

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

**Submitted by: WakeMed Health & Hospitals
October 1, 2019**

A total of five CON applications were filed for the September 1, 2019 review cycle requesting operating rooms in the Wake County service area, all pursuant to the need determination for two operating rooms identified in the 2019 State Medical Facilities Plan (SMFP):

- WakeMed Cary Hospital (“WakeMed Cary”) Project No. J-11759-19: Develop one additional shared OR at its existing campus at 1900 Kildaire Farm Road in Cary. Total project cost is \$2,265,178.
- Wake Spine and Specialty Surgery Center (“Wake Spine”) (J-11747-19): Develop a new ambulatory surgical facility (ASF) with one OR and three procedure rooms, with a total cost of \$5,680,000. The proposed facility will be located at 5241 E. Six Forks Road in Raleigh.
- Triangle Orthopaedics Surgery Center (“Triangle”) (J-11752-19): Add two ORs at its existing ASF located at 7921 ACC Boulevard in Raleigh. Total project cost is \$5,652,176.
- Duke University Health System, Inc. (“Duke-Green Level”) (J-11753-19): Add two ORs to its approved ASC proposed for 3208 Green Level West Road in Cary. Total project cost is \$6,000,000.
- Rex Hospital, Inc. (“Rex”) (J-11761-19): Add two shared ORs at its existing campus at 4420 Lake Boone Trail in Raleigh. The total project cost is \$789,000.

The five applicants in the review proposed a total of 8 operating rooms. Because the Agency can approve no more than two operating rooms, per the 2019 SMFP allocation, not all of the applications can be approved. The applicants in this review are in agreement on the need for additional operating room capacity in Wake County. The decision before the Agency is how these additional resources can be most effectively deployed in meeting the needs of Wake County residents and patients from outside Wake County who utilize Wake County facilities. WakeMed appreciates the challenging task at hand for the Agency, and has opted to keep its competitive remarks as concise as possible.

The WakeMed Cary proposal, to add one additional OR at its existing campus, is comparatively superior to the other proposals under review. In addition, there are serious deficiencies in the other proposals that render them non-conforming with applicable CON review criteria. The details for these conclusions are set forth below.

Maximize Geographic Access to Surgical Services

The applications in this review proposed operating rooms at new and existing locations throughout Wake County. Two applications seek to add new operating rooms at existing acute care hospital campuses (WakeMed Cary and Rex). Two applications seek to add new operating rooms at existing (Triangle) or proposed (Duke-Green Level) ASFs. One applicant (Wake Spine) plans to develop a new ASC in Raleigh.

Only one applicant in the review, Wake Spine, proposes to serve a unique patient population. Wake County has no existing ASF geared toward outpatient spine and neurosurgery. The Wake Spine project would offer significant differentiation in surgical care and access to care within Wake County.

The WakeMed Cary application stands apart in that it seeks to add shared OR capacity at the only acute care hospital currently operational in southwestern Wake County, where the county's population is growing most rapidly. WakeMed Cary recently increased its bed complement by 22 licensed beds, and 30 additional beds are under development. The growth in acute care capacity, in addition to other factors, necessitates this request for additional operating room capacity.

Freestanding vs. Hospital-Based Surgical Operating Rooms

Most of the applicants in the review propose to develop operating rooms in freestanding ASFs. Two applicants, WakeMed Cary (J-11759-19) and Rex (J-11761-19) seek to add hospital-based operating rooms at existing campuses. While the majority of ORs in Wake County are in acute care hospitals, most of these recently-approved ORs in Wake County were awarded to new ASFs. In the 2018 Wake County Operating Room review, 4 of the six allocated ORs were awarded to new ASFs; the remaining 2 were awarded to Rex Hospital.

WakeMed understands that both freestanding ASFs and hospital-based ORs are important components in the healthcare continuum, and that each setting offers significant benefits for patient care. Freestanding ASFs can usually provide outpatient surgery at a much lower cost than comparable cases performed in a hospital setting; however, an adequate supply of hospital-based ORs are still necessary to allow for more complex inpatient and outpatient surgical cases to be performed.

For the 2019 Wake County OR review, there is an opportunity for the Agency to approve applicants seeking both freestanding and hospital-based operating rooms.

Several factors point toward the WakeMed Cary application being the most effective alternative in this review. Specifically:

- WakeMed Cary is the only acute care hospital currently operational in southwestern Wake County, the region of Wake County where population growth is highest.
- WakeMed Cary recently increased its acute care bed capacity from 156 to 178 beds, and capacity will increase to 208 beds in 2021. This is a significant expansion in beds that will enhance demand for surgical services.
- From FY 2015-2019, WakeMed Cary's inpatient surgery cases grew at a rate of 5.27 percent per year, and outpatient surgery increased 3.24 percent per year, despite the approval of several new ASFs in Wake County.
- Average surgical case times for inpatient and outpatient surgery at WakeMed Cary increased 82 percent and 113 percent, respectively, from 2015 to 2019.
- WakeMed Cary was recently designated as a Level III Trauma Center by the Office of Emergency Medical Services. This status will increase the need for additional OR capacity.
- The WakeMed Cary application proposed the earliest completion date in the review, making additional operating room capacity available sooner than the other applicants.

**Triangle Orthopaedics Surgery Center – Convert to Multi-Specialty ASF with Conversion of Two Procedure Rooms to Operating Rooms
Project No. J-11752-19**

The Triangle application seeks to convert a their single-specialty, freestanding ASF to a multi-specialty ASF. In addition, Triangle proposes to convert two previously-approved procedure rooms that are currently under construction into licensed operating rooms. For Triangle, its primary objective appears to be the conversion to a multi-specialty ASF, which requires it show conformity with “Criteria and Standards for Surgical Services and Operating Rooms” specifically 10A NCAC 14C.2103, not necessarily the addition of two licensed ORs.

This application is nonconforming with several CON Review Criteria, based on the following analysis.

