

COMMENTS REGARDING CERTIFICATE OF NEED APPLICATIONS FILED
FOR OPERATING ROOMS IN WAKE COUNTY

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CON Section

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Overview of CON Applications for Operating Rooms in Wake County

A total of five CON applications were submitted for the March 1, 2010 review cycle requesting operating rooms in Wake County, pursuant to a need for three additional operating rooms identified in the 2010 North Carolina State Medical Facilities Plan (SMFP):

- WakeMed d/b/a WakeMed Cary Hospital (J-8463-10) – Proposal to add three shared multispecialty operating rooms to its WakeMed Cary Hospital at a total cost of \$5,867,854. WakeMed Cary is located at 1900 Kildaire Farm Road in Cary.
- Duke University Health System d/b/a Duke Raleigh Hospital (J-8467-10) – Proposal to add three shared, multispecialty operating rooms to Duke Raleigh Hospital at a total cost of \$8,700,000.¹ Duke Raleigh Hospital is located at 3400 Wake Forest Road in Raleigh.
- Rex Hospital, Inc. d/b/a Rex Healthcare (J-8468-10) – Proposal to develop a new multispecialty ambulatory surgery center with 2 operating rooms in Rex Healthcare at Holly Springs at a total cost of \$7,586,384. The facility is proposed to be located at 704 Avent Ferry Drive in Holly Springs in leased space.
- Rex Hospital, Inc. d/b/a Rex Healthcare (J-8469-10) – Proposal to develop one new shared operating room at Rex Hospital at a total cost of \$1,143,785. Rex Hospital is located at 4420 Lake Boone Trail in Raleigh.
- Holly Springs Surgery Center, LLC (J-8471-10) – Proposal to develop a new freestanding, multispecialty ambulatory surgery center with 3 operating rooms and one procedure room at a total cost of \$8,204,090. The facility is proposed to be located at Rosewood Centre Drive at N. Main Street/Highway 55 in Holly Springs.

All of the applicants seeking approval in this review cycle are in agreement on the need for additional operating room capacity in Wake County. The decision before the CON Section is how these additional resources can be most effectively deployed in meeting the needs of Wake County residents.

¹ The capital costs presented in Section VIII of the Duke Raleigh application do not sum to the total of \$8,700,000. The error appears to be in "Consultant Fees" on p. 62 of the application, which sum to \$1,153,393 rather than the \$1,175,200 stated in the application.

The WakeMed proposal to add operating rooms at WakeMed Cary Hospital is superior to the other proposals under review. In addition, there are serious deficiencies in the other four proposals that render them nonconforming with applicable CON criteria. The bases for these conclusions are set forth in the following discussion. Furthermore, both Rex-Holly Springs and Duke Raleigh Hospital did not respond to the most current "Criteria and Standards for Surgical Services and Operating Rooms", found in 10A NCAC 14C .2100, *et seq.*, which were updated effective February 1, 2010; Duke Raleigh Hospital used the incorrect application form; and Holly Springs Surgery Center did not include responses to application Questions III.3-III.9.

Historical Utilization

Table 1 presents the most recent inventory and utilization data for operating rooms in Wake County for 2009.

Table 1
Wake County Surgical Providers - Existing & Approved
2009 Operating Room Utilization Rate

Provider	Inpatient Surgeries*	Outpatient Surgeries	Total Surgeries	Total Surgical Hours**	Adjusted ORs	Threshold Utilization	Percent Utilization
Shared Hospital Based --							
Duke Raleigh Hospital	3,004	10,817	13,821	25,238	13	24,336	103.7%
Rex Hospital	8,273	14,678	22,951	46,836	24	44,928	104.2%
WakeMed Cary	1,947	7,273	9,220	16,751	9	16,848	99.4%
WakeMed Raleigh	6,704	9,334	16,038	34,113	21	39,312	86.8%
Total Shared Hospital Based	19,928	42,102	62,030	122,937	67	125,424	98.0%
Dedicated Ambulatory --							
Blue Ridge Surgery Center	-	5,904	5,904	8,856	6	11,232	78.8%
Raleigh Women's Health	-	2,170	2,170	3,255	2	3,744	86.9%
Rex Cary	-	2,945	2,945	4,418	4	7,488	59.0%
Rex Wakefield	-	346	346	519	3	5,616	9.2%
Southern Eye Center	-	515	515	773	2	3,744	20.6%
WakeMed North	-	3,843	3,843	5,765	4	7,488	77.0%
Total Operational Dedicated Ambulatory	-	15,723	15,723	23,585	21	39,312	60.0%
Orthopedic Surgery Center of Raleigh	-	-	-	-	4	7,488	0.0%
Rex Macon Pond	-	-	-	-	4	7,488	0.0%
WakeMed Raleigh Surgery Center	-	-	-	-	8	14,976	0.0%
Total Approved Dedicated Ambulatory	-	-	-	-	16	29,952	0.0%
Total Approved+Existing Dedicated Ambulator	-	15,723	15,723	23,585	33	61,776	38.2%

*Excluding C-sections performed in dedicated c-section ORs, open heart surgeries in dedicated open heart rooms, and trauma surgeries for WakeMed Raleigh

**Based on SMFP standards of 3.0 hours per inpatient surgery and 1.5 hours per outpatient surgery.

Source: 2010 Licensure Renewal Application; 2010 SMFP

Included in Table 1 are approved facilities that did not report utilization in 2009, which include the WakeMed Raleigh Surgery Center, Rex-Macon Pond, and the Orthopedic Surgery Center of Raleigh. In addition, Rex-Wakefield was only open for a portion of 2009.

