



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

October 1, 2018

Mike McKillip, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Comments on Wake County OR CON Applications

Dear Mr. McKillip:

On August 15, 2018, Duke University Health System, Inc. (DUHS) submitted two complementary CON applications in response to the need determination in the 2018 SMFP for six (6) new operating rooms (ORs) in Wake County. These applications are CON Project ID# J-11557-18 Green Level Ambulatory Surgical Center and CON Project ID# J-11558-18 Duke Raleigh Hospital.

Enclosed please find comments prepared by DUHS regarding the competing CON applications to develop the need determined ORs in Wake County. We trust that you will take these comments into consideration during your review of all the applications.

If you have any questions about the information presented here, please feel free to contact me at (919) 668-0857. I look forward to seeing you at the public hearing.

Sincerely,

Catharine W. Cummer

Catharine W. Cummer

COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS WAKE COUNTY OPERATING ROOMS

**Submitted by Duke University Health System
October 1, 2018**

Five providers submitted nine Certificate of Need (CON) applications in response to the need identified in the *2018 State Medical Facilities Plan (SMFP)* for six new operating rooms (ORs) in Wake County. DUHS submitted two complementary CON applications in this batch review: CON Project ID# J-11557-18 Green Level Ambulatory Surgical Center (Green Level ASC) and CON Project ID# J-11558-18 Duke Raleigh Hospital (DRAH).

In accordance with N.C. Gen. Stat. § 131E-185(a.1)(1), this document includes comments relating to the representations made by the competing applicants, and a discussion about whether the material in their applications complies with the relevant review criteria, plans, and standards. These comments also address the determination of which of the competing proposals represents the most effective alternative for development of six new ORs in the service area.

Specifically, the Healthcare Planning and Certificate of Need Section, in making the decision, should consider several key issues, including the extent to which each proposed project:

- (1) Best meets the county need for additional ORs;
- (2) Provides greatest access for county residents to new multi-specialty ORs;
- (3) Enhances market competition for surgical services and provides local patients with a new alternative source for multi-specialty outpatient surgery in Wake County;
- (4) Maximizes healthcare value in the delivery of health care services for development of the need-determined ORs, with competitive charges and costs;
- (5) Demonstrates that projected surgical utilization is based on reasonable and adequately supported assumptions; and
- (6) Demonstrates conformity with applicable review criteria and standards.

The Agency typically performs a comparative analysis when evaluating all applications in a competitive batch review. The purpose of the comparative analysis is to identify the proposal(s) that would bring the greatest overall benefit to the community. The table on the following page summarizes comparative metrics that the Agency should use for comparing the nine applications in this OR batch review.

**Wake County OR Batch Review
Applicant Comparative Analysis**

	Green Level ASC	Duke Raleigh Hospital	RAC Surgery Center	UNC Health Care Panther Creek ASC	Rex Surgery Center of Garner	Rex Hospital	OrthoNC ASC	WakeMed Surgery Center North Raleigh	WakeMed Surgery Center Cary
Conformity with Regulatory Rules & Statutory Review Criteria	Equally Effective	Equally Effective	Least Effective	Least Effective	Least Effective	Least Effective	Least Effective	Least Effective	Least Effective
Meeting the Need for Additional Operating Rooms	Most Effective	Most Effective	Least Effective	Least Effective	Least Effective	Least Effective	Least Effective	Least Effective	Least Effective
Geographic Accessibility	Most Effective	Least Effective	Least Effective	Least Effective	Less Effective	Least Effective	Least Effective	Least Effective	Least Effective
Physician Support	Equally Effective								
Patient Access to Alternative Providers	Most Effective	Least Effective	Equally Effective	Least Effective	Least Effective	Least Effective	Equally Effective	Least Effective	Least Effective
Patient Access to Low Cost Outpatient Surgical Services	Equally Effective	Least Effective	Equally Effective	Equally Effective	Equally Effective	Least Effective	Equally Effective	Equally Effective	Equally Effective
Patient Access to Multiple Surgical Specialties	Most Effective ASC	Equally Effective Hospital-Based	Least Effective	Less Effective	Less Effective	Equally Effective Hospital-Based	Least Effective	Less Effective	Less Effective
History of Developing OR Projects	Equally Effective	Equally Effective	Equally Effective	Least Effective	Least Effective	Least Effective	Equally Effective	Equally Effective	Equally Effective

Access by Underserved Groups	Inconclusive Comparison
Projected Average Net Revenue per Case	Inconclusive Comparison
Projected Average Operating Expense per Case	Inconclusive Comparison

Based on this comparative analysis, which shows Green Level ASC and DRAH rank most favorably on the comparative metrics, and considering that the Green Level ASC and DRAH applications conform to the Review Criteria and best achieves the Basic Principles of the 2018 SMFP (Policy GEN-3), Green Level ASC and DRAH are the most effective alternatives for development of the six need-determined operating rooms in Wake County.

Comparative Analysis

Conformity with Review Criteria

Without establishing conformity with all applicable statutory and regulatory review criteria, an application cannot be approved. For the reasons discussed later in this document:

Rex Surgery Center of Garner is non-conforming with Criteria 1, 3, 4, 5, 6, 12, & 18a.

UNC Health Care Panther Creek ASC is non-conforming with Criteria 1, 3, 4, 5, 6, 12, & 18a.

Rex Hospital is non-conforming with Criteria 1, 3, 4, 5, 6, & 18a.

WakeMed Surgery Center-North Raleigh is non-conforming with Criteria 1, 3, 4, 5, 6, 12, 13, & 18a.

WakeMed Surgery Center-Cary is non-conforming with Criteria 1, 3, 4, 5, 6, 13, & 18a.

OrthoNC ASC is non-conforming with Criteria 1, 3, 4, 5, 6, & 18a.

RAC Surgery Center is non-conforming with Criteria 1, 3, 4, 5, 6, 12, 14, & 18a.

Meeting the Need for Additional Operating Rooms

The need determination for six (6) ORs in the 2018 SMFP is based solely on the surgical utilization at DRAH and the need for additional surgical capacity at DRAH to accommodate the growth of DUHS surgical cases. The following table summarizes the 2020 projected OR need in Wake County based on the 2018 SMFP standard methodology.

Table 6B: Wake County Projected OR Need for 2020, 2018 SMFP

Facility	2020 Projected OR Deficit (Surplus)
Raleigh Orthopaedic Surgery Center -West Cary	-1.00
Raleigh Orthopaedic Surgery Center	0.37
<i>Raleigh Orthopaedic Total</i>	<i>-0.63</i>
Rex Holly Springs	-3.00
Rex Wakefield	-2.00
Rex Cary	-0.97
Rex Hospital	3.95
<i>UNC Health Care Total</i>	<i>-2.02</i>
Capital City Surgery Center	-2.26
WakeMed	3.47
WakeMed Cary	-3.93
<i>WakeMed Total</i>	<i>-2.72</i>
Blue Ridge Surgery Center	-3.00
Duke Raleigh Hospital	6.77
Holly Springs Surgery Center	-3.00
Raleigh Plastic Surgery Center	-0.00
Triangle Orthopaedics Surgery Center	-2.00

Source: Table 6B: Projected OR Need for 2020 (Column M), 2018 SMFP

The state’s need methodology reflects that Duke Raleigh Hospital needs an additional 45 percent (6.77/15) capacity to meet anticipated surgical demand. To put this information in context, the following table compares the inventory of ORs amongst existing Wake County surgery providers.

Wake County Operating Inventory

Provider	Total ORs	Surplus/Deficit
WakeMed	47	2.72 surplus
UNC Health Care	34	2.02 surplus
Duke University Health System	15	6.77 deficit
Freestanding ASCs	19	8.63 surplus
Total Wake County ORs	115	

Source: Table 6A Operating Room Inventory, 2018 SMFP

As the previous table indicates, DUHS has only 13 percent (15/115) of the Wake County OR inventory, while its projected operating room deficit constitutes 100 percent of the need in Wake County for additional operating rooms (per the 2018 SMFP). DRAH has less than half (15 vs. 34) of the Wake County licensed operating room inventory of UNC Health Care, and less than one-third (15 vs. 47) of the licensed operating room inventory of WakeMed. DUHS is grossly under capacity with respect to ORs in Wake County. More importantly, this capacity constraint affects DUHS’s ability to provide timely access to needed surgical services for patients.

As shown in Table 6B of the 2018 SMFP, of the existing surgical providers that propose to add ORs, DUHS is the only provider projected to have a deficit (6.77 ORs) in 2020. The 2018 SMFP shows that UNC Health Care is projected to have a surplus of two ORs by 2020 and that WakeMed is projected to have a surplus of 2.72 ORs by 2020. This is an important consideration because UNC Health Care submitted three CON applications to develop new ORs pursuant to the 2018 SMFP need determination. Similarly, WakeMed submitted two CON applications to develop new ORs pursuant to the 2018 SMFP need determination. Neither of these health systems nor any of the other applicants in this competitive batch review are projected in the 2018 SMFP to have a deficit of ORs. The following table summarizes the relative effectiveness of the competing proposals with respect to meeting the need for additional operating rooms based on the 2018 SMFP.

**Comparative Factor:
 Meeting the Need for Additional Operating Rooms**

Applicant	Health System	Meeting the Need for Additional Operating Rooms
Green Level ASC	DUHS	Most Effective
Duke Raleigh Hospital		Most Effective
UNC Health Care Panther Creek ASC	UNC Health Care	Least Effective
Rex Surgery Center of Garner		Least Effective
Rex Hospital		Least Effective
WakeMed Surgery Center North Raleigh	WakeMed	Least Effective
WakeMed Surgery Center Cary		Least Effective
RAC Surgery Center & Fresenius Vascular Care Raleigh	N/A	Least Effective
OrthoNC ASC	N/A	Least Effective

With regard to meeting a need for additional operating rooms, the applications submitted by Duke University Health System (i.e. Green Level ASC and Duke Raleigh Hospital) are the most effective alternatives in this Wake County competitive batch review.

DUHS notes a similar comparison was used in the 2013 Mecklenburg County acute care bed batch review. Therefore, it is reasonable for the Agency to compare applicants based on “Meeting the Need for Additional ORs” in this Wake County OR batch review, especially since several other comparative factors result in inconclusive comparisons (e.g. Access by Underserved Groups, Projected Average Net Revenue per Case, and Projected Average Operating Expense per Case).

Patient Access to Alternative Providers

In this Wake County OR batch review, two applicants propose to locate additional ORs at existing hospitals: Duke Raleigh Hospital and Rex Hospital each propose to develop two additional ORs in their respective hospital facilities.

UNC Health Care operates an existing freestanding ASC in Wake County (i.e., Rex Surgery Center of Cary) and already has CON approval to develop operating rooms at Rex Surgery Center of Wakefield and Rex Hospital Holly Springs. The UNC Health Care system also includes Raleigh Orthopaedic Surgery Center (ROSC) and ROSC-West Cary (see page 38 of Rex Surgery Center of Garner application, CON Project ID# J-11553-18), for a total of three freestanding ASCs in Wake County. Therefore, the proposals by UNC Health Care to develop a new ASC in Panther Creek and a new ASC in Garner would not provide patient access to alternative providers because UNC already provides surgical services in multiple hospital-based and freestanding ASC settings within Wake County.

WakeMed also provides surgical services in both hospital-based and freestanding ASC settings. In addition to its hospital-based ORs in Wake County, WakeMed maintains ownership in Capital City Surgery Center located in Raleigh. Therefore, the two proposals by WakeMed Surgery Center North Raleigh and WakeMed Surgery Center Cary would not provide patient access to alternative providers.

