



High Point Regional Health System

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Received by the
CON Section

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May 3, 2010

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

Dear Mr. Smith:

Please find attached comments by High Point Regional Health System filed in relation to the following CON applications:

Project I.D. # G-8492-10: Kernersville Orthopaedic Surgery Center, LLC Application for Two New Demonstration Project Single Specialty Ambulatory Surgery Facility ORs in Forsyth County; and

Project I.D. # G-8479-10: Orthopaedic Surgical Center of the Triad Holdings, LLC and GSW Real Estate, LLC CON Application for a Single Specialty Ambulatory Surgery Facility Demonstration Project in Guilford County.

Thank you for your assistance. Please contact me at (336)878-6095 with any questions.

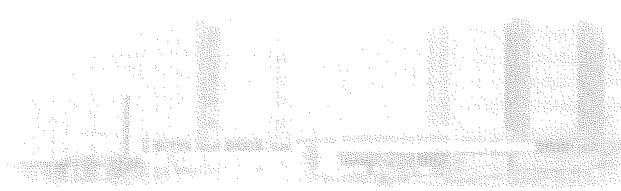
Sincerely,

Molly Jordan

Molly D. Jordan
Strategic Planning

/mdj

Attachments



**Comments in Opposition from High Point Regional Health System
Regarding Orthopaedic Surgical Center of the Triad Holdings, LLC and
GSW Real Estate, LLC CON Application for a
Single Specialty Ambulatory Surgery Facility Demonstration Project
in Guilford County
Submitted March 15, 2010
Project I.D. # G-8479-10**

In accordance with N.C. Gen. Stat. §131E-185(a1)(1), High Point Regional Health System (HPRHS) submits the following comments regarding the CON Application of Orthopaedic Surgical Center of the Triad Holdings, LLC and GSW Real Estate, LLC (“Applicants”) for a Single Specialty Ambulatory Surgery Facility Demonstration Project in Guilford County (Project I.D. # G-8479-10).

I. Background

Orthopedic Surgical Center of the Triad Holdings, LLC (“OSCT”) and GSW Real Estate, LLC (“GSW”) propose to develop a new single-specialty ambulatory surgery center demonstration project with two surgical operating rooms and one procedure room. The facility will be located in the Triad Area on a four-acre site on Sandy Ridge Road at the entrance to the Farmers Market in Colfax, NC.

II. Misinterpretation of Criteria for Single Specialty Ambulatory Surgery Demonstration Project

The 2010 State Medical Facilities Plan (“SMFP”) provides the criteria for the Single-Specialty Ambulatory Surgery Demonstration Project as part of the discussion under operation room need determination as follows (*see* page 81 of the SMFP):

“...In addition, the North Carolina State Health Coordinating Council has determined that there is a need for a Single Specialty Ambulatory Surgery Demonstration Project, consisting of three facilities with two operating rooms each. Therefore, there is a need determination for one facility to be located in each of the following areas: Charlotte Area (Mecklenburg, Cabarrus, Union counties), Triad (Guilford, Forsyth counties), Triangle Area (Wake, Durham, Orange counties). The demonstration project facilities must meet the criteria described in Table 6D...”

The first criterion in Table 6D of the SMFP, is as follows (*see* page 82 of the SMFP):

“Establish a special need determination for three new separately licensed single specialty ambulatory surgical 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)

- Wake, Durham, Orange counties (Triangle)

Further, the basic principle and rationale for the criterion is stated as follows (see page 82 of the SMFP):

“At least one county in each of the groups of counties has a current population greater than or equal to 200,000 and more than 50 total ambulatory/shared operating rooms and at least 1 separately licensed Ambulatory Surgery Center. Locating facilities in high population areas with a large number of operating rooms and existing ambulatory surgery providers prevents the facilities from harming hospitals in rural areas, which need revenue from surgical services to offset losses from other necessary services such as emergency department services.”[Emphasis added]

Opposing Comment

According to the criteria set forth in the SMFP, it is not the intention of the Single-Specialty Ambulatory Surgery Demonstration Project to serve the entire region in each of the groups of counties, but rather to be located “in high population areas with a large number of operating rooms and existing ambulatory surgery providers.” The intent is to avoid impacting existing providers by locating these facilities in densely populated areas. In fact, it would be unreasonable to expect that a small, single-specialty Ambulatory Surgery Center with only two operating rooms would service a multi-county area.

The map provided as Exhibit I below shows the proposed location of OSCT as well as the surrounding Zip Codes. The 2009 estimated populations for each of the Zip Codes in the vicinity of the proposed facility are provided in Table 1 following the map.

