

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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY JOHNSTON AREA) DECLARATORY RULING
GASTROENTEROLOGY, P.A.)**

I, Jeff Horton, Acting Director of the Division of Health Service Regulation (the “Department”), hereby issue this declaratory ruling to Johnston Area Gastroenterology, P.A. (“Petitioner”) 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. Petitioner has filed a Declaratory Ruling Request (the “request”) asking the Department to issue a ruling that Petitioner may develop two unlicensed endoscopy procedures rooms at a site other than the site previously identified to the Department, prior to seeking licensure of the resulting endoscopy facility, without the necessity to obtain a certificate of need (“CON”). For the reasons given below, I conclude that Petitioner’s requested ruling should be denied.

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. William R. Shenton of Poyner Spruill LLP, counsel for Petitioner, has requested this ruling on behalf of Petitioner and has provided the statement of facts upon which this ruling is based. The material facts as provided by Petitioner and as shown in records of the Department are set out below.

STATEMENT OF THE FACTS

In August of 2005, the General Assembly amended N.C.G.S. § 131E-178(a) to read:

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.

The effective date of section (a) was August 31, 2005.

In October, 2005, Petitioner submitted to the Department an affidavit, stating that as of August 31, 2005, it was operating two gastrointestinal endoscopy rooms at its location at 415-C North 7th Street in Smithfield, Johnston County, North Carolina (the "Original Site"). Petitioner states in its request that by December 31, 2006, it submitted an application for licensure based on its accreditation by the Accreditation Association for Ambulatory Health Care. Based on Petitioner's compliance with the requirements of N. C. Gen. Stat. § 131E-178(a), Petitioner was not required to obtain a certificate of need to operate two gastrointestinal endoscopy rooms at its Original Site.

In September 2007, Petitioner requested a Declaratory Ruling from the Department which would permit Petitioner to relocate the ambulatory surgical facility in Smithfield to Clayton, Johnston County (“Clayton Site”). As reasons for its relocation to the Clayton Site, Petitioner asserted that it could better serve its patients by constructing a new building which would house both an office clinic space and a physically distinct endoscopy center. In addition, building a new building would avoid problems with the Department’s construction standards due to the age of the building at the Original Site.

On October 30, 2007, the Department issued a Declaratory Ruling (“2007 Declaratory Ruling”) allowing Petitioner to apply for an ambulatory surgical facility license for the new site in Clayton without the issuance of a certificate of need. The Declaratory Ruling was subject to the following conditions:

- (1) Plans for the [Clayton site] must be submitted to the Construction Section within 45 days of the date of [the 2007 Declaratory Ruling].
- (2) The two gastrointestinal endoscopy rooms to be located at the [Clayton site] must become operational within one year after the date the Construction Section approves Petitioner’s plans.
- (3) The two gastrointestinal endoscopy rooms to be located at the [Clayton site] are to be developed in place of the two gastrointestinal endoscopy rooms at the [Smithfield site] and not in addition to any existing or proposed gastrointestinal endoscopy rooms.

Petitioner states that it met the requirements of the 2007 Declaratory Ruling by submitting the plans for the Clayton facility within 45 days of the issuance of the 2007 Declaratory Ruling and that the Construction Section never formally approved its proposed plans.

However, on March 27, 2008, the Construction Section at the Division of Facility Services was notified that Petitioner was contemplating changes in the project at the Clayton Site. After being advised that the design for the endoscopy unit at the Clayton Site was “locked

in,” on July 24, 2008, the Construction Section asked Petitioner’s design consultant to submit the “signed sealed Construction Documents.” The Construction Section next received correspondence on February 16, 2009 when Petitioner’s design consultant advised that Petitioner now intended to renovate a building in Smithfield.

In its current request, Petitioner states that it has determined that instead of developing the Clayton Site, it can better serve its patients by developing a new site for the gastrointestinal endoscopy rooms at 423 North 7th Street in Smithfield (the “New Site”), adjacent to the Original Site. The proposed location will house two gastrointestinal endoscopy rooms in an existing building which adjoins Petitioner’s medical offices and the Original Site of its in-office gastrointestinal endoscopy rooms.