As described in the Green Level ASC CON application, DUHS is the only hospital system in Wake County without a freestanding ASC. The proposed Green Level ASC project will represent a new opportunity for Wake County residents and DUHS patients to access surgical services in a facility with a freestanding charge structure; thereby, creating a new ASC provider in Wake County.

The table on the following page summarizes the competing applications with respect to patient access to alternative providers.

**Comparative Factor:
 Patient Access to Alternative Providers**

Applicant	Patient Access to Alternative Providers
Green Level ASC	Yes (most effective)
Duke Raleigh Hospital	No
UNC Health Care Panther Creek ASC	No
Rex Surgery Center of Garner	No
Rex Hospital	No
WakeMed Surgery Center North Raleigh	No
WakeMed Surgery Center Cary	No
RAC Surgery Center	Yes (less effective)
OrthoNC ASC	Yes (less effective)

Therefore, with regard to providing Wake County patients with access to an alternative provider of outpatient OR services, the proposals submitted by Green Level ASC, RAC Surgery Center and OrthoNC ASC are effective alternatives.

However, DUHS notes that the RAC Surgery Center and OrthoNC ASC proposals would each create a new one-OR, single-specialty ASC. Thus, the extent to which these proposals would each provide access to alternative providers is significantly limited compared to Green Level ASC, which proposes multiple surgical specialties. Therefore, Green Level ASC is the most effective alternative for this comparative metric.

Geographic Accessibility

The following table identifies the locations of the existing and approved ORs in Wake County.¹

Facility	Surgical Facility Type*	Location Within Wake County	City/Town
Blue Ridge Surgery Center	MS	Central	Raleigh
Duke Raleigh Hospital	MS	Central	Raleigh
Raleigh Plastic Surgery	SS	Central	Raleigh
ROSC-West Cary**	SS	Southwest	Cary
ROSC	SS	Central	Raleigh
Rex Hospital Holly Springs**	MS	Southwest	Holly Springs
Rex Healthcare of Wakefield **	MS	Northern	N. Raleigh
Rex Hospital	MS	Central	Raleigh
Rex Surgery Center of Cary	MS	Southwest	Cary
WakeMed Cary Hospital	MS	Southwest	Cary
WakeMed North	MS	Northern	N. Raleigh
WakeMed Raleigh Campus	MS	Central	Raleigh
Capital City Surgery Center	MS	Central	Raleigh
Holly Springs Surgery Center	MS	Southwest	Holly Springs
Surgical Center for Dental Professionals of Raleigh**	SS	Central	Raleigh

*MS = Multi-specialty; SS = Single-specialty.

**Approved by the Certificate of Need Section, but not yet operational.

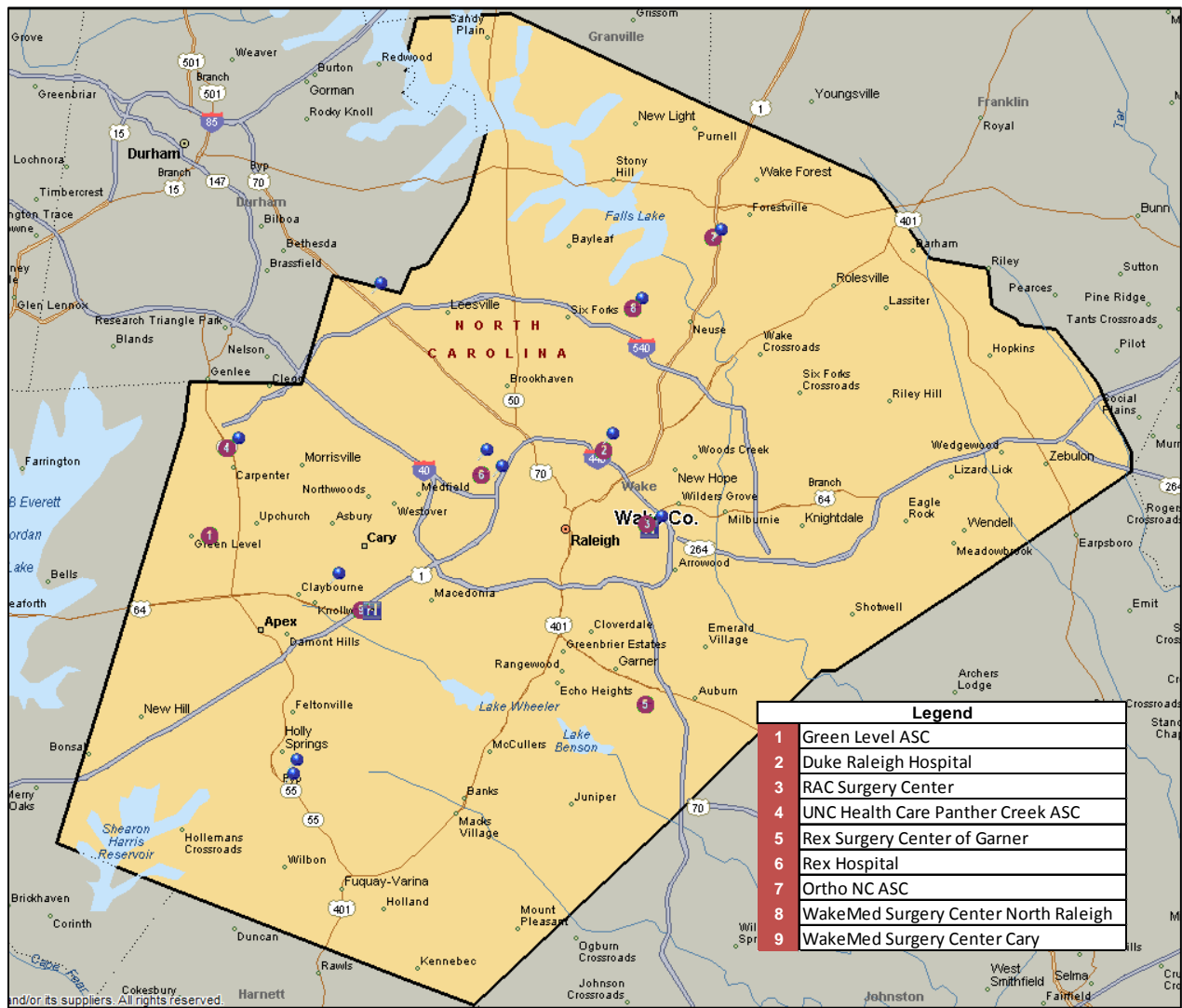
In this review, two applicants propose to locate two additional ORs at existing hospitals: DRAH and Rex Hospital. WakeMed Surgery Center-North Raleigh proposes to develop a new ASC on the campus of WakeMed North, and WakeMed Surgery Center-Cary proposes to develop a new ASC across the street from WakeMed Cary Hospital. OrthoNC ASC proposes to develop a 1-

¹ Location of existing facilities is consistent with the Agency's geographic analysis included in the Comparative Analysis of the 2008 Wake County OR Batch Review. Facilities and locations have been updated, as appropriate, based on the development of new facilities subsequent to the 2008 Wake County OR Batch Review.

OR single-specialty ASC less than ½ mile from Rex Healthcare of Wakefield. RAC Surgery Center proposes to develop a 1-OR single-specialty ASC across the street from WakeMed in Raleigh. UNC HealthCare Panther Creek ASC proposes to develop a 2-OR ASC less than ½ mile from Raleigh Orthopaedic Surgery Center-West Cary (ROSC-West Cary).

Only two applicants propose to develop ORs in new geographic locations that are not proximate to existing surgical facilities or hospitals: Green Level ASC and Rex Surgery Center of Garner. The map below illustrates the locations of all existing hospitals and surgical facilities (indicated by blue pins), and the proposed locations for this Wake County batch review (red numbers).

Wake County Locations of Existing ORs and Proposed Locations in Wake County OR Batch Review



As described in the Green Level ASC CON application, although the proposed ASC has a Cary address, the proposed site is in fact located in the Town of Cary extra-territorial jurisdiction (ETJ) and not in the Town of Cary itself. The location is proximate to and associated with Apex. Duke's proposed location has a greater population and is projected to grow at a significantly faster rate compared to Rex's proposed Garner location (see Wake County population data on page 30 of Green Level ASC CON Project ID# J-11557-18). Moreover, Green Level ASC proposes to develop four ORs offering nine surgical specialties, which represents greater access compared to the Rex Surgery Center of Garner application which proposes to develop two ORs offering only three surgical specialties.

Therefore, with regard to improving geographic access to surgical services, the Green Level ASC is the most effective alternative compared to all other applications in this review.

Patient Access to Low Cost Outpatient Surgical Specialties

The Wake County OR service area has 115 existing and approved ORs (13 inpatient + 34 ambulatory + 68 shared = 115). Operating rooms can be licensed either under a hospital license or an ASC that does not operate under a hospital license. Many, but not all outpatient surgical services can either be performed in a hospital licensed operating room or in a non-hospital licensed operating room (ASC); the cost for a given procedure is typically lower if performed in a freestanding ASC operating room rather than a hospital operating room.

ASCs offer valuable surgical and procedural services at a lower cost when compared to hospital charges for the same outpatient services. Medicare payments to ASCs are lower than or equal to Medicare payments to hospital outpatient departments (HOPD) for comparable services for 100 percent of procedures.

In this review, two applicants propose to add two ORs at existing hospitals: DRAH and Rex Hospital. All other applicants propose to develop new freestanding ASCs. Therefore, as to patient access to freestanding outpatient surgical services Green Level ASC, UNC Health Care Panther Creek, Rex Surgery Center of Garner, WakeMed Surgery Center North Raleigh, WakeMed Surgery Center Cary, RAC Surgery Center, and OrthoNC ASC are all equally effective alternatives.

Among hospital applications, DRAH's existing volumes generated the need for additional operating room capacity in the county and its application is a more effective alternative than Rex Hospital for reasons stated above. Combined, DRAH's two applications will provide both inpatient and outpatient surgical services needed in the service area.

Patient Access to Multiple Surgical Specialties

DRAH and Rex Hospital each provide access to a wide array of surgical specialties.

DUHS’s proposed Green Level ASC will be a multi-specialty facility providing general surgery, gynecology, ophthalmology, orthopaedic, otolaryngology, neurology, plastic, urology, and vascular surgery (**nine specialties**).

WakeMed Surgery Center-North Raleigh proposes a multi-specialty facility providing general surgery, orthopaedic, gynecology, urology, ophthalmology, and plastic surgery (**six specialties**).

WakeMed Surgery Center-Cary proposes a multi-specialty facility providing general surgery, orthopaedic, gynecology, urology, and ophthalmology (**five specialties**).

Rex Surgery Center of Garner proposes a multi-specialty facility providing otolaryngology, orthopaedic, and general surgery (**three specialties**).

UNC Health Care Panther Creek ASC proposes a multi-specialty facility providing otolaryngology, plastic, and general surgery (**three specialties**).

RAC Surgery Center proposes a **single-specialty** (vascular) ASC.

OrthoNC ASC proposed a **single-specialty** (orthopaedic) ASC.

**Comparative Factor:
 Patient Access to Multiple Surgical Specialties**

Applicant	Patient Access to Multiple Surgical Specialties
Green Level ASC	Most Effective
Duke Raleigh Hospital	Most Effective
UNC Health Care Panther Creek ASC	Less Effective
Rex Surgery Center of Garner	Less Effective
Rex Hospital	Most Effective
WakeMed Surgery Center North Raleigh	Less Effective
WakeMed Surgery Center Cary	Less Effective
RAC Surgery Center	Least Effective
OrthoNC ASC	Least Effective

Therefore, with regard to providing Wake County patients with access to more multiple surgical specialties DRAH, Rex Hospital, and Green Level ASC are the most effective alternatives, while RAC Surgery Center and OrthoNC ASC are the least effective alternatives.

