

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

IN RE: REQUEST FOR)	
DECLARATORY RULING BY)	
PRESBYTERIAN HOSPITAL)	DECLARATORY RULING
MATTHEWS and THE PRESBYTERIAN)	
HOSPITAL)	

I, Jeff Horton, Acting Director of the Division of Health Service Regulation (the “Department” or the “Agency”), hereby issue this declaratory ruling to Presbyterian Hospital Matthews (“PHM”) and The Presbyterian Hospital (“TPH”) (collectively “Petitioners”) pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. Petitioners have filed a Declaratory Ruling Request (the “Request”) asking the Department to issue a ruling as to the applicability of Chapter 131E, Article 9 of the North Carolina General Statutes to the facts described below. For the reasons given below, I conclude that I must deny Petitioners’ requested ruling.

This ruling is binding on the Department and the person requesting it if the material facts stated in the Request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department reserves the right to change the conclusions which are contained in this ruling. Denise M. Gunter of Nelson Mullins Riley and Scarborough, LLP has requested this ruling on behalf of Petitioners and has provided the statement of facts upon which this ruling is based. Certain other facts are based on the Department’s files. The material facts are set out below.

STATEMENT OF THE FACTS

Effective 29 July 1983, the CON Section issued a CON to TPH for Project I.D. No. F-1810-83 for a new cardiac catheterization service at its hospital in Charlotte. In the CON application for the cardiac catheterization project TPH stated “Space exists to meet a requirement of open heart surgery capability, and an application will be submitted for this service at the appropriate time.” In fact, TPH submitted an application (Project I.D. No. F-1803-83) requesting approval to develop open heart surgery and a separate CON was issued to TPH effective July 29, 1983, for a new open heart surgery service at its hospital in Charlotte. Petitioners represent that the cardiac catheterization machine acquired as part of Project I.D. No. F-1810-83 was installed in “Cath Lab #1” at TPH and was replaced in 1996 pursuant to a replacement equipment exemption.

Effective 17 November 1999, the CON Section issued a CON to PHM, lessor, and TPH, lessee, for Project I.D. No. F-5978-99 allowing TPH to acquire one cardiac catheterization machine to be installed and operated in leased space at PHM in Matthews. Petitioners stated in their CON application for Project I.D. No. F-5978-99 that PHM did not provide open heart surgery and that the proposed cardiac catheterization machine would be used to perform only diagnostic cardiac catheterization procedures and not therapeutic cardiac catheterization procedures.

On 30 July 2007, Petitioners were authorized to replace the original cardiac catheterization machine located at PHM which was acquired as part of Project I.D. No. F-5978-99 because they demonstrated compliance with exemption requirements for replacement equipment. Petitioners represent that, pursuant to this exemption, TPH acquired and installed a replacement cardiac catheterization machine which is capable of performing therapeutic and

diagnostic cardiac catheterizations at PHM. TPH did not state in its request for the replacement equipment exemption that the new equipment would be used to perform therapeutic cardiac catheterization procedures.

In this request for a declaratory ruling, Petitioners state that they propose a “virtual” relocation of Cath Lab #1 from TPH to PHM in which the CON which is held by TPH for Cath Lab #1 is transferred to PHM but the equipment physically remains at TPH. Petitioners represent that they propose this “virtual” relocation in order to be able to perform therapeutic cardiac catheterization services at PHM using the equipment already located at PHM.

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 proposal by Petitioners to “virtually” relocate Cath Lab #1 from TPH to PHM in order for the Petitioners to perform therapeutic cardiac catheterization procedures on the existing equipment located at PHM represents a change in the scope of both projects and a change in the

physical location of the approved services and CON issued for Project I.D. No. F-1803-83. The proposed “virtual relocation” also constitutes a failure to materially comply with the representations made by Petitioners in the two CON applications.

Project I.D. No. F-1810-83

The criteria and standards for cardiac catheterization equipment set forth in 10 N.C.A.C. 03R.1608(a), which was in effect when TPH originally submitted its CON application for Project I.D. No. F-1810-83, provided, in pertinent part, that:

A proposal to establish a new cardiac catheterization service will not be approved unless the hospital also provides open-heart surgery in the facility, or proposes to and will be able to offer open-heart surgery in the facility within three years of the catheterization project’s initiation.

TPH stated in its CON application for Project I.D. No. F-1810-83 that, “space exists to meet a requirement of open heart surgery capability, and an application will be submitted for this service at the appropriate time.” TPH submitted an application and received a CON effective July 29, 1983 to develop and offer open heart surgery services. Because TPH represented in its CON application that it would provide open-heart surgery services in the hospital in which the cardiac catheterization services would be provided, the Agency determined the application was conforming to the applicable criteria and standards and issued a CON to TPH for the proposed cardiac catheterization service. No information was provided by Petitioners in the Request that documents open heart surgery services are currently available at PHM. The proposed transfer or “virtual relocation” of the CON issued for Project I.D. No. F-1810-83 from TPH’s hospital in Charlotte to PHM’s hospital in Matthews would be a change in scope of the project and would not be in material compliance with representations made by TPH in its application because open heart surgery services are not provided at PHM. Further, the change in location of the CON

from a hospital in Charlotte which provides open heart surgery to a hospital in Matthews which does not provide open heart surgery services constitutes a material change in location of the CON and the proposed cardiac catheterization service.

