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

IN RE: REQUEST FOR DECLARATORY	)	
RULING BY CAROMONT HEALTH, INC.	)	
AND GASTON MEMORIAL HOSPITAL,	)	
INC. d/b/a GASTON MEMORIAL HOSPITAL	)	
AND LINCOLN RADIATION ONCOLOGY	)	DECLARATORY RULING
ASSOCIATES, LLC d/b/a LINCOLN	)	
RADIATION ONCOLOGY CENTER	)	
Project I.D. No. F-8585-10	)	
Project I.D. No. F-8116-08	)	

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.

CaroMont Health, Inc. and Gaston Memorial Hospital, Inc. d/b/a Gaston Memorial Hospital (collectively, "CaroMont") and Lincoln Radiation Oncology Associates, LLC d/b/a Lincoln Radiation Oncology Center ("LROA") (collectively, the "Parties") have requested a declaratory ruling allowing the parties to refurbish an existing linear accelerator which is currently located at Gaston Memorial Hospital ("GMH") and relocate it to Lincolnton, instead of purchasing a new linear accelerator for Lincolnton, as described in Project I.D. Nos. F-8585-10 and F-8116-08. This ruling will be binding upon the Department and the entity 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. Wallace C. Hollowell, III of Nelson Mullins Riley & Scarborough LLP has requested this ruling on behalf of the Parties and has provided the material facts upon which this ruling is based.

### STATEMENT OF THE FACTS

In a CON application filed on September 15, 2010, CaroMont proposed to acquire a replacement linear accelerator and replacement CT simulator in Gaston County. The CON Section conditionally approved that application on December 9, 2010. The CON Section issued a CON to CaroMont effective January 9, 2011, authorizing it to acquire a Varian True Beam linear accelerator to replace the Varian 21EX linear accelerator currently located at GMH (the "CaroMont Project").

In a separate CON application filed on May 15, 2008, LROA, a joint venture between CaroMont and Radiation Oncology Centers of the Carolinas, Inc., proposed to acquire an existing linear accelerator from GMH through ownership transfer, replace the linear accelerator, and relocate the new linear accelerator to Lincolnton, in Lincoln County (the "LROA Project"). As part of the LROA Project, LROA proposed that the linear accelerator it would acquire from GMH would be a Philips SL75-5. LROA would then replace the Philips machine by purchasing a new Varian Clinac to be located in Lincolnton. LROA would dispose of the Philips by removing it from the state. A CON was issued on October 27, 2008, authorizing development of the project.

CaroMont first proposes that in Lincolnton, instead of the proposal in the LROA application to acquire the Philips machine from GMH and replace it with a newly purchased Varian Clinac, LROA will instead acquire the 21EX linear accelerator from GMH and refurbish that machine. LROA would then relocate that refurbished 21EX to Lincoln County.

CaroMont next proposes that instead of disposing of the existing Varian 21EX upon installation of the True Beam machine, as is a condition of CON approval for the CaroMont Project, it be allowed to transfer ownership of the 21EX to LROA, so that it can be refurbished and relocated to Lincoln County. Instead of replacing the 21EX with the True Beam machine as originally proposed in the CaroMont application, CaroMont would instead replace the Philips machine with the True Beam machine. This means that the Philips machine would not be acquired by LROA as originally proposed, but would be retained by CaroMont and replaced with the True Beam.

#### **ANALYSIS**

N.C.G.S. § 131E-181(a) states:

A certificate of need shall be valid only for the defined scope, physical location, and person named in the application.

N.C.G.S. § 131E-181(b) further provides that:

A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need. The Department shall require any recipient of a certificate of need, or its successor, whose service is in operation to submit to the Department evidence that the recipient, or its successor, is in material compliance with the representations made in its application for the certificate of need which granted the recipient the right to operate that service.

Thus, the CON law requires a full review of Petitioners' proposal when it represents a material change in the physical location, scope of the project or person named in the application. The proposed changes do not constitute material changes in the physical location or the scope of the proposed projects for the following reasons.

In the aggregate, instead of acquiring two machines through the two CON approvals (the True Beam at GMH and the Clinac at LROA) and disposing of two machines (the Philips and the 21EX, both at GMH), the parties will acquire only one machine (the True Beam), will dispose of one machine (the Philips), and will refurbish one machine (the 21EX). Thus, in both scenarios, the inventory of linear accelerators will not increase.

These proposed changes will not increase any of CaroMont's or LROA's charges to the public or operating costs.

These proposed changes will not change the scope of services to be offered by CaroMont, LROA or GMH at their facilities.

Based on the quotations obtained by CaroMont for these two alternatives, the proposal described herein would save a total of \$2,103,559 for CaroMont and LROA.

N.C.G.S. § 131E-189(b) allows the Agency to withdraw the Certificates of Need for CaroMont and LROA if they fail to develop the service in a manner consistent with the representations made in the application or with any conditions that were placed on the CON. CaroMont and LROA will not be developing their projects in a manner that is materially different from the representations made in their applications, nor will they be developing their projects in a manner that is inconsistent with any of the conditions that were placed on its CON.

### **CONCLUSION**

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the CaroMont and LROA Projects, described herein, will not and do not constitute material changes in the physical location or scope of the project, will not violate N.C.G.S. § 131E-181, and will not and do not constitute a failure to satisfy a condition of the CON in violation of N.C.G.S. § 131E-189(b).

This the day of June, 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 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**

Wallace C. Hollowell, III Nelson Mullins Riley & Scarborough, LLP GlenLake One, Suite 200 4140 Parklake Avenue Raleigh, NC 27612

This the	day of June, 2011.	
	T. CCAT.	
	Jeff Horton	
	Chief Operating Officer	