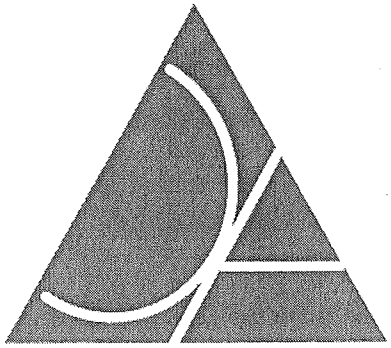


December 22, 2010

Michael McKillip, 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 Triangle Area Single Specialty ASC Demonstration Project CON Applications

Dear Mr. McKillip:

Enclosed please find comments prepared by Triangle Orthopaedic Surgery Center, LLC regarding the competing CON applications for the single-specialty ambulatory surgery center demonstration project in the Triangle service area, to meet the need identified in the *2010 State Medical Facilities Plan*. We trust that you will take these comments into consideration during your review of the applications.

If you have any questions about the information presented here, please feel free to contact me at 919.281.1807. I look forward to seeing you at the public hearing.

Sincerely,

Charles H. Wilson
CEO

COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS TRIANGLE AREA SINGLE-SPECIALTY ASC DEMONSTRATION PROJECT

Submitted by Triangle Orthopaedics Surgery Center, LLC
December 31, 2010

Three applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2010 State Medical Facilities Plan (SMFP)* for a single-specialty ambulatory surgery center (ASC) in the Triangle service area (Durham, Orange and Wake counties); North State Surgery Center, LLC (NSSC), Obesity Management Center of the Carolinas, LLC (OMCC), and Triangle Orthopaedic Surgery Center, LLC (TOSC). In accordance with N.C.G.S. §131E-185(a.1)(1), this document includes comments relating to the representations made by the other applicants, and a discussion about whether the material in each application complies with the relevant review criteria, plans, and standards. These comments also address the determination of which of the competing proposals represents the most effective alternative for development of a single-specialty ASC in the Triangle area.

Specifically, the CON Section, in making the decision, should consider several key issues, including the extent to which each proposed project:

(1) Selects the surgical specialty that represents the most effective alternative for a single specialty ambulatory surgery center;
(2) Offers the most effective geographic location in the Triangle area;
(3) Best improves access to ambulatory surgical services for all residents of Durham, Orange and Wake counties, including for medically underserved populations;
(4) Proposes a physician-driven ownership structure, which is the most effective model for development of a single specialty ASC demonstration project;
(5) Represents the most cost-effective (developmental and operational) alternative for creating a single specialty ASC;
(6) Best documents support from local referring physicians in the Triangle service area; and
(7) Reasonably demonstrates the need the population has for the proposed services.

Based on conformity to the special criteria for the demonstration project, and consistency with the Basic Principles of the 2010 SMFP (Policy Gen-3), TOSC represents the most effective alternative for development of the single specialty ASC demonstration project.

The remainder of this document consists of comparative comments, as well as specific commentary about each competing application.

Comparative Analysis

Single Specialty Surgery

Orthopaedic Surgery

Of the three competing proposals, two applicants (NSSC and OMCC) propose general surgery, while the other applicant (TOSC) proposes orthopaedic surgery. TOSC maintains that orthopaedic surgery is the most effective alternative to meet the identified need for an ASC demonstration project. According to the 2006 National Survey of Ambulatory Surgery, the total number of orthopaedic surgical cases is higher than any other specialty in the United States. Over 7.7 million total outpatient surgical procedures were performed by surgeons specializing in orthopaedics.

Consistent with this national data, orthopaedic ambulatory surgery represents the largest volume of all outpatient surgical utilization by specialty in the Triangle service area. According to the most recent data, orthopaedic surgery represents 25.03% of all outpatient surgical cases in the single-specialty service area. By contrast, general surgery was only 17.52% of the outpatient surgical cases in the Triangle. Please refer to the following table.

FY2009 Outpatient Surgical Utilization by Specialty

Specialty Area	Wake Co. OP	Durham Co. OP	Orange Co. OP	Total OP	% of Total
Orthopedics	**17,690**	**8,574**	**2,300**	**28,564**	**25.03%**
Ophthalmology	8,469	9,628	1,532	19,629	17.20%
General	12,782	4,329	2,889	20,000	17.52%
Otolaryngology	9,675	2,879	2,775	15,329	13.43%
Gynecology	8,303	3,074	2,787	14,164	12.41%
Urology	2,618	1,602	500	4,720	4.14%
Plastic Surgery	1,458	1,190	1,205	3,853	3.38%
Neurosurgery	1,583	556	125	2,264	1.98%
Oral Surgery	262	258	1,035	1,555	1.36%
Other	750	513	95	1,358	1.19%
Vascular	606	66	590	1,262	1.11%
Podiatry	478	350	0	828	0.73%
Cardiothoracic	25	320	260	605	0.53%
Total	**64,699**	**33,339**	**16,093**	**114,131**	**100.00%**

