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CON Section

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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 Cabarrus Orthopaedic Surgery Center, LLC CON application

Dear Mr. Brown:

Enclosed please find comments prepared by Gateway Ambulatory Surgery Center, LLC regarding the CON application submitted by Cabarrus Orthopaedic Surgery Center, LLC to establish a new demonstration project single-specialty ambulatory surgery center in Cabarrus County. We trust that you will take these comments into consideration during your review of the application.

Sincerely,

A handwritten signature in black ink, appearing to read "Jon Langford", written in a cursive style.

Jon Langford, MD
President

**COMMENTS & OPPOSITION REGARDING
CABARRUS ORTHOPAEDIC SURGERY CENTER, LLC
CON PROJECT ID# F-8552-10**

**Submitted by Gateway Surgery Center
August 31, 2010**

Gateway Surgery Center (GSC) represents a partnership of local physicians and Carolinas Healthcare System (CHS). GSC has provided high-quality ambulatory surgical services to residents of Cabarrus and surrounding counties since 2006. GSC operates four operating rooms and two procedure rooms at its existing facility on NorthEast Gateway Court in Concord. Currently, more than 70 physicians perform surgery at GSC, representing a variety of specialties, including gastroenterology, general surgery, gynecology, ophthalmology, orthopedics, otolaryngology, pediatric oral surgery, physiatry, plastic surgery, podiatry and urology. During FY2009, these physicians performed 5,990 surgical cases at GSC. Our physicians all live and work in Cabarrus County. One of our members, CMC NorthEast, is a not-for-profit hospital that also serves this area. Thus, GSC is knowledgeable regarding the local need for surgical services in the service area, and is well positioned to evaluate the CON proposal by Cabarrus Orthopaedic Surgery Center, LLC (COSC) for a new single-specialty ambulatory surgery center in Cabarrus County.

COSC proposes to serve Cabarrus County and other area patients. As a current provider of surgical services in Cabarrus County, and 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 COSC 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. COSC's application does not achieve these objectives.

Specifically:

- COSC's application is inconsistent with the applicable policies in the 2010 State Medical Facilities Plan (SMFP), and specifically Policy GEN-3: Basic Principles, in that

the proposed project does not promote equitable access, and does not maximize healthcare value for resources expended.

- COSC's proposed project does not satisfy CON Review Criterion 3 in that it does not adequately identify the population to be served by the proposed project, nor does it demonstrate the need the identified population has for the proposed project.
- COSC fails to satisfy Review Criterion 4 in that the applicant provides no justification that the proposed project represents the lowest cost or most effective alternative to serving the health service area.
- The application is non-conforming to Review Criterion 5. COSC failed to adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenue.
- COSC is non-conforming to Review Criterion 6. Specifically, COSC does not demonstrate that the proposed project will not result in unnecessary duplication of existing service capabilities and facilities.
- The application is non-conforming to Review Criterion 12. The proposed project unduly increases the costs of providing health services.
- COSC's application is non-conforming to Review Criterion 18. COSC did not adequately demonstrate that its proposal to develop a single-specialty ambulatory surgery center would have a positive impact upon the cost effectiveness, quality, and access to the proposed services.
- COSC's application failed to conform to all applicable administrative rules.

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

Noncompliance with 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, operating rooms, or home health offices that may be approved.*

COSC's proposed application is not consistent with applicable policies in the SMFP. The application does not demonstrate how the project will promote equitable access and maximize healthcare value. Therefore, COSC fails to be consistent with Policy GEN-3: Basic Principles, and is thus non-conforming to Review Criterion (1).

Access

COSC's proposal does not reasonably project to improve access to services for residents of the Demonstration Project service area. COSC proposes to develop its facility in a remote corner of the Demonstration Project service area, distant from most of the residents of the service area. Further, COSC's projected patient origin is not realistic. Please refer to Review Criterion (3).

In addition, COSC projects lesser access to care for medically underserved patients compared to the competing applicants. As shown on the table below, two other applicants projected to serve a much greater percentage of patients who are either medically indigent or have government insurance.

**Projected Payor Mix
Self Pay, Medicare & Medicaid
Project Year 2**

	Cabarrus Orthopaedic Surgery Center	Cotswold Surgery Center	Randolph Surgery Center	University Surgery Center
Combined Self Pay, Medicare & Medicaid	40.7%	66.2%	32.0%	48.0%

Source: CON Applications

Value

COSC did not reasonably identify the population it proposes to serve, nor did it adequately demonstrate the need the population it proposes to serve has for the proposed project. The applicant also did not demonstrate that the project it proposed is financially feasible. Therefore, COSC did not demonstrate the process by which it plans to maximize healthcare value expended. Consequently, the application is not conforming to Policy Gen-3. Please see Review Criteria (3) and (5) for discussion.

