Catharine W. Cummer
Regulatory Counsel, Strategic Planning

October 2, 2019

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

RE: Comments on Wake County OR CON Applications

Dear Mr. McKillip:

On August 15, 2019, Duke University Health System (DUHS) submitted a CON application (CON Project ID# J-11753-19 Green Level Ambulatory Surgical Center) in response to the need determination in the 2019 State Medical Facilities Plan for two new operating rooms in Wake County.

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

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

Sincerely,

Catharine W. Cummer

Catharine W. Cummer

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COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS
WAKE COUNTY OPERATING ROOMS

Submitted by Duke University Health System
October 1, 2019

Five providers submitted Certificate of Need (CON) applications in response to the need identified in the *2019 State Medical Facilities Plan (SMFP)* for two new operating rooms (ORs) in Wake County. DUHS submitted one CON application in this batch review: CON Project ID# J-11753-19 Green Level Ambulatory Surgical Center (Green Level ASC).

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

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

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

The Agency typically performs a comparative analysis when evaluating all applications in a competitive batch review. The purpose of the comparative analysis is to identify the proposal that would bring the greatest overall benefit to the community. The table on the following page summarizes comparative metrics for this 2019 Wake County OR batch review. These metrics are consistent with those which the Agency has used in other recent OR reviews.

2019 Wake County OR Batch Review
Applicant Comparative Analysis

Comparative Factor	Duke Green Level ASC	UNC Rex Hospital	WakeMed Cary Hospital	WSSSC	TOSC
Geographic Accessibility	Effective	Not Approvable	Not Approvable	Not Approvable	Less Effective
Physician Support	Effective	Not Approvable	Not Approvable	Not Approvable	Effective
Patient Access to New Provider	Effective	Not Approvable	Not Approvable	Not Approvable	Not Effective
Patient Access to Multiple Surgical Services	Effective	Not Approvable	Not Approvable	Not Approvable	Less Effective
Patient Access to Lower Cost Surgical Services	Effective	Not Approvable	Not Approvable	Not Approvable	Effective
Access by Underserved Groups: Charity Care	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups: Medicare	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups: Medicaid	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive

Based on this comparative analysis, which shows Green Level ASC ranks most favorably on the comparative metrics, and considering that the Green Level ASC application conforms to the Review Criteria and best achieves the Basic Principles of the 2019 SMFP (Policy GEN-3), Green Level ASC is the most effective alternative for development of the two need-determined operating rooms in Wake County.

Comparative Analysis

Conformity with Review Criteria

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

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

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

WSSSC is non-conforming with Criteria 1, 3, 4, 5, 8, 13, & 18a.

Patient Access to New Provider

In this 2019 Wake County OR batch review, two applicants propose to locate additional ORs at existing hospitals: UNC Rex Hospital and WakeMed Cary Hospital each propose to develop two additional ORs in their respective hospital facilities. Both are part of the two hospital systems that currently control the majority of operating rooms in Wake County. Therefore, those two applications are not the most effective alternative regarding new providers.

Similarly, TOSC is an existing ASC in Wake County, and therefore would not provide patient access to a new provider.

As described in the Green Level ASC CON application, DUHS is the only hospital system in Wake County without an operational freestanding ASC. The approved Green Level ASC project represents a new opportunity for Wake County residents and DUHS patients to access surgical services in a facility with a freestanding charge structure. Yet this facility is only approved for one operating room. Therefore, regarding providing Wake County patients with access to a new provider of outpatient OR services, the proposal submitted by Green Level ASC to add two operating rooms is the most effective alternative.

DUHS notes that WSSSC proposes to create a new one-OR, single-specialty ASC. However, the WSSSC is not conforming to various CON review criteria and is thus not

approvable. An application that is not approvable cannot be an effective alternative. Therefore, Green Level ASC is the most effective alternative for this comparative metric.