History of Developing OR Projects

Two of the UNC Health Care system's recent Wake County operating room projects have experienced significant delays. In Project No. J-11161-16, UNC Health Care proposed the creation of a new ambulatory surgery center by relocating one operating room from Raleigh Orthopedics Surgery Center; the ASC was originally proposed to be in service in September 2018. In the project's latest progress report dated June 1, 2018, however, it offered a "tentative" opening date of December 2019, at least 15 months from now, having not yet broken ground at that date.

Similarly, in Project No. J-8669-11, Rex Healthcare proposed the development of a new hospital with 3 operating rooms. Its original CON, issued in 2014, included a projected offering of services in February 2017. However, in its most recent progress report dated July 13, 2018, Rex states that it "held off beginning the Holly Springs project" in order first to proceed with its heart hospital project. The project is still in the design stage, and Rex now projects an opening date of 2020. These significant delays call into question both the need for any new operating room projects within the system as well as UNC Health Care's ability and intention to complete any additional operating room projects as proposed. Therefore, UNC Health Care Panther Creek ASC, Rex Surgery Center of Garner, Rex Hospital are the least effective alternatives with regard to this factor.

Access by Underserved Groups

Due to significant differences in the types of surgical services proposed by the applicants for each location which naturally serve varying patient populations by age, it is not possible to make conclusive comparisons with regard to percentage of Medicare/Medicaid cases.

Projected Average Net Revenue per Case

Due to significant differences in the types of surgical services proposed by the applicants for each location which have widely varying costs and reimbursements, it is not possible to make conclusive comparisons with regard to net revenue per surgical case.

Projected Average Operating Expense per Case

Due to significant differences in the types of surgical services proposed by the applicants for each location which have widely varying costs, it is not possible to make conclusive comparisons with regard to operative expense per surgical case.

Comments regarding Rex Surgery Center of Garner, LLC /CON Project I.D. #B-11520-18

General Comments

Rex Surgery Center of Garner is wholly-owned by Rex Hospital, Inc. and the University of North Carolina (UNC) Health Care System is the sole member and parent of Rex Healthcare, Inc. UNC Health Care has the second highest number of approved and operational ORs in the Wake County OR service area [(3 inpatient + 7 ambulatory + 24 shared = 34 ORs) + 4 ambulatory ORs (ROSC & ROSC-West Cary) = 38 ORs].² The UNC Health Care System already includes four existing and approved ASCs (ROSC, ROSC-West Cary, Rex Surgery Center of Cary, Rex Surgery Center of Wakefield) and two hospitals (UNC Rex Hospital and UNC Rex Hospital Holly Springs). With this extensive inventory of ORs and facility locations, the 2018 SMFP projects a surplus of ORs for UNC Health Care. Data from Table 6B of the 2018 SMFP is provided below for reference.

Table 6B: Wake County Projected OR Need for 2020, 2018 SMFP

Facility	2020 Projected OR Deficit (Surplus)
Raleigh Orthopaedic Surgery Center -West Cary	-1.00
Raleigh Orthopaedic Surgery Center	0.37
<i>Raleigh Orthopaedic Total</i>	-0.63
Rex Holly Springs	-3.00
Rex Wakefield	-2.00
Rex Cary	-0.97
Rex Hospital	3.95
<i>UNC Health Care Total</i>	-2.02
Capital City Surgery Center	-2.26
WakeMed	3.47
WakeMed Cary	-3.93
<i>WakeMed Total</i>	-2.72
Blue Ridge Surgery Center	-3.00
Duke Raleigh Hospital	6.77
Holly Springs Surgery Center	-3.00
Raleigh Plastic Surgery Center	-0.00
Triangle Orthopaedics Surgery Center	-2.00

Source: Table 6B: Projected OR Need for 2020 (Column M), 2018 SMFP
 UNC Health Care states on page 32 of the Rex Surgery Center of Garner CON application that it “believes that both hospital-based and freestanding (ASC) operating rooms should be approved in this review.” As described previously in this document, the

² Source: Table 6A: OR Inventory and Grouping, 2018 SMFP

need determination for six ORs in the 2018 SMFP is based solely on the surgical utilization at DRAH and the need for additional surgical capacity to accommodate the growth of DUHS surgical cases. DUHS is the only hospital system in Wake County without a freestanding ASC. The proposed Green Level ASC project will represent a new opportunity for Wake County residents and DUHS patients to access surgical services separate from the hospital charge structure; therefore, creating a new ASC provider in Wake County. By contrast, the Rex Surgery Center of Garner application is inconsistent with the documented 2018 SMFP surplus of ORs for UNC Health Care, and the proposal will not promote competition in Wake County.

For these reasons and the reasons previously described in this document, the Rex Surgery Center of Garner application is comparatively inferior to DUHS’s Green Level ASC application

Comments specific to Criterion 1

Rex Surgery Center of Garner does not adequately demonstrate that the projected utilization is based on reasonable and adequately supported assumptions. See discussion regarding Criterion 3. Therefore, Rex Surgery Center of Garner does not adequately demonstrate its proposal would maximize healthcare value. Consequently, the application is not consistent with Policy GEN-3 and is not conforming to Criterion 1.

Comments specific to Criterion 3 and Rules

Rex Surgery Center of Garner failed to demonstrate that its projected surgical utilization is based on reasonable and supported assumptions.

UNC Health Care Ambulatory Surgery Growth Rate

Page 3 of Section Q states, “*UNC Rex has experienced a planned and deliberate decline in outpatient cases driven by a shift of cases to freestanding ASCs within UNC Health Care.*” However, upon review of UNC Health Care’s outpatient surgical cases, even considering the shift of cases to freestanding ASCs within UNC Health Care, there is little growth in ambulatory surgical utilization. The following table is from page 3 of Section Q of the Rex Surgery Center of Garner CON application.

Outpatient Surgical Cases

	UNC Rex Hospital	Rex Surgery Center of Cary	Raleigh Orthopaedic Surgery Center	UNC Health Care Total Wake County Facilities

FFY 2012	17,059	4,350	N/A	21,409
FFY 2013	15,993	5,108	411	21,512
FFY 2014	13,702	4,735	3,148	21,585
FFY 2015	13,216	4,145	3,739	21,100
FFY 2016	13,026	3,786	3,766	20,578
FFY 2017	12,636	4,854	4,384	21,874
CAGR 2012-2017	-5.8%	2.2%	N/A	0.4%

Source: Rex Surgery Center of Garner CON application: Section Q, page 3

If there were truly a shift of ambulatory cases from hospital-based settings to freestanding ASC settings in the UNC Health Care system accompanied by a growth in demand for outpatient surgery services, then the negative growth rate exhibited at UNC Rex Hospital would be more than offset by the growth rate at its freestanding ASC. Instead, the net change in ambulatory cases for UNC Health Care in Wake County is near zero. In five years (2012-2017) the total number of ambulatory surgical cases for the UNC system in Wake County increased by only 465 cases (2017: 21,874 - 2012: 21,409).

Acknowledging the stagnant growth of its ambulatory surgical cases, UNC Health Care projects that its outpatient volume will remain constant from SFY 2018 through SFY 2024. This rationale is inconsistent with its described need to develop two additional ASCs in Wake County (Rex Surgery Center of Garner and UNC Health Care Panther Creek ASC). As described previously, Table 6B of the 2018 SMFP projects a surplus of 2.65 ORs for UNC Health Care (2.02 + 0.63) by 2020. It is important to note the 2018 SMFP methodology incorporates a Growth Factor based on each service area's projected population change between the data year and the target year for need projections. The Growth Factor for Wake County is 8.67% from 2016 to 2020. Thus, despite this Growth Factor, the 2018 SMFP projects a surplus of nearly three ORs for UNC Health Care by 2020. UNC Health Care's assumption of zero growth in ambulatory surgical cases during SFY 2018 to SFY 2024, would result in an even greater surplus of ORs.

Given the projected growth of the Wake County population, continued medical and technological advancements, and financial incentives from payors to utilize lower cost settings (like ASCs), the demand of outpatient surgical cases performed in Wake County is likely to increase, just as it has in recent years. Zero growth at existing UNC Health Care facilities which are already projected to have a surplus of ORs – while undoubtedly consistent with the historical lack of increased demand for services at these locations – is inconsistent with the need for UNC Health Care to develop yet more ORs in Wake County. Therefore, the need for Rex Surgery Center of Garner is not supported by UNC Health Care's assumption that its system-wide outpatient surgery cases will experience zero growth during each of the next six years.

Rex Surgery Center of Garner Surgical Cases

The methodology for projecting surgical cases at the proposed Rex Surgery Center of Garner is described on pages 13-15 of CON Project ID J-11553-18. UNC Health Care states four existing surgeons anticipate performing incremental surgical cases at the new facility; however, these four surgeons are projected to perform only 20 total cases (5 total cases per physician) by the third project year. The remainder of the projected surgical cases “are expected to be incremental to UNC Health Care and are not expected to recruit from existing sites of care.” In other words, the vast majority (99%) of projected surgical cases at Rex Surgery Center of Garner will be the result of new market share attributed to physicians who have yet to be recruited or identified. The following table summarizes Rex Surgery Center of Garner’s projected surgical cases.

Rex Surgery Center of Garner

<i>Specialty</i>	<i>Practice</i>	<i>Physician</i>	<i>Projected OR Cases</i>
Neurological Surgery	Rex Neurosurgery and Spine Clinic	Robert Lacin	5
Neurological Surgery	Rex Neurosurgery and Spine Clinic	Robin Koleveld	5
Neurological Surgery	Rex Neurosurgery and Spine Clinic	Grant Buttram	5
Neurological Surgery	Rex Neurosurgery and Spine Clinic	Engler (New Recruit)	5
ENT	Rex Physicians	New Recruit	280
Ortho	Rex Physicians	New Recruit	180
Podiatry	Rex Physicians	New Recruit	420
General Surgery	Rex Physicians	New Recruit	180
Ortho	Raleigh Orthopaedic Clinic	New Recruit	910
Total			1,990

Source: Rex Surgery Center of Garner CON application: Section Q, page 13

The applicant refers to Exhibit I.2 for letters of support indicating the intention to recruit or relocate surgeons. Exhibit I.2 contains letters from Bob Ricker, Vice President, Physician Services and Sean Tehrani, MD, Vice President of Regional Hospitalist Services and Neurosciences Service Line at UNC Rex stating their respective intent to recruit new physicians. However, Rex identifies no new physicians by name, nor does Rex describe any active efforts to recruit new physicians. In other words, it is UNC Health Care’s strategy to recruit the physicians IF the Rex Surgery Center of Garner application is approved. This equates to a “Build it and they will come” approach.

Additionally, the Rex letters do not contain any information regarding the assumptions or methodology used to project OR cases for each new physician anticipated to be recruited and who will purportedly utilize the proposed new ASC. Furthermore, Section Q does not contain any information regarding the assumptions or methodology used to project OR cases for each new physician to be recruited and who will utilize the proposed new ASC.

Page 13 of Section Q states that Rex estimated surgical case volumes for each surgeon based on the following:

- The historical experience of UNC Rex-affiliated surgeons within these specialties;
- The amount of time that each surgeon is expected to practice at the proposed facility;
- The specialty or sub-specialty mix of the expected procedures; and,
- The expertise of the administrator or clinicians leading each service line.

