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

Submitted by: WakeMed Health & Hospitals
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A total of nine CON applications were filed for the September 1, 2018 review cycle requesting operating rooms in the Wake County service area, all pursuant to a need for six operating rooms identified in the 2018 State Medical Facilities Plan (SMFP):

- WakeMed Surgery Center-North Raleigh, LLC ("WakeMed-Cary") (J-11564-18) - Develop a new ASC with two ORs and two procedure rooms, with a total project cost of $11,315,130. The proposed facility will be located at 10004 Falls of Neuse Road in Raleigh.

- WakeMed Surgery Center-Cary, LLC ("WakeMed-North Raleigh") (J-11565-18) - Develop a new ASC with 2 ORs in Cary, with a total project cost of $8,598,738. The facility will be located on Ashville Avenue in Cary.

- RAC Surgery Center, LLC ("RAC") (Project No. J-11551-18) - Develop a new ASC with one OR and two procedure rooms for vascular access procedures for ESRD patients, at a total cost of $2,000,000. The proposed facility will be located at 3031 New Bern Avenue in Raleigh.

- Rex Surgery Center of Garner, LLC ("Rex-Garner") (J-11553-18) - Develop a new ASC in Garner with two ORs, with a total cost of $16,163,394. The proposed facility will be located on Timber Drive East in Garner.

- University of North Carolina Hospitals at Chapel Hill ("UNC-Panther Creek") (J-11554-18) - Develop a freestanding ASC by developing two ORs, with a total project cost of $16,622,944. The facility will be located at N.C. Highway 55 at McCrimmon Parkway in Cary.

- Rex Hospital, Inc. ("Rex-Main") (J-11555-18) - Add two ORs at its existing campus at 4420 Lake Boone Trail in Raleigh. The total project cost is $789,000.

- Duke University Health System, Inc. ("Duke-Green Level") (J-11557-18) - Develop a new ambulatory surgical center with four ORs, at a total cost of $34,300,000. The proposed facility will be located at 3208 Green Level West Road in Cary.

- Duke University Health System, Inc. ("Duke-Raleigh") (J-11558-18) - Develop two additional shared ORs for a total of 17 ORs at its existing location at 3400 Wake Forest Road in Raleigh. The project's total cost is $2,000,000.

- OrthoNC ASC, Inc. ("OrthoNC") (J-11561-18) - Develop a new ASC with one OR and one procedure room, with a total cost of $3,859,995. The proposed facility will be located at 11208 Common Oaks Drive in Raleigh.

In all, a total of 18 operating rooms were proposed in this review. Because the Agency can approve no more than six operating rooms, per the SMFP allocation, not all of these applications can be approved. All of the applicants in this review cycle 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 other counties in North Carolina who utilize Wake County facilities. Given the differences in the respective applications' locations, scopes of services and need methodologies, fair and objective comparisons are difficult to make. WakeMed appreciates the challenging task at hand for the Agency, and has opted to keep its competitive comments as concise as possible.

The WakeMed proposals to add freestanding ambulatory surgical operating rooms in ambulatory surgical facilities (ASFs) adjacent to WakeMed North Hospital and WakeMed Cary Hospital are 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 criteria. The bases for these conclusions are set forth in the following discussion.

Maximize Geographic Access to Surgical Services

The applications in this review propose operating rooms at new and existing locations throughout Wake County. Two applications seek to add new operating rooms at existing acute care hospital campuses in Raleigh. The remaining applications plan for new ambulatory surgical facilities in Cary (3 applications), Raleigh (3 applications) and Garner (1 application).

The WakeMed-North Raleigh and WakeMed-Cary applications stand apart from the other ASF proposals because they seek to develop freestanding, multispecialty ASFs adjacent to the campuses of existing acute care hospitals in southwest and northern Wake County, the regions of Wake County whose populations are growing most rapidly. The chief reasoning for doing so is three-fold:

1. To geographically align with the existing concentrations of surgeons who locate their offices near acute care hospitals;
2. To allow surgeons more daily efficiency, by allowing them to perform surgical cases in ASF and hospital settings that are in close proximity; and,
3. To provide close and easy access to acute care emergency departments in the event that a medical emergency arises with an ASF patient during or after a procedure.

The other freestanding multispecialty ASF applicants in the review propose to locate their surgery centers far from existing surgeons' offices, and not close to local acute care hospitals.

In a growing county such as Wake, this will hinder surgeons' efforts to minimize their daily non-productive time.

Freestanding vs. Hospital-Based Surgical Operating Rooms

The majority of the applications in this review propose to develop operating rooms in freestanding ASFs. Two applications, Rex-Main (J-11555-18) and Duke-Raleigh (J-11558-18), propose to add hospital-based operating to existing campuses. The WakeMed-North Raleigh and WakeMed-Cary proposals will add new freestanding ASF operating room capacity in the fastest-growing regions of Wake County, providing additional lower-cost alternatives to patients and physicians, in an era where containment of healthcare costs remains paramount.

With over 70 percent of existing and approved Wake County surgical operating rooms located in acute care hospitals, there is a need for additional freestanding ambulatory surgery ORs. Growth in freestanding ASF volumes has been constrained by a lack of capacity, particularly for multispecialty ASFs. Additional freestanding ASF ORs will allow more outpatient surgical cases be performed outside the hospital, providing hospital ORs greater capacity for more complex inpatient surgical cases and higher-acuity outpatient cases.

Multi-Specialty vs Single-Specialty Surgical Operating Rooms

Of the nine applicants, only RAC Surgery Center (J-11551-18) and OrthoNC (J-11561-18) propose to develop single-specialty operating rooms. The remaining applicants propose multispecialty operating rooms, either in a hospital-based or freestanding ASF setting. Both the WakeMed-North Raleigh and WakeMed-Cary applications propose multispecialty outpatient surgery for a wide variety of surgical specialties, including:

- General Surgery (North Raleigh and Cary);
- Urological Surgery (North Raleigh and Cary);
- Bariatric Surgery (Cary);
- Breast Surgery (Cary);
- Eye Surgery (North Raleigh & Cary);
- Pain Management (North Raleigh);
- Plastic/Cosmetic Surgery (North Raleigh and Cary);
- Neurological Surgery (Cary);
- Spine Surgery (Cary);
- Orthopaedic Surgery (North Raleigh and Cary); and,
- Gynecological Surgery (North Raleigh and Cary);

Wake County is already served by three existing/approved dedicated orthopaedic surgical centers, raising the question of whether a fourth orthopaedic ASF can be justified. RAC proposes a single-specialty ASF limited only to vascular access procedures for ESRD patients. Because Wake County has not been allocated general-use surgical operating rooms in the SMFP since 2010, approval of another limited-use facility is counter-productive to meeting the greater neec. Among the freestanding, multispecialty ASF applicants in the review, WakeMed-North

Raleigh and WakeMed-Cary propose to offer the largest number of surgical specialties, in order to accommodate the widest variety of surgeons to ensure maximum utilization.

Accessibility by Local Surgeons

Among the seven freestanding ASF applicants, the WakeMed-North Raleigh and WakeMed-Cary proposals stand out as being the only surgery centers that will be accessible by non-employed and unaffiliated surgeons based in Wake County. Based on information provided in the respective CON applications, the surgery centers proposed by RAC, OrthoNC, Rex-Garner, UNC-Panther Creek and Duke-Green Level will be restricted to employed, affiliated, or otherwise financially invested surgeons. Likewise, the Rex-Main and Duke-Raleigh applications provided surgeon letters of support only from their employed/affiliated physicians.