Exhibit I : Proposed Location of OSCT and Surrounding Zip Codes

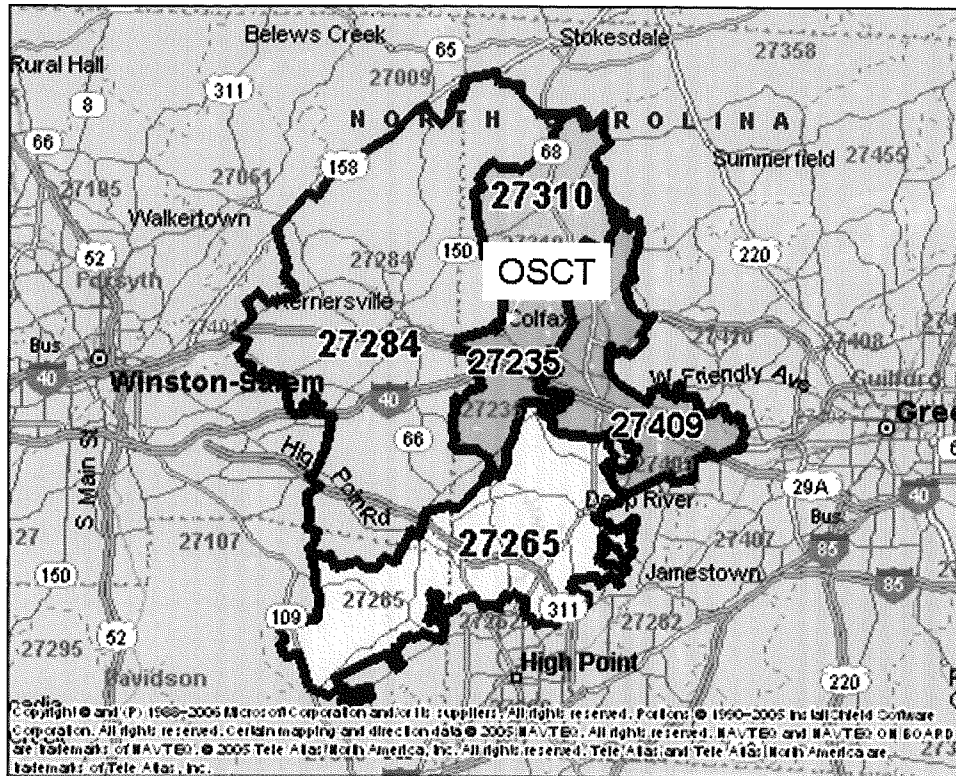


Table 1: 2009 Population for Zip Codes Surrounding Proposed OSCT Ambulatory Surgery Center

Zip Code	2009 Population
27235	3,652
27409	13,943
27310	5,792
27265	44,878
27284	51,707
Total	119,972

Source: Kernersville Orthopaedic Surgery Center, LLC CON Application, Project # G-8492-10, p.210.

It is important to note that the proposed site for the OSCT Single-Specialty Ambulatory Surgery Facility Demonstration Project is in Zip Code 27235, which had an estimated population in 2009 of 3,652! By any standards, this would be considered a rural area.

Even when the populations of all of the surrounding Zip Codes are added to the population base, the total population is still only 119,972. This is far less than the 200,000 population base indicated in the SMFP and clearly not the intended demographics for the project.

Further, the site is not located in a Medical Community. It is undeveloped acreage close to the Farmers Market. It was the intention of the SMFP to locate the specialized operating rooms in an urban area, where they may serve a concentrated population of patients and be supported by a well-established medical community.

Table 2 below contains the estimated 2009 population for the Triad area (Forsyth and Guilford counties) as designated for the Demonstration Project.

Table 2: Estimated 2009 and Project 2014 Population by Zip Code for Forsyth and Guilford Counties				
Zip Code	Town	County	Estimated 2009	Projected 2014
27284	Kernersville	Forsyth	51,707	57,196
27106	Winston Salem	Forsyth	47,313	50,366
27107	Winston Salem	Forsyth	43,301	46,313
27105	Winston Salem	Forsyth	41,306	42,581
27127	Winston Salem	Forsyth	32,001	35,178
27103	Winston Salem	Forsyth	29,973	31,912
27104	Winston Salem	Forsyth	28,252	29,639
27012	Clemmons	Forsyth	26,356	29,212
27101	Winston Salem	Forsyth	20,304	21,241
27023	Lewisville	Forsyth	12,298	13,342
27040	Pfafftown	Forsyth	10,821	11,759
27051	Walkertown	Forsyth	7,938	8,495
27045	Rural Hall	Forsyth	7,897	8,333
27050	Tobaccoville	Forsyth	4,607	4,948
27009	Belews Creek	Forsyth	2,534	2,689
27110	Winston Salem	Forsyth	1,200	1,228
	Total Forsyth County		367,808	394,432
27410	Greensboro	Guilford	54,424	59,402
27406	Greensboro	Guilford	53,061	55,264
27407	Greensboro	Guilford	48,208	51,385
27265	High Point	Guilford	44,878	51,441
27405	Greensboro	Guilford	44,005	46,756
27260	High Point	Guilford	27,573	28,997
27455	Greensboro	Guilford	26,512	29,374
27262	High Point	Guilford	25,331	26,602
27403	Greensboro	Guilford	19,169	19,524
27401	Greensboro	Guilford	18,904	19,325
27408	Greensboro	Guilford	17,510	17,916
27282	Jamestown	Guilford	15,894	17,374
27409	Greensboro	Guilford	13,943	15,341
27358	Summerfield	Guilford	11,085	11,909
27249	Gibsonville	Guilford	10,397	11,012
27214	Browns Summit	Guilford	8,738	9,420
27301	McLeansville	Guilford	7,161	7,856
27313	Peasant Garden	Guilford	7,096	7,581
27310	Oak Ridge	Guilford	5,792	6,381
27377	Whitsett	Guilford	5,208	5,701
27235	Colfax	Guilford	3,652	4,160
27413	Greensboro	Guilford	3,271	3,440
27283	Julian	Guilford	2,948	3,037
27411	Greensboro	Guilford	1,294	1,351
	Total Guilford County		476,054	510,549
	Total Forsyth and Guilford Counties		843,862	904,981

Source: Kernersville Orthopaedic Surgery Center, LLC CON Application, Project # G-8492-10, p. 210.

When the data above is reviewed, it becomes obvious that there were significant alternative geographic locations for the proposed Single-Specialty Ambulatory Surgery Facility Demonstration Project which offer a more densely populated area. In fact, the population residing in the Zip Codes immediately surrounding the Applicant's proposed location in 2009 represented only 14.2 percent (119,972 / 843,862) of the total population residing in the designated Triad Demonstration Project area.

Locating the Single-Specialty Ambulatory Surgery Facility Demonstration Project in a rural area such as this would increase travel times for most patients using the facility as well as travel time for other medical support services.

III. CON Review Criteria

The following comments are based on the CON Review Criteria (N.C. Gen. Stat. §131E-183). While some comments apply to more than one Criterion, they are discussed under the most relevant review Criterion and referenced in others to which they apply.

Criterion (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.

The Applicants are non-conforming to Criterion (1) because, as discussed in Criterion (3) below, the Applicants failed to adequately support a quantitative and qualitative need for the project at the proposed location.

Criterion 3

The application 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, 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 provided.

The proposed project is non-conforming to Criterion (3) because the Applicants failed to appropriately identify the population served. Further, the Applicants provided two conflicting utilization forecasts.

Failure to Appropriately Identify Population Served

As previously discussed in section II above, the Applicants identify the entire Triad area (Forsyth and Guilford counties) as the service area for the Single-Specialty Ambulatory Surgery Facility Demonstration Project. This service area is unrealistic for a two-room

surgery center. Historically, most providers of these services, whether single or multi-specialty, define their primary service area as the Zip Code in which the facility is located and the Zip Codes in the surrounding vicinity.

