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

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/21st 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. § 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