

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

IN RE: REQUEST FOR DECLARATORY)	
RULING BY COLUMBUS REGIONAL)	DECLARATORY RULING
SAME DAY SURGERY, LLC,)	
COLUMBUS REGIONAL PROPERTIES,)	
LLC, AND COLUMBUS REGIONAL)	
HEALTHCARE SYSTEM)	

I, Jeff Horton, Acting Director of the Division of Health Service Regulation (the “Department” or the “Agency”), hereby issue this declaratory ruling to Columbus Regional Same Day Surgery, LLC (“Same Day Surgery”), Columbus Regional Properties, LLC (“Properties”), and Columbus Regional Healthcare System (the “Hospital”) (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. William R. Shenton and Wilson Hayman of Poyner Spruill LLP have requested this ruling on behalf of Petitioners and have provided the statement of facts upon which this ruling is based. The material facts are set out below.

STATEMENT OF THE FACTS

Effective October 27, 2006, the Certificate of Need (“CON”) Section issued a CON to Same Day Surgery and Properties for Project ID # O-7552-06 to develop a freestanding ambulatory surgery center in Whiteville, Columbus County, North Carolina (the ambulatory surgery center is hereafter referred to as “ASC”). Same Day Surgery and Properties represented in their CON application that Properties would purchase the land and construct the facility at 824 Jefferson Street, Whiteville. Same Day Surgery proposed to lease the facility, up fit the interior space and operate the ASC.

During the time the ASC application was under review by the CON Section, Same Day Surgery and Properties filed another CON application for Project ID # O-7618-06 (“GI Application”) to add one gastrointestinal (“GI”) endoscopy room to the previously proposed ASC at 824 Jefferson Street in Whiteville. The GI Application was approved and the CON was issued on November 30, 2006. Both applications and the Request represent that 50% of the membership interests in Same Day Surgery are owned by the Hospital and 50% by local physicians, while 70% of the membership interests in Properties are owned by the Hospital and 30% are owned by members of the community, including a number of physicians.

Since the applications were filed, the Centers for Medicare and Medicaid Services (“CMS”) have decreased Medicare reimbursement for many of the procedures performed in an ASC or GI endoscopy room setting. Effective January 1, 2008, CMS modified the existing ambulatory surgery center pay structure to pay ASCs through ambulatory payment category (“APC”) methodology linked to the Hospital outpatient prospective payment system. The APC methodology pays flat rates for procedures, with additional payments for specialized drugs, supplies, or implants that are identified on the bill. According to Petitioners, as a consequence of this change, hospital outpatient departments (HOPDs) will be paid at rates 41% more than are ASCs for the exact same services.

In both CON applications, the applicants represented that the policies regarding charity care at the ASC would be consistent with hospital policies. They estimated that 27% of projected revenues would be from Medicare, and 13% from Medicaid. Thus, the reimbursement changes would impact about 40% of the projected case load.

Due to the changes in the APC methodology, Petitioners now seek a declaratory ruling permitting the Hospital to develop the projects under its existing license as a hospital outpatient department (“HOPD”). In order to achieve this goal, Petitioners request that Same Day Surgery be allowed to transfer its ownership interests in the CONs for the ASC and the GI room to the Hospital. Properties, in which the Hospital owns a 70% interest, would become 100% owned by the Hospital and would own 100% interest in the CONs. Then, Petitioners assert, the Hospital could develop the two projects under its existing license as a HOPD.

According to Petitioners, the proposed conversion of the ASC to a HOPD reflects a corporate reorganization to enhance efficiency and to meet the challenges presented by the changes in the APC methodology. Petitioners state that the Hospital's operating suite and the new ASC will both operate with greater efficiency and productivity if the ASC is operated under the Hospital's license. In addition, Petitioners claim the change will lead to better utilization of the Hospital's total capacity because it will permit the coordination of all surgical services under the management of the Hospital.

ANALYSIS

Same Day Surgery and Properties received a CON for Project ID # O-7552-06 to develop a freestanding ASC in Whiteville and a CON for Project ID # O-7618-06 to add a GI endoscopy room to the same freestanding ASC. These projects have not yet been completed. Because operating the facility as a HOPD would permit the ASC to receive enhanced reimbursement, Petitioners assert that good cause exists to transfer the two CONS to the Hospital and to allow the Hospital to develop both projects as an outpatient department of the licensed hospital rather than a separately licensed ambulatory surgical facility.

