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Competitive Comments on Triangle Area Single Specialty Ambulatory Surgery Demonstration Project Applications

submitted by

Obesity Management Center of the Carolinas, LLC

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Obesity Management Center of the Carolinas, LLC (OMCC) submits the following comments related to competing applications to develop two operating rooms to be developed as a Single Specialty Ambulatory Surgery Demonstration Project and located in the Triangle Area (Wake, Durham, and Orange counties) as identified in the *2010 State Medical Facilities Plan* (*SMFP*). A total of three applications were submitted in response to the special need identified in the *2010 SMFP*.

- Triangle Orthopaedics Surgery Center, LLC (TOSC); Project ID # F-8616-10
- North State Surgery Center, LLC (NSSC); Project ID # F-8621-10
- Obesity Management Center of the Carolinas, LLC (OMCC); Project ID # F-8620-10

OMCC's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards.*" See N.C. GEN. STAT. § 131E-185(a1)(1)(c).

As outlined in these comparative comments and the application specific comments, OMCC represents the most effective alternative for the development of the Single Specialty Ambulatory Surgery Demonstration Project identified in the *2010 SMFP* based on the specific nature of the special need determination, as well as the analyses presented in OMCC's application. The following points, summarized below in turn, demonstrate the superiority of OMCC's application and why it should be approved.

- **The Proposal Submitted by OMCC Represents the Only Proposal For a Single Specialty Ambulatory Surgery Demonstration Project in the Triangle Area that is Conforming with the Need Determination**
- **Wake County represents the most effective location for a Single Specialty Ambulatory Surgery Demonstration Project in the Triangle Area**
- **The Proposed Specialty, Focus, and Design of OMCC's Proposal Represents the Most Effective Alternative for the Development of a Single Specialty Ambulatory Surgery Demonstration Project in the Triangle Area**

- **The ownership structure proposed in the OMCC application—a 60/40 joint venture between Rex and Triangle Area Bariatric Surgeons, LLC—represents the most effective alternative for the development of a Single Specialty Ambulatory Surgery Demonstration Project in the Triangle Area**
- **OMCC's proposal represents the most effective alternative with regard to documentation of physician support necessary to support a two-room Single Specialty Ambulatory Surgery Demonstration Project in the Triangle Area**

THE PROPOSAL SUBMITTED BY OMCC REPRESENTS THE ONLY PROPOSAL FOR A SINGLE SPECIALTY AMBULATORY SURGERY DEMONSTRATION PROJECT IN THE TRIANGLE AREA THAT IS CONFORMING WITH THE NEED DETERMINATION

As noted previously, a total of three applications were submitted in response to the special need identified in the *2010 SMFP*. Upon review of the applications, OMCC determined that neither TOSC nor NSSC is conforming with the need determination identified in the *2010 SMFP* and as such do not represent effective alternatives for the development of a Single Specialty Ambulatory Surgery Demonstration Project in the Triangle Area. OMCC will discuss the issues that render TOSC and NSSC nonconforming with the Single Specialty Ambulatory Surgery Demonstration Project criteria, as outlined in Table 6D (pages 82-85) of the *2010 SMFP*, in turn below.

TOSC

TOSC failed to adequately demonstrate that all of the physician owners of the ASC currently have or will have emergency department coverage responsibilities in at least one hospital within the service area in accordance with the Single Specialty Ambulatory Surgery Demonstration Project criteria, as outlined in Table 6D (page 84) of the *2010 SMFP*. As stated in Table 6D (page 84) of the *2010 SMFP*:

> *Physicians affiliated with the demonstration project facilities are **required to establish or maintain hospital staff privileges with at least one hospital and to begin or continue meeting Emergency Department coverage responsibilities with at least one hospital,** with the following caveat:*
>
> *This requirement has to be available to the physicians and not denied based upon charges that physicians are engaging in competitive behavior by providing services at a facility that is perceived to be in competition with the hospital if it so happens that the CON is issued to an organization other than the hospital.*
>
> *Additionally, physicians affiliated with the demonstration project facilities are required to provide annually to the Agency data related to meeting*

their hospital staff privilege and Emergency Department coverage responsibilities. Specific data to be reported, such as number of nights on call, will be determined by the Agency. (emphasis added)

In Section I of its application (page 5), TOSC identifies the physician owners of its proposed ASC as follows:

Julian Aldridge, MD
Kimberly Barrie, MD
Richard Bruch, MD
Mark Burt, MD
Philip Clifford, MD
David Dellaero, MD
Thomas Dimming, MD
Dina Eisinger, MD
Peter Gilmer, MD
William Hage, MD
Paul Kerner, MD
Ralph Liebelt, MD
William Mallon, MD
Jeffrey Murray, MD
David Musante, MD
Raphael Orenstein, MD
Sheperd Rosenblum, MD
William Silver, MD
Robert Wilson, MD
Steven Winters, MD
Charlie Yang, MD
Eugenia Zimmerman, MD

In its application, TOSC refers to Exhibit 10 for documentation that physicians owning the proposed single specialty demonstration facility will meet emergency department coverage requirements in accordance with Table 6D and 10A NCAC 14C .2105(d). As illustrated in the table below, contrary to TOSC's representations in its application, Exhibit 10 does not contain documentation that all of the physician owners of the ASC currently have or will have emergency department coverage responsibilities in at least one hospital within the service area. In particular, while TOSC provides letters from

hospitals in the service area to document that its physician owners have emergency department coverage responsibilities, none of the letters provided address the four physician owners listed in the table below.

TOSC Physician Owners With No Documentation of ED Coverage
Richard Bruch, MD
Dina Eisinger, MD
Raphael Orenstein, MD
Eugenia Zimmerman, MD

OMCC maintains that TOSC's failure to provide documentation of emergency department coverage for all of its physician owners renders TOSC's application inconsistent with the need determination for a Single Specialty Ambulatory Surgery Demonstration Project in the Triangle Area. This interpretation is consistent with the Triad Area Single Specialty Ambulatory Surgery Demonstration Project Review. In the Triad Area Review, the application submitted by Orthopaedic Surgical Center of the Triad Holdings, LLC (OSC) was found inconsistent with the need determination where the applicants failed to adequately demonstrate that the physician owners of the facility will have emergency department coverage responsibilities with at least one hospital in the service area. See 2010 Triad Area Single Specialty Ambulatory Surgery Demonstration Project Review Findings page 9. Such inconsistency factored into the finding of nonconformity under Criterion 1 and impacted the outcome of the comparative factor "Conformity with the Need Determination." It is important to note that the information (or rather, lack thereof) provided by OSC is directly analogous to that provided by TOSC in the current review. In particular, while both OSC and TOSC provide letters from hospitals in the service area in an attempt to document that its physician owners have emergency department coverage responsibilities, neither provides documentation for all of its physician owners as identified in Section I of their respective applications.

In addition, TOSC failed to adequately demonstrate that the physicians associated with the ASC will have hospital staff privileges in the service area in accordance with the Single Specialty Ambulatory Surgery Demonstration Project criteria, as outlined in Table 6D (page 84) of the *2010 SMFP*.

In Section V of its application (page 94), TOSC identifies the orthopaedic surgeons who are expected to utilize the proposed ASC:

Julian Aldridge, MD
Kimberly Barrie, MD
Richard Bruch, MD
Mark Burt, MD
Philip Clifford, MD
David Dellaero, MD
Thomas Dimming, MD
William Hage, MD
Paul Kerner, MD
William Mallon, MD
Jeffrey Murray, MD
Sheperd Rosenblum, MD
William Silver, MD
Robert Wilson, MD
Charlie Yang, MD

In its application, TOSC refers to Exhibit 10 for documentation that physicians with privileges to practice at the proposed single specialty demonstration facility will continue to be active members in good standing at general acute care hospitals within the service area in accordance with Table 6D and 10A NCAC 14C .2105(c). As illustrated in the table below, contrary to TOSC's representations in its application, Exhibit 10 does not contain documentation that all of the physician with privileges to practice at the proposed single specialty demonstration facility will continue to be active members in good standing at general acute care hospitals within the service area. In particular, while TOSC provides letters from hospitals in the service area to document that the physicians with privileges to practice at the proposed single specialty demonstration facility will continue to be active members in good standing, none of the letters provided address Dr. William Mallon.

NSSC

NSSC failed to adequately demonstrate that its proposal is for a "single specialty" ASC in accordance with the Single Specialty Ambulatory Surgery Demonstration Project criteria, as outlined in Table 6D (page 84) of the *2010 SMFP*. As stated in Table 6D (page 82) of the *2010 SMFP* applicants must:

> *Establish a special need determination for three new separately licensed* ***single specialty*** *ambulatory surgery facilities with two operating rooms*

each, such that there is a need identified for one new ambulatory surgical facility in each of the three following service areas:

- *Mecklenburg, Cabarrus, Union counties (Charlotte Area)*
- *Guilford, Forsyth counties (Triad Area)*
- *Wake, Durham, Orange counties (Triangle Area)*

It follows that just as applicants must propose no more than two operating rooms, they must also propose to develop a "single specialty" ASC in order to meet the need as identified in the *2010 SMFP*. "Specialty area" is defined under 10A NCAC 14C .2101(12) as "*an area of medical practice in which there is an approved medical specialty certificate issued by a member board of the American Board of Medical Specialties and includes the following: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, urology, orthopedics, and oral surgery.*" In its application NSSC proposes to develop a two-operating room ASC with a procedure room. NSSC fails to address what types of procedures will be performed in its proposed procedure room; rather NSSC simply states that "[t]*o maximize utilization of the proposed General Surgery ambulatory surgical facility and to meet the needs of surgeons in the proposed service area, NSSC will include one procedure room*[.]" See NSSC's Application page 79. Given NSSC's failure to adequately document what type of procedures will occur in the procedure room, it is unclear whether NSSC is truly proposing a "single specialty" ASC in accordance with the need determination. Such an interpretation is consistent with the Triad Area Single Specialty Ambulatory Surgery Demonstration Project Review. In the Triad Area Review, the application submitted by Kernersville Orthopaedic Surgery Center Holdings, LLC (KOSC) was found inconsistent with the need determination where the applicant proposed to develop a two-room orthopaedic ASC with a procedure room for physiatrist cases. The Analyst determined that physiatry is recognized as a physician specialty by the American Board of Medical Specialties and as such, KOSC proposed two specialties, not one. The Analyst went on to note that it was irrelevant that the physiatrists would only use the procedure room. See 2010 Triad Area Single Specialty Ambulatory Surgery Demonstration Project Review Findings page 11. Therefore, NSSC's statements that the procedure room "*will be limited in size and will not be in a sterile environment*[,] [i]*t will not be a surgical operating room, and will not be capable of converting to a surgical operating room in the future without substantial cost, renovation, and CON approval*[,]" are likewise irrelevant. See NSSC's Application page 79. The inconsistency identified by the Analyst relative to KOSC factored into the finding of nonconformity under Criterion 1 and impacted the outcome of the comparative factor "Conformity with the Need Determination."

In addition, NSSC failed to adequately document physician ownership in its proposed ASC in accordance with the Single Specialty Ambulatory Surgery Demonstration Project criteria, as outlined in Table 6D (page 82) of the *2010 SMFP*.

In choosing among competing demonstration project facilities, priority will be given to facilities that are owned wholly or in part by physicians.

NSSC's documentation of physician ownership is significantly limited and precarious at best. Moreover, as discussed below, as of the date of submission, NSSC's physician owners are not identifiable. NSSC proposes having two classes of membership interests—Class A and Class B. Foundation Health Systems Corporation (FHSC), a wholly owned subsidiary of Novant Health, Inc. will be the sole Class B member. The Class B member, FHSC, would be responsible for funding the NSSC project, would own 100 percent of the equity in NSSC, and would be entitled to 100 percent of the income generated by NSSC. The Class A members are defined by NSSC on page 1 of its application as "*those general surgeons who are employed by Novant Medical Group ("NMG") and who perform at least 20% of their outpatient general surgical procedures at NSSC.*" These Class A members would "*have the right to participate in governance by electing three out of the seven members of the NSSC board of directors, as well as the right to vote on NSSC clinical matters.*" See NSSC's Application page 1. As defined in the North Carolina Limited Liability Company Act, a membership interest is "*all of a member's rights in the limited liability company, including any share of the profits and losses of the limited liability company, any right to receive distributions of the limited liability company assets, any right to vote on matters relating to the limited liability company, and any right to participate in the management of the limited liability company's affairs.*" See N.C. Gen. Stat. § 57C-1-03(15). As defined in NSSC's Application, the Class A members' rights are limited to governance and voting. Therefore, not only are the membership interests of the physicians significantly limited, but also **as of the date of submission, the Class A physician members are not even identifiable**. According to NSSC's own definition of its Class A members, there are no Class A (physician) members at the time of submission. That is, given that the ASC is not operational, the NMG physicians who will perform at least 20 percent of their outpatient general surgery procedures at NSSC are unknown. **Further, none of four general surgeon support letters provided in Exhibit 3 of NSSC's Application refer to ownership of the proposed ASC nor do they contain a commitment to perform at least 20 percent of their outpatient general surgery procedures at NSSC.**[1] As such, it is possible that no NMG general surgeons will satisfy the requirements of a Class A member.

