High Point Regional Health System

601 North Elm Street P.O. Box HP-5 High Point, NC 27261 (336) 878-6000 www.highpointregional.com





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 D. Jordan Strategic Planning

/mdi

Attachments

Comments in Opposition from High Point Regional Health System Regarding Kernersville Orthopaedic Surgery Center, LLC Application for Two New Demonstration Project Single Specialty Ambulatory Surgery Facility ORs in Forsyth County Submitted March 15, 2010 Project I.D. # G-8492-10

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 Specialists of the Carolinas ("Applicants") for two new demonstration project single specialty ambulatory surgery facility ORs in Forsyth County (Project I.D. # G-8479-10).

I. Background

Orthopaedic Specialists of the Carolinas is proposing to develop Kernersville Orthopaedic Surgery Center (KOSC) a new single-specialty orthopedic ambulatory surgery center with two operating rooms and one non-surgical procedure room to be located in Kernersville, NC. This project was filed pursuant to the need determination in the 2010 State Medical Facilities Plan (SMFP), Chapter 6, Table 6C for a 2 OR Single Specialty Ambulatory Surgery Demonstration.

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):

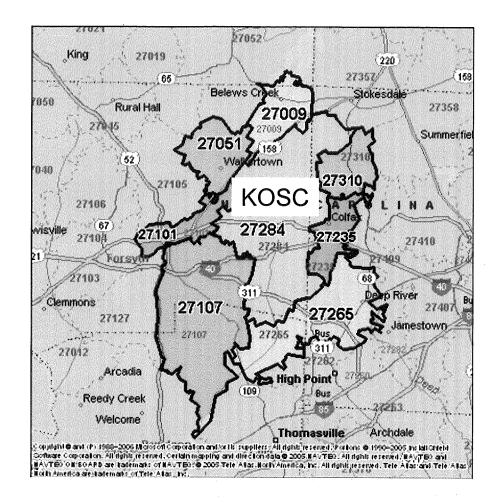
"At least one county in each of the groups of counties has a current population greater than or equal to 200,000 and more than 50 total ambulatory/shared operating rooms and at least 1 separately licensed Ambulatory Surgery Center. Locating facilities in high population areas with a large number of operating 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 KOSC 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 KOSC and Surrounding Zip Codes



	Population for unding Proposed y Surgery Center
Zip Code	2009 Population
27235	3,652
27009	2,534
27310	5,792
27265	44,878
27284	51,707
27051	7,897
27101	20,304
27107	43,301
Total	180,065
Source: Kernersville Or	thopaedic
Surgery Center, LLC Co	ON Application,
Project # G-8492-10, p.	210.

It is important to note that the proposed site for the KOSC Single-Specialty Ambulatory Surgery Facility Demonstration Project is in Zip Code 27284. While this Zip Code and the surrounding areas has a moderate population base, the total estimated population in 2009 in the vicinity of the proposed facility was 180,065. This is less than the 200,000 population base indicated in the SMFP and clearly not the intended demographics for this project.