WakeMed-North Raleigh and WakeMed-Cary will have open medical staffs, allowing non-investors and independent physicians the opportunity to schedule and perform their outpatient surgical cases. WakeMed believes in the importance of working with local surgeons who choose to remain independent.

In the following pages, applications under common ownership are grouped and evaluated separately.

RAC Surgery Center – Develop Freestanding ASC with One Operating Room
Project No. J-11551-18

The RAC application proposes to develop a single- specialty, freestanding ASF with 1 operating room. The surgery center will serve end-stage renal disease patients requiring vascular access procedures for dialysis. This application, while well-intentioned, is not the most effective alternative in meeting the needs of Wake County residents. The RAC application is non-conforming with a number of Review Criteria.

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.

On Page 12, RAC states: "Without the approval of the proposed project, many patients will be forced to seek vascular access procedures in the hospital setting." Vascular access procedures for ESRD patients are not new, and have traditionally been done in an office-based setting. The demographics of ESRD patients, while growing, has not changed in a meaningful way to justify the proposed project. Throughout its application, RAC describes the benefits of performing vascular access procedures in licensed operating rooms. However, the primary reason is that reimbursement for vascular access cases is now more lucrative when performed in an ASF.

On Pages 22-23, the RAC application describes the benefits of a dedicated vascular access center, citing lower costs, better coordination of care, and improved clinical outcomes. Much of the information included in this section is anecdotal, with only nominal demonstrated improvements. While ESRD is a growing chronic health issue, the description of need provided in Section C does not warrant approval of an ASF dedicated to vascular access procedures.

RAC states that approval of its project will obviate the need to refer patients to hospitals, including emergency departments, for vascular access procedures. However, on Page 16, RAC indicates that its ASF will be open from 7:00 a.m. – 4:00 p.m. Based on this information, it is apparent that patients in need of vascular access procedures on evenings and weekends will still need to visit a hospital emergency department if they have an urgent after-hours issue. Thus, there is little benefit to patients from approval of this project. While hospital-based care may be more expensive and less convenient to patients, nothing in the RAC application suggests that this type of procedure could not be performed in a multispecialty ASF.

The RAC project will serve only a limited subset of patients, who require specialized procedures to allow vascular access for dialysis. In Section C, RAC provides its projected patient origin in Project Years 1-3. Of note is that the majority of cases will be performed on patients originating from outside Wake County.

For these reasons, the RAC 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, the RAC project describes the alternatives to the proposed project. RAC discusses the pitfalls with maintaining the status quo, as well as expanding the current office based vascular access centers. There is significant discussion regarding the disadvantages of performing vascular access procedures in a hospital setting, primarily due to higher cost.

RAC dismissed the alternative of serving ESRD patients requiring vascular access in general ambulatory surgery centers as "not a reasonable or practical option in most cases", but failed to elaborate on why their physicians could not perform their procedures in existing ASFs in the community. RAC did not document efforts to partner with any existing ASFs in Wake County to offer vascular access, or that these existing ASFs would be unwilling to do so. RAC did not state that they have approached existing ASFs, but were rebuffed. Unless all existing ASFs are at full capacity, an opportunity to perform vascular access in these centers exists.

For these reasons, the RAC proposal does not conform with Review Criterion 4.

Review Criterion 5

Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

The RAC application projects the highest average charge per case and highest net income per case among the freestanding ASFs in this review, with projections that are significantly higher than multispecialty ASFs. Please see the following table.

Comparison of Selected Financial Statistics, Project Year 3
Sorted in Descending Order by Average Charge Per Case
Source: Application Pro Formas in Section Q

Facility	Type	Average Charge Per Case	Net Revenue Per Case	Net Income Per Case
Duke-Raleigh	Hospital	$36,976.14	$10,689.83	$833.36
Rex-Main	Hospital	$34,058.10	$12,441.42	$3,557.06

Comparison of Selected Financial Statistics, Project Year 3 Sorted in Descending Order by Average Charge Per Case Source: Application Pro Formas in Section Q				
Facility	**Type**	**Average Charge Per Case**	**Net Revenue Per Case**	**Net Income Per Case**
RAC Surgery Center	Freestanding ASF	$11,447.11	$8,474.32	$3,431.56
Duke-Green Level	Freestanding ASF	$9,429.57	$3,381.38	$487.32
OrthoNC	Freestanding ASF	$8,336.35	$3,631.67	$812.94
Rex-Garner	Freestanding ASF	$8,133.17	$3,216.82	$109.67
UNC-Panther Creek	Freestanding ASF	$7,985.08	$3,583.00	$638.23
WakeMed-Cary	Freestanding ASF	$5,710.88	$3,822.28	$1,415.44
WakeMed-North Raleigh	Freestanding ASF	$4,740.68	$3,122.12	$962.31

The RAC proposal's net revenue per case is the second-highest in the review, and well above all other freestanding ASF applications, and its net income per case is nearly as great as that of Rex-Main, the highest in the review. It is difficult to see how the RAC application will offer a cost savings to consumers. Therefore, the RAC application is not conforming with Review Criterion 5.

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 impacted on cost-effectiveness, quality and access to the services proposed, the applicants shall demonstrate that its application is for a service on which competition will not have a favorable impact.

Despite the assertion that the RAC application will have a positive impact on competition in the service area, there is no information provided to substantiate this claim. The RAC proposal represents a limited-use, single-specialty surgery center that will serve a narrow subset of patients in central North Carolina. Cases proposed for this facility could be performed in existing ASFs in the community. Approval of this project would not enhance competition and would continue to limit access to freestanding ASF ORs. For this reason, the RAC application does not conform with Review Criterion 18a.

Rex Surgery Center of Garner – Develop Freestanding ASC with Two Operating Rooms
Project No. J-11553-18

UNC Health Care – Develop Freestanding ASC with Two Operating Rooms
Project No. J-11554-18

Rex Hospital – Develop Two Additional Hospital-Based Operating Rooms
Project No. J-11555-18

In the aforementioned projects, UNC Health Care and Rex Health Care propose to develop a total of six surgical operating rooms in Wake County. These applications are nonconforming with a number of 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 proposed services.

<u>UNC-Panther Creek: Projected Patient Origin is Unreasonable</u>

On Page 25 of the UNC-Panther Creek application provides projected patient origin for the facility. UNC-Panther Creek proposes to perform approximately two-thirds of total cases on Wake County residents, and approximately one-third to Durham County residents. Given that the proposed medical staff of this ASF will be employed UNC physicians, who serve patients from a wide geographic area, it would stand to reason that there would be cases performed on residents of more than just these two counties. On Page 24, UNC-Panther Creek shows the historic patient origin for surgical services at UNC Hospitals – the table lists 21 counties that contributed at least 1 percent of surgical cases (which sums to 78 percent), and a line item for "Other" counties with 22 percent of total. Will surgery at UNC-Panther Creek be restricted to only patients originating from Wake and Durham Counties?