Two conflicting projections provided

The Applicants offer two conflicting projections for utilization of the proposed facility with no discussion of how the two approaches should be reconciled. The first projection is provided on page 44 of the application and is the result of totaling physician estimated utilization. The second method uses a statewide ambulatory surgery use rate and projected population.

Population Projections and Statewide Ambulatory Surgery Use Rates

On pages 45-48 of the application, the Applicants present a six-step process for calculating projected utilization based on statewide ambulatory surgery use rates and projected population. After adjusting the cases downwards by 15 percent for cases which they believe can be handled in the procedure room, the year three utilization was projected to be 2,612 as shown in Table 3 below:

Table 3: OSCT Projected Year 3 Utilization and OR Need	
Based on Statewide Ambulatory Surgery Use Rate and Projected Population	
Projected Surgical Cases	2,612
Hours per Case	1.5
Total Hours	3,918
ORs Needed (Total Hours / 1872)	2.09

These hours translate into a need for 2.09 operating rooms in the third year of operation.

Individual Physician Utilization

Alternatively, projected utilization by orthopedists in the area is provided on page 44 of the application and is the result of totaling physician estimated utilization from letters of support. In addition, the Applicants estimate that an additional ten orthopedists will be recruited and that they will perform an additional 100 to 175 ambulatory surgical cases per physician per year. The projected utilization using this method is summarized in Table 4 below:

Table 4: OSCT Projected Year 3 Utilization and OR Need	
Based on Physician Estimates and Recruiting Plans	
Physician Projected Surgical Cases	4,022
Add'l Cases from New MDs (10 x100)	1,000
Total Cases	5,022
Adjusted for procedures (85%)	4,269
Hours per Case	1.5
Total Hours	6,403
ORs Needed (Total Hours / 1872)	3.42

Consistent with the Applicant's assumptions in the prior projection, these cases were adjusted downwards by 15 percent for procedures that could be handled in the procedure room. Using this method, the proposed facility is undersized to serve the physicians who intend to practice there since the number of ORs needed is estimated to be 3.42.

It is important to note that the physician estimates were not provided as a general indication of need for the project, but were, instead, *specific commitments* from the physicians of volumes of work that they would perform *at this specific facility*.

Need for Single-Specialty Orthopedic Services Unsupported

Table 5 below summarizes the operating room inventory in Forsyth and Guilford Counties as presented in the 2010 SMFP:

Facility	Cases		Surgical Hours ¹			Operating Rooms			
	Inpatient	Ambulatory	Inpatient	Ambulatory	Total	Adjusted #	Calculated Need*	Excess/ (Deficit)	Occupancy
Forsyth Medical Center	10,361	12,626	31,083	18,939	50,022	38			70.3%
Medical Park Hospital	1,085	10,531	3,255	15,797	19,052	7			145.4%
North Carolina Baptist Hospitals	13,251	17,999	39,753	26,999	66,752	38			93.8%
Plastic Surgery Center of North Carolina	-	411	-	617	617	3			11.0%
Subtotal Forsyth County	24,697	41,567	74,091	62,351	136,442	86	73	13	84.8%
Carolina Birth Center	-	545	-	818	818	1			43.7%
Greensboro Specialty Surgery Center	-	1,888	-	2,832	2,832	3			50.4%
Surgical Center of Greensboro ²	-	13,984	-	20,976	20,976	13			86.2%
High Point Regional Health System	3,621	3,935	10,863	5,903	16,766	10			89.6%
High Point Surgery Center	-	4,888	-	7,332	7,332	6			65.3%
Kindred Hospital - Greensboro	929	46	2,787	69	2,856	1			152.6%
Moses Cone Health System	13,723	20,083	41,169	30,125	71,294	51			74.7%
Triad Neurosurgery (CON approved)	-	-	-	-	-	2			0.0%
Piedmont Surgical Center (includes Podiatry)	-	1,012	-	1,518	1,518	2			40.5%
Premier Surgical Center (CON approved)	-	-	-	-	-	2			0.0%
Surgical Eye Care	-	3,019	-	4,529	4,529	4			60.5%
Subtotal Guilford County	18,273	49,400	54,819	74,100	128,919	95	69	26	72.5%
Total Forsyth and Guilford Facilities	42,970	90,967	128,910	136,451	265,361	181	142	39	78.3%

Sources: License renewal applications and SMFP.

Notes: ¹Surgical hours: inpatient cases were multiplied by 3.0 hours to calculate total inpatient surgical hours.
 Ambulatory cases were multiplied by 1.5 hours to calculate total ambulatory surgical hours.
²Estimated Cases for Surgical Center of Greensboro: The number of orthopedists was divided by the total number of surgical specialists to derive an estimated caseload attributable to orthopedists (31/133 = 23.3%). This percentage was then applied to the total ambulatory cases reported in the 2010 SMFP for the facility (23.3% x 13,984 = 3,258).
³Calculated Need for ORs was calculated by dividing the total surgical hours for the county by 1872 per SMFP guidelines.

There are currently 13 providers of ambulatory surgical services in Forsyth and Guilford Counties. An additional two providers have obtained CONs and are in the process of developing new facilities. When the number of operating rooms are compared with the calculated need for operating rooms (total estimated surgical hours divided by 1872 standard hours per operating room), it appears that there is already excess capacity in both counties; 13 excess operating rooms in Forsyth County and 26 excess operating rooms in Guilford County. On page 59 of the Application, the Applicants state the following:

“Orthopaedic Surgical Center of the Triad includes a very large number of individual surgeons whose annual productivity is constrained by the inefficiency of the existing hospital-based shared operating rooms and ambulatory multi-specialty operating rooms. The proposed project will enable the surgeons to boost their total surgical volumes.”

The implication is that there is a “pent up” demand for services. This statement would be supportable in a region where the ORs are running close to capacity. However, Table 5 clearly indicates otherwise.

Table 6 below summarizes the ambulatory orthopedic cases performed in facilities in Forsyth and Guilford Counties as reported in the 2009 License Renewal Applications for the facilities.