- (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.*

COSC proposes to develop a single-specialty ASC in Kannapolis. The 2010 SMFP indicates the Charlotte Metro operating room service area for the Demonstration Project consists of Mecklenburg, Cabarrus, and Union counties. The three applicants competing with COSC each propose to develop their project in Mecklenburg County. This is understandable, as Mecklenburg County is by far the most populous county in the Demonstration Project Service Area. As shown in the population projection below, Mecklenburg County is home to nearly 70% of all service area residents.

Service Area Population

Projected 2014

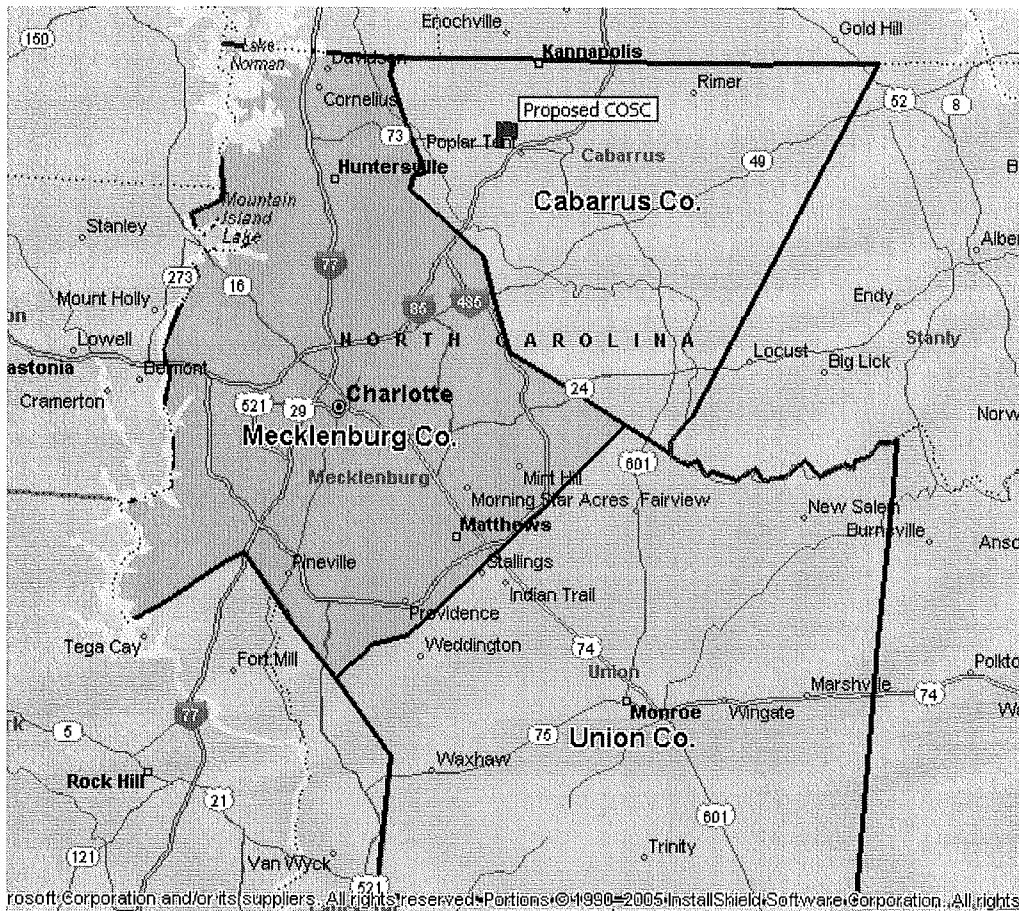
County	Patients	% of Total
Mecklenburg	969,667	69.5%
Cabarrus	203,942	14.6%
Union	220,784	15.8%
Total	1,394,393	100.0%

Source: NC State Office of Budget & Management

By contrast, Cabarrus County is the least populous of the three counties. More importantly, COSC proposes to develop its facility on the northern border of Cabarrus County, adjacent to Rowan County. This location is not a central location for this

Demonstration Project, and is inconvenient to most service area residents, as shown in the map below.

Single Specialty ASC Service Area



Yet despite this remote service area location for the Demonstration Project, COSC somehow projects that nearly half of its patients will originate from Mecklenburg County. Aside from the geographic unreasonableness of this presumption, COSC's projected patient origin does not square with the historical patient origin of the ambulatory surgery providers who are currently meeting the need in Cabarrus County. Currently, three Cabarrus County facilities offer ambulatory surgery: Gateway Surgery Center, Eye Surgery and Laser Clinic, and CMC- NorthEast. The tables below compare COSC's projected patient origin by county, with the combined average of the existing Cabarrus County providers.

