five (5) HLB machines that would remain located and operated at WakeMed.

The Agency has issued numerous declaratory rulings and no review letters that acknowledge that acquisition of ownership interests 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 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.*


Mr. Craig R. Smith, Chief  
Ms. Martha Frisone, Assistant Chief  
February 8, 2012  
Page 2

Similarly, the Department approved the sale of 100% of the issued and outstanding stock of 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 stock purchase transaction. *See Declaratory Ruling, In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. and North Carolina Radiation Therapy Management Services, Inc.*, September 14, 2007.

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,

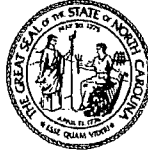
SMITH MOORE LEATHERWOOD LLP

A handwritten signature in cursive script that reads "Maureen Demarest Murray".

Maureen Demarest Murray

cc: Stan Taylor, WakeMed





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/dhss/>

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



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

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

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

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

# K&L|GATES

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

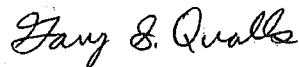
definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Stock or membership interest ownership is not integral to clinical management. *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc., January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

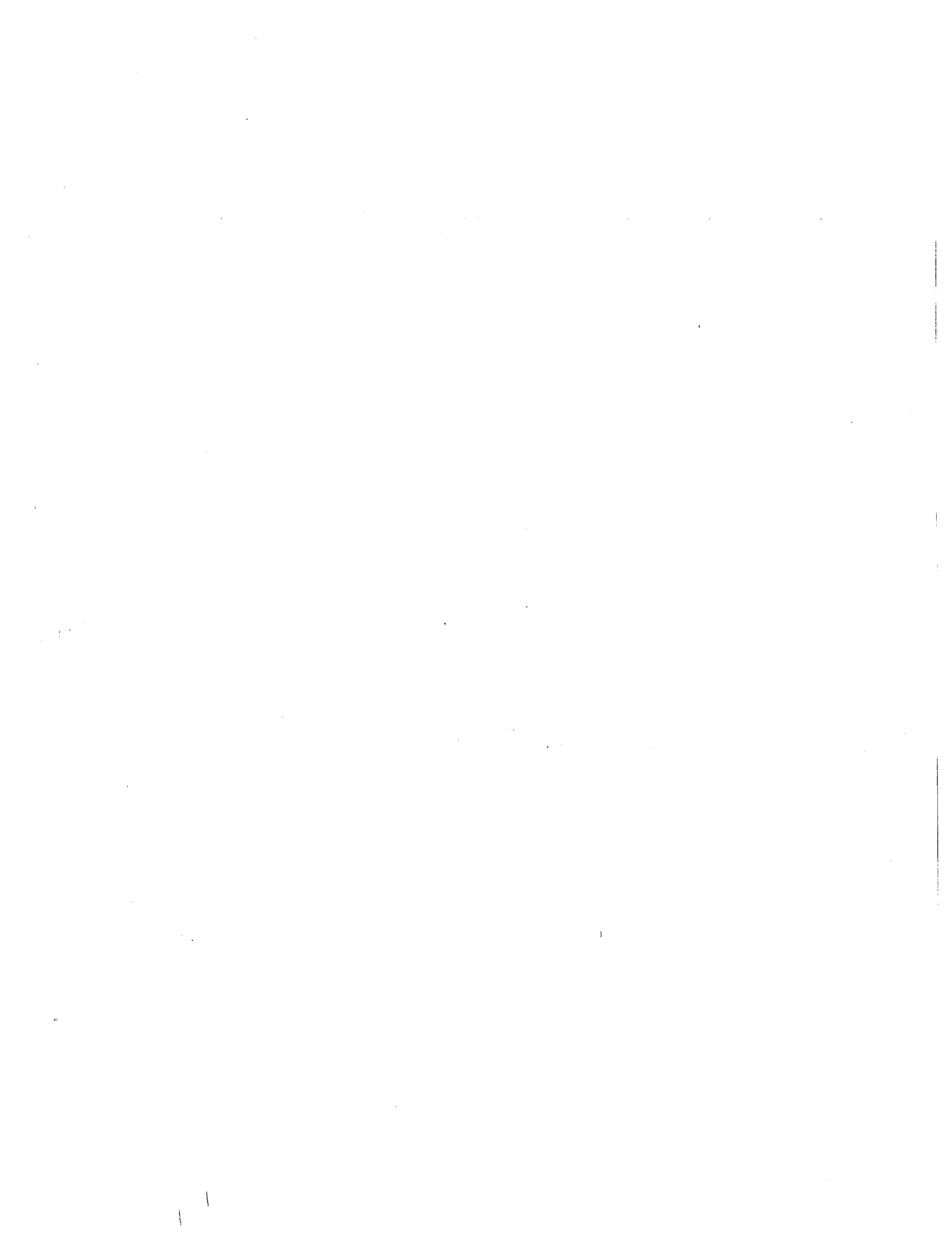
We would appreciate written confirmation from you that the anticipated transaction does not require CON review. If you require additional information to consider this request, please contact us. We appreciate your consideration.

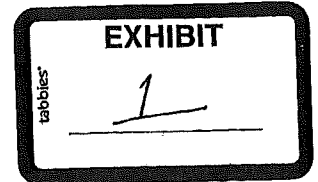
Sincerely yours,

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



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

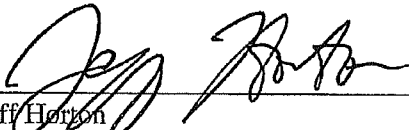
**CERTIFICATE OF SERVICE**

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