One striking fact from this utilization summary is the significant disparity in utilization between hospital-based and freestanding operating rooms in Wake County. The utilization of hospital-based providers was 98 percent of capacity, while the utilization of freestanding ambulatory operating rooms that were operational in 2009 was only 60.0 percent. If the Agency-approved but not operational, dedicated outpatient operating rooms are included (WakeMed Raleigh Surgery Center, Rex-Macon Pond, and Orthopedic Surgery Center of Raleigh), the utilization of freestanding operating rooms drops to 38.2 percent.

In terms of overall utilization rates, Rex Hospital had the highest percentage in 2009 (104.2 percent) by a small margin, followed by Duke Raleigh Hospital and WakeMed Cary Hospital. While Rex Hospital has relatively high utilization currently, there are several projects that will affect utilization at Rex Hospital in the future:

- Orthopedic Surgery Center of Raleigh LLC (Project No. J-8170-08) (OSCR) – This project was approved in 2009 and will permit the construction of four new dedicated ambulatory surgical operating rooms. Rex is a joint venture partner in this project, and expects to shift outpatient surgical cases in orthopedics and certain other specialties from Rex Hospital to OSCR. In Rex's applications in this review cycle, Rex predicts that 2,657 outpatient surgeries will shift to OSCR in 2013. This shift will reduce utilization of Rex Hospital's operating rooms.
- Rex-Wakefield, with three dedicated ambulatory surgical operating rooms, opened on April 27, 2009. During its initial 8 months of operation, it performed only 346 outpatient surgeries. In the applications in this review cycle for Rex Hospital and Rex-Holly Springs, Rex projects that Rex-Wakefield will perform 4,146 outpatient surgeries in 2013, or 3,800 more than it performed in 2009. It is reasonable to expect a significant portion of these new patients at Rex-Wakefield will be redirected from Rex Hospital.
- Rex recently syndicated shares in its Rex-Cary surgery center facility to area surgeons. While Rex anticipates that this change in ownership will bring some surgical patients to Rex-Cary from providers outside of the Rex system, it will also likely result in some patients currently receiving surgery at Rex Hospital being shifted to Rex-Cary.

Rex Hospital also received approval to relocate four operating rooms from Rex Hospital to a new outpatient surgical facility near the Rex main campus. While this change will not result in new operating room capacity, it will provide more dedicated operating rooms for outpatients in Wake County. Rex has sufficient capacity in its system to meet its long-term needs.

Neither WakeMed Cary Hospital nor Duke Raleigh Hospital has new operating room capacity approved; therefore, these two providers have a greater need for surgical operating rooms in the future than Rex, based on historical utilization.

Shared versus Dedicated Ambulatory/Outpatient Operating Rooms

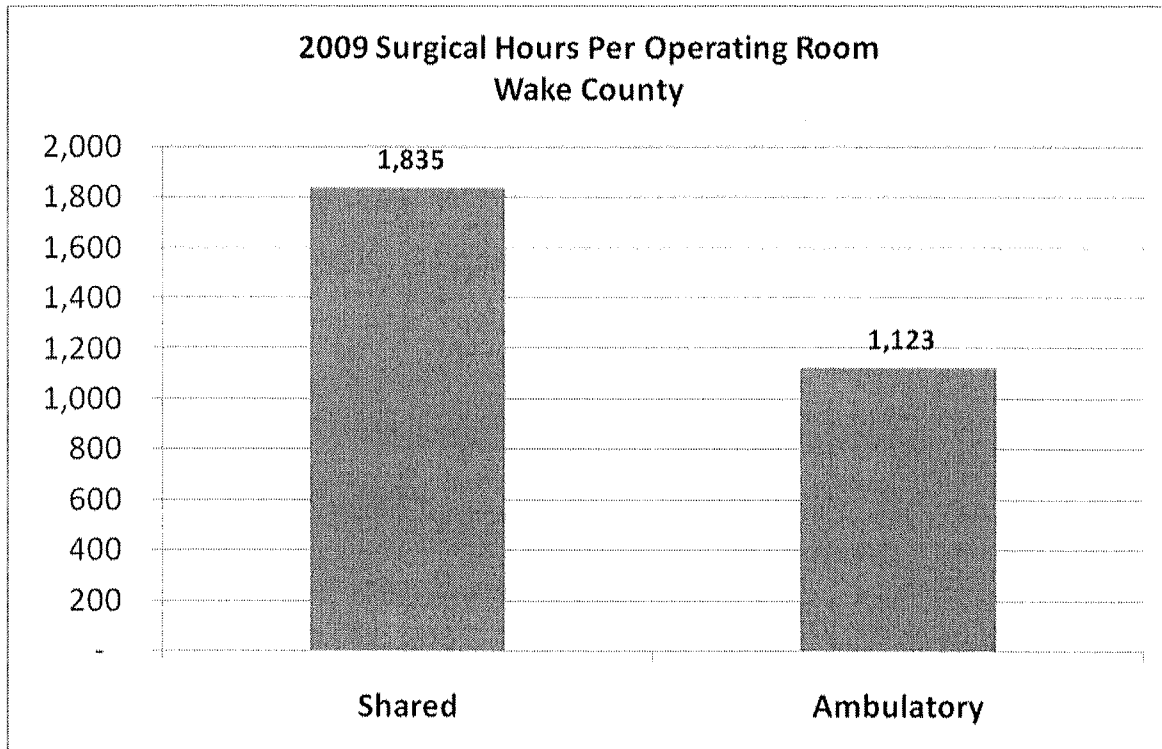
WakeMed Cary Hospital and Duke Raleigh Hospital are each requesting the addition of shared operating rooms that will operate under a hospital license. These rooms will be available to unscheduled emergency patients, as well as scheduled inpatient and outpatient surgeries. Rex is proposing to add only one shared operating room to Rex Hospital and two operating rooms to its Rex-Holly Springs facility to create another ambulatory surgery center. Novant's Holly Springs Surgery Center proposes to place all three of the operating rooms identified as needed in a new freestanding ambulatory surgery center.