Review Criterion 3

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

Projected Patient Origin

On page 23-24, Triangle states: “The patient origin is expected to remain very similar to the historical patient origin with the vast majority of additional surgeons on the Triangle medical staff with practice location near the facility.” While historic patient origin is often a reasonable proxy for projected patient origin, the likelihood of Triangle’s patient origin remaining absolutely static over three full calendar years is exceedingly improbable for the following reasons:

- Triangle seeks to convert from a single-specialty ASF to multi-specialty ASF. With the addition of new surgeons and new surgical specialties, it would be unlikely that the projected patient origin would match historic origin.
- As rationale for seeking approval of two additional ORs, Triangle states on Page 10 that in addition to patients from the Triangle region, they would like to serve patients from other areas of the state. This would imply an increase of patients from these other decidedly distant parts of the state, from which Triangle expects patients to travel.
- On Page 18, Triangle states that it proposes to convert from a single-specialty ASF to a multi-specialty ASF, adding general surgery, plastic surgery, and pain management. Different specialties draw patients from various distances dependent upon how specialized the service. Decisions to add new specialties with an aggressive growth strategy rarely occurs without extensive analyses, which is not reflected in the data

shared in this application evidenced by using exactly the same patient origins year over year for three consecutive years.

- On Page 23, Triangle notes that a majority of their additional surgeons reside in practices near their facility. It would stand to reason that those additional surgeons would contribute a patient panel largely comprised of residents from Wake, and surrounding, counties – thereby, at the very least, increasing their patient origin from Wake and Durham Counties.

Ambulatory Case Time

As an Ambulatory Surgery Demonstration Project, information regarding Triangle's ORs, including volume and average case times, have not been reported in the annual SMFP, although Triangle will be included in the 2020 SMFP, as its Demonstration Project has ended. On Pages 26 and 44 in Section C, Triangle states that Dr. Amy Craddock instructed the use of 92 minutes per case, as reported in Triangle's 2018 License Renewal Application, during a pre-application conference, seemingly without documented authorization. Dr. Craddock represents the Healthcare Planning Section, not the CON Section which retains jurisdiction of CON applications. It is questionable whether the CON Section would agree with Dr. Craddock's direction, as there is no documentation of this discussion or corroboration by the CON Section. Because Triangle's Final Outpatient Case Time is not reported in the 2019 SMFP, it would be more appropriate for Triangle to use a Final Ambulatory Case Time of 76.6 minutes, which is the Category 6 standard for new ASFs in the 2019 SMFP. Applying this Case Time would reduce Triangle's need for operating rooms.

Comparison of Health Care Costs

On Page 33, Triangle cites the Blue Cross Blue Shield of North Carolina (BCBSNC) Cost Estimator as evidence their charges are lower when compared to Capital City Surgery Center and selected acute care hospitals, specifically UNC Hospitals and Duke Raleigh Hospital. That Triangle, as a freestanding ASF, would have lower costs per procedure than an acute care hospital is not remarkable. However, the BCBSNC Cost Estimator has many limitations. Most notably, it is only calculating the contractual rate for BCBSNC plans, it does not reflect any other commercial or governmental payers, nor does it reflect the cost for self-pay patients. It also requires selection of a particular plan within BCBSNC plan offerings; therefore, these are simply the contractual rates for a singular plan offered within a singular payer in a single state. It cannot, and should not, be generalized to entire populations even if that population is solely BCBSNC insured patients.

Triangle sought to use the BCBSNC data to selectively choose procedures where its own costs are lower. However, closer analysis of BCBSNC Cost Estimator shows that, for the *same procedures* listed on Page 33, some of Triangle's costs are actually *higher* than other Wake County ASFs, as shown in the chart below.

Comparison of BCBS Estimated Treatment Costs	Rex Surgery Center	Capital City Surgery Center	Blue Ridge Surgery Center	Raleigh Orthopaedic Surgery Center	Triangle Orthopaedic Surgery Center
Carpal Tunnel	N/A	\$2,755	\$2,784	\$2,630	\$3,279
Knee Arthroscopy with Cartilage Repair	\$3,686	\$5,377	\$4,818	\$3,797	\$4,104
Shoulder Arthroscopy with Rotator Cuff Repair	\$16,187	\$11,666	\$12,545	\$11,762	\$10,242

Another limitation of the BCBSNC Cost Estimator sees dollar amounts reported for individual surgeons as well as entire surgical centers, typically with extreme variations. The dollar amounts reported in Triangle’s application have been cherry-picked to report the dollar amount for their surgeon with the lowest cost, not the cost for their overall facility. This further diminishes the validity of using “charge data” or a commercial payer’s “cost estimator” as the basis for proving real value to the citizens of Wake County. In the example provided below for Shoulder Arthroscopy with Rotator Cuff Repair, Triangle reported the cost for Dr. William Silver, an EmergeOrtho physician, rather than for its overall facility.

Ex: Shoulder Arthroscopy with Rotator Cuff Repair:

Triangle Orthopaedics Surgery Center LLC 7921 Acc Blvd Raleigh, NC 27617	Blue Value \$15,294 Blue Options, Blue Advantage \$15,294
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William Silver Triangle Orthopaedics Surgery Center LLC 7921 Acc Blvd Raleigh, NC 27617	Blue Value \$10,242 Blue Options, Blue Advantage \$10,242
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Need for Two Additional ORs Overstated

On Page 34, Triangle provided case projections by specialty in an attempt to justify the need for two additional licensed ORs. Triangle is already constructing two CON-exempt procedure rooms, which will unquestionably decompress any perceived capacity constraints to their two current ORs. The range of their projections for existing EmergeOrtho surgeons is between 4,220-5,585 cases, the average being 4,902.5 cases, which includes their recently recruited surgeons. Triangle states these projections were based merely on physician letters of support, markedly without any analytical or statistical significance. Additional “projections” are for Interventional Pain Management specialists. All of those physicians are board-certified in Physical Medicine & Rehabilitation. Interventional Pain Management procedures *do not*

require a licensed operating room – this has been confirmed by Nell Panten, DNP, MSN, BSN, RN, NEA-BC, Director of Surgical Services at WakeMed Cary Hospital.