Table 6: Ambulatory Orthopedic Cases Performed in Forsyth and Guilford County Facilities						
Facility	County	Orthopedics				
		Ambulatory Cases	Ambulatory Hours ¹	Equivalent OR ³ s	Percent of total cases	Volume Rank
Forsyth Medical Center	Forsyth	2,971	4,457	2.4	23.4%	2
Medical Park Hospital	Forsyth	1,980	2,970	1.6	18.8%	2
North Carolina Baptist Hospitals	Forsyth	3,507	5,261	2.8	19.5%	1
<i>Subtotal Forsyth County</i>		8,458	12,687	6.8	20.5%	
Greensboro Specialty Surgery Center	Guilford	64	96	0.1	3.4%	3
Surgical Center of Greensboro ²	Guilford	3,258	4,887	2.6	23.3%	1
High Point Regional Health System	Guilford	838	1,257	0.7	21.3%	2
High Point Surgery Center	Guilford	1,246	1,869	1.0	25.5%	1
Moses Cone Health System	Guilford	5,433	8,150	4.4	27.1%	1
Piedmont Surgical Center (includes Podiatry)	Guilford	1,012	1,518	0.8	100.0%	1
Premier Surgical Center (CON approved)	Guilford					
<i>Subtotal Guilford County</i>		11,851	17,777	23.1	25.9%	
<i>Total Forsyth and Guilford Facilities</i>		20,309	30,464	29.8	23.3%	

Sources: License renewal applications and SMFP.

Notes: ¹Surgical hours: Inpatient cases were multiplied by 3.0 hours to calculate total inpatient surgical hours. Ambulatory cases were multiplied by 1.5 hours to calculate total ambulatory surgical hours.

²Estimated Cases for Surgical Center of Greensboro: The number of orthopedists was divided by the total number of surgical specialists to derive an estimated caseload attributable to orthopedists ($31/133 = 23.3\%$). This percentage was then applied to the total ambulatory cases reported in the 2010 SMFP for the facility ($23.3\% \times 13,984 = 3,258$).

³Equivalent ORs was calculated by dividing the total surgical hours for the county by 1872 per SMFP guidelines.

Currently, there are nine facilities where ambulatory orthopedic procedures are performed in Forsyth and Guilford Counties. Two of these facilities, High Point Regional Hospital and High Point Surgery Center, are affiliated with HPRHS. High Point Regional Hospital is wholly owned and operated by HPRHS. Orthopedic cases constitute 21.3 % of the ambulatory cases at High Point Regional Hospital and are the second highest volume specialty for the facility. High Point Regional Hospital is located 9.8 miles from the proposed Colfax site. Further, HPRHS is 50 percent owner of High Point Surgery Center. Orthopedic cases constitute 25.5 percent of the ambulatory cases at the center and are the highest volume specialty at High Point Surgery Center, which is located 9.9 miles from the proposed Colfax site.

In addition, HPRHS has an approved CON to develop Premier Surgical Center which will offer orthopedic services as the second largest volume specialty in its complement of services. Specifically, the projected percentages of orthopedic cases as a proportion of total cases during its first three years of operation are as follows: 2011 – 26%, 2012 – 27 % and 2013 - 27%. The proposed Colfax site is 5.1 miles from Premier Surgery Center. In addition, the secondary site listed in the application is located at Sunshine Way in Guilford County. If this site is ultimately selected, it will be located only 3.2 miles from Premier Surgery Center.

Overall, of the facilities that perform ambulatory orthopedic cases in Forsyth and Guilford Counties, the specialty represents a significant portion of the total cases performed. In Forsyth County, 20.5 % of all ambulatory surgery cases performed in these facilities were orthopedic cases. In Guilford County, an estimated 25.9 % of the cases performed in these facilities were orthopedic cases. Further, when the relative ranking in terms of volume of cases by specialty was reviewed, all nine providers that currently provide orthopedic services reported that orthopedic cases were one of the three highest volume specialties.

HPRHS is clearly dependent on orthopedic ambulatory surgery services in order for its facilities to remain financially viable. Adding two dedicated orthopedic operating rooms in this geographic area would negatively impact HPRHS as well as the other existing providers and constitute an unnecessary duplication of services.

Criterion (4)

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

The Applicants are non-conforming to Criterion (4) because they failed to propose the least costly or most effective approach.

Failure to Propose the Least Costly Approach

The Applicants have proposed potentially the *most* costly approach to the project. They have proposed a ‘green field’ approach to building the facility in an undeveloped area. No medical support services are available in the area and essentially all staff is proposed to be independently hired and trained.

Total capital cost per square foot is discussed under Criterion (12).

Failure to Propose the Most Effective Approach

As discussed previously under section II, the applicants are proposing to build the Single Specialty Ambulatory Surgery Demonstration Project in a rural area. It was the intention of the SMFP to locate the specialized operating rooms in an urban area, where they may serve a concentrated population of patients and be supported by a well-established medical community. Locating the Ambulatory Surgery Center in a Zip Code with a 2009 population of 3,652 does not meet this objective. The total 2009 population in the two-county area was 843,862. The residents of this Zip Code constitute 0.4 percent of the total population base of the designated demonstration project area.

Criterion (5)

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

The Applicants are non-conforming to Criterion (5). As discussed in the comments associated with Criterion (3), the Applicants offered two conflicting surgical case volume projections with no reconciliation of methods. Since the utilization projections are used in Form B of the financial analysis, the entire financial forecast cannot be relied upon.

It is also important to note that the individual physicians who will constitute the ownership group (see Exhibit in application) are a subset of five different group practices in Greensboro. This lack of a unified group should raise concern over the ability to manage the facility in a consistent, efficient manner. The group has no history of practicing together. In essence, each of the physicians will have split responsibility, first to their group practice and second to OSCT.

The Applicants present conflicting information both as to the location and the cost for the proposed Colfax site. First, on page 95 of the application, the address of the site is stated to be: "2918 and 2918 Sandy Ridge Road." On the same page, the purchase price for the land is stated to be "\$1,300,000." Later, on Exhibit 28, the Applicants list the address as: "2918 and 2920 Sandy Ridge Road." Here, the purchase price is documented as being "\$1,500,000." This inconsistency in crucial capital cost information brings the validity of the entire financial projection into question. It is interesting to note that the tax value of the real estate is listed as follows: 2918 Sandy Ridge Road - \$37,800; 2920 Sandy Ridge Road - \$79,300.