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

p Code		r Forsyth and Guilfe County	Estimated 2009	Projected 2014
27284	Kernersville	Forsyth	51,707	57,19
27106	Winston Salem	Forsyth	47,313	50,36
27107	Winston Salem	Forsyth	43,301	46,31
	Winston Salem	Forsyth	41,306	42,58
	Winston Salem	Forsyth	32,001	35,17
	Winston Salem	Forsyth	29,973	31,91
	Winston Salem	Forsyth	28,252	29,63
	Clemmons	Forsyth	26,356	29,21
	Winston Salem	Forsyth	20,304	21,24
	Lewisville	Forsyth	12,298	13,34
****	Pfafftown	Forsyth	10,821	11,75
	Walkertown	Forsyth	7,938	8,49
	Rural Hall	Forsyth	7,897	8,33
	Tobaccoville	Forsyth	4,607	4,94
	Belews Creek	Forsyth	2,534	2,68
	Winston Salem	Forsyth	1,200	1,22
		otal Forsyth County		394,43
				00-1,-10
27410	Greensboro	Guilford	54,424	59,40
27406	Greensboro	Guilford	53,061	55,26
27407	Greensboro	Guilford	48,208	51,38
27265	High Point	Guilford	44,878	51,44
27405	Greensboro	Guilford	44,005	46,75
27260	High Point	Guilford	27,573	28,99
	Greensboro	Guilford	26,512	29,37
27262	High Point	Guilford	25,331	26,60
	Greensboro	Guilford	19,169	19,52
27401	Greensboro	Guilford	18,904	19,32
	Greensboro	Guilford	17,510	17,91
	Jamestown	Guilford	15,894	17,37
	Greensboro	Guilford	13,943	15,34
	Summerfield	Guilford	11,085	11,90
	Gibsonville	Guilford	10,397	11,01
	Browns Summit	Guilford	8,738	9,42
	McLeansville	Guilford	7,161	7,85
	Peasant Garden	Guilford	7,096	7,58
	Oak Ridge	Guilford	5,792	6,38
	Whitsett	Guilford	5,208	5,70
	Colfax	Guilford	3,652	4,16
27413	Greensboro	Guilford	3,271	3,44
27283		Guilford	2,948	3,03
	Greensboro	Guilford	1,294	1,35
	Market Committee of the	tal Guilford County	476,054	510,54
			,	3.0,04
	DD 4 X DD 4 X	Guilford Counties	843,862	904,98

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 21.4 percent (180,065 / 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 less central 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 Applicant is non-conforming to Criterion (1) because, as discussed in Criterion (3) below, the Applicant 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 Applicant failed to appropriately identify the population served. Further, the Applicant failed to adequately demonstrate the need that this population has for these services.

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 multispecialty, define their primary service area as the Zip Code in which the facility is located and the Zip Codes in the surrounding vicinity.

Shift of Patients from Guilford County is Unsupported

The Applicants project that approximately 40 percent of Orthopaedic Specialists of the Carolinas outpatient surgical volume performed in all facilities in Forsyth and Guilford counties will shift to the proposed facility (see page 66 of CON Application). They further project that they will capture 542 new cases by Year 3 of operations (see page 204 of CON Application). A summary of current and projected utilization for the proposed facility is provided in Table 3 below.

County	Current OSC Volume	Percent of Total	Projected KOSC Volume Year 3	Percent of Total	Percent Shift of Existing Volume to KOSC
Forsyth	2,790	60.1%	1,093	46.4%	39%
Guilford	98	2.1%	581	24.6%	593%
Stokes	442	9.5%	173	7.3%	39%
Davie	329	7.1%	129	5.5%	39%
Yadkin	282	6.1%	111	4.7%	39%
Davidson	277	6.0%	109	4.6%	39%
Surry	165	3.6%	65	2.8%	39%
All Other	258	5.6%	97	4.1%	38%
Total	4,641	100.0%	2,358	100.0%	

Source: Remersville Orthopaedic
Surgery Center, LLC CON Application,
Project # G-8492-10, p.204.

When the detail by county is reviewed, the shift to Guilford County is unreasonable. The only explanation offered by the applicants is on page 84, as follows:

"...KOSC used OSC's current patient origin included in Exhibit 2, Table 6, by county to determine future patient origin. In addition, the projected new procedures were assumed to be from residents of Guilford County based on KOSC's belief that once the facility is developed and operational, additional orthopedic surgeons from Guilford County may seek to join the KOSC medical staff to take advantage of the unique single specialty design of the facility and the dedicated orthopedic staff..."

This new case volume in from Forsyth County would require a 100% shift of existing OSC patients plus an additional 483 patients. This new case volume will all apparently be

accomplished by merely opening the doors to the facility. Such a projection is not reasonable.