On Page 35, Triangle states: “EmergeOrtho has made continued progress regarding physician recruitment with the recent additions of orthopedic surgeons Deren Bagsby, MD and Scott Buckel, DO. EmergeOrtho is currently recruiting three orthopedic specialists to the Triangle area; one each in spine surgery, adult reconstruction and upper extremity and hand surgery. Over the next three years, EmergeOrtho intends to recruit at least eight additional orthopedic surgeons for office locations in Wake and Durham Counties.” Based on Triangle’s apparent and aggressive recruitment strategy that is notably already underway, it would be highly improbable that such specialized surgeons with extraordinarily high salaries would be brought on staff without having access to facility space in which to perform their surgeries. This would imply that Triangle has the capacity needed, between their two existing ORs and two approved procedure rooms, to support their projected growth.

On Page 38, Triangle states: “Expanding Triangle’s capacity and scope of services to become a multispecialty ASF builds on its track record of success and improves patient access.” This rationale is contradictory to their calculations attempting to justify a need for two additional ORs. Mainly, their motivation for seeking two additional ORs on Page 26 being that Triangle is a single-specialty facility that has outgrown two ORs – however, an addition of three other specialties would diminish access for the single orthopaedic specialty their Facility Demonstration Project was tasked with supporting.

Based on the reasons described above, the Triangle application does not conform with Review Criterion 3.

Review Criterion 4

“Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.”

In Section E, Triangle proposes four alternatives. Triangle discusses the difficulties of staff fatigue, limited space for procedures to be performed, and greater scheduling capacity, but failed to provide sufficient evidence showing a level of demand for procedures requiring a licensed OR that warrants two additional ORs.

As noted, Triangle is already approved to develop procedure rooms which would significantly decompress their two current ORs by moving minor procedures to these procedure rooms. On Page 58, the application states: “The alternative of developing the CON-exempt project that adds two procedure rooms to TOSC is not an effective alternative...”. If this statement is true, there is no record of Triangle withdrawing its Letter of Exemption from the CON Section, which Triangle requested in April 2019 and the Agency granted in May 2019, well after the 2019 SMFP was published. Aside from needing CON approval to convert from single-specialty to multi-specialty ASF, it not clear what Triangle intends to accomplish by applying for additional OR capacity when it already has approved procedure rooms.

These procedure rooms could also easily accommodate multiple specialties, which would allow their future surgeons to build up demand for more complex procedures that would require a licensed OR.

For these reasons, Triangle's application does not conform with Review Criterion 4.

Review Criterion 18a

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

Despite Triangle's claim that there is a current deficit of non-health system affiliated ambulatory surgery facility options in Wake County, there are actually several such facilities in the county. In 2019, two "independent" facilities – RAC Surgery Center and OrthoNC ASC – were approved with a total of 2 operating rooms and 3 procedure rooms. These new facilities will provide additional access, capacity, and competition to support the current ambulatory growth in the county. There is no basis to Triangle's claim that RAC and OrthoNC, as "de novo facilities", will have undue difficulties in recruiting staff, managing start-up costs, or obtaining accreditation or payer certification. These are issues that any new provider would face and which Triangle itself would have faced while under development. Rather, awarding additional operating rooms to an existing ASF will do little to enhance competition in Wake County.

On Page 91, Triangle discusses the supposed higher productivity and cost savings that can be obtained with four operating rooms. Yet, Triangle sought and was granted approval earlier in 2019 to develop two procedure rooms at its existing ASF. Triangle does not describe how an ASF with 4 ORs is more competitive, cost effective, or accessible than a facility with 2 ORs and 2 procedure rooms. Therefore, Triangle's application does not conform with Review Criterion 18a.

Duke University Health System – Two Additional Operating Rooms at Approved Facility Project No. J-11753-19

Duke proposes to develop 2 additional ORs at its recently-approved Green Level facility (Project No. J-11557-18), for a total of 3 ORs and 5 procedure rooms upon project completion. This application is nonconforming with several CON Review Criteria, as evidenced below.

Review Criterion 3

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

Overview

The Duke Green Level facility will be a new freestanding ASF located in 40,000 square feet in a medical office building to be developed in west Cary, with a total of 3 ORs and 5 procedure rooms upon completion. The Duke-Green Level project will be developed to allow Duke Medicine physicians based in Durham and Raleigh access to a freestanding ASF located in Wake County.

Despite claims that the ASF will improve geographic access for patients, the Duke-Green Level project will be located far from Duke's major acute care facilities. The proposed site is approximately 20 road miles from Duke University Hospital and 23 road miles from Duke Raleigh Hospital. The project's success is dependent upon a number of factors, including:

- Large shifts of current patient case volumes from existing facilities and to several proposed facilities;
- Surgeons from Duke Medicine's Private Diagnostic Clinic (PDC) many of whom practice at two or more Duke practice locations, including Duke University Hospital in Durham, Duke Raleigh Hospital, and other community locations throughout the Triangle area; and,
- That patients from a wide geographic area will be attracted to the Duke-Green Level facility, despite being located more closely to other Duke and non-Duke surgery centers in the region.

According to Google Maps, the Duke-Green Level location is 9.9 road miles from Duke's Arrington Ambulatory Surgery Center (Project No. 11508-18) currently under development, a site which is physically located in Durham County but which is less than one-half mile from the Wake/Durham county line. Approval of the proposed Duke-Green Level project will give Duke Health System 5 freestanding outpatient ORs and 9 procedure rooms essentially in Wake

County. Although Duke-Arrington and Duke-Green Level will be developed in separate SMFP Operating Room Service Areas, their relative closeness suggests that the two facilities are duplicative. Please also see the discussion for Review Criterion 6.