Criterion (6)

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

The Applicants are non-conforming to Criterion (6). As discussed in the comments associated with Criterion (3), the Applicants are proposing to build Orthopedic Ambulatory Operating Rooms in an area already saturated with these services. Additional capacity for this specialty will have a negative impact HPRHS as well as on other existing providers.

Criterion (12)

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

The Applicants are non-conforming to Criterion (12). Table 7 below summarizes the proposed total cost per square foot in several recent CON applications. When compared to the proposed cost to implement new ambulatory ORs in recent CON applications, the Applicant's total construction cost per square foot is the highest.

Table 7: Total Capital Cost/SF for Recent CON Applications for Ambulatory Surgery ORs	
J-8471-10: Novant Holly Springs Surgery Center	\$246
J-8468-10: Rex Healthcare of Holly Springs	\$339
G-8492-10: Kernersville Orthopaedic Surgery Center	\$495
G-8479-10: OSCT	\$753
Source: CON Applications.	

**Comments in Opposition from High Point Regional Health System
Regarding Orthopaedic Surgical Center of the Triad Holdings, LLC and
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I. Background

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II. Misinterpretation of Criteria for Single Specialty Ambulatory Surgery Demonstration Project

The 2010 State Medical Facilities Plan (“SMFP”) provides the criteria for the Single-Specialty Ambulatory Surgery Demonstration Project as part of the discussion under operation room need determination as follows (*see* page 81 of the SMFP):

“...In addition, the North Carolina State Health Coordinating Council has determined that there is a need for a Single Specialty Ambulatory Surgery Demonstration Project, consisting of three facilities with two operating rooms each. Therefore, there is a need determination for one facility to be located in each of the following areas: Charlotte Area (Mecklenburg, Cabarrus, Union counties), Triad (Guilford, Forsyth counties), Triangle Area (Wake, Durham, Orange counties). The demonstration project facilities must meet the criteria described in Table 6D...”

The first criterion in Table 6D of the SMFP, is as follows (*see* page 82 of the SMFP):

“Establish a special need determination for three new separately licensed single specialty ambulatory surgical 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)

- Wake, Durham, Orange counties (Triangle)

Further, the basic principle and rationale for the criterion is stated as follows (see page 82 of the SMFP):

“At least one county in each of the groups of counties has a current population greater than or equal to 200,000 and more than 50 total ambulatory/shared operating rooms and at least 1 separately licensed Ambulatory Surgery Center. Locating facilities in high population areas with a large number of operating rooms and existing ambulatory surgery providers prevents the facilities from harming hospitals in rural areas, which need revenue from surgical services to offset losses from other necessary services such as emergency department services.” [Emphasis added]

Opposing Comment

According to the criteria set forth in the SMFP, it is not the intention of the Single-Specialty Ambulatory Surgery Demonstration Project to serve the entire region in each of the groups of counties, but rather to be located “in high population areas with a large number of operating rooms and existing ambulatory surgery providers.” The intent is to avoid impacting existing providers by locating these facilities in densely populated areas. In fact, it would be unreasonable to expect that a small, single-specialty Ambulatory Surgery Center with only two operating rooms would service a multi-county area.

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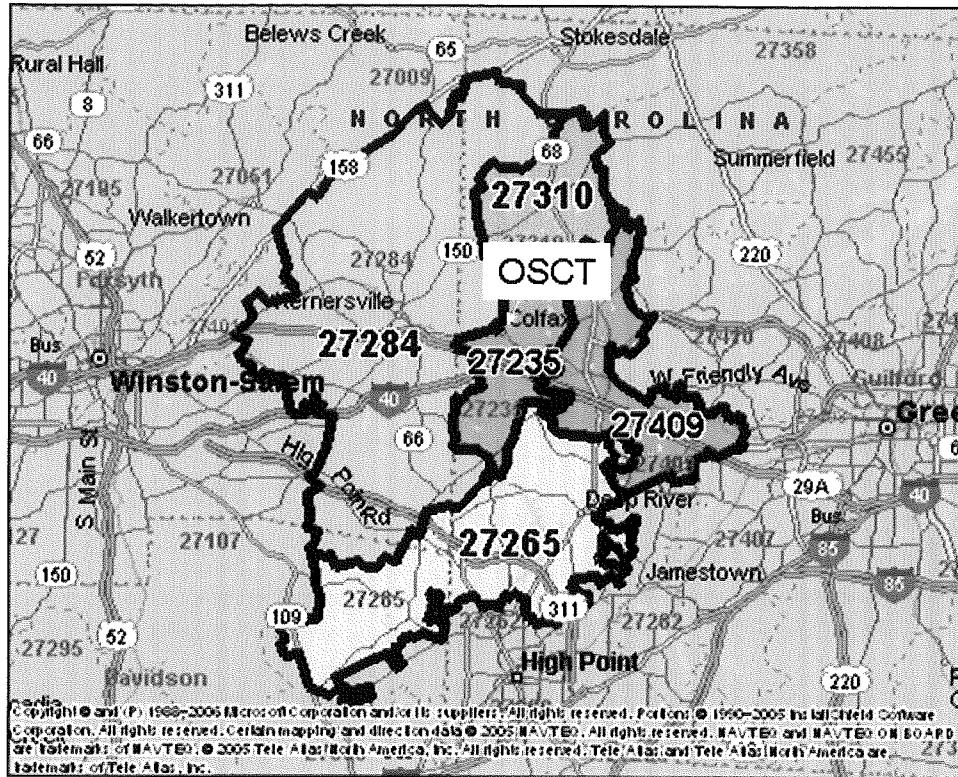


Table 1: 2009 Population for Zip Codes Surrounding Proposed OSCT Ambulatory Surgery Center

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27284	51,707
Total	119,972

Source: Kernersville Orthopaedic Surgery Center, LLC CON Application, Project # G-8492-10, p.210.