Source: 2010 Hospital & ASC License Renewal Applications

Currently, there are no dedicated orthopaedic ambulatory surgery centers in North Carolina. The Orthopaedic Surgery Center of Raleigh (OSCR) received CON approval (CON Project ID# J-8170-08) to develop an ambulatory surgery center near Rex Hospital; however, this facility will offer surgical services in several specialties, including orthopaedics, podiatry and physical medicine & rehabilitation. Furthermore, and of significant note, OSCR is not a demonstration project, and will not be submitting annual reports to the Agency regarding access for medically underserved, patient outcomes and cost effectiveness. This reporting requirement is a critical component of the 2010 Single Specialty ASC Demonstration Project.

Since orthopaedic surgery is, by far, the most common outpatient surgical specialty in the Triangle, and because the Triangle does not have a dedicated orthopaedic surgery center, TOSC's proposed orthopaedic ASC is the most effective alternative to demonstrate the benefits and effectiveness of a single specialty ASC.

Projected Surgical Utilization

The approved application in this batch review will serve as one of three ASC's in North Carolina that will report data to the Agency regarding various metrics, including patient outcomes and access to the medically underserved. Thus, it is important to consider the extent to which each proposed facility will be utilized. TOSC proposes to perform more surgery cases compared to the competing applications. Please refer to the table below.

Projected Surgery Cases

	Triangle Orthopaedics Surgery Center	Obesity Management Center of the Carolinas	North State Surgery Center
Project Year 1	**4,269**	1,552	1,777
Project Year 2	**4,348**	1,743	2,011
Project Year 3	**4,428**	1,959	2,239

Source: CON applications

TOSC projects utilization well above the State's definition of practical capacity. According to .2703(b)(1), outpatient surgical cases are estimated at 1.5 hours. Thus, based on a practical capacity of 1,248 per operating room (1,872 / 1.5), OMCC proposes to utilize its facility at only 78.5% capacity [1,959 / (1,258 x 2)] and NSSC proposes to utilize its facility at only 89.7% capacity. Given many general surgery cases take much less than 1.5 hours, OMCC and NSSC do not propose to utilize their proposed operating

rooms to their full potential. Most of the procedures that will be performed at TOSC take less than 1.5 hours, thus TOSC's projected utilization is reasonable and very conservative.

TOSC's proposed project will provide the greatest access to service area residents, the greatest amount of data regarding patient outcomes and cost. Therefore, TOSC is the most effective alternative for the proposed demonstration project.

