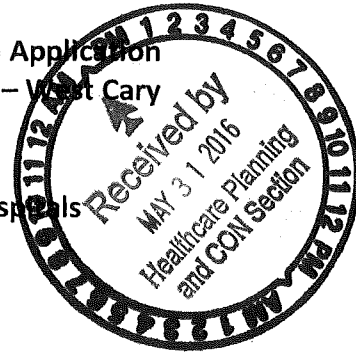


Comments Regarding the Certificate of Need Application
Filed by Raleigh Orthopaedic Surgery Center – West Cary
Project No. J-11161-16

Submitted by: WakeMed Health & Hospitals
May 31, 2016



Overview

A certificate of need application was filed for the May 1, 2016 review cycle to develop a single-specialty ambulatory surgery center with one surgical operating room and two procedure rooms by Orthopaedic Surgery Center of Raleigh LLC, Group I Ventures, ASC JV LLC, Rex Orthopaedic Ventures LLC and Rex Hospital (referred to hereafter as "ROSC-West Cary") in Cary, by relocating one surgical operating room from Raleigh Orthopaedic Surgery Center in Raleigh.

The following comments will demonstrate that the ROSC-West Cary application should not be approved, as it does not conform to all applicable certificate of need Review Criteria found in N.C.G.S. §131E-183 as discussed below.

Review 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 ROSC-West Cary application does not conform to Review Criterion 3. The applicants failed to demonstrate that the project is needed for the following reasons:

- Volume projections and their underlying assumptions are not reliable;
- There is no basis for the shift in cases to the new facility;
- The application failed to consider the impact of other surgery projects under development;
- The proposed location does not materially improve access to surgical services in Wake County;
- Development of a new surgery center in Wake County does not equate to improved utilization of an existing facility.

Volume Projections Not Reliable

In its application, ROSC-West Cary describes the rapid increase in surgical volume at Raleigh Orthopaedic Surgery Center in Raleigh (“ROSC-Raleigh”) since its opening in Spring 2013. ROSC-Raleigh performed 3,739 operating room cases in FY 2015, an increase of 18.8% from the prior year. Measured against the “capacity” threshold of 1,872 hours per OR per year, ROSC-Raleigh was utilized at 74.9% in FY 2015 [calculation: (3739 cases x 1.5 hrs/case) ÷ (1872 hrs/OR/year x 4 ORs = 0.749 = 74.9%]. From this calculation it is clear that ROSC-Raleigh is well-utilized, though not fully utilized.

The application indicates that ROSC-Raleigh volume is projected to increase 4.0% per year beginning in calendar year 2016. By Project Year 3, ROSC-Raleigh will be utilized at 98.4% with its remaining 3 operating rooms. Rather than continuing to build volume and operating efficiencies at ROSC-Raleigh, where the majority of Raleigh Orthopaedic Clinic physicians practice, the applicants have proposed to relocate one surgical operating room – effectively 25% of ROSC-Raleigh’s current capacity – to a new location in Cary. By Project Year 3, both ROSC-Raleigh and ROSC-West Cary will be utilized at over 90%.

The projections for ROSC-Raleigh and ROSC-West Cary contain flaws and inconsistencies that call into question their accuracy and reliability. For ROSC-Raleigh’s historic data, cases were provided for the fiscal years ending September 30, 2015. Interim and projected volumes for ROSC-Raleigh, as well as projected volumes for the proposed ROSC-West Cary, are provided for the *calendar* year. Please see the table below, showing data from page 32 of the ROSC-West Cary application.