While the criteria excerpted above refers to priority being given to those applicants demonstrating that their facility will be owned in whole or part by physicians, it does not negate any responsibility on the part of the applicant to document physician ownership. To do so would not only be in direct conflict with the nature of the demonstration project, but would also ignore applicable operating room regulations such as 10A NCAC 14C .2102(d)(2) which requires an applicant proposing to develop a single specialty ASC pursuant to the demonstration project identified in the *2010 SMFP* to provide "*a*

[1] NSSC does not provide projected surgical cases by physician.

description of the ownership interests of physicians in the proposed ambulatory surgical facility." Moreover, it is important to note that the ownership structure proposed in NSSC's application is identical to that proposed by Cabarrus Orthopaedic Surgery Center (COSC) in the Charlotte Area Review. One of the applicants in the Charlotte Area Review, Randolph Surgery Center (RSC), raised these same concerns regarding the tenuous nature of COSC's physician ownership during the comment period. In its response COSC failed to directly address the concerns raised by RSC relative to its ownership structure and instead quickly conceded, citing the Triad Area Review Findings, that the projects that proposed 100 percent physician ownership are comparatively superior in terms of ownership structure. As discussed in more detail later in these comments OMCC does not agree with COSC's interpretation of the Triad Area Review Findings. For the purposes of this review, NSSC has failed to adequately document that its proposal involves physician ownership.

WAKE COUNTY REPRESENTS THE MOST EFFECTIVE LOCATION FOR A SINGLE SPECIALTY AMBULATORY SURGERY DEMONSTRATION PROJECT IN THE TRIANGLE AREA

The following table identifies the location of the existing and approved operating rooms in the Triangle Area.

Provider	*Location within the Triangle Area*
Duke University Hospital	Durham
Durham Regional Hospital	Durham
James E. Davis Ambulatory Surgery Center	Durham
North Carolina Specialty Hospital	Durham
Chapel Hill Surgical Center	Orange
University of North Carolina Hospitals	Orange
Orthopaedic Surgery Center of Raleigh	Wake
Duke Health Raleigh Hospital	Wake
Blue Ridge Surgery Center	Wake
Raleigh Plastic Surgery Center	Wake
Raleigh Women's Health Organization	Wake
Rex Hospital	Wake
Rex Surgery Center of Cary	Wake
Southern Eye Associates Ophthalmic Surgery Center	Wake
WakeMed Raleigh Surgery Center	Wake
WakeMed Cary Hospital	Wake
WakeMed Raleigh Hospital	Wake
Holly Springs Surgery Center	Wake

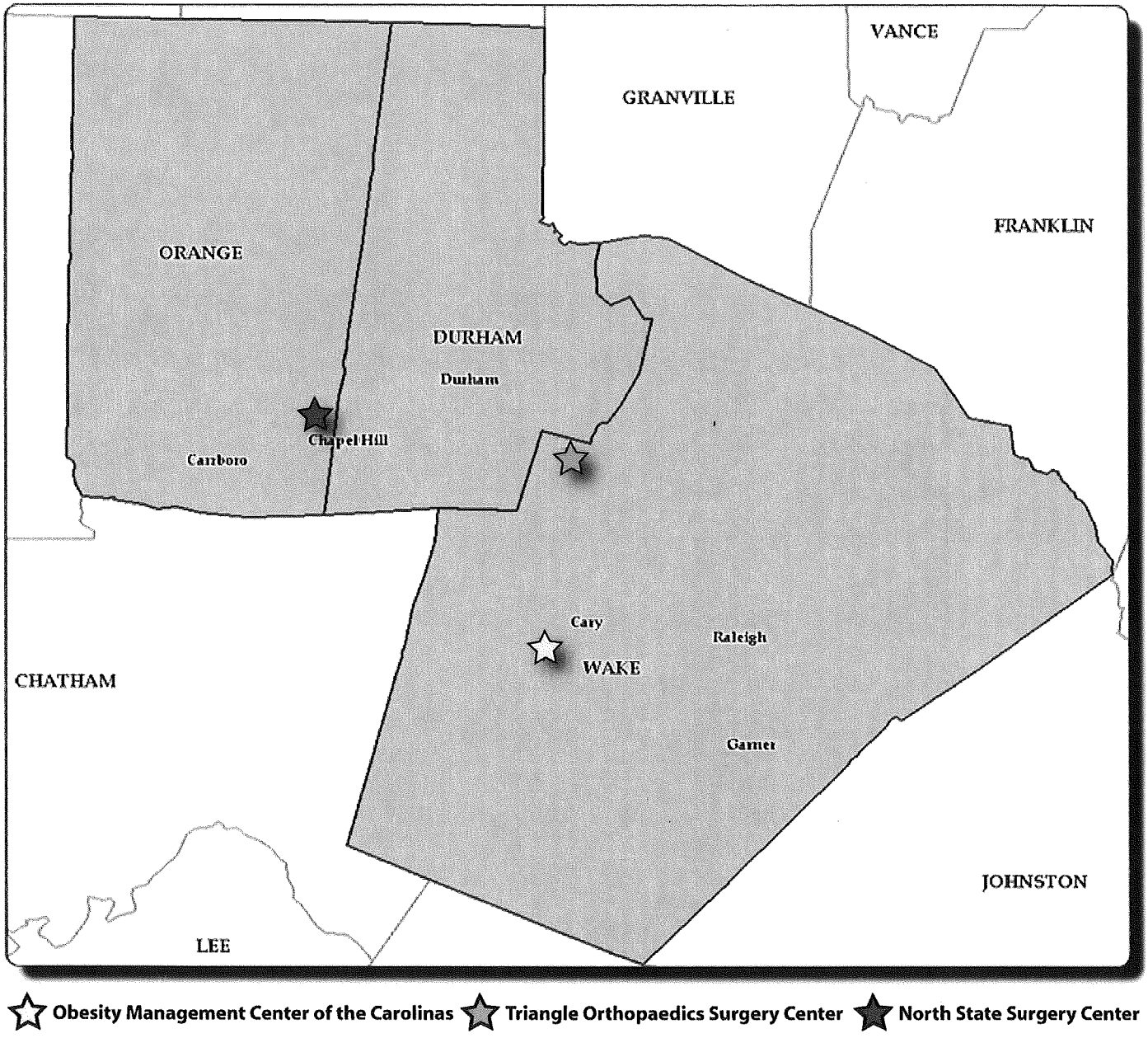
Of these facilities in the Triangle Area, there are a total of nine existing or approved freestanding ASCs. The following table identifies the freestanding ASCs in the Triangle Area by county and specialty status.

Provider	*Location within the Triangle Area*	*One Specialty*	*Greater than One Specialty*
James E. Davis Ambulatory Surgery Center	Durham		X
Chapel Hill Surgical Center	Orange	X	
Orthopaedic Surgery Center of Raleigh*	Wake		X
Blue Ridge Surgery Center	Wake		X
Raleigh Plastic Surgery Center	Wake	X	
Raleigh Women's Health Organization	Wake	X	
Southern Eye Associates Ophthalmic Surgery Center	Wake	X	
WakeMed Raleigh Surgery Center	Wake		X
Holly Springs Surgery Center	Wake		X

*In response to 10A NCAC 14C .2102(a), OSCR identified the specialty areas as "orthopedics, podiatry, and physical medical and rehabilitation." See OSCR's Application page 21. Although OSCR proposed more than one specialty, it is important to note that OSCR's ASC does not qualify as a multispecialty ambulatory surgery program which is defined in N.C. GEN. STAT. 131E-176(15a) as *"a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery."*

In this review, two of the three applications propose to develop the Single Specialty ASC Demonstration Project in Wake County: TOSC and OMCC. In the remaining application, NSSC proposes to locate the operating rooms in Orange County. The table and map below detail the locations proposed by the three applicants discussed in these comments.

	Proposed Location		
	Applicants		
	TOSC	*NSSC*	*OMCC*
County	Wake	Orange	Wake
Address	7921 ACC Boulevard Raleigh, NC 27617	100 Europa Drive, First Floor Chapel Hill, NC 27517	1505 SW Cary Parkway Cary, NC 27511



OMCC maintains that neither Orange nor Durham County represents the most effective location for the Single Specialty ASC Demonstration Project to be developed in the Triangle Area, as discussed in its application (see pages 84-85, 115-116, and 126). Of the Triangle Area counties, Wake County is where the highest concentration of the Triangle Area population resides and is accessible to all counties in the Triangle Area.

Wake County was one of the fastest growing counties between 2000 and 2009, and this trend is projected to continue. Furthermore, the population in Wake County is consistently the highest among the Triangle Area counties. In addition, Wake County has

the fastest growing population of individuals disproportionately affected by obesity. It is important to note that even the demonstration project special criteria acknowledge the importance of locating the facility in a high population area: "[l]*ocating facilities in high population areas with a large number of operating rooms and existing ambulatory surgery providers prevents the facilities from harming hospitals in rural areas, which need revenue from surgical services to offset losses from other necessary services such as emergency department services.*" See the *2010 SMFP* page 82.

As the table below indicates, although Wake County has the highest population, it ranks last in number of freestanding ASCs per 100,000 population. The following table shows the distribution of existing and approved freestanding ASCs per 100,000 population for the counties in the Triangle Area that represent locations proposed by the applicants—Wake and Orange counties.

Triangle Area County	*Existing/Approved Freestanding ASCs*	*2010 Population***	*ASCs Per 100,000 Population*
Wake	6*	919,938	0.65
Orange	1	133,507	0.75

*Please note that Raleigh Women's Health has been excluded from this analysis as there is a CON under review, Project ID # J-8567-10, to relocate the two operating rooms to Duke Raleigh Hospital where they will become shared multi-specialty operating rooms.
**Source: NC OSBM-Population Projection Overview, 2000-2030, Exhibit 1.

Of the two counties, the population of Wake has the lowest number of existing and approved freestanding ASCs per 100,000 population. Clearly, Wake County, as the most populous county with the lowest ratio of ASCs to population, is in a position to support a freestanding Single Specialty ASC Demonstration Project.

In addition, as OMCC noted in its application, in the aggregate, both Durham and Orange counties have underutilized operating rooms. Of the Triangle Area counties, Wake County is the only county to show a need for additional operating rooms in the past five years. Given the underutilization of operating rooms in the Durham and Orange counties, OMCC decided neither Durham nor Orange county represented the ideal location for development of the demonstration project for the Triangle Area. As noted in Section III.1.(a) of OMCC's application, Wake County has experienced high surgical and population growth. Moreover, the location of the proposed ASC—western Wake County—is easily accessible to the other Triangle Area counties (Durham and Orange).

Therefore, for the reasons discussed above, within the Triangle Area (Wake, Durham, and Orange counties), TOSC and OMCC propose the most effective location—Wake County.

THE PROPOSED SPECIALTY, FOCUS, AND DESIGN OF OMCC'S PROPOSAL REPRESENTS THE MOST EFFECTIVE ALTERNATIVE FOR THE DEVELOPMENT OF A SINGLE SPECIALTY AMBULATORY SURGERY DEMONSTRATION PROJECT IN THE TRIANGLE AREA

In this review, two of the three applications propose to develop a Single Specialty ASC Demonstration Project dedicated to general surgery: NSSC and OMCC. The third applicant, TOSC, proposes to develop a Single Specialty ASC Demonstration Project dedicated to orthopaedics.

Proposed Specialty			
	Applicants		
	TOSC	*NSSC*	*OMCC*
Specialty	Orthopaedics	General Surgery	General Surgery

As discussed in detail in its application (see pages 78-82), OMCC maintains that general surgery, specifically with a focus on the obese patient population, is the most effective alternative to meet the need identified in the *2010 SMFP* for a Single Specialty ASC Demonstration Project to be located in the Triangle Area.

In its application, OMCC examined ambulatory surgery volume by specialty as reported in 2010 License Renewal Applications (LRAs) to determine which specialties have sufficient volume to support a Single Specialty ASC in the Charlotte Area. The table below includes those counties and specialties proposed in the applications at issue in these comments.

Triangle Area County	*Orthopaedics*	*General Surgery*
Wake	**17,690**	**12,782**
Orange	2,300	2,889

Source: 2010 LRAs; relevant excerpts provided in Exhibit 2.

A two-room ASC is required to perform at least 1,872 procedures per year to meet the performance standards outlined in 10A NCAC 14C .2103.[2] While both of the proposed specialties had more than 1,872 procedures performed in each of the two counties in fiscal year 2009, OMCC maintains that orthopaedics does not represent the most effective alternative for this demonstration project in the Triangle Area. In particular, an application for an orthopaedic ASC has been already been approved for the Triangle Area—Orthopaedic Surgery Center of Raleigh (OSCR), a joint venture between Rex

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[2] The single specialty ASC service area includes Wake, Durham, and Orange counties. As such, in order to demonstrate the need for two operating rooms in the service area, the formula outlined in 10A NCAC 14C .2103(a)(1) must result in a number greater than 1.5. The minimal number of procedures needed to obtain a result greater than 1.5 is 1,872 (1,872 procedures x 1.5 hours = 2,808 total hours / 1,872 = 1.5).

HealthCare and Raleigh Orthopaedic Clinic, Project ID # J-8170-08. Although not subject to the demonstration project criteria, this approval will provide access to an orthopaedic ASC with physician ownership in the Triangle Area. Given the approval of OSCR, OMCC maintains that orthopaedics does not represent the most effective alternative for development of the proposed Single Specialty ASC Demonstration Project. In particular, this Demonstration Project should be used as an opportunity to explore a specialty that does not have (or has not been approved to develop) a Single Specialty ASC in the Triangle Area.

In addition, the Triangle Area has a hospital focused on orthopaedics—the NC Specialty Hospital. The NC Specialty Hospital is a physician owned, primarily outpatient facility which also serves as the headquarters for Triangle Orthopaedic Associates (the physicians proposing the TOSC ASC). The hospital's four operating rooms provided over 7,600 surgeries in FFY 2009 according to the 2010 HLRA of which over 82 percent were outpatient cases. In that same year, 60 percent of the NC Specialty Hospital's total surgeries were orthopaedics cases; orthopaedics cases comprised 99 percent of the hospital's inpatient cases and 51 percent of its outpatient cases. Clearly, the NC Specialty Hospital is focused on the provision of orthopaedic care.

