SCA Surgical Care Affiliates

August 31, 2010

Les Brown, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
701 Barbour Drive
Raleigh, North Carolina 27626-0530

RE: Comments on Randolph Surgery Center, LLC CON application

Dear Mr. Brown:

Enclosed please find comments prepared by Charlotte Surgery Center regarding the CON application submitted by Randolph Surgery Center, LLC to establish a new single specialty ENT ambulatory surgery center with two operating rooms in Mecklenburg County. We trust that you will take these comments into consideration during your review of the applications.

Sincerely,

K. Collins

Kelli Collins
Vice President Operations
Surgical Care Affiliates

COMMENTS & OPPOSITION REGARDING RANDOLPH SURGERY CENTER, LLC CON PROJECT ID# F-008550-10

Submitted by Charlotte Surgery Center
August 31, 2010

Charlotte Surgery Center (CSC) represents a partnership between local surgical providers and Surgical Care Affiliates (SCA), an experienced provider of ambulatory surgical services. With its affiliated physicians and partners, SCA is one of the largest national providers of specialty surgical services, operating 124 ambulatory surgery centers and surgical hospitals across the country, with more than 2,000 physician partners.

CSC has provided high-quality ambulatory surgical services to residents of Mecklenburg counties for several years. CSC operates 7 operating rooms at its existing facility on Randolph Road in Charlotte (Mecklenburg County). Thus, CSC is knowledgeable regarding the local need for surgical services in the service area, and is well positioned to evaluate the CON proposal by Randolph Surgery Center, LLC (RSC) for a new ambulatory surgery center in Mecklenburg County.

RSC has applied to establish a new single specialty ENT ambulatory surgery center with two operating rooms in Mecklenburg County. SCA is a current provider of surgical services in Mecklenburg County. Because of our commitment to serving the best interests of citizens in this area, and in support of the State's Certificate of Need (health planning) objectives, we feel compelled to express our concerns about the RSC application.

We recognize that your decision will be based upon the State's CON objectives. Particular focus is on the need to provide residents with access to quality care, without unnecessary and costly duplication of services. Any existing or new health service provider must accurately assess local needs and services, and should develop a plan that represents the least costly or most effective alternative. RSC's application does not achieve either objective.

Specifically:

- RSC's proposed project does not satisfy CON Review Criterion 3 in that it does not demonstrate the need the identified population has for its proposed project.
- RSC fails to satisfy Review Criterion 4 in that the applicant fails to demonstrate that the proposed project represents the most effective alternative for serving the health service area.
- RSC is non-conforming to Review Criterion 6. Specifically, RSC does not demonstrate that the proposed project will not result in unnecessary duplication of existing service capabilities and facilities.
- RSC is non-conforming to Review Criterion 8. The RSC application fails to provide an explanation for the arrangement of all required ancillary services.
- RSC's application is non-conforming to Review Criterion 13 with regard to access to services by the medically underserved.
- RSC's application failed to conform to all applicable administrative rules.

Subsequent comments are based on the State's health-planning goals and review criteria that are relevant to the RSC application.

Need Methodology/Utilization Projections

Need for a Dedicated ENT ASC

On page 81 of its application, RSC concedes that both ophthalmology and orthopedics are specialties with a higher surgical volume than ENT in Cabarrus, Mecklenburg, and Union Counties. RSC attempts on pages 83 and 84 of its application to argue that because there are already 3 existing programs in Mecklenburg Count focused on orthopedics, ENT is a more effective use of the proposed single specialty demonstration ASC project. However, RSC neglects to address two important points:

First, the disparity in volume between orthopedic surgeries and ENT surgeries is not negligible. As demonstrated in the chart on page 81 of the RSC application, orthopedics accounted for 23,694 procedures, while ENT accounted for only 12,849 procedures in 2009. Furthermore, according to Exhibit 39 of the RSC application,

ASC orthopedic surgeries have seen a 2.3% increase in volume from 2007 to 2009 while ENT (otolaryngology) surgeries in ASCs have seen a .9% decrease in volume.