Table 1 Historic and Projected Surgical Cases ROSC-Raleigh and ROSC-West Cary								
Facility	Previous 10/1/13– 9/30/14	Previous 10/1/14– 9/30/15	Interim 10/1/15– 12/31/15	Interim 1/1/16 – 12/31/16	Interim 1/1/17- 12/31/17	Year 1 1/1/18- 12/31/18	Year 2 1/1/19- 12/31/19	Year 3 1/1/20- 12/31/20
ROSC-Raleigh	3,148	3,739	No data provided	3,889	4,044	3,406	3,542	3,684
ROSC-West Cary	NA	NA	NA	NA	NA	1,050	1,092	1,136

While this is not an issue *per se* for ROSC-West Cary, there is a three-month interim period prior to the opening of ROSC-West Cary, October 1-December 31, 2015, where there is no utilization data provided for ROSC-Raleigh. Because this interim utilization is missing, the omission casts doubt on the reliability of the subsequent projections, given that the majority of ROSC-West Cary’s projected cases are expected to shift from ROSC-Raleigh.

No Basis Provided for Case Shift

The applicants assume that 800 cases, or approximately 20% of ROSC-Raleigh's CY 2017 volume, will shift to ROSC-West Cary in Project Year 1, and that this volume will increase 4% per year. The applicants also assume that 250 cases will shift from UNC Hospitals to ROSC-West Cary in Year 1, also increasing 4% per year. These assumptions are not supported with any data, either statistical or anecdotal, that would lead the Agency to believe these volumes could be achieved. Physicians who wrote letters of support for ROSC-West Cary merely expressed an interest in performing cases at the new facility; they did not quantify a numeric range of cases they plan to perform annually in the new facility.

Aside from a basic discussion of population growth in Wake County and in the western Wake County ZIP Codes, the applicants performed no detailed analysis to demonstrate that there is a need for an additional operating room in western Wake County greater than the need in any other part of the county. Although the ROSC-West Cary application lists Wake County as the primary service area, the projected patient origin in Section III is identical to that of ROSC-Raleigh, despite being located closer to Chatham, Durham and Lee Counties, and more distant from Franklin, Wayne, Sampson and Nash Counties.

Ambulatory Surgery OR Inventory in Wake County

Wake County is currently served by 6 freestanding ambulatory surgery centers with a total of 25 surgical operating rooms. Another existing ASC, Rex Surgery Center of Wakefield, is in the process of converting its 3 ORs from hospital-based to freestanding (Project No. J-10284-14). Holly Springs Surgery Center (Project No. J-8471-10), approved for 3 freestanding ASC ORs, is under development. Upon completion of these projects, Wake County will be home to 8 freestanding ASCs with 31 total ORs. Should the ROSC-West Cary project be approved, the number of ASCs would increase to 9, but the total number of ORs in those centers would remain the same.

Of the existing ASCs in Wake County, two, ROSC-Raleigh and Triangle Orthopaedic Surgery Center, are dedicated to orthopaedic surgery. ROSC-West Cary would be a third ASC dedicated exclusively to orthopaedic surgery. However, the proposed project provided no evidence that another ASC for orthopaedics in the county is needed.

Surgery Centers Proposed for Development

On page 24, ROSC-West Cary notes approved operating room projects in Wake County that are not yet operational. Two projects, Holly Springs Surgery Center, with 3 approved ambulatory surgical operating rooms, and Rex Hospital Holly Springs (Project No. J-8669-11), with 3 shared surgical operating rooms, will be located close to the proposed ROSC-West Cary site. Because these projects have not yet been developed, their impact on the surgery market and physician practice patterns of western Wake County surgeons has not yet been determined. To continue to add operating room capacity to this market, even an existing operating room, without fully

understanding the impact on competition is unwise, particularly for a project with a substantial capital cost.

No Material Improvement in Access

The ROSC-West Cary application provides no tangible evidence that residents of the service area have suffered for lack of ambulatory surgery services in the Cary area. There was no statistical data or anecdotal information provided to suggest that residents of the service area have been detrimentally affected by travel to existing facilities offering surgical services. The proposed surgery center is located 7.8 miles from Rex Surgery Center of Cary, 12.2 miles from WakeMed Cary Hospital, and approximately 14 miles from both ROSC-Raleigh and Blue Ridge Surgery Center. Each of these facilities is in close proximity to the proposed site, currently provides outpatient surgery, and offers a greater number of surgical specialties than those proposed for ROSC-West Cary. Given the presence of these existing surgery providers, and other approved surgical providers in Holly Springs, it is not clear how the proposed project would improve accessibility for residents of the service area, aside from simply being located in Cary. The project's \$9.5 million capital cost represents a large investment for just one operating room.