<u>Rex-Main/Rex-Garner: Impact of Rex-Holly Springs Hospital</u>

The Rex-Main proposal is predicated on the assumption that most of the operating room capacity in the 3 ORs approved for relocation to Rex-Holly Springs Hospital (J-8669-11) will be backfilled with the 2 operating rooms planned in this project. Surgical utilization at Rex-Main has been increasing in recent years, primarily on the inpatient side. According to the Rex-Main application, Rex-Holly Springs, for which the CON was issued in 2014, is not anticipated to open until mid-2021. UNC Rex is assuming that some surgical volume at Rex-Main will shift to Rex-Holly Springs. Until Rex-Holly Springs opens, it is impossible to gauge the impact of that facility on Rex-Main's operations and volumes. Further, projections for Rex-Holly Springs were made

in 2011, making them unreliable in 2018 for projections through 2024. 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. Therefore, UNC Rex's surgery projections for Rex-Main, as well as Rex-Garner, are unreliable.

Rex-Main: Increasing Shift from Inpatient to Outpatient Surgery

As more and more surgical procedures are performed on an outpatient basis, and as more outpatient surgery is performed in freestanding ambulatory surgical facilities, the proportion of surgical cases performed outside acute care hospitals will continue to increase. Thus, acute care hospitals' surgical volumes are more likely to experience growth in inpatient cases, as outpatient cases are shifted outside hospitals.

On pages 25-27 of the Rex-Main application, UNC Rex admits that demand for outpatient surgery is accelerating and that third-party payers are increasing their incentives to move surgery to less expensive settings. Therefore, it is not reasonable to continue to approve additional operating room capacity in acute care hospitals. To do so will continue to suppress growth in freestanding ASFs. The Rex-Main application does not acknowledge this reality and seeks to maintain the status quo.

Rex-Main: Need for Additional OR Capacity

On pages 30-31, UNC Rex states that "the redeployment of hospital-based operating rooms to ASCs, while beneficial to patients for multiple reasons, has effectively decreased the surgical capacity in the county, by removing operating rooms from hospital-based settings." This statement is misleading: the number of surgical operating rooms in Wake County has, with the exception of the approval of single-specialty OR demonstration projects for orthopaedic surgery and dental surgery, not changed. The conversion of some hospital-based ORs to freestanding ASF ORs, has been in response to payer and patient demands for more less-expensive surgical assets.

As described above, UNC Rex cites the development of Rex-Holly Springs Hospital, with 3 operating rooms relocated from Rex-Main, as justification to approve new OR capacity at Rex-Main. UNC Rex states on Page 33 that "…the three operating rooms that will relocate from UNC REX main campus to UNC REX Holly Springs are assumed to have 450 fewer hours of operation annually…". However, ORs at Rex-Holly Springs will be shared ORs, and can operate the same number of hours daily as those at Rex-Main. The notion that ORs at Rex-Holly Springs will be somehow unequal to those at Rex-Main is disingenuous.

Rex-Main: Ability to Provide Low Cost Care

On Page 34, Rex-Main states:

> "UNC REX provides lower costs per procedure for Blue Cross and Blue Shield patients than Duke Raleigh, WakeMed Cary or WakeMed Raleigh Campus. In fact, it is likely UNC REX will continue to offer the lowest cost of care to patient for surgical services in Wake Couinty when compared to other hospital providers as changes to the health insurance landscape unfold."

To accompany this passage, the Rex-Main application provides the table "Estimated Health Care Costs of Select Top 20 Outpatient Surgical Procedures" from Blue Cross Blue Shield of North Carolina. While this table is offered as evidence of Rex-Main's supposed lower surgical costs, only 4 procedures are listed in the table, with direct comparison between all Wake County hospitals' provided for only *one* surgical procedure: Knee Replacement. No comparable information is provided for freestanding ASFs. UNC Rex has conveniently cherry-picked data from a single insurer as proof that it is the supposed "low cost provider" of surgical services in Wake County. Without a full analysis of surgical costs across all payers, including Medicare, this information is without merit.

<u>Rex-Garner/UNC-Panther Creek/Rex-Main: Accessibility</u>

On Pages 35-36[1], the Rex-Main application describes the recent announcement from Blue Cross Blue Shield of North Carolina (BCBSNC) that it will discontinue its Blue Local insurance plan, which served patients in central North Carolina who utilized UNC, Duke Health and WakeMed, and switch these enrollees to the Blue Value plan, which will exclude Duke and WakeMed providers. Rex states that has many as 50,000 BCBSNC enrollees may switch to the Blue Value plan. In reality, the effect of this shift is yet to be determined. It is also possible that many Blue Local enrollees will switch to another insurance plan that allows access to all local healthcare systems' facilities and physicians. What the UNC and Rex applications tout as an advantage of their proposals may actually represent a *decrease in accessibility* to services in Wake County. If Blue Value enrollees can only access UNC Health Care services, does this truly enhance access to care?

<u>Rex-Garner/UNC-Panther Creek: Growth in Wake County</u>

The Rex-Main application provides an analysis of projected population growth located within a 15-minute drive time of each existing ASF in Wake County, as well as the proposed Rex-Garner and UNC-Panther Creek ASFs. This information, which is included to demonstrate population growth throughout Wake County, is useful only to degree. There is no disputing Wake County's rapid population growth and increasing demand for health care services. What is equally, if not more, important in considering locations for new operating room capacity is concentration of surgeons practicing in the county. Surgeons are more likely to utilize facilities that maximize their daily efficiency, as opposed to locations that require significant drive times.

[1] Analysis also provided on Pages 35-36 of the UNC-Panther Creek application, and Pages 36-37 of the Rex-Garner application.

See the discussion under Section Q.

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.

Rex-Main

The Rex-Main application describes three alternatives considered, in addition to the alternative outlined in its CON application. In particular, the second and third alternatives address the complementary applications filed in this review for the Rex-Garner and UNC-Panther Creek projects. When combined, these three projects seek approval for all six operating rooms allocated to Wake County in the 2018 SMFP.

Given the trend toward greater proportions of surgery being performed on an outpatient basis, and the cost savings this represents to payers and patients (as described on Rex-Main application Pages 30-31) , it is unusual that UNC Rex would propose to create additional surgical capacity at Rex-Main. While the proposed project has the lowest capital cost in the review, it also proposes the highest charge per case. In Section C, UNC-Rex did not describe any difficulties in accommodating surgery patients with Rex-Main's existing complement of ORs.

When compared with other proposals in this review, the Rex-Main application is not the least costly or most effective alternative, and does not conform with Review Criterion 4.

Rex-Garner

Part of the justification for the Rex-Garner project is the anticipated completion of the final stages of Interstate 540 through Garner and southeastern Wake County. On Page 48, the Rex-Garner application describes the potential impact of this roadway on this portion of the oounty. While it is true that the completion of Interstate 540 will increase traffic through southeast Wake County, the North Carolina Department of Transportation has not yet finalized the route for this roadway. The current timetable indicates that bids for construction will not be awarded until 2027, with no estimate of completion of construction[2]. It is likely that even if this schedule does not change, the completion of the roadway will be well past 2030.

Thus, while the Garner area will continue to experience growth in population and medical services, the need for an ASF in this area is not as acute as that currently experienced in southwest Wake and northern Wake County. Therefore, the Rex-Garner application is not the most effective alternative in this review.

[2] Source: N,C. DOT website, accessed at https://www.ncdot.gov/projects/complete-540/Pages/default.aspx.

