

University Surgery Center, LLC

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CON SECTION

August 26, 2010

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Mr. Craig Smith, Chief  
Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704

RE: Comments regarding Certificate of Need Applications:  
#F-8550-10 - Randolph Surgery Center, LLC;  
#F-8545-10 - Cotswold Surgery Center, LLC  
Single Specialty Ambulatory Surgical Facility in the Service Area that includes Mecklenburg,  
Cabarrus and Union Counties

Dear Mr. Smith:

On behalf of University Surgery Center, LLC, thank you for the opportunity to comment on the above referenced project applications. These comments are submitted in accordance with NCGS 131E-185(a1)(1) and reference specific statutory criteria and special demonstration project criteria and rules relevant to this review.

Thank you for your consideration of the enclosed information. Should you have any questions, please do not hesitate to contact me.

Sincerely,



David J. French  
Consultant to University Surgery Center, LLC  
[dj french45@bellsouth.net](mailto:dj french45@bellsouth.net)

In CON project application #F-8550-10, Randolph Surgery Center, LLC, which is managed by Carolinas Healthcare System and staffed by CEENTA Surgery II, LLC, proposes to develop a new single specialty freestanding ambulatory surgery center with two operating rooms. Owners of Randolph Surgery Center, LLC include Carolinas Healthcare System (50%) and CEENTA Surgery II, LLC (50%). Twenty-three physicians are cited as the medical staff for the facility.

The Randolph Surgery Center application fails to conform to the specific CON criteria as follows:

1. Unreasonable assumptions, flawed methodology and unreliable utilization projections causing the application to be nonconforming to multiple CON review criteria and regulatory standards
2. Failure to identify any specific anesthesiology and pathology physicians or groups to serve the proposed project
3. Unjustified excess facility space for the proposed project
4. Inadequate documentation of support from community physicians and no documented support from community clinics or health departments

CON Review Criteria:

- (1) *The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, surgical operating rooms, or home health offices that may be approved.*

The need determination for two operating rooms in the Area (Mecklenburg / Cabarrus / Union Counties) is pursuant to the Single Specialty Ambulatory Surgery Facility Demonstration Project. The 2010 State Medical Facilities Plan includes written criteria. The SMFP plan states "The demonstration project must meet the criteria described in Table 6D." The Randolph application fails to conform to Criterion 1 because Randolph projects that more than 20.8% of its patients will originate from rural counties and other states that are outside of the boundaries of Mecklenburg, Cabarrus and Union Counties.

- 1) The SMFP-defined service area and special need determination includes only the population for the service area of Mecklenburg, Cabarrus and Union Counties. This is a determinative limitation and no unmet need for single specialty operating rooms extends to other populations.
  - 2) The applicant wrongly projects to increase the number of patients leaving other counties to obtain access at the proposed facility. Page 91 of the 2010 SMFP, "Locating facilities in high population areas with a large number of operating rooms and existing ambulatory surgery providers prevents the facilities from harming hospitals in rural areas, which need revenue from surgical services to offset losses from other necessary services such as emergency department services."
  - 3) CEENTA has twelve different physician office locations that have great variation in distance and travel times to the location of the proposed project. Therefore it is unreasonable to assume that the patient origin for the proposed demonstration project in Charlotte should be based on the combined CEENTA physicians' patient origin data from numerous offices outside of Charlotte.
- (3) *The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all*

*residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.*

The Randolph application fails to conform to CON Review Criterion 3 because the volume projections are overstated and based on unreasonable assumptions.

