

WakeMed
Comments in Opposition to
Rex Hospital, Inc. and Orthopaedic Surgery Center of Raleigh, LLC
Certificate of Need Applications to Add ORs in Wake County
September 1, 2021 CON Review Cycle

INTRODUCTION

The 2021 State Medical Facilities Plan ("SMFP") recognized a need for three operating rooms ("ORs") in Wake County. Four applicants filed Certificate of Need ("CON") applications for additional ORs in response to the identified need:

- J-12114-21 WakeMed North Hospital ("WakeMed North");
- J-12115-21 WakeMed ("WakeMed Raleigh");
- J-12119-21 Orthopaedic Surgery Center of Raleigh, LLC ("OSCR" or "Raleigh Orthopaedic Surgery Center"); and
- J-12122-21 Rex Hospital ("UNC Rex").

The comments herein are submitted on behalf of both WakeMed Raleigh and WakeMed North. This document provides comments in opposition to both the OSCR and UNC Rex applications. The identified areas of non-conformity of OSCR's and UNC Rex's applications, along with the comparative analysis set forth below, reveal that WakeMed's applications are the most effective applicants in this review and, as such, should be approved.

OVERVIEW

UNC Rex Hospital proposes to develop two additional ORs on its existing campus. OSCR, an existing ambulatory surgery facility (ASF) and an affiliate of UNC Rex, proposes to develop one additional OR on its campus. UNC Rex identifies these projects as complementary. Many of the arguments made to demonstrate need are the same between both projects. Accordingly, a vast majority of WakeMed's comments in opposition apply to both UNC Rex and OSCR and are presented below for the applications collectively where noted.

WakeMed will demonstrate that both UNC Rex's and OSCR's CON applications are riddled with unsupported, inaccurate, or misconstrued information that render both applications non-conforming with applicable Review Criteria and Performance Standards for surgical services and operating rooms. As such, neither application can be approved, as will be described in detail below.

NON-CONFORMITY WITH REVIEW CRITERIA

Criterion (1) and Policy GEN-3

For the same reasons discussed in relation to Criteria (3) and (5) below, both applications filed by OSCR and UNC Rex are not consistent with Criterion (1) and Policy GEN-3. As such, both projects cannot be approved. See WakeMed's comments related to Criterion (3) and (5).

Criterion (3)

UNC Rex Hospital

UNC Rex states that “the specific need for the project proposed in this application demand for surgical services and need for additional capacity for UNC Health’s patients”; see page 41. However, UNC Rex does not prove the need for its specific proposed project, as detailed below.

UNC Rex Fails to Provide Quantitative Data Establishing Need Specific to UNC Rex Hospital

UNC Rex presents several data tables providing trends in surgical volume and OR utilization based on its organization fiscal year (“SFY”) 2019 data but presents no other quantitative data specifically establishing need for additional OR capacity at UNC Rex Hospital. UNC Rex cites recruitment efforts and physician partnerships as “proof” of the need for additional OR capacity, but all of this information is anecdotal and none of it is unique to UNC Rex. If UNC Rex was truly experiencing operational constraints that necessitated additional OR capacity, this would be reflected in data related to scheduling delays or staff overtime hours. UNC Rex provides no such data. Even UNC Rex’s letters of support lack any narrative related to OR constraints at UNC Rex.

UNC Rex is not as Highly Utilized as It Claims

In support of the need for its proposed project, UNC Rex repeatedly claims that it is *currently* the largest provider of inpatient surgical services, as well as the largest provider of surgical services as a whole in Wake County (Page 34 and Page 52, UNC Rex CON application). This conclusion is wrong for the following reasons:

- UNC Rex presents outdated data from Federal Fiscal Year (FFY) 2019 (October-September), ignoring readily available, more current data.
- WakeMed is *currently* the largest provider of inpatient surgical services and the largest provider of surgical services overall in Wake County, based on data from the Proposed 2022 SMFP (**Figure 1** below).

Figure 1
WakeMed and UNC Rex FFY 2020 Surgical Volume

	IP	OP	Total Cases
WakeMed*	7,952	11,194	19,146
UNC Rex	7,631	10,839	18,470

Source: Proposed 2022 SMFP

*Includes WakeMed North

UNC Rex states that “UNC Health system facilities in Wake County are among the most highly utilized facilities in the county based on the Operating Room Methodology in the *2021 SMFP*” (UNC Rex CON application, Page 52). All hospital ORs in Wake County are well utilized based on the standard hours per OR threshold set forth in the OR Methodology. Additionally, UNC Rex’s OR utilization table on page 53 of its application is incorrect. WakeMed identified the following corrections:

- WakeMed ORs were utilized at 114.5 percent of total standard OR hours in FFY 2019 and were the highest utilized ORs in the county.
- The WakeMed system ORs were utilized at over 97 percent of total standard OR hours in FFY 2019.