Given the aforementioned, OMCC maintains that another orthopaedic ASC is not the most effective alternative for the Single Specialty ASC Demonstration Project. For the reasons discussed above and in its application, OMCC maintains that general surgery represents the most appropriate specialty without an existing or approved ASC in the Triangle Area and with adequate volume for the Single Specialty Two-Room ASC Demonstration Project.

Moreover, OMCC's proposal for a general surgery ASC should be distinguished from NSSC's proposal for a general surgery ASC. As described in OMCC's application, OMCC's proposed ASC while dedicated to general surgery cases will focus on the unique needs of the obese patient population. By focusing on the needs of obese patients, OMCC will provide many benefits to its patients that cannot be provided in either a hospital setting, in a multi-specialty surgery center, or even in a single specialty surgery center that is not focused on this patient population. As discussed in detail in OMCC's application, obesity has been recognized as a major health challenge. Currently, only those who have the ability to pay or have adequate insurance have access to interventions to alleviate symptoms. Conversely, the indigent and Medicaid populations do not have access to such interventions and instead are limited to managing the disease. Given the clear economic disparities that exist for obese patients, the cost of managing this disease relative to indigent and Medicaid populations places an enormous burden on the system. OMCC's proposed general surgery ASC with a focus on the obese patient population offers unique advantages for this demonstration project that no other surgical specialty can offer, (including NSSC as it does not propose

the focus OMCC's proposal does) namely a demonstration of a promising cost-effective solution to a critical driver of health care costs nationwide: the obesity epidemic.

In addition, OMCC's proposed ASC will be developed to accommodate the physical needs and conditions of the obese patient population. It is important to note that the vast majority of hospitals in the United States are under-equipped to accommodate the growing number of obese patients. One reason for the lack of accommodations is the lack of design guidelines relative to weight. Currently, neither the American Institute of Architects (AIA) nor the American Disabilities Act (ADA) provides specific guidance on physical design for obese patients. OMCC maintains that its proposed design features will benefit the obese patient population; particularly given the fact that often this population will avoid or delay medical treatment based on access and sensitivity to their health care environment.

THE OWNERSHIP STRUCTURE PROPOSED IN THE OMCC APPLICATION REPRESENTS THE MOST EFFECTIVE ALTERNATIVE FOR THE DEVELOPMENT OF A SINGLE SPECIALTY AMBULATORY SURGERY DEMONSTRATION PROJECT IN THE TRIANGLE AREA

The table below details the ownership structure proposed by the three applicants discussed in these comments.

Proposed Ownership Structure			
	Applicant		
	TOSC	*NSSC*	*OMCC*
Proposed Ownership Structure	100% physician owned	100% of Class A membership – Novant Medical Group Physicians performing at least 20% of orthopaedic surgeries at NSSC (their rights would relate to governance and voting – not equity) 100% of Class B membership – Novant Health wholly owned subsidiary	60/40 joint venture between physicians and health system

Pursuant to the Single Specialty Ambulatory Surgery Demonstration Project criteria, as outlined in Table 6D (page 82) of the *2010 SMFP*,

> *In choosing among competing demonstration project facilities, priority will be given to facilities that are owned wholly or in part by physicians.*

The criterion excerpted above indicates that priority is given to those applicants who adequately demonstrate that they are owned wholly or in part by physicians. It is important to note that the language does not indicate a preference between facilities

owned wholly by physicians and those owned in part by physicians nor does it even suggest a ranking, with higher preference to those with a higher percentage of physician ownership. Rather, priority is given to those applicants who adequately demonstrate either.

As discussed below, the physician ownership proposed by NSSC is precarious at best. The remaining two applicants, TOSC and OMCC, adequately demonstrate physician ownership. Therefore, according to the criterion excerpted above, TOSC and OMCC would both receive priority in the review. However, as discussed below, while both TOSC's and OMCC's proposal warrant priority, OMCC maintains that the structure proposed in its application offers benefits that distinguish its proposal from TOSC's proposal and render it the most effective alternative for development of the proposed demonstration project.

As discussed in detail earlier in these comments, NSSC proposes having two classes of membership interests—Class A and Class B. The Class A, or physician members, are defined as *"those general surgeons who are employed by Novant Medical Group ("NMG") and who perform at least 20% of their outpatient general surgical procedures at NSSC."* These Class A members' rights are limited to governance and voting. Therefore, not only are the membership interests of the physicians significantly limited, but also as of the date of submission, the Class A physician members are not even identifiable. Given that the ASC is not operational, the NMG physicians who will perform at least 20 percent of their outpatient general surgery procedures at NSSC are unknown. **Further, none of four general surgeon support letters provided in Exhibit 3 of NSSC's Application contain a commitment to perform at least 20 percent of their outpatient orthopaedic procedures at NSSC.** As such, it is possible that no NMG orthopaedic surgeons will satisfy the requirements of a Class A member. Thus, NSSC's documentation of physician ownership is significantly limited and precarious at best.

TOSC proposes an ownership structure whereby the ASC would be 100 percent physician owned. On page 96 of its application TOSC noted that it *"considered developing a joint venture for the proposed project, but was unable to develop any such agreement prior to the submission of this CON application."* As discussed below, OMCC maintains that its proposed ownership structure offers benefits that cannot be realized under the structure proposed by TOSC and that as such, the structure proposed by OMCC represents the more effective alternative for development of the demonstration project.

Of the applicants, OMCC is the only one to propose a 60/40 joint venture between physicians and a health system. It should be noted that the value basic principle as outlined in the *2010 SMFP* states that "[t]*he SHCC encourages the development of value-driven health care by promoting collaborative efforts to create common resources such as shared health databases, purchasing cooperatives, and shared information management, and by promoting coordinated services that reduce duplicative and conflicting care."* See *2010 SMFP* page 4.

OMCC's proposed ownership structure seeks to do just that, promote collaborative efforts. The proposed ownership structure—a 60/40 joint venture between Triangle Bariatric Surgeons, LLC and Rex IV, LLC—facilitates collaboration and fosters a synergistic relationship, all to the benefit of Triangle Area patients. The proposed project will draw from the strengths and resources of both parties. The manager of the proposed ASC, Rex, brings to the venture its surgical management expertise and access to its many resources while the physician members bring their clinical expertise in management of the surgical patients. It is important to note that the physician members of OMCC are leaders in their field—and the proposed project is no exception. The medical director of the proposed ASC, Dr. Paul Enochs, is the nation's leader in single incision (SILS) LAP-BAND surgery. He performed North Carolina's first SILS LAP-BAND and first SILS sleeve gastrectomy. Dr. Enochs is the only surgeon to be recognized by the LAP-BAND Company as a proctor and trainer for this technique. Moreover, Rex and community physicians, including the physician owners, have worked diligently to establish Rex as a Bariatric Surgery Center of Excellence (inpatient and outpatient). As such, the proposed project is a natural extension of the members' collaborative efforts. Together the members can utilize their shared expertise to establish a new manner of delivering disease management care for the obese patient population at the proposed ASC.

For the reasons discussed above and in its application, OMCC maintains that its proposed ownership structure is the most effective alternative for the development of a Single Specialty Two-Room ASC Demonstration Project in the Triangle Area.

ACCESS TO UNDERSERVED

The General Assembly has recognized the need to ensure access to health care in as equitable a manner as possible. See, e.g., N.C. GEN. STAT. §§ 131E-175(3), (3a) and 131E-183(a)(3), (13). The following table illustrates each applicant's projected percentages of surgical cases to be provided to Medicaid and Medicare recipients in the second year of operation following completion of the project.

	Medicare as Percent of Total Cases	*Medicaid as Percent of Total Cases*
TOSC	23.9%	9.3%
NSSC	24.7%	12.0%
OMCC	7.2%	1.5%

Sources: Section VI

Please note that the payor mixes of the proposed facilities are not comparable as they are highly dependent on the specialties proposed. For example, Medicare and Medicaid do not reimburse for bariatric surgery in an ASC setting, and as a result,

OMCC will treat Medicare and Medicaid patients as Self Pay/Charity patients. As such, the payor mixes are not comparable.

The following table shows the charity care and bad debt proposed by each facility in the second year of operation following the completion of each project.

	Total Charity Care	*% of Net Revenue*	*Total Bad Debt*	*% of Net Revenue*
TOSC	$646,358	12.0%	$533,611	9.9%
NSSC	$287,387	9.73%	$115,656	3.9%
OMCC	$3,080,991	44.8%	$134,129	1.9%

Source: Section VI. Please note that NSSC provided charity care and bad debt for its proposed operating rooms and procedure room separately. The operating room numbers are included in the table above.

As shown in the table above, OMCC proposes the most charity care and the second most bed debt. When viewed in total, OMCC proposes to provide more charity care plus bad debt than any other applicant both in dollar amounts and as a percentage of net revenue. This is a result of OMCC's generous charity care policy and OMCC's proposal to treat Medicare and Medicaid patients, whose primary insurance will not reimburse for bariatric surgery, under its charity care policy.

In fact, the Need Determination for the three Single Specialty Ambulatory Surgery Demonstration Projects provides the CON Section with a specific calculation by which to measure an applicant's provision of access to the uninsured. 10A NCAC 14C .2102 (d) requires applicants to demonstrate that the percentage of the facility's total collected revenue that is attributable to Self-Pay and Medicaid exceeds seven percent. The following table shows the percentage of total collected revenue that is attributable to Self-Pay and Medicaid for each facility in the third year of operation following the completion of the each project

	Self-Pay/Medicaid Percentage
TOSC	7.1%
NSSC	7.8%
OMCC	9.7%

Source: Section II.

As demonstrated, OMCC proposes to provide the highest percentage of total collected revenue attributable to Self-Pay and Medicaid.

REVENUE

The following table compares the applicants' gross revenue per surgical case in project year 3.

Facility	*Gross Revenue*	*Surgical Cases*	*Gross Revenue/Surgical Case*
TOSC	$26,727,643	4,428	$6,036
NSSC	$9,194,911	2,239	$4,107
OMCC	$20,607,180	1,959	$10,519

Source: Form B for each application.

The following table compares the applicants' net revenue per surgical case in project year 3.

Facility	*Net Revenue*	*Surgical Cases*	*Net Revenue/ Surgical Case*
TOSC	$5,574,267	4,428	$1,259
NSSC	$3,853,924	2,239	$1,721
OMCC	$8,044,221	1,959	$4,106

Source: Form B for each application.

As noted previously, it is difficult to compare the financial metrics of the Single Specialty ASCs because each center has a different focus. While OMCC and NSSC will both be general surgery single specialty facilities, OMCC will focus on the unique needs of obese patients and as a result will provide a substantial number of bariatric surgery cases. These cases require highly expensive medical supplies and as a result are reimbursed at a higher level. Moreover, different specialties and subspecialties have different charge and reimbursement structures. As such, the revenues provided above cannot be compared.

OPERATING EXPENSES

The following table compares the applicants' operating expenses per surgical case in project year 3.

Facility	*Operating Expenses*	*Surgical Cases*	*Operating Expenses/Surgical Case*
TOSC	$4,456,829	4,428	$1,007
NSSC	$3,376,835	2,239	$1,508
OMCC	$7,601,223	1,959	$3,880

Source: Form B for each application.

As noted previously, it is difficult to compare the financial metrics of the Single Specialty ASCs because each center operates differently. For example, the medical device used in a LAP-BAND procedure can cost between $2,000 and $3,000 which is more than the total operating expenses for TOSC and NSSC's proposed projects. As such, the expenses for each facility are different and operating expenses cannot be compared.

APPLICATION-SPECIFIC COMMENTS

As stated in OMCC's general comments regarding the Triangle Area Single Specialty ASC review, OMCC believes it provides the best alternative for developing a two room single specialty ASC allocated to the Triangle Area in the *2010 State Medical Facilities Plan*. The following items are among the reasons Triangle Orthopaedics Surgery Center, LLC and North State Surgery Center, LLC should be found non-conforming.

Triangle Orthopaedics Surgery Center, LLC (TOSC)

(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.*

TOSC failed to demonstrate that its project is consistent with the applicable policies and need determination as identified in the *2010 SMFP*.

Failure to Adequately Demonstrate Consistency with the Applicable Demonstration Project Criteria Found in Table 6D of the *2010 SMFP*

Failure to Adequately Document that Physicians with Privileges to Practice at TOSC Will Be Active Members in Good Standing at a General Acute Care Hospital within the Service Area or Documentation of Contacts Made to Establish Staff Privileges

As noted previously, TOSC failed to provide documentation that each of the physicians expected to practice at its facility meet this requirement. Although TOSC refers to Exhibit 10 for documentation that physicians with privileges to practice at the proposed single specialty demonstration facility will continue to be active members in good standing at general acute care hospitals within the service area in accordance with 10A NCAC 14C .2105(c) and the demonstration project criteria found in Table 6D of the *2010 SMFP*, Exhibit 10 does not provide documentation for all of the physicians expected to utilize the proposed ASC as identified in Section V of TOSC's application.

Failure to Document that the Physician Owners Will Meet ED Coverage Responsibilities

As noted previously, TOSC failed to provide documentation that each of its physician owners meets this requirement. Although TOSC refers to Exhibit 10 for documentation, the exhibit does not provide documentation for all of the physician owners of the proposed ASC as identified in Section I of TOSC's application. This interpretation is consistent with the Triad Area Single Specialty Ambulatory Surgery Demonstration Project Review. In the Triad Area Review, the application submitted by OSC was found inconsistent with the need determination where the applicants failed to adequately demonstrate that the physician owners of the facility will have emergency department coverage responsibilities with at least one hospital in the service area. See 2010 Triad Area Single Specialty Ambulatory Surgery Demonstration Project Review Findings page 9.

