

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

**IN RE: REQUEST FOR DECLARATORY )  
RULING BY NOVANT HEALTH ) DECLARATORY RULING  
PRESBYTERIAN MEDICAL CENTER )  
Project ID No. F-7518-06 )**

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.

Novant Health Presbyterian Medical Center (“Presbyterian”) has requested a declaratory ruling for authorization of a change in location of a linear accelerator from Novant Health Matthews Medical Center (“Matthews Site”) to Novant Health Huntersville Medical Center (“Huntersville Site”) for Project I.D. No. F-7518-06 on the grounds that the change does not constitute a material change in scope or physical location or a failure to materially comply with the representations made by Presbyterian in its Certificate of Need (“CON”) application for its project. N.C.G.S. §§ 131E-181(a). 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 Presbyterian and has provided the material facts upon which this ruling is based.

## STATEMENT OF THE FACTS

The 2006 State Medical Facilities Plan (“SMFP”) contained a need determination for one additional linear accelerator in Service Area 7 (Mecklenburg, Anson, and Union counties). As a result of the need determination, Presbyterian filed a CON application, Project I.D. No. F-7518-06, on March 15, 2006. Presbyterian’s application proposed to replace a refurbished linear accelerator to be installed in a medical office building in the Ballantyne area of southern Mecklenburg County. At the time, three other applicants (CMC-Union, Pineville Radiation Therapy, LLC and Radiation Oncology Centers of the Carolinas, Inc.) also filed CON applications pursuant to the 2006 SMFP linear accelerator need determination.

The CON Section approved the CMC-Union application, Project I.D. #F-7525-06, and disapproved the other applicants. Presbyterian and Pineville Radiation Therapy Center, LLC appealed the CON Section’s decision. The parties were able to reach a settlement in mediation. The settlement allowed Presbyterian to develop their proposed project, contingent upon their ability to demonstrate that Presbyterian installed and operated the refurbished linear accelerator for less than \$750,000. Presbyterian was able to successfully demonstrate to the Department that it installed and operated the refurbished linear accelerator for that amount. Therefore, the Agency issued Presbyterian a CON (Project I.D. No. F-7518-06) to replace the refurbished linear accelerator with a new linear accelerator and relocate the replacement linear accelerator to Ballantyne.

In 2009, the Department issued a declaratory ruling to Presbyterian allowing it to relocate the replacement linear accelerator from Ballantyne to the Matthews Site. Presbyterian stated that in the 2009 declaratory ruling request that the linear accelerator was needed in Matthews to assist in handling the high number of radiation therapy cases being handled by the Southeastern

Radiation Oncology Group, P.A. (SERO) linear accelerator located on the Matthews campus. However, linear accelerator growth at the Matthews Site was not substantiated. Linear accelerator volumes reported in the draft 2014 SMFP are significantly lower than the volumes reported in the 2009 SMFP.

On October 23, 2013, the Department submitted a notice of intent to consider withdrawal of a CON to Presbyterian for Project I.D. No. F-7518-06 because the project was significantly behind schedule and little to known progress had been made. Presbyterian responded to the Department's letter by submitting a comprehensive progress report (CPR) on December 16, 2013. Simultaneously, Presbyterian submitted this request for declaratory ruling. In the CPR, Presbyterian summarized the project, provided justification for delays and changes in the project and referenced this proposed declaratory ruling request to change sites as demonstration of their intent to move forward to complete the project. Presbyterian stated in the CPR, that offering of services for the linear accelerator will be March 31, 2015. Presbyterian stated in the CPR that the linear accelerator can be developed most effectively at the Huntersville Site located at 10030 Gilead Road, Huntersville, North Carolina 28072.

### **ANALYSIS**

The CON law would require a full review of Presbyterian's proposal 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 requested linear accelerator relocation does not constitute a material change in the physical location or the scope of the proposed project for the following reasons:

At the time Presbyterian proposed to locate the linear accelerator at the Matthews Site, radiation volumes on the single linear accelerator at Matthews Radiation Oncology were growing significantly. However, the growth was not sustained. There is no linear accelerator anywhere in

the Town of Huntersville or in the neighboring northern Mecklenburg towns of Cornelius and Davidson, forcing cancer patients who are being treated by Novant Health physicians to travel to Presbyterian for their radiation therapy treatments. Relocating the Presbyterian linear accelerator to the Huntersville Site would enhance the services already offered by Huntersville's growing cancer program, and meet the needs of the growing cancer patient population in that area. The population around the Matthews Site, which was approved in the 2009 declaratory ruling, is significantly smaller than that at the Huntersville Site, and the existing linear accelerator in Matthews has experienced volume decreases. Presbyterian will not incur any additional cost to develop the linear accelerator at the Huntersville Site. There will be no increases in costs or charges to the public as a result of the declaratory ruling request. There is no ownership change proposed. The only change being proposed is a location change. The Ballantyne area, the Matthews Site, and the Huntersville Site are all in Mecklenburg County therefore the linear accelerator will remain in linear accelerator Service Area 7 (Mecklenburg, Anson, and Union counties). The linear accelerator can be developed and operated at the Huntersville Site in substantial material compliance with all aspects of Presbyterian's application including any applicable settlement materials.

N.C.G.S. § 131E-189(b) allows the Agency to withdraw Presbyterian's CON if Presbyterian 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. Presbyterian 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 Presbyterian's proposal to change sites for the replacement and relocation of a linear accelerator from 1500 Matthews Township Parkway in Matthews to 10030 Gilead Road in Huntersville does not constitute a material change in the physical location or scope of the project, does not violate N.C.G.S. § 131E-181, and does not constitute a failure to satisfy a condition of the CON in violation of N.C.G.S. § 131E-189(b).

The Certificate of Need Section has extended the timetable for the project documented in the Department's acknowledgement of receipt of progress report letter dated December 20, 2013. The approved timetable for the project is as follows:

<b><u>Milestone</u></b>	<b><u>Completion Date</u></b>
Schematic Design Review & Sign-off Design Development	March 17, 2014
Design Development Review & Sign-off Construction Documents	April 21, 2014
Construction Documents Submitted to Construction, DHSR	June 9, 2014
Contract award	July 7, 2014
Ordering of medical equipment	September 8, 2014
25% completion of construction	September 8, 2014
50% completion of construction	November 10, 2014
75% completion of construction	January 12, 2015
Completion of construction	March 16, 2015
Offering services	March 31, 2015

Presbyterian will be held to the March 31, 2015 offering of services date and Huntsville Site location with no exceptions for additional timetable extensions or site relocations. The Department does not intend to approve any additional changes to the timetable or location of the project.

This the \_\_\_\_\_ day of February, 2014.

---

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

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that I have this day served the foregoing Declaratory Ruling upon the nonagency party by certified mail, return receipt requested, by causing a copy of same to be placed in the United States Mail, 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, North Carolina 27103

This the \_\_\_\_\_ day of February, 2014.

---

Cheryl Ouimet  
Chief Operating Officer