- As shown in Figure 9 of WakeMed Raleigh’s CON application (or Figure 15 of WakeMed North’s CON application) which presents FY 2020 OR Utilization, WakeMed’s ORs continued to be the most highly utilized in the county at 110.7 percent of total standard OR hours, even amidst the peak of the COVID-19 pandemic.
- Capital City Surgery Center was utilized at 74.6 percent of total standard OR hours in FFY 2019.

Case Mix Index Analysis is Flawed and Irrelevant

UNC Rex makes the argument that it has the highest case mix index (CMI) among Wake County hospitals, based on data from the American Hospital Directory (page 55 of UNC Rex application). However, according to the American Hospital Directory, UNC Rex’s CMI was actually 1.99 and not 2.02 as it purports; thus, it does not have the highest CMI in the county; Duke Raleigh does.

UNC Rex attempts to link its CMI and inpatient (IP) case time analyses together to draw the conclusion that it is the most efficient provider of low-cost surgical care in the county (Page 56 of UNC Rex application). UNC Rex’s conclusions regarding CMI and IP case times of Wake County providers are unsupported, and/or misleading for the following reasons:

- It is unreasonable to compare the acuity of patients served at WakeMed Cary to tertiary and/or trauma providers in the county.
- Hospital CMI is only one of many ways to measure acuity and includes all patients served by the hospital, not just surgery patients.
- WakeMed is the only Level I trauma center in Wake County.
- CMI reflects the diversity, clinical complexity, and resource needs of all the patients in the hospital. The marginal difference between the CMIs of Wake County hospitals that provide a relatively similar level of care (i.e. UNC Rex, WakeMed, and Duke Raleigh) does not address the operational efficiencies of the hospitals.
- UNC Rex’s comparison of IP case times to establish that it is more efficient is meritless. There are many factors that can impact case times – such as complexity of cases, the percent of trauma/emergency cases, set up and clean up times – which may vary based on hospital policies, OR schedule, staffing, etc.
- UNC Rex presents IP case times for FFY 2019 that are incorrect. WakeMed Cary’s IP case time in FFY 2019 was 112.7 minutes, not 193 minutes as presented on page 56 of UNC Rex’s CON application.
- UNC Rex is the only hospital provider in Wake County whose IP case times have substantially decreased in recent years, even in years prior to FFY 2020, which was impacted by COVID. See **Figure 2**.

Figure 2
Recent Trend in Inpatient OR Case Times - Wake County Providers

	FFY 2017	FFY 2018	FFY 2019	FFY 2020	CAGR FFY 2017 - 2019	CAGR FFY 2017 - 2020
WakeMed	179.3	190.9	192.1	182.6	3.5%	0.6%
WakeMed Cary	107.0	102.5	112.7	124.0	2.6%	5.0%
UNC Rex	192.0	186.3	183.0	180.0	-2.4%	-2.1%
Duke Raleigh	207.0	215.0	213.0	222.8	1.4%	2.5%

Source: 2018 – 2021 Hospital LRAs

UNC Rex’s OR Deficit Does not Support the Need for the Proposed Project

UNC Rex also cites its OR deficits over time as support for its project (page 54 of UNC Rex CON application). However, UNC Rex’s OR deficit has decreased in recent years, based on data provided in recent SMFPs. See **Figure 3** below.

Figure 3
UNC Rex OR Deficit FFY 2017 – FFY 2019

2019 SMFP FFY 2017	2020 SMFP FFY 2018	2021 SMFP FFY 2019	2022 SMFP FFY 2020	% Change FFY 2017 - 2020
5.93	5.5	2.11	-1.77	-129.8%

Source: 2019 - Proposed 2022 SMFP

Regardless, the OR methodology only accounts for deficits when determining a service area’s need. It is not disputed that there is a need for additional OR capacity in Wake County. UNC Rex’s argument related to OR deficits is irrelevant and actually demonstrates that it does not need OR capacity based on more recent utilization data.