- 1) Page 21 of the project application acknowledges that Carolinas Healthcare System “has attempted to relocate underutilized operating rooms throughout the county to increase access to the citizens of Mecklenburg County.” CHS perpetuates its longstanding trend of having underutilized facilities throughout Mecklenburg County by keeping ORs in transition and various stages of development at multiple locations. In the 2010 State Medical Facilities Plan, CHS still has an abundance of underutilized operating rooms:
  - Carolinas Medical Center Mercy and Pineville (H0042) is underutilized at only 72.63% utilization for its 19 existing ORs plus 6 CON-approved ORs.
  - Carolinas Medical Center University (H0255) is underutilized at only 56.17% utilization for its licensed OR capacity (13 ORs minus 2 ORs for CON adjustment).
  - Carolinas Surgical Center - Randolph is underutilized at only 50.30% utilization based on its 5,022 reported ambulatory surgery cases in eight licensed operating rooms.
- 2) As seen on page 113 of the Randolph application, the proposed facility is positioned to serve a six-county service area that includes Gaston County, NC York County, SC and Lancaster County, SC in addition to the SMFP defined service area for Mecklenburg, Cabarrus and Union Counties. The map shows that the applicant intends to divert patients from rural counties that are outside of the area that was defined for the demonstration project. Furthermore, the patient origin data for CEENTA offices in South Carolina and other remote NC office locations should not be included in this project application because the data overstates the expected number of patients coming from an excessively large and unjustified region.
- 3) Existing ambulatory surgery centers service the populations of Gaston County, York County, SC and Lancaster County, SC. These include Caromont Surgery Center, Carolinas Surgery Center (SC) and Surgery Center at Edgewater. No unmet need exists for the populations in these counties because the existing facilities already offer high levels of access to ambulatory surgery patients. Furthermore, the application fails to demonstrate physician support to justify the stated projections of patients from outlying counties.
  - No letters of support are provided from York County, South Carolina community physicians where 6.6% of patients are predicted to originate.
  - No letters of support are provided from Gaston County community physicians where 4.3% of patients are predicted to originate.
  - No letters of support are provided physician from the 33 other North Carolina counties and 13 other SC counties where 8 percent of the patients are expected to originate.
- 4) The utilization projections for Randolph Surgery Center are unreasonable because page 103 of the application states that proposed project will divert 1,709 surgery cases from SouthPark Surgery Center in 2012. But this assumption is inconsistent with the projections in Exhibit 17, page 485, showing that utilization at SouthPark

Surgery Center will continue to increase based on the compound annual growth rate assumption of 7.4%. The following table illustrates the inconsistency in the application projections.

	Actual	Actual	Annualized	Projection	Projection	Projection	Projection
RSC Exhibit 17, Page 485	2008	2009	2010	2011	2012	2013	2014
SouthPark Utilization Outpatient Cases	9,864	8,730	10,430	11,197	12,021	12,906	13,856
Future Years Annual Growth Assumption				7.4%	7.4%	7.4%	7.4%
RSC Application Page 103 states 2012 (FFY12) the number of CEENTA cases shifted from SouthPark Surgery Center				Not stated	-1,709	Not stated	Not stated
				in application		in application	in application

Randolph Surgery Center fails to subtract the 1,709 cases from the future years' projections at SouthPark Surgery Center (CEENTA has partial ownership). Furthermore, the application fails to explain the number of cases that will be shifted by CEENTA physicians in 2011, 2013 and 2014. Therefore the projections for the proposed project and the SouthPark Surgery Center are entirely inconsistent and unreliable.

Randolph Surgery Center states that "a significant portion of its volume [at its proposed ASC] will result from physicians shifting their volume from other facilities to the new ASC." See, for example, page 486. However, Randolph Surgery Center provides inconsistent information with regard to the number of cases expected to shift in each of the three Project Years. On page 103 of its application, Randolph Surgery Center projects that in FFY 2012 (Project Year 1), the following numbers of cases are expected to shift to the proposed ASC:

Facility	Cases Expected to Shift to Proposed ASC in Federal Fiscal Year <u>2012 (Project Yr 1)</u>
SouthPark Surgery Center	1,709
CMC	515
CMC-Pineville	145
CMC-University	122
NorthCross Surgery Center	32

Source: Randolph Surgery Center CON App., p. 103

Yet, on pages 435, 471, 475, 482 and 486, Randolph Surgery Center projects that in FFY 2014 (Project Year 3), only these exact same numbers of cases are expected to shift to the proposed ASC:

Facility	Cases Expected to Shift to Proposed ASC in Federal Fiscal Year <u>2014 (Project Yr 3)</u>
SouthPark Surgery Center	1,709
CMC	515
CMC-Pineville	145
CMC-University	122
NorthCross Surgery Center	32

Source: Randolph Surgery Center CON App., pp. 435, 471, 475, 482, and 486

- If the number of cases expected to shift does not increase between Project Years 1 and 3, Randolph Surgery Center cannot reach its forecasted utilization projections.
- If the number of cases expected to shift does increase by 2.5% over each of two years, Randolph has failed to account for the full magnitude of shifting cases in Exhibit 17 of its CON application.

At no point in its CON Application does Randolph Surgery Center explain this material discrepancy in its utilization projections; this inconsistency renders the application projections unreliable and inaccurate and causes the application to be nonconforming to Criterion 3.