Secondly, RSC failed to report that there are also at least 2 existing programs in the service area focused on ENT. SouthPark Surgery Center (which is partially owned by several of the CEENTA physicians) reported to have performed 4,068 ENT cases out of 8,730 total surgical cases in its 2010 License Renewal Application. The remainder of the cases at SouthPark was ophthalmology procedures, which RSC reports in its application (on page 83) are declining to such an extent that CEENTA has "concern regarding the viability of an ASC dedicated to ophthalmology." Given its experience in ENT paired with its anticipated decline in ophthalmology volume, SouthPark's emphasis on ENT procedures should increase significantly in the coming years, obviating any need for an additional ASC focused on ENT. Furthermore, NorthCross Surgery Center, located in Huntersville, NC (just north of Charlotte) reports that "[e]ar, nose and throat procedures such as tonsillectomies, pediatric ear tube placement and reconstruction of inner ear components to improve hearing make up the majority of procedures performed at NorthCross Surgery Center."[1]

Moreover, RSC's reference to Charlotte Surgery Center ("CSC") on page 83 of its application as evidence of programs focused on orthopedics is misguided. CSC is a full service, multi-specialty facility. RSC is correct that in 2009, orthopedics accounted for more than half of CSC's 7833 *surgical* procedures as reported in its 2010 License Renewal Application. However, the accuracy of the suggestion that CSC's facility is focused on orthopedics is called into question when all of the facility's 12,596 cases (including non-surgical pain management cases) for calendar year 2009 are taken into account. Furthermore, despite the overall growth of orthopedics volumes in the service area, CSC has actually experienced a drop in its orthopedics practice (based on 2010 annualized figures), a trend that is expected to continue. Rather than orthopedics, CSC's anticipated growth is in ophthalmology, particularly with the addition of approximately 1,800 ophthalmology cases per year from one physician expected in the coming years.

RSC reports on page 75 the average procedure times for the types of ENT procedures it intends to perform in an apparent effort to emphasize the speed with which ENT procedures can be performed. However, the listed procedure times are not reliable. On page 663 of Exhibit 39 to the RSC application, surgeries for otitis media and Eustachian tube disorders (myringotomy) in ASCs are reported to last

[1] http://www.cmc-university.org/body.cfm?id=54

on average 10.2 minutes, whereas RSC indicates such procedures last only 5 minutes. Exhibit 39 further indicates that treatment of chronic diseases of tonsils and adenoids takes 20.6 minutes on average, while the RSC application indicates that the average is 15-20 minutes.

RSC has therefore failed to demonstrate why ENT would be the best alternative for the single specialty ASC demonstration project when there are other single specialties that have more volume and more demonstrated need in the service area.

Projected Volume Shift

CEENTA, which is one of the applicant members, currently provides outpatient surgical services at SouthPark Surgery Center, which is its multispecialty ASC. RSC alleges in its application that the number of surgical cases at SouthPark has grown at a steady rate of 5% per year. (Page 18) However, the information contained in the 2010 SMFP (as reported on the SouthPark 2009 License Renewal Application) indicates that SouthPark performed 9,664 surgical cases in 2008. In the 2010 SouthPark License Renewal Application, SouthPark reported only 8,730 total surgical cases in 2009, which represents a decrease in surgical cases at SouthPark of almost 1,000 cases in comparison to the previous year. In spite of the already declining volumes at SouthPark, RSC projects that the majority of the cases at the proposed facility will be shifted from SouthPark.

On page 102 of its application, RSC attempts to project the total OR need at SouthPark by using the annualized FFY 2010 total surgical cases. RSC concludes that SouthPark's volume could support an additional 2.4 ORs. However, because the volume figure used by RSC is annualized based on a partial year's data, and because it projects an increase of 1,700 cases in comparison to the last reported year, this figure is unrealistic and unreliable. If RSC were to use the more reliable figure of 8,730 from the previous year (and assuming no further decline in cases), the chart on page 102 would resemble the below:

Projected 2010 Cases	8,730
Hours (1.5 Hours per Case)	13,095
Hours/1,872	6.995
Total ORs	6
OR Need	**1**

Whereas the RSC application reports that SouthPark's current volume could support "at least two additional operating rooms," the actual volume figures tell a

much different story. Especially considering the historic decline in surgical volume at SouthPark based upon its License Renewal Applications, reliance upon phantom volume increases at SouthPark is not a realistic or reliable means by which to project a significant volume shift from SouthPark to the proposed facility.