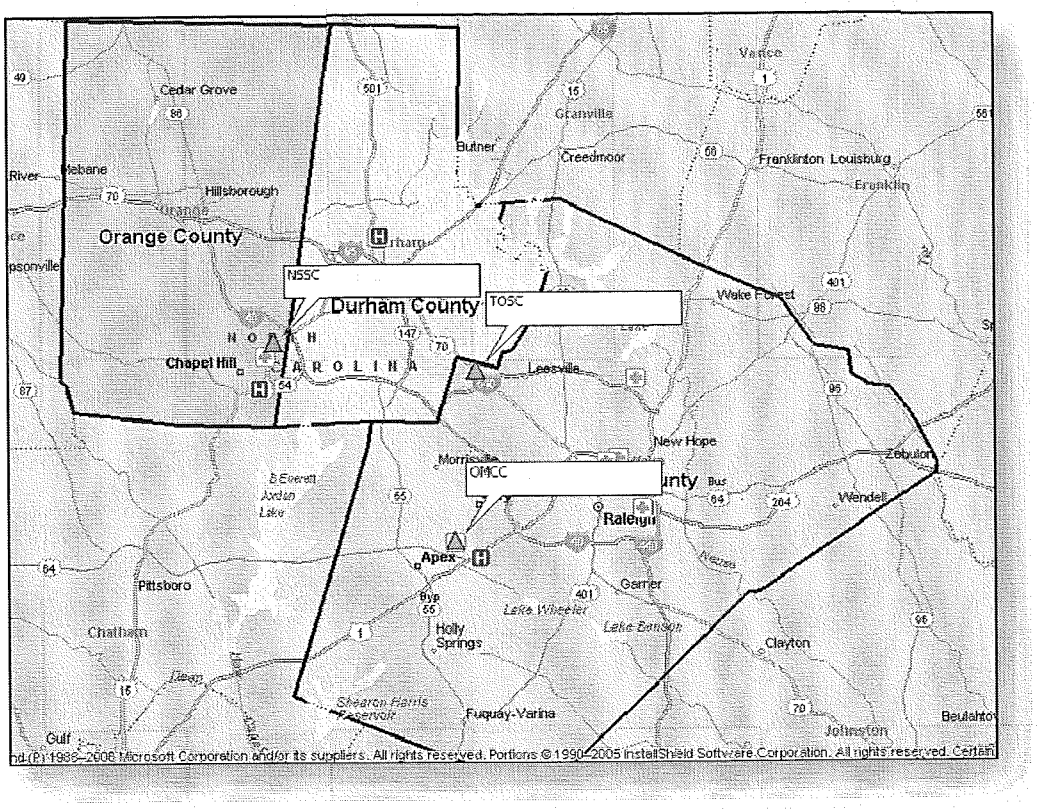
Geographic Access

Another important consideration in comparing the relative benefit of the alternative applications is improving geographic access to outpatient surgical services. A proposed new ASC in the Triangle should be targeted to most effectively increase convenient geographic access to ambulatory surgical services, and should project equitable and well distributed geographic access by residents of all three service area counties. TOSC's proposal is the most effective alternative in regard to geographic access, as described below.

Location

Two applicants (TOSC and OMCC) propose to develop their ASC in Wake County, while the other applicant (NSSC) proposes to develop an ASC in Orange County. Wake County is clearly the preeminent county for most effectively improving access to ambulatory surgery services. And of the two Wake County applicants, TOSC's proposed surgery center will provide the best geographic access for residents of the single specialty service area. TOSC proposes to develop an ambulatory surgery center that is centrally located in the Brier Creek area, at 7921 ACC Boulevard. TOSC is the only facility that will be centrally located in the Triangle Service Area, and will be easily accessible by residents of all three counties (Wake, Durham, and Orange counties). The proposed TOSC facility will be located adjacent to primary thoroughfares US Highway 70 and I-540, with direct links to I-40 and the Durham Freeway (NC 147). Please refer to the map on the following page.

Triangle Area ASC Demonstration Project
Applicant Proposed Locations



County Demographics

Of the three counties in the Triangle Service Area, Wake County has the greatest need for a new ambulatory surgery center. Wake County is one of North Carolina's largest counties in land area. More importantly, Wake County is currently the second most populous county in North Carolina. According to the North Carolina Office of State Budget and Management, Wake County is expected to become the most populous county in North Carolina by 2013, hosting more than one million residents. The population of Wake County is significantly larger than the combined population of both Durham and Orange counties. Additionally, Wake County's projected annual population growth rate is more than double the rate of Orange County, where NSSC proposes to develop its facility. Please refer to the following table.

Single Specialty ASC
Triangle Service Area
Projected Population, 2010 - 2014

	2010	2011	2012	2013	2014	*10-14 CAGR*
Wake	919,938	947,459	974,978	1,002,495	1,030,015	*2.3%*
Durham	271,580	277,031	282,480	287,929	293,378	*1.6%*
Orange	133,507	135,182	136,824	138,434	140,012	*1.0%*
Total	**1,325,025**	**1,359,672**	**1,394,282**	**1,428,858**	**1,463,405**	**2.5%**

Source: North Carolina Office of State Budget & Management http://demog.state.nc.us/

As the population is increasing, it is also aging rapidly. As thousands of Baby Boomers in the service area reach retirement age, the demand for orthopaedic surgery will continue to increase. The population in the proposed service area has a growing number of residents age 65 and older. Please refer to the following table.

Single Specialty ASC Service Area
Age 65+ Population

	2010	2014	10-14 CAGR
Wake County			
Population Age 65+	72,441	92,071	**4.9%**
Durham County			
Population Age 65+	26,301	31,023	**3.4%**
Orange County			
Population Age 65+	13,109	16,122	**4.2%**

Source: North Carolina Office of State Budget & Management http://demog.state.nc.us/
Totals may not foot due to rounding.

The population age 65 and older in Wake County is much larger than that of Durham and Orange counties combined, and projects to increase at rates that are higher than either Durham or Orange counties. For example, in Wake County the population age 65 and older is projected to increase over two times faster than the overall population (65+ = 4.9%, overall = 2.3%). The growing population age 65 and older will have a dramatic impact on the demand for orthopaedic surgical services.

As evidence of this population growth and aging in Wake County, it is notable that Wake is the only county that has shown a need for additional operating rooms for the past five years.

The proposed TOSC facility in Wake County is the best alternative to meet the outpatient surgical needs of this growing community. As the Triangle Service Area population continues to age rapidly, the resulting high demand for outpatient orthopaedic surgery offers a tremendous opportunity to improve quality, value and access through an orthopaedic ambulatory surgery center.

Patient Origin

TOSC proposes the highest patient origin for residents from the three counties in the Triangle service area. With its central location in Brier Creek, TOSC projects the most evenly distributed patient origin of Wake, Durham, and Orange counties. By contrast, OMCC practically ignores residents of Durham and Orange counties, while NSSC is essentially unavailable to Wake County residents. Please refer to the following table.