It is important to note that the proposed site for the OSCT Single-Specialty Ambulatory Surgery Facility Demonstration Project is in Zip Code 27235, which had an estimated population in 2009 of 3,652! By any standards, this would be considered a rural area.

Even when the populations of all of the surrounding Zip Codes are added to the population base, the total population is still only 119,972. This is far less than the 200,000 population base indicated in the SMFP and clearly not the intended demographics for the project.

Further, the site is not located in a Medical Community. It is undeveloped acreage close to the Farmers Market. It was the intention of the SMFP to locate the specialized operating rooms in an urban area, where they may serve a concentrated population of patients and be supported by a well-established medical community.

Table 2 below contains the estimated 2009 population for the Triad area (Forsyth and Guilford counties) as designated for the Demonstration Project.

**Table 2: Estimated 2009 and Project 2014 Population by Zip Code
for Forsyth and Guilford Counties**

Zip Code	Town	County	Estimated 2009	Projected 2014
27284	Kernersville	Forsyth	51,707	57,196
27106	Winston Salem	Forsyth	47,313	50,366
27107	Winston Salem	Forsyth	43,301	46,313
27105	Winston Salem	Forsyth	41,306	42,581
27127	Winston Salem	Forsyth	32,001	35,178
27103	Winston Salem	Forsyth	29,973	31,912
27104	Winston Salem	Forsyth	28,252	29,639
27012	Clemmons	Forsyth	26,356	29,212
27101	Winston Salem	Forsyth	20,304	21,241
27023	Lewisville	Forsyth	12,298	13,342
27040	Pfafftown	Forsyth	10,821	11,759
27051	Walkertown	Forsyth	7,938	8,495
27045	Rural Hall	Forsyth	7,897	8,333
27050	Tobaccoville	Forsyth	4,607	4,948
27009	Belews Creek	Forsyth	2,534	2,689
27110	Winston Salem	Forsyth	1,200	1,228
Total Forsyth County			367,808	394,432
27410	Greensboro	Guilford	54,424	59,402
27406	Greensboro	Guilford	53,061	55,264
27407	Greensboro	Guilford	48,208	51,385
27265	High Point	Guilford	44,878	51,441
27405	Greensboro	Guilford	44,005	46,756
27260	High Point	Guilford	27,573	28,997
27455	Greensboro	Guilford	26,512	29,374
27262	High Point	Guilford	25,331	26,602
27403	Greensboro	Guilford	19,169	19,524
27401	Greensboro	Guilford	18,904	19,325
27408	Greensboro	Guilford	17,510	17,916
27282	Jamestown	Guilford	15,894	17,374
27409	Greensboro	Guilford	13,943	15,341
27358	Summerfield	Guilford	11,085	11,909
27249	Gibsonville	Guilford	10,397	11,012
27214	Browns Summit	Guilford	8,738	9,420
27301	McLeansville	Guilford	7,161	7,856
27313	Peasant Garden	Guilford	7,096	7,581
27310	Oak Ridge	Guilford	5,792	6,381
27377	Whitsett	Guilford	5,208	5,701
27235	Colfax	Guilford	3,652	4,160
27413	Greensboro	Guilford	3,271	3,440
27283	Julian	Guilford	2,948	3,037
27411	Greensboro	Guilford	1,294	1,351
Total Guilford County			476,054	510,549
Total Forsyth and Guilford Counties			843,862	904,981

Source: Kernersville Orthopaedic Surgery Center, LLC CON Application,
Project # G-8492-10, p. 210.

When the data above is reviewed, it becomes obvious that there were significant alternative geographic locations for the proposed Single-Specialty Ambulatory Surgery Facility Demonstration Project which offer a more densely populated area. In fact, the population residing in the Zip Codes immediately surrounding the Applicant's proposed location in 2009 represented only 14.2 percent (119,972 / 843,862) of the total population residing in the designated Triad Demonstration Project area.

Locating the Single-Specialty Ambulatory Surgery Facility Demonstration Project in a rural area such as this would increase travel times for most patients using the facility as well as travel time for other medical support services.

III. CON Review Criteria

The following comments are based on the CON Review Criteria (N.C. Gen. Stat. §131E-183). While some comments apply to more than one Criterion, they are discussed under the most relevant review Criterion and referenced in others to which they apply.

Criterion (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.

The Applicants are non-conforming to Criterion (1) because, as discussed in Criterion (3) below, the Applicants failed to adequately support a quantitative and qualitative need for the project at the proposed location.

Criterion 3

The application 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, 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 provided.

The proposed project is non-conforming to Criterion (3) because the Applicants failed to appropriately identify the population served. Further, the Applicants provided two conflicting utilization forecasts.

Failure to Appropriately Identify Population Served

As previously discussed in section II above, the Applicants identify the entire Triad area (Forsyth and Guilford counties) as the service area for the Single-Specialty Ambulatory Surgery Facility Demonstration Project. This service area is unrealistic for a two-room

surgery center. Historically, most providers of these services, whether single or multi-specialty, define their primary service area as the Zip Code in which the facility is located and the Zip Codes in the surrounding vicinity.

Two conflicting projections provided

The Applicants offer two conflicting projections for utilization of the proposed facility with no discussion of how the two approaches should be reconciled. The first projection is provided on page 44 of the application and is the result of totaling physician estimated utilization. The second method uses a statewide ambulatory surgery use rate and projected population.

Population Projections and Statewide Ambulatory Surgery Use Rates

On pages 45-48 of the application, the Applicants present a six-step process for calculating projected utilization based on statewide ambulatory surgery use rates and projected population. After adjusting the cases downwards by 15 percent for cases which they believe can be handled in the procedure room, the year three utilization was projected to be 2,612 as shown in Table 3 below:

Table 3: OSCT Projected Year 3 Utilization and OR Need	
Based on Statewide Ambulatory Surgery Use Rate and Projected Population	
Projected Surgical Cases	2,612
Hours per Case	1.5
Total Hours	3,918
ORs Needed (Total Hours / 1872)	2.09

These hours translate into a need for 2.09 operating rooms in the third year of operation.