Geographic Accessibility

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

Location	Facility
Holly Springs	Rex Hospital Holly Springs
North Raleigh	Rex Surgery Center of Wakefield
Cary	Rex Surgery Center of Cary
Raleigh	Rex Hospital
Raleigh	Raleigh Orthopedic Surgery Center
Cary	Raleigh Orthopedic Surgery-West Cary
Raleigh	Capital City Surgery Center
Raleigh	WakeMed
North Raleigh	WakeMed North Hospital
Cary	WakeMed Cary Hospital
Cary	WakeMed Surgery Center-Cary*
Apex	DUHS Green Level ASC*
Holly Springs	Holly Springs Surgery Center
Raleigh	Blue Ridge Surgery Center
Raleigh	Raleigh Plastic Surgery Center
Raleigh	Triangle Orthopedic Surgery Center
Raleigh	Duke Raleigh Hospital
Raleigh	Surgical Center for Dental Professionals
Raleigh	RAC ASC*
Raleigh	OrthoNC ASC*

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

In this review, two applicants propose to locate two additional ORs at existing hospitals: UNC Rex Hospital and WakeMed Cary Hospital. TOSC proposes to expand its existing ASC. WSSSC proposes to develop a 1-OR single-specialty ASC on Six Forks Road. DUHS proposes to add two operating rooms to its approved but not yet operational ASC in Apex.

As described in the Green Level ASC CON application, although the ASC has a Cary address, the proposed site is in fact located in the Town of Cary extra-territorial jurisdiction (ETJ) and not in the Town of Cary itself. The location is proximate to and associated with Apex. As the table above shows, Apex does not currently host any

operating rooms, while Raleigh has many surgical facilities. Moreover, Green Level ASC proposes to develop two ORs offering 10 surgical specialties, which represents greater access compared to the WSSSC application which proposes to develop one OR offering only one surgical specialty.

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

Patient Access to Lower Cost Outpatient Surgical Specialties

The Wake County OR service area has 122 existing and approved ORs (13 inpatient + 35 ambulatory + 68 shared + 6 approved via 2018 Wake County SMFP need determination = 122). Operating rooms can be licensed either under a hospital license or an ASC that does not operate under a hospital license. Many, but not all outpatient surgical services can either be performed in a hospital licensed operating room or in a non-hospital licensed operating room (ASC); however, the cost for that same service is typically lower if received in a non-hospital licensed operating room.

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

In this review, two applicants propose to add two ORs at existing hospitals: UNC Rex Hospital and WakeMed Cary Hospital. The three other applicants propose to develop or expand existing, approved or new freestanding ASCs. However, the WSSSC application is not conforming to CON review criteria and therefore cannot be considered an effective alternative. Therefore, as to patient access to lower cost outpatient surgical services, Green Level ASC and TOSC are effective alternatives.

Patient Access to Multiple Surgical Specialties

While UNC Rex Hospital and WakeMed Cary Hospital each provide access to multiple surgical specialties, their proposed projects do not reflect a need for additional capacity for those services.

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

TOSC is currently a single-specialty ASC that proposes to convert to a multi-specialty facility providing general surgery, orthopaedic, plastic, and pain **(four specialties).** However, despite the support of four physicians practicing in the surgical specialties identified in §131E-176(15a), TOSC will essentially remain a single-specialty ASC, which is consistent with EmergeOrtho's own identification on its website as "one of the largest physician-owned orthopedic practices in North Carolina" (https://emergeortho.com/about-us/, emphasis added). Based on the estimates of annual OR cases by physician specialty on page 73 of TOSC's application, approximately 90.7% of projected OR cases will be orthopedic specialty cases.

WSSSC proposes a **single-specialty** (neurosurgery) ASC.

UNC Rex Hospital, WakeMed Cary Hospital and Green Level ASC project the most surgical specialties. However, the UNC Rex and WakeMed Cary applications are not approvable. Therefore, Green Level ASC is the most effective alternative regarding providing Wake County patients with access to multiple surgical specialties.

Access by Underserved Groups

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

Projected Average Net Revenue per Case

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

Projected Average Operating Expense per Case

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

Specific comments regarding the UNC Rex Hospital application/CON Project I.D. #J-11761-19

General Comments

UNC Health Care is the sole member and parent of Rex Healthcare, Inc. The UNC Health Care System includes four existing and approved ASCs (ROSC, ROSC-West Cary, Rex Surgery Center of Cary, Rex Surgery Center of Wakefield) and two hospitals (UNC Rex Hospital and UNC Rex Hospital Holly Springs). UNC Health Care already has an extensive inventory of ORs and facility locations in Wake County, specifically controlling the second highest number of ORs in the Wake County OR service area [(6 ambulatory + 29 shared = 35 ORs) + 4 ambulatory ORs (ROSC & ROSC-West Cary) = 39 ORs].[1] Further, UNC Rex Hospital has been approved to develop two additional operating rooms pursuant to Project ID J-11555-18 in response to the need for operating rooms identified in the 2018 SMFP. For this reason, and the reasons previously described in this document, the UNC Rex Hospital CON application is comparatively inferior to the DUHS CON application with respect to improving geographic access and competition.