(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.*

TOSC failed to demonstrate the need of the population for the proposed project, based on the following reasons:

Failure to Demonstrate the Need for Pre/Post Space

As shown in the line drawings provided in Exhibit 14, TOSC proposes to develop three pre-operative bays, four PACU bays, three step-down/Phase II bays, and one private recovery room. However, TOSC fails to demonstrate a need for these project components. As such, the application should be found non-conforming with Criterion 3. See page 15 of Agency Findings for Project ID # B-7132-04, Fletcher Hospital, Inc. d/b/a Park Ridge Hospital, which state the need for applicants to demonstrate the need for all project components. Please see Exhibit 3 for the relevant excerpt from these Findings.

(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 fails to demonstrate the proposed location is the most effective alternative for its project. As noted in its response to Section III.5, the plurality of TOSC's proposed patients are from Durham County (36.2 percent compared to 32.3 percent from Wake County). In addition, 11.6 percent of TOSC's patients will originate from Orange County. Given

Durham County's central location between Orange and Wake counties and that it is home to the plurality of TOSC patients, it is only logical that Durham County would be chosen for the proposed project and not Wake County. In discussing its considered alternatives, TOSC states that "*Brier Creek is a central geographic location for the Triangle Service Area. Currently there are nor operating rooms located in Brier Creek*" (page 83). However, these facts do not distinguish the proposed Brier Creek location from locations in Durham County which also lack operating rooms, are also centrally located, and would be closer to the plurality of patients proposed to be served by the facility.

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

TOSC failed to adequately demonstrate that its proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities based on the following reasons:

In its application, TOSC states that it will "*offer local residents a new choice of provider. Currently, there is no dedicated orthopaedic ambulatory surgery center in North Carolina, thus TOSC will provide access to the only ASC in the service area that is 100% dedicated to orthopaedic surgical cases and 100% owned by orthopaedic physicians*" (page 15). In a footnote on that same page, TOSC states "*Note: The Orthopaedic Surgery Center of Raleigh (CON Project ID # J-8170-08) is a multi-specialty ASC. In Section II.10, page 21 of application, the applicants identify the specialty areas to be provided in the facility as* 'orthopaedics, podiatry, and physical medicine and rehabilitation.'" TOSC's argument is clearly disingenuous as the TOSC's project is clearly duplicative of OSCR's approved project. OSCR is partially owned by a physician group which, like the physicians of TOSC, specializes in orthopaedics. As part of the provision of orthopaedic services, both the OSCR physicians and the TOSC physicians offer care for foot, ankle, or lower leg issues (or podiatry) as well as physical medicine and rehabilitation. As noted of Triangle Orthopedic Associates' website, www.triangleortho.com, Drs. Bruch, Kerner, Burt, and Gilmer compose the physician group's "foot and ankle section" and each of these physicians is an owner in TOSC (see print out from website accessed on December 13, 2010 in Exhibit 4). Similarly, Drs. Wilson, Eisinger, Orenstein, and Zimmerman also physician owners of TOSC and noted as physical medicine and rehabilitation specialists on Triangle Orthopedic Associates' website (see Exhibit 4). Given this evidence, it is clear that the proposed TOSC project is nearly identical to the approved OSCR project

with the difference being not in the services provided but in the strictures placed upon it by the Single Specialty Demonstration Project rules and criteria. If in fact, there is a distinction between TOSC and OSCR, it may be that TOSC has decided to not offer the full range of services that its physicians can provide, namely podiatry and physical medicine and rehab, in order to distinguish itself from OSCR. However, TOSC has not provided any evidence to suggest that the division of related services would be beneficial in any way for patients, nor an improvement in the costs, charges, or quality of the facility.

In addition, the Triangle Area has a hospital focused on orthopaedics—the NC Specialty Hospital. The NC Specialty Hospital serves as the headquarters for and is owned in part by Triangle Orthopaedic Associates (the physicians proposing the TOSC ASC). The NC Specialty Hospital is a unique facility in North Carolina. It operates 18 general med/surg beds and yet is not a Critical Access Hospital. This is because it operates a hospital specializing in surgery and orthopaedic surgery in particular. The hospital's four operating rooms provided over 7,600 surgeries in FFY 2009 according to the 2010 HLRA of which over 82 percent were outpatient cases. In that same year, 60 percent of NC Specialty Hospital's total surgeries were orthopaedics cases; orthopaedics cases comprised 99 percent of the hospital's inpatient cases and 51 percent of its outpatient cases. Clearly, NC Specialty Hospital is another surgical provider focused on the provision of orthopaedics care.

TOSC fails to address the impact of its proposed project on either OSCR or NC Specialty Hospital, both of which are surgical providers focused on orthopaedics. TOSC makes no attempt to demonstrate that a third provider of orthopaedics-focused surgery services is needed in its proposed service area and that it would not duplicate those services.

(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.*

TOSC failed to demonstrate that the cost and design of its proposed ASC are reasonable.

On page 140 of its application TOSC refers to Exhibit 14 for the architect construction cost estimate. However, contrary to TOSC's statements,

Exhibit 14 of its application does not include a certified construction cost estimate. Given TOSC's failure to provide a certified construction cost estimate, it has failed to adequately demonstrate that the cost and design of the facility are reasonable and that the construction costs will not unduly increase the costs of the proposed services.

CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

The proposal submitted by TOSC is not conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms as promulgated in 10A NCAC 14C .2100, *et seq.*, as indicated below.

10A NCAC 14C .2105(c)

This rule states that "*(c) The applicant shall provide documentation that physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the service area in which the facility is, or will be, located or documentation of contacts the applicant made with hospitals in the service area in an effort to establish staff privileges.*"

As noted previously, TOSC failed to provide documentation that each of the physicians expected to practice at its facility meet this requirement. Although TOSC refers to Exhibit 10 for documentation that physicians with privileges to practice at the proposed single specialty demonstration facility will continue to be active members in good standing at general acute care hospitals within the service area in accordance with 10A NCAC 14C .2105(c) and the demonstration project criteria found in Table 6D of the *2010 SMFP*, Exhibit 10 does not provide documentation for all of the physicians expected to utilize the proposed ASC as identified in Section V of TOSC's application.

10A NCAC 14C .2105(d)

This rule states that "*(c) The applicant shall provide documentation physicians owning the proposed single specialty demonstration facility will meet Emergency Department coverage responsibilities in at least one hospital within the service area, or documentation of contacts the applicant made with hospitals in the service area in an effort to commit its physicians to assume Emergency Department coverage responsibilities.*"

As noted previously, TOSC failed to provide documentation that each of its physician owners meets this requirement. Although TOSC refers to Exhibit 10 for documentation, the exhibit does not provide documentation for all of the physician owners of the proposed ASC as identified in Section I of TOSC's application. This interpretation is consistent with the Triad Area Single Specialty Ambulatory Surgery Demonstration Project Review. In the Triad Area Review, the application submitted by OSC was found inconsistent with the need determination where the applicants failed to adequately demonstrate that the physician owners of the facility will have emergency department

coverage responsibilities with at least one hospital in the service area. See 2010 Triad Area Single Specialty Ambulatory Surgery Demonstration Project Review Findings page 9.

North State Surgery Center, LLC (NSSC)

(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.*

NSSC failed to demonstrate that its project is consistent with the applicable policies and need determination as identified in the *2010 SMFP*.

Failure to Adequately Demonstrate Consistency with the Applicable Demonstration Project Criteria Found in Table 6D of the *2010 SMFP*

Failure to Adequately Document the Ownership Interests of Physicians

Under 10A NCAC 14C .2102(d)(2) an applicant proposing to develop a single specialty ASC pursuant to the demonstration project identified in the *2010 SMFP* must provide a "*description of the ownership interests of physicians in the proposed ambulatory surgical facility.*" As discussed previously, NSSC has failed to document or identify its physician owners as of the date of submission. In fact, the manner in which NSSC describes its physician members renders it impossible to ascertain the physician members until the ASC is operational. NSSC defines its physician members on page 1 of its application as "*those general surgeons who are employed by Novant Medical Group ("NMG") and who perform at least 20% of their outpatient general surgical procedures at NSSC.*" According to NSSC's own definition of its physician members, there are no physician members at the time of submission. That is, given that the ASC is not operational, the NMG physicians who will perform at least 20 percent of their outpatient general surgery procedures at NSSC are unknown. **Further, none of four general surgeon support letters provided in Exhibit 3 of NSSC's Application contain a commitment to perform at least 20 percent of their outpatient general surgery procedures at NSSC.** As such, it is possible that no NMG general surgeons will satisfy the requirements of a physician member.

Failure to Adequately Document that Procedures Will Be Performed in a Single Specialty Area

As noted previously, NSSC fails to discuss what types of procedures will be performed in the procedure room. As such, it is unclear whether NSSC has truly proposed a "single specialty" ASC in accordance with the need identified in the *2010 SMFP*. Although in response to 10A NCAC 14C .2102(d)(1) NSSC identifies general surgery as the specialty area "*to be performed in the two Demonstration Project operating rooms*[,]" its failure to provide any discussion of substance relative to the types of procedures that will be performed in its proposed procedure room raises concerns regarding whether classifying the project as "single specialty" is feasible particularly given the Triad Area Review Findings where in determining whether an applicant proposed a single specialty the Analyst considered the types of procedures performed in the procedure room in addition to those performed in the operating rooms. See 2010 Triad Area Single Specialty Ambulatory Surgery Demonstration Project Review Findings page 11. The Triad Area Review Findings seem to suggest that the single specialty nature of the demonstration project applies to the entire ASC, not simply the operating rooms. Therefore, NSSC's statements that the procedure room "*will be limited in size and will not be in a sterile environment*[,] [i]*t will not be a surgical operating room, and will not be capable of converting to a surgical operating room in the future without substantial cost, renovation, and CON approval*[,]" are irrelevant. See NSSC's Application page 79. What is relevant—the types of procedures to be performed in the procedure room—are not provided by NSSC. Given NSSC's omission of any information relative to the types of procedures to be performed in the procedure room, the Analyst will be unable to conclusively determine whether NSSC has proposed a single specialty ASC and NSSC has failed to meet the burden of demonstrating that its proposed project is consistent with the need identified in the *2010 SMFP*. It is important to note that the Agency has stated that an applicant must conform with criteria and standards within the application and may not submit information during the public comment period to conform with those rules. Please see Exhibit 5 for a July 10, 2003 letter from CON regarding Letters of Support Submitted for Certificate of Need Applications (noting that "*all information the applicant intends to rely on to demonstrate conformance of the application with the review criteria must be provided by the applicant in its application when first submitted to the agency*"). Further, pursuant to 10A NCAC 14C .0204, "[a]*n applicant may not amend an application.*" Therefore, NSSC cannot submit additional information relative to its proposed procedure room in order to render its proposal consistent with the need identified in the *2010 SMFP*.

(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.*

Double-Counting of RSA Surgical Cases at NSSC and Previously Approved Holly Springs Surgery Center

As described in detail below under Criterion 6, NSSC proposes to serve the surgical patients of Regional Surgical Associates (RSA). However, in a previously approved application, Holly Springs Surgery Center (Project ID # F-8471-10), which is currently under appeal, Novant proposes to serve general surgery patients at a Wake County facility and RSA provides the only general surgery physician support. Thus, NSSC is proposing to serve patients that are already to be served at Novant's Holly Springs facility and thus has not demonstrated the need for the proposed project. Please see the discussion under Criterion 6 for greater discussion of this issue.

Failure to Identify the Population to be Served

On page 92 of its application, NSSC states that "*[t]he proposed NSSC Primary Service Area is Orange and southern Durham Counties and is defined as those zip codes within a 15-mile radius of the proposed facility . . . [t]he Secondary Service Area includes the remainder of Durham County and extends into Chatham, Person, and Granville Counties.*" The map identifying the service area shows zip codes colored in blue and red presumably to delineate between primary and secondary service areas. As the blue colored zip codes include Orange and southern Durham zip codes it can be assumed to indicate the primary service area. Yet, the primary service area as shown in the map includes portions of Alamance, Caswell, Chatham, Granville, and Franklin counties, none of which are mentioned in the narrative as part of the primary service area. In addition, Alamance, Caswell, and Franklin counties are not mentioned as part of the secondary service area. Finally, neither Caswell nor Franklin County is included in the projected patient origin shown in response to Section III.5.

Failure to Demonstrate the Need for Pre/Post Space

As shown in the line drawings provided in Exhibit 14, NSSC proposes to develop four pre-operative bays and six recovery bays. However, NSSC fails to demonstrate a need for these project components. As such, the

application should be found non-conforming with Criterion 3. See page 15 Agency Findings for Project ID # B-7132-04, Fletcher Hospital, Inc. d/b/a Park Ridge Hospital, which state the need for applicants to demonstrate the need for all project components. Please see Exhibit 3 for the relevant excerpt from these Findings.

Failure to Demonstrate the Need for Procedure Room

In its application NSSC proposes to develop a two-operating room ASC with a procedure room. NSSC fails to address the use and need for its proposed procedure room; rather NSSC simply states that "[t]*o maximize utilization of the proposed General Surgery ambulatory surgical facility and to meet the needs of surgeons in the proposed service area, NSSC will include one procedure room*[.]" See NSSC's Application page 79. Not only is the discussion on page 79 of NSSC's application inadequate to justify the need for a procedure room, but also as discussed below, given the nature of the proposed demonstration project—a "single specialty" ASC—NSSC's failure to adequately document the types of procedures to be performed in the procedure room effectively prevents the Analyst from being able to conclusively determine that NSSC's proposal is actually for a "single specialty" ASC.