These four statements are not sufficient to demonstrate the projected surgical utilization is based on reasonable and supported assumptions. Specifically:

- UNC Health Care failed to provide any information regarding the historical experience of UNC Rex-affiliated surgeons by specialty. No historical utilization by physician by specialty was described or provided in the application.
- UNC Health Care failed to provide any information in its application regarding the amount of time that each surgeon is expected to practice at the proposed facility. Indeed, the physicians who purportedly will perform 90 percent of the surgical cases at Rex Surgery Center of Garner have not even been identified or recruited. Thus, the applicant's reference to this assumption is in no way reasonable or supported.
- UNC Health Care failed to provide any information in its application regarding the mix of surgical cases by specialty or sub-specialty to be performed at the proposed facility. Indeed, the physicians purportedly responsible for performing 90 percent of the surgical cases at Rex Surgery Center of Garner have not even been identified or recruited. Thus, the applicant's reference to this assumption is in no way reasonable or supported.
- While UNC Health Care provided letters from Vice Presidents responsible for recruitment of new physicians, no information is provided in the application regarding the historical experience of surgeons by specialty.
- To the extent that UNC Health Care posits that the mere fact of recruiting new physicians will generate additional volumes, this is contradicted by the recent lack of growth throughout the system. Either UNC Health Care has not recruited any new surgeons in the past five years – which would make its proposed recruitment plans questionable – or such recruitment is not correlated to increased utilization.

There is zero information available in the Rex Surgery Center of Garner application to describe how the specific numbers of projected OR cases by physician (most of whom

have not yet been recruited or identified) to be performed at the new facility were calculated or derived. Absent this critical information and based on the reasons previously described, the Rex Surgery Center of Garner is not conforming to Criterion 3 and 10A NCAC 14C .2103(a) because projected surgical utilization is not based on reasonable and adequately supported assumptions.

Comments specific to Criterion 4

On page 69 of the Rex Surgery Center of Garner CON application, UNC Health Care describes that the project is needed to increase access for Johnston County residents stating, “*there are no existing or approved surgical ASCs in Johnston County...*”. However, in 2014, Johnston Health finalized a partnership with UNC Health Care whereby UNC Health Care obtained part ownership of Johnston Health Services Corp. which operates two hospitals in Johnston County (Johnston Health in Smithfield and Johnston Health Clayton in Clayton). Therefore, UNC Health Care maintains ownership in existing health service facilities with ORs in Johnston County. If access to freestanding, non-hospital based ORs is such a priority to UNC Health Care, it in fact directly has the means to pursue establishing such access in Johnston County. For example, according to Table 6B of the 2018 SMFP, Johnston Health is projected to have a surplus of 2.19 ORs by 2020. Therefore, it is conceivable that Johnston Health could relocate two existing ORs to develop a new freestanding ASC in Johnston County (subject to CON approval). In fact, UNC Health Care is the only provider who can do this.

Moreover, the needs of Johnston County residents should not be a significant factor in this CON batch review because Johnston County is not included in the applicable OR service area (i.e., Wake County) for the six need-determined ORs. Furthermore, as previously described, UNC Health Care has available alternatives for meeting the need for ambulatory surgical services in Johnston County.

Finally, Rex Surgery Center of Garner does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because it is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative, and is therefore non-conforming to Criterion 4.

Comments specific to Criterion 5

Rex Surgery Center of Garner does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. See discussion regarding Criterion 3. Therefore, Rex Surgery Center of Garner does not adequately demonstrate its proposal is based upon reasonable projections of the costs of and charges for providing health services. Consequently, the application is not conforming to Criterion 5.

Comments specific to Criterion 6

Rex Surgery Center of Garner did not adequately demonstrate that its proposal would not result in unnecessary duplication of surgical services in Wake County. Specifically, Rex Surgery Center of Garner did not adequately demonstrate in its application that the new ORs it proposes to develop are needed, and that it will not unnecessarily duplicate the ORs that UNC Health Care already owns in Wake County and that demonstrate a surplus of capacity. See discussion regarding projected utilization in Criterion 3. Therefore, the Rex Surgery Center of Garner application is non-conforming to Review Criterion 6.

Comments specific to Criterion 12

Rex Surgery Center of Garner did not adequately document its proposed site in Garner. Specifically, on page 90 of its application Rex Surgery Center of Garner indicates the proposed primary site is on Timber Drive East. The letter in Exhibit F.1 does not specifically identify the parcel of land that is proposed. Timber Drive East is a road that is at least one mile long, and without an address and no other documentation included in the application, it is undefined and unclear as to which parcel of land is targeted for the proposed project. Further, the applicant claims that the proposed site is zoned appropriate for development of the proposed project, but offers no supporting documentation to validate that statement. This is particularly important because the applicant did not otherwise disclose the specific targeted site. Without documentation there is no way for the applicant or the CON Project Analyst to validate necessary information about the site. Therefore, the Rex Surgery Center of Garner application did not demonstrate that the proposed construction represents the most reasonable alternative, and is non-conforming to Review Criterion 12.

Comments specific to Criterion 18a

For the same reasons that the Rex Surgery Center of Garner application is non-conforming with Criteria 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a. In simply adding to an existing surplus within the UNC Health Care system, this project would not enhance competition and the project will not have a positive impact on the cost effectiveness, quality and access to the proposed services. UNC Health Care did not adequately demonstrate the financial feasibility of the proposal and did not reasonably identify the need the population has for the proposed service.

Comments regarding UNC Health Care Panther Creek Ambulatory Surgery Center /CON Project I.D. #J-11554-18

General Comments

UNC Health Care has the second highest number of ORs in the Wake County OR service area [(3 inpatient + 7 ambulatory + 24 shared = 34 ORs) + 4 ambulatory ORs (ROSC & ROSC-West Cary) = 38 ORs].³ The UNC Health Care System includes four existing and approved ASCs (ROSC, ROSC-West Cary, Rex Surgery Center of Cary, Rex Surgery Center of Wakefield) and two hospitals (UNC Rex Hospital and UNC Rex Hospital Holly Springs). With this extensive inventory of ORs and facility locations, the 2018 SMFP projects a surplus of ORs for UNC Health Care. Data from Table 6B of the 2018 SMFP is provided below for reference.

Table 6B: Wake County Projected OR Need for 2020, 2018 SMFP

Facility	2020 Projected OR Deficit (Surplus)
Raleigh Orthopaedic Surgery Center -West Cary	-1.00
Raleigh Orthopaedic Surgery Center	0.37
<i>Raleigh Orthopaedic Total</i>	-0.63
Rex Holly Springs	-3.00
Rex Wakefield	-2.00
Rex Cary	-0.97
Rex Hospital	3.95
<i>UNC Health Care Total</i>	-2.02
Capital City Surgery Center	-2.26
WakeMed	3.47
WakeMed Cary	-3.93
<i>WakeMed Total</i>	-2.72
Blue Ridge Surgery Center	-3.00
Duke Raleigh Hospital	6.77
Holly Springs Surgery Center	-3.00
Raleigh Plastic Surgery Center	-0.00
Triangle Orthopaedics Surgery Center	-2.00

Source: Table 6B: Projected OR Need for 2020 (Column M), 2018 SMFP

³ Source: Table 6A: OR Inventory and Grouping, 2018 SMFP

UNC Health Care states on page 31 of the Panther Creek ASC CON application it “believes that both hospital-based and freestanding (ASC) operating rooms should be approved in this review.” As described previously in this document, the need determination for six ORs in the 2018 SMFP is based solely on the surgical utilization at DRAH and the need for additional surgical capacity to accommodate the growth of DUHS surgical cases. DUHS is the only hospital system in Wake County without a freestanding ASC. The proposed Green Level ASC project will represent a new opportunity for Wake County residents and DUHS patients to access surgical services separate from the hospital charge structure; therefore, creating a new ASC provider in Wake County. By contrast, the Panther Creek ASC application is inconsistent with the documented 2018 SMFP surplus of ORs for UNC Health Care and the proposal will not promote competition in Wake County.

For these reasons and the reasons previously described in this document, the Panther Creek ASC application is comparatively inferior to DUHS’s Green Level ASC application.

Comments specific to Criterion 1

UNC Health Care does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. See discussion regarding Criterion 3. Therefore, UNC Health Care does not adequately demonstrate its proposal would maximize healthcare value. Consequently, the application is not consistent with Policy GEN-3 and is not conforming to Criterion 1.

Comments specific to Criterion 3 and Rules

UNC Health Care failed to demonstrate that surgical utilization is based on reasonable and supported assumptions.

UNC Health Care Ambulatory Surgery Growth Rate

Page 3 of Section Q states, “*UNC Rex has experienced a planned and deliberate decline in outpatient cases driven by a shift of cases to freestanding ASCs within UNC Health Care.*” However, upon review of UNC Health Care’s outpatient surgical cases, even considering the shift of cases to freestanding ASCs within UNC Health Care, there is little growth in ambulatory surgical utilization. The following table is from Section Q of the UNC Health Care Panther Creek CON application.

	UNC Rex Hospital	Rex Surgery Center of Cary	Raleigh Orthopaedic Surgery Center	UNC Health Care Total Wake County Facilities
FFY 2012	17,059	4,350	N/A	21,409
FFY 2013	15,993	5,108	411	21,512
FFY 2014	13,702	4,735	3,148	21,585
FFY 2015	13,216	4,145	3,739	21,100
FFY 2016	13,026	3,786	3,766	20,578
FFY 2017	12,636	4,854	4,384	21,874
CAGR 2012-2017	-5.8%	2.2%	N/A	0.4%

Source: Panther Creek ASC CON application: Section Q, page 3

If there were truly a shift of ambulatory cases from hospital-based settings to freestanding ASC settings in the UNC Health Care system accompanied by a growth in demand for outpatient surgery services, then the negative growth rate exhibited at UNC Rex Hospital would be more than offset by the growth rate at its freestanding ASC. Instead, the net change in ambulatory cases for UNC Health Care in Wake County is near zero. In five years (2012-2017) the total number of ambulatory surgical cases for the UNC system in Wake County increased by only 465 cases (2017: 21,874 - 2012: 21,409).

Acknowledging the stagnant growth of its ambulatory surgical cases, UNC Health Care projects that its outpatient volume will remain constant from SFY 2018 through SFY 2024. This rationale is inconsistent with its described need to develop two additional ASCs in Wake County (Rex Surgery Center of Garner and UNC Health Care Panther Creek ASC). As described previously, the 2018 SMFP projects a surplus of 2.65 ORs for UNC Health Care (2.02 + 0.63) by 2020. It is important to note the 2018 SMFP methodology incorporates a Growth Factor based on each service area's projected population change between the data year and the target year for need projections. The Growth Factor for Wake County is 8.67% from 2016 to 2020. Thus, despite this Growth Factor, the 2018 SMFP projects a surplus of nearly three ORs for UNC Health Care by 2020. UNC Health Care's assumption of zero growth in ambulatory surgical cases during SFY 2018 to SFY 2024, would result in an even greater surplus of ORs.

Given the projected growth of the Wake County population, continued medical and technological advancements, and financial incentives from payors to utilize lower cost settings (like ASCs), the demand of outpatient surgical cases performed in Wake County is likely to increase, just as it has in recent years. Zero growth at existing UNC Health Care facilities which are already projected to have a surplus of ORs – while undoubtedly consistent with the historical lack of increased demand for services at these locations -- is

inconsistent with the need for UNC Health Care to develop yet more ORs in Wake County. Therefore, the need for the proposed Panther Creek ASC is not supported by UNC Health Care’s assumption that its system-wide outpatient surgery cases will experience zero growth during each of the next six years.