Projected Patient Origin
Triangle Service Area
Year One

County	TOSC	OMCC	NSSC
Wake	32.30%	63.66%	5.10%
Durham	36.20%	3.25%	50.20%
Orange	11.60%	0.48%	22.30%
Total	**80.10%**	**66.91%**	**77.60%**

Source: CON Applications

The TOSC proposal is the most effective alternative for equitably serving the residents of the entire Triangle ASC demonstration project area.

Medically Underserved

A key factor in measuring the accessibility of the alternative proposals is the extent to which the applicants propose to serve the medically needy, particularly uninsured and Medicaid patients. TOSC projects to serve the highest number of self-pay indigent care and Medicaid cases in the second project year. In fact, TOSC projects to serve more than

double the number of self-pay and Medicaid patients compared to the other applicants. Please refer to the following table.

Self-Pay/Indigent & Medicaid Cases
Second Project Year

	TOSC	OMCC	NSSC
Self-Pay/Indigent	254	282	80
Medicaid	402	26	241
Total	**654**	**308**	**321**

Source: CON Applications

In terms of expanding access for the medically underserved, TOSC's proposal represents the most effective alternative by serving the greatest number of uninsured patients. TOSC projects to serve the most indigent and Medicaid patients of any of the competing applicants. The TOSC project will provide much needed charity care, and demonstrates a high level of commitment to serving the medically needy. This is conforming to Review Criterion 13, consistent with Policy GEN-3, and responsive to the special ASC demonstration project criteria in the 2010 SMFP, to provide access for patients with limited financial resources.

Furthermore, TOSC has documented its commitment to improve access for the medically underserved population from community agencies. TOA has a long-standing relationship with Lincoln Community Health Center (LCHC) to provide care at little to no cost to LCHC patients. LCHC is a federally funded community health center meeting the needs of uninsured and underinsured individuals in the Durham community. LCHC is a leader in providing accessible, affordable, high quality outpatient health care services to the medically underserved. Over 85% of the orthopaedic care delivered to LCHC patients is administered by TOA physicians. The proposed surgery center will be available to LCHC patients.

TOA also provides episodes of care at no charge to Project Access of Wake and Durham County[1]. Project Access links people without health insurance into a local network of clinics, laboratories, pharmacies and hospitals that donate their efforts to help those in need. TOA provides all of its services to Project Access patients, e.g., office visits, surgery, diagnostic imaging, rehabilitation, etc. The proposed TOSC surgery center will also be available to Project Access patients who need orthopaedic surgery.

[1] Episodes of care are limited to 240 for Durham and 96 for Wake. Episodes of care are delivered during a 90 day period for each patient.

Physician Ownership Structure & Participation

As shown in the following table, the three applicants each propose a different ownership structure for their ASC demonstration projects. The TOSC proposal represents the most effective alternative for development of a single specialty ambulatory surgery facility.

Proposed Physician Ownership Structure

	TOSC	OMCC	NSSC
Physician ownership %	100%	60%	<50%*

*NSSC proposes two classes of ownership, Class A for a very limited group of physicians, and Class B for Novant. Novant will clearly dominate the venture, with 100% capital funding, 100% equity, 100% of income, and control of the LLC board.
Source: CON Applications

NSSC is the least effective alternative in terms of satisfying the demonstration project criteria of physician ownership. Not only does NSSC propose minority physician ownership, but also it proposes the most restrictive physician access policy. Specifically, the only surgeons who can be considered for NSSC ownership are surgeons employed by Novant Medical Group. Further, this limited group of surgeons is further culled by Novant, with the requirement that these physicians perform at least 20% of their outpatient general surgery procedures at NSSC.

TOSC is a more effective alternative than OMCC in that it proposes 100% physician ownership. Table 6D in 2010 SMFP (i.e., the need determination for the demonstration project) states: "In choosing among competing demonstration project facilities, priority will be given to facilities that are owned wholly or in part by physicians." Giving priority to demonstration project facilities owned wholly by physicians is an innovative idea and has great potential to improve safety, quality, access and value. Awarding the CON to an applicant with 100% physician ownership will enable the State Health Coordinating Council to monitor and evaluate the innovation's impact.

Further, as shown in the following table, TOSC projects broader physician participation in the proposed demonstration project facility. TOSC documents 16 surgeons who have indicated that they will utilize the single specialty ASC. OMCC and NSSC project far fewer surgeons using their facilities. Thus, the TOSC will be more broadly accessible for local residents in need of outpatient surgery.