Surgical Utilization at Duke Raleigh Hospital

Throughout Section C, the Duke-Green Level proposal describes growth in surgical utilization at Duke Raleigh Hospital, and capacity constraints on its existing operating rooms and procedure rooms. Because Duke-Raleigh’s outpatient surgery volume has been increasing by 5 percent annually, the facility has begun using unlicensed procedure rooms to perform surgical cases.

Claims Regarding Improved Geographic Access Are Exaggerated

Throughout the application, Duke insists that development of the Green Level ASF will increase access to outpatient surgical services. Despite these assertions, the Duke-Green Level project will be located far from Duke’s major acute care facilities, and presumably, many of the surgeons who currently practice there. The proposed site is approximately 20 road miles from Duke University Hospital and 23 miles from Duke Raleigh Hospital. In fact, the Duke-Arrington site is closer to Duke-Raleigh than will be Duke-Green Level. Please see the following table.

From Duke Raleigh Hospital (3400 Wake Forest Rd, Raleigh, NC 27609) to:	Shortest Route		Fastest Route	
	Distance (miles)	Drive Time (minutes)	Distance (miles)	Drive Time (minutes)
Duke-Green Level 3028 Green Level West Rd., Cary, NC 27519	22.5	30	23.9	27
Duke-Arrington 5601 Arrington Park Dr., Morrisville, NC 27560	16.8	28	17.1	22

Source: Google Maps, www.google.com/maps, accessed 9/24/2019.

The Duke-Green Level project’s success is dependent upon a number of factors, including:

- Large shifts of current patient case volumes from existing facilities and to several proposed facilities;
- Support from surgeons from Duke Medicine’s Private Diagnostic Clinic (PDC) many of whom practice at two or more Duke practice locations, including Duke University Hospital in Durham, Duke Raleigh Hospital, and other community locations throughout the Triangle area; and,
- The assumption that patients from a wide geographic area will be attracted to the Duke-Green Level facility, despite being located more closely to other Duke and non-Duke surgery centers in the region.

On Pages 31-33, the Duke-Green Level application describes projected population growth in Wake County at the ZIP Code level, stating that: “[m]any of the zip codes in the western half of Wake County have projected population growth rates that exceed the overall county growth rate.” WakeMed does not dispute this statement, as its own application for WakeMed Cary

Hospital (Project No. J-11759-19) contains a similar discussion. However, on Pages 19-20, the application states the Duke-Green Level projected patient origin: “is based on the FY2019 ambulatory surgical patient origin for Duke Raleigh Hospital (DRAH)”, and that the vast majority of Green Level’s projected volumes “are based on the projected shift of ASC-appropriate cases from DRAH to the proposed expanded Green Level ASC.” This is problematic in the sense that Duke projects no difference in patient origin between Duke-Raleigh and Duke-Green Level, despite the fact that the new ASF will be located 23 road miles from Duke-Raleigh, geographically closer to the high-growth areas of western Wake County as well as Durham County. One would expect Duke-Green Level’s patient origin to have higher proportions of patients from Wake and Durham Counties (projected in the application to be 52.0 percent and 3.9 percent, respectively), and smaller proportions from areas such as Johnston, Franklin, Cumberland, and Nash Counties, which are located further away from Duke-Green Level. Duke-Green Level will also be closer to Chatham County, a contiguous county which is projected to experience significant population growth, yet Duke-Green Level projects Chatham will comprise only 0.6 percent of volume throughout Project Years 1-3.

In Section Q, Duke projects that 88 percent of Duke-Green Level’s volume will result from a shift of cases from Duke-Raleigh, which received nearly 24 percent of its FY 2019 outpatient surgery patients from “Other States” and “Other NC Counties” – how many patients from these unspecified areas originated from counties south and east of Wake County and will be further away from Duke-Green Level? The new ASF will be less proximate for many residents of Wake County and the region. With slightly more than one-half of its patients projected to originate in Wake County, as well as the relative proximity of Duke-Arrington, Duke-Green Level does little to enhance geographic access.

WakeMed believes that failure to account for a shift in patient origin proves that the Duke-Green Level application does not improve geographic access to outpatient surgical services.

Discrepancies in Surgery Volumes Reported at Duke Raleigh Hospital

Duke submitted two CON applications for operating rooms in the Wake County Operating Room Service Area in 2018, based on the need determination in the 2018 SMFP:

- Project No. J-11557-18: Develop a freestanding ASF (Duke-Green Level) with four ORs;
- Project No. J-11558-18: Develop two additional shared ORs at Duke Raleigh Hospital.

The 2018 Wake County Operating Room Service Area need determination for six ORs was driven largely by the surgical volumes reported for Duke Raleigh Hospital. Just prior to the Agency’s decision date, Duke withdrew Project No. J-11558-18 - Duke-Raleigh had been erroneously combining the volumes performed in its licensed operating rooms and unlicensed procedure rooms, which had overstated Duke-Raleigh’s surgical volumes for an undetermined number of years. Because the 2018 Duke-Green Level application’s utilization projections were integrally tied to volume shifts from Duke-Raleigh, the Agency denied this application, due to the unreliability of the Duke-Raleigh volumes.

In the 2019 Duke-Green Level application, there is no mention of these reporting errors from the prior year's application, much less how they have been reconciled. Rather, Duke describes its outpatient surgical volumes at Duke-Raleigh as having been performed in ORs or in procedure rooms. Duke cites no difference in reimbursement based on location where the case is performed. Because Duke-Green Level's projections are still largely dependent on cases to be shifted from Duke-Raleigh, Duke's failure to note how it has accounted for its prior reporting errors at Duke-Raleigh make the projections in this application unreliable.

Review Criterion 4

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

The Duke-Green Level application describes several alternatives to the proposed project, including maintaining the status quo, developing additional ORs at Duke Raleigh Hospital, relocating ORs from Duke-Raleigh to Duke-Green Level, and developing a new ASF in another location. The application does not provide an adequate discussion as to why developing 2 additional ORs at Duke-Green Level is the most optimal alternative.