- 5) The Randolph Surgery Center application is based on an assumption of 2.5% annual growth that is unsupported and unreasonable. Page 84 of the application shows that outpatient ENT surgery cases declined in the period from April 2008 to March 2009 as compared to the previous year. The growth that occurred in the more recent year April 2009 to March 2010 does not establish a sufficient trend to calculate a Compound Annual Growth Rate for future years' projections. The 2.5% annual growth assumption is also contradicted by Thompson Reuters, May 2010 (Health Leaders Fact File) where national data shows that ambulatory surgery otolaryngology cases declined by 0.9% between 2007 and 2009.
- 6) The application fails to identify the providers of anesthesia services as required by administrative rules. No anesthesiologist or anesthesia group has expressed willingness to provide services to the proposed project. Based on the lack of this essential service, the utilization projections are unreasonable.

Clearly the projected numbers of patients from outside of the SMFP-defined service area (Mecklenburg / Cabarrus / Union Counties) are unjustified and should be excluded from the applicant's projections. The application makes inconsistent projections regarding the impact of the proposed project to the utilization at SouthPark Surgery Center. In addition, multiple other CHS facilities in Mecklenburg County have underutilized operating rooms. Based on these facts, the Randolph Surgery Center application is nonconforming to CON Review Criterion 3.

- (4) *Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.*

The Randolph Surgery Center application fails to conform to CON Review Criterion 4 because the utilization projections are unreliable and the financial projections are inaccurate. The comments regarding Criterion 3 explain why the utilization projections are unreliable in terms of unreasonable patient origin, inadequate community support, and unreliable assumptions and projections.

The financial projections are based on unreasonable and overstated utilization projections. Please see the comments above regarding Criteria 3 and 5. Revenues are overstated based on unreasonable and overstated utilization projections.

The facility plan for the proposed project includes 14,087 square feet of space that far exceeds the amount that is necessary for a demonstration project ambulatory surgery center with two operating rooms. The facility plan's square footage is excessive. One would reasonably expect

that this overly large facility would result in higher operating costs including facility maintenance and utilities. However, these facility-related operating costs are understated in the financial pro forma statement and assumptions.

- (5) *Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.*

The financial projections are based on unreasonable and overstated utilization projections. Please see the comments above regarding Criterion 3. Revenues are overstated based on unreasonable and inflated utilization projections with over 600 cases per year from outside of the SMFP-defined service area counties. These cases and resulting revenues are unjustified and should be excluded from both the operational and financial calculations.

	YR 1	YR 2	YR 3
RSC Total Cases	2,990	3064	3,140
Subtract Out of Service Area Cases	-622	-637	-652
Remaining Service Area Cases	2,368	2,427	2,488
Financial pro forma Net Revenue per Case	\$1,588	\$1,623	\$1,659
RSC Net Revenue without Out of Service Area Cases	\$3,759,263	\$3,938,855	\$4,127,646
Adjusted Total Expenses (lower volume reduces supply cost)	\$4,681,681	\$4,854,584	\$5,062,267
RSC Gain or Loss	-\$922,418	-\$915,730	-\$934,621

Randolph Surgery Center fails to show a gain from operations with the exclusion of the unsupported surgery cases from outside of the SMFP-defined service area.

Additional flaws in the financial pro forma statement include:

- Projected charges are unrealistically based on a three percent annual increase and increasing reimbursement rates. The upcoming healthcare reform offers no increases in ASC reimbursement for Medicare.
- The proposed ASC payor mix is based on unusually low percentages of Medicare and Medicaid patients.
- Utility expenses are understated and fail to include the cost of electricity.

- (6) *The applicant shall demonstrate that the proposed project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.*

**The proposed project fails to comply with CON Review Criterion 6 because the application does not conform to CON Review Criterion 3. CHS has multiple facilities with underutilized operating rooms including CMC Mercy / Pineville, CMC University and Carolinas Surgical Center-Randolph. Future projections for the proposed project and SouthPark Surgical Center are inconsistent and unreasonable as previously discussed.**

**The proposed project is located in facility space that includes unnecessary space with the most grossly oversize area being the surgical suite, which totals 6,800 square feet.**

- (7) *The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.*

**The project application does not comply with Criterion 7 because the project includes no staff or contract service arrangements for pharmacy. The application fails to name anesthesiology and pathology providers. Page 26 of the application states that anesthesia will be administered by anesthesiologists and CRNAs, but the application fails to identify any anesthesiologists or anesthesia groups that have expressed a willingness to perform this service. The application does not identify any specific pathologists or pathology groups, nor does it mention the availability of pathology services in any capacity.**

- (8) *The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with existing health system.*

**The application does not comply with Criterion 8 because the project includes no documentation of a North Carolina licensed anesthesiologist or a named anesthesia group to provide required services.**

- (18a) *The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.*

**The Randolph Surgery Center application does not comply with Criterion 18a because the application is nonconforming with CON Review Criteria 3, 4, and 5. The applicant projects that more than 20% of its patients are from rural counties that are outside of the boundaries of the service area counties.**

The application is not conforming to the Criteria and Standards for Surgical Services and Operating Rooms as follows.

