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**January 3, 2011 Comments in Opposition
from North State Surgery Center, LLC
Regarding Triangle Orthopaedics Surgery Center, LLC
CON Application for a Single Specialty Orthopaedic Ambulatory
Surgical Center (Project I.D. # J-8616-10)
Submitted November 15, 2010 for December 1, 2010 Review**

In accordance with N.C.G.S. Section 131E-185(a1)(1), North State Surgery Center, Regiona Surgical Associates, and Novant Health, Inc. submit the following comments regarding the CON Application of Triangle Orthopaedics Surgery Center, LLC for a Single Specialty Orthopedic Ambulatory Surgical Center (Project I.D. # J-8616-10).

I. Introduction

The following three CON applications were submitted on November 15, 2010 in response to the need determination identified in the *2010 State Medical Facilities Plan (2010 SMFP)* for a single-specialty ambulatory surgery center demonstration project with two surgical operating rooms in the Wake-Orange-Durham Service Area:

- J-8616-10: Triangle Orthopaedics Surgery Center, LLC ("TOSC") proposes to develop a \$2.4 million facility in the Brier Creek area of Raleigh (Wake County) in which to perform orthopedic surgery.
- J-8520-10: Obesity Management Center of the Carolinas, LLC proposes a \$5.9 million facility in Cary (Wake County) in which to perform general surgery with a focus on obese patients.
- J-8621-10: Foundation Health Systems Corp. and Regional Surgical Associates propose to develop North State Surgery Center, a \$5.4 million surgery center in Chapel Hill (Orange County) in which to perform general surgery.

II. Triangle Orthopaedics Surgery Center Proposal

A. Project Description

Alexander Investment Group, LLC (AIG) will construct a 9,755 square foot shell building on a 2.32 acre site it owns located at 7921 ACC Boulevard in the Brier Creek area of Raleigh, zip code 27617, and will up-fit that facility into a licensed orthopaedic ambulatory surgery center ("the proposed ASC"), which Triangle Orthopaedic Surgery Center, LLC (TOSC) will lease. TOSC will incur tenant improvement costs via its lease agreement with AIG.

However, as reflected in Exhibit 14 of the TOSC Application, the entire "shell" building is being built just for this project and it is reasonable to assume that it will not be constructed if the project is not approved. The developer of the building is constructing an ambulatory surgery center, not a medical office building. No physician offices are included in the drawings in Exhibit 14. Therefore, the developer should be identified as a

co-applicant and construction cost for the building should be included in the total capital cost of the project in Section VIII of the TOSC CON Application.

National Surgical Hospitals (NSH) will “manage and operate”¹ the proposed orthopaedic ambulatory surgery center.

TOSC projects that the proposed single specialty ambulatory surgery demonstration project will become operational on January 1, 2012. Project Years are presented as calendar years.

B. Project Cost and Financing

TOSC states that the project cost of \$2,400,207 will be financed through loans from Wells Fargo Bank.² TOSC fails to include the construction cost of the building and therefore has understated the cost of the project to be identified by the applicant in Section VIII of the TOSC CON Application.

TOSC projects start up expenses related to facility preparation, equipment testing, clinical staff training, and supply inventory for a total working capital start up of \$626,383.³ TOA accumulated reserves will be used to fund the working capital for this project.⁴

The total financial outlay for the proposed project is \$3,026,590 (\$2,400,207 + \$626,383).

C. There is Only One Named Applicant on the CON Application – There should be Two Co-Applicants on the CON Application

TOSC is the only named applicant for the proposed single specialty ambulatory surgery demonstration project. AIG should be named as a co-applicant.

Alexander Investment Group, LLC (AIG) is the owner of land on which it will build a facility and up-fit that facility for the purpose of operating the proposed ambulatory surgery center. AIG will then lease that facility to TOSC. By having not included AIG as a co-applicant, none of the costs of site acquisition⁵, preparation, and construction is included in the total capital cost of the proposed ASC. As such, the proposed project understates the true and complete project capital cost be provided by the applicant in Section VIII of the CON Application form for operating rooms.