Throughout the application, Duke describes the continued growth in surgical volume and related OR capacity issues at Duke Raleigh Hospital, and posits that the most effective alternative to deal with this growth is to develop additional ORs, not at Duke-Raleigh, but at Duke-Green Level. On Pages 24-25, the application describes the current facility expansion/renovation project underway at Duke-Raleigh, which will increase the number of private patient rooms. Rather than proposing an increase in licensed surgical OR capacity at Duke-Raleigh, which could be accomplished for relatively low capital cost (the Duke-Raleigh CON application for ORs filed in 2018 (Project No. J-11558-18) had a project capital cost of only \$2,000,000), Duke has opted to spend an additional \$6 million to expand capacity at Duke-Green Level, before the facility has even been built.

Given the continued growth in surgery volumes at Duke-Raleigh, another more effective alternative would be to develop a new ASF adjacent to Duke Raleigh Hospital, where surgeons could easily access both ASF and hospital ORs and where patients would not be unduly indisposed by additional travel time. This alternative was not discussed.

On Page 61, the Duke-Green Level application contains the following statement: "...the proposed additional ORs to be developed at Green Level ASC would increase access to cost effective, dedicated ambulatory surgical services for many of the patients whose surgical cases have historically been performed in DRAH's ORs and procedure rooms." However, there is little evidence provided that shifting cases from Duke-Raleigh to a proposed site located 23 miles west would increase access for residents located in areas south and east of Wake County.

The most recent publicly available outpatient surgery patient origin for Duke Raleigh Hospital was provided in the 2019 Hospital License Renewal Application, which contains FY 2018 data. In FY 2018, Duke-Raleigh performed 7,474 outpatient surgery cases on patients from 89 North Carolina counties. Of these, 2,085 cases, or 27.9 percent of total, came from 42 counties located either due south or east of Wake County, and thus further away from Duke-Green Level than Duke-Raleigh. Therefore, it could be assumed that the Duke-Green Level project will be *less accessible* for up to 27.9 percent of its potential patients, not including patients with potentially reduced access from parts of Wake County. Please see the following table.

Duke Raleigh Hospital FY 2018 Outpatient Surgery Cases for Counties Located South and East of Wake County Listed in descending order by number of cases		
County of Origin	FY 2018 OP Surgery Cases	Percent of Total Duke Raleigh Cases
Johnston	375	5.0%
Cumberland	232	3.1%
Franklin	224	3.0%
Nash	141	1.9%
Pitt	126	1.7%
Wayne	97	1.3%
Wilson	93	1.2%
Robeson	64	0.9%
Halifax	61	0.8%
New Hanover	59	0.8%
Beaufort	49	0.7%
Onslow	47	0.6%
Sampson	43	0.6%
Brunswick	42	0.6%
Carteret	39	0.5%
Craven	37	0.5%
Warren	32	0.4%
Lenoir	27	0.4%
Bertie	26	0.3%
Edgecombe	26	0.3%
Duplin	24	0.3%
Chowan	21	0.3%
Hoke	21	0.3%
Pender	20	0.3%
Scotland	19	0.3%
Hertford	18	0.2%
Columbus	17	0.2%
Northampton	15	0.2%
Washington	13	0.2%
Dare	12	0.2%
Bladen	11	0.1%
Martin	11	0.1%

Duke Raleigh Hospital FY 2018 Outpatient Surgery Cases for Counties Located South and East of Wake County Listed in descending order by number of cases		
County of Origin	FY 2018 OP Surgery Cases	Percent of Total Duke Raleigh Cases
Greene	9	0.1%
Pasquotank	7	0.1%
Richmond	7	0.1%
Jones	4	0.1%
Pamlico	4	0.1%
Perquimans	4	0.1%
Hyde	3	0.0%
Gates	2	0.0%
Tyrrell	2	0.0%
Currituck	1	0.0%
Subtotal	2,085	27.9%
Total for Duke Raleigh	7,474	

Source: Duke Raleigh Hospital, 2019 Hospital License Renewal Application, page 34

A more effective alternative would be to shift some cases, where reasonable, to the Duke-Arrington facility and develop either additional licensed OR capacity at, or a freestanding ASF adjacent to, Duke Raleigh Hospital.

Another alternative apparently not considered, one would be potentially far less expensive, would be to convert 2 of the 5 procedure rooms at Duke-Green Level, approved in Project No. J-11557-18, to licensed operating rooms. Such a proposal would only require equipment necessary to upfit the new ORs – the shell space for the ASF was approved in J-11557-18.

For these reasons, the Duke-Green Level application does not conform with Review Criterion 4.

Review Criterion 8

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

The Duke-Green Level application provides a number of support letters from local physicians. There is no standard regarding a minimum of number of letters expected or required. However, it is worth noting that all surgeon letters of support were provided by surgeons employed or otherwise affiliated with Duke Health System. The following surgical groups provider letters of support:

- Duke Orthopaedic Surgery
- Duke Sports Medicine
- Duke Orthopaedics of Raleigh
- Duke Orthopaedics Heritage
- Duke Women's Health Associates
- Duke Eye Center
- Duke University Department of Head and Neck Surgery & Communication Sciences
- Duke Neurosurgery
- Duke Surgery at Duke Raleigh Hospital

On Page 84, the Duke-Green Level application states: "...any other community or North Carolina physicians will be able to continue to refer patients to DUHS, for treatment by DUHS physicians." The intent to make the ORs at Duke-Green Level available only to employed physicians demonstrates a lack of coordination with the existing health care system, and is a disservice to independent surgeons who do not wish to be employed by a larger system. The Duke physicians who provided letters of support are based either in Durham, Raleigh or Wake Forest, and will be the only surgeons who may work at Duke-Green Level. For this reason, the application does not conform to Review Criterion 8.

