



**Strategic
Healthcare
Consultants**

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CON Section
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April 29, 2010

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

RE: Comments Regarding Certificate of Need Applications: #G-8477-10 Piedmont
Outpatient Surgery Center and Stratford Executive Associates LLC;
#G-8492-10 Kernersville Orthopaedic Surgery Center Holdings and Orthopaedic
Specialists of the Carolinas / (Forsyth – Guilford Service Area)

Dear Mr. Smith:

Please review the enclosed public comments regarding the Certificate of Need
applications submitted for the demonstration project single specialty ambulatory surgical
facility in the Forsyth / Guilford service area. These comments are submitted in
accordance with NCGS 131E-185(a1) (1).

Thank you for your consideration.

Sincerely,

David J. French
Consultant to Orthopaedic Surgical Center of the Triad

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In CON Project Application # G-8477-10, Piedmont Outpatient Surgery Center ("POSC") proposes to develop a new single specialty freestanding ambulatory surgery center with two operating rooms. Nine physicians of Piedmont Ear Nose and Throat Associates are listed as the medical staff for the facility.

The POSC proposal fails to conform to CON review criteria as follows:

- 1) Nonconforming to specific demonstration project criteria
- 2) Unreasonable patient origins and overstated surgery volumes
- 3) Inaccurate financial projections
- 4) Lack of adequate staff to perform necessary services

These issues are explained as they relate to the specific CON criteria as follows:

CON Review Criteria:

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

The need determination for two operating rooms in the Triad Area (Guilford / Forsyth Counties) is pursuant to the Single Specialty Ambulatory Surgery Facility Demonstration Project. The 2010 State Medical Facilities Plan includes written criteria. The SMFP plan states "The demonstration project must meet the criteria described in Table 6D." The POSC application fails to conform to Criterion 1 because:

POSC projects that more than 50% of its patients will originate from rural counties that are outside of the boundaries of Guilford and Forsyth Counties.

POSC fails to project adequate levels of care to the indigent population based on the calculations of the percentage of self pay and Medicaid as described in the SMFP demonstration project criteria.

- (3) *The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.*

The POSC application fails to conform to CON Review Criterion 3 because the volume projections are overstated and based on unreasonable assumptions.

- 1) The POSC application fails to adequately explain how nine PENTA surgeons can perform the same level of office visits and surgery as the current ten PENTA surgeons. As seen on page 8, one of the ten current PENTA physicians will retire before the proposed project begins. Lacking a physician recruitment plan, PENTA physicians will have 10% less physician availability to provide their current level of office visits at multiple locations, as well as maintain inpatient surgery and on-call coverage at hospitals. Therefore it is unreasonable for the application to

predict future growth in ambulatory surgery with less physician manpower than is currently available. The POSC application fails to deduct 10 percent of future surgery volumes and fails to document a plan and timeline to recruit any new physicians.

- 2) Tonsillectomy and adenoidectomy procedures involve potential complications including bleeding and pain management, that could require emergency treatment, including a prompt return to surgery. Therefore, pediatric patients from distant counties are much less likely to utilize a freestanding ASC that lacks observation beds because referring physicians will choose to utilize existing hospital-based ambulatory surgery centers.
- 3) The 2010 State Medical Facilities Plan shows no unmet need for operating rooms in counties adjacent to Forsyth and Guilford. The applicant erroneously includes patients from distant counties to inflate its projected patient numbers. POSC defines a primary service area for the project that includes more than 50 percent of its patients from outside of Forsyth and Guilford Counties; this service area is inconsistent with the service area that is specifically defined by the demonstration project need determination. Patients from the outlying counties have more convenient geographical access to hospitals that offer ambulatory and inpatient surgery. Hospitals can provide 23-hour observation for post-surgical pediatric patients whereas the proposed POSC lacks this capability.
- 4) The proposed new surgery center location in Kernersville is distant from Davidson, Davie, Rockingham, Rowan, Surry, Watauga, Wilkes and Yadkin Counties. The applicant wrongly assumes that historical surgical patient origin data for its multiple PENTA office locations (Winston-Salem, Mount Airy and Kernersville) could be used to predict the patient origin for the proposed project in Kernersville.

The service area definition and patient origin projections for the project are incorrect to include hundreds of patients from outside of Guilford and Forsyth Counties. The application includes unsupported patient origin percentages of Davidson (9.94%), Davie (5.48%), Stokes (7.98%), Surry (14.6%), Wilkes (3.94%) and Yadkin (4.25%) and 3.05% from "Other" (that is not defined).