(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.*

NSSC fails to demonstrate the proposed location is the most effective alternative for its project. In discussing its proposed location as the most effective alternative, NSSC states that "*NSSC will be in the town of Chapel Hill in Orange County, centrally located between the towns of Chapel Hill and Durham.*" Clearly, NSSC is not centrally located between Chapel Hill and Durham as it is in Chapel Hill. NSSC's proposed patient origin, which is based on RSA's historic patient origin shows that the majority of patients will originate from Durham County (50.2 percent) and not from Orange County (22.3 percent) where the facility will be located. NSSC's location is near southern Durham County, but there is no evidence that NSSC's patients are concentrated in southern Durham County. In fact, NSSC's Durham office and the Durham County locations where RSA perform their surgeries are in the central portion of the county, and north of the city of Durham. As such, NSSC has failed to demonstrate that a Durham County location would not provide a more effective location for its project.

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

Double-Counting of RSA Surgical Cases at NSSC and Previously Approved Holly Springs Surgery Center

In its application, NSSC projects surgical volumes that will be performed entirely by one group of general surgeons, RSA. In fact, NSSC contends that all of RSA's outpatient surgeries will be performed at the proposed facility as shown in NSSC's statement on page 77: *"**all** of the RSA outpatient surgery volume will be performed in the new general surgery center"* (emphasis added). However, this assumption is unreasonable because RSA and its surgical volume is a key component of an approved surgery center in Wake County which is currently under appeal.

In February 2010, Novant filed an application to build an ASC with three operating rooms and a procedure room in Holly Springs, NC hereafter referred to as Holly Springs Surgery Center or HSSC (Project ID # F-8471-10). Throughout that application, Novant states that the HSSC will offer general surgery (see pgs 18, 21, 34, 36, 71, 74, 76, 80, 90, and 126) and in particular, justifies the assumptions made in its utilization methodology by stating that *"HSSC will provide those specialties most often provided in ambulatory surgical settings such as General Surgery (hernia, breast implant removal, bilateral breast implant) and Orthopedics (knee repair, carpal tunnel release knee excision)"* (page 74). In addition, of its projected top 20 surgical procedures most commonly performed, the first and second most commonly performed are general surgery procedures and four of the 20 total procedures are general surgery.

HSSC Projected Top 20 Surgical Procedures Most Commonly Performed

CPT	*Description*	*Procedure Type^*
19120	EXC CYST/ABERRANT BREAST TISSUE OPEN 1/>LES	General Surgery
19125	EXC BRST LES PREOP PLMT RAD MARKER OPN 1 LES	General Surgery
20680	RMVL IMPLT DP	Orthopedics
23120	OPEN SURGICAL PARTIAL REMOVAL OF COLLAR BONE	Orthopedics
23410	OPEN REPAIR OF ROTATOR CUFF, RECENT	Orthopedics
25111	EXC GANGLION WRST DORSAL/VOLAR PRIM	Orthopedics
62365	REMOVE SPINE INFUSION DEVICE	Spine
47562	LAPS SURG CHOLECSTC	General Surgery
30140	SBMCSL RESCJ INF TURBINATE PRTL/COMPL ANY METH	ENT
29888	ARTHRS AIDED ANY CRUCIATE LIGM RPR/AGMNTJ/RCNSTJ	Orthopedics

29806	ARTHRS SHO SURG CAPSULORRHAPHY	Orthopedics
29807	SHOULDER SCOPE, REPAIR CARTILAGE TEAR	Orthopedics
29824	SHOULDER SCOPE, PARTIAL REMOVAL COLLAR BONE	Orthopedics
49505	RPR 1ST INGUN HRNA AGE 5 YRS/> REDUCIBLE	General Surgery
29827	SHOULDER SCOPE, ROTATOR CUFF REPAIR	Orthopedics
29875	ARTHRS KNE SYNVCT LMTD SPX	Orthopedics
29877	ARTHRS KNE DBRDMT/SHVG ARTCLR CRTLG CHNDPLS	Orthopedics
29880	ARTHS KNE SURG W/MENISCECTOMY MED&LAT W/SHVG	Orthopedics
64719	REVISE ULNAR NERVE AT WRIST	Neurosurgery
62350	IMPLANT SPINAL CANAL CATH	Spine

Source: HSSC Application (Project ID # F-8471-10), page 22.
^Procedure types based on The Advisory Board Company Outpatient Map.

Novant justifies its proposal to offer general surgery at HSSC by demonstrating the support of four general surgeons - the physicians of RSA; no other general surgeons provided support for HSSC. In its letter of support for HSSC, RSA states *"[w]e intend to seek privileges to practice at the proposed Holly Springs Surgery Center in southern Wake County and to perform outpatient surgical cases that are clinically appropriate for this setting"* (page 251).

NSSC fails to assess the impact of the development of HSSC on its proposed project. NSSC provides projections for HSSC which are taken directly from the HSSC application with no analysis to determine the impact of NSSC. As such, NSSC's methodology has failed to include a critical step which addresses the impact of HSSC. OMCC contends that NSSC's volume includes a substantial number of cases which will in fact be performed at HSSC.

In order to quantify this impact, OMCC analyzed data provided in both the NSSC and HSSC applications. As Rex, a minority owner of OMCC, stated in its comments on the HSSC application, *"only general surgeons, orthopedists, neurosurgeons, and spine surgeons provided support to its project. As such, it can be assumed that Novant will only offer general surgery, orthopedics, neurosurgery, and spine surgery"* (page 46 of Competitive Comments on Wake County Operating Room Application submitted by Rex Healthcare on March 31, 2010). In order to determine the number of cases that would likely be general surgery cases at HSSC, OMCC applied the case mix demonstrated by the Wake County outpatient surgery providers cited by HSSC.

FFY 2009 Wake County Providers
Case Mix for HSSC Provided Specialties

	General Surgery	*Neuro-surgery*	*Orthopedic Surgery*	*Total of HSSC Specialties**
Rex Hospital	5,637	425	5,269	11,331
Duke Health Raleigh	2,175	552	5,817	8,544
WakeMed	2,052	593	2,032	4,677
WakeMed Cary	2,711	13	767	3,491
Blue Ridge SC	0	0	2,676	2,676
WakeMed North	207	0	1,129	1,336
TOTAL	**12,782**	**1,583**	**17,690**	**32,055**
Case Mix	**39.9%**	**4.9%**	**55.2%**	**100.0%**

Source: 2010 Hospital and Ambulatory Surgery License Renewal Applications; pertinent excerpts provided in Exhibit 6.
*The License Renewal Applications do not provide a spine surgery separately, but that these cases are assumed to be included in the neurosurgery or orthopedic surgery cases.

Based on the data provided above, OMCC assumes that 39.9 percent of HSSC's total volume will be general surgery cases. As noted above, the only general surgeons who supported HSSC's application are RSA physicians. Therefore, OMCC assumes that RSA physicians will perform all of the general surgery cases at HSSC and in the project years for the NSSC will perform the following number of cases at HSSC.

Projected General Surgery Cases at HSSC to be Performed by RSA

	PY1 (CY 2013)	*PY2 (CY 2014)*	*PY3 (CY 2015)*
Total HSSC Projected Surgical Cases	2,533	2,964	3,425
General Surgery Cases as % of Total	39.9%	39.9%	39.9%
HSSC General Surgery Cases to be Performed by RSA	1,011	1,183	1,367

Source: NSSC Application page 46.

As these RSA cases will be performed at HSSC, they must be subtracted from the total number of RSA cases that NSSC projects to provide.

Projected RSA Cases by Location

	PY1 (CY 2013)	*PY2 (CY 2014)*	*PY3 (CY 2015)*
Total RSA Projected Surgical Cases	1,777	2,011	2,239
HSSC General Surgery Cases to be Performed by RSA	1,011	1,183	1,367
Remaining RSA Cases that Can Be Shifted to NSSC	766	828	872

As shown, RSA will perform the majority of its cases at HSSC and by project year three will only perform 872 cases at the proposed ASC, which is not enough to justify the proposed two operating rooms.

The above analysis is vital to any assessment of NSSC's proposal. Novant has, in effect, double-counted RSA surgical cases. NSSC's application proposes RSA will perform all of its surgical cases at NSSC while HSSC's application proposes to offer general surgery and relies upon the support of RSA physicians to substantiate that assumption. Both applications cannot be accurate. Given that the CON Section has already approved the HSSC application, it must assess the newly filed NSSC application in that light.

NSSC appears to suggest in its application that the CON Section should not assess its application with respect to the HSSC application because "*[t]he agency decision for this project remains in litigation, and thus no Certificate of Need has yet been issued to Holly Springs Surgery Center*" (page 46). A prior project's lack of resolution should not allow an applicant to file subsequent applications that contradict it without any explanation for the disparity. As the preceding analysis demonstrates, this is clearly not the case for NSSC application. OMCC contends that Novant's representations in this review indicate a material change in its previously approved project for HSSC; thus, the CON Section cannot approve the NSSC application without also withdrawing its approval of the HSSC application, which would be left with no supporting general surgeons, as explained above.

Unreasonable Surgical Case Projections

On pages 75 and 76 of its application, NSSC projects total outpatient general surgery volume performed in Orange and Durham counties will increase by 7.3 percent annually and that by the third year of operation, market share for RSA surgeons will increase from 15 percent to 20 percent. As a result, NSSC is projecting a 15 percent annual growth rate for its physicians from FFY 2010 to FY 2016.

Projected Growth of RSA Cases

	RSA Cases
FFY 2010 Historical	1,025
FFY 2016 Projected	2,359
CAGR	14.9%

This projected internal growth rate for RSA cases is clearly unreasonable in light of its historical growth from FFY 2008 to FFY 2010, which has only been three percent.

Historical Growth of RSA Cases

	RSA Cases
FFY 2008 Historical	938
FFY 2010 Historical	1,025
CAGR	3.0%

NSSC is projecting its future volume to grow at a rate five times higher that it has historically shown. Clearly, the projected surgical cases are unreasonable. Moreover, as noted above, many of RSA's surgical cases have been proposed to be performed at HSSC and thus cannot be used to support NSSC's application.

Further, in support of its future growth, NSSC argues that "*ongoing marketing programs and future recruitment of an additional general surgeon to coincide with the second year of operation of the* NSSC" will lead to its proposed market share increases (see page 76). The only supporting evidence NSSC provides for the ongoing marketing programs are printed pages from RSA's website and a single page summarizing the practices services and staff physicians in Exhibit 20. There is no mention of how RSA will actually communicate its message to referring providers and patients. In fact, NSSC provides more detail about the ways in which its practice will be negatively impacted in the future by Duke's decision to

incentivize its employees to choose physicians on its specialty panel from which RSA was removed. The actions of an influential employer are substantial evidence that RSA's market share will decline in the future and NSSC fails to provide arguments to the contrary. NSSC notes that it will recruit an additional general surgeon. However, this physician recruitment is not even mentioned in NSSC's response to Section VII.7.(b) which states: *"Describe the details of any physician recruitment plan. Provide support documentation."* Moreover, from the physician specific volumes provided on page 67 of its application, it appears that Dr. Baerman joined the practice CY 2008 and, yet RSA surgical volume has remained relatively flat since that time. Thus, it is unclear whether additional physician recruitment will lead to increased market share as manpower may not be the driver of volume in RSA's marketplace, but instead may be more related to decisions of influential employers and the actions of the two large integrated health systems, UNC Healthcare and Duke Health.

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

NSSC fails to demonstrate the availability of resources, including health manpower and management personnel, for the provision of the surgical services proposed. As discussed in detail below, NSSC fails to provide adequate documentation of physician support for its proposed project in light of prior commitments by those same physicians. NSSC provides general letters of support for its proposed ASC from four general surgeons (Regional Surgical Associates (RSA)). In its application, NSSC assumes that the four RSA physicians will perform all of their general surgical cases at its proposed ASC. However, NSSC's assumption directly contradicts the recently approved Holly Springs Surgery Center (HSSC) which is currently under appeal, which relies upon the support of the same four RSA physicians to substantiate its assumption that HSSC will provide general surgical cases. It is important to note that both projects—NSSC and HSSC—are funded by Novant. As such, it is reasonable to assume that Novant would be aware of any potential overlap or duplication of support impacting either project's feasibility. Although no CON has been issued to HSSC, Novant should not be permitted to, relative to NSSC, rely on support which would render its HSSC project unfeasible. The volume from the four RSA physicians may count for HSSC or NSSC, but not both.

(8) *The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary*

ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

Failure to Adequately Demonstrate the Availability of Necessary Ancillary and Support Services

NSSC also fails to adequately demonstrate how its proposed ASC will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. NSSC's application proposes to receive anesthesia support from the Charlotte based Presbyterian Anesthesia Associates. See NSSC's application page 315 (Exhibit 3 of NSSC's application), Exhibit 7. Although the letter from Joseph P. Ducey, MD, President of Presbyterian Anesthesia Associates, states that Presbyterian Anesthesia Associates will *"provide on-site anesthesia coverage and supervision of CRNA services for surgery patients of the proposed North State Surgery Center in Chapel Hill, NC*[,]" the letter does not reference relocating or commuting. Given the proposed location of the ASC—Chapel Hill—the reasonableness of such an arrangement is questionable and seems to suggest lack of coordination with the existing health care system.