Need for Single-Specialty Orthopedic Services Unsupported

Table 4 below summarizes the current operating room inventory in Forsyth and Guilford Counties as presented in the 2010 SMFP:

Table 4: Curren	t Operating	g Room In	ventory in	Forsyth a	nd Guilfor	d Counti	es			
		ses		Surgical Hours¹			Operating Rooms			
Facility	Inpatient	Ambulatory	Inpatient	Ambulatory	Total	Adjusted #	Calculated Need ³	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 - Greeensboro	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: 'Surgical 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).

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.

Table 5 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.

		Orthopedics							
Facility	County	Ambulatory Cases	Ambulatory Hours¹	Equivalent OR³s	23.4% 18.8% 19.5% 20.5% 3.4% 23.3% 21.3% 25.5% 27.1% 100.0%	Volume Rank			
Forsyth Medical Center	Forsyth	2,971	4,457	2.4	23.4%				
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%	,			
Subtotal Forsyth County		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%	-			
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%	-			
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								
Subtotal Guilford County		11,851	17,777	23.1	25.9%				
Total Forsyth and Guilford Facilities		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.

Currently, there are nine facilities where ambulatory orthopedic procedures are performed in Forsyth and Guilford Counties. In addition, Premier Surgical Center has an approved CON and will offer orthopedic services as part of its complement of services. 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.

These existing providers are clearly dependent on orthopedic services to remain financially viable. Adding two dedicated orthopedic operating rooms in this geographic area would negatively impact the existing providers and constitute an unnecessary duplication of services.

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. Further, HPRHS is 50 percent owner of High Point

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).

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

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.

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%.

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 Applicant is non-conforming to Criterion (4) because they failed to propose the most effective approach.

Failure to Propose the Most Effective Approach

As discussed previously under section II, the Applicant is proposing to build the Single Specialty Ambulatory Surgery Demonstration Project in a less central area of Forsyth County. It was the intention of the criteria for the Demonstration Project set forth in 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 Kernersville does not meet this objective.

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 Applicant is non-conforming to Criterion (5). As discussed in the comments associated with Criterion (3), the Applicant did not appropriately define the Project's target population or adequately support its patient origin data when developing forecasted utilization. Since the utilization projections are used in Form B of the financial analysis, the entire financial forecast cannot be relied upon.

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 Operation 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.

Comments in Opposition from High Point Regional Health System Regarding Kernersville Orthopaedic Surgery Center, LLC Application for Two New Demonstration Project Single Specialty Ambulatory Surgery Facility ORs in Forsyth County Submitted March 15, 2010 Project I.D. # G-8492-10

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 Specialists of the Carolinas ("Applicants") for two new demonstration project single specialty ambulatory surgery facility ORs in Forsyth County (Project I.D. # G-8479-10).

I. Background

Orthopaedic Specialists of the Carolinas is proposing to develop Kernersville Orthopaedic Surgery Center (KOSC) a new single-specialty orthopedic ambulatory surgery center with two operating rooms and one non-surgical procedure room to be located in Kernersville, NC. This project was filed pursuant to the need determination in the 2010 State Medical Facilities Plan (SMFP), Chapter 6, Table 6C for a 2 OR Single Specialty Ambulatory Surgery Demonstration.

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 KOSC 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 KOSC and Surrounding Zip Codes