¹ CON Application J-8616-10 at page 125.

² CON Application J-8616-10 at page 123.

³ CON Application J-8616-10 at page 128.

⁴ CON Application J-8616-10 at page 128.

⁵ CON Application J-8616.10 at Exhibit 14 is a document entitled “Wake County Real Estate Data Account Summary” for the 2.32 acre lot at 7921 ACCC Blvd. That document lists the assessed value of the 2.32 acre lot at \$1,045,961.

D. Physician Ownership and Physicians Expected to Use the Proposed ASC

Triangle Orthopaedic Associates, PA (TOA) owns 100% of the membership interests in TOSC. TOA has 22 physician shareholders, each of which has a 4.55% membership interest in TOSC.

According to page 28 of the Application, some of the 22 TOA physician shareholders are partial owners (28.65%⁶) of North Carolina Specialty Hospital.⁷ Those TOA physician shareholders who also own 28.65% of North Carolina Specialty Hospital are not identified.

The 22 physician owners of TOSC are on the medical staffs of 7 hospitals, to include North Carolina Specialty Hospital, Durham Regional Hospital, Rex Hospital, and WakeMed.⁸ There is no information provided in the Application about the ambulatory surgery center medical staff membership of the 22 physician owners of TOSC.

TOSC expects that “[u]pon completion of the proposed project, at least 16 orthopaedic surgeons are expected to utilize the proposed facility initially.”⁹ TOSC refers to those 16 physicians as “TOSC User Physicians.”

The following table shows a comparison among the TOA physicians, TOA/TOSC individual physician owners of the proposed orthopaedic ambulatory surgery center, and the TOA/TOSC physicians expected to provide orthopaedic ambulatory surgical services at the proposed orthopaedic ambulatory surgery center (TOSC User Physicians).

⁶ CON Application J-8616-10 at page 28, FN 5

⁷ <http://triangleortho.com/index.cfm/fuseaction/site.content/type/39492/custom/1.cfm>

⁸ CON Application J-8616-10 at page 8.

⁹ CON Application J-8616-10 at page 66.

**TOA Physicians,
TOA/TOSC Individual Physician Owners, and
TOA/TOSC Physicians Expected to Provide Surgical Services at the Proposed ASC (TOSC
User Physicians)**

TOA Physicians	TOA/TOSC Individual Physician Owners of Proposed ASC	TOA/TOSC Physicians Expected to Provide Orthopaedic Ambulatory Surgery Services at Proposed ASC (TOSC User Physicians)
Julian Aldredge, MD	Julian Aldredge, MD	Julian Aldredge, MD
Kimberly Barrie, MD	Kimberly Barrie, MD	Kimberly Barrie, MD
Richard Bruch, MD	Richard Bruch, MD	Richard Bruch, MD
Mark A. Burt, MD	Mark Burt, MD	Mark Burt, MD
Philip Clifford, MD	Philip Clifford, MD	Philip Clifford, MD
David Dellaero, MD	David Dellaero, MD	David Dellaero, MD
Thomas Dimming, MD	Thomas Dimming, MD	Thomas Dimming, MD
Dina Eisinger, MD	Dina Eisinger, MD	
William Hage, MD	William Hage, MD	William Hage, MD
Paul Kerner, MD	Paul Kerner, MD	Paul Kerner, MD
Ralph Liebelt, MD	Ralph Liebelt, MD	
William Mallon, MD	William Mallon, MD	William Mallon, MD
Jeffrey Murray, MD	Jeffrey Murray, MD	Jeffrey Murray, MD
David Musante, MD	David Musante, MD	
Raphael Orenstein, MD	Raphael Orenstein, MD	
Shepard Rosenblum, MD	Shepard Rosenblum, MD	Shepard Rosenblum, MD
William Silver, MD	William Silver, MD	William Silver, MD
Robert Wilson, MD	Robert Wilson, MD	
Steven Winters, MD	Steven Winters, MD	
Charlie Yang, MD	Charlie Yang, MD	Charlie Yang, MD
Eugenia Zimmerman, MD	Eugenia Zimmerman, MD	
Brett J. Gilbert, MD		Brett J. Gilbert, MD
Joseph B. Wilson, MD		Joseph B. Wilson, MD
Perico N. Arcedo, MD		
Peter W. Gilmer, MD		
Stephen N. Lang, MD		
Leslie "Les" R. Phillips, PhD – Behavioral Health Provider		
Russell R. Zelko, MD		
Total = 29*	Total = 22	Total = 16