On page 28, the applicants describe the rationale for the proposed project:

"Relocating one operating room to the proposed new ASC in West Cary will decrease travel times for ROC physicians who practice in the Cary office. Currently these physicians have to travel up to 15 miles to the Orthopaedic Surgery Center of Raleigh to perform most of their ambulatory surgery cases."

The Raleigh Orthopaedic Clinic (ROC) Cary office is located at 222 Ashville Avenue in Cary, adjacent to WakeMed Cary Hospital. According to Google Maps, the most optimal route between this office and the proposed ROSC-West Cary site is 15.5 miles/19 minutes' travel time. The ROC Cary office is actually closer to ROSC-Raleigh -- 10.2 miles/13 minutes. Thus, there is no evidence that the proposed project will enhance access for surgical services for physicians or patients. In fact, the opposite is the case -- physicians at the ROC Cary office would be traveling a greater distance to practice at the proposed site.

For these reasons, the ROSC-West Cary application is nonconforming with Review Criterion 3.

CON Review 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.

The ROSC-Raleigh facility opened in 2013, and had been operational for only two full fiscal years at the time this application was filed. Operating rooms at this ASC are not yet fully utilized.

On page 44, the applicants describe the alternatives to the proposed project that were considered, and why these were deemed unacceptable. With regard to maintaining the status quo, the application states:

“The option of maintaining the status quo is not an effective alternative because the existing Raleigh Orthopaedic Surgery Center with four operating rooms in Raleigh has limited capacity to support the future needs of additional surgeons that are being recruited. Keeping all four operating rooms at the facility in Raleigh will cause ROC physicians to have limited schedule options that will require travel to and from the Cary office.” [emphasis added]

This passage is confusing, given that the proposed project will not increase the capacity of surgical operating rooms in Wake County. It is difficult to understand how simply relocating one operating room will accommodate additional physicians, when no additional OR capacity is being created.

The second option, “Relocating Two Operating Rooms”, was not selected because “[t]he existing Orthopaedic Surgery Center of Raleigh has a large medical staff that has achieved high utilization.” What is unclear from this statement is why relocating one operating room *away* from ROSC-Raleigh will meet the needs of said medical staff more effectively than simply keeping all 4 ORs at their present location. The reasoning as to why Options 1 and 2 were not selected is contradictory.

The chosen alternative, and the subject of Project No. J-11161-16, was selected because it “provides increased capacity and scheduling flexibility for the surgeons.” However, no evidence was provided to support this claim, particularly given that the ROSC-West Cary project will not change the inventory of surgical operating rooms in Wake County, and *will not add ambulatory surgical capacity in Wake County*. It is also illogical to assume that the 4 operating rooms currently located at ROSC-Raleigh can be more efficient if they are split into two separate locations. ASCs with only one OR are inherently less efficient, prone to scheduling delays, and do not have the economies of scale to spread their overhead costs. The touted, but dubious, improvement in accessibility to operating rooms does not justify the project’s \$9.5 million capital cost. Maintaining the status quo would obviate this unnecessary capital cost.

The applicants did not fully explore additional alternatives to the proposed project, including, but not limited to, having ROC physicians seek to perform surgical cases at other ASCs or hospitals in Wake County. With existing and approved surgical operating rooms available at a number of locations, including the Cary area, there would appear to be a number of options for ROC physicians who would like to perform cases close to ROC’s Cary office. The ROSC-West Cary application provided no evidence that other such locations were considered and/or contacted regarding operating room availability. Existing and approved locations with surplus capacity would provide an option for these surgeons, without incurring an unnecessary capital cost.

For these reasons, the ROSC-West Cary project does not conform with Review Criterion 4.

Review 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 and charges for providing health services by the person proposing the service.