Review Criterion 12

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

With a capital cost of \$6,000,000, the Duke-Green Level proposal is the most expensive in the review, especially when considering that the project is an upfit of approved shelled space. On Page 88, Duke notes that the proposed project involves renovation of 40,000 square feet. This represents *one entire floor* of the Duke-Green Level 5-story MOB shown on the site plan in Exhibit K.2. It can be assumed that the \$6 million project cost involves only upfit of space for 2 additional ORs, yet it cannot be determined how many square feet this upfit entails.

With a capital cost of \$150.00 per square foot [$6,000,000 \div 40,000 = 150.00$], the Duke-Green Level project would *appear* to be, based information provided in the application, the lowest-cost project in the review. However, given that the proposed project proposes to upfit space for only 2 ORs, the cost per square foot is likely much higher. The line drawing provided in Exhibit K.2 was not of sufficient quality to ascertain the square footage of each proposed OR. If one assumes each upfitted OR will be generously-sized at 650 square feet, the total project cost would be \$4,615.38 per square foot [$6,000,000 \div (650 \times 2) = 4615.38$], making it one of the most expensive projects in the review, and the most expensive for an approved applicant.

For these reasons, the Duke-Green Level application does not conform with Review Criterion 12.

Review Criterion 18a

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

The Duke-Green level application provides rationale for how the proposed project will increase competition for surgical services in Wake County. On Page 109, Duke states:

“DUHS is the only integrated health system currently without a freestanding ASC in Wake County. This will therefore better serve local residents and will promote competition in the Wake County service area.”

The following paragraph states:

“The planned ASC project represents a new opportunity for Wake County residents and DUHS patients to access Duke outpatient surgical services separate from the hospital charge structure.”

It is not clear how either of these statements demonstrate a positive effect on competition. Although Duke Health System does not *currently* operate a freestanding ASF in Wake County, it has several facilities under development either in or adjacent to Wake County:

- Duke-Green Level facility has been approved for 1 OR and 5 procedure rooms in western Wake County via Project No. J-11557-18.
- The Duke-Arrington facility (Project No. J-11508-18), approved to develop an ASF with 4 ORs and 4 procedure rooms, less than one-half mile from the Wake/Durham county line, is currently scheduled to open in mid-2020.
- Duke also owns Same Day Surgery Center-Franklin (“SDSC-Franklin”) (Project Nos. K-8357-09 & K-10229-13), which is approved to develop a freestanding ASF with 2 ORs in Youngsville in southern Franklin County, approximately 4 miles from the Wake/Franklin county line. This project is currently slated to open in mid-2021 per its most recent progress report. SDSC-Franklin will give Duke physicians yet another venue for outpatient surgery that is very close to, although not physically within, Wake County.

Given that Duke has two ASF projects already approved for development just outside the physical boundary of Wake County that will ultimately offer a total of 6 ORs, the effect on competition of additional ORs at Duke-Green Level is superfluous. For these reasons, the Duke-Green Level application does not conform with Review Criterion 18.

Section P: Timetable

Duke states that the Green Level ASF project will open in October 2022, which would be the last project in the review to become operational.

Section Q: Projections/Pro Formas

Duke ASFs Located Outside Wake County

In Section Q, the Duke-Green Level application provides a lengthy discussion regarding OR capacity and utilization in the Duke system, both in Wake and Durham Counties. The methodology describes the historic surgical volumes at all Duke locations, regardless of location, as well as the projected shift of cases between Duke facilities. The discussion is confusing at times, because so many Duke facilities are impacted by so many proposed volume shifts between counties.

On Page 121, the application states that Duke-Green Level:

“...will not result in any unnecessary duplication of services in the applicable service area (i.e., Wake County). The need for Green Level ASC is complementary to but independent of the need to develop Arrington ASC.”

This passage is important because Duke is using a technicality in the SMFP Operating Room Need Methodology to declare that because Duke-Green Level and Duke-Arrington are located in separate counties, and therefore separate in OR Service Areas, the two facilities cannot be duplicative. This position would be more credible if the Duke-Green Level utilization methodology did not specifically mention proposed shifts in case volumes from Duke-Raleigh to Duke-Arrington.

The utilization methodology in Section Q contains no discussion of projected shifts in outpatient surgical volumes between Duke Raleigh Hospital and its SDSC-Franklin facility. Per Google Maps, this ASF will be located approximately 17 road miles from Duke-Raleigh and only 8.4 miles from Duke Health-Heritage. SDSC-Franklin will be located somewhat closer to Duke-Raleigh than will Duke-Green Level, yet the Duke-Green Level utilization methodology provides no description of the impact of SDSC-Franklin on surgical utilization at Duke facilities.

Projected Utilization of Procedure Rooms

In Project No. J-11-558-18, Duke-Green Level was approved in Settlement negotiations for 1 licensed OR and 5 unlicensed procedure rooms. In Project No. J-11753-19, Duke-Green Level seeks two additional licensed ORs, with no change in approved procedure room capacity. The utilization projections provided in Section Q show that Duke-Green Level’s projected procedure room volumes will be very low, calculated to be less than 1 case per room per day throughout Project Years 1-3. Please see the following table.

Duke-Green Level ASC			
Projected Procedure Room Utilization Following Project Completion			
	Year 1	Year 2	Year 3
Number of Procedure Rooms	5	5	5
Annual Days of Operation	260	260	260
Procedure Room Cases	339	566	819
Cases/Room/Day	0.26	0.44	0.63

The Year 3 utilization of only 1 procedure room at Duke Green Level would be 3.15 cases per room per day [819 ÷ 260 = 3.15].

Although there is no State standard regarding procedure room utilization and capacity, the Duke-Green Level volumes are exceedingly low. In the CON application for Project No. J-11558-18, procedure room volume projections at Duke-Green Level were higher, even though that application proposed *fewer* procedure rooms. Please see the following table.