UNC-Panther Creek

Need for the UNC-Panther Creek application is predicated on the notion that surgery cases in the ASF will be limited solely to UNC Faculty Practice physicians based in Chapel Hill, who will travel to western Wake County to perform surgeries on their Wake and Durham County patients. This application is not the least costly or most effective alternative in the review. The fact that surgeons not employed by UNC Health Care will not have access to the facility is a significant shortcoming. Nearly all of the surgeons who will utilize the facility have not been recruited, so the case volumes associated with these new physicians I are purely hypothetical. It would be a disservice to award 2 operating rooms to a project that relies on such scant evidence.

For these reasons, the UNC-Panther Creek application does not conform with Review Criterion 4.

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.

Rex-Main/Rex-Garner/UNC-Panther Creek

Page 81 of the Rex-Main application contains the following statement: "No other provider can meet the needs of UNC REX Hospital's patients." This statement is totally unsupported, and assumes that Wake County's growing and aging population will automatically choose Rex facilities for their care. At issue in this review how best to make additional OR capacity available for all patients. Of Wake County's 105 existing and approved surgical operating rooms, over 70 percent are housed in acute care hospitals. It is likely that growth in freestanding ASF volumes have been suppressed by a lack of OR capacity.

Approval of all three UNC and Rex applications would serve to duplicate a single system's services in Wake County. UNC Health Care System is already approved for six locations 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

Approval of additional UNC Health Care ASF locations would only serve to exacerbate the imbalance of ASF facilities in Wake Counties. This is particularly important in light of the fact

that the Rex-Garner and UNC-Panther Creek proposals, like their existing approved counterparts, seek to accommodate only physicians employed or affiliated with UNC Health Care.

For these reasons, the Rex-Main, Rex-Garner and UNC-Panther Creek applications do not conform with Review Criterion 6.

Review Criterion 8

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

Rex-Main

The Rex-Main application contains a number of support letters from local physicians, for the Rex-Main project, as well as the Rex-Garner and UNC-Panther Creek CON applications. There is no standard regarding a minimum number of letters. However, it is worth noting that all surgeon letters of support were provided by surgeons employed or otherwise affiliated with Rex or UNC Health Care, either based in Raleigh or Chapel Hill. The following surgical groups provided letters of support:

- UNC OB-Gyn – employed
- North Carolina Surgery – employed
- NC Heart & Vascular – employed
- Rex Cardiac Surgical Specialists – employed
- UNC Urogyencology & Reconstructive Pelvic Surgery – employed
- Rex Vascular Specialists – employed
- Rex Neurosurgery & Spine – employed
- UNC Children's – employed
- Raleigh Orthopaedic Clinic – affiliated

No letters of support from *non-employed or unaffiliated* surgeons based in Wake County accompanied the Rex-Main application. The lack of independent, "community-based" surgeon support suggests that the Rex-Main application, as well as the Rex-Garner and UNC-Panther Creek proposals, will only accommodate surgeons who are allied with the UNC Health Care System. Further, it suggests that Rex may ultimately "close" their medical staff to unaffiliated physicians. Such an action, while neither illegal nor unethical, would leave independent surgical practices with fewer options to perform their surgical cases.

Rex-Garner

The Rex-Garner project will be developed to cater to physicians employed or otherwise affiliated with UNC Health Care. In Section Q, Page 13, the Rex-Garner application lists surgeons who are expected to perform cases at the new ASF, represented by the following practices:

- North Carolina Heart & Vascular – employed
- Rex Neurosurgery and Spine – employed
- Rex Physicians – employed
- Raleigh Orthopaedic Clinic - affiliated

Of the 13 physicians listed on Page 13, 5 are unidentified "new recruits" who will comprise the bulk of the ASF's surgical OR volume. All will be employed by either Rex Physicians by Raleigh Orthopaedic Clinic, a UNC Health Care affiliate, which provided most of the letters of support for the project in Exhibit I.2. Of note is that none of the physician letters of support provided projected volumes at Rex-Garner to corroborate the volumes provided in Section Q, Page 13. In addition, Raleigh Orthopaedic Clinic operates a freestanding ASF in Raleigh, and is approved to develop a second freestanding ASF in Cary.

Despite proposing a new multispecialty ASF location in Wake County, the Rex-Garner application demonstrated no efforts to collaborate or coordinate with other local, independent surgeons based in Wake County.

UNC-Panther Creek

The UNC-Panther Creek project is intended to be open only to surgeons of UNC Faculty Practice. In Exhibit I.2, the application provides letters of support from the following surgical practices, all affiliated with UNC:

- UNC School of Medicine Otolaryngology/Head & Neck Surgery
- UNC OB-Gyn
- UNC Department of Surgery
- UNC School of Medicine Division of Gastrointestinal Surgery
- UNC School of Medicine Division of Vascular Surgery
- UNC Plastic Surgery
- UNC School of Medicine Division of Cardiothoracic Surgery
- UNC School of Medicine General & Acute Care Surgery
- UNC School of Medicine Division of Surgical Oncology
- UNC School of Medicine Department of Urology

Like the Rex-Garner application, the intent to make the ORs at UNC-Panther Creek available only to employed physicians demonstrates a lack of coordination with the existing health care

system, and is a disservice to independent surgeons. The UNC physicians who provided letters of support are all based in Chapel Hill, as will be the surgeons who will work at the proposed ASF. Although UNC Panther Creek will be located as close to Chapel Hill as possible while still having a Wake County address, it is unreasonable to assume these physicians will be able to effectively work in two disparate sites located approximately 16 road miles and a 20-30 minute drive apart.

For these reasons, the Rex-Main, Rex-Garner and UNC-Panther Creek proposals do not conform with 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.

Rex-Main

UNC Rex proposes to renovate 870 square feet at the Rex-Main campus to accommodate the 2 new shared operating rooms. These rooms are designated on the line drawing in Exhibit C.1 as "OR 58" and "OR 59". However, the line drawing does not identify the existing surgical ORs at Rex-Main, thus it is not possible for the Agency to verify that Rex-Main will have 24 licensed surgical ORs at project completion.

Thus, the Rex-Main application does not conform to 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 impacted on cost-effectiveness, quality and access to the services proposed, the applicants shall demonstrate that its application is for a service won which competition will not have a favorable impact.

UNC and Rex have collectively proposed to develop all six operating rooms in the 2018 Wake County review. Approval of all three of these applications would have a detrimental effect on competition for surgical services in Wake County. Because the UNC's and Rex's projects will accommodate only their employed and affiliated surgeons, the remaining non-employed and

unaffiliated surgeons based in Wake County will have no additional options in which to perform surgery. Please also see the discussion for Review Criterion 8.

On Page 102, the Rex-Main application reiterates UNC Rex's claim of being Wake County's low-cost hospital provider and states: "…it is likely that UNC REX will continue to offer the lowest cost of care to patients for surgical services when compared to other hospital providers as changes to the healthcare landscape unfold". This statement is completely unsupported, as discussed in Review Criterion 3 above. Cost containment is a major initiative in every health system, and payer-provider relationships are constantly shifting in response to market changes.

Section P: Timetable

The UNC and Rex applications state that all three projects will open in July 2021, making them among the last projects in the review to become operational. For the Rex-Main project, this can be excused, given that 3 ORs at Rex-Main will be relocated to Rex-Holly Springs Hospital, which is slated to open in July 2021. Although Rex could renovate space at its main campus to accommodate 2 additional hospital-based operating rooms prior to the opening of Rex-Holly Springs, it has chosen to renovate OR spaces vacated by this relocation.