UNC Health Care Panther Creek ASC Surgical Cases

The methodology for projecting surgical cases at the proposed Panther Creek ASC is described on pages 10-12 of CON Project ID J-11554-18. UNC Health Care states “*the proposed ASC will be the surgical home for seven newly recruited surgeons and one existing surgeon.*” The following table summarizes Rex Surgery Center of Garner’s projected surgical cases.

Rex Surgery Center of Garner

<i>Specialty</i>	<i>Physician</i>	<i>Projected OR Cases</i>
Surgical Oncology	New Recruit	250
General/GI	New Recruit	600
Vascular Surgery	New Recruit	250
Plastics	New Recruit	225
General OB/GYN	New Recruit	100
ENT	New Recruit	250
Urology (Men's Health/Reconstructive Surgery)	Dr. Brad Figler	50
Urology (Men's Health/Reconstructive Surgery)	New Recruit	150
Total		1,875

Source: Rex Surgery Center of Garner CON application: Section Q, page 13

UNC Health Care states, “*these surgical cases are expected to be incremental to UNC Health Care and are not expected to shift cases from existing sites of care.*” In other words, nearly all (97%) the projected surgical cases at Rex Surgery Center of Garner will be the result of new market share attributed to physicians who have yet to be recruited or identified.

The applicant refers to Exhibit I.2 for letters of support indicating the intention to recruit or relocate new surgeons. Exhibit I.2 contains letters from various UNC Hospitals Department Chairs stating their respective intent to recruit new physicians; however, no new physicians are identified by name nor are there any active efforts to recruit new physicians. In other words, it is UNC Health Care’s strategy to recruit the physicians IF

the Panther Creek ASC application is approved. This equates to a “Build it and they will come” approach. Additionally, the letters do not contain any information regarding the assumptions or methodology used to project OR cases for each new physician to be recruited and who will utilize the proposed new ASC. Furthermore, Section Q does not contain any information regarding the assumptions or methodology used to project OR cases for each purported new physician to be recruited who will assumedly utilize the proposed new ASC.

Page 10 of Section Q states, surgical case volumes for each surgeon were estimated based on the following:

- The historical experience of UNC Faculty Physician surgeons within these specialties;
- The amount of time that each surgeon is expected to practice at the proposed facility;
- The specialty or sub-specialty mix of the expected procedures; and,
- The expertise of the administrator or clinicians leading each service line.

These four statements are not sufficient to demonstrate the projected surgical utilization is based on reasonable and supported assumptions. Specifically:

- UNC Health Care failed to provide any information regarding the historical experience of UNC Faculty Physician surgeons by specialty. No historical utilization by physician by specialty was described or provided in the application.
- UNC Health Care failed to provide any information in its application regarding the amount of time that each prospective surgeon is expected to practice at the proposed facility. Indeed, the physicians purportedly responsible for performing 97 percent of the surgical cases at Panther Creek ASC have not even been identified or recruited. Thus, the applicant’s reference to this assumption is in no way reasonable or supported.
- UNC Health Care failed to provide any information in its application regarding the mix of surgical cases by specialty or sub-specialty to be performed at the proposed facility. Indeed, the physicians purportedly responsible for performing 97 percent of the surgical cases at Panther Creek ASC have not even been identified or recruited. Thus, the applicant’s reference to this assumption is in no way reasonable or supported.
- While UNC Health Care provided letters from various UNC Hospitals Department Chairs responsible for the recruitment of the new physicians, no information is provided in the application regarding the historical experience of surgeons by specialty or the basis by which this information may have been used to project surgical cases by physician by specialty at Panther Creek ASC.
- To the extent that UNC Health Care posits that the mere fact of recruiting new physicians will generate additional volumes, this is contradicted by the recent lack of growth throughout the system. Either UNC Health Care has not recruited any

new surgeons in the past five years – which would make its proposed recruitment plans questionable – or such recruitment is not correlated to increased utilization.

There is insufficient information available in the Panther Creek ASC application to describe how the specific numbers of projected OR cases by physician (none of whom have yet to be recruited or identified) to be performed at the new facility were calculated or derived. Absent this critical information and based on the reasons previously described, the Panther Creek ASC is not conforming to Criterion 3 and 10A NCAC 14C .2103(a) because projected surgical utilization is not based on reasonable and adequately supported assumptions.

Comments specific to Criterion 4

As described previously, UNC Health Care does not demonstrate that projected surgical utilization at Panther Creek ASC is based on reasonable and adequately supported assumptions. Therefore, the application is not conforming to Criterion 4.

Moreover, UNC Health Care does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because it is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative, and is therefore non-conforming to Criterion 4.

Comments specific to Criterion 5

UNC Health Care does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. See discussion regarding Criterion 3. Therefore, UNC Health Care does not adequately demonstrate its proposal is based upon reasonable projections of the costs of and charges for providing health services. Consequently, the application is not conforming to Criterion 5.

Comments specific to Criterion 6

UNC Health Care did not adequately demonstrate that its proposal would not result in unnecessary duplication of surgical services in Wake County. Specifically, UNC Health Care did not adequately demonstrate in its application that the new ORs it proposes to develop are needed, and that it will not unnecessarily duplicate the ORs that UNC Health Care already owns in Wake County and that demonstrate a surplus of capacity. See discussion regarding projected utilization in Criterion 3 and below. Therefore, the UNC Health Care application is non-conforming to Review Criterion 6.

Furthermore, projected utilization for Rex Surgery Center of Wakefield, which is part of UNC Health Care, is not based on reasonable or supported assumptions. Section Q, pages 16-17 of UNC Health Care’s CON application describe the methodology for projecting surgical utilization at Rex Surgery Center of Wakefield. The following table summarizes historical surgical utilization at Rex Surgery Center of Wakefield.

Historical Rex Surgery Center of Wakefield Utilization

	<i>SFY15</i>	<i>SFY16</i>	<i>SFY17</i>	<i>SFY18</i>	<i>CAGR</i>
Outpatient Cases	1,555	1,969	1,998	1,356	-4.5%

Source: Rex Surgery Center of Garner CON application: Section Q, page 16

The applicant states SFY 18 cases decreased “*due to the one-time event of changing licensure and reducing capacity by one operating room.*” It is unclear how changing licensure from a hospital-based ASC to a freestanding ASC impacts the volume of surgical cases at an ASC. It is also unclear how the recent reduction in capacity from three ORs to two ORs is consistent with the applicant’s assumption that future surgical cases at Rex Surgery Center of Wakefield will increase 7.1 percent annually during SFY 19 through SFY 2024. Furthermore, the projected growth rate of 7.1 percent is grossly inconsistent with historical surgical utilization at the facility. The applicant attempts to rationalize the growth rate by assimilating it with the growth in OR cases per OR. For example, there were 666 cases performed per OR in SFY 17 ($1,998 \div 3 \text{ ORs} = 666$) and there were 774 cases performed per OR in SFY 18 ($1,356 \div 2 = 774$). However, the recent reduction in capacity from three ORs to two ORs artificially increases the growth rate for the number of OR cases per OR. The denominator changes in the annual calculation of cases per OR; therefore, the applicant’s stated historical growth rate of 14.3% is not representative of actual utilization at the facility. The fact remains that fewer cases were performed at Rex Surgery Center of Wakefield during SFY 18 than during the previous three years, resulting in a compound annual growth rate of -4.5%. The applicant’s assumption that OR cases at Rex Surgery Center of Wakefield will increase 7.1% annually during SFY 19 through SFY 2024 is not supported by this historical utilization. Consequently, UNC Health Care did not adequately demonstrate in its application that it will not unnecessarily duplicate the ORs that UNC Health Care already owns in Wake County.

Comments specific to Criterion 12

UNC Health Care did not adequately document its proposed site in Cary. Specifically, on page 88 of its application UNC Health Care indicates the proposed primary site is on McCrimmon Parkway, but does not specifically identify the parcel of land that is proposed. Without an address and no other documentation included in the application, it is undefined and unclear as to which parcel of land is targeted for the proposed project.

Further, the applicant claims that the proposed site is zoned appropriate for development of the proposed project, but offers no supporting documentation to validate that statement. This is particularly important because the applicant did not otherwise disclose the specific targeted site. Without documentation there is no way for the applicant or the CON Project Analyst to validate necessary information about the site. Therefore, the UNC Health Care application did not demonstrate that the proposed construction represents the most reasonable alternative, and is non-conforming to Review Criterion 12.

Comments specific to Criterion 18a

For the same reasons that the UNC Health Care application is non-conforming with Criteria 3, 4, 5, and 6 it should also be found non-conforming with Criterion 18a. In simply adding to an existing surplus within the UNC Health Care system, this project would not enhance competition and the project will not have a positive impact on the cost effectiveness, quality and access to the proposed services. UNC Health Care did not adequately demonstrate the financial feasibility of the proposal and did not reasonably identify the need the population has for the proposed service.

Comments regarding the Rex Hospital application/CON Project I.D. #J-11555-18

General Comments

UNC Health Care is the sole member and parent of Rex Healthcare, Inc. UNC Health Care has the second highest number of ORs in the Wake County OR service area [(3 inpatient + 7 ambulatory + 24 shared = 34 ORs) + 4 ambulatory ORs (ROSC & ROSC-West Cary) = 38 ORs].⁴ The UNC Health Care System includes four existing and approved ASCs (ROSC, ROSC-West Cary, Rex Surgery Center of Cary, Rex Surgery Center of Wakefield) and two hospitals (UNC Rex Hospital and UNC Rex Hospital Holly Springs). With this extensive inventory of ORs and facility locations, the 2018 SMFP projects a surplus of ORs for UNC Health Care. Data from Table 6B of the 2018 SMFP is provided below for reference.

Table 6B: Wake County Projected OR Need for 2020, 2018 SMFP

Facility	2020 Projected OR Deficit (Surplus)
Raleigh Orthopaedic Surgery Center -West Cary	-1.00
Raleigh Orthopaedic Surgery Center	0.37
<i>Raleigh Orthopaedic Total</i>	-0.63
Rex Holly Springs	-3.00
Rex Wakefield	-2.00
Rex Cary	-0.97
Rex Hospital	3.95
<i>UNC Health Care Total</i>	-2.02
Capital City Surgery Center	-2.26
WakeMed	3.47
WakeMed Cary	-3.93
<i>WakeMed Total</i>	-2.72
Blue Ridge Surgery Center	-3.00
Duke Raleigh Hospital	6.77
Holly Springs Surgery Center	-3.00
Raleigh Plastic Surgery Center	-0.00
Triangle Orthopaedics Surgery Center	-2.00

Source: Table 6B: Projected OR Need for 2020 (Column M), 2018 SMFP

⁴ Source: Table 6A: OR Inventory and Grouping, 2018 SMFP

UNC Health Care states on page 30 of the Rex Hospital CON application it “*believes that both hospital-based and freestanding (ASC) operating rooms should be approved in this review.*” As described previously in this document, the need determination for six ORs in the 2018 SMFP is based solely on the surgical utilization at DRAH and the need for additional surgical capacity to accommodate the growth of DUHS surgical cases. Conversely, the 2018 SMFP projects a surplus of ORs for UNC Health Care.

For these reasons and the reasons previously described in this document, the Rex Hospital CON application is comparatively inferior to DRAH’s CON application.

Comments specific to Criterion 1

Rex Hospital does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. See discussion regarding Criterion 3. Therefore, Rex Hospital does not adequately demonstrate its proposal would maximize healthcare value. Consequently, the application is not consistent with Policy GEN-3 and is not conforming to Criterion 1.