Individual Physician Utilization

Alternatively, projected utilization by orthopedists in the area is provided on page 44 of the application and is the result of totaling physician estimated utilization from letters of support. In addition, the Applicants estimate that an additional ten orthopedists will be recruited and that they will perform an additional 100 to 175 ambulatory surgical cases per physician per year. The projected utilization using this method is summarized in Table 4 below:

Table 4: OSCT Projected Year 3 Utilization and OR Need	
Based on Physician Estimates and Recruiting Plans	
Physician Projected Surgical Cases	4.022
Add'l Cases from New MDs (10 x100)	1.000
Total Cases	5.022
Adjusted for procedures (85%)	4.269
Hours per Case	1.5
Total Hours	6.403
ORs Needed (Total Hours / 1872)	3.42

Consistent with the Applicant's assumptions in the prior projection, these cases were adjusted downwards by 15 percent for procedures that could be handled in the procedure room. Using this method, the proposed facility is undersized to serve the physicians who intend to practice there since the number of ORs needed is estimated to be 3.42.

It is important to note that the physician estimates were not provided as a general indication of need for the project, but were, instead, *specific commitments* from the physicians of volumes of work that they would perform *at this specific facility*.

Need for Single-Specialty Orthopedic Services Unsupported

Table 5 below summarizes the operating room inventory in Forsyth and Guilford Counties as presented in the 2010 SMFP:

Facility	Cases		Surgical Hours ¹			Operating Rooms			
	Inpatient	Ambulatory	Inpatient	Ambulatory	Total	Adjusted #	Calculated Need ²	Excess/ (Deficit)	Occupancy
Forsyth Medical Center	10,361	12,626	31,083	18,939	50,022	38			70.3%
Medical Park Hospital	1,085	10,531	3,255	15,797	19,052	7			145.4%
North Carolina Baptist Hospitals	13,251	17,999	39,753	26,999	66,752	38			93.8%
Plastic Surgery Center of North Carolina	-	411	-	617	617	3			11.0%
Subtotal Forsyth County	24,697	41,567	74,091	62,351	136,442	86	73	13	84.8%
Carolina Birth Center	-	545	-	818	818	1			43.7%
Greensboro Specialty Surgery Center	-	1,888	-	2,832	2,832	3			50.4%
Surgical Center of Greensboro ³	-	13,984	-	20,976	20,976	13			86.2%
High Point Regional Health System	3,621	3,935	10,863	5,903	16,766	10			89.6%
High Point Surgery Center	-	4,888	-	7,332	7,332	6			65.3%
Kindred Hospital - Greensboro	929	46	2,787	69	2,856	1			152.6%
Moses Cone Health System	13,723	20,083	41,169	30,125	71,294	51			74.7%
Triad Neurosurgery (CON approved)	-	-	-	-	-	2			0.0%
Piedmont Surgical Center (includes Podiatry)	-	1,012	-	1,518	1,518	2			40.5%
Premier Surgical Center (CON approved)	-	-	-	-	-	2			0.0%
Surgical Eye Care	-	3,019	-	4,529	4,529	4			60.5%
Subtotal Guilford County	18,273	49,400	54,819	74,100	128,919	95	69	26	72.5%
Total Forsyth and Guilford Facilities	42,970	90,967	128,910	136,451	265,361	181	142	39	78.3%

Sources: License renewal applications and SMFP.

Notes: ¹Surgical hours: Inpatient cases were multiplied by 3.0 hours to calculate total inpatient surgical hours.
²Ambulatory cases were multiplied by 1.5 hours to calculate total ambulatory surgical hours.
³Estimated Cases for Surgical Center of Greensboro: The number of orthopedists was divided by the total number of surgical specialists to derive an estimated caseload attributable to orthopedists (31/133 = 23.3%). This percentage was then applied to the total ambulatory cases reported in the 2010 SMFP for the facility (23.3% x 13,984 = 3,258).
⁴Calculated Need for ORs was calculated by dividing the total surgical hours for the county by 1872 per SMFP guidelines.

There are currently 13 providers of ambulatory surgical services in Forsyth and Guilford Counties. An additional two providers have obtained CONs and are in the process of developing new facilities. When the number of operating rooms are compared with the calculated need for operating rooms (total estimated surgical hours divided by 1872 standard hours per operating room), it appears that there is already excess capacity in both counties; 13 excess operating rooms in Forsyth County and 26 excess operating rooms in Guilford County. On page 59 of the Application, the Applicants state the following:

“Orthopaedic Surgical Center of the Triad includes a very large number of individual surgeons whose annual productivity is constrained by the inefficiency of the existing hospital-based shared operating rooms and ambulatory multi-specialty operating rooms. The proposed project will enable the surgeons to boost their total surgical volumes.”

The implication is that there is a “pent up” demand for services. This statement would be supportable in a region where the ORs are running close to capacity. However, Table 5 clearly indicates otherwise.

Table 6 below summarizes the ambulatory orthopedic cases performed in facilities in Forsyth and Guilford Counties as reported in the 2009 License Renewal Applications for the facilities.

Table 6: Ambulatory Orthopedic Cases Performed in Forsyth and Guilford County Facilities						
Facility	County	Orthopedics				
		Ambulatory Cases	Ambulatory Hours ¹	Equivalent OR ³ s	Percent of total cases	Volume Rank
Forsyth Medical Center	Forsyth	2,971	4,457	2.4	23.4%	2
Medical Park Hospital	Forsyth	1,980	2,970	1.6	18.8%	2
North Carolina Baptist Hospitals	Forsyth	3,507	5,261	2.8	19.5%	1
<i>Subtotal Forsyth County</i>		8,458	12,687	6.8	20.5%	
Greensboro Specialty Surgery Center	Guilford	64	96	0.1	3.4%	3
Surgical Center of Greensboro ²	Guilford	3,258	4,887	2.6	23.3%	1
High Point Regional Health System	Guilford	838	1,257	0.7	21.3%	2
High Point Surgery Center	Guilford	1,246	1,869	1.0	25.5%	1
Moses Cone Health System	Guilford	5,433	8,150	4.4	27.1%	1
Piedmont Surgical Center (includes Podiatry)	Guilford	1,012	1,518	0.8	100.0%	1
Premier Surgical Center (CON approved)	Guilford					
<i>Subtotal Guilford County</i>		11,851	17,777	23.1	25.9%	
<i>Total Forsyth and Guilford Facilities</i>		20,309	30,464	29.8	23.3%	

Sources: License renewal applications and SMFP.
Notes: ¹Surgical hours: Inpatient cases were multiplied by 3.0 hours to calculate total inpatient surgical hours.
²Ambulatory cases were multiplied by 1.5 hours to calculate total ambulatory surgical hours.
³Estimated Cases for Surgical Center of Greensboro: The number of orthopedists was divided by the total number of surgical specialists to derive an estimated caseload attributable to orthopedists (31/133 = 23.3%). This percentage was then applied to the total ambulatory cases reported in the 2010 SMFP for the facility (23.3% x 13,984 = 3,258).
³Equivalent ORs was calculated by dividing the total surgical hours for the county by 1872 per SMFP guidelines.