As noted previously, the utilization of freestanding outpatient operating rooms is dramatically lower than shared operating rooms under hospital licensure in Wake County. In addition, approved CON projects will result in a significant increase in the number of operating rooms in a facility dedicated to outpatients, including:

- 8 operating rooms that will be constructed at the WakeMed Raleigh Surgery Center;
- 4 operating rooms at the new Rex outpatient surgical facility near its campus (Rex-Macon Pond); and
- 4 operating rooms at the OSCR facility.

With 16 new dedicated ambulatory surgical operating rooms added to the 21 dedicated ambulatory operating rooms already in operation in Wake County, there will be ample capacity to meet the needs of patients who might seek services in this setting. It is important to maintain an adequate number of shared, hospital-based operating rooms that will meet the needs of all types of patients, not only scheduled outpatient procedures.

The following chart displays graphically the disparity in utilization rates between shared operating rooms in hospitals and dedicated ambulatory operating rooms. In 2009, Wake County's shared operating rooms were utilized an average of 1,835 hours per room, 63.4 percent more hours per OR than the county's dedicated ambulatory operating rooms.



It would make little sense from a health planning perspective to allocate any of the three operating rooms needed in Wake County to dedicated ambulatory surgery centers.

Geographic Access

Both Rex-Holly Springs and Holly Springs Surgery Center argue in their applications that there is a need for improved access to surgical services in the Holly Springs area of southern Wake County. As maps presented in each application demonstrate, existing facilities in Wake County are accessible to the residents of Holly Springs. In particular, WakeMed Cary Hospital and Rex-Cary are conveniently located to serve Holly Springs. Because the operating rooms proposed by both Rex-Holly Springs and Holly Springs Surgery Center will be dedicated to outpatient surgical cases, they will only accommodate scheduled, lower risk patients. The incremental improvement in travel time for scheduled outpatients is not sufficient to outweigh the need for additional shared operating rooms in a hospital setting in Wake County.

As Rex notes in both of its CON applications under review, Rex-Cary’s operating rooms are underutilized today. Because Rex-Cary is the closest ambulatory surgery facility to Holly Springs, it would be a poor health planning decision to add more ambulatory surgery capacity to an adjacent community, particularly when there is a greater need for shared operating rooms provided in a hospital setting.

**Comments on Duke University Health System d/b/a Duke Raleigh Hospital
Project No. J-8467-10**

Throughout the application, Duke Raleigh Hospital (DRH) failed to provide the information requested, in the manner requested. Significantly, DRH failed to provide assumptions and data supporting the methodology used to create its projections in the application, and failed to explain the methodology used. DRH also failed to clearly define its service area; for example, in its Exhibit III.5(b) it provides a service area map showing Wake, Franklin, and Harnett Counties, but when asked to identify and provide the utilization for all providers of each service component located in the service area, DRH responds that: "...[t]he providers of surgical procedures in Wake County and their utilization during FY2008 are reported in the 2010 State Medical Facilities Plan", implying that only Wake County should be considered the service area (see DRH application, p. 33). DRH also did not provide evidence of any community support for the project, apart from physicians who practice at DRH and others affiliated with DRH or the Duke University Health System, and did not provide any information regarding the energy-efficient methods to be used in construction. Finally, it appears that DRH used the wrong application form and did not respond to the most current version of the Rules, so it is unclear whether DRH provided all the information requested by the CON Section in the correct application form.

Specifically, the Duke Raleigh is nonconforming with CON Review Criteria, as follows.

Criterion 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.

DRH failed to document the need for its proposal and therefore fails to satisfy Review Criterion 3. A particular problem is the lack of documentation to support the projected surgical volumes in the DRH application. DRH describes a short-term trend in increasing surgeries at the hospital, population growth in service area, and its future recruitment plans for surgeons. It fails, however, to present a market-based quantitative methodology that documents the number of surgeries projected in the future for the service area, DRH's projected market share, and the impact on market shares of other providers. These projections are unsubstantiated and therefore cannot be relied on to determine need for its proposed addition of three operation rooms.

Duke Raleigh does not adequately identify the population to be served, because it projects 24.3 percent of its surgical inpatients and 15.9 percent of its ambulatory surgery patients as coming from "Other NC Counties". No specificity is provided, and there is no documentation of the need for the "Other NC Counties". DRH has not demonstrated the need for one-quarter of its inpatient surgical cases, and nearly one-sixth of its outpatient surgeries.

DRH also fails to adequately demonstrate the access of low income persons to its services. In the response to Question VI.6, DRH states, "Patients with income between 200 and 300 percent of the federal poverty level are eligible for discounts between 50 and 80 percent." However, DRH did not include a copy of its charity care policy in the application, merely one page from a presentation made to the Duke Board in November 2008 (DRH application, p. 323). Information included in this presentation states: "Partial coverage is available, on a sliding scale, for those whose income is between 200% and 300% of FPL. Example: Family of 4 making \$61,950 eligible for a 20% discount". In November 2008, \$61,950 was between 200 and 300 percent of the federal poverty level (Source: *Federal Register*, Vol. 73, No. 15, pp. 3971-3972). Therefore, DRH has provided inconsistent information on its charity care policy and has not adequately identified the extent to which low income persons will have access to services.

DRH also fails to provide a copy of its policies regarding credit collection procedures; fails to provide information regarding bad debt; and fails to provide any information regarding how traditionally underserved groups will have access to DRH, apart from the statement that DRH does not discriminate (DRH application, pp. 44, 45, 41).

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 alternative has been proposed.

DRH discusses the alternatives of developing a freestanding ambulatory surgery center and maintaining the status quo. Without credible projections of future utilization for DRH's surgical program, it is not possible for DRH to demonstrate that it will require two additional operating rooms in the future, and that its proposed project is therefore an effective way to meet the need in Wake County for additional operating rooms.