Projected Surgeon Utilization

	TOSC	OMCC	NSSC
Total Surgeons	16	5	4

Source: CON Applications

The criteria for the single-specialty ASC demonstration project in the 2010 SMFP specifically encourage applicants to provide an open access policy to physicians. TOSC's application is consistent with this policy and includes the largest estimate of surgeons who will provide ambulatory surgical services. Conversely, the OMCC and NSSC applications propose relatively lesser access.

Another important factor to consider when evaluating competing proposals is the extent to which the community supports each proposed project. Notably, TOSC provided more letters of support from local physicians than OMCC and NSSC. This speaks volumes to the support that TOSC received from the local medical community. Furthermore, all of TOSC's letters of support are based on non biased, unfettered referral sources. TOSC does not employ or financially incentivize any of the non-TOA individuals that provided a letter of support. The same statement cannot be made by NSSC and OMCC. Finally, half of OMCC's letters of support are from Rex's Holly Springs and Single Operating Room Applications filed February 15, 2010. Thus, these letters cannot even be considered for the proposed batch review.

Value

Capital & Start-up Costs

In its application, TOSC demonstrates that the cost, design, and means of construction, and facility development represent the most reasonable alternative of the three applications, and that the TOSC project will not unduly increase the costs of providing health services, or the costs to the public of providing health services. Please refer to the following table for project-related costs.

Demonstration Project Development Costs

	TOSC	OMCC	NSSC
Capital Cost	$2,400,207	$5,911,398	$5,462,423
Working Capital	$626,383	$625,189	$714,111
Total	$3,026,590	$6,536,587	$6,176,534
% Higher	--	216%	204%

Source: CON Applications

TOSC projects, by far, the lowest project initiation costs among the competing applicants. In the current economic climate, effective initiatives to contain unnecessary costs and expenditures are especially important to promote value in healthcare. Declining reimbursement rates and augmented government regulations are increasingly placing downward pressure on healthcare providers to effectively do more with less. Thus, efficient management of project capital and start-up costs is crucial to providing value.

Average Reimbursement per Procedure

Another issue to consider when evaluating the competing applications is the extent to which each proposed project represents a cost-effective alternative for provision of outpatient surgical services. In the current healthcare marketplace, where cost of care is a major concern with payors and the public, the projected average reimbursement is an important measure of consumer value. TOSC projects very reasonable reimbursement and costs. In fact, TOSC projects the lowest average reimbursement and operating costs among the competing applicants. Please see the table on the following page.

Projected Average Reimbursement per Case*

Project Year	TOSC	OMCC	NSSC
1	**$1,222**	$3,795	$1,432
2	**$1,240**	$3,949	$1,319
3	**$1,259**	$4,106	$1,505

Source: CON Applications
*Reflects only technical charges

Average Cost per Procedure

Similar to the comparison of reimbursement, TOSC projects the lowest cost per case of all the applicants.

Projected Average Cost per Case

Project Year	TOSC	OMCC	NSSC
1	**$992**	$3,780	$1,466
2	**$999**	$3,889	$1,383
3	**$1,007**	$3,880	$1,324

Source: CON Applications

While, average reimbursement and cost are important measures of value, TOSC notes that comparatives among different specialties are not necessarily a fair "apples to apples" comparison. Thus, the cost and reimbursement of providing general surgery is not directly comparable to orthopaedic surgical services. However, this analysis demonstrates TOSC's commitment to competitive pricing and cost-effectiveness. TOSC most effectively satisfies the value requirement of Policy GEN-3.

Availability of Services

It is useful to compare the service availability dates of competing applicants. Applicants who propose to offer services sooner are better suited to address the established need; especially for a demonstration project. Collection of patient outcome data thus can be collected sooner, and its respective benefits to patients, providers, and payors can be realized sooner. As shown in the table below, TOSC projects to make operational its ASC before either of the competing applicants.

Projected Operational Date

	TOSC	OMCC	NSSC
Start Date	January 2012	March 2013	January 2013

Thus, TOSC is the most effective alternative for making the demonstration project available to service area residents, and also by providing vital patient outcome data to the State Health Coordinating Council in a timelier manner.

Specific comments regarding the OMCC application

- OMCC is not conforming to .2102 (d)(3). OMCC's calculations provided in response to .2102(d) (3) are fundamentally flawed. Specifically, as stated on page 58 of OMCC's application, "Medicare does not provide reimbursement for bariatric cases in an ASC setting", thus there is no Medicare allowable amount for self-pay and Medicaid bariatric surgical cases. Below provides the actual percent of total revenue collected for bariatric surgical cases in OMCC's proposed facility.