Comments Specific to Criterion 3

<u>UNC Rex's "Need" to Replace OR Capacity</u>

UNC states on page 13 of its application and "*in Sections C.1 and C.4, UNC REX Hospital's need for additional operating room capacity is based in part by the fact that three operating rooms are slated to be relocated from UNC REX Hospital's main campus to UNC REX Holly Springs Hospital*[2]*.*" In other words, UNC Rex needs to replace the three ORs that will be relocated to UNC REX Holly Springs Hospital when it opens in State Fiscal Year (SFY) 2022. However, the three ORs have already been replaced via recently approved projects. Specifically,

- UNC Rex states in Section Q, page 10 "*UNC REX Hospital was approved to relocate one of Rex Surgery Center of Wakefield's three operating rooms to UNC REX Hospital's main campus (Project ID # J-11198-16). That operating room was relocated on July 1, 2017.*" Please see Attachment 1 which contains pages from UNC Rex License Renewal Applications documenting the net increase in ORs at UNC Rex's main

[1] Source: UNC Rex Hospital application, page 35.
[2] UNC Rex is approved to develop UNC REX Holly Springs Hospital (CON Project I.D. #J-8669-11) whereby UNC Rex will relocate three (3) ORs from its main hospital facility to the new Holly Springs Hospital.

hospital facility as a result of Project ID J-11198-16. Therefore, Project ID J-11198-16 effectively replaces one of the UNC Rex main hospital ORs that will be relocated to Holly Springs.

- As stated on page 7 of its CON application, "*Pursuant to the settlement of the 2018 Wake County Operating Room Review, UNC REX Hospital will develop two additional operating rooms*." Therefore, the settlement of the 2018 Wake County OR review effectively replaces two of the UNC Rex main hospital ORs that will be relocated to Holly Springs.

The combination of Project ID J-11198-16 (i.e. one incremental OR at UNC Rex main hospital) and the settlement of the 2018 Wake County OR review (i.e. two incremental ORs at UNC Rex main hospital) effectively replace the three UNC Rex main hospital ORs that will be relocated to Holly Springs when the facility opens in SFY2022.

It is unclear why UNC Rex fails to acknowledge the correlation between the recently approved OR projects and the incremental impact they have on its complement of ORs at the main hospital facility.

It appears UNC Rex considers OR capacity to be replaced only when it develops additional ORs in the exact spaces from which ORs will be reduced/relocated. For example, UNC states "*Please note that the scope of the proposed project, the backfilling of Rooms 58 and 59 that will be vacated upon the opening of UNC REX Holly Springs Hospital, is identical to the scope proposed in UNC REX Hospital's application in the 2018 Wake County Operating Room review. UNC REX Hospital will develop the two additional operating rooms that were ultimately awarded pursuant to the settlement of the 2018 review in other locations within its main hospital facility and not in Rooms 58 and 59*."

The fact that the two additional ORs approved via the 2018 Wake County settlement will be developed in other areas of UNC Rex's main hospital, and not specifically in Rooms 58 and 59, does not diminish the fact that the two additional ORs effectively replace the remaining OR capacity that will be relocated to UNC REX Holly Springs Hospital.

In summary, to the extent UNC Rex relies on a stated need to replace the three ORs which are slated to be relocated from UNC Rex Hospital's main campus to UNC REX Holly Springs Hospital (pp. 13, 27, 76), this need has already been met via development of Project ID # J-11198-16 (one additional OR at UNC Rex main hospital) and the 2018 Wake County settlement (two additional ORs at UNC Rex main hospital).

Flawed Analyses

"Hospital-based ORs Should be Approved in this Review"

UNC Rex provides an analysis on page 22 of its application illustrating why it believes hospital-based ORs should be approved in this review. However, UNC Rex's analysis is flawed and misleading. UNC Rex acknowledges the approval of five new ASFs in Wake County pursuant to the 2018 SMFP and the settlement of the subsequent appeal. UNC Rex provides a table on page 22 attempting to estimate the effective utilization of Wake County freestanding ASFs based on the addition of the five new ASFs to the market. The table on page 22 is reproduced below for reference.