ROSC-West Cary failed to demonstrate that the financial and operational projections are based on reasonable assumptions, as required by this Criterion. In Section VIII, the Project Capital Cost tables on pages 71-72 reference a total capital cost of \$9,521,498. However, upon closer inspection, the calculated total capital cost, based on the items provided in the tables, is \$9,522,218, a difference of \$720. Please see the following table.

Table 2 ROSC-West Cary Project Capital Cost			
	<u>Lessee</u> (p. 71)	<u>Lessor</u> (p.72)	<u>TOTAL</u>
Site Costs	\$0	\$2,126,500	\$2,126,500
Construction	\$0	\$4,564,342	\$4,564,342
Fixed Equipment	\$79,569	\$0	\$79,569
Moveable Equipment	\$1,480,807	\$0	\$1,480,807
Furniture	\$150,000	\$0	\$150,000
A&E Fees	\$0	\$411,000	\$411,000
Financing Costs	\$10,000	\$10,000	\$20,000
Contingency	\$190,000	\$500,000	\$690,000
TOTAL PROJECT COST:			
listed in application	\$1,909,656	\$7,611,842	\$9,521,498
calculated above	\$1,910,376	\$7,611,842	\$9,522,218
Difference	\$720	\$0	\$720

The discrepancy appears to occur on the Lessee side, but it is impossible to reconcile the listed and calculated capital costs. Therefore, the financial viability of the project, including its profitability, depreciation and project financing, cannot be verified, and by extension the project does not conform to Review Criterion 5.

Please also see the discussion for Review Criterion 3 above.

Review Criterion 6

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

Please see the narrative for Criterion 3. The ROSC-West Cary represents no change in operating room capacity in Wake County, but will relocate one operating room closer to other approved surgical facilities in western Wake County. Because two Agency-approved surgical services projects have not yet opened, it is impossible to determine if additional operating rooms are needed in western Wake County. The ROSC-West Cary application offered no analysis of the surgery market in western Wake County, including the reason(s) that the proposed site was selected over other locations in the county. Therefore, the proposed project does not conform to Review Criterion 6.

Review Criterion 8

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

The ROSC-West Cary application lists the arrangement for provision of ancillary and support services. On page 82, the application lists Rex Hospital as the location of ancillary, support and emergency services, approximately 15 miles and 17 minutes from the project site. The proposed project will actually be located closer to the emergency department and ancillary and support services at WakeMed Apex Healthplex (6.7 miles/12 minutes). However, there was no documentation that the applicants contacted WakeMed or plan to transport patients requiring these services to the closest facility. The application did not include a letter of support from Rex Healthcare, which is purported to be the manager of the proposed ASC and will accept its patient transfers, including emergency patients.

The ROSC-West Cary project does not appear to be coordinated with the existing local health care system, and therefore is not conforming with Criterion 8.

Review Criterion 12

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

The ROSC-West Cary project capital cost is significant, considering that it only seeks to relocate one existing surgical operating room to a new site. There is no information provided in the application to justify the excessive project cost.

Although the ROSC-West Cary project involves construction and upfit of 13,025 square feet for the ASC, the floor plans provided for the project in Exhibit 39 show a total of 30,136 square feet

to be constructed. The only description of the remaining 17,111 square feet is a notation on the floor plan indicating "Future Medical Tenants". The capital cost for the ROSC-West Cary CON application does not include the capital cost associated with the shell space, although the floor plans provided clearly show access points connecting the ASC to the shell space.

If the applicants intend to construct a 30,136 square foot facility, the associated capital costs with this additional square footage should have been included in the Project Capital Cost, and also duly reflected in the Project Financial Statements (e.g., depreciation, financing costs). Failure to do this makes the application nonconforming with Criterion 12.