OMCC - Bariatric Surgical Cases
Year 3

YR 3	Total Surgical Cases	Self-Pay %	Surgical Cases	Medicare Allowable Amount per Case	Projected Revenue	Revenue Collected	Difference	Total Net Revenue	Percentage
Self Pay	803	24.70%	198	$0	$0	$53,134	-$53,134	$4,142,366	-1.28%
Medicaid	803	0.0%	0	$0	$0	$0	$0	$4,142,366	0.00%
Total	**803**		**198**	**$0**	**$0**	**$53,134**	**-$53,134**	**$4,142,366**	**-1.28%**

Source: OMCC CON Application

The table below provides the percent of total revenue collected for non-bariatric surgical cases in OMCC's proposed facility.

OMCC - Non-Bariatric Surgical Cases
Year 3

YR 3	Total Surgical Cases	Self-Pay %	Surgical Cases	Medicare Allowable Amount per Case	Projected Revenue	Revenue Collected	Difference	Total Net Revenue	Percentage
Self Pay	1,156	10.30%	119	$1,565	$186,341	$20,344	$165,997	$4,058,598	4.09%
Medicaid	1,156	2.5%	29	$1,565	$45,229	$62,651	-$17,423	$4,058,598	-0.43%
Total	**1,156**		**148**	**$1,565**	**$231,570**	**$82,995**	**$148,575**	**$4,058,598**	**3.66%**

Source: OMCC CON Application

The following table provides the sum of bariatric and non-bariatric surgical cases at OMCC's proposed facility. Clearly, OMCC does not meet the 7.0% minimum to satisfy .2102(d)(3), thus the application is non-conforming.

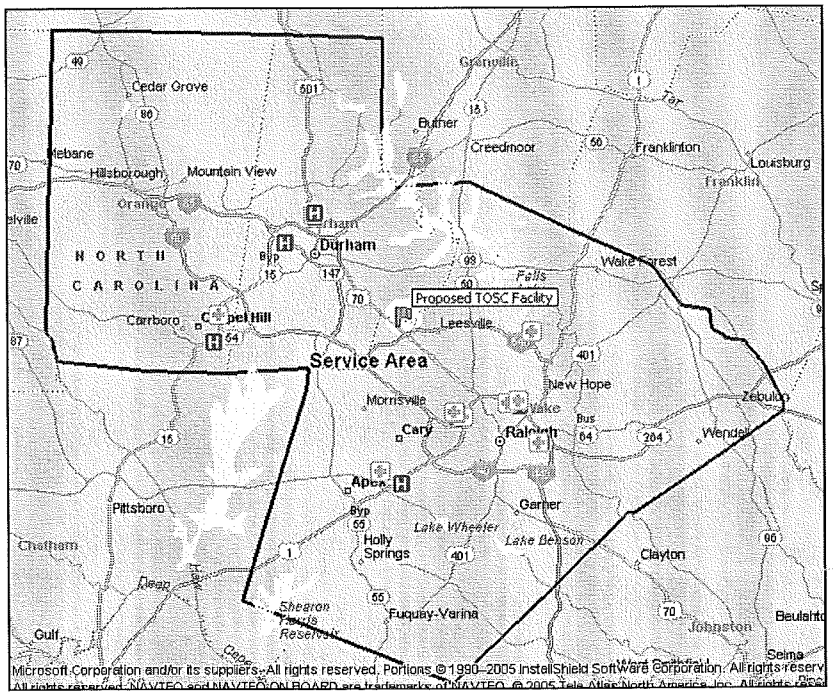
OMCC - Total Surgical Cases
Year 3

YR 3	Projected Revenue	Revenue Collected	Difference	Total Net Revenue	Percentage
Self Pay	$186,341	$73,478	$112,863	$8,200,964	1.38%
Medicaid	$45,229	$62,651	-$17,423	$8,200,964	-0.21%
Total	**$231,570**	**$136,129**	**$95,441**	**$8,200,964**	**1.16%**

Source: OMCC CON Application

- OMCC proposes to establish a new ASC in Wake County in close proximity to existing operating rooms. Currently there are no operating rooms in Brier Creek. TOSC is the only applicant that will provide much-needed geographic access in a new location. The map shows TOSC's proposed facility location relative to the existing Triangle-area ASC providers.

Triangle Service Area
Inpatient and Ambulatory ORs



- OMCC projects only 3% patient origin from Durham County, and less than 0.5% from Orange County. Clearly, OMCC ignores residents from two of the three service area counties. As such, OMCC does not provide any letters of support from Durham or Orange County surgeons and referring physicians. Therefore, OMCC is not an effective alternative in terms of broad geographic access.

- OMCC proposes to develop its bariatric surgery center in Cary. As OMCC describes in its application, obesity is a health status that has higher prevalence in both black populations, and low income citizens. Thus, Cary is not the most effective location for such a center, if the objective is to increase access to services for these populations. The following tables provide data related to income and race for the major population centers in the Single Specialty Service Area.