Exhibit 1

NC OSBM
Population Overview, 2000-2030

County	*Jul-10*	*Jul-15*	*Numerical Growth*	*% Growth*
Wake	919,938	1,057,534	137,596	15.0%
Durham	271,580	298,826	27,246	10.0%
Orange	133,507	141,560	8,053	6.0%
Total Triangle Area	1,325,025	1,497,920	172,895	13.0%
STATE	9,519,028	10,202,505	683,477	7.2%

Last updated 13SEP2010

Exhibit 2

Surgical and Non-Surgical Cases

NOTE: Read the following instructions carefully.

Surgical Cases by Specialty Area Table - Enter the number of surgical cases by surgical specialty area in the chart below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Cases
Cardiothoracic	
General Surgery	
Neurosurgery	
Obstetrics and GYN	955
Ophthalmology	
Oral Surgery	
Orthopedics	
Otolaryngology	
Plastic Surgery	
Urology	
Vascular	
Other Surgeries (specify)	
Other Surgeries (specify)	
Total Surgical Cases	955

Non-Surgical Cases by Category Table - Enter the number of non-surgical cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 5.**

Non-Surgical Category	Cases
Pain Management	
Cystoscopy	N/A
Non-GI Endoscopies *(not reported on page 5)*	
GI Endoscopies *(not reported on page 5)*	N/A
YAG Laser	
Other (specify)	
Other (specify)	
Other (specify)	
Total Non-Surgical Cases	0

8. **Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures** *(continued)*

(**Campus** – *If multiple sites*: _____)

d) **Surgical Cases by Specialty Area Table**
Enter the number of **surgical** cases by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery) CARD/THORACIC	554	260
Open Heart Surgery (from 7.(b) 4.)	380	
General Surgery TRANSP/BURN/GI/TRAUMA/PEDS/ONC	4,481	2,889
Neurosurgery	932	126
Obstetrics and GYN (excluding C-Sections) MFM/ONC/GYN/REPRO/URO/OR	688	1,832
Ophthalmology	80	1,532
Oral Surgery ORA/MED/PEDENT/ORAMAX	221	1,035
Orthopedics	1,473	2,300
Otolaryngology	738	2,775
Plastic Surgery	533	1,205
Urology	500	500
Vascular	370	590
Other Surgeries (specify) ANES/RAD/MED/DENT/PDMED	111	95
Other Surgeries (specify)	-	
Number of C-Section's Performed in Dedicated C-Section ORs	1160	
Number of C-Section's Performed in Other ORs	-	
Total Surgical Cases	12,221	15,138

e) **Non-Surgical Cases by Category Table**
Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 8.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Pain Management	NOT COLLECTED	
Cystoscopy	226	1,597
Non-GI Endoscopies *(not reported in 8. c)*		
GI Endoscopies *(not reported in 8. c)* – PEDS GI	143	571
YAG Laser	8	166
Other (specify) – PEDS PULMONARY	449	993
Other (specify) – ADULT PULMONARY	351	573
Other (specify)		
Total Non-Surgical Cases	1,177	3,900

8. **Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures** *(continued)*

(**Campus** – ***If multiple sites:*** _____)

d) Surgical Cases by Specialty Area Table

Enter the number of **surgical** cases by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)		
Open Heart Surgery (from 7.(b) 4.)		
General Surgery	1062	2175
Neurosurgery	352	552
Obstetrics and GYN (excluding C-Sections)	33	305
Ophthalmology	4	1096
Oral Surgery Dental	0	136
Orthopedics	1415	5817
Otolaryngology ENT	12	461
Plastic Surgery	25	121
Urology	19	117
Vascular	35	23
Other Surgeries (specify) Gastro/Colorectal	47	14
Other Surgeries (specify)		
Number of C-Section's Performed in Dedicated C-Section ORs		
Number of C-Section's Performed in Other ORs		
Total Surgical Cases	3004	10,817

e) Non-Surgical Cases by Category Table

Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 8.**

	Non-Surgical Category	Inpatient Cases	Ambulatory Cases
*	Pain Management	77	4405
**	Cystoscopy	52	227
	Non-GI Endoscopies *(not reported in 8. c)*		
	GI Endoscopies *(not reported in 8. c)*		
	YAG Laser		
	Other (specify)		
	Other (specify)		
	Other (specify)		
	Total Non-Surgical Cases	129	4632

* Pain management are pain clinic patients

**Cystoscopy are excluded from urology surgical cases

All responses should pertain to October 1, 2008 *thru* September 30, 2009.

Surgical and Non-Surgical Cases

NOTE: Read the following instructions carefully.

Surgical Cases by Specialty Area Table - Enter the number of **surgical** cases by surgical specialty area in the chart below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Cases
Cardiothoracic	0
General Surgery	0
Neurosurgery	0
Obstetrics and GYN	0
Ophthalmology	1822
Oral Surgery	0
Orthopedics	2012
Otolaryngology	339
Plastic Surgery	0
Urology	159
Vascular	0
Other Surgeries (specify) Podiatry	415
Other Surgeries (specify)	
Total Surgical Cases	4749

Non-Surgical Cases by Category Table - Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location;** *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 5.

Non-Surgical Category	Cases
Pain Management	2593
Cystoscopy	
Non-GI Endoscopies *(not reported on page 5)*	
GI Endoscopies *(not reported on page 5)*	
YAG Laser	
Other (specify)	
Other (specify)	
Other (specify)	
Total Non-Surgical Cases	

All responses should pertain to October 1, 2008 *thru* September 30, 2009.

Surgical and Non-Surgical Cases

NOTE: Read the following instructions carefully.

Surgical Cases by Specialty Area Table: Enter the number of **surgical** cases by surgical specialty area in the chart below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area - the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Cases
Cardiothoracic	
General Surgery	
Neurosurgery	
Obstetrics and GYN	
Ophthalmology	
Oral Surgery	
Orthopedics	
Otolaryngology	
Plastic Surgery	276
Urology	
Vascular	
Other Surgeries (specify)	
Other Surgeries (specify)	
Total Surgical Cases	276

Non-Surgical Cases by Category Table: Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category - the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location,** *except* **do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 5.**

Non-Surgical Category	Cases
Pain Management	
Cystoscopy	
Non-GI Endoscopies *(not reported on page 5)*	
GI Endoscopies *(not reported on page 5)*	
YAG Laser	
Other (specify) Plastic Surgery	[illegible]
Other (specify)	
Other (specify)	
Total Non-Surgical Cases	[illegible]

Surgical and Non-Surgical Cases

NOTE: Read the following instructions carefully.

Surgical Cases by Specialty Area Table - Enter the number of **surgical** cases by surgical specialty area in the chart below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Cases
Cardiothoracic	
General Surgery	
Neurosurgery	
Obstetrics and GYN	2170
Ophthalmology	
Oral Surgery	
Orthopedics	
Otolaryngology	
Plastic Surgery	
Urology	
Vascular	
Other Surgeries (specify)	
Other Surgeries (specify)	
Total Surgical Cases	

Non-Surgical Cases by Category Table - Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 5.**

Non-Surgical Category	Cases
Pain Management	
Cystoscopy	
Non-GI Endoscopies *(not reported on page 5)*	
GI Endoscopies *(not reported on page 5)*	
YAG Laser	
Other (specify)	
Other (specify)	
Other (specify)	
Total Non-Surgical Cases	

8. **Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures** *(continued)*

(**Campus** – *If multiple sites*: MAIN)

d) **Surgical Cases by Specialty Area Table**

Enter the number of **surgical** cases by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)	224	20
Open Heart Surgery (from 7.(b) 4.)	299	
General Surgery	2,175	5,399
Neurosurgery	57	360
Obstetrics and GYN (excluding C-Sections)	721	2,547
Ophthalmology	10	4,993
Oral Surgery	2	15
Orthopedics	2,785	3,808
Otolaryngology	57	1,680
Plastic Surgery	81	455
Urology (excludes circumcision)	560	1,252
Vascular	422	547
Other Surgeries (specify)		
Other Surgeries (specify)		
Number of C-Section's Performed in Dedicated C-Section ORs	1,050	
Number of C-Section's Performed in Other ORs	1,406	
Total Surgical Cases	9,849	21,276

e) **Non-Surgical Cases by Category Table**

Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 8.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Pain Management	51	3,566
Cystoscopy	76	408
Non-GI Endoscopies *(not reported in 8. c)*	0	0
GI Endoscopies *(not reported in 8. c)*	0	0
YAG Laser	0	0
Other (specify) Non-OR Diagnostic	870	1,273
Other (specify) Non-OR Therapeutic	9,166	11,040
Other (specify)		
Total Non-Surgical Cases	10,163	14,287

8. **Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures** *(continued)*

(Campus – *If multiple sites*: Cary)

d) **Surgical Cases by Specialty Area Table**

Enter the number of **surgical** cases by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)		1
Open Heart Surgery (from 7.(b) 4.)		[redacted]
General Surgery		185
Neurosurgery		43
Obstetrics and GYN (excluding C-Sections)		129
Ophthalmology		4
Oral Surgery		10
Orthopedics		1,206
Otolaryngology		1,361
Plastic Surgery		
Urology		2
Vascular		4
Other Surgeries (specify)		0
Other Surgeries (specify)		[redacted]
Number of C-Section's Performed in Dedicated C-Section ORs		[redacted]
Number of C-Section's Performed in Other ORs		[redacted]
Total Surgical Cases		2945

e) **Non-Surgical Cases by Category Table**

Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 8.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Pain Management		
Cystoscopy		
Non-GI Endoscopies *(not reported in 8. c)*		
GI Endoscopies *(not reported in 8. c)*		
YAG Laser		
Other (specify) Non-OR Diagnostic	[redacted]	5
Other (specify) Non-OR Therapeutic		211
Other (specify)		
Total Non-Surgical Cases		216

8. **Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures** *(continued)*

(Campus – *If multiple sites*: WAKEFIELD)

d) **Surgical Cases by Specialty Area Table**

Enter the number of **surgical** cases by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)		
Open Heart Surgery (from 7.(b) 4.)		
General Surgery		53
Neurosurgery		22
Obstetrics and GYN (excluding C-Sections)		5
Ophthalmology		
Oral Surgery		
Orthopedics		255
Otolaryngology		7
Plastic Surgery		
Urology		4
Vascular		
Other Surgeries (specify)		
Other Surgeries (specify)		
Number of C-Section's Performed in Dedicated C-Section ORs		
Number of C-Section's Performed in Other ORs		
Total Surgical Cases		346

e) **Non-Surgical Cases by Category Table**

Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 8.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Pain Management		187
Cystoscopy		0
Non-GI Endoscopies *(not reported in 8. c)*		0
GI Endoscopies *(not reported in 8. c)*		0
YAG Laser		0
Other (specify) Non-OR Diagnostic		2
Other (specify) Non-OR Therapeutic		95
Other (specify)		
Total Non-Surgical Cases	0	284

8. Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures *(continued)*

(Campus – *If multiple sites*: Combined)

d) Surgical Cases by Specialty Area Table

Enter the number of **surgical** cases by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)	224	21
Open Heart Surgery (from 7.(b) 4.)	299	
General Surgery	2,175	5,637
Neurosurgery	57	425
Obstetrics and GYN (excluding C-Sections)	721	2,681
Ophthalmology	10	4,997
Oral Surgery	2	25
Orthopedics	2,785	5,269
Otolaryngology	57	3,048
Plastic Surgery	81	655
Urology	560	1,258
Vascular	422	551
Other Surgeries (specify)		
Other Surgeries (specify)		
Number of C-Section's Performed in Dedicated C-Section ORs	1,050	
Number of C-Section's Performed in Other ORs	1,406	
Total Surgical Cases	9,849	24,567

e) Non-Surgical Cases by Category Table

Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 8.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Pain Management	51	3,753
Cystoscopy	76	408
Non-GI Endoscopies *(not reported in 8. c)*		
GI Endoscopies *(not reported in 8. c)*		
YAG Laser		
Other (specify) Non-OR Diagnostic	270	1,288
Other (specify) Non-OR Therapeutic	9,766	11,346
Other (specify)		
Total Non-Surgical Cases	10,163	16,787

Surgical and Non-Surgical Cases

NOTE: Read the following instructions carefully.