Wake County Operating Room Utilization by Site of Care
Following 2018 Operating Room Review

	*Total Surgical Hours**	*Standard OR Hours^*	*Standard OR Hours Added per 2018 Review***	*Revised Standard OR Hours Total*	*Percent Utilization*
Freestanding ASFs	27,225	36,736	6,560	43,296	63%
Hospitals	137,460	133,425	1,950	135,375	102%

*From Total Surgical Hours for Grouping per Table 6A in *SMFP*.
^From Standard Hours per OR per Year x OR inventory per Table 6A in *SMFP* excluding any CON adjustments for future projects in order to accurately determine actual utilization in the years above.
Source: *Proposed 2020 SMFPs.*

UNC Rex's table and resulting analysis on page 22 is flawed because it only considers the net increase in 2018 total surgical hours (based on five rooms x 1,312 hours per room = 6,560 net OR hours) and not the projected utilization of the existing and approved ASFs. UNC Rex admits the ASF percent utilization in the previous table is based on assuming FFY 2018 utilization, which naturally excludes the utilization of the approved 2018 Wake County ASF ORs that are not yet operational but that may shift utilization of appropriate ambulatory surgery cases from hospitals to an outpatient setting. Furthermore, the five new ASFs that will be developed pursuant to the 2018 SMFP and the settlement of the subsequent appeal are inherently needed as evidenced by their recent approval by the Healthcare Planning and Certificate of Need Section. UNC Rex's analysis runs counter to this point. Therefore, to the extent Rex attempts to establish a greater need for hospital-based ORs based on this flawed analysis, such efforts should be disregarded in the context of the Agency's analysis of Criterion 3.

UNC References to Duke Surgical Volume

UNC makes several incorrect assumptions about DRAH's surgical utilization, which in turn, render multiple analyses invalid.

On page 23 of its application, UNC Rex states "*Prior to FFY2018, Duke Raleigh's inpatient cases were overstated as they included "all cases performed in the surgical suite, including procedures in both licensed operating rooms and in procedure rooms.*" UNC Rex also provides a table on the same page summarizing Wake County inpatient surgical volume by system which depicts Duke Raleigh declining in volume. As described in DUHS's Green Level ASC application (CON Project ID #J-11557-18), the decrease in inpatient surgical volume from FY2016-FY2017 and FY2017-FY2018 were due to specific occurrences including the loss of community-based providers (which have now been replaced) and changes to the Medicare inpatient-only list. As described in the 2019 Green Level ASC which provided updated historical surgical volumes (CON Project ID# J-11753-19), DRAH inpatient surgery cases increased by a CAGR of 1.6 percent during FY2015-FY2019. For information purposes, in FY2019 DRAH also performed 73 additional inpatient surgical cases in its procedure rooms.

On pages 25-26 of its application, UNC Rex summarizes 2018 Wake County OR utilization by facility and the projected OR deficit/(surplus) for Wake County facilities. However, UNC Rex excludes DRAH from its analysis citing "*Duke Raleigh is excluded as it reported all cased performed in the surgical suite in its 2018 Hospital License Renewal Application including procedures in both licensed operating rooms and in procedure rooms,*" although DRAH's 2019 license renewal application was available to UNC Rex and documented the hospital's OR-only volumes. By excluding DRAH, UNC Rex concludes "*no system outside of the UNC Health Care System will have a deficit sufficient to demonstrate the need for two additional operating rooms*." As described on page 26 of the Green Level ASC CON application (CON Project ID# J-11753-19), based on the volume reported in its 2019 license renewal application, DRAH currently exhibits enough demand to fully utilize more than 19 ORs compared to its current complement of 15 licensed ORs. Thus, DUHS exhibits a great demand for additional OR capacity in Wake County. However, hospital-based surgical services are not the most cost-effective alternative for all DUHS surgical patients; for many ambulatory surgery patients, an ASC presents a more convenient and cost-effective option. Thus, the Green Level ASC proposal in this 2019 Wake County OR review is an effective alternative.

On page 28 of its application, UNC Rex makes improper assumptions regarding its surgical efficiency compared to DRAH. UNC Rex correctly acknowledges that DRAH had the longest case time for inpatient cases among all Wake County providers in FY2018. However, UNC incorrectly assumes that "*These differences suggest that UNC REX Hospital's operating rooms provide more efficient service than Duke Raleigh or*

WakeMed." UNC Rex assumes that comparable case mix indexes (CMI) should result in similar surgical case times among DRAH and UNC Rex; however, UNC Rex did not consider that the mix of surgical specialties and cases may differ between the two facilities, which can contribute greatly to the average surgical case time. It is not appropriate for UNC Rex to assume it is more efficient simply on a comparison of CMI and average case times.