**Cabarrus Orthopaedic Surgery Center
Projected 2015 Ambulatory Patient Origin**

County	Patients	% of Total
Cabarrus	459	22.5%
Rowan	46	2.3%
Stanly	12	0.6%
Mecklenburg	994	48.6%
Other	533	26.1%
Total	2,044	100.0%

Source: 2010 CON Application

**Combined Existing Providers
FY2009 Ambulatory Patient Origin**

County	Patients	% of Total
Cabarrus	9,295	61.8%
Rowan	2,972	19.8%
Stanly	1,432	9.5%
Mecklenburg	670	4.5%
Other	666	4.4%
Total	15,035	100.0%

Source: 2010 License Renewal Applications

As this table demonstrates, COSC's projection is unreasonable. Mecklenburg County residents represent only 4.5% of current patient origin, and totaled only 670 patients. Yet somehow COSC assumes that nearly 1,000 Mecklenburg residents will travel to Cabarrus County for ambulatory surgery.

This claim is even more unreasonable when one considers the surgical staff that COSC anticipates for its ASC. None of the surgeons are on the medical staff for the existing hospital located in Cabarrus County. Indeed, none of the surgeons are based in Cabarrus County. In fact, most of the COSC surgeons are not even located in the Demonstration Project service area, but rather are from Rowan County. It is unreasonable to assume that surgeons based in Rowan County, operating at an ASC located in northern Cabarrus County, will serve a larger number of Mecklenburg County patients than are currently served by the three local surgery facilities.

COSC did not adequately demonstrate that the population needs the services it proposes. Specifically, COSC's utilization projection methodology suffers from multiple flaws, including:

- The calculation of outpatient orthopedic surgical cases is not based on outpatient surgical use rates by county. Given that COSC's proposed service area includes a minority of the Demonstration Project Service Area, and does not include Union County, utilization should have been analyzed based on an historical use rate specific to the proposed COSC service area.
- COSC provides no reasonable justification for its market share assumption of 10% in the first project year. This is particularly unrealistic given that none of the projected COSC surgeons currently work in Cabarrus County.

- COSC’s spine surgery methodology is dependent on an unrealistic annual growth rate of 27%. Based on a two-year historical increase of only 78 cases (from 129 cases in 2007 to 207 in 2009, as stated on page 79 of the application), COSC projects an increase to over 1,000 cases in 2016. This is a very small sample size from which to project such immense utilization growth. In any case, the historical growth is not particularly relevant because it represents the practice of the spine physicians in Mecklenburg County, whereas this proposal is for a facility in Cabarrus County, where the spine physicians have no established presence.
- The projection tables included in Exhibit 2 (tables 2 & 3) appear to have discrepancies related to the ramp-up assumptions, as the potential COSC calendar case volumes do not appear to foot to any other number on the tables.

In summary, COSC did not reasonably identify the population to be served, and did not adequately demonstrate that the population needs the services it proposes. The COSC application is thus nonconforming with this criterion.

(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 application is not conforming to all other applicable statutory and regulatory review criteria. Please see Review Criteria (1), (3), (5), (6), (12), (18a) and Criteria and Standards for Surgical Services and Operating Rooms in 10A NCAC 14C .2100.

In addition, as shown in the tables on the following page, COSC projects the second highest average procedure charges, reimbursement, and costs of all the applicants.

**Projected Average Charge/Procedure
Project Year 2**

	Cabarrus Orthopaedic Surgery Center	Cotswold Surgery Center	Randolph Surgery Center	University Surgery Center
Average Gross Charge	\$3,814	\$5,165	\$3,262	\$3,165

Source: CON Applications

**Projected Average Reimbursement/Procedure
Project Year 2**

	Cabarrus Orthopaedic Surgery Center	Cotswold Surgery Center	Randolph Surgery Center	University Surgery Center
Average Net Charge	\$1,665	\$2,912	\$1,623	\$1,353

Source: CON Applications

**Projected Average Cost/Procedure
Project Year 2**

	Cabarrus Orthopaedic Surgery Center	Cotswold Surgery Center	Randolph Surgery Center	University Surgery Center
Average Cost	\$1,976	\$2,647	\$1,492	\$1,221

Source: CON Applications

Therefore, COSC did not adequately demonstrate that its proposal is an effective alternative, and the COSC application is nonconforming with this criterion.