In addition, Duke Raleigh's average charge per surgical case in Project Year 3, as presented in Form D of the Pro Formas, is projected at \$34,586, which is by far the highest average charge per case among applicants in the review. Duke Raleigh's net revenue per surgical case is also highest in the review. Please see Table 2.

Table 2

Year 3 Average Charge Per Case and Net Revenue Per Case for Applicants in 2010 Wake County Operating Room CON Review		
Applicant	Average Charge (Gross Revenue) Per Surgical Case	Net Revenue Per Surgical Case
Holly Springs Surgery Center	\$2,814	\$1,418
Rex-Holly Springs	\$11,780	\$4,411
Rex-Main	\$15,832	\$5,713
WakeMed Cary	\$19,117	\$5,995
Duke Raleigh	\$34,586	\$9,608

Also, the DRH project's total capital cost of \$8,678,193 and per-operating room capital cost of \$4,339,097 are the most expensive in the review. Therefore, DRH is non-conforming with Review Criterion 4, because it does not present the least costly alternative.

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 immediate financial feasibility relates to the ability of the applicant to fund the capital expenditure and initiate the project. As noted earlier, the project costs presented in Section VIII do not sum to the stated total of \$8,700,000. The problem appears to be with an erroneous subtotal in "Consultant Fees." These misstated costs call into question whether the project costs and related documentation of funding are accurately presented.

The key driver of the financial projections is the projected utilization for the proposed operating rooms, which DRH has failed to document. The relationship between the utilization projections presented in Exhibit IV.1 of the DRH application and the utilization projections in Forms D and E in the financial projections for the project is unclear. DRH's Forms D and E present projected surgical utilization of 2,142 procedures in Year 1; 3,348 procedures in Year 2; and 4,373 procedures in Year 3. These projected procedures are a fraction of the total projected surgeries reflected in Exhibit IV.1. The failure to base these financial projections on reasonable assumptions renders DRH's project nonconforming with Review Criterion 5.

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

Because DRH has failed to demonstrate that it has reasonably projected utilization or demonstrated a need for two additional operating rooms at DRH, the project is not consistent with Criterion 6. It is not sufficient for there to be a need in the SMFP for three additional operating rooms in Wake County. DRH cannot comply with this Criterion unless it can demonstrate the need for two additional operating rooms at its facility through reasonable, well-founded projections.

Criterion 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.

DRH failed to provide documentation and information necessary to demonstrate that staffing and other resources will be available for the project. For example, when asked to document the availability of necessary ancillary and support services for the project, DRH responded that evidence of the availability of ancillary and support services is afforded by the fact that DRH

currently provides surgical services and that it proposes to increase its staff, but did not provide any specific documentation that sufficient ancillary and support services would be available (see DRH application, p. 10). DRH stated that it would recruit 14 additional subspecialty surgeons, but failed to provide the requested physician recruitment plan (DRH application, pp. 12, 57). DRH also failed to describe staffing requirements necessary to staff multiple shifts and to explain how the proposed staffing will be sufficient (DRH application, p. 55).

Criterion 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.

DRH will not enhance competition in Wake County because the need for its proposal is not documented. The effect of the proposal on cost effectiveness, quality, and access cannot be evaluated. The application is therefore inconsistent with Criterion 18(a).

**Comments on Rex-Holly Springs
Project No. J-8468-10**

**Comments on Rex Hospital
Project No. J-8469-10**

Rex submitted two applications to address the need for three operating rooms in Wake County: a proposal to develop two hospital-based ambulatory surgical operating rooms in Holly Springs ("Rex-Holly Springs"), and a proposal to develop one shared operating room at its main campus ("Rex-Main"). The applications rely on many common arguments and identical need projections. Additionally, the two applications are premised on Rex shifting surgical patients from its main campus to the proposed Rex-Holly Springs surgical center. As a consequence, the comments on these projects will be combined.

Criterion 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.

Rex has failed to demonstrate the need for its projects. As described above in the discussion of historical utilization, Rex has several projects under way that will increase both its overall surgical capacity and the number of dedicated outpatient operating rooms in its system.

- The OSCR project, which will result in four new, dedicated outpatient operating rooms. Rex is a joint venture partner in this project and expects to shift outpatient surgical cases in orthopedics and certain other specialties from Rex Hospital to OSCR.
- Rex-Wakefield, with 3 dedicated outpatient operating rooms, which opened on April 27, 2009.
- Rex recently syndicated shares in its Rex-Cary surgery center facility to area surgeons that will also result in some patients currently receiving surgery at Rex Hospital being shifted to Rex-Cary.
- Rex Hospital also received approval to relocate four operating rooms from Rex Hospital to a new outpatient surgical facility near the Rex campus.

Despite all of the additional capacity that Rex is already adding as dedicated outpatient operating rooms, it proposes to place two of the three surgical operating rooms allocated in the 2010 SMFP in a new surgery center located in Holly Springs. There is no demonstrated need for more dedicated outpatient operating rooms in Wake County. As indicated in Table 1, the utilization rate in Wake County of existing dedicated outpatient operating rooms is far below

the utilization rates of shared rooms. Dedicated outpatient operating rooms are limited to serving lower risk, scheduled patients, while shared rooms in hospitals can accommodate inpatients, outpatients, and emergency patients.

Rex’s analysis deems the Holly Springs area (southern Wake County) the “fastest growing submarket in Wake County”, based on percentage growth. While the population of southern Wake County is certainly growing rapidly, larger growth in numeric population is occurring in other areas of the county, as shown in Table 3, which uses Claritas population data provided in the Rex-Holly Springs application.