On page 29 of its application, UNC Rex assimilates need with comparatively lower costs per surgical procedure than DRAH. "*UNC REX Hospital provides lower costs per procedure for BCBS patients than Duke Raleigh*." However, this only supports Duke's proposed project that will enable ASC-appropriate procedures to shift from the hospital-based setting to a freestanding ASF. Indeed, 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 would otherwise be performed in DRAH's surgical suite. Therefore, UNC Rex's comparison of costs per surgical procedure does not support a perceived need for additional OR capacity at UNC Rex Hospital.

In summary, for the foregoing reasons UNC Rex does not demonstrate the need it has for two additional ORs at its main hospital facility.

Conformity to Criteria 1, 4, 5, 6, 18a

Based on the facts described in these written comments specific to Criterion 3 (incorporated herein by reference), these same facts result in the UNC Rex application being non-conforming to Criteria 1, 4, 5, 6, and 18a.

Specific comments regarding the WakeMed Cary Hospital application/ CON Project I.D. #J-11759-19

General Comments

WakeMed has the greatest number of ORs in the Wake County OR service area [(10 inpatient + 29 shared = 39 ORs) + 8 ambulatory ORs (Capital City Surgery Center) = 47 ORs].[3] With this vast inventory of ORs, the 2019 SMFP projects a surplus of ORs for WakeMed. Data from Table 6B of the 2019 SMFP is provided below for reference.

Table 6B: WakeMed Projected OR Need for 2021, 2019 SMFP

Facility	2021 Projected OR Deficit (Surplus)
Capital City Surgery Center	-3.52
WakeMed	1.53
WakeMed Cary	-2.99
WakeMed Total	***-4.97***

Source: Table 6B: Projected OR Need for 2021 (Column M), 2019 SMFP

Additionally, WakeMed has been approved to develop a new ASF with one incremental operating room pursuant to Project No. J-11565-18, in response to the need determination for the Wake County service area in the 2018 SMFP. Therefore, this project adds an additional OR to the WakeMed health system inventory, which would result in a 2021 projected WakeMed OR surplus of 5.97 based on the OR methodology in the 2019 SMFP.

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

Comments specific to Criterion 3 and 10A NCAC 14C.2103

WakeMed Cary Hospital does not demonstrate the need it has for two additional ORs.

WakeMed states on page 17 of its application, "*The growth in the service area population, which in turn is spurring growth in utilization at WakeMed Cary, is the catalyst for the need for*

[3] Source: Table 6A: OR Inventory and Grouping, 2019 SMFP

additional surgical capacity." While DUHS does not dispute the fact that growth in population is a contributing factor to increasing surgical demand in Wake County, WakeMed has approved incremental surgical capacity it has yet to develop. As stated on page 9 of the WakeMed Cary Hospital application, "*The CON Section approved relocation of 1 operating room from WakeMed Raleigh Campus to WakeMed Cary Hospital in Project No. J-11428-17*." Section Q (p.122) indicates the incremental OR will be operational in FY2020. Thus, WakeMed Cary Hospital will soon have additional OR capacity available to accommodate its surgical volume.

Separately and more importantly, WakeMed Cary Hospital's projected utilization does not conform to 10A NCAC 14C .2103. 10A NCAC 14C .2103(a) states:

> *An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area* ***shall demonstrate the need*** *for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project* ***based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan****. The applicant is not required to use the population growth factor* (emphasis added).

Section Q, page 122 includes Table Q. 14A which projects OR surplus/deficit at WakeMed Cary Hospital based on the OR methodology set forth in the 2019 SMFP. Table Q. 14A and Form C clearly show WakeMed Cary Hospital is projected to have a **surplus of 3.88 (rounded to 4) ORs** during Project Year 3. The applicant attempts to provide a revised Table Q 14B utilizing average case times from its LRAs and subtracting one OR from its inventory based on its recent designation as a Level III Trauma Center. However, 10A NCAC 14C .2103(a) states the OR Methodology in the 2019 SMFP must be applied, and the OR Methodology in the 2019 SMFP utilizes adjusted case times. Furthermore, the OR Methodology in the 2019 SMFP excludes one OR for each Level I and Level II Trauma Center. WakeMed Cary Hospital is designated as a Level III Trauma Center; thus, it is not appropriate to exclude one OR from its inventory when demonstrating need pursuant to 10A NCAC 14C .2103(a).