Source: CON Application J-8616-10 at pages 5 and 67

*TOA Physician List at

<http://triangleortho.com/index.cfm/fuseaction/site.content/type/39672/custom/1.cfm>

There is no information provided in the Application to explain why not all of the TOA physicians and TOA/TOSC physician owners, respectively, will use the proposed orthopaedic ambulatory surgery center.

III. CON Review Criteria

The following comments are submitted based upon the CON Review Criteria found at G.S.131E-183. While some issues impact multiple Criteria, they are discussed under the most relevant review Criteria and referenced in others to which they apply.

G.S. 131E-183 (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.

A. SMFP Policy GEN-3 – Basic Principles

The plain language of “SMFP Policy GEN-3: Basic Principles” requires that:

“A certificate of need applicant applying to develop or offer a new institutional health service for with there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan, as well as addressing the needs of all the residents in the service area. [Emphasis added.]

As discussed in detail in the context of Criterion (3) below, TOSC fails to adequately demonstrate the quantitative and qualitative need for the project, and therefore failed to document how its projected volumes incorporate the Basic Principles in meeting the need identified in the 2010 SMFP for a single specialty ambulatory surgery demonstration project in the Wake-Durham-Orange Demonstration Project Service Area. Consequently, the Application is not conforming to Policy GEN-3, and does not conform to Criterion (1).

B. Operating Room Need Methodology – Results in Overstated Surgical Volume

As discussed in detail in the context of Criterion (3) below, surgical volume is overstated. As a result, the projected utilization is unreasonable and cannot be used to justify the proposed two single specialty ambulatory operating rooms in Brier Creek/Wake County. Therefore, the Application is derivatively non-conforming to Criterion (1).

For these reasons, the proposed project is non-conforming to Policy GEN-3: Basic Principles and Basic Assumptions included in the Operating Room Need Methodology.

G.S. 131E-183 (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.

**A. TOSC did not Provide per TOA/TOSC Physician
Historical Orthopaedic Ambulatory Surgery Utilization**

On page 67, TOSC includes a table showing total ambulatory surgery cases in CY 2008, CY 2009, and CY 2010 Annualized for the 16 TOA/TOSC physicians who are expected to use the proposed ASC (TOSC User Physicians). That table is presented in the following table.

**TOSC User Physicians
Historical Ambulatory Surgical Cases**

	CY 2008	CY 2009	CY 2010*
Orthopaedic Ambulatory Surgery Cases	4,292	4,762	5,057

**Annualized based on nine months data (Jan-Sept)*

Source: Triangle Orthopaedic Association, P.A.

It however, cannot be determined from the text and table on page 67:

- At what surgical facility those cases were performed.
- Whether those cases were performed in Wake, Durham, and Orange Counties or elsewhere.
- Whether those cases were performed in a licensed operating room or unlicensed procedure room.
- Whether those cases that were performed in a licensed operating room were appropriately performed in that venue or should have been performed in an unlicensed procedure room.