Surgical Cases by Specialty Area Table - Enter the number of **surgical** cases by surgical specialty area in the chart below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Cases
Cardiothoracic	
General Surgery	
Neurosurgery	
Obstetrics and GYN	
Ophthalmology	515
Oral Surgery	
Orthopedics	
Otolaryngology	
Plastic Surgery	
Urology	
Vascular	
Other Surgeries (specify)	
Other Surgeries (specify)	
Total Surgical Cases	515

Non-Surgical Cases by Category Table - Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 5.**

Non-Surgical Category	Cases
Pain Management	
Cystoscopy	
Non-GI Endoscopies *(not reported on page 5)*	
GI Endoscopies *(not reported on page 5)*	
YAG Laser	147
Other (specify) cryoretinopexy	52
Other (specify) laser (PRP, Focal, MLT, ALT,PDT)	83
Other (specify) intravitreal injection,lesion removal	175
Total Non-Surgical Cases	457

8. **Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures** *(continued)*

(**Campus** – *If multiple sites*: WakeMed Cary Hospital Only)

d) **Surgical Cases by Specialty Area Table**
Enter the number of **surgical** cases by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)	2	0
Open Heart Surgery (from 7.(b) 4.)	0	
General Surgery	1,095	2,711
Neurosurgery	5	13
Obstetrics and GYN (excluding C-Sections)	120	1,454
Ophthalmology	3	933
Oral Surgery	12	33
Orthopedics	519	767
Otolaryngology	13	624
Plastic Surgery	16	130
Urology	147	607
Vascular	15	1
Other Surgeries (specify)	0	0
Other Surgeries (specify)	0	
Number of C-Section's Performed in Dedicated C-Section ORs	821	
Number of C-Section's Performed in Other ORs	0	
Total Surgical Cases	**2,768**	**7,273**

e) **Non-Surgical Cases by Category Table**
Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 8.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Pain Management	11	205
Cystoscopy	77	354
Non-GI Endoscopies *(not reported in 8. c)*	0	0
GI Endoscopies *(not reported in 8. c)*	8	6
YAG Laser	0	110
Other (specify)	2	541
Other (specify)	0	0
Other (specify)	0	0
Total Non-Surgical Cases	98	1,216

8. Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures *(continued)*

(Campus – *If multiple sites*: WakeMed Raleigh All Sites)

d) Surgical Cases by Specialty Area Table

Enter the number of **surgical** cases by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)	427	4
Open Heart Surgery (from 7.(b) 4.)	834	
General Surgery	1,992	2,259
Neurosurgery	837	593
Obstetrics and GYN (excluding C-Sections)	421	1,693
Ophthalmology	0	734
Oral Surgery	30	68
Orthopedics	2,172	3,161
Otolaryngology	369	3,145
Plastic Surgery	108	276
Urology	121	477
Vascular	312	31
Other Surgeries (specify) See pages 9.1 & 9.2	198	736
Other Surgeries (specify) See pages 9.1 & 9.2	18	
Number of C-Section's Performed in Dedicated C-Section ORs	1,288	
Number of C-Section's Performed in Other ORs	0	
Total Surgical Cases	9,127	13,177

e) Non-Surgical Cases by Category Table

Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 8.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Pain Management	0	444
Cystoscopy	0	0
Non-GI Endoscopies *(not reported in 8. c)*	0	0
GI Endoscopies *(not reported in 8. c)*	0	0
YAG Laser	0	0
Other (specify) Dental	0	918
Other (specify)	0	0
Other (specify)	0	0
Total Non-Surgical Cases	0	1,362

8. **Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures** *(continued)*

(Campus – *If multiple sites*: WakeMed Raleigh New Bern Avenue Only)

d) **Surgical Cases by Specialty Area Table**

Enter the number of **surgical** cases by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)	427	4
Open Heart Surgery (from 7.(b) 4.)	834	
General Surgery	1,992	2,052
Neurosurgery	837	593
Obstetrics and GYN (excluding C-Sections)	421	1,483
Ophthalmology	0	1
Oral Surgery	30	63
Orthopedics	2,172	2,032
Otolaryngology	369	1,964
Plastic Surgery	108	148
Urology	121	445
Vascular	312	31
Other Surgeries (specify) IP: Cystos; OP: Cystos-496;Endos-17; Podiatry-5	198	518
Other Surgeries (specify) Endoscopies	18	
Number of C-Section's Performed in Dedicated C-Section ORs	1,288	
Number of C-Section's Performed in Other Ors	0	
Total Surgical Cases	**9,127**	**9,334**

e) **Non-Surgical Cases by Category Table**

Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 8.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Pain Management	0	0
Cystoscopy	0	0
Non-GI Endoscopies *(not reported in 8. c)*	0	0
GI Endoscopies *(not reported in 8. c)*	0	0
YAG Laser	0	0
Other (specify) Dental	0	918
Other (specify)	0	0
Other (specify)	0	0
Total Non-Surgical Cases	**0**	**918**

8. Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures *(continued)*

(Campus – *If multiple sites*: WakeMed North HealthPlex Only)

d) Surgical Cases by Specialty Area Table
Enter the number of **surgical** cases by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases, including surgical cases operated on in procedure rooms or in any other location.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)	0	0
Open Heart Surgery (from 7.(b) 4.)	0	
General Surgery	0	207
Neurosurgery	0	0
Obstetrics and GYN (excluding C-Sections)	0	210
Ophthalmology	0	733
Oral Surgery	0	5
Orthopedics	0	1,129
Otolaryngology	0	1,181
Plastic Surgery	0	128
Urology	0	32
Vascular	0	0
Other Surgeries (specify) Podiatry-200; Cosmetic-13; Other-5	0	218
Other Surgeries (specify)	0	
Number of C-Section's Performed in Dedicated C-Section ORs	0	
Number of C-Section's Performed in Other ORs	0	
Total Surgical Cases	**0**	**3,843**

e) Non-Surgical Cases by Category Table
Enter the number of **non-surgical** cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 8.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Pain Management	0	444
Cystoscopy	0	0
Non-GI Endoscopies *(not reported in 8. c)*	0	0
GI Endoscopies *(not reported in 8. c)*	0	0
YAG Laser	0	0
Other (specify)	0	0
Other (specify)	0	0
Other (specify)	0	0
Total Non-Surgical Cases	0	444

Exhibit 3

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: February 25, 2005
FINDINGS DATE: March 3, 2005

PROJECT ANALYST: Ronald Loftin
CHIEF: Lee Hoffman

PROJECT I.D. NUMBER: B-7132-04/ Fletcher Hospital, Inc. d/b/a Park Ridge Hospital/ Construct new hospital space and renovate existing space to add 11 new licensed acute care beds, replace eight acute care beds and expand women's services, ambulatory surgery, telemetry, and intensive care departments/Henderson County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(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, ambulatory surgical operating rooms, or home health offices that may be approved.

C

Fletcher Hospital, Inc. d/b/a Park Ridge Hospital (**"Park Ridge"**) located in Fletcher in northern Henderson County, currently has 62 licensed acute care beds and 41 psychiatric beds. Park Ridge proposes to construct 45,500 square feet of new space and renovate 28,550 square feet of existing hospital space to add 11 new licensed acute care beds, replace eight existing licensed acute care beds and expand women's services, ambulatory surgery, telemetry, and intensive care departments. The 2004 State Medical Facilities Plan identifies a need for 11 additional acute care beds in Henderson County by 2008. The 2004 SMFP also states:

The applicant also projects its market share of ICU patients in its primary service area to increase from 20.5% in 2004 to 35.4% in 2009. Park Ridge also proposes to increase its market share in its secondary service area in the same time period from 6.2% to 10.4%. However, the applicant does not adequately demonstrate that projected market share increases of ICU patients are reasonable in light of the fact that ICU utilization has been somewhat flat in the past two years and Park Ridge has not documented that it has been successful in recruiting new physicians since 2002. Also, the applicant did not demonstrate that it is reasonable to project significant increases in admissions from the secondary service area, given that residents of this area live in closer proximity to Mission Hospitals than to Park Ridge.

Other Project Components

The applicant also proposes to relocate Pre/Post-Operative spaces (for outpatient and inpatient) from the northeast side of the first floor to new construction on the northwest corner of the hospital to put patients in close proximity to the operating rooms. On page 14, the applicant proposes to construct 21 pre/post operative bays. The applicant states on page 54:

> *"PRH proposes to expand its pre- and post- operatives. The existing spaces are crowded and partitioned only by 3-sided curtains. This is not ideal as patients can experience anxiety prior to an operative procedure and are often in pain as they recover. Private bays will allow patients improved privacy and comfort. Additionally, some of the existing pre- and post- operative spaces are not located in close proximity to the OR suites. For example, Level II recovery is located down a long hall away from the operating rooms."*

However, the applicant does not provide documentation of the need for 21 bays.

Upon the proposed relocation of the current Outpatient Pre/Post-Op, the applicant proposes to expand the Laboratory into the vacated space. The applicant states on page 54:

> *"Currently, the existing lab space is significantly undersized and lacks safety and privacy measures as well. In fact, PRH's most recent JCAHO review specifically notes the lack of lab space. ... (T)he emergency shower is crowded by waste receptacles and storage items that should be safely located in a controlled area. ... PRH's laboratory also lacks a private blood drawing room."*

On page 12, the applicant states that the proposed first floor new construction would include outpatient Women's Services reception and waiting and relocated radiology equipment for mammography, ultrasound, stereotactic breast biopsy, and

Exhibit 4

Orthopaedic Specialties
Foot and Ankle Surgeries
Hand and Wrist Surgeries
Shoulder Surgeries
Spine Surgeries
Sports Injuries / Surgeries
Sports Medicine Outreach
Strains, Sprains and Fractures
Total Joint Replacements
General Orthopaedics
Rehabilitation / Pain Management
Non-Surgical Spine
Urgent Care Centers
Locations
Ancillary Services »
North Carolina Specialty Hospital
Patient Forms and Survey

Foot and Ankle Surgeries

Below are the most common surgeries performed by our foot and ankle section:

Foot

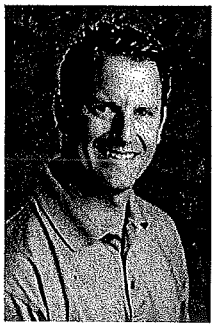
- Hallux Valgus Correction (Bunions)
- Hammertoe Corrections
- Clawtoe Corrections
- Excision Morton's (Interdigital) Neuroma
- Hallux Rigidus Correction (Stiff Great Toe)
- Correction of Small Toe Deformities (Tailors' Bunions)

Ankle

- Reconstruction of Chronic Sprained Ankles
- Repair of Achilles' Tendon Ruptures
- Repair of Tendon Problems about the Ankle
- Operative Fixation of Ankle Fractures

Richard F. Bruch, M.D.

Paul J. Kerner, M.D.



Mark A. Burt, M.D.

Peter W. Gilmer, M.D.

Printable View

Main Offices:
Durham - 120 William Penn Plaza, Independence Park, Durham, North Carolina 27704
Phone: 919-220-5255. Toll Free: 1-800-359-3053. Fax: 919-220-6379
Raleigh - 3100 Duraleigh Road, Raleigh, North Carolina 27612
Phone: 919-788-8797 Fax: 919-788-8798

Orthopaedic Specialties
Foot and Ankle Surgeries
Hand and Wrist Surgeries
Shoulder Surgeries
Spine Surgeries
Sports Injuries / Surgeries
Sports Medicine Outreach
Strains, Sprains and Fractures
Total Joint Replacements
General Orthopaedics
Rehabilitation / Pain Management
Non-Surgical Spine
Urgent Care Centers
Locations
Ancillary Services »
North Carolina Specialty Hospital
Patient Forms and Survey

Rehabilitation / Pain Management

As specialists in Physical Medicine and Rehabilitation, we are ideally suited to help patients with acute and chronic pain problems. We offer a full range of diagnostic testing such as EMG, Discograms, Stellate and Sympathetic blocks as well as many treatment plans of the non-surgical nature. These include Epidural Steroid Injections, Facet Blocks, Radio Frequency Lesioning , Prolo Therapy and Spinal Cord Stimulators. Our services include state of the art facilities for physical, occupational and aquatic therapy as well as an on site Psychologist to complete their treatment.

Pain Management - Non-surgical approach to pain and injury

Our Approach to Pain Management - Treat the person and the pain using a multidisciplinary treatment approach.

We have specialists in:

- Orthopaedics
- Physiatry
- Psychology
- Physical/Occupational Therapy
- Vocational Rehabilitation
- Ergonomic Evaluation

Triangle Orthopaedics offers a broad range of pain management services including:

Medical Management
- Expert evaluation and diagnosis
- Coordinated care
- Medical management
- Treatment planning

Interventional Pain Management
- Trigger point injections
- Peripheral joint injections
- Prolotherapy
- Epidural steroid injections
- Selective Spinal nerve blocks
- Facet joint blocks
- Sympathetic blocks/Stellate ganglion blocks
- RFL (Radiofrequency Lesion)
- Intra-Discal Electrothermal Annuloplasty (IDET)
- Spinal Cord Stimulator
- Discogram (Cervical/Thoracic/Lumbar Spine)

Cognitive/Behavioral Pain Management
- Biofeedback
- Hypnosis
- Behavioral Therapy

Physical Therapy/Occupational Therapy
- Physical Therapy
- OT/Certified Hand Therapist
- Work Conditioning Programs
- Functional Capacity Evaluations
- Certified Ergonomic Assessments & Work Evaluations

Common Conditions
- Complex Regular Pain Syndrome
- Reflex Sympathetic Dystrophy (RSD)
- Chronic Low Back Pain/Neck Pain
- Failed Back Syndrome

Robert J. Wilson, M.D.

Dina Eisinger, M.D.

Raphael S. Orenstein, M.D.

Eugenia F. Zimmerman, M.D.

HNP/Sciatica
Chronic Myofascial Pain
Fibromyalgia

Perico N. Arcedo, D.O.

Leslie "Les" R. Phillips, Ph. D.

What is a physiatrist?

Printable View

Main Offices:
Durham - 120 William Penn Plaza, Independence Park, Durham, North Carolina 27704
Phone: 919-220-5255. Toll Free: 1-800-359-3053. Fax: 919-220-6379
Raleigh - 3100 Duraleigh Road, Raleigh, North Carolina 27612
Phone: 919-788-8797 Fax: 919-788-8798

Exhibit 5

NC Division of Health Service Regulation

Certificate of Need Section

Letters of Support Submitted for Certificate of Need Applications

To: Interested Parties

From: Lee B. Hoffman, Chief, CON Section

Date: July 10, 2003

The purpose of this memorandum is to clarify procedures relative to acceptance of letters of support for a project after the application has been filed to assure conformance with the Certificate of Need law and administrative rules regarding the written comment period and amendments to the application.