2010 Income Per Capita

	2010
Cary	$39,621
Chapel Hill	$30,808
Durham	$25,599
Raleigh	$28,647

Source: Claritas

2010 African American Population

	2010 Pop	2010 African American Pop	% of Total Pop
Cary	134,302	8,683	6.5%
Chapel Hill	54,860	6,062	11.0%
Durham	228,763	88,614	38.7%
Raleigh	383,883	108,538	28.3%

Source: Claritas

OMCC's proposed location in Cary is not the most effective alternative for increasing access to surgical services for obese patients, including black populations and low income citizens. Cary's African American population is only 6.5% of the total population and it has the highest income per capita when compared to Raleigh, Durham and Chapel Hill. Durham has the lowest income per capita and the highest percentage of black population; however, OMCC essentially alienates Durham County residents based on its 3% projected patient origin. The location of OMCC's proposed ASC is not effective and raises concern regarding the reasonableness of its projections. Therefore, OMCC's proposal is not the most effective alternative for the ASC demonstration project.

- OMCC's need methodology is unreasonable. OMCC utilizes an aggressive 12.4% growth rate to project surgical cases for its project. OMCC states its growth rate is reasonable because it believes there is a large existing underserved market of patients who seek bariatric and relates surgeries. Thus, OMCC's methodology is based on the "build it and they will come" rationale. This is woefully inadequate evidence to support a 12.4% growth rate. OMCC states their "belief" that there is an underserved market of patients who seek bariatric surgery. However, OMCC provides no evidence of such a market. OMCC cites the number IP addresses that visited a bariatric surgery device website; however, this does not demonstrate that patients are actively seeking elective surgery. Hits to the website could be attributed to researchers, competitors or providers, thus, this is not sufficient evidence to prove there is an "untapped market" for outpatient bariatric surgery. OMCC also cites the recent closing of FirstHealth Moore Regional Hospital's (FMRH) bariatric surgery program as a reason to expect 12.4% annual growth. However, based on discussions with FMRH leadership, FMRH's bariatric surgery program was primarily an inpatient program. Thus, these patients would not be appropriate for OMCC's proposed ASC.

OMCC failed to analyze historical ambulatory surgery utilization for the Single Specialty Service area. Specifically, ambulatory surgery experienced a two-year compound annual growth rate of 5.9% from FY2007 to FY2009.

Single Specialty Service Area
Ambulatory Surgery Cases

	FY2007	FY2008	FY2009
Wake County	55,773	61,360	64,699
Durham County	32,403	33,192	33,339
Orange County	13,525	14,819	16,093
Total	**101,701**	**109,371**	**114,131**
% Change	**--**	***7.54%***	***4.35%***

Source: State Medical Facility Plans, License Renewal Applications

OMCC's growth rate is more than double the historical growth rate of ambulatory surgery in the service area. OMCC failed to demonstrate that a 12.4% growth rate is realistic compared to actual historical growth of ambulatory surgery in the service area. In summary, OMCC's projections are based on an

unrealistic and aggressive growth rate. Therefore the application is not conforming to Criterion 3.

- OMCC's proposed project will limit access to ambulatory surgery for service area residents. OMCC proposes to develop an ASC to serve a specific sub-specialty of general surgery (bariatric surgery). As described previously in these comments, general surgery is only 17.52% of the ambulatory surgery market in the service area. OMCC proposes serve a very specific subset of this market, thus further limiting access for all patients. Further, neither Medicaid nor Medicare reimburses for bariatric surgery in the ASC setting. Thus, medically underserved patients will not have access to the proposed facility.

- OMCC is focused on bariatric surgery within the general surgery specialty. As stated in its application, OMCC is designing its facility, and would train its staff, "on the unique patient needs of the obese population". Indeed, to accommodate the severely and morbidly obese patients it is targeting, OMCC will design such facility features as:

    - Wider doorways
    - Heavy-duty beds, chairs, stretchers, wheelchairs, tables, etc.
    - Overhead lifts
    - Bariatric furniture
    - Heavy-duty toilets and sinks

  This leads one to question the assumption that OMCC is making, that the non-obese population will want to travel to a facility that is labeled as, and designed for, bariatric surgery. This further supports the unreasonableness of OMCC's 12.4% growth rate.

- In its application, OMCC tries to sell its proposal as "effectively creating a disease management center, rather than an ASC for a one-time surgical event" (page 97 of OMCC application). This is very misleading because it implies much more than will actually be included in and offered by the proposed licensed facility. OMCC describes the psychological and nutrition counseling that are required for a weight management program, as well as the associated ancillary services (laboratory tests, diagnostic imaging, and sleep studies). Yet, as OMCC acknowledges in its application, "these services are not provided by OMCC". Thus, one is left to wonder how exactly the proposed ASC is a disease management center.

- OMCC projects a rich management fee for Rex Hospital (8% of net revenues, compared to 6% of net revenues for the other two applicants). This leads one to wonder if this is truly an arm's length transaction.