- (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.*

COSC failed to adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenue. Please refer to Review Criterion (3).

In addition, COSC did not demonstrate that it has sufficient funding to develop the project. Specifically, in addition to the project capital cost, COSC projects working capital requirements totaling \$483,023 (page 158 of the application). As stated on that page, COSC claims that Novant Health will fund all the working capital requirements. However, in Exhibit 4 of the application, the Novant Health funding letter specifies that it will only fund \$69,293 for the project's working capital needs. And in fact, the necessary working capital may indeed be much higher than the total shown on page 158, since COSC projects losses on the income statement through the initial two project years. Thus, COSC does not have sufficient funding to develop and operate the project. Therefore, the COSC application is not conforming to this criterion.

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

The applicant does not adequately demonstrate the need the population it proposes to serve has for the proposed single-specialty ambulatory surgery center. Please see Review Criterion (3) for discussion.

Gateway Surgery Center already provides the services proposed by COSC. As an accredited multi-specialty ambulatory surgery center, Gateway Surgery Center provides quality, access and value, consistent with Policy GEN-3: Basic Principles of the SMFP. Thus, Gateway Surgery Center is better positioned than COSC to meet the community need.

Further, Cabarrus County already hosts a two operating room single-specialty ambulatory surgery center: Eye Surgery and Laser Center. Therefore, COSC did not adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved surgical services, and is not conforming to this criterion.

- (12) *Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.*

As previously noted in Review Criteria (3) and (6), COSC did not document why the geographic location of the proposed ASC is the most effective alternative. Additionally, COSC's utilization projections are constructed from unsupported assumptions, and do not

demonstrate the need the population has for the proposed project. Therefore, the COSC project is not needed, and results in unnecessary duplication of existing services.

Further, COSC proposes by far the highest project capital costs of any of the four applicants, as demonstrated in the table below.

Projected Capital Costs

	Cabarrus Orthopaedic Surgery Center	Cotswold Surgery Center	Randolph Surgery Center	University Surgery Center
Capital Cost	\$6,221,805	\$3,270,323	\$1,307,500	\$4,876,155

Source: CON Applications

Therefore, COSC’s application is not conforming to Review Criterion (12).

(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.

COSC did not adequately demonstrate that its proposal to develop a single-specialty ambulatory surgery center would have a positive impact upon the cost effectiveness, quality, and access to the proposed services. Therefore, COSC’s application is nonconforming to this criterion. Please see Review Criteria (1), (3), (4), (5), (6), and (12).

Section .2100 – Criteria and Standards for Surgical Services and Operating Rooms

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory

surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall not be approved unless:

- (1) *the applicant reasonably demonstrates the need for the number of proposed operating rooms in the facility, which is proposed to be developed or expanded, in the third operating year of the project based on the following formula: {(Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)} divided by 1872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms. The number of rooms needed is determined as follows:*
 - (A) *in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;*

COSC is non-conforming to this performance standard. COSC did not reasonably project the need for a Demonstration Project for two single-specialty ambulatory surgery operating rooms in Cabarrus County. Please refer to the discussion in Review Criterion 3.

Conclusion

With the justifications in the above paragraphs, the Agency has standing to find the COSC project non-conforming on many Statutory Review Criteria, and on the Operating Room Administrative Rules.

- COSC's application is inconsistent with the applicable policies in the 2010 State Medical Facilities Plan (SMFP), and specifically Policy GEN-3: Basic Principles, in that the proposed project does not promote equitable access, and does not maximize healthcare value for resources expended. Therefore, the application is non-conforming to Review Criterion 1.
- COSC's proposed project does not satisfy CON Review Criterion 3 in that it does not adequately identify the population to be served by the proposed project, nor does it demonstrate the need the identified population has for the proposed project.

- COSC fails to satisfy Review Criterion 4 in that the applicant provides no justification that the proposed project represents the lowest cost or most effective alternative to serving the health service area.
- The application is non-conforming to Review Criterion 5. COSC failed to adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenue.
- COSC is non-conforming to Review Criterion 6. Specifically, CSOC does not demonstrate that the proposed project will not result in unnecessary duplication of existing service capabilities and facilities.
- The application is non-conforming to Review Criterion 12. The proposed project unduly increases the costs of providing health services.
- COSC's application is non-conforming to Review Criterion 18. COSC did not adequately demonstrate that its proposal to develop a single-specialty ambulatory surgery center would have a positive impact upon the cost effectiveness, quality, and access to the proposed services.
- COSC's application failed to conform to all applicable administrative rules.

As it conducts a careful evaluation of the COSC application, the Agency may find other flaws in the application.