Review Criterion 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:

- a. The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;*
- b. Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;*
- 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; and*
- d. That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.*

The ROSC-West Cary application provides projected payer mix and projected revenues for medically underserved groups in Section VI. On page 56, ROSC-West Cary projects charity care for Years 1 (\$48,121) and (\$51,552), which equate to 0.8% of net revenue and 0.26% of gross revenue. Considering the Year 1 average charge is projected to be \$18,764, ROSC-West Cary's total charity care equates to approximately 2.5 cases. ROSC-West Cary is clearly a project not geared toward providing service to medically underserved groups.

The table below provides FY 2015 payer mixes for freestanding ambulatory surgery centers located in Wake County. ROSC-West Cary's Year 2 payer mix is provided for comparison..

Payer	Blue Ridge Surgery Center	Raleigh Plastic Surgery Center	Rex Surgery Center of Cary	Capital City Surgery Center	Triangle Ortho Surgery Center	ROSC-Raleigh	Year 2 Proposed ROSC-West Cary
Self-Pay/Charity	0.8%	4.8%	1.0%	0.6%	10.0%	0.6%	0.6%
Medicare	25.2%	19.6%	15.7%	27.8%	11.9%	18.4%	18.4%
Medicaid	11.2%	0.8%	4.6%	4.5%	4.2%	0.0%	3.0%
Commercial Insurance	0.2%	74.8%	6.4%	63.7%	65.5%	68.8%	65.8%
Managed Care	56.9%	0.0%	72.0%	0.0%	0.9%	0.0%	0.0%
Other	5.7%	0.0%	0.3%	3.4%	7.5%	12.2%	12.2%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
% Self Pay/Charity +Medicare+Medicaid	37.2%	25.2%	21.3%	32.9%	26.1%	19.0%	22.0%
% Self Pay/Charity +Medicaid	12.0%	5.6%	5.6%	5.1%	14.2%	0.6%	3.6%

In total, ROSC-West Cary projects that it will devote only 22% of its total surgical case volume to medically underserved groups – Self-Pay/Charity, Medicare and Medicaid. If Medicare patients are excluded, this proportion drops to only 3.6%. ROSC-West Cary's payer mix is modeled exactly after the payer mix of ROSC-Raleigh, which reported *no Medicaid cases in FY 2015* on its most recent License Renewal Application. ROSC-Raleigh's combined service to Self-Pay/Charity and Medicaid patients was the lowest among Wake County freestanding ASC providers, and was significantly less than that of Triangle Orthopaedic Surgery Center, ROSC-Raleigh's most analogous facility in terms of scope of service. With other Wake County ASCs providing a greater share of service to these payer groups, it is clear that ROSC-West Cary and its predecessor ROSC-Raleigh would provide only a tacit commitment to the medically underserved in Wake County. For these reasons, ROSC-West Cary is not conforming with Review Criterion 13, particularly Part 13a.

Review 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 applicants shall

demonstrate that its application is for a service on which competition will not have a favorable impact.

The ROSC-West Cary application provides no tangible evidence of enhanced competition for surgical services in Wake County. While it has been well-established that cases performed in ambulatory surgery centers are generally less expensive than cases performed in hospitals, there are already a number of ASCs in Wake County, both hospital-based and freestanding. Relocation of a single OR to western Wake County would have virtually no impact on competition, nor would it materially affect cost effectiveness or quality. Aside from improving convenience to a few surgeons, there is nothing to justify the project's hefty price tag from the perspective of enhancing competition or improving cost effectiveness, access or quality.

Summary

The ROSC-West Cary application is an ill-timed, ill-devised proposal that, if approved, would contribute little, if anything, to the provision of surgical services in Wake County. The application seeks to relocate a single operating room from a relatively new, well-utilized ASC to a new location already served by multiple providers of ambulatory surgery. The proposal appears to be solely designed to improve convenience to a small group of surgeons, although it is not immediately apparent how this would be achieved. Access to medically underserved groups would not be enhanced.

The project is also problematic because a single-OR ambulatory surgery center would operate less efficiently than an ASC with multiple operating rooms. The ASC's expenses would be spread over only one OR, resulting in an ASC with diminished operating efficiency.

The application does not conform to a number of CON Review Criteria, and for the reasons listed above should not be approved.