Specific comments regarding the NSSC application

- NSSC's projection methodology is aggressive and unreasonable. As described in Step 3 of, NSSC expects its percent of total general surgical volume in Orange and Durham counties for its RSA surgeons will increase from 15% in 2009 to 20% by year three of its project. NSSC attempts to justify this dramatic increase based on physician support, recruitment of an additional general surgeon and marketing efforts. NSSC provided fewer physician support letters compared to TOSC, and the majority of letters were from Novant-affiliated physicians. Furthermore, none of the four projected surgeons at NSSC included volume projections in their letters of support. This specific lack of documentation calls into question the reliability of the utilization projections for the NSSC facility.

  NSSC assumes that one additional general surgeon will generate between 644 and 1,134 annual cases. However, NSSC provides no evidence of commitment from an additional general surgeon, thus it is unreasonable to base an increase in utilization on this rationale. Furthermore, NSSC failed to perform any analysis regarding historical growth for general surgery procedures in the service area to determine if 644 to 1,134 additional annual cases is reasonable. NSSC's projection methodology results in a five year compound annual growth rate of 18.1%. Please refer to the following table.

NSSC Surgery Case Projections

	2010	2011	2012	2013	2014	2015	10-15 CAGR
OP Surgical Cases	1,025	n/a	n/a	1,720	2,199	2,359	18.1%

Source: pp 76-77, NSSC CON application

NSSC's projected growth rate is more than three times greater than the historical compound annual growth rate for ambulatory surgery in the service area. Please refer to the following table.

Single Specialty Service Area
Ambulatory Surgery Cases

	FY2007	FY2008	FY2009
Wake County	55,773	61,360	64,699
Durham County	32,403	33,192	33,339
Orange County	13,525	14,819	16,093
Total	**101,701**	**109,371**	**114,131**
% Change	*--*	***7.54%***	***4.35%***

Source: State Medical Facility Plans, License Renewal Applications

Ambulatory surgery in the demonstration project service area experienced a two-year compound annual growth rate of 5.9% from FY2007 to FY2009. OMCC's growth rate is more than triple this rate. OMCC failed to demonstrate that an 18.1% growth rate is realistic compared to actual historical growth of ambulatory surgery in the service area. In summary, OMCC's projections are based on an unrealistic and aggressive growth rate. Therefore the application is not conforming to Criterion 3.

- The proposed NSSC facility will be located at 100 Europa Drive in Orange County. Comparatively, as previously shown in these comments, Orange County has the smallest population and the slowest annual population growth of the three counties in the Triangle single specialty ASC demonstration project service area. The population of Wake County is over four times the size of Orange County and is growing at a much faster rate. Therefore, NSSC's proposal to develop the facility in Orange County is the least effective alternative in terms of geographic access. Because NSSC will not provide geographical access to residents of Wake County, the largest and fastest growing county in the Triangle Area, the proposed facility will not meet the outpatient surgical needs of this growing community.

- Despite Wake County being the largest and fastest growing county in the Triangle Area, NSSC does not include Wake County in its primary service area. Specifically, only 5.10% of NSSC's patient origin is expected to originate from Wake County. Further, NSSC does not include any letters of support from Wake County referring physicians. Therefore, by not proposing to serve the most populous county in the Triangle, NSSC is the least effective alternative.

- Despite proposing a facility location in Orange County, NSSC projects 50% Durham County patient origin, and only 22% Orange County. NSSC states the

projected patient origin is based on the historical RSA patient origin for outpatient general surgery patients; however, NSSC failed to provide any data regarding historical patient origin. Therefore, the projected patient origin is questionable at best. Additionally, NSSC is essentially unavailable to Wake County residents. Thus, NSSC is not the most effective alternative in terms of access for service area residents.

- NSSC only nominally complies with the demonstration project criteria of physician ownership of the facility. Table 6D in 2010 SMFP (i.e., the need determination for the demonstration project) states: "In choosing among competing demonstration project facilities, priority will be given to facilities that are owned wholly or in part by physicians." NSSC is the least effective alternative with regard to physician ownership. Specifically, as described on the very first page of its application, NSSC will have two classes of ownership interest; Class A for physicians, and Class B for Novant. Novant will be responsible for funding the entire project, will own 100% of the equity in NSSC, and would be entitled to 100% of the NSSC net income. Further, Novant would control four of the seven NSSC board positions, and thus will also control NSSC governance. NSSC is not an effective alternative for the proposed demonstration project from a physician ownership perspective.

- The combined charity care and bad debt projections for NSSC are much lower than the competing applications. For example, in Project Year 2, NSSC projects a total of $403,043 (Form C – Surgery Component only). This is only 20% of the TOSC projection, and only 13% of the OMCC projection.