Duke-Green Level ASC		
Comparison of Procedure Room Volume Projections		
Between the 2018 and 2019 Applications		
	Duke-Green Level Project No. J-11558-18	Duke-Green Level Project No. J-11753-19
Procedure Rooms Proposed	4	5
Project Year 1 Volume	687	339
Project Year 2 Volume	1,007	566
Project Year 3 Volume	1,517	819

It could be argued that the proposed capital outlay to develop 2 additional operating rooms at Duke-Green Level would be better spent converting 2 underutilized procedures rooms to licensed ORs.

**Rex Hospital – Develop Two Additional Hospital-Based Operating Rooms
 Project No. J-11761-19**

Review Criterion 3

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

Impact of Rex-Holly Springs

The Rex proposal, like the application filed in 2018 (Project No. J-11555-18), is based on premise of backfilling part of the OR capacity slated to be relocated to Rex-Holly Springs Hospital. Surgical utilization at Rex has been increasing, particularly on the inpatient side – this has been a common theme among acute care facilities where the number of freestanding ASFs has increased and more outpatient cases are being performed outside the hospitals.

Rex is assuming that some surgical volume at Rex-Main will shift to Rex-Holly Springs. However, until Rex-Holly Springs opens, it is impossible to gauge the impact of that facility on Rex-Main’s operations and volume. Further, projections for Rex-Holly Springs were made in 2011, making them unreliable in 2019 for projections through 2025. Given the changes in demographics and physician alignment in Wake County during the intervening years, Rex should have provided updated projections and assumptions for Rex-Holly Springs in this application.

On Page 23, Rex states that “[a]mong all systems in Wake County, UNC REX Hospital has demonstrated the highest growth in inpatient cases...”. Rex cites the period 2012-2018, where its CAGR of 3.4 percent is slightly higher than the WakeMed system’s annual growth rate of 2.9 percent. Closer analysis reveals that over the *most recent four years (2015-2018)*, WakeMed has actually experienced the highest growth in inpatient surgery volumes among Wake County providers. Please see the following table.

Inpatient Surgery Volumes at Wake County Hospital Systems, 2015-2018			
Excludes cases performed in dedicated C-section ORs			
Year	UNC Rex	WakeMed	Duke Raleigh
2015	7,984	10,385	3,616
2016	8,557	11,421	4,389
2017	8,453	11,225	4,094
2018	8,366	10,914	3,328
CAGR 2015-18	1.6%	1.7%	-2.7%

Source: Hospital License Renewal Applications on file at DHSR/2017 to Proposed 2020 SMFPs

While Rex had the highest growth in inpatient surgical volume for 2012-18, WakeMed had the highest increase over the most recent four years. Much of this growth can be attributed to the opening of WakeMed North Hospital, as well as the continued growth in inpatient bed capacity and surgical specialties at WakeMed Cary Hospital.

While Rex's statement that it has the highest inpatient and outpatient surgery volume of any single provider in Wake County is true, it is also true that Rex-Main has the highest number of surgical operating rooms among Wake County providers.

Comparison of Health Care Costs

Like Triangle, on Pages 28-29 Rex provides data from the Blue Cross Blue Shield of North Carolina (BCBSNC) web site, "Estimated Health Care Costs of Select Top 20 Outpatient Surgical Procedures", comparing health care costs for two selected outpatient surgical procedures. The data is accompanied by the following sentence:

"As demonstrated in the table above, UNC REX Hospital provides lower costs per procedure for BCBS patients than Duke Raleigh (WakeMed Cary and WakeMed Raleigh's cost data was not available in the Blue Cross Blue Shield tool)."

This statement alone is disqualifying, since Rex opted to use data that did not contain information for all Wake County hospitals. Any analysis that does not include all Wake County hospital providers carries no weight. In the next sentence, Rex states:

"In fact, it is likely that UNC REX Hospital will continue to offer the lowest cost of care to patients for surgical services in Wake County when compared to other hospital providers as changes to the health insurance landscape unfold."

While the table on Page 29 is offered as evidence of Rex's supposed lower surgical costs, only 2 procedures are listed on the table, with no direct comparisons between all Wake County hospitals. Rex has conveniently cherry-picked data from a single insurer, for only *two* surgical procedures, and for which data is available for only *two* hospitals, as proof that it is the "low cost provider" for surgical services in Wake County. Without a more complete analysis of surgical costs across multiple payers, including Medicare, that includes all providers, this information is meaningless.

Review Criterion 4

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

The Rex application describes several options that were considered, in addition to the chosen alternative. Given the trend toward greater proportions of surgery being performed on an

outpatient basis, and the cost savings this represents to payers and patients, it is unusual that Rex would propose to create additional inpatient capacity at Rex-Main. In Section C, Rex did not describe any difficulties in accommodating surgery patients with Rex-Main's existing complement of ORs, which will be supplemented with the 2 additional ORs approved in Project No. J-11555-18.

When compared with other proposals in this review, the Rex application is neither the least costly nor most effective alternative, and thus does not conform with Review Criterion 4.

One alternative apparently not considered was to seek additional OR capacity at Rex Holly Springs, which has yet to be developed, thereby leaving Rex's main campus OR inventory intact.

Review Criterion 6

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

Page 57 of the Rex application contains the following statement: "No other provider can meet the needs of UNC REX Hospital's patients." This statement is totally unsupported, and it assumes that Wake County's growing and aging population will automatically choose UNC facilities for their care. At issue in this review is how best to make additional OR capacity available for all patients.

In Settlement negotiations, Rex Hospital was approved for 2 of the 6 operating rooms allocated to Wake County in the 2018 SMFP. UNC Health Care System, Rex's parent company, already operates or is approved for six locations in Wake County where surgical services are performed, including 4 freestanding ASFs:

- Rex Hospital – Main Campus
- Rex Surgery Center of Cary
- Rex Surgery Center of Wakefield
- Raleigh Orthopaedic Surgery Center-Raleigh
- Raleigh Orthopaedic Surgery Center-West Cary
- Rex Holly Springs Hospital – under development

While Rex maintains that it is seeking additional OR capacity at its main campus to offset ORs earmarked for relocation to Rex Holly Springs Hospital, this is same justification it provided in its 2018 application. Thus, Project No. J-11761-19 is duplicative of the approved Project No. J-11555-18.