TOSC did not provide historical data for each of the 16 TOA/TOSC physicians (TOSC User Physicians) that intend to perform orthopaedic surgery in the proposed ASC. Such data would provide necessary basis for TOSC’s projected future volumes at the proposed demonstration project orthopedic surgery center.

On page 70, TOSC provides a table containing a list of 16 TOA/TOSC physicians (TOSC User Physicians) and the number of orthopaedic ambulatory surgical cases he/she will

perform in Project Year 1 (CY 2012). That table totals 4,269 orthopaedic ambulatory surgical cases, as shown in the following table.

**Triangle Orthopaedics Surgery Center
User Physician Projected Surgical Cases Project Year 1**

Physician	Surgical Cases	% of Total
J Mack Aldridge, MD	50	1.2%
Kimberly A Barrie, MD	1,300	30.5%
Richard F. Bruch, MD	120	2.8%
Mark A. Burt, MD	40	0.9%
Philip Clifford, MD	22	0.5%
David Dellaero, MD	250	5.9%
Thomas Dimming, MD	20	0.5%
Brett J. Gilbert, MD	50	1.2%
William Hage, MD	479	11.2%
Paul Kerner, MD	317	7.4%
William Mallon, MD	100	2.3%
Jeffrey Murray, MD	250	5.9%
Shepard Rosenblum, MD	414	9.7%
William Silver, MD	396	9.3%
Joseph B. Wilson, MD	349	8.2%
Charlie Yang, MD	112	2.6%
Total	4,269	100.0%

Source: Attachment 1, Table 8

As shown in the previous table, Kimberly Barrie, MD, is projected to perform 1,300 orthopaedic ambulatory surgery cases (30%) of the 4,269 total orthopaedic ambulatory surgery cases at TOSC in Project Year 1. Dr. Barrie's primary specialty is Hand/Upper Extremity Surgery.¹⁰

There is no information provided by TOSC in its CON Application to allow the Agency to determine the basis on which these cases allocated by physician or to evaluate whether they are based on a physician's historical practice pattern.

TOSC also does not provide any information on which to evaluate whether each physician will continue to perform the same percentage of total orthopaedic ambulatory surgery cases in Project Years 2 and 3, respectively. Total orthopaedic ambulatory surgery cases in Project Years 2 and 3, respectively, are shown in the following table.

Projected Orthopaedic Ambulatory Surgery Cases TOC User Physicians at TOSC

	CY 2012	CY 2013	CY 2014
Orthopaedic Ambulatory Surgery Cases	4,269	4,348	4,428

Source: CON Application J-8616-10, page 70

¹⁰ <http://www.triangleortho.com/index.cfm/fuseaction/site.physicians/action/dtl/phys/99794532.cfm>

There is no independent basis on which to determine the reasonableness of the per physician projected orthopaedic ambulatory surgical cases in any of the Project Years.

Lastly, it cannot be determined from the text and table on page 70 whether any of those cases that will be performed in a licensed operating room can be appropriately performed in an unlicensed procedure room.

B. Orthopaedic Ambulatory Surgical Cases Shifting to the Proposed ASC from an Existing Surgical Facility

On page 89 of the Application, TOSC states that:

[t]he proposed project will result in some reduction of procedures currently performed in existing licensed facilities. As described in Section III.1., the majority of cases performed by anticipated TOSC user physicians are currently being performed in hospital-based settings, [...]

TOSC does not identify:

- The licensed surgical facilities from which “procedures” will shift to the proposed ASC.
- The number of “procedures” that will be shifted from each licensed surgical facility.
- The TOA/TOSC physician who will be performing the “procedures” shifted from licensed surgical facilities to the proposed ASC.

Without that data, it is impossible to evaluate independently the impact of a shift on existing hospital-based outpatient surgery settings of 4,269 surgical cases in Project Year 1, 4,348 surgical cases in Project Year 2, and 4,428 surgical cases in Project Year 3. Evaluation of that impact is of particular importance when a licensed surgical facility has surplus operating room inventory.