Further, with regard to the other facilities from which RSC intends to shift surgical cases, the majority of these facilities are currently operating at far below 80% of their total OR capacity, as is explained in further detail in the section of these comments under the heading, "Unnecessary Duplication of Services." In addition, it should be pointed out that at least 3 of the remaining facilities (Presbyterian Hospital, CMC-University, and CMC-Pineville) have reported declines in their ambulatory surgical cases in their 2010 License Renewal Applications in comparison to the volumes reported in the 2010 SMFP. (See RSC application pages 646, 650, and 651)

CEENTA Physicians

Despite the fact that a report cited by RSC (and included in its application as Exhibit 39) indicated that ENT surgical procedures experienced a .9% (CAGR) decline in volume from 2007 to 2009, RSC projects on page 105 that each of its physicians will increase their ENT surgical volume by 2.5% (CAGR) from 2012 to 2014. This growth figure is based on a historic growth rate of 2.5% (CAGR) in total ENT cases performed by CEENTA physicians in the three-year period from 2007-08 to 2009-10. (Page 102). However, this historic growth is explained in its entirety by the addition of 3 physicians in the third year period of 2009-10, which is shown on Exhibit 41 (page 666). In fact, if the 2009-10 procedures performed by Dr. Falcone, Dr. Heavner, and Dr. Tebbit (none of whom performed any ENT surgical cases with CEENTA before that period) are removed from the equation, the total surgical cases performed by CEENTA physicians actually declined in the period between 2008-09 and 2009-10 by 105 cases. This represents an even greater decline than the 14 procedure drop experienced by CEENTA physicians between 2007-08 and 2008-09.

Furthermore, an analysis of each physician with any data upon which to create a historical trend indicates that of the 22 CEENTA physicians shown on Exhibit 41, only 3 had any increase in volume at all over the three-year period of 2007-08 through 2009-10. Each of the remainder of them experienced an overall decline during the period selected by RSC in its application.

Because of the unrealistic and unreliable projections with respect to the individual physicians involved in the project and with respect to the downward trend in ENT surgical procedures, RSC has failed to demonstrate the need for its proposed facility. Therefore, the RSC application does not conform to Review Criterion 3.

Medically Underserved

RSC does not demonstrate the expansion of access to medically underserved patient groups through their services. RSC application failed to provide *any* assumptions for its payor mix breakdown. The Agency has recently found a CON application non-conforming to Criterion 13(c) for failure to provide the assumptions used to project the future payor mix.[2]

Furthermore, the RSC application demonstrates that it would provide significantly less care to underserved patients than SouthPark (which is owned by the same CEENTA physicians that propose to own 50% of RSC) provided in its last full operating year, as shown in the table below.

Current SouthPark and Projected Year 2 RSC Payor Mix

	SouthPark Current Payor Mix	RSC Proj Yr 2 Payor Mix	% *Decrease*
Medicare/Medicare Managed Care	35%	13%	-22%
Medicaid	10%	6%	-4%

Source: 2010 CON Application; SouthPark Surgery Center, LLC 2010 License Renewal Application

RSC emphasizes the extent of its pediatric practice and the growth of the pediatric population in the service area. Thus, the projected decrease in Medicaid patients is especially troubling considering that Exhibit 32 to the RSC application indicates (on page 632) that in the case of pediatric tonsillectomy/adenoidectomy (which RSC would provide), Medicaid is billed for approximately **28%** of the procedures. Further, it is projected in Exhibit 28 to the RSC application (on page 614) that with regard to ENT surgeries:

> [m]any surgery centers are reporting a recent increase in the

[2] See Agency Findings for Project I.D. #F-8380-09

> proportion of Medicaid patients relative to commercial payers. Medicaid will continue to expand under the new health care reform law, so providers should continue to expect to see increases in commercial payers.

