

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

IN RE: REQUEST FOR)
DECLARATORY RULING BY) **DECLARATORY RULING**
PRIVATE DIAGNOSTIC CLINIC, P.L.L.C.)

I, Robert J. Fitzgerald, Director of the Division of Facility Services (the “Department”), hereby issue this declaratory ruling to the Private Diagnostic Clinic, P.L.L.C. (“PDC”) 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. PDC has filed a Declaratory Ruling Request (the “Request”) asking the Department to issue a ruling as to the applicability of N.C.G.S. § 131E-178(a) to the facts described below. For the reasons given below, I conclude that PDC may be licensed as an ambulatory surgical facility without first having to obtain a Certificate of Need (“CON”).

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. Wallace C. Hollowell, III of Nelson Mullins Riley & Scarborough, LLP, has requested this ruling on behalf of PDC and has provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for PDC are set out below.

STATEMENT OF THE FACTS

N.C.G.S. 131E-178(a), effective 31 August 2005, states:

No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department; provided, however, no person who provides gastrointestinal endoscopy procedures

in one or more gastrointestinal endoscopy rooms located in a nonlicensed setting, shall be required to obtain a certificate of need to license that setting as an ambulatory surgical facility with the existing number of gastrointestinal endoscopy rooms, provided that:

(1) The license application is postmarked for delivery to the Division of Facility Services by December 31, 2006;

(2) The applicant verifies, by affidavit submitted to the Division of Facility Services within 60 days of the effective date of this act, that the facility is in operation as of the effective date of this act or that the completed application for the building permit for the facility was submitted by the effective date of this act;

(3) The facility has been accredited by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of Ambulatory Surgical Facilities by the time the license application is postmarked for delivery to the Division of Facility Services of the Department; and

(4) The license application includes a commitment and plan for serving indigent and medically underserved populations.

All other persons proposing to obtain a license to establish an ambulatory surgical facility for the provision of gastrointestinal endoscopy procedures shall be required to obtain a certificate of need. The annual State Medical Facilities Plan shall not include policies or need determinations that limit the number of gastrointestinal endoscopy rooms that may be approved.

PDC states that it opened a physician office building (the "Facility") in June 2006. The Facility is located at 10441 Moncreiffe Road, Suite 101, Raleigh, Wake County. The Facility contains physician offices and two gastrointestinal endoscopy rooms.

In anticipation of opening the Facility and in an effort to comply with N.C.G.S. § 131E-178(a)(2), PDC states that it submitted an affidavit to the Department on 19 October 2005, verifying that the completed application for the building permit for the Facility was submitted by the effective date of the act.

On 23 June 2006, PDC submitted an ambulatory surgical facility license application for the Facility. The application, postmarked before 31 December 2006, included a commitment and plan for serving indigent and medically underserved populations. PDC included with the application a letter from the Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”), stating that the Facility site had been accredited by JCAHO.

A JCAHO representative confirmed in a letter to PDC dated 20 December 2006 that PDC:

. . . notified me within appropriate timeframes of the opening of a new site called Gastroenterology at Brier Creek located at 10441 Moncreiffe Road, Suite 101, in Raleigh, NC 27617. This site provides the medical services of Gastroenterology and the Surgery/Anesthesia services of Endoscopy under moderate sedation. Since your organization is already accredited for Surgery/Anesthesia services and the addition of this site has not significantly increased the overall amount of volume being performed in this category, no extension survey was warranted. We have administratively extended accreditation to that site until your organization undergoes its full unannounced triennial survey sometime in 2007.

PDC’s accredited program is listed on JCAHO’s website as “Ambulatory Care,” with Endoscopy and Gastroenterology shown as Services at the Facility site. The brief program description for Ambulatory Care on the JCAHO website is: “Ambulatory care providers, including outpatient surgery facilities, rehabilitation centers, infusion centers, group practices, and others.”

PDC states that in December 2006, it was contacted by the section chief of the Department’s Acute Care and Home Care Licensure and Certification Section (“Section”), who advised that a different type of accreditation would be required for licensure. PDC represents that, although it disagreed with the Section’s interpretation of N.C.G.S. § 131E-178(a), it attempted to satisfy the requirements for the other accreditation, but neither JCAHO nor the

Accreditation Association for Ambulatory Health Care were able to meet the deadline of 31 December 2006 on such short notice.

ANALYSIS

PDC contends that it has satisfied all of the requirements for licensure in N.C.G.S. § 131E-178(a). The only issue is whether its accreditation by JCAHO is sufficient, or whether it needed further accreditation as an ambulatory surgical facility.

The applicable statutory language provides that an applicant's facility must have "been accredited by . . . The Joint Commission on Accreditation of Healthcare Organizations . . . by the time the license application is postmarked for delivery to the Division of Facility Services of the Department." The statute does not specify the category or level of accreditation required.

The clear purpose of the statute was to provide a mechanism and a window of opportunity by which existing or substantially planned gastrointestinal endoscopy facilities could be licensed as ambulatory surgical facilities without the need for a CON. The Facility is within the category of facilities to which the statute applies. The accreditation that the Facility received from JCAHO is consistent with a gastrointestinal endoscopy facility, and therefore satisfies the requirement for accreditation established in N.C.G.S. § 131E-178(a)(3).

No issues of patient safety or quality of care have been raised with respect to PDC or its Facility that relate to this question.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the PDC timely met the requirement of N.C.G.S. § 131E-178(a)(3) that the Facility be accredited by JCAHO.

This ____ day of _____, 2007.

Robert J. Fitzgerald, Director
Division of Facility Services
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 prepaid envelope addressed as follows:

CERTIFIED MAIL

Wallace C. Hollowell, III
Nelson Mullins Riley & Scarborough, LLP
GlenLake One, Suite 200
4140 Parklake Avenue
Raleigh, NC 27612

This ____ day of _____, 2007

Jeff Horton
Chief Operating Officer