BCBS NC “Blue Premier” Model is not Unique to UNC Rex

UNC Rex highlights its participation in BCBS NC’s “Blue Premier” model, which focuses on lowering cost and improving inefficiencies as support for the need for its project (page 56-57 of UNC Rex’s application). It is important to note that all hospital systems operating in Wake County – Duke Health, UNC Health, and WakeMed – participate in the program. Thus, additional hospital OR capacity in Wake County in general would align with the purpose of the Blue Premier program and increase quality, cost, and access to care. UNC Rex’s participation in the program does not prove need for its proposed project over any other hospital-based project.

Raleigh Orthopaedic Surgery Center

UNC Rex Fails to Prove the Need for Additional Capacity at Raleigh Orthopaedic Surgery Center

OSCR states that the specific need for its proposed project includes demand for surgical services, the need for additional capacity for Raleigh Orthopaedic Clinic’s (ROC’s) patients, and the need for additional capacity at OSCR. However, OSCR falls short of proving a specific need for additional ASF capacity in Wake County as proposed. Like UNC Rex’s application, OSCR makes claims of capacity constraints but presents no actual data to support this claim. Instead, OSCR provides historical outpatient utilization trend data and anecdotal “evidence” which does not quantitatively prove need supported by the methodology.

- OSCR highlights that outpatient surgery represents nearly 70 percent of total surgical cases in Wake County (page 44). However, the percentage of outpatient surgery in Wake County is not dissimilar to that of North Carolina (72.6 percent in North Carolina versus 73.4 percent in Wake County. See Pages 44 and 45 of the OSCR CON application.).
- The fact that a majority of patients in need of surgical services are outpatients is not a remarkable phenomenon upon which to base need for an ASF. Outpatients are served in both ASF and hospital settings, depending on acuity and surgical complexity.

WakeMed updated OSCR’s exhibit on page 44 of its CON application to include FFY 2020 and inpatient OR cases as a percent of total OR cases performed in Wake County. See **Figure 4** below.

Figure 4
Wake County Surgical Volume FFY 2014 – FY 2020

Year	Inpatient	Outpatient	Total	% Inpatient	% Outpatient
FFY 2014	20,264	59,560	79,824	25.4%	74.6%
FFY 2015	21,985	59,558	81,543	27.0%	73.0%
FFY 2016	24,367	61,545	85,912	28.4%	71.6%
FFY 2017	23,772	63,240	87,012	27.3%	72.7%
FFY 2018	22,608	62,885	85,493	26.4%	73.6%
FFY 2019*	23,032	63,429	86,461	26.6%	73.4%
FFY 2020	21,819	58,969	80,788	27.0%	73.0%
2014-2019 CAGR	2.6%	1.3%	1.6%	1.0%	-0.3%
2014-2020 CAGR	1.2%	-0.2%	0.2%	1.0%	-0.4%

Source: 2016 –Proposed 2022 SMFPs.

*Raleigh Orthopaedic Surgery Center FFY 2019 cases are adjusted to reflect only those cases performed in its operating rooms as reported on its amended 2020 LRA.

Figure 4 shows that:

- Despite the annual growth in outpatient surgical services in Wake County, outpatient cases as a percent of total cases decreased from FFY 2018 to 2020.
- The volume of inpatient surgical case in Wake County increased at double the annual rate of outpatient case volume from FFY 2014-2019. Inpatient cases as a percent of total cases also increased over the same time period.
- In FFY 2020 during the pandemic, a majority of the outpatient surgery was performed in the hospital setting (55.3 percent).¹ This speaks to the demand for hospital-based ORs and the community’s continued dependency on hospital-based services.

Growth in ASF Volume is a Function of ASF Development in lieu of Addressing Hospital Constraints

OSCR presents the trend in Wake County outpatient surgical volume by site of care from FFY 2014 to FFY 2019 to demonstrate that ASF volume is growing more quickly than hospital-based surgical volume. In the last three OR Review Cycles for Wake County, all ORs have been awarded to ASFs with the exception of two ORs awarded to UNC Rex during the 2018 Review Cycle through a Settlement Agreement with the State. If the increased OR capacity in the entire county has been primarily dedicated to ASFs while the hospitals’ OR needs continue to be overlooked, it only follows that ASF volumes would increase at a rate that is faster than that of capacity constrained hospitals. Further, within the trend time period (FFY 2014-2019), a nationwide initiative was launched to shift routine surgical cases out of the hospital and into the ASF setting, providing more hospital-based capacity for complex, high acuity patients. This contributes to the growth in ASF volume but does not negate the need for hospital-based ORs. ASFs are not an alternative for many complex surgeries that require hospital resources.