10A NCAC 14C .2102 (b) (5) - The application is non-conforming because the methodology and assumptions are unreasonable as described in the comments regarding CON Review Criterion 3.

10A NCAC 14C .2102 (b) (9) - The application is non-conforming because the identification of the anesthesiologist (physician) is omitted.

10A NCAC 14C .2103 (b) and (c) – The application is non-conforming due to overstated utilization projections that include unsubstantiated cases from multiple counties outside of the SMFP-defined service area, unreasonable and overstated utilization projections and inconsistent assumptions regarding the number of cases to be shifted from SouthPark to the proposed project. Based on the erroneous volumes, the numbers of charity care and Medicaid are unreliable. Furthermore, the revenue projections for the project are wrong.



In CON Project Application #F-8545-10, Cotswold Surgery Center, LLC proposes to develop a new single specialty freestanding ambulatory surgery center with two operating rooms and one small procedure room. The proposed project will initially be staffed by eleven ophthalmologists.

The Cotswold application fails to conform to the specific CON criteria as follows:

5. Unreasonable patient origin projections, flawed methodology and unreliable utilization projections causing the application be nonconforming to multiple CON review criteria and regulatory standards
6. Unjustified procedure room with no utilization and no financial projections
7. Inaccurate revenue and expenses based on overstated surgery cases
8. Understated expenses with staff positions omitted
9. Inconsistent and omitted staffing positions
10. Unacceptably low access for Medicaid patients

*CON Review Criteria:*

- (1) *The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, surgical operating rooms, or home health offices that may be approved.*

The Cotswold application fails to conform to Criterion 1 because more than 30.6 % of its patients are projected to originate from outside of the boundaries of Mecklenburg, Cabarrus and Union Counties. Pages 87 and 88 of the application show that the proposed project is based on a seven county service area that includes Iredell County, NC, Gaston County, NC, York County, SC and Lancaster County, SC in addition to the service area specified in the State Medical Facilities Plan of Mecklenburg, Cabarrus and Union Counties. The applicant unreasonably plans to divert patients from adjoining counties who currently have access to existing ambulatory surgery facilities and hospitals.

Cotswold's seven county service area conflicts with the written criteria of the demonstration project in the 2010 SMFP. The need determination for two operating rooms in the Service Area (Mecklenburg / Cabarrus / Union Counties) is pursuant to the Single Specialty Ambulatory Surgery Facility Demonstration Project. The SMFP- defined service area and special need determination includes only the population of Mecklenburg, Cabarrus and Union Counties. This is a determinative limitation and no unmet need for single specialty operating rooms extends to other locations and populations. Page 91 of the 2010 SMFP states, "Locating facilities in high population areas with a large number of operating rooms and existing ambulatory surgery providers prevents the facilities from harming hospitals in rural areas, which need revenue from surgical services to offset losses from other necessary services such as emergency department services."

The application fails to explain the rationale for the ownership interest and participation of the Doctors of Optometry that is described on page 19. Contrary to the single specialty need determination, the Cotswold application involves two separate specialties, ophthalmology and optometry.

(3) *The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.*

The application fails to conform to CON Review Criterion 3 because the surgery projections are overstated and based on unreasonable assumptions:

- Cotswold defines an unjustified seven county service area that is inconsistent with the service area definition included in the 2010 State Medical Facilities Plan. Patient volumes based on an excessively large service area are overstated with 30.6% of the patients projected from distant counties.
- Page 75 of the application show the unreasonable assumption that the proposed facility intends to shift 94 patients away from Iredell Hospital in 2012. It is entirely unreasonable to project that hundreds of elderly patients will be willing to drive from Statesville to south Charlotte. It is unreasonable to assume that large numbers of patients from Iredell and Gaston Counties in North Carolina and York and Lancaster Counties in South Carolina will drive to the proposed facility for surgery when these patients have access to facilities in their home counties.
- The applicant's failure to adequately identify all counties for patient origin destroys the overall credibility of the surgery projections. Page 83 of the application shows that, in addition to the unjustified seven county service area, hundreds of patients (comprising 9.6% of the total) are projected to originate from "Other NC, Other SC and Other States." Such vague representation fails to identify the actual location of patient origin and should be rejected. The utilization projections for the proposed facility should not include the unjustified patient volumes from outside the SMFP-defined service area counties. The following table shows the results when the patient volumes for Iredell County, NC, Gaston County, NC, York County, SC Lancaster County, SC, "Other NC, Other SC and Other States" are excluded from the total Cotswold projections.

	YR 1	YR 2	YR 3
Cotswold Total Cases	2,511	2,551	2,592
Subtract Out of Service Area Cases	-768	-779	-793
Remaining Service Area Cases	1,743	1,772	1,798
Cases x 1.5 hrs each	2,615	2,658	2,697
ORs needed at 1872 annual hours	1.4	1.4	1.4

The Cotswold Surgery Center fails to demonstrate the need for two operating rooms based on the number of cases that are projected to originate from within the SMFP-defined service area of Mecklenburg, Cabarrus and Union Counties. Furthermore the application proposes to develop a procedure room within the proposed facility. No utilization projections are included to justify the need the population has for the proposed procedure room.

- Cotswold fails to provide letters of support from referring physicians and community representatives in the counties and "Other" areas where 30.6% of the total utilization is expected to originate.
- The Cotswold Surgery Center includes a small procedure room (see page 27 of application) in its facility plan, but the CON application omits its utilization data and facility charges. The missing information causes the application to fail to comply with Criterion 3 because there is no need for a procedure room that has zero volume.
- Page 71 of the application shows that total number of eye surgery cases for the seven county service area declined by 3 percent from 24,381 cases in 2008 down to 23,622 cases in 2009. This trend of declining surgery cases for the total population certainly refutes the 1.6% growth assumption that is used in the methodology on page 73.
- Cotswold relies upon a growth rate of 7.4% to reach its 2010 projection to which it applies a 1.6% growth rate to reach its 2014 projection. Cotswold's 2010 annualized projection is unacceptable, however, because Cotswold did not provide the actual utilization statistics for the first four months of 2010 to substantiate its projected growth rate. Because the 2010 projection is unsubstantiated, the projection for 2014 is likewise called into question.<sup>1</sup>

(4) *Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.*

The Cotswold application fails to conform to CON Review Criterion 4 because the utilization projections are unreliable and the financial projections are inaccurate. The comments regarding Criterion 3 explain why the utilization projections are unreliable in terms of unreasonable patient origin, inadequate community support, and unreliable assumptions and projections. No justification is provided by the applicant for the procedure room.

The financial projections are based on unreasonable and overstated utilization projections. Consequently the revenues are also overstated based on unreasonable and overstated utilization

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<sup>1</sup> In Required State Agency Findings dated December 5, 2008 for Project I.D. Numbers M-8133-08/ Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System and N-8143-08/ The Radiation Medicine Group, PLLC and The Radiation Medical Center, LLC, the Analyst noted with respect to Cape Fear that:

*"The applicant did not provide the actual number of external beams treatments that were performed in the first six months of FY2008 to substantiate the projected 4.80% growth rate for 2008."*

In other words, the Agency took issue with projections based on an annualized number when the applicant failed to furnish the actual numbers to support its annualized figure. Cotswold similarly relies on "annualized volumes through April of this year" to claim a 7.4% growth rate but, like Cape Fear, Cotswold did not provide the actual number of outpatient surgeries to substantiate its projected growth rate for 2010. Just as it did in the Cape Fear review, the Agency should find Cotswold's application nonconforming to Criterion 3 based on the applicant's failure to provide actual surgery numbers to support its projections.

projections. Expenses are omitted making it impossible to evaluate the cost effectiveness of this proposal. Please see the comments regarding Criteria 3 and 5.

- (5) *Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.*

The financial projections are based on unreasonable and overstated utilization projections. Please see the comments above regarding Criterion 3. Revenues are overstated based on unreasonable and inflated utilization projections with over 768 cases per year from outside of the SMFP-defined service area counties.

These cases and resulting revenues are unjustified and should be excluded from both the operational and financial calculations. The following table shows that the Cotswold project is not financially feasible with the exclusion of the surgery cases from outside of the SMFP-defined service area.