Thus, RSC's projection of drop from 10% to 6% for Medicaid demonstrates an unexplained decrease and an unreasonably low percentage in any case. In conclusion, decreases in access to medically underserved populations do not promote the reduction of barriers to access. The RSC proposal is not consistent with the Basic Principles of the 2010 SMFP, reduces access to surgical services for the medically underserved and is therefore non-conforming to Review Criterion 13.

Unnecessary Duplication of Services

On page 115 of its application, RSC admits that it "quickly rejected" as an alternative to its proposal the maintenance of the status quo relative to the provision of ENT surgical services. However, in the remainder of that paragraph, RSC fails to weigh the benefits of continuing to have its member physicians provide ENT surgical services in the facilities where they currently provides them. Rather, RSC simply promotes its members as "the best alternative for developing the demonstration project in the Charlotte area." Nowhere to be found is any discussion as to why the proposed ASC would be superior to the continuation of surgeries at existing locations. The fact that the applicant members considered their application to be superior to all other applicants' potential proposals (with which they would not have had any intimate familiarity) is not a valid argument for the proposition that the RSC proposal would be more effective than allowing the ENT surgeries to proceed at already under-utilized facilities in the service area.

Furthermore, on page 103 of its application, RSC lists the existing facilities from which it plans to shift surgical procedures to the proposed facility in its first year. RSC proposes to shift 1,709 cases from SouthPark in its first year. As explained above, the annualized figure for surgical cases at SouthPark cited in the RSC application is unreliable. Based upon reported cases in SouthPark's 2010 License Renewal Application, SouthPark had 8,730 surgical cases in its last reported full year. A shift of 1,709 cases would leave the SouthPark facility with 7,021 cases. Assuming 1.5 hours per case, SouthPark would have 10,531 surgical hours remaining. Therefore, SouthPark's six ORs would operate at only 75% of full capacity [10,531 / (9 hours x 260 days x 1.00 available time = 2,340 x 6 = 14,040) = 0.75007] following the proposed shift in cases.

With regard to the remaining facilities from which RSC intends to shift surgical cases, all but one of them were operating at under 80% of capacity as reported in the 2010 SMFP:

Facility	***Percent of OR Capacity***
CMC	76%
CMC-Pineville	58%
CMC-University	45%
Presbyterian-Matthews	60%
SDSC at Ballantyne	14%
Presbyterian Hospital	62%

Source: 2010 SMFP; RSC CON Application

Thus, considering the source of the cases proposed to be shifted to the proposed facility, the proposed ASC would clearly be a duplication of existing health service capabilities and facilities. Further, as indicated above, at least 3 of the remaining facilities (Presbyterian Hospital, CMC-University, and CMC-Pineville) have reported declines in their ambulatory surgical cases in their 2010 License Renewal Applications in comparison to the volumes reported in the 2010 SMFP. (See RSC application pages 646, 650, and 651)

In conclusion, RSC is non-conforming to Criterion 4 in that it does not demonstrate that the least costly or most effective alternative has been proposed; and it is non-conforming to Criterion 6 because it has failed to demonstrate that the proposed project will not duplicate existing health service capabilities and facilities.

Availability of Ancillary Services

RSC has failed to provide any explanation for the means by which it will coordinate with anesthesiologists for the provision of required anesthesia services at its proposed facility. As a result, the RSC is non-conforming to Review Criterion 8.

Financial Feasibility

Because RSC's utilization projections are unreasonable, RSC's financial operating projections (that are based those utilization projections) are also unreasonable.

This deficiency in RSC's financial projections results in the application being non-conforming to Review Criteria 4, 5, and 12.

CONCLUSION

For all of the foregoing reasons, the CON Section should find that RSC's application does not conform to the statutory review criteria, and RSC's application should be disapproved.