

**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, INC. AND)
FORSYTH MEMORIAL HOSPITAL, INC.) DECLARATORY RULING
d/b/a FORSYTH MEDICAL CENTER)
Project ID No. G-8129-08)**

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.

Novant Health, Inc. (“Novant”) and Forsyth Memorial Hospital, Inc., d/b/a Forsyth Medical Center (“Forsyth”) (collectively “Petitioners”) have requested a declaratory ruling that would allow the acquisition of a mobile positron emission tomography (“PET”) / computed tomography (“CT”) scanner rather than the originally proposed fixed site PET scanner, contending that such acquisition would not constitute a change in scope for purposes of N.C. Gen. Stat. § 131E-181 of the certificate of need (“CON”) law, and that the location change would not affect Forsyth’s material compliance with representations made in the CON application or the conditions imposed upon the CON. The CON law would require a full review of Forsyth’s proposal if it represented a material change in the physical location or scope of the project. N.C. Gen. Stat. § 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 Novant and Forsyth, and has provided the material facts upon which this ruling is based.

Comments in opposition to this request were received by the following:

- (1) Terrill Johnson Harris, of Smith Moore Leatherwood LLP, on behalf of Cone Health.
- (2) David J. French on behalf of Alliance Imaging Inc.

STATEMENT OF THE FACTS

The 2008 State Medical Facilities Plan (“SMFP”) contained two need determinations for fixed site PET scanners: one for Health Service Area (“HSA”) II and one for HSA III. On November 13, 2008, the CON section issued a CON to Novant and Forsyth to acquire a fixed site PET/CT scanner to be installed at the Forsyth facility located at 3333 Silas Creek Parkway, Winston-Salem, NC 27103, known as Project ID No. G-8129-08. According to Novant and Forsyth, this project has not yet been implemented. Carolinas Medical Center – Union (“CMC – Union”) received the CON allowing acquisition of a fixed site PET scanner for HSA III. The 2008 SMFP concluded there was no need for any mobile PET scanners anywhere in the state.

Rather than acquire a fixed site PET/CT scanner, Petitioners seek to acquire a mobile PET/CT scanner that would be operated at Forsyth as authorized by the previously issued CON, but, in addition, would be operated at Thomasville Medical Center (“Thomasville”) located in Davidson County, Rowan Regional Medical Center (“Rowan”) located in Rowan County, and Kernersville Medical Center (“Kernersville”) located in Forsyth County, each of which is owned by Novant.

ANALYSIS

N.C. Gen. Stat. § 131E-181(a) provides that a CON “shall be valid only for the defined scope, physical location, and person named in the application.” Petitioners’ proposal to acquire a mobile PET/CT scanner must be denied based upon the provisions of N.C. Gen. Stat. § 131E-181(a).

The proposal constitutes a material change in the physical location and scope of the proposed project. As set forth in the factual statement above, Project ID No. G-8129-08 originally contemplated utilization of a fixed PET/CT scanner at the Forsyth facility located in Winston-Salem. Petitioners now propose utilization of a mobile scanner at the Forsyth facility in addition to the Thomasville, Rowan, and Kernersville facilities.

Pursuant to the 2008 SMFP, under which Petitioners originally acquired a fixed PET/CT scanner for HSA II, “there is no need for any additional mobile dedicated PET scanners anywhere in the state.” 2008 SMFP at 117. In fact, there has not been a need for any additional mobile PET scanners anywhere in the state since Petitioners’ application for the fixed PET/CT scanner. *See* 2009 SMFP at 133, 2010 SMFP at 139, 2011 SMFP at 143. Similarly, the proposed 2012 SMFP concludes there is no need for any additional mobile PET scanners in the state. In addition, CMC-Union was awarded the CON to acquire a fixed site PET scanner to serve the need identified in the 2008 SMFP for HSA III.

Not only does the methodology prevent additional acquisitions of mobile PET scanners, acquiring a mobile PET scanner would constitute a material change in the scope of the project as well as the physical location of the project given the proposed mobile sites. Petitioners’ contention that the mobile scanner would simply serve the same population originally proposed for the fixed scanner is without merit. In the same manner that Petitioners anticipated that

residents of Rowan County would travel to the fixed scanner in Forsyth County, it is reasonable to anticipate that locating a mobile scanner in Rowan County would extend the radius of potential patients far beyond the borders of Rowan County into territory that was not included in Petitioners' original proposal.

Petitioners' proposal constitutes a material change in the physical location and scope of the project and must be denied.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the proposal to acquire a mobile PET/CT scanner rather than a fixed site PET/CT scanner constitutes a material change in the physical location and scope of the project, violates N.C. Gen. Stat. § 131E-181, and, therefore, must be denied.

This the _____ day of October, 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

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

This the _____ day of October, 2011.

Jeff Horton
Chief Operating Officer