C. TOSC Projects Orthopaedic Ambulatory Surgery Volume Exceeding the State-Defined Capacity for a Licensed Surgical Operating Room

For purposes of the annual *State Medical Facilities Plan (SMFP)*, the average operating rooms is anticipated to be staffed 9 hours per day for 260 days per year, and utilized at least 80% of the available time. The standard number of hours per operating room based on those assumptions is 1,872 hours.

On page 15 of the Application, TOSC states that it will “operate the proposed surgery center five days per week, 52 weeks per year, from 6:15 am to 5:00 pm.” Based on that information, the proposed ASC will be operational 10 hours, 45 minutes per day. Missing from operational hours is information to include:

- At what time TOSC’s first orthopaedic ambulatory surgery case will begin.
- At what time TOSC’s last orthopaedic ambulatory surgery case will begin.
- How much time will be allocated per day for staff lunch and break times.

That information is necessary to determine whether TOSC proposes to perform orthopaedic ambulatory surgery cases at, below or above the anticipated 9 hours per day for 260 days per year, and utilized at least 80% of the available time.

The Operating Room Need Methodology in the annual *SMFP* also assumes that each outpatient/ambulatory surgery will have a case time of 1.5 hours. “Case time” is defined as “Time from Room Set-up Start to Room Clean-up Finish.”¹¹

TOSC has not provided any information from which to assess independently whether the “case time” for the projected orthopaedic ambulatory cases will be less than, equal to or more than 1.5 hours.

The following table shows the number of licensed operating rooms that would be needed if TOSC were to operate the proposed surgery center at 9 hours per day for 260 days per year, and utilized at least 80% of the available time, and have a “case time” of 1.5 hours.

Projected Orthopaedic Ambulatory Surgery Cases TOC User Physicians at TOSC

	CY 2012	CY 2013	CY 2014
Orthopaedic Cases	4,269	4,348	4,428
Weighted Cases = Orthopaedic Cases x 1.5 Hrs/Case	6,404	6,522	6,642
ORs Needed at 1,872 Hrs/Year	3.4	3.5	3.5
Proposed ORs	2	2	2
Surplus (+)/Deficit (-)	-1.4	-1.5	-1.5

Source: CON Application

The previous table shows that TOSC would experience a deficit of 1.4 operating rooms in Year . This deficit is projected to grow to 1.5 operating rooms in Years 2 and 3, respectively. Thus, it appear that the proposed two new ORs may not adequately accommodate the projected TOSC volume. There is no acknowledgment by TOSC that its projected surgical volume will result in a need for additional operating rooms from the date of operation.

D. TOSC Projects Orthopaedic Ambulatory Surgery Volume to Exceed the Current Orthopaedic Ambulatory Surgery Case Volume of All but One Surgical Facility in the Demonstration Project Service Area

¹¹ Definition 2.4 from the Procedural Times Glossary of the AACD, as approved by ASA, ACS, and AORN. It is the definition used by the State of North Carolina.

The following table shows the orthopaedic ambulatory surgery volume for each surgical facility in the Demonstration Project Service Area for the most recent twelve months of publicly available data.

**Orthopaedic Ambulatory Surgery Volume by Surgical Facility
in Demonstration Project Service Area: October 2008 – September 2009**

Surgical Facility	FY 2009
Wake County	
Duke Raleigh Hospital	5,817
Blue Ridge Surgery Center	2,676
Rex Hospital	3,808
Rex Surgery Center of Cary	1,206
Rex Wakefield	255
WakeMed Cary	767
WakeMed Raleigh - New Bern	2,032
WakeMed North	1,129
Total	17,690
Durham County	
Duke University Hospital	4,080
Durham Regional Hospital	564
North Carolina Specialty Hospital	3,222
James E. Davis Ambulatory Surgical Center	708
Total	8,574
Orange County	
UNC Hospitals	2,300
Demonstration Project Service Area	
Total	28,564

Source: CON Application and LRAs

The previous table shows that only one surgical facility, Duke Raleigh Hospital, has an orthopaedic ambulatory surgery volume that exceeds TOSC's projected Year 1 (CY 2012) volume of 4,269 cases. All other surgical facilities, to include "related entity" North Carolina Specialty Hospital, have lower current volume. It is noteworthy that all of the surgical facilities shown in the previous table have operating room inventory that exceeds the two rooms proposed by TOSC.