Project I.D. No. F-5978-99

The criteria and standards for cardiac catheterization equipment that are currently in effect are set forth in 10A N.C.A.C. 14C .1604, and provide:

- (a) If the applicant proposes to perform therapeutic cardiac catheterization procedures, the applicant shall demonstrate that open heart surgery services are provided within the same facility.
- (b) If the applicant proposes to perform diagnostic cardiac catheterization procedures, the applicant shall document that its patients will have access to a facility which provides open heart surgery services, and that the patients can be transported to that facility within 30 minutes and with no greater risk than if the procedure had been performed in a hospital which provides open heart surgery services; with the exception that the 30 minute transport requirement shall be waived for equipment that was identified as needed in the State Medical Facilities Plan based on an adjusted need determination or the determination of a need for shared-fixed cardiac catheterization equipment.

Petitioners stated in their CON application for Project I.D. No. F-5978-99 that PHM did not provide open heart surgery services and that the proposed cardiac catheterization machine would be used to perform only diagnostic cardiac catheterization procedures, and not therapeutic procedures. Because Petitioners represented in their CON application that they proposed to perform only diagnostic cardiac catheterization procedures, they were not required to demonstrate open heart surgery services are provided in the same facility. Instead, Petitioners only had to document that the patients at PHM would have access to a facility within a reasonable distance that provides open heart surgery services pursuant to the requirements in 10A N.C.A.C. 14C .1604(b).

Petitioners argue that no condition was placed upon the 1999 CON issued for Project I.D. No. F-5978-99 which addressed any limitation on the types of procedures which could be performed using the approved cardiac catheterization equipment. Petitioners' contention is incorrect. The CON for Project I.D. No. F-5978-99 contained the condition that Petitioners "shall materially comply with all representations made in its Certificate of Need Application except as amended by supplemental information submitted September 15 and 28, 1999." All of the representations made by Petitioners in their application were that the proposed cardiac catheterization equipment physically located at PHM would be utilized to perform only diagnostic procedures, not therapeutic procedures. Neither the supplemental information submitted September 15 and 28, 1999 nor any of the information provided by Petitioners in this Request documents that open heart surgery services are currently available at PHM. Therefore, Petitioners' proposal to "virtually" relocate Cath Lab #1 and offer therapeutic cardiac catheterization services at PHM would constitute a change in the scope of services offered at PHM and, therefore, a change in the scope of Project I.D. No F-5978-99. Also, the "virtual relocation" of Cath Lab #1 and consequent addition of therapeutic cardiac catheterization services at PHM would constitute a failure to comply with the representations in the CON application for Project I.D. No. F-5978-99.

Petitioners further contend that because there have been numerous advancements in cardiac care and cardiac catheterization technology since 1999, therapeutic catheterizations can be safely and effectively performed in a hospital that does not have on-site open heart back up. Petitioners cited two professional articles, which they attached to the Request, in support of their position. However, these articles are unpersuasive. The authors of one of the articles specifically note that they "do not support the wide-spread use of PCI [percutaneous coronary

intervention] without on-site surgery especially in the United States, but acknowledge that this practice may be appropriate in some circumstances.” In addition, the authors of the other article Petitioners cite point out that “disagreement exists about whether hospitals with cardiac catheterization laboratories, but without onsite cardiac surgery, should develop PCI programs.” Regardless, the criteria and standards for cardiac catheterization equipment in 10A N.C.A.C. 14C .1604, are still in effect and are required to be applied in every review of a CON application for new cardiac catheterization equipment.

CONCLUSION

For all the foregoing reasons, I conclude that Petitioners’ proposal to add therapeutic cardiac catheterization services at PHM by “virtually” relocating the new cardiac catheterization service which was authorized as part of Project I.D. No. F-1810-83 (referred to by Petitioners as Cath Lab #1) from TPH to PHM would constitute:

(1) a material change in the scopes of both Project I.D. Nos. F-5978-99 and F-1810-83 in violation of N.C. Gen. Stat. § 131E-181(a);

(2) a material change in the location of Project I.D. No. F-1810-83 in violation of N.C. Gen. Stat. § 131E-181(a);

(3) a failure to comply with the representations made in Petitioners’ CON applications for both Project I.D. Nos. F-5978-99 and F-1810-83 in violation of N.C. Gen. Stat. § 131E-181(b).

For the foregoing reasons, I conclude that Petitioners’ request for declaratory ruling must be denied.

This the _____ day of _____, 2009.

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-Suite 530
Winston-Salem, NC 27103

This the _____ day of _____, 2009.

Jesse Goodman
Acting Chief Operating Officer