- 5) The need methodology wrongly uses total population growth for seven counties to predict future growth in surgery volumes for the proposed project. This is incorrect because the pediatric population served by POSC is not expected to grow in proportion to the total population. For example, the 2010 Stokes County population 0-17 years of age of 9,959 is projected to decrease to 9,434 (-5.3%) by 2015.
- 6) The application fails to demonstrate that the 87.4% adjustment factor on page 61 is accurate because the historical data reflects the volume and practice pattern of ten surgeons, whereas the proposed project involves only 9 surgeons. The percent distribution of surgical cases differs for the individual physicians.
- 7) The application fails to justify the alarmingly high ratio of 1.414 procedures per case. This ratio assumption is based on historical inpatient and outpatient cases

without any adjustment for high-complexity cases that must be performed at a hospital and therefore is unreasonable.

- 8) POSC's discussion of historical growth at the Regional ENT Ambulatory Surgical Centers in Georgia and South Carolina has no applicability to the proposed project because these facilities serve dissimilar populations and have different numbers of surgeons. Also, these facilities in other states are not demonstration projects subject to the CON law and the criteria in the North Carolina 2010 State Medical Facilities Plan.
- 9) The patient origin percentages and numbers on pages 66 and 67 are mathematically incorrect for Forsyth County and Surry County patient origins. If Forsyth County patients represent 42.39% of the Total, then Year 1 should be 1,174 and not 1,187 as shown in the table on page 66 of the CON and Year 2 should be 1,189 and not 1,206 as seen in the table on page 67. If the Surry County patient origin percent is 14.6% then the numbers of patients should be 404 and 409 in Years 1 and 2 and not 396 and 398 respectively.

The application is based on unsubstantiated assumptions and inadequate support from physicians:

- No adjustment is made for the pending retirement and 10 percent reduction in the current number of PENTA physicians and the diminished surgical volumes.
- No adjustment is made for the facility location that will deter patients from outlying counties (Watauga, Wilkes, Davie, Surry, Yadkin and others) to travel to POSC.

The application contains inadequate documentation of physician support to justify the projections of patients from outlying counties.

- No letters of support are provided from Surry County community physicians where 14.6% of patients are predicted by POSC.
- No letters of support are provided from Stokes County community physicians where 7.98% of patients are predicted by POSC.
- No letters of support are provided from Yadkin County community physicians where 4.25% of patients are predicted by POSC.

The application includes 81 patients (3.05%) from "Other" which is an inadequate description of patient origin for these 81 patients.

Clearly the projected numbers of POSC patients from outside of Forsyth and Guilford Counties should be excluded from the applicants' projections. The following table provides the calculation of the projected number of cases for the project that originate from within Forsyth and Guilford Counties. This table uses the applicant's numerical projections for Forsyth and Guilford based on page 61, Table 19 multiplied times the POSC adjustment factor 87.40% shown in Step 5:

	YR 1	YR 2	YR 3
Forsyth County Cases	1,187	1,206	1,224
Guilford County Cases	167	170	173
Combined Forsyth and Guilford Cases	1,354	1,376	1,398

The following table shows that the POSC projected number of cases from Forsyth and Guilford Counties is inadequate to support two operating rooms:

	YR 1	YR 2	YR 3
Combined Forsyth and Guilford Cases	1,354	1,376	1,398
Multiply x 1.5 hrs per case	2,031	2,064	2,096
Divide by 1872 equals number of ORs needed	1.08	1.10	1.12

Based on operating room performance standard 10A NCAC 14C.2103 (b), the application fails to demonstrate a need for two surgical operating rooms.

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

The POSC application fails to conform to CON Review Criterion 4 because the utilization projections are unreliable and the financial projections are inaccurate. The comments regarding Criterion 3 explain why the POSC utilization projections are unreliable in terms of diminished physician manpower, unreasonable patient origin, overstated population growth, inadequate community support, incorrect math and nonconformance with the Operating Room performance standard.

The financial projections are based on unreasonable and overstated utilization projections. Please see the comments above regarding Criterion 3. Revenues are overstated based on unreasonable and overstated operational projections.

POSC does not conform to the SMFP demonstration project criterion related to access to indigent population.

- (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 financial projections are based on unreasonable and overstated utilization projections. Please see the comments above regarding Criterion 3. Revenues are overstated based on unreasonable and overstated operational projections.

Revenue projections for forms C, D and E are based on the expected numbers of procedures instead of the projected number of cases. When a surgical case involves more than one procedure, Medicare, Medicaid and Commercial Insurers typically reimburse the primary procedure at the allowable / contract amount but usually reimburse the secondary procedure at 50 percent of the allowable amount or less. The POSC application does not adequately explain the assumptions related to reimbursement of cases that include multiple procedures.

The financial assumptions on page 133 state "Revenue per procedure for each payor category is based on the projected Medicare Fee Schedule." However the application does not explain if the revenue per procedure equals the Medicare reimbursement or if the revenue is based on a mark up or multiplier applied to the Medicare Fee Schedule.