As discussed above, the methodology used by TOSC to document a quantitative need for the proposed ASC is unreasonable and results in overstated projections. The Application does not conform to Criterion (3), and should be denied.

G.S. 131E-183 (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.

TOSC could have, but did not document that locating the demonstration project in either Durham or Orange County are not less costly and/or more effective alternatives.

Additionally, TOSC fails to discuss that 33.1%, a majority of TOA/TOSC physicians' historical orthopaedic ambulatory surgery patients, are residents of Durham County¹². **TOSC projects that Durham County residents will account for 36.2%, a majority of its total orthopaedic ambulatory surgery patients at TOSC, in Project Years 1, 2, and 3, respectively.**¹³

The majority of Durham and Orange County residents are closer to the existing NC Specialty Hospital in Durham. In its application, TOSC did not explain why these patients would choose to seek care at TOSC, rather than in Wake County. TOSC did not consider Durham County as a less costly and/or more effective alternative to the proposed Brier Creek area of Raleigh, where as documented in response to Criterion (6) below, there are 6 approved and existing surgical facilities with an inventory of 52 operating rooms within a 13.2-mile/18-minute one-way drive of the proposed TOSC project for a 2-OR orthopedic surgery center.

The burden is on the Applicant to demonstrate that the proposed project is the least costly or most effective alternative, which burden TOSC does not carry. As a result, the Application does not conform to Criterion (4).

G.S. 131E-183 (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.

TOSC is the only named applicant for the proposed single specialty ambulatory surgery demonstration project. AIG should be named as a co-applicant.

Alexander Investment Group, LLC (AIG) is the owner of land on which it will build a facility and up-fit that facility for the purpose of operating the proposed ambulatory surgery center. AIG will then lease that facility to TOSC. By having not included AIG

¹² CON Application J-8616-10 at page 68.

¹³ CON Application J-8616-10 at page 79.

as a co-applicant, none of the costs of site acquisition¹⁴, preparation, and construction is included in the total capital cost of the proposed ASC. As such, the proposed project understates the true and complete project cost.

In addition, as discussed above in the context of Criterion (3), surgical case volume projections are unreasonable and unsupported. TOSC used those surgical case volume projections as the basis for CON Pro Forma Forms B through E. Therefore, financial projections are also derivatively non-conforming.

For these reasons, the Application does not conform to Criterion (5).

G.S. 131E-183 (6)

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

A. The Proposed ASC is Duplicative of an Approved Orthopaedic Ambulatory Surgery Center in Wake County

TOSC is correct that the co-applicants in the August 15, 2008 CON application for the development of Orthopaedic Surgery Center of Raleigh (OSCR) identified the specialty areas to be provided in the facility as “orthopedics, podiatry, and physical medicine and rehabilitation.”¹⁵ Both podiatry and physical medicine and rehabilitation are complementary specialties to orthopaedic surgery.