OSCR’s ASF CON Application is Contradictory to UNC Rex’s Hospital CON Application

UNC Rex agrees with the sentiment that the need for hospital-based OR capacity in Wake County has gone largely unaddressed in several years while the State focused approvals to ASFs. The OSCR ASF application

¹ According to 2021 LRAs for Wake County OR providers: Wake County Hospital Outpatient Cases/Total Wake County Outpatient Cases = 32,289/58,380 = 55.3 percent.

is in direct contradiction to UNC Rex’s stance in other filings, as well as statements made in its UNC Rex Hospital CON application. For instance, in Summer 2021, UNC Rex presented a petition to the State Health Coordinating Council to include an adjusted need determination in the 2022 SMFP for 6 ORs in Wake County solely dedicated to existing acute care hospitals. In this petition, UNC Rex makes several arguments against the need for additional ASF capacity. UNC Rex presents some of the same analysis to support the need for hospital OR capacity instead of ASF capacity. On page 7 of the petition, UNC Rex states:

If capacity constraints at hospitals are not relieved and ASFs continue to operate less highly utilized ORs given the limitations of ASF capacity (shorter hours of operation, etc.), the OR utilization of hospital systems in Wake County will continue to generate more need, ASFs will continue to be approved, and so on with no relief for hospitals in sight, thus duplicating resources as new ASFs are developed in response to hospital-generated needs in the SMFP year after year.

Similarly, in its application pages 47-52, UNC Rex highlights the dire need for hospital-based OR capacity that has gone unaddressed, as the Agency has approved only ASFs in Wake County for several Review Cycles. Yet, in the OSCR application, OSCR attempts to prove the need for additional ASF capacity based on growth in ASF development and consequently ASF volume. OSCR fails to prove the need for additional ASF capacity in Wake County, particularly one solely dedicated to orthopaedic services, such as UNC Rex and its partners propose; especially not in lieu of additional hospital-based OR capacity which as UNC Rex argues, has been essentially neglected over the past several years. It is contradictory for UNC Rex to vehemently advocate for hospital capacity in its hospital-based OR application while simultaneously claiming there is a need for additional ASF capacity in Wake County in the OSCR application, further clarifying these applications are driven by convenience, not necessity.

There is No Need for ORs Dedicated Solely to Orthopaedic Surgery

OSCR does not prove a need for ORs solely dedicated to orthopaedic services. Several ORs dedicated solely to outpatient orthopaedic surgery have recently become operational or will soon open in Wake County:

- OrthoNC ASC – awarded 1 OR during 2018 Review Cycle
- Triangle Orthopaedics Surgery Center – awarded 1 OR during 2019 Review Cycle
- Orthopaedic Surgery Center of Garner (“Garner”) – awarded 1 OR during 2020 Review Cycle
- Raleigh Orthopaedic Surgery Center-West Cary (“West Cary”) (Project ID# J-11161-16) – 1 OR opened in early FY 2021.

Two of these ASFs (Garner and West Cary) are affiliated with UNC Rex. On page 60 of the OSCR application, OSCR highlights UNC Health’s development of ASFs including the two UNC Health-affiliated orthopaedic ASFs. This only proves that UNC Health’s recent ASF developments, especially those that have yet to be implemented, can accommodate the purported need for additional orthopaedic ASF capacity, and there is no need for the proposed project.

On page 57 of its application, OSCR presents a table showing orthopaedic cases by health system to show that UNC Health performed the most orthopaedic cases of any other health system in Wake County. This point is irrelevant, as UNC Health is the only health system with ASFs dedicated solely to orthopaedic surgery and offers no proof of continued need for the proposed project.

On page 54 of its application, OSCR presents a table showing its trend in historical utilization, including both operating room and procedure room volumes. This shows an artificially higher growth trend than what is actually performed in an OR. It is misleading to present procedure room volume and OR volumes aggregated together, as volume performed in a procedure room is not of the same acuity as cases performed in the OR. The State does not acknowledge procedure room volumes in the OR methodology. OSCR is essentially admitting that it operates an unapproved, unlicensed additional OR.

OSCR's Utilization Trend

OSCR presents its utilization trend based on internal data for its fiscal year which is the State Fiscal Year (SFY) that ends in June, not the FFY. However, the trend for OR volume only is not presented anywhere in the OSCR application. Accordingly, **Figure 5** provides the trend in OSCR's OR volume from FFY 2015 – FFY 2020 according to OSCR's LRAs. OSCR experienced a 1 percent annual growth through 2019 and a 2 percent annual growth through 2020. This growth rate is not comparatively high enough to warrant additional ORs, especially when the trend from FFY2018 to FFY 2020 shows a decline.