- (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 proposed project fails to comply with CON Review Criterion 6 because the application does not conform to CON Review Criterion 3.

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

POSC does not comply with Criterion 7 because the project includes no staff or contract service arrangements for pharmacy consulting and equipment preventative maintenance staff. These services are typically required for licensure and accreditation.

- (8) *The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with existing health system.*

The application does not comply with Criterion 8 because the project includes no staff or contract service arrangements for pharmacy consulting and equipment preventative maintenance. These services are typically required for licensure and accreditation.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services.

POSC fails to project an adequate level of care to the indigent population based on the calculations of the percentage of self pay and Medicaid as described in the SMFP criteria. The application fails to comply with 10A NCAC 14C .2102 (d) (3), (4), (5), (6), and (7).

Analysis for Piedmont Outpatient Surgery Center									
	Self Pay Procedures	x	Medicare allowable per procedure	=	Medicare Allowable Amount for Self Pay	minus	Self Pay Revenue Collected	=	Amount SP
YR 1		56	Not provided in application		\$29,206		\$7,488		\$21,718
YR 2		57	Not provided in application		\$29,728		\$7,621		\$22,107
YR 3		57	Not provided in application		\$29,728		\$7,621		\$22,107
	Medicaid Procedures	x	Medicare allowable per procedure	=	Medicare Allowable for Medicaid	minus	Medicaid Revenue Collected	=	Amount Mcd
YR 1		1092	Not provided in application		\$ 415,022		\$ 260,846		\$ 154,175
YR 2		1105	Not provided in application		\$ 419,962		\$ 263,951		\$ 156,011
YR 3		1118	Not provided in application		\$ 424,903		\$ 267,057		\$ 157,846
							Combined Amounts SP plus Mcd		
							YR 1		\$175,894
							YR 2		\$178,117
							YR 3		\$179,953
							Total Revenue Collected		
							YR 1		\$3,738,903
							YR 2		\$3,786,119
							YR 3		\$3,830,479
							Percentages		
							Combined Amounts SP plus Mcd of Total Revenue Collected		
							YR 1		4.70%
							YR 2		4.70%
							YR 3		4.70%
							POSC does not meet the 7% rule		

Instead of providing projections based on the number of self pay and Medicaid cases as required by the criteria, POSC provides projections based on procedures. As seen in the worksheet above, the POSC application fails to demonstrate that the 7 percent rule has been met.

Furthermore, when a surgical case involves more than one procedure, Medicare, Medicaid and Commercial Insurers typically reimburse the primary procedure at the allowable / contract amount but usually reimburse the secondary procedure at 50 percent

of the allowable amount or less. The POSC application does not adequately explain the assumptions related to reimbursement of cases that include multiple procedures.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

POSC does not comply with Criterion 18a because the application is nonconforming with CON Review Criteria 3, 4, and 5. The applicant projects that more than 50% of its patients are from rural counties that are outside of the boundaries of Guilford and Forsyth Counties. POSC fails to project an adequate level of care to the indigent population based on the calculations of the percentage of Self Pay and Medicaid as described in the SMFP criteria.

The proposal submitted by POSC is not conforming to all applicable Criteria and Standards for Surgical Services and Operating Rooms.

10A NCAC 14C .2102 (b) (5) - POSC is non-conforming because the methodology and assumptions are unreasonable as described in the comments regarding CON Review Criterion 3.

10A NCAC 14C .2102 (d) (3) - POSC is non-conforming due to incorrect calculations regarding Self Pay and Medicaid as seen in the attached analysis.

10A NCAC 14C .2102 (d) (4) - POSC is non-conforming due to the failure to provide the number of Self Pay cases. The rule specifically reads cases not procedures.

10A NCAC 14C .2102 (d) (5) - POSC is non-conforming due to the failure to provide the number of Medicaid cases. The rule specifically reads cases not procedures.

10A NCAC 14C .2102 (d) (6) - POSC is non-conforming due to the failure to provide the number of Self Pay cases and Medicare allowable amount. The rule specifically reads cases not procedures.

10A NCAC 14C .2102 (d) (7) - POSC is non-conforming due to the failure to provide the number of Medicaid cases and the Medicare allowable amount. The rule specifically reads cases not procedures.

10A NCAC 14C .2103 (b) and (c) - POSC is non-conforming due to overstated utilization projections that include unsubstantiated cases from multiple counties outside of the Guilford / Forsyth service area.