At the time of the submission of the OSCR CON application, the Agency gave preference in competitive reviews to CON applications that proposed multispecialty ambulatory surgery centers. In order to be considered on equal footing with other applicants in a competitive review for a need determination in the 2008 SMFP for four operating rooms in Wake County, the OSCR co-applicants made a strategic decision. On January 29, 2009, the Agency approved development of OSCR, a 12,587 square foot ambulatory orthopedic surgical facility with four surgical operating rooms to be located at the intersection of Edward Mills Road and Macon Pond Road in Raleigh.¹⁶

In point of fact, the OSCR CON application contains letters from 19 orthopedic surgeons expressing support for the project and their intention to perform surgeries at the proposed ambulatory surgical facility. **No other letters were submitted letters from surgeons stating their intent to perform surgeries at OSCR. The OSCR CON application projected volume for orthopaedic ambulatory surgical cases.**

¹⁴ CON Application J-8616.10 at Exhibit 14 is a document entitled “Wake County Real Estate Data Account Summary” for the 2.32 acre lot at 7921 ACCC Blvd. That document lists the assessed value of the 2.32 acre lot at \$1,045,961.

¹⁵ Orthopaedic Surgery Center of Raleigh, LLC CON Application J-8170-08, Section II.10, page 21

¹⁶ Project I.D. # J-8170-08/Orthopaedic Surgery Center of Raleigh, LLC

As will be documented in Subsection C. below, OSCR will be located in close proximity to the proposed ASC – no more than a 9.5-mile/14-minute one-way drive from OSCR.

B. The Proposed ASC is Duplicative of the Existing Orthopaedic Hospital in Durham County

TOSC is duplicating services currently provided by Triangle Orthopaedic Associates at the existing North Carolina Specialty Hospital in Durham. As stated on page 67 of the application, surgeons associated with the proposed project performed 5,057 surgical cases in 2010, which utilized 4.1 operating rooms (5,057 outpatient cases x 1.5 hours per case / 1872).

On page 70, TOSC estimates that 81.4%¹⁷ of all projected surgical procedures performed by TOSC surgeons will be shifted from existing surgical locations which reflects the equivalent of 3.3 operating rooms in existing facilities.

C. Residents of the Brier Creek Area of Raleigh have Ample Access to Approved and Existing Surgical Facilities in Raleigh, Wake County, and Durham County.

Residents of the Brier Creek area of Raleigh have ample access to approved and existing surgical facilities in Raleigh, other parts of Wake County, as well as Durham County. It is noteworthy that over the last several years, the Agency has declined to approve any proposed surgical operating rooms in the Brier Creek area of Raleigh¹⁸. The following table shows the one way driving distance in miles/minutes from the proposed TOSC ASC. Each facility is/will be no more than a 13.2-mile/18-minute one-way drive from the proposed ASC.

One Way Driving Distance in Miles/Minutes to Proposed TOSC ASC from Approved and Existing Durham and Wake County Surgical Facilities

From:	To: 7921 ACC Boulevard, Raleigh 27617
Rex Raleigh Campus	9.5 miles/14 minutes
Orthopaedic Surgery Center of Raleigh	9.5 miles/14 minutes
Blue Ridge Surgery Center	9.8 miles/14 minutes
WakeMed North Healthplex	11.6 miles/13 minutes
Duke Raleigh Hospital	12 miles /16 minutes
North Carolina Specialty Hospital	13.2 miles/18 minutes

Source: Mapquest.com

¹⁷ Calculation: 4,269 projected cases in 2012 at TOSC/ 5,246 total outpatient surgical procedures by TOSC surgeons in 2012.

¹⁸ CON Application J-8051-08/WakeMed Brier Creek Surgery Center, LLC/Relocation of ambulatory surgery center approved in Project I.D. #J-7350-05 from Apex in Southwestern Wake County to Brier Creek area of Northwestern Wake County. Agency decision on July 23, 2008 to deny CON Application J-8051-08.

There are 52 operating rooms in 6 approved and existing surgical facilities within a one-way driving distance no more than 13.2 miles/18 minutes from the proposed ASC, as shown in the following table. The applicant, TOSC did not explain why its application did not mention that its "related entity" North Carolina Specialty Hospital is within a 13.2-mile/18-minute radius of the proposed ASC.