However, it is unclear why development of the Rex-Garner and UNC-Panther Creek projects, which will be new freestanding ASFs, would need to be delayed until July 2021. These ASFs would open over 2 years after the anticipated decision, making them less effective than proposals that would open sooner. Presumably, the new ASFs would not need to be constructed to institutional standards, allowing for more expedient development. Because of their development timetables, the Rex-Garner and UNC-Panther Creek applications are not the most effective choices for making surgical services available in Wake County.

Section Q: Projections/Pro Formas

<u>Shift of Inpatient Surgery Cases from UNC Hospitals to Rex-Main</u>

In Section Q, Page 6, the UNC and Rex applications describe the projected shift in cases from UNC Hospitals to Rex-Main:

> "This shift is part of the ongoing effort to relieve capacity constraints at UNC Hospitals and to serve patients closer to home. The 2018 SMFP and Proposed 2019 SMFP identify deficits of 6.48 and 9.38 operating rooms, respectively at UNC Hospitals. As a result, the 2018 SMFP includes a need determination for six operating rooms in Orange County and the Proposed 2019 SMFP includes a need determination for three operating rooms (net of the placeholder for six operating rooms in the 2018 SMFP)."

UNC Hospitals is based in Orange County and controls 100 percent of that county's existing licensed operating rooms. Orange County will be allocated a total of nine new operating rooms in 2018 and 2019, per SMFP need determinations. As the only provider of surgical services in

Orange County, there is a high probability that UNC Hospitals will be awarded *all nine* of these available ORs. This additional OR capacity would appear sufficient to relieve any supposed "capacity constraints" at UNC Hospitals. Therefore, it would seem improbable that 1,050 inpatient surgery cases would shift from UNC Hospitals to Rex-Main each year from FY 2021-2024. UNC Hospitals has announced plans to make a major capital investment in surgical services with the development of a $290 million, seven-story Surgical Tower on its campus, which is slated for completion by 2022.[3] With this significant investment in surgical services, what is the likelihood that such a large number of cases would shift from UNC Hospitals to Rex-Main?

The UNC and Rex applications did not describe:

1. How many surgical cases, if any, have already shifted from UNC Hospitals to Rex-Main;
2. How the maximum shift of 1,050 cases per year was derived; or,
3. Why the case shift does not continue to increase after FY 2021.

Upon closer examination, the true reason for the projected shift in inpatient surgery cases from UNC Hospitals to Rex-Main becomes obvious: without this shift in cases (and their associated surgical hours), Rex-Main would actually have a negligible OR deficit by Project Year 3, making the 2 additional operating rooms proposed in J-11555-18 unnecessary. Please see the table below.

Surgical Volume and Operating Room Need at Rex-Main Excluding Inpatient Surgical Cases Projected to Shift from UNC Hospitals						
	FY 2019	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**	**FY 2024**
Inpatient Cases	9,301	9,938	10,590	10,637	10,864	11,095
less: Cases Shifted from UNC Hospitals	525	788	1,050	1,050	1,050	1,050
Total Inpatient Cases less UNC Shift	8,776	9,150	9,540	9,587	9,814	10,045
Outpatient Cases	10,898	10,898	10,898	10,236	9,842	9,433
Total Surgical Cases	19,674	20,048	20,438	19,823	19,656	19,478
Inpatient Hours (assuming 154.0 min or 2.5667 hrs per case)	22,525	23,485	24,486	24,607	25,190	25,783
Outpatient Hours (assuming 113.3 min or 1.8883 hrs per case)	20,579	20,579	20,579	19,329	18,585	17,812
Total Surgical Hours	43,104	44,064	45,065	43,936	43,774	43,595
Standard Hours per OR	1,950	1,950	1,950	1,950	1,950	1,950
OR Need (Surgical Hrs ÷ 1950)	22.1	22.6	23.1	22.5	22.4	22.4
OR Capacity[4]	25	25	25	22	22	22
OR Deficit/(Surplus)	(2.9)	(2.4)	(1.9)	0.5	0.4	0.4

[3] https://www.bizjournals.com/triangle/news/2018/07/11/unc-hospitals-ready-to-break-ground-on-new.html.
[4] 3 ORs relocate to Rex-Holly Springs Hospital in FY 2022.

This calculation above demonstrates that the Rex-Main application utilization projections are dependent on the inpatient cases projected to shift from UNC Hospitals. If these cases are excluded, there is virtually no need for additional ORs at Rex-Main.

Volumes Projections at UNC-Panther Creek

According to the application, the UNC-Panther Creek project will be utilized exclusively by UNC Faculty Practice surgeons. The table on Section Q, Page 10 shows projected operating room cases and procedure room procedures for 7 yet-to-be-recruited surgeons and one existing surgeon, Dr. Bradley Figlar. UNC projects Dr. Figlar's volume at UNC-Panther Creek to be 50 surgical cases and 20 procedure room procedures. However, the letter of support provided from Dr. Figlar in Exhibit I.2 does not mention specific case volumes to be performed at UNC-Panther Creek. Aside from Dr. Figlar, any volume projected to be performed by physicians who have not been recruited is speculative and unreliable.

In Section Q Page 10, UNC-Panther Creek 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." Given the proposed shifts in surgery volume between Rex's facilities in Wake County and between UNC Hospitals to Rex-Main, it is remarkable that no cases are projected to shift to UNC-Panther Creek.

Volume Projections at Rex-Garner

The Rex-Garner project will shift some outpatient surgical cases from Rex-Main to Rex-Garner. According to the table provided in Section Q, Page 13, approximately one-half of Rex-Garner's projected volume will come from Raleigh Orthopaedic Clinic, already practices at 2 ASFs in Raleigh and Cary. Although several letters of support were provided from Raleigh Orthopaedic surgeons, no case volumes were included to substantiate the projections. Nearly all of the remaining volume at Rex-Garner cases will come from surgeons yet to be recruited. The Rex-Garner projections are unreasonable because although the application identifies which surgery practices will provide case volumes, there is no verification that this will occur from the surgeons themselves.

Rex-Garner is projected to perform 1,990 cases in Project Year 3, which is 22 percent of the estimated "potential" outpatient surgery volume originating within a 15-minute drive time of the Rex-Garner site, as described in Section C. Rex prorates the 2017 use rate of 60.3 outpatient surgical cases per 1000 Wake County residents (obtained from 2018 License Renewal Applications) equally across all Wake County ZIP Codes to estimate the projected total surgical cases by ZIP Code for the interim years and Project Years 1-3. Aside from the physician volumes speculated in Section Q, there is no assumption provided regarding how the 22 percent "share" is derived. The Rex-Garner projections are not reliable, because the project methodology assumes that demand for Wake County outpatient surgical cases will be spread equally across all regions according to their population, and that the identified and unidentified surgeons will actually perform the number of cases Rex-Garner claims.

The application projects that 33 outpatient cases will shift from Rex-Main in Project Year 1, increasing to 65 cases by Project Year 3. Missing from this analysis is a rational explanation of how these volumes were estimated. The case volumes to be shift do not correspond to a volume percentage; rather, they are merely an estimate that cannot be substantiated.