In CON Project Application # G-8492-10, Kernersville Orthopaedic Surgery Center (“KOSC”) proposes to develop a new single specialty freestanding ambulatory surgery center with two operating rooms and one procedure room. The facility will be operated by Ambulatory Surgical Management, LLC, a subsidiary of Novant Health. The proposed project will be located in an established medical park in Kernersville. Orthopaedic surgeons and physiatrists with Orthopaedic Specialists of the Carolinas and orthopaedic surgeons of RoMedical are listed as the medical staff for the proposed facility.

The POSC proposal fails to conform to the CON review criteria as follows:

- 1) Nonconforming to specific demonstration project criteria
- 2) Overstated surgical case projections
- 3) Inaccurate financial projections

CON Review Criteria:

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

The need determination for two operating rooms in the Triad Area (Guilford / Forsyth Counties) is pursuant to the Single Specialty Ambulatory Surgery Facility Demonstration Project. The 2010 State Medical Facilities Plan includes written criteria. The SMFP plan states “The demonstration project must meet the criteria described in Table 6D.” The KOSC application fails to conform to Criterion 1 because:

The proposed project includes two specialty areas; orthopedics and physical medicine and rehabilitation which exceed the single specialty designation of the need determination.

KOSC does not comply with the open access criteria because both the management of the facility and the granting of medical staff privileges are assigned to Novant / Forsyth Medical Center which restricts access to only those physicians who are willing to practice at the Novant-controlled facilities.

KOSC fails to project an adequate level of care to the indigent population based on the calculations of the percentage of self pay and Medicaid as described in the SMFP criteria.

KOSC projects that 30% of its patients will originate from rural counties that are outside of the boundaries of Guilford and Forsyth Counties. This includes 4.3% of patients from unknown origin that reside in “Other” Counties.

- (3) *The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.*

The KOSC patient origin data unreasonably includes high percentages of patients from multiple counties that are geographically distant from the proposed facility. The historical patient origin data for OSC surgeons is based on surgery performed at hospitals / facilities located in Winston-Salem that have inpatient and observation beds. In contrast the proposed project will have no observation beds and the location is Kernersville. KOSC

unreasonably projects that 30% of its patients will originate from rural counties that are outside of the boundaries of Guilford and Forsyth Counties. The application lacks letters of support from referring physicians in the outlying counties. Most of the letters of support are from physicians in Winston-Salem and Kernersville. No letters of support are provided by referring physicians located in Stokes, Davie, Yadkin, Davidson and Surry Counties. KOSC includes 4.3% of patients from "Other" Counties which is an inadequate description of patient origin.

The application is based on the unreasonable projection of approximately 30% of patients from outside of Guilford and Forsyth Counties. KOSC fails to identify the patient origin for 4.3% of the projected patients.

The project application does not demonstrate the need for the proposed project with two operating rooms in Kernersville in addition to the two existing orthopaedic operating rooms licensed to Forsyth Medical Center (FMC) that is located in the medical office building at Kimel Park in Winston-Salem. These FMC "hospital-based" operating rooms are located in the same building as Orthopaedic Specialists of the Carolinas and are used only for orthopedic ambulatory surgery as seen in the attached forms. The 2010 Hospital License Renewal application for Forsyth Medical Center shows that the 2 operating rooms located at Kimel Park Drive performed a total of 2791 cases.

The CON application fails to provide the utilization projections for the existing and CON approved operating rooms that are owned by Forsyth Medical Center or Medical Park in Forsyth County. The utilization projections are required because, page 67 states that the proposed project will begin to shift cases from these facilities beginning January 1, 2012.

The application fails to demonstrate that all of the participating physicians will obtain medical staff privileges at local hospitals. Page 47 and Exhibit 3 of the KOSC application list only 16 orthopaedic surgeons with active staff privileges at Medical Park and Forsyth Medical Center. Participating physicians who lack documentation of medical staff privileges at Medical Park and Forsyth Medical Center include the two physiatrists David R. O'Brien, MD and Benjamin C. Chasnis, MD.

Page 62 of the application provides inconsistent information regarding outpatient orthopedic surgery volumes. The table at the top of the page describes data for Forsyth and Guilford Counties. In contrast, the table at the bottom of the page provides data for Mecklenburg and Union Counties with some identical statistics. The application provides confusing and unreliable information.

The information on page 66 provides the historical outpatient orthopedic surgery cases performed at Forsyth Medical Center and Medical Park Hospital by the surgeons of Orthopaedic Specialists of the Carolinas. The application fails to explain the number of outpatient surgery patients that required observation at the hospital following outpatient surgery.

Page 67 of the KOSC application references the "KOSC OSC Surgeons Percent of Total Meck. Union Orthopedic Outpatient Percent Held Constant" The application's repeated references to Mecklenburg and Union Counties demonstrates that the methodology is confusing and unreliable.