Table 3

Rex Submarket/Region	Towns	2009 Population	2014 Population	Numeric Change in Population, 2009-2014
Central	Raleigh, Garner	405,269	462,789	57,250
Wakefield/North	Raleigh (north), Wake Forest, Rolesville	164,222	197,540	33,418
Cary/West	Cary, Apex (part), Morrisville	177,209	207,174	29,965
Holly Springs/South	Holly Springs, Fuquay-Varina, New Hill, Willow Spring, Apex (part)	81,916	99,585	17,669
Knightdale/East	Knightdale, Wendell, Zebulon	43,965	48,294	4,329

Source: Excerpted from Rex-Holly Springs CON application, pages 67-68

This indicates that the numeric populations of central, northern and western Wake County are all projected to grow more than southern Wake County during the period 2009-2014. Thus while southern Wake County is projected to grow by a high *proportion*, the region’s *numeric* population growth actually lags behind other areas of the county.

On pages 72-73, Rex provides two maps showing the geocoded locations of its FY 2009 surgical patients. Both maps show high concentrations of surgical patients in Raleigh and Cary, which are the largest population centers in Wake County. Aside from these concentrations, Rex’s surgery patients originate from throughout Wake County and the surrounding regions. There were no significant concentrations of patients from Holly Springs; at least, no more so than from Garner, Wake Forest and Apex.

The chief premise of the Rex-Holly Springs proposal is the supposed lack of “local access to surgical services” in certain parts of Wake County, namely the Holly Springs and Knightdale areas. However, Rex’s use of the term “local access” is nebulous. Is Rex suggesting that each town in Wake County is deserving of its own surgery center? More importantly, what is the maximum travel distance acceptable to meets the criteria for “local access”? This fundamental question is not addressed in the Rex-Holly Springs application.

On page 69, the Rex-Holly Springs application contains the following statement: “Currently, all of Wake County’s operating rooms are located in the Cary, Central and Wakefield submarkets.”

Not mentioned in the application is the fact that approximately 86 percent of Wake County's 2009 total population resides in these three areas. The Holly Springs submarket, as defined by Rex, constitutes only about 9 percent of Wake County's population. (The Knightdale submarket represents the remaining 5 percent of total.)

The map provided on page 70 of the Rex-Holly Springs application illustrates that all existing hospitals with operating rooms, as well as nearly all existing/approved surgery centers, are located adjacent to a major thoroughfare, which permits access from all areas of Wake County. The Rex-Holly Springs proposal, which will be located in southern Wake County, will not be accessible by a major highway for several years.

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 alternative has been proposed.

Rex does not propose the most effective projects, taken together, because:

- It will add only one shared room and the two other proposed operating rooms will be limited to ambulatory patients only; and
- It will not improve geographic access.

Rex argues in its application that each of its projects can be supported independently and does not rely on the approval of the other. As a practical matter, only the approval of the Rex-Main application allows a different applicant to be approved (DRH), because the remaining applicants each propose to add three operating rooms. Because Rex has chosen to allocate two of the three rooms to Rex-Holly Springs, it is not adding capacity where it is most needed: in a shared, hospital-based environment.

The closest existing surgical facilities to the proposed Rex-Holly Springs are WakeMed Cary Hospital, approximately 9.5 miles away, and Rex-Cary, located approximately 11 miles away. As noted previously, Rex-Cary has historically been underutilized. Rex is attempting to boost utilization of Rex-Cary by bringing in physician investors; however, the Rex-Holly Springs project will compete directly with Rex-Cary. Before adding new outpatient capacity to southern Wake County now, Rex should wait until a future date when it can demonstrate that its Rex-Cary facility is effectively utilized.

Rex is also not proposing the most cost effective alternative to patients for a satellite outpatient surgery center. Rex's application states that the two operating rooms in Holly Springs will be licensed under the hospital license, and not a separately licensed and Medicare- and Medicaid-certified, freestanding ambulatory surgical facility. Because the rooms will be under the hospital license, they will be reimbursed by Medicare and Medicaid as hospital-based operating rooms, which tend to be reimbursed at a higher rate than freestanding operating rooms. Many

insurance co-pays and deductibles are higher for hospital-based rooms. Rex's proposal, therefore, projects reimbursement at the higher rate without offering the flexibility and advantages of a shared operating room based at a hospital with immediately available emergency and other hospital services.

The total project cost of Rex-Holly Springs is \$7,586,384, or \$3,793,193 per operating room. When combined with the Rex-Main capital cost of \$1,143,785, Rex's total capital outlay for three ORs is \$8,730,170, or \$2,910,057 per operating room, the highest capital cost among all applicants. By contrast, the WakeMed Cary application has a total capital cost of \$5,867,854, or only \$1,955,951 per OR – this is both the lowest total cost and lowest cost per OR in the review cycle.

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

Rex's proposal to place two dedicated outpatient operating rooms at Rex-Holly Springs will unnecessarily duplicate existing facilities. Dedicated outpatient operating rooms in Wake County achieved only a 60 percent utilization rate in 2009, and the Rex-Holly Springs proposal will create more unneeded dedicated outpatient operating rooms. This factor is especially significant given the chronic underutilization of the Rex-Cary facility, which is located approximately 11 miles from the proposed Rex-Holly Springs location. According to utilization data provided in the Rex Hospital 2010 License Renewal Application, 2,945 outpatient surgical procedures were performed at Rex-Cary in 2009, which equates to a surplus of 1.6 ORs, as calculated below:

2,945 outpt. cases x 1.5 hours per case = 4,417.5 outpatient hours, rounded to 4,418
4,418 outpt. hours ÷ 1872 per OR per year = 2.36 ORs needed, rounded to 2.4
2.4 ORs needed minus 4 existing ORs = *surplus of 1.6 ORs*

Rex Surgery Center of Cary is underutilized, yet the proposed project would develop 2 new ambulatory surgical operating rooms in Holly Springs, approximately 11 miles, and 15 minutes, away from an existing, underutilized Rex facility.