Duke Raleigh Hospital – Two Additional Hospital-Based Operating Rooms
Project No. J-11157-18

Duke University Health System – Develop Freestanding ASC with Four Operating Rooms
Project No. J-11558-18

In the aforementioned projects, Duke University Health System proposes to develop a total of six surgical operating rooms in Wake County. These applications are nonconforming with a number of CON Review Criteria, as evidenced below.

The CON applications submitted for the aforementioned projects by the applicant, Duke University Health System (DUHS), include numerous instances in which both applications each mention and make reference to the other DUHS CON application. Further, the two CON applications are extraordinarily interrelated and interdependent in terms of: large shifts of current patient case volumes from an existing facility and to a proposed facility; the viability of each application depends upon both applications being approved (which would take all six available ORs with all other applicants being left out); and surgeons from Duke Health's Private Diagnostic Clinic (PDC), many of which who 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. The Duke-Green Level application states that certain PDC physicians will move between 82-91 percent of their current caseloads from Duke-Raleigh to the proposed ASC, but these percentages cannot be substantiated.

Review Criterion 3

<u>Duke-Raleigh/Duke-Green Level</u>

The Duke-Raleigh application proposes to develop 2 new hospital-based operating rooms at Duke Raleigh Hospital. According to the 2018 SMFP, Duke-Raleigh has a calculated deficit of 6.77 operating rooms, and "the need determination for six (6) ORs in the 2018 SMFP is based solely on the surgical utilization of DRAH…" (Page 22). Yet, Duke-Raleigh is proposing to add only 2 operating rooms at its existing facility in this review, opting to develop an additional 4 ORs at Duke-Green Level.

Its complementary application, the Duke-Green Level application, will be a new freestanding ASF located in West Cary with 4 operating rooms and 4 procedure rooms. Like the UNC-Panther Creek proposal, the Duke-Green Level project will be developed to allow Duke Medicine physicians based in Durham and Raleigh access to an ASF located in Wake County.

The new ASF will be located near N.C. Highway 540, approximately 20 road miles and 30 minutes' drive time from Duke-Raleigh, and is nearly the same distance from Duke University Hospital (20 road miles/22 minutes). The distance between these facilities is significant, and given the growing population of Wake County, drive time between is likely to increase over

time. Given that physicians who practice at both Duke-Raleigh and Duke University are likely to utilize the facility, travel times and surgeon efficiency are an important consideration.

The most recent patient origin distribution for Duke Raleigh Hospital for FY 2018 is used identically, down to each tenth of a percent by county, for all projected patient origin assumptions in both Duke CON applications. The application for the Duke-Green Level ASF goes to great lengths to discuss locational demographic factors, not only at the county level for Wake County, but then drills down further to the Zip Code Level, focusing on only several specific ZIP Codes in the Cary area of southwestern Wake County. It is totally unreasonable to put forth a projected patient origin distribution exclusively for surgery outpatients that is identical to the past patient origin distribution of Duke-Raleigh, a medium-sized surgical specialty hospital, approximately 30% of whose patients are inpatients. It is not reasonable to expect that as Duke-Raleigh shifts thousands of its ambulatory surgical cases to Duke-Green Level's proposed ASC, that the patient origin distributions for both facilities either be identical or remain identical.

On Page 17, the Duke-Raleigh application shows historic FY 2018 patient origin at Duke-Raleigh, shown below in Table A.

Table A
Duke Raleigh Hospital CON Application
Duke Raleigh Historical Patient Origin
FY 2018
Outpatient Surgeries by Patients' County of Origin

County	# Cases	% of Total
Wake	7,071	56.1%
Johnston	580	4.6%
Durham	530	4.2%
Franklin	479	3.8%
Cumberland	302	2.4%
Nash	252	2.0%
Harnett	239	1.9%
Orange	164	1.3%
Granville	138	1.1%
Vance	101	0.8%
Alamance	88	0.7%
Chatham	76	0.6%
Person	50	0.4%
Guilford	50	0.4%
Other States	404	3.2%
Other NC Counties*	2,080	16.5%
Total	**12,604**	**100.00%**

On Page 20, the Duke-Raleigh application provides the projected patient origin for Duke-Raleigh's surgical patients in Project Year 3 (FY 2023).

Table B **Duke Raleigh Hospital CON Application** **Projected Outpatients for FY 2023, Year 3** **Outpatient Surgeries by** **Patients' County of Origin**		
County	**# Cases**	**% of Total**
Wake	7,072	56.1%
Johnston	580	4.6%
Durham	529	4.2%
Franklin	479	3.8%
Cumberland	303	2.4%
Nash	252	2.0%
Harnett	239	1.9%
Orange	164	1.3%
Granville	139	1.1%
Vance	101	0.8%
Alamance	88	0.7%
Chatham	76	0.6%
Person	50	0.4%
Guilford	50	0.4%
Other States	403	3.2%
Other NC Counties*	2,080	16.5%
Total	**12,605**	**100.00%**

On Page 18 of the Duke-Green Level application, the following table provides the projected patient origin for that facility. Year 2 (FY 2023) is shown below in Table C.

Table C **Duke Green Level ASC CON Application** **Projected Outpatients for FY 2023** **Outpatient Surgeries by Patients'** **County of Origin**		
County	**# Cases**	**% of Total**
Wake	1,866	56.1%
Johnston	153	4.6%
Durham	140	4.2%
Franklin	126	3.8%
Cumberland	80	2.4%

Nash	67	2.0%
Harnett	63	1.9%
Orange	43	1.3%
Granville	36	1.1%
Vance	27	0.8%
Alamance	23	0.7%
Chatham	20	0.6%
Person	13	0.4%
Guilford	13	0.4%
Other States	107	3.2%
Other NC Counties*	549	16.5%
Total	**3,327**	**100.00%**

The *combined* Duke-Raleigh and Duke-Green Level outpatient surgery patient volumes are shown below in Table D.

Table D
Duke's Two CON Projects, Combined
Projected Outpatients for FY 2023
Outpatient Surgeries by Patients' County of Origin

County	# Cases	% of Total
Wake	8,938	56.1%
Johnston	733	4.6%
Durham	669	4.2%
Franklin	605	3.8%
Cumberland	383	2.4%
Nash	319	2.0%
Harnett	302	1.9%
Orange	207	1.3%
Granville	175	1.1%
Vance	128	0.8%
Alamance	111	0.7%
Chatham	96	0.6%
Person	63	0.4%
Guilford	63	0.4%
Other States	510	3.2%
Other NC Counties*	2,629	16.5%
Total	**15,931**	**100.00%**

The *incremental* outpatient surgery volume for the Duke-Raleigh and Duke-Green Level projects is provided below in Table E.

Table E **Duke's Two CON Projects, Combined** **Net Incremental OP Surgeries,** **FY 2018 vs FY 2023** **Outpatient Surgeries by Patients' County of Origin**		
County	**# Cases**	**% of Total**
Wake	1,867	56.1%
Johnston	153	4.6%
Durham	139	4.2%
Franklin	126	3.8%
Cumberland	81	2.4%
Nash	67	2.0%
Harnett	63	1.9%
Orange	43	1.3%
Granville	37	1.1%
Vance	27	0.8%
Alamance	23	0.7%
Chatham	20	0.6%
Person	13	0.4%
Guilford	13	0.4%
Other States	106	3.2%
Other NC Counties*	549	16.5%
Total	**3,327**	**100.00%**

It should be noted that the projected volume for Duke-Green Level in Table C is *identical* to the combined incremental net outpatient surgeries for Duke-Raleigh and Duke-Green Level in Table E. Also noteworthy is that Duke-Raleigh's projected outpatient surgery volume for FY 2023 is *identical* to its outpatient surgery volume in FY 2018. The data demonstrates that Duke merely intends to backfill the case volume it plans to shift from Duke-Raleigh to Duke-Green Level. Although Section Q provides a lengthy methodology, the patient origin tables in the respective applications offer a simplified explanation, and proves that the 2 projects are interrelated and dependent upon one another.