According to Petitioner, the New Site will more cost-effectively serve the practice and its patients because (1) the financial feasibility of the proposed site in Clayton was based in part upon the assumption that Petitioner would be adding a second physician, which has not yet occurred; (2) Petitioner has conducted an informal survey of its patients in the Smithfield area, and found that the Smithfield location would be at least as convenient for a significant number of patients; (3) estimates indicate that the upfitting of the existing building at the proposed New Site will cost approximately one-half the cost of constructing and upfitting an entirely new building in Clayton to accommodate both Petitioner’s medical offices and the two endoscopy rooms, thus significantly reducing the cost of the project; and (4) the New Site is available and suitable for the development of the ambulatory surgical facility.

Petitioner expects to submit plans to the Department’s Construction Section as soon as possible, with a move-in date of approximately 12 months after the Construction Section approves the plans. Petitioner represents that when the practice is relocated to the New Site, the existing procedure rooms will no longer be used for gastrointestinal procedures.

ANALYSIS

No person shall offer or develop a new institutional health service without first obtaining a CON, N. C. Gen. Stat. § 131E-178(a), unless exempted from the requirement by some other provision of law. The construction, development, establishment or relocation of a gastrointestinal endoscopy room in a licensed health service facility is a new institutional health service. N. C. Gen. Stat. § 131E-176(16)(u). Petitioner argues that its development of the ambulatory surgical facility at the New Site should be exempt from the CON requirement pursuant to the 2005 amendment to N. C. Gen. Stat. § 131E-178(a) and the 2007 Declaratory Ruling.

The amendment allowed physicians who were currently providing gastrointestinal endoscopy procedures in an unlicensed setting to become a licensed ambulatory surgical facility without a CON so long as they met the requirements in the statute. Petitioner timely submitted the required information and applied for a license to operate an ambulatory surgical facility at its Original Site.

However, prior to receiving the license for the Original Site, Petitioner requested to develop its facility at the Clayton Site. The 2007 Declaratory Ruling provided that Petitioner could build two gastrointestinal endoscopy rooms at the Clayton Site rather than the Original Site, without applying for a CON provided it met certain conditions placed in the ruling. Petitioner was required to complete its project within one year after the Construction Section approved its plans. However, when the Construction Section asked for the completed construction documents, it did not receive a response for more than six months.

Moreover, the ruling clearly stated that the change in site applied only to that specific request. Nothing in the 2007 Declaratory Ruling contemplated or allowed another change in Petitioner's proposed location.

Now, more than two years after meeting the licensing requirements of N. C. Gen. Stat. § 131E-178(a), Petitioner has yet to become a licensed ambulatory surgical facility. Furthermore, according to Petitioner, the building will not be occupied, and thus, not licensed, until approximately a year after the approval of construction plans.

In reviewing the request I have considered the purpose of the certificate of need law and N. C. Gen. Stat. § 131E-178(a) concerning gastrointestinal endoscopy rooms and I find that it is appropriate to deny the declaratory ruling that Petitioner has requested. The August 31, 2005 amendment to N. C. Gen. Stat. § 131E-178(a) provided a window of time for the development of an ambulatory surgical facility by existing providers without first obtaining a CON. Nothing in the amendment provided for a change in location of the site proposed in the affidavit and the 2007 Declaratory Ruling was limited to the request to develop the Clayton site. Petitioner had the opportunity to develop an ambulatory surgical facility without a CON at both the Original Site and at the Clayton Site. Development at the New Site, Petitioner's third proposed site, must comply with the current provisions of the law.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude Petitioner may not apply for an ambulatory surgical facility license at the New Site without the issuance of a certificate of need.

This ____ day of March, 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 a first class, postage prepaid envelope addressed as follows:

CERTIFIED MAIL

William R. Shenton
Poyner Spruill LLP
301 Fayetteville Street, Suit 1900 (27601)
Post Office Box 1801
Raleigh, North Carolina 27602-1801

This _____ day of March, 2009.

Jesse Goodman
Acting Chief Operating Officer