Comments specific to Criterion 3

The methodology for projecting surgical cases at Rex Hospital is described on pages 3-8 of CON Project ID J-11558-18. Inpatient surgical cases are projected based on an annual growth rate of 4.3 percent and ambulatory surgical cases are assumed to remain constant from SFY 2018 to SFY 2024. The applicant then accounts for the projected shifts of surgical cases from Rex Hospital to the approved UNC Rex Holly Springs Hospital and proposed Rex Surgery Center of Garner.

The last assumption of the methodology is based on the shift of 1,050 inpatient surgical cases from UNC Hospitals to Rex Hospital. However, the applicant provides no information regarding how this projection was derived. Although page 6 of Section Q states, “*many UNC Hospitals patients originate from areas that are closer to Raleigh than to Chapel Hill*”, there is no information in the submitted application to describe the number of patients who originate from Raleigh and travel to UNC Hospitals for surgery. Furthermore, the methodology does not describe whether the 1,050 inpatient surgical cases will be patients from Wake County or other counties. Absent any information about the methodology and/or assumptions used to determine a projected shift of 1,050 inpatient surgical cases from UNC Hospitals to Rex Hospital, the projection is unreasonable and not adequately supported. Consequently, Rex Hospital is not conforming to Criterion 3 and 10A NCAC 14C .2103(a) because projected surgical utilization is not based on reasonable and adequately supported assumptions.

Comments specific to Criterion 4

As described previously, Rex Hospital does not demonstrate that projected surgical utilization is based on reasonable and adequately supported assumptions. Therefore, the application is not conforming to Criterion 3.

Moreover, Rex Hospital does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because it is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative, and is therefore non-conforming to Criterion 4.

Comments specific to Criterion 5

As described previously, Rex Hospital does not demonstrate that projected surgical utilization is based on reasonable and adequately supported assumptions. Because Rex Hospital does not reasonably project utilization of its facility, it does not demonstrate the financial feasibility of the proposal. Therefore, the application is not conforming to Criterion 5.

Comments specific to Criterion 6

Rex Hospital did not adequately demonstrate that its proposal would not result in the unnecessary duplication of surgical services in Wake County. Specifically, Rex Hospital did not adequately demonstrate in its application that the new ORs it proposes to develop are needed, and that it will not unnecessarily duplicate the ORs that UNC Health Care already owns in Wake County. See discussion regarding projected utilization in Criterion 3. Therefore, the Rex Hospital application is non-conforming to Review Criterion 6.

Comments specific to Criterion 18a

For the same reasons that the Rex Hospital application is non-conforming with Criteria 1, 3, 4, 5, and 6, it should also be found non-conforming with Criterion (18a). Rex Hospital did not adequately demonstrate the need the population projected to be served has for the proposed project and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of surgical services in Wake County. Thus, the proposed Rex Hospital project will not have a positive impact on competition.

**Comments regarding the WakeMed Surgery Center-North Raleigh application/CON
 Project I.D. #J-11564-18**

General Comments

WakeMed has the greatest number of ORs in the Wake County OR service area [(10 inpatient + 29 shared = 39 ORs) + 8 ambulatory ORs (Capital City Surgery Center) = 47 ORs].⁵ With this inventory of ORs and facility locations, the 2018 SMFP projects a surplus of ORs for WakeMed. Data from Table 6B of the 2018 SMFP is provided below for reference.

Table 6B: Wake County Projected OR Need for 2020, 2018 SMFP

Facility	2020 Projected OR Deficit (Surplus)
Raleigh Orthopaedic Surgery Center -West Cary	-1.00
Raleigh Orthopaedic Surgery Center	0.37
<i>Raleigh Orthopaedic Total</i>	<i>-0.63</i>
Rex Holly Springs	-3.00
Rex Wakefield	-2.00
Rex Cary	-0.97
Rex Hospital	3.95
<i>UNC Health Care Total</i>	<i>-2.02</i>
Capital City Surgery Center	-2.26
WakeMed	3.47
WakeMed Cary	-3.93
<i>WakeMed Total</i>	<i>-2.72</i>
Blue Ridge Surgery Center	-3.00
Duke Raleigh Hospital	6.77
Holly Springs Surgery Center	-3.00
Raleigh Plastic Surgery Center	-0.00
Triangle Orthopaedics Surgery Center	-2.00

Source: Table 6B: Projected OR Need for 2020 (Column M), 2018 SMFP

As described previously in this document, the need determination for six ORs in the 2018 SMFP is based solely on the surgical utilization at DRAH and the need for additional

⁵ Source: Table 6A: OR Inventory and Grouping, 2018 SMFP

surgical capacity to accommodate the growth of DUHS surgical cases. Conversely, the 2018 SMFP projects a surplus of ORs for WakeMed.

As described in the Rex Surgery Center of Garner CON application (Project ID# J-11554-18), Rex Surgery Center of Wakefield was historically licensed as hospital-based ORs and part of UNC Rex Hospital. Pursuant to Project ID# J-10280-14, Rex Surgery Center of Wakefield became a separately licensed ASC in July 2018. Therefore, patients in northern Wake County currently have access to a freestanding ASC via Rex Surgery Center of Wakefield; the proposed WakeMed Surgery Center-North Raleigh will not enhance geographic access to ambulatory surgery services in Wake County.

For these reasons and the reasons previously described in this document, the WakeMed Surgery Center-North Raleigh CON application is comparatively inferior to Green Level ASC's CON application.

Comments specific to Criterion 1

WakeMed Surgery Center-North Raleigh does not adequately demonstrate that the proposed facility will not unnecessarily duplicate existing surgical services. See discussion regarding Criterion 6. Therefore, WakeMed Surgery Center-North Raleigh does not adequately demonstrate its proposal would maximize healthcare value. Consequently, the application is not consistent with Policy GEN-3 and is not conforming to Criterion 1.

Comments specific to Criterion 3

WakeMed Surgery Center-North Raleigh does not adequately demonstrate that the proposed facility will not unnecessarily duplicate existing surgical services. See discussion regarding Criterion 6. Therefore, WakeMed Surgery Center-North Raleigh does not adequately demonstrate the need for its proposed services. Consequently, the application is not conforming to Criterion 3.

Comments specific to Criterion 4

WakeMed Surgery Center-North Raleigh does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because it is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative, and is therefore non-conforming to Criterion 4.

Comments specific to Criterion 5

As described in the discussion regarding Criterion 13, WakeMed provides conflicting information regarding the projected payor mix for the proposed WSCNR. As a result, the applicant did not demonstrate financial feasibility based upon reasonable projections of charges for providing health services. Therefore, WakeMed is non-conforming to Criterion 5, and the CON application is not approvable.

The WakeMed application also includes several inconsistencies with regard to the financial projections. Specifically:

- On page 134, WakeMed states that financing costs are equivalent to 5.5% of total project cost, and interest during construction is assumed to be 4.5% of the total project cost. However, those percentages are not reflected in Form F.1a on page 133. As shown there, the financing cost is \$161,645, which is just 1.43% of total project cost, and interest during construction is \$484,933, which is 4.29% of total project cost.
- The interest expenses do not stack up in Form F.3. Specifically, page 142 references interest expense based on \$8.6M loan at 5.5%, which totals \$473,000. Form F.3 does not show such a figure for interest expense. Further, the \$8.6M loan total does not match the total loan amounts of \$11.4M as indicated in Exhibit F.2.1. Further, none of these figures appears to include any interest expense associated with the working capital requirement of \$1.5M, as indicated on page 53 of the application.
- On page 14 WakeMed projects “*more than \$230,000 in charity care*”. However, Form F.3 on page 136 shows just \$99,600 for charity care.
- On page 142 WakeMed calculates the facility rent to be \$477,731 inflated 3.0% annually. However, on Form F.3 on page 136, the annual rent expense is portrayed as \$430,238 in PY1, \$440,993 in PY2, and \$452,018 in PY3, lower than \$477,731, and representing a 2.5% annual inflation rate, not 3.0%.
- The application reflects three different figures for the size of the proposed facility. Page 77 states 10,500 SF, page 142 states 12,825 SF, and Exhibit F.2.1 indicates 11,000 SF. The actual line drawing included in Exhibit K.1 does not show a square footage total.
- The management agreement in Exhibit A.9 indicates a management fee of 5%; page 142 of the application indicates a management fee of 6%.

For all these reasons, WakeMed did not demonstrate financial feasibility of the proposed project because it did not reasonably project the costs and charges for the proposed health services, and therefore the application is not conforming to Criterion 5.

Comments specific to Criterion 6

Projected utilization for Capital City Surgery Center, in which WakeMed has majority ownership, is not based on reasonable or supported assumptions. As described previously, the 2018 SMFP projects Capital City Surgery Center to have a surplus of 2.26 ORs by 2020. The Proposed 2019 SMFP projects Capital City Surgery Center to have an even larger surplus of 3.52 ORs by 2021. The following table summarizes recent utilization at Capital City Surgery Center.

Capital City Surgery Center Surgical Utilization

	<i>FY2015</i>	<i>FY2016</i>	<i>FY2017</i>	<i>CAGR</i>
Surgical Cases	6,647	6,123	5,388	-10.0%

Source: Section Q, page 121 WakeMed Surgery Center-North Raleigh CON application

As portrayed by the historical surgical utilization provided in WakeMed Surgery Center-North Raleigh’s CON application, Capital City Surgery Center has experienced consistently decreasing volume during recent years, resulting in a negative compound annual growth rate of 10 percent. (By comparison, total ambulatory surgery cases in Wake County increased by a CAGR of 3.25% during the same period of FY201-FY2017.) In stark contrast to the facility’s recent negative growth trend, WakeMed Surgery Center-North Raleigh projects that surgical cases at Capital City Surgery Center will increase 3.93 percent annually beginning FY2018 through FY2023. Notably, the applicant failed to provide surgical utilization for FY2018 year-to-date, which could reflect as much as 10 months data. Regardless, the projected annual growth rate of 3.93 percent at Capital City Surgery Center is in no way supported by the facility’s historical utilization decline. The applicant provides no supporting narrative or documentation to substantiate the reasonableness of a 3.93 percent annual growth rate at Capital City Surgery Center when CCSC has actually been experiencing a recent steady decline in surgical cases. The application did not include letters from physicians indicating their intent to utilize Capital City Surgery Center. Therefore, projected utilization at Capital City Surgery Center is unreasonable and not adequately supported. Consequently, WakeMed Surgery Center-North Raleigh did not demonstrate that its proposed facility is needed in addition to the existing facilities WakeMed currently owns in Wake County. In fact, the proposal unnecessarily duplicates WakeMed’s existing, extensive OR platforms.

Furthermore, WakeMed Surgery Center-North Raleigh incorrectly assessed the inventory of freestanding multispecialty ASC facilities in Wake County and was thus misguided in its assumption that its project would not unnecessarily duplicate existing surgical services in the identified service area. Page 60 of WakeMed Surgery Center-North Raleigh’s

CON application incorrectly states, “*Specifically, northern Wake County, the region where the proposed project will be located, currently has no freestanding multispecialty ASFs...The development of a freestanding multispecialty ASF in northern Wake County will not be duplicative of existing surgical resources.*” However, pursuant to Project ID# J-10280-14, Rex Surgery Center of Wakefield became a separately licensed ASC in July 2018. Moreover, as shown in Section Q, page 16 of the Rex Surgery Center of Garner CON application, the Rex Surgery Center of Wakefield ASC has steadily lost surgical volume during the last four years (-4.5 percent CAGR) and is currently performing only 774 surgical cases per OR (based on annualized SFY18 data described in Project ID# J-11554-18). This indicates there is adequate available capacity at the existing freestanding Rex Surgery Center of Wakefield ASC facility.