For these reasons, the Rex application does not conform with Review Criterion 6.

Review Criterion 12

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

Rex proposes to renovate 870 square feet at its main campus to accommodate the two new shared surgical operating rooms. The rooms are designated on the line drawing in Exhibit C.1 as "OR 58" and "OR 59". WakeMed could only identify 12 ORs in the line drawing in Exhibit C.1. On Page 16, Rex indicates that ORs 58 and 59 were the rooms originally proposed for development in its 2018 CON application (Project No. J-11558-19), and that the two ORs awarded in Settlement of the 2018 Wake County Operating Room review will be located "in other locations within its main hospital facility and not in Rooms 58 and 59." The line drawing does not identify all the existing surgical ORs at Rex, thus is not possible for the Agency to verify that Rex will have 25 surgical ORs upon project completion.

For this reason, the Rex application does not conform with Review Criterion 12.

Review Criterion 18a

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

Rex has proposed to develop both operating rooms allocated in the 2019 Wake County review, after Rex and its parent company, UNC Health Care, sought approval for all 6 ORs available in the 2018 Wake County review. On Page 73, Rex describes the cost containment program being enacted by Blue Cross Blue Shield of North Carolina (BCBSNC), and how the proposed project "will assist UNC Rex Hospital to better meet the goals of these payors, which will ultimately lower costs, expand access, and improve the quality of care for its patients." The program described will affect all North Carolina health care facilities that treat BCBSNC enrollees. It is not clear how Rex's proposed project will positively affect costs, access and quality to meet the goals of the program.

Section P: Timetable

The Rex application states that the proposed project will open in January 2022, making it one of the last projects in the review to become operational.

Section Q: Projections/Pro Formas

Projected Utilization at Rex Hospital

In Section Q, the Rex application describes projected surgical utilization at all facilities owned by UNC Health Care in Wake County. For Rex Hospital, the utilization methodology projects inpatient surgery to increase by a modest 1.0 percent per year through 2025, although inpatient CAGR for 2015-2019 was 2.2 percent. For outpatient surgery, Rex again projects a conservative annual growth rate of 4.5 percent through 2025, matching its historic CAGR for 2017-2019.

Closer examination of Rex's surgery volume suggests that its outpatient case volumes may be growing more slowly than disclosed in the application. When data from 2015 and 2016 (from Rex Hospital's 2016 and 2017 LRAs, excluding Rex-Wakefield) were added to the timeline to match the corresponding time period for inpatient surgery, Rex's actual historic outpatient surgery CAGR was much lower, as shown below.

Rex Hospital Outpatient Surgery Volume Excluding Rex Surgery Center of Wakefield FYs 2015-2019		
Rex FY	OP Cases	Source
2015	11,577	Rex LRA
2016	11,062	Rex LRA
2017	10,720	Rex internal data
2018	10,898	Rex internal data
2019	11,705	Rex internal data
CAGR	0.3%	

It is not clear why Rex chose to omit its FYs 2015-2016 outpatient case volumes, but its outpatient surgery CAGR for 2015-2019 indicates flat growth. The data indicates that development of additional surgery centers in Wake County in recent years, including Raleigh Orthopaedic Surgery Center-Main, Raleigh Orthopaedic Surgery Center-West Cary, Triangle Orthopaedics Surgery Center, and Holly Spring Surgery Center may have impacted Rex's outpatient surgery volumes, at least in the short-term. Applying a lower growth rate through 2025 would negatively impact Rex's projected outpatient volumes, as well as its financial projections.

Shift of Cases to Rex Holly Springs

Rex Holly Springs Hospital (Project No. J-8669-11) was proposed in 2011 and originally slated for completion in 2014. According to the Rex application in this review, the new hospital is currently scheduled to open in SFY 2022. Projections for Holly Springs Hospital have not been modified since originally proposed in 2011. However, the demographics of Wake County have changed dramatically since then, and the number of existing and approved surgical providers and ORs throughout the county is much larger. Although the Agency found the projected shift of cases from Rex-Main to Rex-Holly Springs to be reasonable in the 2018 Wake County OR review, there have been sufficient changes in the Wake County healthcare landscape in recent years to warrant re-examining these projections. Several issues can be raised, including:

- Is it still reasonable to assume that 90 percent of Rex-Holly Springs' surgical volumes will be the result of cases shifted from Rex-Main?
- Should projections for Rex-Holly Springs have been modified to reflect demographic changes in Wake County and the Holly Springs area during the interim years since originally proposed?
- Will the development of new ASFs in Wake County affect projected surgery utilization at Rex-Holly Springs?
- Will the opening of Rex Holly Springs Hospital impact utilization at Rex Surgery Center of Cary and/or Raleigh Orthopaedic Surgery Center-West Cary?

Such questions are not unreasonable, given the amount of time that has passed since Rex Holly Springs was first proposed.

**Wake Spine and Specialty Surgical Center
Project No. J-11747-19**

Wake Spine's application to develop a new ASF with one licensed operating room and three procedure rooms in midtown Raleigh provides a compelling argument that not only satisfies the CON Review Criteria, but provides a unique alternative to other existing and proposed ambulatory surgery options in the service area. Wake Spine proposes a facility that provides an opportunity to increase access, lower costs, and gain efficiencies by doing less acute surgeries and procedures at the proposed surgery center.

The proposed ASF will be located at a site that is centrally-located in Wake County, and which will be accessible to acute care hospitals and major thoroughfares. The proposal to locate the ASF within a medical office building will be convenient for both patients and the surgeons based there. The new ASF proposes an open medical staff that will allow non-investors an opportunity to utilize the facility, thereby increasing access to non-investors and their patients.

Wake Spine's utilization methodology is based on realistic and conservative assumptions. The ASF's focus toward Spine surgery and Neurosurgery would be distinctive within Wake County, and will likely draw many patients from outside the service area.