	YR 1	YR 2	YR 3
Cotswold Total Cases	2,511	2,551	2,592
Subtract Out of Service Area Cases (30.6%)	-768	-779	-793
Remaining Service Area Cases	1,743	1,772	1,798
Financial pro forma Net Revenue per Case	\$1,141	\$1,142	\$1,142
Cotswold Net Revenue without Out of Service Area Cases	\$1,989,422	\$2,022,761	\$2,053,272
Adjusted Total Expenses (lower volume reduces supply cost)	\$2,311,213	\$2,371,861	\$2,427,196
Cotswold Loss	-\$321,791	-\$349,100	-\$373,924

The total expenses in the table above are adjusted to decrease the supply cost based on the reduced volume of cases. Even so, without the 30.6% cases from outside the SMFP- defined service area, Cotswold lacks sufficient utilization to conform to the CON performance standard and it will suffer huge operating losses.

Addition errors in the financial pro forma statements include:

- Inaccurate and understated salary expenses due to the omission of Quality Advisor, Sterile Processing Tech and Pharmacy staff positions that are listed in the table on page 26, Section II but omitted in the staffing tables and salary calculations.
- Revenue and expenses for the procedure room are omitted from the statements. It appears that the application omitted the CPT codes, charges, revenues and expenses related to YAG laser capsulotomy, which is typically performed in procedure rooms. Section VIII, page 132 shows that the applicant intends to acquire the YAG laser and table.

- The applicant unreasonably assumes an increase in Medicare reimbursement rates in 2012.

(7) *The applicant shall demonstrate that the proposed project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.*

The proposed project fails to comply with CON Review Criterion 6 because the application does not conform to CON Review Criterion 3. The project is unsustainable based on the projected number of surgery cases that the applicant claims can be diverted from facilities from within the service area. With such dismal volumes, the applicant has resorted to diverting surgery cases from distant counties including Iredell County, NC, Gaston County, NC, York County, SC Lancaster County, SC and the "Other NC, Other SC and Other States."

(7) *The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.*

The Cotswold application provides inconsistent staffing information and fails to comply with Criterion 7. Staffing for the procedure room is omitted from the staffing table in Section VII. Page 26 in Section II states that the procedure room will be staffed by RNs. However, page 125 omits the assignment of RNs to a procedure room. This staffing discrepancy causes the allocations of other RN staff in the facility to be unreliable. Additional staffing discrepancies include:

Page 26 Section II - Facility Staff Description of Positions	Page 125, Section VII - Employee Categories
Quality Advisor Staff Position	No corresponding position listed
Sterile Processing Technician Staff Position	No corresponding position listed
Pharmacy Staff Position	No pharmacy positions listed

(8) *The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with existing health system.*

The application does not comply with Criterion 8 because the project includes no documentation of a pathology group, individual or company to provide services. No contract service arrangements are described for pharmacy functions.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and members of the medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicaid recipients, racial and ethnic minorities and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving priority. For the purpose of determining the extent to which the proposed services will be accessible, the applicant shall show:

- c. That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to

which each of these groups is expected to utilize the proposed services;

According to Section VI of its application, Cotswold proposes to serve only six percent Medicaid. This is unacceptably low as compared to other surgical specialties represented in the competitive review. Furthermore, the applicant fails to demonstrate that the level of access for Medicaid patients at the proposed facility will be enhanced based on the overly large seven county service area and the extended driving distances for patients to travel from Iredell County, NC, Gaston County, NC, York County, SC and Lancaster County, SC. The proposed project provides poor access to low income patients and Medicaid patients who often lack transportation. The six percent projection for Medicaid access reflects a substandard commitment to the medically underserved population.

*(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.*

The Cotswold application does not comply with Criterion 18a because the application is nonconforming with CON Review Criteria 3, 4, and 5. The applicant projects that more than 30.6% of its patients are from counties that are outside of the boundaries of the service area counties.

The Cotswold application is not conforming to the Criteria and Standards for Surgical Services and Operating Rooms as follows.

10A NCAC 14C .2102 (b) (5) - The application is non-conforming because the methodology and assumptions are unreasonable as described in the comments regarding CON Review Criterion 3.

10A NCAC 14C .2102 (b) (9) - The application is non-conforming because the identification of the pathology provider and laboratory are omitted.