Therefore, patients in northern Wake County currently have access to a freestanding ASC via Rex Surgery Center of Wakefield, and the proposed WakeMed Surgery Center-North Raleigh will unnecessarily duplicate existing surgical resources.

Comments specific to Criterion 12

The application reflects three different figures for the size of the proposed facility. Page 77 states 10,500 SF, page 142 states 12,825 SF, and Exhibit F.2.1 indicates 11,000 SF. The actual line drawing included in Exhibit K.1 does not show a square footage total. Without adequate documentation there is no way for the applicant or the CON Project Analyst to validate necessary information about the design and construction, and the inconsistency cannot be reconciled. Therefore, WakeMed did not demonstrate that the means of construction represents the most reasonable alternative, and is non-conforming to Criterion 12.

Comments specific to Criterion 13

WakeMed provides much conflicting information regarding the projected payor mix for the proposed WSCNR. First, on page 14 of the application, WakeMed states that it projects 22.4% of patients will be Medicare, and 6.0% of patients will be Medicaid. This contrasts with the projection found on page 84 which indicates a patient payor mix of 21.7% Medicare and 6.3% Medicaid. The issue of projected access is further obscured by inconsistencies for the projected payor mixes for the operating rooms and the procedure rooms. As shown on the table below, WakeMed provided information on page 84 that conflicts with the payor mix projections utilized in the proforma financials included in Section Q.

WSCNR Payor Mix Projections, PY2

	<i>P.84 Medicare</i>	<i>Section Q Medicare</i>	<i>P.84 Medicaid</i>	<i>Section Q Medicaid</i>	<i>P.84 Self-Pay/Charity Care</i>	<i>Section Q Self-Pay/Charity Care</i>
Operating Rooms	14.1%	13.3%	7.8%	8.7%	1.8%	1.6%
Procedure Rooms	50.9%	57.6%	6.0%	2.9%	0.9%	0.8%

Source: Page 84 & Section Q, pages 137-138 WakeMed Surgery Center-North Raleigh CON application

On page 84, WakeMed states that it “used the FY2017 outpatient surgery payer mixes for WakeMed North Hospital and Capital City Surgery Center as the basis for projecting payer mix in this application.” However, WakeMed did not actually include any backing data or support for the assumptions in its application. So, there is no way for the CON Project Analyst to be able to attempt to reconcile the conflicting payor mix data, nor to determine which, if either, of the payor mix projections is accurate. Therefore, WakeMed is non-conforming to Criterion 13c because it did not adequately identify the extent to which each medically underserved group is expected to utilize the proposed services.

Comments specific to Criterion 18a

For the same reasons that the WakeMed Surgery Center-North Raleigh application is non-conforming with Criteria 3, 4, 5, 6 and 13 it should also be found non-conforming with Criterion 18a. In simply adding to an existing surplus within the WakeMed system, this project would not enhance competition and the project will not have a positive impact on the cost effectiveness, quality and access to the proposed services. WakeMed did not adequately demonstrate the financial feasibility of the proposal, did not adequately demonstrate access to the proposed services, and did not reasonably identify the need the population has for the proposed service.

Comments regarding the WakeMed Surgery Center-Cary application/CON Project I.D. #J-11565-18

General Comments

WakeMed has the greatest number of ORs in the Wake County OR service area [(10 inpatient + 29 shared = 39 ORs) + 8 ambulatory ORs (Capital City Surgery Center) = 47 ORs].⁶ Despite this vast inventory of ORs and facility locations, the 2018 SMFP projects a surplus of ORs for WakeMed. Data from Table 6B of the 2018 SMFP is provided below for reference.

Table 6B: Wake County Projected OR Need for 2020, 2018 SMFP

Facility	2020 Projected OR Deficit (Surplus)
Raleigh Orthopaedic Surgery Center -West Cary	-1.00
Raleigh Orthopaedic Surgery Center	0.37
<i>Raleigh Orthopaedic Total</i>	<i>-0.63</i>
Rex Holly Springs	-3.00
Rex Wakefield	-2.00
Rex Cary	-0.97
Rex Hospital	3.95
<i>UNC Health Care Total</i>	<i>-2.02</i>
Capital City Surgery Center	-2.26
WakeMed	3.47
WakeMed Cary	-3.93
<i>WakeMed Total</i>	<i>-2.72</i>
Blue Ridge Surgery Center	-3.00
Duke Raleigh Hospital	6.77
Holly Springs Surgery Center	-3.00
Raleigh Plastic Surgery Center	-0.00
Triangle Orthopaedics Surgery Center	-2.00

Source: Table 6B: Projected OR Need for 2020 (Column M), 2018 SMFP

As described previously in this document, the need determination for six ORs in the 2018 SMFP is based solely on the surgical utilization at DRAH and the need for additional

⁶ Source: Table 6A: OR Inventory and Grouping, 2018 SMFP

surgical capacity to accommodate the growth of DUHS surgical cases. Conversely, the 2018 SMFP projects a surplus of ORs for WakeMed.

For these reasons and the reasons previously described in this document, the WakeMed Surgery Center-Cary CON application is comparatively inferior to Green Level ASC's CON application.

Comments specific to Criterion 1

WakeMed Surgery Center-Cary does not adequately demonstrate that the proposed facility will not unnecessarily duplicate existing surgical services. See discussion regarding Criterion 6. Therefore, WakeMed Surgery Center-Cary does not adequately demonstrate its proposal would maximize healthcare value. Consequently, the application is not consistent with Policy GEN-3 and is not conforming to Criterion 1.

Comments specific to Criterion 3

WakeMed Surgery Center-Cary does not adequately demonstrate that the proposed facility will not unnecessarily duplicate existing surgical services. See discussion regarding Criterion 6. Therefore, WakeMed Surgery Center-Cary does not adequately demonstrate the need for its proposed services. Consequently, the application is not conforming to Criterion 3.

Comments specific to Criterion 4

WakeMed Surgery Center-Cary does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because it is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative, and is non-conforming to Criterion 4.

Comments specific to Criterion 5

As described below in the discussion regarding Criterion 13, WakeMed provides conflicting information regarding the projected payor mix for the proposed WSCC. As a result, the applicant did not demonstrate financial feasibility based upon reasonable projections of charges for providing health services. Therefore, WakeMed is non-conforming to Criterion 5, and the CON application is not approvable.

The WakeMed application also includes several inconsistencies with regard to the financial projections. Specifically:

- On page 132, WakeMed states that financing costs are equivalent to 5.5% of total project cost, and interest during construction is assumed to be 4.5% of the total project cost. However, those percentages are not reflected in Form F.1a on page 131. As shown there, the financing cost is \$122,839, which is just 1.43% of total project cost, and interest during construction is \$368,517, which is 4.29% of total project cost.
- The interest expense shown on Form F.3 on page 134 does not reflect any interest associated with the working capital requirement of \$1.5M, as indicated on page 54 of the application.
- On page 14 WakeMed projects “*more than \$490,000 in charity care*”. However, Form F.3 on page 134 shows just \$210,039 for charity care.
- On page 140 WakeMed states the facility rent will be inflated 3.0% annually. However, on Form F.3 on page 134, the annual rent expense inflation rate is actually 2.5% annually, not 3.0%.
- The application reflects three different figures for the size of the proposed facility. Page 75 states 11,250 SF, page 142 states 12,825 SF, and Exhibit F.2 indicates 11,000 SF. The actual line drawing included in Exhibit K.1 does not show a square footage total.
- The management agreement in Exhibit A.9 indicates a management fee of 5%; page 140 of the application indicates a management fee of 6%.

For all these reasons, WakeMed did not demonstrate financial feasibility of the proposed project because it did not reasonably project the costs and charges for the proposed health services, and therefore the application is not conforming to Criterion 5.

Comments specific to Criterion 6

Projected utilization for Capital City Surgery Center, of which WakeMed has majority ownership, is not based on reasonable or supported assumptions. As described previously, the 2018 SMFP projects Capital City Surgery Center to have a surplus of 2.26 ORs by 2020. The Proposed 2019 SMFP projects Capital City Surgery Center to have a surplus of 3.52 ORs by 2021. The table below summarizes recent utilization at Capital City Surgery Center.

Capital City Surgery Center Surgical Utilization

	<i>FY2015</i>	<i>FY2016</i>	<i>FY2017</i>	<i>CAGR</i>
Surgical Cases	6,647	6,123	5,388	-10.0%

Source: Section Q, page 119 WakeMed Surgery Center-Cary CON application

As demonstrated by the historical surgical utilization provided in WakeMed Surgery Center-Cary’s CON application, Capital City Surgery Center has experienced consistently decreasing volume during recent years, resulting in a negative compound annual growth rate of 10 percent. In stark contrast to the facility’s negative growth trend, WakeMed Surgery Center-Cary projects that surgical cases at Capital City Surgery Center will increase 3.93 percent annually beginning FY2018 through FY2023. Notably, the applicant failed to provide surgical utilization for FY2018 year-to-date, which could reflect as much as 10 months data. Regardless, the projected annual growth rate of 3.93 percent at Capital City Surgery Center is in no way supported by the facility’s historical utilization. The applicant provides no supporting narrative or documentation to substantiate the reasonableness of a 3.93 percent annual growth rate at Capital City Surgery Center. For example, no explanation is provided in the application as to why surgical cases have been steadily declining at Capital City Surgery Center and the application did not include letters from physicians indicating their intent to utilize Capital City Surgery Center. Therefore, projected utilization at Capital City Surgery Center is unreasonable and not adequately supported. Consequently, WakeMed Surgery Center-Cary did not demonstrate that its proposed facility is needed in addition to the facilities WakeMed currently maintains ownership in Wake County.

Comments specific to Criterion 13

WakeMed provides conflicting information regarding the projected payor mix for the proposed WSCC. First, on page 14 of the application, WakeMed states that it projects 22.3% of patients will be covered by Medicare. This contrasts with the projection found on page 83 which indicates a patient payor mix of 22.0% Medicare. The issue of projected access is further obscured by inconsistencies for the projected payor mixes for the operating rooms and the procedure rooms. As shown on the table below, WakeMed provided information on page 83 that differs from the payor mix projections utilized in the proforma financials included in Section Q.

WSCC Payor Mix Projections, PY2

	<i>P.83 Medicare</i>	<i>Section Q Medicare</i>	<i>P.83 Medicaid</i>	<i>Section Q Medicaid</i>	<i>P.83 Self- Pay/Charity Care</i>	<i>Section Q Self- Pay/Charity Care</i>
Operating Rooms	16.8%	16.9%	4.2%	4.2%	3.0%	2.9%
Procedure Rooms	41.9%	44.5%	2.5%	2.4%	2.1%	2.0%

Source: Page 83 & Section Q, pages 135-136 WakeMed Surgery Center-Cary CON application

On page 83, WakeMed states that it “*used the FY2017 outpatient surgery payer mixes for WakeMed North Hospital and Capital City Surgery Center as the basis for projecting payer mix in this application.*” However, WakeMed did not actually include any backing data or support for the assumptions in its application. So, there is no way for the CON Project Analyst to be able to attempt to reconcile the conflicting payor mix data, nor to determine which, if either, of the payor mix projections is the right one. Therefore, WakeMed is non-conforming to Criterion 13c because it did not adequately identify the extent to which each medically underserved group is expected to utilize the proposed services.