Rex also failed to acknowledge the potential impact of Harnett Health System Central Campus, a 50-bed acute care facility with 3 shared surgical operating rooms, slated for construction in Lillington. This facility was recently approved for funding from the U.S. Department of Agriculture's Rural Development Community Facilities Loan Program, and is scheduled to open in early 2012.

According to MapQuest.com, Holly Springs is located approximately 20 road miles from Lillington. On page 142, Rex-Holly Springs projects that 17.8 percent of its total cases will originate in Harnett County. It is reasonable to assume that many of Rex-Holly Springs'

prospective surgery patients from Harnett County could be served at Harnett Health-Central Campus.

Based on this analysis, Rex-Holly Springs would appear to be duplicative of existing providers, and will result in only a minimal improvement in access to surgical services in Wake County. Therefore, the Rex-Holly Springs proposal does not conform with Review Criterion 6.

Criterion 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.

The two Rex proposals are inconsistent with this Criterion in that they will offer no enhancements in competition that will have positive impacts on the cost effectiveness, quality, and access to the services. Rex already operates a freestanding ambulatory surgery center near Holly Springs, Rex-Cary. The allocation of two of the three allocated operating rooms to Rex-Holly Springs will only exacerbate an excess of dedicated outpatient operating room capacity and not enhance competition.

Rex's proposals will not enhance access because they will add only one shared operating room, which provides access to a broader range of patients with varying surgery needs than dedicated outpatient surgery rooms, and instead limits access by proposing two of the operating rooms to be dedicated outpatient operating rooms. The utilization of the Rex-Cary facility, as well as other dedicated outpatient facilities, also suggests that the proposed Rex-Holly Springs will not be effectively utilized. Lower utilization likely will have a negative impact on cost effectiveness.

Other applications submitted in this review, which propose additional shared inpatient/outpatient surgical operating rooms at existing facilities closer to Wake County's population centers, would more adequately serve the county's residents.

For these reasons, the Rex proposals do not conform with this Criterion.

**Comments on Holly Springs Surgery Center, LLC
Project No. J-8471-10**

Holly Springs Surgery Center, LLC (HSSC), owned by Novant Health, Inc., proposes to develop a freestanding ambulatory surgery center with 3 operating rooms in Holly Springs in southwestern Wake County. HSSC fails to demonstrate that it can effectively meet the need Wake County has for additional operating room services. HSSC relies throughout the application on information prepared for the Holly Springs Hospital application, Novant's 2008 failed bid to construct a hospital in Holly Springs, including some of the documentation of community support and traffic counts. Much of this information is therefore out of date and, in the case of community support documentation in favor of a Holly Springs Hospital proposed in 2008, not relevant.

Specifically, the HSSC is nonconforming with CON Review Criteria, as follows.

Criterion 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 HSSC project must be found non-conforming with Review Criterion 3 because the application fails to respond to Questions III.3 through III.9 of the CON form. These questions are not even listed in the document. Without providing any information regarding consistency with policies in the SMFP, the geographic boundaries of its service area, projected patient origin, alternatives considered, or historical utilization of other providers, HSSC cannot demonstrate that it satisfies this Criterion.

In addition to this significant omission of information, HSSC does not adequately demonstrate the need for its project. HSSC has no historical presence in Wake County, and its projected utilization is without foundation. The key assumption in HSSC's utilization projections is the market share by census tract. These market shares in Year 3 range from 10 percent to 60 percent. The only supporting documentation that HSSC offers is a discussion of Novant's reputation with local physicians, Novant's ability to recruit, and the lack of any other surgical facility in its proposed service area. Novant currently operates no licensed health care facilities in Wake County, and it would face significant competition from Rex/UNC, Duke and WakeMed, who are long-established health care providers in the service area.

For HSSC, the key driver of projected utilization is the assumed market share for surgical services. HSSC's high utilization is predicated on attaining high market shares within its service area during the first three years following project completion. HSSC has assumed that its market shares will increase rapidly, and that, even as a new entrant for surgical services offering a limited range of specialties, it can quickly attain high market shares. Utilization

projections for HSSC are unreasonable because there is no basis for the high market shares projected for surgery, shown in Table 4.

Table 4

Holly Springs Surgery Center Surgical Cases Market Share Assumptions by Census Tract				
Census Tract	CY 2012	CY 2013	CY 2014	CY 2015
532	48%	48%	54%	60%
531.01	28%	28%	32%	35%
531.03	28%	28%	32%	35%
531.04	28%	28%	32%	35%
529	28%	28%	32%	35%
534.04	8%	8%	9%	10%

Source: HSSC application, page 75

HSSC does not adequately document its ability to attain these market shares. On page 35 and in application Exhibit 3, HSSC provides a list of physicians and surgeons who support its proposal. Of the 27 surgeons listed in Exhibit 3, 7 letters of support were included from surgeons who practice in Durham and Chapel Hill and 8 who are based in Cary. Letters from 12 surgeons and physiatrists listed with Triangle Orthopaedics were not included in the application. Surgeons located in Durham and Chapel Hill will not be likely to seek privileges at HSSC, and it is doubtful that their patients will want to drive past other acute care facilities in order to have their surgery done at HSSC.

Moreover, none of the primary care physicians who provided letters of support for the HSSC project and claim they will refer surgery patients to HSSC practice in Holly Springs or Fuquay-Varina. Of the 25 physicians listed in Exhibit 3, 13 are located in Durham, 8 in North Raleigh, and 4 in Wake Forest. It is unrealistic to believe that primary care physicians in Wake Forest would refer patients to a surgical provider in Holly Springs, approximately 40 miles away.