On Page 23, the Duke-Raleigh application states that Duke Health System "has only 13 percent of the Wake County OR inventory", and that "DUHS is grossly under capacity with respect to ORs in Wake County." These 2 statements are not congruent, as they assume that Duke's need for ORs in the county is based on the need for parity in OR inventory.

Duke-Green Level's patient origin is modeled after Duke-Raleigh's, as shown on Page 18:

Wake	56.1%
Johnston	4.6%

Durham	4.2%
Franklin	3.8%
Cumberland	2.4%
Nash	2.0%
Other Counties	26.9%
Total	100.0%

Because Duke-Green Level will be located approximately 20 road miles west of Duke-Raleigh, it is unreasonable to assume that the patient origins for these 2 facilities will be identical. One would expect Duke-Green Level to receive greater proportions of patients from Durham, Orange and Chatham Counties, and fewer from Franklin, Nash, and other counties located further east. Because over one-quarter of Duke-Green Level cases will originate from unspecified areas, it is impossible to determine if these are geographically more accessible to the ASF than to Duke-Raleigh.

For these reasons, the Duke-Raleigh and Duke-Green level applications are non-conforming with Review Criterion 3.

Review Criterion 4

Duke-Raleigh

Throughout the Duke-Raleigh application, there is discussion regarding the lack of OR capacity at Duke Raleigh Hospital, and how additional ORs are justified. Duke-Raleigh describes the need for additional ORs to accommodate growing outpatient surgical volumes. However, the Duke-Raleigh project proposes to develop only 2 of the 6 ORs available in the 2018 SMFP. While Duke Health System does not have a freestanding ASF located in Wake County, the application did not discuss the alternative of developing such a facility in closer proximity to Duke-Raleigh, where a large number of Duke-employed and Duke-affiliated physicians already practice. The application mentions the significant capital investment being made at Duke-Raleigh, yet there was no discussion of developing an ASF nearby, where Duke-Raleigh patients and physicians could gain the most benefit. Assuming continued growth in demand for surgical services at Duke-Raleigh, it would seem nonsensical to propose only 2 additional ORs at the facility.

Therefore, the Duke-Raleigh project is nonconforming with Review Criterion 4.

Duke-Green Level

The Duke-Green Level application describes several alternatives to the proposed project, including maintaining the status quo, develop 6 ORs at Duke-Raleigh, relocating ORs from Duke-Raleigh to develop an ASF, and developing an ASF at a different location than the one proposed. Duke-Green Level did not discuss the alternative of developing a smaller number of

ORs in the project, or developing the project closer to Duke-Raleigh. The application does not discuss why developing 4 ORs is the most optimal alternative.

Page 58 contains the following statement: "DUHS determined that patients will greatly benefit from development of a Duke freestanding ASC in Wake County." However, there is no justification or analysis to back up this remark. On the same page, Duke-Green Level states that locating 6 ORs at Duke-Raleigh "would not increase geographic access", although such an ASF would be located adjacent to a large group of physicians and surgeons.

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

Review Criterion 8

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

Duke-Raleigh

Duke-Raleigh is an existing facility, The Duke-Raleigh proposal contained a number of letters of support from local physicians. However, all letters of support came from Duke-employed or –affiliated surgeons. Letters were received from the following practices:

- Duke Eye Center
- Duke Center for Minimally Invasive Gynecologic Surgery
- Duke Orthopaedics of Raleigh
- Duke School of Medicine – Division of Gastroenterology
- Duke Interventional Pulmonology
- Duke Neurosurgery
- Duke Eye Center of Raleigh
- Duke Colorectal and Surgical Oncology of Raleigh
- Duke University Division of Urologic Surgery
- Duke Advanced Oncologic and Gastrointestinal Surgery
- Duke Orthopaedics – Southeastern Orthopedics Shoulder Center
- Duke Neurosurgery of Raleigh
- Duke Center of Women's Cancer Center Raleigh

No letters of support from *non-employed or unaffiliated* surgeons based in Wake County accompanied the Duke-Green Level application. The lack of independent, "community-based" surgeon support suggests that the Duke-Green Level project, as well as the Duke-Raleigh proposal, will only accommodate surgeons who are allied with the Duke Health System. No letters of support were included from non-Duke affiliated referring physicians. Further, it

suggests that Duke may ultimately "close" their medical staff to unaffiliated physicians. Such an action, while neither illegal nor unethical, would leave independent surgical practices with fewer options to perform their surgical cases.

For this reason, the Duke-Raleigh proposal is nonconforming with Review Criterion 8.

Duke-Green-Level

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

- Duke Eye Center
- Duke Orthopaedics of Knightdale
- Duke Center for Minimally Invasive Gynecologic Surgery
- Duke Orthopaedics of Raleigh
- Duke Pain Medicine
- Duke Urology of Raleigh
- Duke Interventional Pulmonology
- Duke Neurosurgery
- Duke Neurosurgery of Raleigh
- Duke Colorectal and Surgical Oncology of Raleigh
- Duke Eye Center of Raleigh
- Duke University Division of Urologic Surgery
- Duke Orthopaedic Surgery
- Duke Advanced Oncologic and Gastrointestinal Surgery
- Duke University Section of Pediatric Urology
- Duke Spine and Pain Management of Raleigh
- Piedmont Spine Specialists (affiliated)
- Duke Orthopaedics – Southeastern Orthopedics Shoulder Center
- Duke Center of Women's Cancer Center Raleigh
- Duke General Surgery
- Duke Shoulder and Sports Medicine of Wake County

Like the Duke-Raleigh application, 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. The Duke physicians who provided letters of support are either based in Durham or Raleigh, as will be the surgeons who will work at the proposed ASF.

For this reason, the Duke-Green Level 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 projection 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 project.

Duke-Green Level

With a capital cost of $34,300,000, the Duke-Green Level project is, by far, the most expensive proposal in the review, more than twice the capital cost of the next-highest applicant, UNC-Panther Creek. This high capital cost translates into higher average charges per case than all other freestanding ASF projects except RAC. In an era where cost containment remains a significant issue in health care delivery, the Duke-Green Level capital cost is unreasonably excessive when compared with the other applicants, and 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 impacted on cost-effectiveness, quality and access to the services proposed, the applicants shall demonstrate that its application is for a service on which competition will not have a favorable impact.

Duke-Raleigh/Duke-Green Level

A review of the Duke-Raleigh and Duke-Green Level applications demonstrates that the two projects are interrelated; that is, one project can only be successful if the other is also approved, as projections for both projects are dependent upon one another. Duke has collectively proposed to develop all six operating rooms in the 2018 Wake County review. Approval of both applications would have a detrimental effect on competition for surgical services in Wake County. Because Duke's projects appear to only accommodate only their employed and affiliated surgeons, the remaining non-employed and unaffiliated surgeons based in Wake County will have no additional options in which to perform surgery. Please also see the discussion for Review Criterion 8.