10A NCAC 14C .2103 (b) and (c) - The application is non-conforming due to overstated utilization projections that include unsubstantiated cases from multiple counties outside of the SMFP-defined service area and unreasonable assumptions. Based on the erroneous volumes, the numbers of charity care and Medicaid cases are unreliable.

CON Comparative Data

Project Applicants	University Surgery Center, LLC	Randolph Surgery Center, LLC and CEENTA Surgery II, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System	Cotswold Surgery Center, LLC and Horizon Investment Company, LLC
Project ID #	F-8543-10	F-8550-10	F-8545-10
Management Company	OrthoCarolina	The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System	Charlotte (Mecklenburg)
Location	Charlotte (Mecklenburg) 4601 Park Road, Suite 250 Charlotte, NC 28209	Charlotte (Mecklenburg) 3621 Randolph Road, Suite 200 NC 28211	135 South Sharon Army Charlotte, NC 28211
Need Address of Primary Site			
Patients Origin %			
Primary County	Mecklenburg--84%	Mecklenburg--60.3%	Mecklenburg--60.40%
Secondary Counties	Cabarrus--15%, Union--1%	Cabarrus--3.2%, Union--15.8%	Iredell, Union, Cabarrus, Gaston--20.50%
Other Counties Named		Gaston--4.3%	22 listed--5.60%
Other Counties Not Identified		8.00%	
Other States		8.50%	13.50%
Totals	100.00%	100.00%	100.00%
Description	Orthopedic ASC with 2 ORs and 1 procedure room	ENT ASC with 2 ORs	Ophthalmic ASC with 2 ORs and one small procedure room (page 27)
Lessor Capital Cost	\$0		\$2,016,361
Lessee Capital Cost	\$4,876,155		\$1,242,186
Total Capital Cost	\$4,876,155	\$1,307,500--renovation of existing ASC	\$3,258,547
Square Footage	9,315	14,087	9,483
Number of ORs	2	2	2
Number of Procedure Rooms	1		1
Number of Participating Physicians	16 Orthopaedic Surgeons	23 ENTs	11 ophthalmologists (potentially 8 more from other practices)
OR Cases (and / or Procedures)			
YR 1	Cases 2,405	Cases 2,990	Cases 2,511
YR 2	2,595	3,064	2,551
YR 3	2,790	3,140	2,592
Procedure Room Cases			
YR 1	424	NA	No utilization for procedure room
YR 2	458		No utilization for procedure room
YR 3	492		No utilization for procedure room
Total FTES Year 2	18.6	21	16
Total RNs Year 2	8	8	5
Payor Mix %			
Medicare	34.00%	13.00%	47.30%
Medicaid	10.00%	6.00%	3.80%
Commercial Insurance	50.00% (+ Managed Care)	0.00%	15.60%
Managed Care		68.00%	18.10%
Other	2.00%	0.00%	0.10%
Self Pay / Indigent	4.00%	13% (includes bad debt and workers comp, and TRICARE)	15.10%

Project Applicants	University Surgery Center, LLC	Randolph Surgery Center, LLC and CEENTA Surgery II, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System	Cotswold Surgery Center, LLC and Horizon Investment Company, LLC
Project ID #	F-8543-10	F-8550-10	F-8545-10
Total Average Gross Charge	Per Case \$2,773 \$2,773 \$2,773	Per Case \$3,167 \$3,262 \$3,360	Per Case \$2,025 \$2,025 \$2,025
Total Net Revenue per Case	Per Procedure \$982 \$982 \$982	\$1,588 \$1,623 \$1,659	Per Case \$1,141 \$1,142 \$1,142
Documentation of:			
Anesthesia	Carolina Anesthesia Associates	No anesthesiologists named - through CHS? See page 28 and 63, 59	Carolina Anesthesia Associates
Pathology	Yes, Celligent, LabCorp	No pathologist named	No Yes, Presbyterian-Main, additional transfer attempted with CMC
Transfer Agreements	CMC University	CMC	Yes Yes Yes Yes
Outcome Measures	Yes	Yes	Yes
Accreditation	Yes	Yes	Yes
Clinical Training Programs	Yes	Yes	Yes
Open Access Policy	Yes	Yes	Yes
Criterion for Charity + Medicaid Amounts to 7% of Total	Yes	Unreasonable utilization causes percentages to be unreliable	Unreasonable utilization causes percentages to be unreliable
WHO Surgical Safety Checklist	Yes	Yes	Yes
Electronic Health Records	Yes	Yes	Yes, no exhibit to document
# of Letters of Support in CON Applications from Physicians in Service Area	78	10	40
Comments and Notes:	Demonstrates need for ORs and procedure room  Highest number of support letters  Strong documentation regarding anesthesia, pathology and pharmacy  Second highest % of Medicaid  100% of patients from within the Service Area  Second lowest average gross charge per case and lowest net revenue per case	Facility plan includes excess S.F. for what is necessary for a 2 OR Surgery Center  Low number of support letters  No pathology or anesthesiology groups or physicians named in application  No projected commercial insurance - may be included in managed care  Second lowest % of Medicaid patients of all applicants  20.8% of Patients from Outside of Service Area  Second highest gross revenue per case and second net revenue per case	Proposes a small procedure room, but no justification, no utilization projections or financial information included  No exhibit on Electronic Health Records  No pathologist group or physician letter in application  Lowest Medicaid % of all applicants  30.6% of Patients originate from outside Service Area