Utilizing Thomson Reuters data, WakeMed calculated Presbyterian Hospital Huntersville's (PHH) outpatient surgery market share history since it opened in 2004 (see Table 5). Service lines were selected based on the types of cases general and orthopaedic surgeons would perform. PHH is located in ZIP Code 28078 and as can be seen in the following table, it has not yet achieved 32 percent market share, which is what HSSC projects it will achieve in its primary service area *in its first year of operation*. PHH achieved its maximum market share in its second year of operation and it has remained relatively flat since then. Therefore, HSSC's market share projections are unrealistic.

Table 5

Top Five Ambulatory Surgery Providers for Huntersville (ZIP Code 28078) FYs 2004-2009 Cases and Market Shares Listed						
Facility	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Presbyterian-Huntersville	0	299	466	486	514	559
	0.0%	20.0%	27.6%	26.7%	26.4%	26.0%
University Hospital	371	299	273	341	341	364
	24.7%	20.0%	16.2%	18.7%	17.5%	16.9%
Carolinas Medical Center	241	182	217	214	213	289
	16.0%	12.2%	12.8%	11.8%	11.0%	13.5%
Lake Norman Reg Med Ctr	283	254	202	236	230	199
	18.8%	17.0%	12.0%	13.0%	11.8%	9.3%
Presbyterian Hospital	119	120	127	162	188	157
	7.9%	8.0%	7.5%	8.9%	9.7%	7.3%
Grand Total	1,504	1,497	1,689	1,820	1,945	2,148
	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Source: Thomson Reuters. Includes Arthroscopy, Back Surgery, Breast Surgery, GI (non-endoscopy), Hernia, Lymphatic & Hemic, Male Reproductive, Orthopedics, Other Procedures, Plastic/Cosmetic, Respiratory.

In Year 3, HSSC projects that it would perform 3,310 surgeries in its proposed facility (see HSSC application, p. 78). To place this projection in context, HSSC would have the third highest level of utilization among all freestanding ambulatory surgery centers in Wake County based on the 2008 utilization data presented in Table 1 above. Such a projection is not credible without strong evidence of specific support by surgeons who commit to move large numbers of cases to the proposed facility. The projection also is inconsistent with the chart provided by Novant on page 64 of its application that shows a decline in ambulatory surgical use rates in Wake County.

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 alternative has been proposed.

HSSC failed to address alternatives to its project in its application. As discussed above, the clear evidence is that there are superior alternatives to the HSSC proposal.

In terms of total project costs, HSSC proposed the second most expensive proposal at a cost \$8,204,090. Given that there is no demonstrated need for the HSSC project, this expenditure is unnecessary.

Table 6

Applicant	Number of ORs	Total Project Cost
Rex Hospital	1	\$1,143,785
WakeMed Cary	3	\$5,867,854
Rex-Holly Springs	2	\$7,586,384
Holly Springs Surgery Center	3	\$8,204,090
Duke Raleigh Hospital	3	\$8,700,000

HSSC also does not propose the most effective project because:

- It will limit the use of the rooms to ambulatory patients only and thus will fail to meet the needs of inpatient and emergency cases;
- It will not improve geographic access;
- It will not improve financial access; and
- It has failed to document that it will achieve a reasonable utilization of the proposed operating rooms consistent with the performance standards in the CON review criteria.

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.

HSSC is nonconforming with Review Criterion 5 because its financial projections are based on flawed utilization projections. HSSC also fails to provide the method of depreciation to be used and the rationale for such use (see HSSC application, p. 130).

HSSC proposes the lowest average charge (gross revenue) per surgical case in the review, projected at \$2,814 in Project Year 3. HSSC's net revenue per surgical case in Year 3 is \$1,418. Please see Table 7.

Table 7

Year 3 Average Charge Per Case and Net Revenue Per Case for Applicants in 2010 Wake County Operating Room CON Review		
Applicant	Average Charge (Gross Revenue) Per Surgical Case	Net Revenue Per Surgical Case
Holly Springs Surgery Center	\$2,814	\$1,418
Rex-Holly Springs	\$11,780	\$4,411
Rex-Main	\$15,832	\$5,713
WakeMed Cary	\$19,117	\$5,995
Duke Raleigh	\$34,586	\$9,608

Source: Pro Forma Financial Statements, Form D

The projected average charge per case and net revenue per case for HSSC are significantly lower than any other applicant, so much lower that it appears unreasonable. Most of the surgeons who provided support letters for HSSC are orthopaedic surgeons based in Wake County. Using Thomson Reuters data, WakeMed examined the FY 2009 outpatient surgery average charge per case for these Wake County surgeons who supported HSSC. The FY 2009 average charge per case for these Wake County-based orthopaedic surgeons was \$11,705, over 4 times higher than HSSC's projected Year 3 average charge per case (see Table 8). Clearly, HSSC has provided financial projections that are unrealistically low.

Table 8

FY 2009 Outpatient Cases and Charges for Surgeons Based in Wake County Who Supported the Holly Springs Surgery Center CON Application			
Surgeon Name	FY 2009 Outpatient Surgery Cases	Total Charges	Average Charge Per Case
Armour, Edouard F	3	\$40,106.51	\$13,369
Carroll, Raymond Mckay	190	\$2,296,821.68	\$12,089
Curzan, Mark Anthony	186	\$1,974,337.33	\$10,615
Gollehon, Douglas L	156	\$1,660,582.21	\$10,645
Martini, Douglas John	151	\$2,046,539.53	\$13,553
Mathur, Sameer	33	\$559,908.73	\$16,967
Reinke, Derek Lawrence	124	\$1,289,340.62	\$10,398
Total	843	\$9,867,636.61	\$11,705

Source: Thomson Reuters, outpatient surgery database

Additionally, Novant Health may not have sufficient short-term assets to fund the HSSC project. Novant's Calendar Year 2008 balance sheet lists Current Assets of \$668,497,000 at of the end of 2008. Novant's pending North Carolina CON projects that are either under review, or approved but not operational, as listed on pages 136-138 of the application, total \$681,941,231. This amount does not include requirements for routine equipment replacement or non-CON capital expenditures. It is unclear whether Novant has additional development expenses in Virginia or South Carolina. Given Novant's significant financial commitments in North Carolina alone, coupled with the flaws in its financial projections, Novant has not demonstrated compliance with this Criterion.