Section Q: Pro Formas

The two Duke applications contain separate need methodologies in Section Q, to justify the need for each project.

Duke-Raleigh

Based on the patient origin tables provided Section C of the Duke-Raleigh and Duke-Green Level applications, it is apparent that Duke-Raleigh will shift sufficient volume to Duke-Green Level to justify the project, then backfill its hospital-based outpatient volume.

On Page 109, the Duke-Raleigh application describes how some Duke-Raleigh outpatient cases are expected to shift to Duke's proposed Arringdon ASF in Durham County. Duke-Raleigh then identifies another subset of outpatient cases that are expected to shift to Duke-Green Level ASF. When these patient shifts occur, Duke-Raleigh's FY 2023 outpatient surgery volume will be identical to its FY 2018 volume – the growth in surgery volume occurs on the inpatient side. See the following table.

Duke Raleigh Hospital
Historic and Projected Inpatient and Outpatient Surgery Case Volumes
FYs 2018-2024
Source: Duke-Raleigh application, Pages 105, 108, 109 & 110

Year	IP Surgery Cases	OP Surgery Cases	*Less*: OP Cases Shifted to Duke-Arringdon	*Less*: OP Cases Shifted to Duke-Green Level	Total Duke-Raleigh OP Cases Following Case Shifts
FY 2018	3,958	12,604			12,604
FY 2019	4,057	13,234			13,234
FY 2020	4,158	13,896			13,896
FY 2021	4,262	14,591	128		14,463
FY 2022	4,369	15,230	369	2,077	12,784[5]
FY 2023	4,478	16,086	565	2,916	12,605
FY 2024	Not provided	Not provided	Not provided	3,933	Not provided

The two additional ORs proposed for Duke Raleigh will serve the facility's inpatient surgery growth.

Step 6 of the methodology on Page 114 shows that Duke-Raleigh is projected to have an OR surplus of 5.05 by its Project Year 3 (FY 2023). Thus, the proposed project does little to assuage the calculated OR need at Duke-Raleigh.

[5] Note: Case volume listed as 12,974 on Page 110 of Duke-Raleigh application.

Duke-Green Level

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, whether located in Durham County or Wake County, 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 134, Step 9 describes the proposed growth rate projections and percentage shifts to Duke-Green Level from other Duke Health System facilities. One of the factors that supposed supports the shift in volumes includes "reduced travel burden for patients seeking ambulatory surgery" and "more timely access to ambulatory surgery". In Section C, Page 18, Duke-Green Level projects the following patient origin, which is identical to the projected patient origin for Duke-Raleigh:

Wake	56.1%
Johnston	4.6%
Durham	4.2%
Franklin	3.8%
Cumberland	2.4%
Nash	2.0%
Other Counties	26.9%
Total	100.0%

By locating an ASF in West Cary, the Duke-Green Level facility will actually be located further away for many of its projected patients. Please also see discussion for Criterion 3.

On Page 135, the Duke-Green level methodology states that a small portion of outpatient surgery cases currently performed at Duke University Hospital is projected to shift to Duke-Green Level, accompanied by the following passage: "This is reasonable and supported based on the growing number of ambulatory surgical cases at DUH and the need to decompress capacity constraints in the hospital-based ORs." It should be noted that Durham County was allocated 4 operating rooms in the 2018 SMFP. With the exception of ORs at North Carolina Specialty Hospital, Duke Health System controls all surgical ORs in Durham County, and it is likely to be awarded some, if not all, of the 4 ORs available in 2018.

On Page 141, the Duke-Green Level application totals the operating room need for all Duke-owned facilities in its FY 2023. According to its projections, Duke-Raleigh will still have a deficit of 5.04 ORs, a result suggesting that more operating rooms could have been proposed at Duke-Raleigh.

OrthoNC ASC – Develop Freestanding ASC with One Operating Room
Project No. 11561-18

Review Criterion 3

The OrthoNC facility will be a freestanding ASF located in north Raleigh near Rex Healthcare of Wakefield. OrthoNC proposes to serve orthopaedic surgery and pain management patients in its ASF, and would create single-specialty ASF in Wake County, joining the following existing/approved facilities dedicated to orthopaedic surgery:

- Raleigh Orthopaedic Surgery Center-Raleigh
- Raleigh Orthopaedic Surgery Center-West Cary
- Triangle Orthopaedic Surgery Center

Orthopaedic surgery is also performed in the other existing multispecialty ASFs located in Wake County. Approval of OrthoNC would offer no differentiation in terms of service specialization within the county. OrthoNC's ASF would be utilized only by physicians in the Orthopaedic Specialists of North Carolina practice, which does nothing to improve accessibility for other local surgeons who may wish to perform more outpatient cases in a non-hospital setting. While OrthoNC is correct that a freestanding ASF can provide services less expensively than a hospital, restricting access only to orthopaedic surgeons in a single practice is unnecessarily restrictive and duplicative of existing and approved resources. Please see the discussion for Review Criterion 6.

For these reasons, the OrthoNC proposal does not conform to 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, OrthoNC offers several alternatives it considered, including the proposed project. Its first alternative, "Construct a new facility rather than upfit leased space", would appear to be directly related to the other alternatives listed, save for the alternative "Do nothing".

On Page 41, OrthoNC indicates that it rejected the alternative of developing a multispecialty ASF, in the name of reducing infection risk and improving patient outcomes. However, anmultispecialty ASF could be designed to allow orthopaedic cases to be performed in one OR, and other surgical specialties to be performed in the remaining OR(s). Such an arrangement would benefit other independent physicians in Wake County.

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.

Approval of the OrthoNC application would create a fourth freestanding ASF in Wake County dedicated to orthopaedic surgery. Using OrthoNC's logic, each orthopaedic surgery practice in Wake County is entitled to its own ASF. However, to do so would be unnecessarily duplicative. Wake County has 9 existing and approved ASFs – 5 of those ASFs are dedicated single-specialty facilities. Development of another dedicated orthopaedic ASF would do nothing to enhance competition for surgical services, and would benefit the surgeons of a single physician practice. Only 4 multispecialty ASFs, which can accommodate orthopaedic surgery as well as a variety of other specialties, are currently operational. For this reason, the OrthoNC proposal does not conform with Review Criterion 6.

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 impacted on cost-effectiveness, quality and access to the services proposed, the applicants shall demonstrate that its application is for a service on which competition will not have a favorable impact.

As described in discussion of Criterion 6, the OrthoNC application would have little, if any, positive effect on competition for surgical services in Wake County. Nearly all freestanding ASCs in Wake County, with the exception of Raleigh Plastic Surgery Center and Surgical Center for Dental Professionals, offer orthopaedic surgery. If approved, OrthoNC would be competing with the 3 existing/approved dedicated orthopaedic ASFs in Wake County. The project offers no improvement in access to surgeons in other specialties. While it is true that orthopaedic surgery performed in an ASF is less expensive to patients and payers than similar procedure performed in an acute care hospital, OrthoNC provided no data to demonstrate that its rates will be competitive with other ASFs in the market. For these reasons, OrthoNC is nonconforming with Review Criterion 18a.