Comments specific to Criterion 18a

For the same reasons that the WakeMed Surgery Center-Cary application is non-conforming with Criteria 3, 4, 5, 6 and 13 it should also be found non-conforming with Criterion 18a. In simply adding to an existing surplus within the WakeMed system, this project would not enhance competition and the project will not have a positive impact on the cost effectiveness, quality and access to the proposed services. WakeMed did not adequately demonstrate the financial feasibility of the proposal, did not adequately demonstrate access to services, and did not reasonably identify the need the population has for the proposed service.

In 2016, WakeMed filed comments regarding a proposed ASC application filed by Raleigh Orthopaedic Surgery Center – West Cary (Project I.D. J.11161-16). In those comments, opposing the development of a new ambulatory surgery center in West Cary, WakeMed stated that that project

“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 equality. 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.” (WakeMed Comments, page 10.)

Those same issues would appear to apply equally to WakeMed’s own ASC proposal.

Comments regarding the OrthoNC ASC, Inc. application/CON Project I.D. #J-11561-18

General Comments

OrthoNC ASC proposes to develop a 1-OR single-specialty ASC less than ½ mile from Rex Healthcare of Wakefield. Therefore, the proposal will not enhance geographic access to new surgical services in Wake County.

Because OrthoNC ASC's proposal is for a 1-OR single-specialty ASC, the extent to which this project would provide access to an alternative provider is much more limited compared to Green Level ASC. Additionally, OrthoNC ASC is the least effective alternative with regard to providing Wake County patients with access to more multiple surgical specialties.

Additionally, there are already two existing and one approved (3 total) orthopaedic single-specialty ASCs in Wake County: Triangle Orthopaedics Surgery Center, Raleigh Orthopaedic Surgery Center, and Raleigh Orthopaedic Surgery Center-West Cary. Wake County residents have sufficient access to dedicated-orthopaedic ORs. The need determination for six ORs in the 2018 SMFP is based solely on the surgical utilization at DRAH and the need for additional surgical capacity to accommodate the growth of DUHS surgical cases across all specialties. Given the existing access to orthopaedic ASCs in Wake County, the OrthoNC ASC proposal is not the most effective alternative for enhancing access to surgical services in this batch review.

For these reasons and the reasons previously described in this document, the OrthoNC ASC CON application is comparatively inferior to Green Level ASC's CON application.

Comments specific to Criterion 1

OrthoNC ASC does not adequately demonstrate the need the population has for the proposed services. See discussion regarding Criterion 3. Therefore, OrthoNC ASC does not adequately demonstrate its proposal would maximize healthcare value. Consequently, the application is not consistent with Policy GEN-3 and is not conforming to Criterion 1.

Comments specific to Criterion 3

OrthoNC ASC does not adequately demonstrate that the proposed facility will not unnecessarily duplicate existing surgical services. See discussion regarding Criterion 6. Therefore, OrthoNC ASC does not adequately demonstrate the need for its proposed services. Consequently, the application is not conforming to Criterion 3.

Comments specific to Criterion 4

OrthoNC ASC does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because it is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative, and is non-conforming to Criterion 4.

Comments specific to Criterion 5

OrthoNC ASC does not adequately demonstrate the need to develop a new ASC. See discussion regarding Criterion 3. Therefore, OrthoNC ASC does not adequately demonstrate its proposal is based upon reasonable projections of the costs of and charges for providing health services. Consequently, the application is not conforming to Criterion 5.

Comments specific to Criterion 6

OrthoNC ASC did not adequately demonstrate that development of a new single specialty orthopaedic ASC will not result in unnecessary duplication of existing health service facilities. There are two existing and one approved (3 total) orthopaedic single-specialty ASCs in Wake County: Triangle Orthopaedics Surgery Center, Raleigh Orthopaedic Surgery Center, and Raleigh Orthopaedic Surgery Center-West Cary. Wake County residents have sufficient access to dedicated-orthopaedic ORs. Therefore, the applicant did not adequately demonstrate that the proposed services would not result in an unnecessary duplication of the existing or approved health services. Consequently, the application is non-conforming to Criterion 6.

Comments specific to Criterion 18a

Because the OrthoNC ASC application is non-conforming with Criteria 3, 4, 5, and 6 it should also be found non-conforming with Criterion 18a. OrthoNC ASC did not adequately demonstrate the financial feasibility of the proposal, did not adequately demonstrate access to services, and did not reasonably identify the need the population has for the proposed service. Thus, the proposed OrthoNC ASC project will not have a positive impact on competition.

Comments regarding the RAC Surgery Center, LLC application/CON Project I.D. #J-11551-18

General Comments

RAC Surgery Center's proposal would create a new 1-OR, single-specialty ASC. Thus, the extent to which this project would provide access to an alternative provider is much more limited compared to Green Level ASC. Additionally, with regard to providing Wake County patients with access to more multiple surgical specialties RAC Surgery Center is the least effective alternative, as RAC Surgery Center proposes to serve only ESRD patients.

RAC Surgery Center proposes to develop a 1-OR single-specialty ASC across the street from WakeMed. Therefore, the proposal will not enhance geographic access to new surgical services in Wake County.

For these reasons and the reasons previously described in this document, the RAC Surgery Center CON application is comparatively inferior to Green Level ASC's CON application.

Comments specific to Criterion 1

RAC Surgery Center does not adequately demonstrate its proposal would maximize healthcare value. Approximately 85 percent of RAC Surgery Center's cases during project year three are procedures that can be (and historically have been) performed in an office-based setting (945 ESRD Stents + 434 ESRD-Thrombectomy = 1,379 office-appropriate cases \div 1,625 = .848). The cost of care for procedures performed in a licensed ASC (which charges a facility fee) are higher compared to the same procedures performed an office-based setting. See comments regarding Criterion 3. Therefore, the cost of care will actually increase for these patients. Consequently, the application is not consistent with Policy GEN-3 and is not conforming to Criterion 1.

Comments specific to Criterion 3

As described on page 32 of RAC Surgery Center's CON application, "*Projected OR utilization is based on the historical experience of cases performed in the office-based, vascular access centers in Raleigh and Cary.*" The vast majority of OR cases the applicant projects to perform in the proposed OR can actually and have historically been performed in an office-based setting which immediately devalues the need for the applicant's proposed licensed OR. RAC Surgery Center indicates on page 32, that the OR is needed to accommodate fistula creations which are currently performed in

hospitals. However, the applicant projects a total of only 246 fistula creations or 15 percent ($246 \div 1,625$) of total OR cases during the third project year. The remainder of OR cases are projected to be comprised of ESRD-Stents and ESRD-Thrombectomy procedures which can be (and have historically been) performed in an office-based setting. The applicant did not adequately demonstrate why the existing office-based vascular access centers cannot continue to effectively serve these patients.

RAC Surgery Center states the proposed OR is needed to reduce the cost of care to patients; however, the cost of care will actually be increasing for the majority of patients projected to be served by the proposed OR. Specifically, the cost of care for procedures performed in a licensed ASC (which charges a facility fee) are typically higher compared to the same procedures performed in an office-based setting. Facility fees allow an ASC to bill patients a service charge for the patient's use of the ASC facility and equipment. In some cases, a patient may be responsible for the service bill if their insurance declines to pay or if the patient has a high deductible health plan. Patients receiving office-based services do not incur facility fees because the physician practice does have comparable overhead expense for performing the service. Approximately, 85 percent of RAC Surgery Center's cases during project year three are procedures that can be (and historically have been) performed in an office-based setting ($945 \text{ ESRD Stents} + 434 \text{ ESRD-Thrombectomy} = 1,379 \text{ office-appropriate cases} \div 1,625 = .848$). Therefore, the cost of care will actually increase for these patients.

Excluding the projected cases that can be (and historically have been) performed in the applicant's office-based, vascular access centers in Wake County, the proposed OR would serve only 246 fistula creation cases. Based on the Group 6 average case time of 68.6 minutes per case, this results in only 281 surgical hours during the third project year, well below the 1,312.5 standard hours per OR. Consequently, RAC Surgery Center did not demonstrate that its proposed ASC is needed and is not conforming to Criterion 3.

Comments specific to Criterion 4

RAC Surgery Center does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because it is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative, and is non-conforming to Criterion 4.

Comments specific to Criterion 5

RAC Surgery Center does not adequately demonstrate the need to develop a new ASC. See discussion regarding Criterion 3. Therefore, RAC Surgery Center does not adequately demonstrate its proposal is based upon reasonable projections of the costs of and charges for providing health services. Consequently, the application is not conforming to Criterion 5.

The RAC Surgery Center application also includes several inconsistencies with regard to the financial projections. Specifically:

- Form F.1a does not include any interest during construction in the project capital cost. The application describes in Section K that the applicants propose to renovate approximately 3,400 SF of space to develop the proposed ASC, with at least \$875,000 in construction costs, and the project timetable in Section P reflects a 7-month construction timetable.
- Form F.3 shows interest expense of \$160,000 in the first project year, but no interest expense in either of the next two years. This does not square with the details of the proposed loan included on page 184 in Exhibit F-2.2, which shows a five-year loan term.
- The interest expense shown on Form F.3 on page 88 does not reflect any interest associated with working capital requirement. In fact, the applicants claim that there will not be any working capital requirements associated with this project. However, this is not reasonable because throughout the application are statements that the applicants propose to develop a new ASC, and that RAC ASC is a proposed new entity.
- The applicants provide confusing and/or conflicting financial information. Page 87 shows a Form F.3 with total revenue figures and net income figures that differ completely from the corresponding figures shown on a second Form F.3 that is included on page 88.

For all these reasons, RAC Surgery Center did not demonstrate financial feasibility of the proposed project because it did not reasonably project the costs and charges for the proposed health services, and therefore the application is not conforming to Criterion 5.

Comments specific to Criterion 6

RAC Surgery Center did not adequately demonstrate the need to develop a new ASC. See Criterion 3 for discussion of need. Therefore, the applicant did not adequately demonstrate that the proposed services would not result in an unnecessary duplication of the existing or approved health services. Consequently, the application is non-conforming to Criterion 6.

Comments specific to Criterion 12

The application reflects two different figures for the construction budget of the proposed facility. Table F.1a on page 83 shows \$875,443 for construction/renovation and \$375,000 for site preparation, which does not match the construction budget of \$900,000 shown in the architect's cost estimate letter in Exhibit K-4. The matter is further confused because the proposed floor plan in Exhibit K-2.2 indicates an overall suite size

of 6,488 SF with 3,400 SF of renovation area, which does not correspond to the current floor plan line drawing shown in Exhibit K-2.1, which indicates 7,912 SF for the existing suite, with an additional 3,759 SF in the adjacent space to be renovated. Without adequate documentation there is no way for the applicant or the CON Project Analyst to validate necessary information about the project design and construction, and the inconsistency cannot be reconciled. Therefore, RAC Surgery Center did not demonstrate that the means of construction represents the most reasonable alternative, and is non-conforming to Criterion 12.

Comments specific to Criterion 14

RAC Surgery Center did not include in its application any documentation that it would accommodate the clinical needs of health professional training programs in the area. Specifically, the application included neither an agreement with a health training program for establishment of a clinical training relationship nor a letter of support from a health training program. Further, the application did not include a letter from RAC Surgery Center to any health professional training program indicating a willingness to establish a clinical training agreement. Therefore, RAC Surgery Center is non-conforming to Criterion 14.

Comments specific to Criterion 18a

For the same reasons that the RAC Surgery Center application is non-conforming with Criteria 1, 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a. RAC Surgery Center did not adequately demonstrate the financial feasibility of the proposal and did not reasonably identify the need the population has for the proposed service. Thus, the proposed RAC Surgery Center project will not have a positive impact on competition.