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

There is ample capacity in dedicated ambulatory surgery centers in Wake County today. HSSC's proposal is not needed and is not the best alternative for addressing the need for operating rooms in Wake County. As a result, it will result in unnecessary duplication of existing and approved health facilities.

The HSSC project will predominately cater to orthopaedic surgeons. Eight of the 15 surgeons who provided letters of support for HSSC are orthopaedic surgeons. (Novant listed another 12 orthopaedic surgeons and physiatrists as being supporters, but did not include support letters.) In October 2009, a certificate of need was awarded to Orthopaedic Surgery Center of Raleigh, a joint venture between Raleigh Orthopaedic Clinic and Rex Hospital that will offer 4 ambulatory surgery operating rooms, ostensibly to provide orthopaedic surgery. Approval of the HSSC application would, in effect, be duplicative of Orthopaedic Surgery Center of Raleigh. The 2010 State Medical Facilities Plan allocated two single-specialty surgical operating rooms to the Research Triangle region, in the December 1, 2010 review cycle; if Novant would like to develop an orthopaedic surgery center, it will have that opportunity to do so.

Criterion 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 information provided by HSSC demonstrates that resources necessary to support the operation of the proposed ambulatory surgical center are not reasonably available. HSSC proposes to send lab work via courier to Forsyth Medical Center, approximately 116 miles away, to a pathology group located in Barnwell, South Carolina, or to "Wake County hospitals," but does not provide any evidence of an agreement with these hospitals (see HSSC application, p. 31). HSSC also states that Presbyterian Anesthesia Associates will provide "on-site anesthesiologist and CRNA services" (HSSC application, p. 274). Presbyterian Anesthesia Associates is located in Charlotte, approximately 150 miles away from Holly Springs. Therefore, HSSC has failed to demonstrate the availability of resources and is nonconforming with this Criterion.

Criterion 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.

The HSSC proposal is inconsistent with this Criterion in that it will offer no enhancements in competition that will have positive impact on the cost effectiveness, quality, and access to the services. There is ample competition and capacity among dedicated ambulatory surgery facilities. There are already six existing and three approved dedicated ambulatory surgery facilities in Wake County. HSSC failed to provide reasonable utilization projections and made errors in its projected financial statements by basing its numbers on those unreasonable projections, so the cost effectiveness of its proposal from the standpoint of operating costs

cannot be effectively assessed. As noted above, HSSC's project costs are among the highest of the applicants. HSSC does not demonstrate that quality of its services will be superior to existing providers in Wake County. Finally, HSSC does not offer any material improvements in geographic access in Wake County.

**Comments on WakeMed Cary Hospital
Project No. J-8463-10**

WakeMed proposes to develop three shared surgical operating room at WakeMed Cary Hospital. On a comparative basis, the WakeMed Cary application best meets the needs of Wake County residents, given the following:

- WakeMed Cary proposes shared surgical operating rooms, which are more needed than operating rooms in dedicated ambulatory surgery centers, and can be used for either inpatient or outpatient surgery.
- WakeMed Cary provides the greatest access to Wake County residents, both geographically and financially.
- WakeMed Cary’s utilization and financial projections are based on reasonable assumptions.
- The WakeMed Cary proposal will help ease surgery capacity constraints within the WakeMed system, particularly at WakeMed Cary Hospital, whose operating rooms were utilized at 99 percent of capacity as defined by the State in FY 2009.
- The WakeMed Cary application has support from a large number of physicians and surgeons, representing a broad base of specialties.
- WakeMed proposes the highest amounts of charity care and bad debt, as shown in the following table:

	WakeMed Cary	Rex-Holly Springs	Rex-Main Campus	Duke Raleigh	Novant/HSSC
Charity Care, Year 2 – <i>project only</i>	\$5,303,324	\$263,537	\$3,848,085	\$2,126,546	\$553,927
Bad Debt, Year 2 – <i>project only</i>	\$2,488,594	\$160,693	\$2,407,369	\$0	\$120,094

Source: Pro Forma Financial Statements, Form C

- WakeMed proposes the lowest operating margins among applicants in this review, as shown below, indicative of a reasonable mix of costs and charges:

	WakeMed Cary	Rex-Holly Springs	Rex-Main Campus	Duke Raleigh	Novant/HSSC
Operating Margin, Year 1	3.9%	8.5%	10.5%	9.4%	-0.5%
Operating Margin, Year 2	4.1%	13.2%	10.1%	10.5%	4.4%
Operating Margin, Year 3	4.5%	14.2%	10.4%	10.1%	9.2%

Source: Pro Forma Financial Statements, Form C

- On a per-operating room basis, the WakeMed Cary proposal's capital cost is lowest among applicants in the review seeking to acquire three operating rooms, as shown in the following table:

Applicant	Total Capital Cost	Number of ORs Proposed	Capital Cost per OR
WakeMed Cary	\$5,867,854	3	\$1,955,951
Novant/Holly Springs Surg.Ctr.	\$8,204,090	3	\$2,734,697
Rex-Holly Springs	\$7,586,385	2	\$3,793,193
Rex-Main Campus	\$1,143,785	1	\$1,143,785
Rex-COMBINED	\$8,730,170	3	\$2,910,057
Duke Raleigh	\$8,678,193	3	\$4,339,097

Source: Question VIII.1

Therefore, WakeMed Cary Hospital has presented the most effective alternative and should be approved by the Certificate of Need Section.