Given the surplus of four ORs during Project Year 3 documented on pp. 122 & 127, WakeMed Cary Hospital does not demonstrate the need for two additional ORs based on the OR need methodology set forth in the 2019 SMFP. Consequently, the application does not conform to Criterion 3 and 10A NCAC 14C .2103(a)-(b).

Conformity to Criteria 1, 4, 5, 6, 18a

Based on the facts described in these written comments specific to Criterion 3 (incorporated herein by reference), these same facts result in the WakeMed Cary Hospital application being non-conforming to Criteria 1, 4, 5, 6, and 18a.

Specific comments regarding the Wake Spine and Specialty Surgical Center, LLC application/CON Project I.D. #J-11747-19

General Comments

Wake Spine and Specialty Surgical Center (WSSSC) does not propose to develop a multispecialty ambulatory surgical program as it claims in its application. §131E-176(15a) states "*multispecialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery*." Page 20 of WSSSC's application states, "*The multi-specialty* [sic] *OR will be available for the performance of all surgical specialties typically provided in an ambulatory setting including but not limited to the following:*

- *Spine*
- *Orthopedic*
- *Neuro*
- *Ophthalmology*
- *Retina*
- *Pain Management*"

As noted by the information provided on page 20 of the WSSSC application, however, the proposed OR is anticipated to provide only two specialty areas included in the definition of a multispecialty ambulatory surgical program per §131E-176(15a). Furthermore, page 26 of the application states the physicians who have demonstrated support for the WSSSC project are "*board-certified or board eligible in spine, orthopedic, and ophthalmology surgical services*." These specialties comprise only two of the three specialty areas needed to be considered a multispecialty ambulatory surgical program. Page 27 of the application includes a table summarizing the physicians by specialty who will perform surgical procedures in the proposed OR, all of whom are described as "*Neurosurgery*". No other physician specialty is identified for the prospective physicians who will utilize the proposed OR. Therefore, the WSSSC proposed project, by definition, cannot be considered a multispecialty ambulatory surgical program and is instead a single-specialty ambulatory surgical program. Thus, WSSSC is the least effective alternative regarding providing OR access to multiple surgical specialties.

Additionally, there are already seven existing and approved single-specialty ASCs in Wake County: Triangle Orthopaedics Surgery Center, Raleigh Orthopaedic Surgery Center, Raleigh Orthopaedic Surgery Center-West Cary, Raleigh Plastic Surgery Center, Surgical Center for Dental Professionals of NC, as well as the OrthoNC ASC and RAC

Surgery Center ASC facilities approved in the 2018 Wake County Operating Room batch review. Approximately one-third of Wake County's OR capacity is allocated to single-specialty ASFs (existing and approved). Therefore, Wake County residents already have adequate access to single-specialty ORs. In addition, single specialty ASCs are vulnerable to changes in Medicare reimbursement or other payors. These facilities may also find it difficult to achieve economies of scale unless they can quickly ramp up utilization. Thus, the WSSSC proposal is not the most effective alternative in this batch review for enhancing access to surgical services.

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

Comments specific to Criterion 1

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

Comments specific to Criterion 3

WSSSC states on page 37 that its utilization methodology is included in Section C.7. Section C.7 of WSSSC's application refers to Form C Utilization and the Form C Utilization Assumptions and Methodology in Section Q. However, Form C and Section Q contain no assumptions and methodology for projecting annual surgical cases during each of the initial three project years at WSSSC. Section Q, p. 88 includes a summary of the projected OR cases from the physician letters of support; however, there is no specific methodology describing how WSSSC arrived at its projected annual surgical cases. While the total projected OR cases (727 cases) included in the physician letters of support are slightly higher compared to project year 3 utilization at WSSSC (700 cases); it is the applicant's burden to describe the specific assumptions and methodology for projecting annual surgical utilization during the initial three project years. Absent any such information in the WSSSC application, the applicant did not meet its burden.

As demonstrated on page 87 of its application, WSSSC projects need for only 0.68 OR during Project Year 3. This is the lowest projected need among the competing applications. Therefore, to the extent the project is needed to expand access to ambulatory surgical services in Wake County, the WSSSC application is not the most effective alternative.