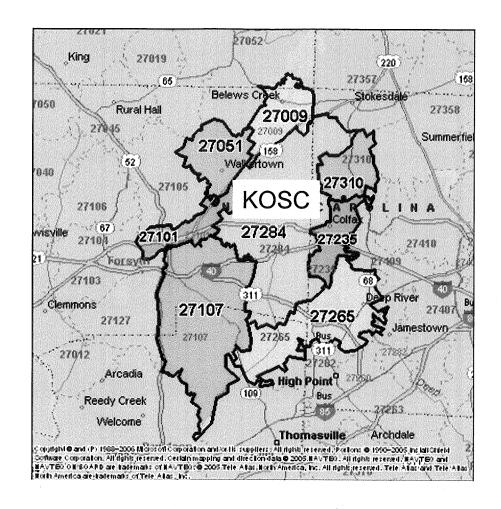


Table 1: 2009 Population for Zip Codes Surrounding Proposed KOSC Ambulatory Surgery Center							
Zip Code	2009 Population						
27235	3,652						
27009	2,534						
27310	5,792						
27265	44,878						
27284	51,707						
27051	7,897						
27101	20,304						
27107	43,301						
Total	180,065						
Source: Kernersville Or	Source: Kernersville Orthopaedic						
Surgery Center, LLC Co	ON Application,						
Project # G-8492-10, p.	210.						

It is important to note that the proposed site for the KOSC Single-Specialty Ambulatory Surgery Facility Demonstration Project is in Zip Code 27284. While this Zip Code and the surrounding areas has a moderate population base, the total estimated population in 2009 in the vicinity of the proposed facility was 180,065. This is less than the 200,000 population base indicated in the SMFP and clearly not the intended demographics for this project.

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

Code	Town	County	Estimated 2009	Projected 2014
	Kernersville	Forsyth	51,707	57,196
27106	Winston Salem	Forsyth	47,313	50,36
27107	Winston Salem	Forsyth	43,301	46,31
	Winston Salem	Forsyth	41,306	42,58
	Winston Salem	Forsyth	32,001	35,17
****	Winston Salem	Forsyth	29,973	31,91
	Winston Salem	Forsyth	28,252	29,63
	Clemmons	Forsyth	26,356	29,21
	Winston Salem	Forsyth	20,304	21,24
	Lewisville	Forsyth	12,298	13,34
	Pfafftown	Forsyth	10,821	11,75
	Walkertown	Forsyth	7,938	8,49
	Rural Hall	Forsyth	7,897	8,33
	Tobaccoville	Forsyth	4,607	4,94
	Belews Creek	Forsyth	2,534	2,68
	Winston Salem	Forsyth	1,200	1,22
		otal Forsyth County	367,808	394,43
				504,40
27410	Greensboro	Guilford	54,424	59,40
-	Greensboro	Guilford	53,061	55,26
	Greensboro	Guilford	48,208	51,38
	High Point	Guilford	44,878	51,44
	Greensboro	Guilford	44,005	46,75
	High Point	Guilford	27,573	28,99
	Greensboro	Guilford	26,512	29,37
	High Point	Guilford	25,331	26,60
	Greensboro	Guilford	19,169	19,52
	Greensboro	Guilford	18,904	19,32
	Greensboro	Guilford	17,510	17,91
	Jamestown	Guilford	15,894	17,37
	Greensboro	Guilford	13,943	15,34
	Summerfield	Guilford	11,085	11,90
	Gibsonville	Guilford	10,397	11,01
	Browns Summit	Guilford	8,738	9,42
	McLeansville	Guilford	7,161	7,850
	Peasant Garden	Guilford	7,096	7,58
	Oak Ridge	Guilford	5,792	6,38
	Whitsett	Guilford	5,208	5,70
	Colfax	Guilford	3,652	4,16
WORK	Greensboro	Guilford	3,271	3,44
27283	WWW.	Guilford	2,948	3,03
27411	Greensboro	Guilford	1,294	1,35
		tal Guilford County	476,054	510,54
		In Julio Goully	770,007	310,34

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 21.4 percent (180,065 / 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 less central 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 Applicant is non-conforming to Criterion (1) because, as discussed in Criterion (3) below, the Applicant 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 Applicant failed to appropriately identify the population served. Further, the Applicant failed to adequately demonstrate the need that this population has for these services.

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 multispecialty, define their primary service area as the Zip Code in which the facility is located and the Zip Codes in the surrounding vicinity.