Page 67, Exhibit 2, Table 3 shows an increase in the OSC Ortho Outpatient Surgical Volume. The application fails to explain if the basis for the assumption of 16.8% for future years

relates to the current number of OSC physicians remaining the same, decreasing or increasing. In order for OSC physicians to maintain a constant percentage (16.8%) of a growing market, the group must add physicians in proportion to the other orthopedic groups in the Forsyth / Guilford market. However, page 68 states that OSC will experience a “decline in physician capacity as OSC surgeons retire and/or adjust practice commitments.”

Page 67 of the application states that 16 OSC surgeons intend to utilize the facility. However, the OSC physician support letters in Exhibit 3 lack numerical utilization projections.

Page 69 of the KOSC application predicts new surgical cases related to physician recruitment that is duplicative of the projected growth in surgery cases shown on page 67. It is unreasonable for the applicant to maintain its 16.8% market share (with increasing numerical volume) without physician recruitment to replace retiring physicians. Therefore the projection of 2% additional market is unsupported.

The application fails to provide a sufficient need methodology and assumptions for the procedure room that is proposed in addition to the two operating rooms. Page 77 of the application states that the proposed minor procedure room will be used to perform “specialized orthopedic and rehabilitation procedures.” However the application fails to provide any specific CPT codes that will be performed in the minor procedure room. Also the application fails to provide the patient origin data for the procedure room patients.

The application states that the ratio of 1 non-surgical procedure to 4.6 surgical cases is based on the Thompson Outpatient Database. However this database includes imaging procedures that are performed in conjunction with outpatient surgery. Therefore the ratio is incorrect and overstated.

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

The KOSC application fails to conform to CON Review Criterion 4 because the utilization projections are unreliable and the financial projections are inaccurate. The application fails to explain the need for OSC physicians to no longer perform outpatient orthopedic surgery at the two operating rooms located at Kimel Park in Winston-Salem. Furthermore, KOSC and Novant fail to discuss the option of converting the two existing operating rooms at Kimel Park to a physician ownership structure.

- (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 KOSC application fails to conform to CON review criterion 5 because the utilization projections are overstated and unreasonable. Consequently the financial projections are unreasonable. The projected volume of cases from patients originating outside of Forsyth and Guilford Counties is unsupported. Minor procedure room cases have no validity because no patient origin is reported for these procedures.

KOSC facility costs are unreliable because the capital cost of the space that will house the project is not accurately represented; the application fails to demonstrate that the basis for the projected rent because of the lease includes "common areas and other facilities." Also the application fails to include the capital cost for the restoration of the leased unit at the end of the lease in accordance with the terms of the agreement.

The application fails to demonstrate that OSC can afford to make the loan payments for the proposed project. As seen in Exhibit 4, OSC currently shows no gains from operations.

The interest expense line item in Form B is blank. OSC fails to provide its financial projections to enable it to cover the interest cost.

The funding letter from David Janeway, MD fails to include the working capital amount for the proposed project.

Salary expenses are unreasonable and do not include funds for staff to operate the portable x-ray equipment and C-arm equipment.

- (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 CON application fails to provide the utilization projections for the existing and CON-approved operating rooms that are owned by Forsyth Medical Center or Medical Park in Forsyth County.

The proposed project is duplicative of the two-OR ambulatory surgery center located at 170 Kimel Park in Winston-Salem. OSC surgeons have exclusive access to these "hospital-based" operating rooms that are licensed as part of Forsyth Medical Center.

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

The application states that the facility staffing will be provided through the leasing of Novant employees. However this level of staffing is inadequate because no staff is budgeted to perform the imaging procedures using the portable x-ray and C-arm equipment.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with existing health system.*

The KOSC application fails to meet this criterion because no staff are assigned to the portable x-ray and C-arm equipment. Pages 115 and 116 include no descriptions of proposed staff with appropriate education and experience that could provide this ancillary service.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients,*

racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services

The application fails to meet this CON review criterion that is related to the SMFP demonstration project and special criterion that requires "a commitment that the Medicare allowable amount for self pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be at least seven percent of the total revenue collected for all surgical cases performed in the proposed facility."

Please see the worksheet below. KOSC only projects to have approximately 1.58 percent which falls short of the 7 percent as required by the rule.