N.C.G.S. § 131E-181 provides in part:

- (a) A certificate of need shall be valid only for the defined scope, physical location, and person named in the application. A certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c).
- (b) 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.

N.C.G.S. § 131E-189(c) states:

The Department may immediately withdraw any certificate of need if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or

the certificate of need. Any transfer after that time will be subject to the requirement that the service be provided consistent with the representations made in the application and any applicable conditions the Department placed on the certificate of need. Transfers resulting from death or personal illness or other good cause, as determined by the Department, shall not result in withdrawal if the Department receives prior written notice of the transfer and finds good cause. Transfers resulting from death shall not result in withdrawal.

N.C.G.S. 131E-176(1b) provides the following definition:

"Ambulatory surgical facility" means a facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program. An ambulatory surgical facility serves patients who require local, regional or general anesthesia and a period of post-operative observation. An ambulatory surgical facility may only admit patients for a period of less than 24 hours and must provide at least one designated operating room or gastrointestinal endoscopy room, as defined in Article 5 Part 1 and Article 6, Part 4 of this Chapter, and at least one designated recovery room, have available the necessary equipment and trained personnel to handle emergencies, provide adequate quality assurance and assessment by an evaluation and review committee, and maintain adequate medical records for each patient. An ambulatory surgical facility may be operated as a part of a physician or dentist's office, provided the facility is licensed under G.S. Chapter 131E, Article 6, Part D, but the performance of incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program as defined in subdivision (1c) of this section and which are performed in a physician's or dentist's office does not make that office an ambulatory surgical facility.

The consequence of the above statutory provisions is that the Request must be denied.

The changes proposed are material changes to the scope of the project described in the ASC and GI Applications and could result in material changes to the location and to the persons named as applicants in the ASC and GI Applications.

The proposed changes described in the request for the declaratory ruling are materially different in scope than the projects described in the ASC and GI applications. Instead of providing surgical and GI services in a licensed ambulatory surgical facility, the services would be provided in an outpatient department of the licensed hospital. Consequently, the Petitioners

state management services for the facility would no longer be provided by HVP, instead the facility would be operated by the hospital's management staff. Also, Petitioners state the proposed full-time administrator or clinical manager would be omitted. Therefore, although the proposed changes would decrease the operating expenses projected in the ASC and GI applications, the changes would result in an increase in the projected reimbursement in the two applications.

Further, according to Petitioners, the proposed changes in the projects are not expected to increase charges for the vast majority of the patients treated. In instances where patients may experience a change in expenses, Petitioners believe most of those patients possess secondary insurance coverage that is adequate to compensate them for any difference to charges. However, Petitioners make no representations that they will work to ensure that the procedure charges will remain price neutral. In other words, Petitioners made no commitment to ensure that there would be no increase in patient charges due to the proposed changes.

Petitioners indicate that the proposed establishment of the ASC as an outpatient department of the hospital may entail a change in the proposed location of the ASC. However, Petitioners do not provide any information about where the facility may be located. Consequently, it is not possible to evaluate the effect, if any, that the potential change in the location of the services could have on provision of the proposed services and on access to the services by prospective patients.

In the Request, Same Day Surgery seeks to transfer its ownership interest in both CONs to the Hospital. However, it is unclear from the Request whether the Hospital will acquire the physicians' membership interest in Same Day Surgery or whether Same Day Surgery will cease to exist and the Hospital will acquire the ASC. Although Petitioners state that the Hospital

currently owns only a 70% interest in Properties, they assert that Properties would become 100% owned by the Hospital without a change in ownership. However, Petitioners make no representation as to how this would be accomplished, i.e., whether Properties will remain intact with the Hospital having a 100% membership interest or whether Properties will be dissolved and the Hospital will acquire its assets. From the Request, there is not enough information to determine if the proposed transfers of ownership result in material changes to the persons named in the ASC and GI Applications.

CONCLUSION

In summary, the proposal described in the Request constitutes a material change in the scope of the project. In addition, inadequate information is provided on which to determine if the proposed changes described in the Request would result in material changes in the location and persons named in the ASC and GI applications. For the foregoing reasons, I conclude that Petitioners' request for a declaratory ruling must be denied.

This ____ day of May, 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

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This _____ day of May, 2009.

Jeff Horton
Acting Director