From this date forward, any letters of support or petitions for a project must be received by the CON Section no later than the last day of the written comment period for the application. Any letters or petitions received after that date, including letters and petitions brought to the public hearing, will not be considered by the agency in the review of the project. This procedure is consistent with G.S. 131E-185(1) which states, "Any person may file written comments and exhibits concerning a proposal under review with the department, not later than 30 days after the date on which the application begins review." Additionally, G.S. 131E-185(2) states that at the public hearing "oral arguments may be made regarding the application or applications under review..." Therefore, the law provides for the public to make oral comments at the public hearing. There is no provision in the law allowing the submittal of written comments at the hearing given that it is held more than 30 days after the review begins. However, a speaker may provide the agency a transcript of his/her oral remarks made at the hearing in accordance with G.S. 131E-185(2) which states "any person may submit a written synopsis or verbatim statement that contains the oral presentation made at the hearing." In addition, an applicant may submit a written response or rebuttal to the written comments made on its application, to the Certificate of Need Section at the public hearing.

As has always been the case, please note that nothing contained in oral or written comments can be used to amend (i.e. revise, change or supplement) the application filed with the Certificate of Need Section. Specifically, 10A NCAC 14C .0204 states, "An applicant may not amend an application. Responding to a request for additional information made by the agency after the review has commenced is not an amendment." Therefore, the application cannot be amended with information contained in any letters or materials received during the written comment period or at the public hearing, even if the applicant states in the application that such letters will be submitted. Consequently, all information the applicant intends to rely on to demonstrate conformance of the application with the review criteria must be provided by the applicant in its application when first submitted to the agency.

If you have any questions regarding this matter, please submit them in writing to Lee Hoffman, Certificate of Need Section, to assist the agency in making consistent responses to all inquiries.

Denotes link to site outside of N.C. DHSR.

This page was last modified on May 27, 2008.

Division of Health Service Regulation

Exhibit 6

D. Beds by Service (Inpatient) *continued*

Number of Swing Beds *	N/A
Number of Skilled Nursing days in Swing Beds	N/A
Number of unlicensed observation beds	N/A

* means a hospital designated **as a swing-bed hospital** by CMS (Centers for Medicare and Medicaid Services)

E. Reimbursement Source (For "Inpatient Days," show Acute Inpatient Days only, excluding normal newborns.)

Primary Payer Source	Inpatient Days of Care (from p. 4, item D. 1.)	Emergency Visits (from p. 6)	Outpatient Visits (excluding Emergency Visits and Surgical Cases)	Inpatient Surgical Cases (from p.8, Table 8. b)	Ambulatory Surgical Cases (from p. 8, Table 8. b)
Self Pay/Indigent/Charity	2,506	12,155	1,717	180	356
Medicare & Medicare Managed Care	53,519	15,570	29,099	3,236	6,509
Medicaid	6,855	5,491	3,022	496	969
Commercial Insurance	406	551	469	42	63
Managed Care	42,991	17,543	57,073	5,763	16,076
Other (Specify)	1,488	4,686	4,969	132	594
TOTAL	107,765	55,996	96,579	9,849	24,567

F. Services and Facilities

1. Obstetrics

	Enter Number of Infants
a. Live births (Vaginal Deliveries)	4,103
b. Live births (Cesarean Section)	2,455
c. Stillbirths	12

d. Delivery Rooms - Delivery Only (not Cesarean Section)	0
e. Delivery Rooms - Labor and Delivery, Recovery	20
f. Delivery Rooms – LDRP (include Item "m" on Page 4)	0
g. Normal newborn bassinets (Level I Neonatal Services) Do not include with totals under the section entitled Beds by Service (Inpatient)	Varies

2. Abortion Services

Number of procedures per Year 615

D. Beds by Service (Inpatient) *continued*

Number of Swing Beds *	0
Number of Skilled Nursing days in Swing Beds	0
Number of unlicensed observation beds	0

* means a hospital designated as a swing-bed hospital by CMS (Centers for Medicare and Medicaid Services)

E. Reimbursement Source (For "Inpatient Days," show Acute Inpatient Days only, excluding normal newborns.)

Primary Payer Source	Inpatient Days of Care (from p. 4, item D. 1.)	Includes Admits Emergency Visits (from p. 6)	Outpatient Visits (excluding Emergency Visits and Surgical Cases)	Inpatient Surgical Cases (from p.8, Table 8. b)	Ambulatory Surgical Cases (from p. 8, Table 8. b)
Self Pay/Indigent/Charity	5331	13691	11,393	526	1722
Medicare & Medicare Managed Care	13,468	5908	22,683	1201	2273
Medicaid	1843	4708	1923	130	351
Commercial Insurance	253	688	819	39	190
Managed Care	6735	8098	26,759	1006	5794
Other (Specify)	472	573	1287	102	487
TOTAL	28,102	33,666	64,864	3004	10,817

NOTE: Total outpatient visits = emergency 33,666 less admissions 3,163 plus outpatient visits 64,864 plus ambulatory surgical cases 10,817 = 106,184

F. Services and Facilities

1. Obstetrics	Enter Number of Infants
a. Live births (Vaginal Deliveries)	0
b. Live births (Cesarean Section)	0
c. Stillbirths	1

d. Delivery Rooms - Delivery Only (not Cesarean Section)	0
e. Delivery Rooms - Labor and Delivery, Recovery	0
f. Delivery Rooms – LDRP (include Item "m" on Page 4)	0
g. Normal newborn bassinets (Level I Neonatal Services) Do not include with totals under the section entitled Beds by Service (Inpatient)	0

2. Abortion Services Number of procedures per Year 0

D. Beds by Service (Inpatient) *continued* WakeMed Raleigh New Bern Avenue Only

Number of Swing Beds *	0
Number of Skilled Nursing days in Swing Beds	0
Number of unlicensed observation beds	73

* means a hospital designated as a swing-bed hospital by CMS (Centers for Medicare and Medicaid Services)

E. Reimbursement Source (For "Inpatient Days," show Acute Inpatient Days only, excluding normal newborns.)

Primary Payer Source	Inpatient Days of Care (from p. 4, item D. 1.)	Emergency Visits (from p. 6)	Outpatient Visits (excluding Emergency Visits and Surgical Cases)	Inpatient Surgical Cases (from p.8, Table 8. b)	Ambulatory Surgical Cases (from p. 8, Table 8. b)
Self Pay/Indigent/Charity	5,709	25,270	28,067	545	836
Medicare & Medicare Managed Care	83,708	17,683	43,087	3,358	1,617
Medicaid	40,981	39,541	40,517	2,006	2,267
Commercial Insurance	3,391	3,509	2,354	203	126
Managed Care	36,104	28,627	89,461	2,645	4,831
Other (Specify)	4,153	5,800	5,305	370	575
TOTAL	**174,046**	**120,430**	**208,791**	**9,127**	**10,252**

F. Services and Facilities

1. Obstetrics

	Enter Number of Infants
a. Live births (Vaginal Deliveries)	3,859
b. Live births (Cesarean Section)	1,302
c. Stillbirths	41

d. Delivery Rooms - Delivery Only (not Cesarean Section)	0
e. Delivery Rooms - Labor and Delivery, Recovery	1
f. Delivery Rooms – LDRP (include Item "m" on Page 4)	32
g. Normal newborn bassinets (Level I Neonatal Services) Do not include with totals under the section entitled Beds by Service (Inpatient)	36

2. Abortion Services

Number of procedures per Year 7

D. Beds by Service (Inpatient) *continued* WakeMed North HealthPlex Only

Number of Swing Beds *	0
Number of Skilled Nursing days in Swing Beds	0
Number of unlicensed observation beds	0

* means a hospital designated **as a swing-bed hospital** by CMS (Centers for Medicare and Medicaid Services)

E. Reimbursement Source (For "Inpatient Days," show Acute Inpatient Days only, excluding normal newborns.)

Primary Payer Source	Inpatient Days of Care (from p. 4, item D. 1.)	Emergency Visits (from p. 6)	Outpatient Visits (excluding Emergency Visits and Surgical Cases)	Inpatient Surgical Cases (from p.8, Table 8. b)	Ambulatory Surgical Cases (from p. 8, Table 8. b)
Self Pay/Indigent/Charity	0	7,058	914	0	241
Medicare & Medicare Managed Care	0	3,597	7,445	0	816
Medicaid	0	6,255	1,899	0	200
Commercial Insurance	0	922	426	0	23
Managed Care	0	15,564	20,835	0	2,438
Other (Specify)	0	1,485	712	0	125
TOTAL	**0**	**34,881**	**32,231**	**0**	**3,843**

F. Services and Facilities

1. Obstetrics

	Enter Number of Infants
a. Live births (Vaginal Deliveries)	0
b. Live births (Cesarean Section)	0
c. Stillbirths	0

d. Delivery Rooms - Delivery Only (not Cesarean Section)	0
e. Delivery Rooms - Labor and Delivery, Recovery	0
f. Delivery Rooms – LDRP (include Item "m" on Page 4)	0
g. Normal newborn bassinets (Level I Neonatal Services) Do not include with totals under the section entitled Beds by Service (Inpatient)	0

2. Abortion Services

Number of procedures per Year 0

D. Beds by Service (Inpatient) *continued* WakeMed Cary Hospital Only

Number of Swing Beds *	0
Number of Skilled Nursing days in Swing Beds	0
Number of unlicensed observation beds	22

* means a hospital designated **as a swing-bed hospital** by CMS (Centers for Medicare and Medicaid Services)

E. Reimbursement Source (For "Inpatient Days," show Acute Inpatient Days only, excluding normal newborns.)

Primary Payer Source	Inpatient Days of Care (from p. 4, item D. 1.)	Emergency Visits (from p. 6)	Outpatient Visits (excluding Emergency Visits and Surgical Cases)	Inpatient Surgical Cases (from p.8, Table 8. b)	Ambulatory Surgical Cases (from p. 8, Table 8. b)
Self Pay/Indigent/Charity	1,275	7,999	1,082	84	181
Medicare & Medicare Managed Care	20,632	9,081	10,524	966	2,025
Medicaid	4,717	5,664	2,121	195	293
Commercial Insurance	235	1,078	386	20	47
Managed Care	13,750	18,225	16,047	1,455	4,595
Other (Specify)	318	1,743	578	48	132
TOTAL	40,927	43,790	30,738	2,768	7,273

F. Services and Facilities

1. Obstetrics

	Enter Number of Infants
a. Live births (Vaginal Deliveries)	1,609
b. Live births (Cesarean Section)	833
c. Stillbirths	9

d. Delivery Rooms - Delivery Only (not Cesarean Section)	0
e. Delivery Rooms - Labor and Delivery, Recovery	10
f. Delivery Rooms – LDRP (include Item "m" on Page 4)	26
g. Normal newborn bassinets (Level I Neonatal Services) Do not include with totals under the section entitled Beds by Service (Inpatient)	26

2. Abortion Services

Number of procedures per Year 3

Average Operating Room Availability and Average Case Times:

The Operating Room Methodology assumes that the average operating room is staffed 9 hours a day, for 260 days per year, and utilized at least 80% of the available time. This results in 1872 hours per OR per year. The Operating Room Methodology also assumes 1.5 hours for each Outpatient Surgery.

Based on **your facility**'s experience, please complete the table below by showing the assumptions for the **average operating room in your facility**.

Average Hours per Day **Routinely** Scheduled for Use *	Average Number of Days per Year **Routinely** Scheduled for Use	Average "Case Time" ** in **Minutes** for Ambulatory Cases
8.5	261	45

* (Use only Hours per Day routinely scheduled when determining. Example: 2 rooms @ 8 hours per day plus 2 rooms @ 10 hours per day equals 36 hours per day, divided by 4 rooms equals an average of 9 hours / per room / per day.)

** **"Case Time" = Time from Room Set-up Start to Room Clean-up Finish**: Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. *NOTE: This definition includes all of the time for which a given procedure requires an OR/PR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure.*

Reimbursement Source

Primary Payer Source	Number of Cases
Self Pay/Indigent/Charity	136
Medicare & Medicare Managed Care	1493
Medicaid	599
Commercial Insurance	44
Managed Care	5812
Other (Specify)	453
TOTAL	8497

Exhibit 7

Anesthesiologist Letter

Presbyterian HEALTHCARE

Remarkable People. Remarkable Medicine.

November 01, 2010

Mr. Craig Smith, Chief
Certificate of Need Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
701 Barbour Drive
Raleigh, North Carolina 27603

RE: Documentation of Compliance with Surgical Services & Operating Room CON Regulations at 10A NCAC 14C.2105 (c) and .2104 (b)(3) for the North State Surgery Center Demonstration Projects with Two ORs and One Procedure Room. CON Application Submitted November 15, 2010 (Orange/Durham/Wake Counties)

Dear Mr. Smith:

I am a member of Presbyterian Anesthesia Associates, (PAA) based in Charlotte, North Carolina. PAA anesthesiologists are active medical staff members in good standing at Presbyterian Healthcare hospitals in Mecklenburg County. Our group will provide on-site anesthesia coverage and supervision of CRNA services for surgery patients of the proposed North State Surgery Center in Chapel Hill, NC located near the Orange/Durham County line. We also intend to seek privileges at an existing acute care hospital in Orange or Durham County. A copy of my curriculum vitae is enclosed.

This new outpatient general surgery center will provide much needed local access to meet the growing demand for surgical services in central and southern Orange & Durham Counties. This additional surgical and procedure room capacity will be of benefit to this rapidly growing area, and will provide more local choices for physicians, their patents and their families.

Please convey to the Certificate of Need Section my support, and the support of Presbyterian Anesthesia Associates for the proposal to establish a new North State Surgery Center in Orange County. Please do not hesitate to contact me should you have any questions.

Sincerely,

Joseph P. Ducey, MD, President
Presbyterian Anesthesia Associates

Enclosure

File: NSSC CONAppAnesthesia.10.2010.doc

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