

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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY NORTH CAROLINA BAPTIST) DECLARATORY RULING
HOSPITAL)
Project I.D. No. F-943495)**

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.

North Carolina Baptist Hospital (hereinafter “NCBH”) has requested a declaratory ruling to allow it to temporarily replace the clinical PET/CT scanner it currently uses for diagnostic and clinical purposes with another, separate, PET/CT that it operates in its Radiation Oncology Department for treatment planning and research purposes.

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. S. Todd Hemphill of Bode, Call & Stroupe, LLP has requested this ruling on behalf of NCBH and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

NCBH received a certificate of need for and operates a clinical PET/CT scanner, which is used for diagnostic and clinical purposes (“Clinical PET/CT”). NCBH also received a certificate of

need pursuant to Policy AC-3 in the State Medical Facilities Plan for a separate PET/CT scanner in the Radiation Oncology Department (“AC-3 PET/CT”), for treatment planning only (i.e., simulation). The Clinical PET/CT is being relocated from the PET Center to the Radiology Department, located in Reynolds Tower. This declaratory ruling requests approval to temporarily replace the Clinical PET/CT with the AC-3 PET/CT for approximately 6 weeks in the Spring of 2010, while the Clinical PET/CT is moved from the PET Center to Reynolds Tower. Once the Clinical PET/CT has been installed in Reynolds Tower, it will once again be used for diagnostic and clinical purposes and the AC-3 PET/CT will be used only for treatment planning.

ANALYSIS

N.C. Gen. Stat. §131E-181 (a) states “A *certificate of need shall be valid only for the defined scope, physical location, and person named in the application.*” However, the Agency has allowed approved applicants to change the physical location named in their application where convenience dictates or the objectives of the CON law are otherwise advanced. This request to approve the temporary replacement of the Clinical PET/CT with the AC-3 PET/CT does not constitute a new institutional health service for the reasons set forth below.

NCBH proposes to use the AC-3 PET/CT as a temporary replacement for the Clinical PET/CT for a limited 6-week period of time, while the Clinical PET/CT is de-installed from the PET Center and relocated to Reynolds Tower. NCBH does not intend to use the AC-3 PET/CT for non-research clinical purposes on a permanent basis. Once the relocation is complete and the Clinical PET/CT is operational again, the AC-3 PET/CT will cease to provide clinical scans and will return to the sole use of treatment planning and research, pursuant to the Policy AC-3 in the SMFP and the original certificate of need.

“Replacement equipment,” is defined in G.S. 131E-176 (22a) as:

“equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.”

NCBH projects that the total cost associated with moving the Clinical PET/CT will be \$114,900, which is substantially less than \$2,000,000. The Clinical PET/CT and the AC-3 PET/CT are comparable. The issue is whether the equipment will be “disposed of.” In this instance, the proposal will not result in an increase in the inventory of PET/CT scanners, which is the intent of the “disposed of” language.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request are true, I conclude that NCBH is not required to first obtain a Certificate of Need in order to temporarily use the AC-3 PET/CT in place of the Clinical PET/CT for a period of six weeks, to occur approximately between February 1, 2010 and March 15, 2010, while the Clinical PET/CT is being relocated from the PET Center to the Reynolds Tower.

This the _____ day of February, 2010.

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 a first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

S. Todd Hemphill
Bode, Call & Stroupe, LLP
3105 Glenwood Avenue, Suite 300
Raleigh NC 27612

This the _____ day of February, 2010.

Jesse Goodman
Acting Chief Operating Officer