Analysis for Kernersville Orthopaedic Surgery Center									
	Self Pay Procedures	x	Medicare Allowable per case	=	Medicare Allowable Amount for Self Pay	minus	Self Pay Revenue Collected	=	Amount SP
YR 1	86		Not provided in application		\$96,132		\$65,770		\$30,362
YR 2	89		Not provided in application		\$101,973		\$69,476		\$32,497
YR 3	92		Not provided in application		\$108,045		\$73,389		\$34,656
	Medicaid Procedures	x	Medicare Allowable per case	=	Medicare Allowable for Medicaid	minus	Medicaid Revenue Collected	=	Amount Mcd
YR 1	174		Not provided in application		\$194,499		\$176,682		\$17,817
YR 2	180		Not provided in application		\$206,237		\$186,639		\$19,598
YR 3	185		Not provided in application		\$217,264		\$197,150		\$20,114
							Combined Amounts SP plus Mcd		
							YR 1	\$48,179	
							YR 2	\$52,095	
							YR 3	\$54,770	
							Total Revenue Collected		
							YR 1	\$3,100,693	
							YR 2	\$3,275,430	
							YR 3	\$3,459,896	
							Percentages		
							Combined Amounts SP plus Mcd of Total Revenue Collected		
							YR 1	1.55%	
							YR 2	1.59%	
							YR 3	1.58%	
							KOSC does not meet the 7% rule		

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

KOSC does not comply with Criterion 18a because the application is nonconforming with CON Review Criteria 3, 4, and 5. The applicant projects that more than 30% of its patients are from rural counties that are outside of the boundaries of Guilford and Forsyth Counties. KOSC fails to project an adequate level of care to the indigent population based on the calculations of the percentage of Self Pay and Medicaid as described in the SMFP criteria.

The proposal submitted by KOSC is not conforming to all applicable Criteria and Standards for Surgical services and Operating Rooms.

10A NCAC 14C .2102 (b) (5) - KOSC is non-conforming because the methodology and assumptions are unreasonable as described in the comments regarding CON Review Criterion 3.

10A NCAC 14C .2102 (d) (3) - KOSC is non-conforming due to the calculations regarding Self Pay and Medicaid reflect approximately 1.6 percent which falls below the 7 percent requirement.

The following provides a comparative analysis of the three competing CON applications:

Access to Services Based on Patient Origin

Orthopaedic Surgery Center of the Triad is comparatively superior to the other application based on Year 2 projections of 100% of its patients originate from within the services area (38.6% patients from Forsyth and 61.4% patients from Guilford.) KOSC projects approximately 70% patients from the Forsyth Guilford service area and fails to identify the patient origin for 4.3% of the projected patients. POSC projects 50% patients from the Forsyth / Guilford service area and fails to identify the patient origin of 3.05% of the projected patients.

Access to Service Based on New Location Alternative

Orthopaedic Surgery Center of the Triad is comparatively superior because the proposed project in Colfax is a new location alternative that is central to the service area without being in close proximity to existing hospitals or ambulatory surgery centers. KOSC proposes a new facility in Kernersville where previously approved operating rooms at Kernersville Hospital are pending. POSC proposed its facility in Winston-Salem where most of the existing licensed operating rooms in Forsyth County are located.

Number of Participating Physicians

Orthopaedic Surgery Center of the Triad far surpasses the other applicants based on the commitment of 29 orthopaedic surgeons. Unlike KOSC and POSC, the proposal from Orthopaedic Surgery Center of the Triad demonstrates a high level of commitment and participation from multiple groups.

Compliance with SMFP Demonstration Project Criteria

The Orthopaedic Surgery Center of the Triad application conforms to all of the demonstration project criteria including the 7 percent criterion related to charity care and Medicaid. KOSC and POSC both fail to meet the 7 percent demonstration project criterion by a large margin.

Net Revenue Per Case

Orthopaedic Surgery Center of the Triad is comparatively superior based on having the lowest net revenue per case as seen in the following table.

Total Net Revenue per Case	OSCT	POSC	KOSC
	Colfax	W-S	Kernersville
YR 1	\$1,283	\$1,350	\$1,395
YR 2	\$1,283	\$1,350	\$1,430
YR 3	\$1,283	\$1,350	\$1,465

Total Cost per Case Comparison

Orthopaedic Surgery Center of the Triad is comparatively superior based on cost per case based on reasonable projections as seen in the following table. As seen in the comments regarding criteria 3 and 5, both POSC and KOSC surgery care projections are unreasonable.

Total Cost per Case	OSCT	POSC	KOSC
	Colfax	W-S	Kernersville
YR 1	\$1,265	Not based on	Not based on
YR 2	\$1,223	reasonable	reasonable
YR 3	\$1,149	assumptions	assumptions

Total Staffing

Orthopaedic Surgery Center of the Triad is comparatively superior based on a comparison of staffing.

Staffing for Year 2	OSCT	POSC	KOSC
	Colfax	W-S	Kernersville
Total FTEs	20.9	14.5	15
RN FTEs	9.0	6.0	7.0

Comparison of the number of registered nurses is important because ambulatory surgery center nurses are essential to respond to emergencies. POSC and KOSC have fewer total RNs available for emergencies, daily operations, and staffing coverage for sick, vacation and holiday time. With two operating rooms and one procedure room, KOSC has the least number of registered nurses and is comparatively understaffed.