## **Comparative Analysis Summary:**

### **Conformity to CON Review Criteria**

The University Surgery Center CON application conforms to all of the CON review criteria and is comparatively superior to both the Randolph and Cotswold application. Randolph Surgery Center application has numerous deficiencies and is nonconforming to CON review criteria 3, 4, 5, 6, 7, 8, 18a. Cotswold Surgery Center application fails to conform to criteria 3, 4, 5, 6, 7, 8, 13c, 18a.

### **Physician and Other Healthcare Providers Letters Support**

The University Surgery Center CON application includes the highest level of physician support including 78 physician letters as well as letters from the anesthesia group and pathology / laboratory providers. In contrast, the Randolph application includes only 10 physician support letters and no documentation of support from anesthesiologists or pathologists. Cotswold has approximately 40 support letters from physician and doctors of optometry but lacks any documentation of support from a pathology / laboratory provider.

### **Utilization by Service Area Population**

University Surgery Center projects the number of surgery cases and patients based on 100% of its patients originating from within the service area that includes Mecklenburg, Cabarrus and Union Counties; these utilization projections are based on reasonable assumptions and meet the operating room criteria and performance standards. The Randolph application includes 20.8 percent from outside the service area; its methodology and projections are unreliable as discussed in Criterion 3 comments. The Cotswold application includes 30.6 percent of its patients from outside of the service area; its projections are unreasonable due to faulty assumptions.

### **Medicare and Medicaid Access**

The University Surgery Center CON application is comparatively superior to the Randolph and Cotswold applications with regard to the Medicare and Medicaid access. University Surgery Center projects to serve higher percentages of Medicaid patients as compared to both Cotswold and Randolph. The University Surgery Center CON application offers the second highest percentage of total surgery cases to Medicare patients of all applicants in this review.

Cotswold projects to serve the highest percentage of Medicare patients but its 3.8 percent access for Medicaid patients is the lowest of all applicants. Randolph proposes the lowest percentage access to Medicare patients at 13 percent and the second lowest percentage access for Medicaid patients at 6 percent.

**Net Revenue Per Case**

The following table compares the Year 2 Net Revenue / Surgery Case:

	<b>YR 2 Net Revenue / Surgery Case</b>
<b>University Surgery Center</b>	<b>\$1,227</b>
<b>Randolph Surgery Center</b>	<b>\$1,623</b>
<b>Cotswold Surgery Center</b>	<b>\$1,142</b>

The Randolph Surgery Center application projects higher revenue per case as compared to the others in the table above. Randolph Surgery Center's operational and financial projections are inaccurate as discussed in the comments regarding Criterion 5. Cotswold Surgery Center projects the lowest net revenue per case. However, Cotswold's revenue projections are unreliable due to overstated volumes and the omission of YAG laser procedures. University Surgery Center is the most effective project based on the lowest net revenue per case based on reasonable operational and financial projections.

**Demonstration Project Criterion Related to Physicians Ownership**

The single specialty ambulatory surgery facility demonstration project criteria includes the following statement: *"In choosing among competing demonstration project facilities, priority will be given to facilities that are owned wholly or in part by physicians."*

The Randolph Surgery Center application is the least compliant proposal based on the ownership interest of Carolinas Healthcare System, a system that already controls nearly half of the operating rooms in Mecklenburg County. Cotswold's proposal is contrary to the single specialty demonstration project criteria because the project involves two separate specialties, ophthalmology and optometry.

In conclusion, University Surgery Center proposes the optimal physician ownership arrangement that is absolutely consistent with the single specialty demonstration project criteria.