Shift of Patients from Guilford County is Unsupported

The Applicants project that approximately 40 percent of Orthopaedic Specialists of the Carolinas outpatient surgical volume performed in all facilities in Forsyth and Guilford counties will shift to the proposed facility (see page 66 of CON Application). They further project that they will capture 542 new cases by Year 3 of operations (see page 204 of CON Application). A summary of current and projected utilization for the proposed facility is provided in Table 3 below.

of C	Table 3: OSC OSC Volume to Current OSC Volume	KOSC Amb			r Percent Shift of Existing Volume to KOSC
Forsyth	2,790	60.1%	1,093	46.4%	39%
Guilford	98	2.1%	581	24.6%	593%
Stokes	442	9.5%	173	7.3%	39%
Davie	329	7.1%	129	5.5%	39%
Yadkin	282	6.1%	111	4.7%	39%
Davidson	277	6.0%	109	4.6%	39%
Surry	165	3.6%	65	2.8%	39%
All Other	258	5.6%	97	4.1%	38%
Total	4,641	100.0%	2,358	100.0%	

Source: Kernersville Orthopaedic

Surgery Center, LLC CON Application,

Project # G-8492-10, p.204.

When the detail by county is reviewed, the shift to Guilford County is unreasonable. The only explanation offered by the applicants is on page 84, as follows:

"...KOSC used OSC's current patient origin included in Exhibit 2, Table 6, by county to determine future patient origin. In addition, the projected new procedures were assumed to be from residents of Guilford County based on KOSC's belief that once the facility is developed and operational, additional orthopedic surgeons from Guilford County may seek to join the KOSC medical staff to take advantage of the unique single specialty design of the facility and the dedicated orthopedic staff..."

This new case volume in from Forsyth County would require a 100% shift of existing OSC patients plus an additional 483 patients. This new case volume will all apparently be

accomplished by merely opening the doors to the facility. Such a projection is not reasonable.

Need for Single-Specialty Orthopedic Services Unsupported

Table 4 below summarizes the current operating room inventory in Forsyth and Guilford Counties as presented in the 2010 SMFP:

Table 4: Curren						a counti			
	Ca	ses	ુ કા	Surgical Hours¹			Operating Rooms		
Facility	Inpatient	Ambulatory	Inpatient	Ambulatory	Total	Adjusted #	Calculated Need ³	Excess/ (Deficit)	Occupanc
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 - Greeensboro	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)	-	- 1	-	-	-	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% \times 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.

Table 5 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.

		Orthopedics							
Facility	County	Ambulatory Cases	Ambulatory Hours¹	Equivalent OR³s	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			
Subtotal Forsyth County		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%	-			
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								
Subtotal Guilford County		11,851	17,777	23.1	25.9%				
Total Forsyth and Guilford Facilities		20,309	30,464	29.8	23.3%				

Sources: License renewal applications and SMFP.

Notes: 'Surgical 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).

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. In addition, Premier Surgical Center has an approved CON and will offer orthopedic services as part of its complement of services. 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.

These existing providers are clearly dependent on orthopedic services to remain financially viable. Adding two dedicated orthopedic operating rooms in this geographic area would negatively impact the existing providers and constitute an unnecessary duplication of services.

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. 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.

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%.

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 Applicant is non-conforming to Criterion (4) because they failed to propose the most effective approach.

Failure to Propose the Most Effective Approach

As discussed previously under section II, the Applicant is proposing to build the Single Specialty Ambulatory Surgery Demonstration Project in a less central area of Forsyth County. It was the intention of the criteria for the Demonstration Project set forth in 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 Kernersville does not meet this objective.

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 Applicant is non-conforming to Criterion (5). As discussed in the comments associated with Criterion (3), the Applicant did not appropriately define the Project's target population or adequately support its patient origin data when developing forecasted utilization. Since the utilization projections are used in Form B of the financial analysis, the entire financial forecast cannot be relied upon.

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 Operation 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.