Comments specific to Criterion 4

On page 45 of its application, WSSSC states there are **no alternatives to meet the need for the proposed project**. However, there are indeed alternatives to WSSSC's proposed project, including the following:

- Seek privileges to perform surgical procedures at an existing ASF in Wake County
- Seek privileges to perform surgical procedures at approved ASFs in Wake County to be developed pursuant to the 2018 SMFP need determination and subsequent settlement agreements
- Develop a new ASF in another geographic location in Wake County that would more effectively improve geographic access
- Develop a multi-specialty ASF

WSSSC failed to identify any of these obvious alternatives and failed to explain how each alternative is more costly or less effective than its selected alternative to develop a single-specialty OR in Raleigh.

For these reasons, the WSSSC application is non-conforming to Criterion 4.

Comments specific to Criterion 5

WSSSC does not provide any assumptions or methodology for projecting surgical cases at its proposed ASC. See discussion regarding Criterion 3. Therefore, WSSSC does not adequately demonstrate its proposal is based upon reasonable projections of the costs of and charges for providing health services. Consequently, the application is not conforming to Criterion 5.

Comments specific to Criterion 8

WSSSC does not adequately demonstrate that it will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. Specifically, WSSSC did not provide a letter from an anesthesiologist indicating a willingness to direct anesthesiology services at WSSSC. Consequently, the application is not conforming to Criterion 8.

Comments specific to Criterion 13c

WSSSC provides a dearth of information regarding the projected payor mix for the proposed ASC. On page 70 of the application, WSSSC states that the projected payor mixes *"are based on the existing payor mixes as reported to WSSSC by the physicians and/or physician groups expected to perform ambulatory surgical cases at WSSSC"*. However, WSSSC did not actually include any backing data or support for the assumptions in its application. So, there is no way for the CON Project Analyst to be able to attempt to determine if the payor mix projections are accurate and reasonable. Because WSSSC is not an existing facility, the burden is higher for the applicant to provide evidence to back up its projected payor mix claims such that the Agency Project Analyst can determine the reasonableness of the projections.

In addition, also on page 70 of its application, WSSSC claims that it will provide $2.35 million in charity care in the third year of operation. On page 91 of the application WSSSC portrays OR charity care in PY3 of $1,343,308, which equates to 29.41% of PY3 net revenues. This claim is not facially reasonable, especially when associated with a proposed for profit, physician-owned, 1-OR ASC. For these reasons, WSSSC is non-conforming to Criterion 13c because it did not adequately or reasonably identify the extent to which each medically underserved group is expected to utilize the proposed services.

Comments specific to Criterion 18a

Because the WSSSC application is non-conforming with Criteria 1, 3, 4, 5, 8 and 13c, it should also be found non-conforming with Criterion 18a. WSSSC did not adequately demonstrate the financial feasibility of the proposal, did not adequately demonstrate access to services, and did not reasonably identify the need the population has for the proposed service. Thus, the proposed WSSSC project will not have a positive impact on competition.

Specific comments regarding the Triangle Orthopaedics Surgery Center, LLC application/CON Project I.D. #J-11752-19

TOSC claims to propose to convert its existing single-specialty ASC to a multi-specialty ASC by adding general surgery, plastic surgery, and pain management. DUHS notes pain management is not a surgical specialty included in §131E-176(15a) which states "*multispecialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery*."

TOSC proposes to facilitate the addition of general surgery based on the support of two EmergeOrtho physicians who are General Surgeons. Their combined anticipated OR cases are equivalent to 7.7% of projected surgical cases at TOSC during Project Year 3 (CON application page 42).

TOSC proposes to facilitate the addition of plastic surgery based on the support of two Plastic Surgeons. Their combined anticipated OR cases are equivalent to 1.6% of projected surgical cases TOSC during Project Year 3 (CON application page 42).

Notwithstanding the support of four physicians consistent with the surgical specialties identified in §131E-176(15a), TOSC will essentially remain a single-specialty ASC. Based on the estimates of annual OR cases by physician specialty on page 73 of TOSC's application, approximately 90.7% of projected OR cases will be orthopedic specialty cases (including pain management[4]).

Thus, the extent to which this proposal would provide access to more multiple surgical specialties is much more limited – and less effective -- compared to Green Level ASC.

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

[4] EmergeOrtho's physicians who will perform interventional pain management cases are Physiatrists specializing in physical medicine and rehabilitation.