OSCT staffing includes a 0.5 FTE biomedical equipment technician position and 1.5 Radiological Technologist. OSCT provides superior staffing resources for biomedical equipment safety and radiation equipment safety as compared to the other applicants in this review. KOSC proposed to include portable x-ray and C-arm but omits any radiology technologist staffing. Neither POSC nor KOSC includes biomedical technician positions to provide on-site equipment inspections, safety checks and preventive maintenance.

Letters of Support from Physicians

Orthopaedic Surgery Center of the Triad is comparatively superior based on obtaining a significantly higher number of letters of support from physicians in the service area that substantiate the utilization projections. The OSCT application includes over 100 physician letters of support and most are from physicians in Forsyth and Guilford Counties.

The POSC application includes 22 physician support letters. However the physician support letters do not corroborate the patient origin projections. No letters of support are provided from Surry County community physicians where 14.6% of patients are predicted by POSC. No letters of support are provided from Stokes County community physicians where 7.98% of patients are predicted by POSC. No letters of support are provided from Yadkin County community physicians where 4.25% of patients are predicted.

The KOSC application includes approximately 69 primary care referring physician support letters. Most of the letters of support are from physicians in Winston-Salem and Kernersville. No letters of support are provided by referring physicians located in Stokes, Davie, Yadkin, Davidson and Surry Counties.

Attachment 1 – Spreadsheet with comparative data for the three CON applications

Attachment 2 – Copy of Forsyth Medical Center License Renewal Application showing two existing operating rooms at Kimel Park location.

ATTACHMENT 1

CON Comparative Data

Project Applicants	GSW Real Estate, LLC and Orthopaedic Surgery Center of the Triad Holdings LLC	Stratford Executive Associates, LLC and Piedmont Outpatient Surgery Center, LLC	Kernersville Orthopaedic Surgery Center Holdings LLC and Orthopaedic Specialists of the Carolinas
Project ID #	G-8479-10	G-8477-10	G-8492-10
Management Company Location	Colfax, (Guilford)	Winston-Salem (Forsyth)	Novant Management Agreement Kernersville (Forsyth)
Patients Origin %	61.40%	5.92%	24.40%
Guilford County	38.60%	42.39%	46.30%
Forsyth County	0%	48.64%	25.00%
Other Counties Named	0%	3.05%	4.30%
Other Counties Not Identified	100.00%	100.00%	100.00%
Totals			
Description	Orthopaedic ASC with 2 ORs and 1 Procedure Room	Otolaryngology ASC with 2 ORs	Orthopaedic ASC with 2 ORs and 1 non-surgical procedure room
Lessor Capital Cost	\$5,430,750	\$2,989,794	No capital cost for "third party developer" that owns the building
Lessee Capital Cost	\$2,190,000	\$1,099,501	\$4,630,881
Total Capital Cost	\$7,620,750	\$4,089,295	\$4,630,881
Square Footage	10,120	9,000	9,346
Number of ORs	2	2	2
Number of Procedure Rooms	1	0	1
Number of Participating Physicians	29 Orthopaedic Surgeons	9 Otolaryngologists	22 Orthopaedic Surgeons and 2 Physiatrists
Number of Physician Owners	22	9	Owned by Orthopaedic Specialists
OR Cases (and / or Procedures)		Based on: Procedures	Cases
YR 1	2086	2770	2223
YR 2	2345	2804	2291
YR 3	2612	2837	2361
Procedure Room Cases			
YR 1	446	0	483
YR 2	527	0	498
YR 3	587	0	513