Approved and Existing Durham and Wake County Surgical Facilities within 13.2 miles/18 minutes from the Proposed TOSC ASC: October 2008 – September 2009

Surgical Facility	Operating Room Inventory*
Rex Raleigh Campus	23
Orthopaedic Surgery Center of Raleigh	4
Blue Ridge Surgery Center	6
WakeMed North Healthplex	4
Duke Raleigh Hospital**	15
North Carolina Specialty Hospital	4
Total	52

Source: 2010 LRAs

**Excludes dedicated C-Section rooms*

***Includes two operating rooms that have been approved to be relocated from National Women's Health Organization to Duke Raleigh Hospital in Project ID J-8567-10*

It is the applicant's burden to demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. For the reasons discussed above, TOSC did not carry its burden. The Application does not conform to Criterion (6).

G.S. 131E-183 (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.

The TOSC facility will be developed in a "medical office building" by Alexander Investment Group, LLC, and the building will be leased to TOSC. TOSC will upfit the leased space for the proposed ASC.

However, as reflected in Exhibit 14 of the TOSC Application, the entire building is being built just for this surgery center project and it is reasonable to assume that it will not be constructed if the project is not approved. The developer of the building is constructing an ambulatory surgery center, not a medical office building. No physician offices are

included in the drawings in Exhibit 14. Therefore, the developer should be identified as a co-applicant and construction cost for the building should be included in the total cost of the project.

For these reasons, the Application does not conform to Criterion (12).

IV. CON Criteria and Standards for Operating Room – 10A NCAC 14C .2100

The proposed project is non-conforming to the Criteria and Standards for Operating Rooms for the following reasons.

10A NCAC 14C .2102(b)(2,3,4)

In a footnote on page 28 TOSC states that North Carolina Specialty Hospital is not a "related entity" because Triangle Orthopaedic Associates does not have a controlling interest in NCSH. However, the definition of "related entity" at 10A NCAC 14C .2101(9) does not require that the joint venture, or shared ownership be a controlling interest. TOSC did not provide historical data or projected utilization from NCSH and therefore is non-conforming to these rules.

In addition, as discussed above in the context of Criterion (3), surgical case volume projections are unreasonable, and unsupported. TOSC fails to justify a need for the proposed two orthopaedic ambulatory operating rooms.

10A NCAC 14C .2102(b)(5)

As discussed in the context of Criterion (3) above, the assumptions and methodology used in the development of the projections required by this Rule are unreasonable and result in overstated projections.

10A NCAC 14C .2103(c)(1,2)

In a footnote on page 28 TOSC states that North Carolina Specialty Hospital is not a "related entity" because Triangle Orthopaedic Associates does not have a controlling interest in NC Specialty Hospital ("NCSH") in Durham. However, the definition of "related entity" at 10A NCAC 14C .2101(9) does not require that the joint venture, or shared ownership be a controlling interest. TOSC did not provide projected utilization from NCSH and the Agency cannot determine if all of the proposed and existing operating rooms for TOSC or a "related entity" meet this requirement, particularly since some volume will be shifted from the existing NCSH to the proposed TOSC. Therefore the project is non-conforming to these rules.

10A NCAC 14C .2103(f)

As discussed in the context of Criterion (3) above, the assumptions and methodology used in the development of the projections required by this Rule are unreasonable and result in overstated projections.

10A NCAC 14C .2104(b)(1), (2), and (3)

TOSC did not provide documentation showing the proximity of the proposed orthopaedic ambulatory surgery center to support services and ancillary services provided by “related entity” North Carolina Specialty Hospital.

V. Conclusion

The CON Application submitted by co-Applicants fails to conform to key Criterion reflected in N.C.G.S. 131E-183. The project fails to document the need for the proposed single specialty ambulatory surgery demonstration project in the Wake-Durham-Orange Service Area. When a CON application is not in conformity with CON Statutory Review Criterion (3), it is also non-conforming with CON Statutory Review Criteria (1), (4), (5), (6) and (12) as discussed above.