Currently, there are nine facilities where ambulatory orthopedic procedures are performed in Forsyth and Guilford Counties. Two of these facilities, High Point Regional Hospital and High Point Surgery Center, are affiliated with HPRHS. High Point Regional Hospital is wholly owned and operated by HPRHS. Orthopedic cases constitute 21.3 % of the ambulatory cases at High Point Regional Hospital and are the second highest volume specialty for the facility. High Point Regional Hospital is located 9.8 miles from the proposed Colfax site. Further, HPRHS is 50 percent owner of High Point Surgery Center. Orthopedic cases constitute 25.5 percent of the ambulatory cases at the center and are the highest volume specialty at High Point Surgery Center, which is located 9.9 miles from the proposed Colfax site.

In addition, HPRHS has an approved CON to develop Premier Surgical Center which will offer orthopedic services as the second largest volume specialty in its complement of services. Specifically, the projected percentages of orthopedic cases as a proportion of total cases during its first three years of operation are as follows: 2011 – 26%, 2012 – 27 % and 2013 - 27%. The proposed Colfax site is 5.1 miles from Premier Surgery Center. In addition, the secondary site listed in the application is located at Sunshine Way in Guilford County. If this site is ultimately selected, it will be located only 3.2 miles from Premier Surgery Center.

Overall, of the facilities that perform ambulatory orthopedic cases in Forsyth and Guilford Counties, the specialty represents a significant portion of the total cases performed. In Forsyth County, 20.5 % of all ambulatory surgery cases performed in these facilities were orthopedic cases. In Guilford County, an estimated 25.9 % of the cases performed in these facilities were orthopedic cases. Further, when the relative ranking in terms of volume of cases by specialty was reviewed, all nine providers that currently provide orthopedic services reported that orthopedic cases were one of the three highest volume specialties.

HPRHS is clearly dependent on orthopedic ambulatory surgery services in order for its facilities to remain financially viable. Adding two dedicated orthopedic operating rooms in this geographic area would negatively impact HPRHS as well as the other existing providers and constitute an unnecessary duplication of services.

Criterion (4)

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

The Applicants are non-conforming to Criterion (4) because they failed to propose the least costly or most effective approach.

Failure to Propose the Least Costly Approach

The Applicants have proposed potentially the *most* costly approach to the project. They have proposed a ‘green field’ approach to building the facility in an undeveloped area. No medical support services are available in the area and essentially all staff is proposed to be independently hired and trained.

Total capital cost per square foot is discussed under Criterion (12).

Failure to Propose the Most Effective Approach

As discussed previously under section II, the applicants are proposing to build the Single Specialty Ambulatory Surgery Demonstration Project in a rural area. It was the intention of the SMFP to locate the specialized operating rooms in an urban area, where they may serve a concentrated population of patients and be supported by a well-established medical community. Locating the Ambulatory Surgery Center in a Zip Code with a 2009 population of 3,652 does not meet this objective. The total 2009 population in the two-county area was 843,862. The residents of this Zip Code constitute 0.4 percent of the total population base of the designated demonstration project area.

Criterion (5)

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

The Applicants are non-conforming to Criterion (5). As discussed in the comments associated with Criterion (3), the Applicants offered two conflicting surgical case volume projections with no reconciliation of methods. Since the utilization projections are used in Form B of the financial analysis, the entire financial forecast cannot be relied upon.

It is also important to note that the individual physicians who will constitute the ownership group (see Exhibit in application) are a subset of five different group practices in Greensboro. This lack of a unified group should raise concern over the ability to manage the facility in a consistent, efficient manner. The group has no history of practicing together. In essence, each of the physicians will have split responsibility, first to their group practice and second to OSCT.

The Applicants present conflicting information both as to the location and the cost for the proposed Colfax site. First, on page 95 of the application, the address of the site is stated to be: "2918 and 2918 Sandy Ridge Road." On the same page, the purchase price for the land is stated to be "\$1,300,000." Later, on Exhibit 28, the Applicants list the address as: "2918 and 2920 Sandy Ridge Road." Here, the purchase price is documented as being "\$1,500,000." This inconsistency in crucial capital cost information brings the validity of the entire financial projection into question. It is interesting to note that the tax value of the real estate is listed as follows: 2918 Sandy Ridge Road - \$37,800; 2920 Sandy Ridge Road - \$79,300.

Criterion (6)

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

The Applicants are non-conforming to Criterion (6). As discussed in the comments associated with Criterion (3), the Applicants are proposing to build Orthopedic Ambulatory Operating Rooms in an area already saturated with these services. Additional capacity for this specialty will have a negative impact HPRHS as well as on other existing providers.

Criterion (12)

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

The Applicants are non-conforming to Criterion (12). Table 7 below summarizes the proposed total cost per square foot in several recent CON applications. When compared to the proposed cost to implement new ambulatory ORs in recent CON applications, the Applicant’s total construction cost per square foot is the highest.

Table 7: Total Capital Cost/SF for Recent CON Applications for Ambulatory Surgery ORs	
J-8471-10: Novant Holly Springs Surgery Center	\$246
J-8468-10: Rex Healthcare of Holly Springs	\$339
G-8492-10: Kernersville Orthopaedic Surgery Center	\$495
G-8479-10: OSCT	\$753
Source: CON Applications.	