Project Applicants	GSW Real Estate, LLC and Orthopaedic Surgery Center of the Triad Holdings LLC	Stratford Executive Associates, LLC and Piedmont Outpatient Surgery Center, LLC	Kernersville Orthopaedic Surgery Center Holdings LLC and Orthopaedic Specialists of the Carolinas
Total FTEs Year 2	20.9	14.5	15
Adequate staff	Yes	No - lacks pharmacy and biomed tech	No - lacks radiology tech for x-ray and biomed tech
Total RNs Year 2	9	6	7
Payor Mix %	30.70%	9.41%	24.72%
Medicare	10.10%	27.88%	7.85%
Medicaid	3.50%	1.43%	3.88%
Self Pay / Charity			
Total Average Gross Charge			
YR 1	Per Case \$2,993	Per Case \$865	Per Case \$2,853
YR 2	Per Case \$2,993	Per Case \$865	Per Case \$2,938
YR 3	Per Case \$2,993	Per Case \$865	Per Case \$3,026
Total Net Revenue per Case			
YR 1	Per Case \$1,283	Per Case \$955	Per Case \$1,395
YR 2	Per Case \$1,283	Per Case \$955	Per Case \$1,430
YR 3	Per Case \$1,283	Per Case \$955	Per Case \$1,465
Documentation of:			
Anesthesia	WFUHS Anesthesia	Piedmont Triad Anesthesiology	Novant Anesthesiology
Pathology	WFUHS Pathology	Pathologist Diagnostic	Novant Pathologist
Transfer Agreements	Yes - WFUBMC and Moses Cone	Yes - Forsyth Medical Center	Yes Novant transfer
Outcome Measures	Yes	Yes	Yes
Accreditation	Yes	Yes	Yes
Clinical Training Programs	Yes	Yes	Yes
Open Access Policy	Yes	Yes	Yes
Criterion for Charity + Medicaid Amounts to 7% of Total	Yes	No	No
WHO Surgical Safety Checklist	Yes	Yes	Yes
Electronic Health Records	Yes	Yes	Yes
# of Letters of Support in CON Applications from Physicians in Guilford and Forsyth	100+	22	90+

ATTACHMENT 2

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
1205 Umstead Drive, 2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only

License # H0209

Medicare # 340014

Computer: 923174

PC _____ Date _____

License Fee:

\$17,032.50

**2010
HOSPITAL LICENSE
RENEWAL APPLICATION**

Legal Identity of Applicant: Forsyth Memorial Hospital, Inc.

(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As

(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: Forsyth Memorial Hospital

Other: John C. Whitaker Rehabilitation Center;

Other: _____

Facility Mailing Address: 3333 Silas Creek Pkwy
Winston Salem, NC 27103

Facility Site Address: 3333 Silas Creek Pkwy
Winston Salem, NC 27103

County: Forsyth

Telephone: (336)718-5000

Fax: (336)718-9250

Administrator/Director: Gregory J. Beier

Title: CEO

(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: Gregory J. Beier Title: CEO/President

(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: Kim Hull Telephone: 336-277-1062

E-Mail: khull@novanthealth.org

All services reported from October 1, 2008 through September 30, 2009.

8. Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures

NOTE: If this license includes more than one campus, please submit the Cumulative Totals and COPY and submit a duplicate of pages 8 and 9 for each campus.

(Campus: Headquater sites: Kinnel Park Drive Campus)

a) Surgical Operating Rooms

Report Additional Operating Rooms built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Health Services Regulation, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites.

Type of Room	Number of Rooms
Dedicated Open Heart Surgery	0
Dedicated C-Section	0
Other Dedicated Inpatient Surgery	0
Dedicated Ambulatory Surgery	2
Shared Inpatient / Ambulatory Surgery	0
Total of Surgical Operating Rooms	2

Number of additional CON approved surgical operating rooms pending development: 0

CON Project ID Number(s): N/A

b) Procedure Rooms (Excluding Operating Rooms and Gastrointestinal Endoscopy Rooms)

Report rooms, which are not equipped for or do not meet all the specifications for an operating room, that are used for performance of procedures other than Gastrointestinal Endoscopy procedures.

Total Number of Procedure Rooms: 0

c) Gastrointestinal Endoscopy Rooms, Cases and Procedures:

Report the number of Gastrointestinal Endoscopy rooms and the Endoscopy cases and procedures performed in these rooms during the reporting period.

Total Number of Existing Gastrointestinal Endoscopy Rooms: 0

Number of additional CON approved GI Endoscopy Rooms pending development: 0

CON/Project ID Number(s): N/A

	Number of Cases	Number of Procedures*
GI Endoscopy	0	0
Non-GI Endoscopy	0	0
Totals	0	0

*Count each patient as one case regardless of the number of procedures performed while the patient was in the GI endoscopy room.

*As defined in 10A NCAC 14C .3901 "Gastrointestinal (GI) endoscopy procedure" means a single procedure, identified by CPT code or ICD-9-CM procedure code, performed on a patient during a single visit to the facility for diagnostic or therapeutic purposes.

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

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

(Campus - If multiple sites: Kimel Park Drive)

d) Surgical Cases by Specialty Area Table

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

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)		
Open Heart Surgery (from 7.(b) 4.)		
General Surgery		
Neurosurgery		
Obstetrics and GYN (excluding C-Sections)		
Ophthalmology		
Otolaryngology		
Orthopedics		2,791
Plastic Surgery		
Urology		
Vascular		
Other Surgeries (specify)		
Other Surgeries (specify)		
Number of C-Section's Performed in Dedicated C-Section ORs		
Number of C-Section's Performed in Other ORs		
Total Surgical Cases	0	2,791

e) Non-Surgical Cases by Category Table

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

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