

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

**IN RE: REQUEST FOR DECLARATORY RULING    )**  
**BY THE PRESBYTERIAN HOSPITAL            ) DECLARATORY RULING**  
**Project I.D. No. F-7518-06                 )**

I, Jeff Horton, as Acting 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 Presbyterian Hospital (“TPH”) has requested a declaratory ruling allowing for a relocation of its fixed linear accelerator for Project I.D. No. F-7518-06 on the grounds that this change does not constitute a material change in physical location or a failure to materially comply with the representations made by TPH in its Certificate of Need (“CON”) application for its project. N.C.G.S. §§ 131E-181(a) and (b). 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. Denise M. Gunter, of Nelson Mullins Riley & Scarborough, LLP, has requested this ruling on behalf of TPH and has provided the material facts upon which this ruling is based. Some of the facts are based on information from the files of the Department.

## STATEMENT OF THE FACTS

The 2006 State Medical Facilities Plan (“SMFP”) contained a need determination for one linear accelerator in Service Area 7, which was comprised of Mecklenburg, Anson and Union Counties. Four applicants (TPH, CMC-Union, Pineville Radiation Therapy, LLC and Radiation Oncology Centers of the Carolinas, Inc.) submitted applications in response to the linear accelerator need determination. The CON Section approved the CMC-Union application and disapproved the applications of the three other applicants. TPH and Pineville Radiation Therapy Center, LLC appealed the CON Section’s decision. The parties reached a settlement whereby a CON was issued to CMC-Union for its project and TPH was required to demonstrate that it had installed and operationalized a refurbished linear accelerator at TPH for less than \$750,000. Once TPH met the requirements of the settlement agreement, the CON Section issued a CON, effective 28 October 2008, to TPH to replace the refurbished linear accelerator and relocate the replacement linear accelerator to the Ballantyne area of Mecklenburg County, Project I.D. No. F-7518-06.

According to TPH, Project I.D. No. F-7518-06 has not yet been developed and the linear accelerator has not yet been installed at the Ballantyne site. In this request, TPH seeks to relocate its linear accelerator, Project I.D. No. F-7518-06, from the Ballantyne site to a freestanding building on the campus of Presbyterian Hospital Matthews (“Matthews”) located at 1500 Matthews Township Parkway, Matthews, in Mecklenburg County (the “Matthews Site”). TPH proposes to build a linear accelerator vault, with associated waiting room, support space and exam space next to the facility owned by the Southeast Radiation Oncology Group, P.A. (“SERO”) located on the Matthews campus. Although the TPH facility on the Matthews campus would share a common wall with the SERO facility, the TPH facility would have its own

separate entrance, check-in, reception, waiting room space, linear accelerator vault, exam rooms, dressing rooms, utility room, nurses' station and physics consultation room. TPH would be the sole owner of the space and the linear accelerator in that space. There are no ownership changes planned as part of this request. Likewise, this request does not propose a joint venture between SERO and TPH. The linear accelerator, Project I.D. No. F-7518-06, will continue to be operated under the license for TPH.

TPH states that the Matthews Site is approximately 12 miles and 17 minutes from the original Ballantyne site. TPH also states that the linear accelerator is needed to assist in handling the high number of radiation therapy cases currently being handled by the SERO linear accelerator located on the Matthews campus. TPH represents that there is overlap between the service area proposed in its original CON application for the Ballantyne location and the proposed Matthews Site service area and that the linear accelerator will be available to all residents of Mecklenburg County.

The approved capital cost for Project I.D. No. F-7518-06 was \$3,774,484. N.C. Gen. Stat. § 131E-176(16)e allows project costs to increase up to 15% of the approved capital cost before a new CON is required. In this case, the maximum amount before a new CON is required is \$4,340,656.60. According to the revised capital cost sheet submitted by TPH, the revised capital cost is \$4,072,818.00. This is \$267,838.60 less than the 15% cost overrun limit contained in N.C. Gen. Stat. § 131E-176(16)e. TPH further represents that there will be no increases in costs or charges to the public for the provision of radiation oncology services as a result of this site change.

## **ANALYSIS**

The CON law would require a full review of TPH's proposed change of site for the linear accelerator if that change were to represent a material change in the physical location or scope of the project. N.C.G.S. § 131E-181(a). The proposed change of the site for the linear accelerator to Matthews does not constitute a material change in the physical location of the proposed project because the linear accelerator will still be located in Mecklenburg County and available to serve the patient population identified in TPH's original CON application. It will not constitute a material change in the scope of the project so long as TPH continues to materially comply with all conditions in its CON application. In addition, there is no proposed change in the person named in the application that would result in a violation of N.C.G.S. § 131E-181(a).

N.C.G.S. § 131E-189(b) allows the Agency to withdraw TPH's CON if TPH fails 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. TPH will not be developing its project in a manner that is materially different from the representations made in its application, nor will it be developing its project 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 relocation of the linear accelerator, Project I.D. No. F-7518-06, from the Ballantyne site to the Matthews Site will not constitute a material change in the physical location or scope of the project, will not violate N.C.G.S. § 131E-181, and will not constitute a failure to satisfy a condition of the CON in violation of N.C.G.S. § 131E-189(b) so long as TPH continues to materially comply with all conditions of the original CON for Project I.D. No. F-7518-06.

This ruling is not intended, and should not be interpreted, to authorize any increases in the approved capital expenditure for this project, a change in the approved timetable, a change in the conditions placed on the certificate of need, or any other change in the approved project.

This the \_\_\_\_\_ day of \_\_\_\_\_, 2009.

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Jeff Horton, Acting 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**

Denise M. Gunter  
Nelson Mullins Riley & Scarborough, LLP  
380 Knollwood Street  
Suite 530  
Winston-Salem, NC 27103

This the \_\_\_\_\_ day of \_\_\_\_\_, 2009.

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Jesse Goodman  
Acting Chief Operating Officer