**Figure 5
Trend in Raleigh Orthopaedic Surgery Center OR Volume Only**

FFY 2015	FFY 2016	FFY 2017	FFY 2018	FFY 2019	FFY 2020	CAGR FFY 2015-2019	CAGR FFY 2015- 2020	CAGR FFY 2018-2020
3,739	3,766	4,384	5,416	3,897	4,126	1.0%	2.0%	-12.7%

Source: OSCR LRAs

Not only is OSCR not rapidly growing, but also volume from this ASF is expected to shift to other newly-approved ASFs. To minimize this fact, OSCR held its shifts from OSCR to other UNC Rex-affiliated ASFs constant, which is contradictory of its claim that there is a need beyond its current capacity (approved and implemented). See Form C Utilization, Page 17. Inconsistencies such as this within the projected utilization for the UNC Health System, including OSCR, will be further discussed below.

UNC Rex and Raleigh Orthopaedic Surgery Center

The comments in this section apply to both the UNC Rex and the OSCR CON applications, as the two projects are complimentary and make some of the same arguments related to need.

UNC Rex's Recent OR Developments and Approvals Address Its Claimed OR Need

UNC Rex and OSCR highlight the recent changes in UNC Health's OR inventory in Wake County including several joint ventures and/or wholly owned ASFs (at least five ASFs) as well as additional ORs awarded to UNC Rex from the 2018 SMFP and the development of a new acute care hospital – UNC Rex Holly Springs (UNC Rex application, Page 35 and OSCR application, Page 41). UNC Health's recent OR developments only prove that it has already been awarded OR capacity both in the hospital and ASF settings to address any purported growth in demand. Several of UNC Health's projects have yet to be implemented or were just recently implemented to accommodate its system-wide demand, including shifts from the hospital to the ASF setting. UNC Rex was the last hospital to be awarded hospital based ORs by the Agency (2 ORs originally proposed in 2018 which were licensed in March 2021). WakeMed, by comparison, has not been awarded hospital-based ORs in several years and has only been granted additional ASF capacity via Settlement Agreement. WakeMed contends that UNC Health System does not need any additional OR capacity beyond what it has already been awarded.

UNC Rex and OSCR Ignore More Recent Data Trends

Throughout Section C of both applications, UNC Rex and OSCR only present volume trends through FY 2019 (or SFY 2019), despite having access to data for FFY 2020, as well as SFYs 2020 and 2021 (as presented in the Form C Utilization Assumptions). UNC Rex and OSCR cite the impact of the COVID-19 pandemic as the reason why they completely ignored data more recent data. There are several issues with this argument:

- Use of data through FFY 2019 is inconsistent with other statements made by UNC Rex. For instance, UNC Rex filed a petition to the SHCC on Feb. 15, 2021, recommending that DHSR use data from October 2019 to March 2020 in the development of the 2022 SMFP, but then in its CON applications completely ignored their internal data for SFY 2020 prior to the impact of COVID (i.e. June 2019 – March 2020).
- UNC Rex treats data after 2019 as if it never happened in its CON application. Hospital-based facilities continued providing emergent surgical services through COVID. Elective surgeries were only suspended for a few weeks in 2020, and hospitals are already rebounding for the impact of COVID-19 nationwide.²
- The operational impact on hospital-based ORs should have been similar for all hospitals in Wake County, particularly those who provide the same or similar level of care (i.e. WakeMed, UNC Rex, Duke Raleigh).³
- In its utilization projection methodology, UNC Rex ignores data from SFYs 2020 and 2021 except for Raleigh Orthopaedic Surgery Center, where it uses growth rates from SFYs 2019 to 2021. UNC Rex cannot pick and choose to use more recent data when it works in their favor. See the discussion on utilization projections below.

UNC Rex's and OSCR's decision to not analyze any data after FY 2019 is a strategic decision to mask the fact that there actually is no need for additional OR capacity within the UNC Health facilities in Wake County.

Utilization Projections are Unsupported and Flawed

Because the OR Performance Standards require that applicants show OR need across the health system, UNC Rex and OSCR use the same methodology to project OR utilization by facility for the UNC Health system. The only difference between the projections in each application is that OSCR's first three full fiscal years are SFYs 2024-2026 while UNC Rex's first three full fiscal years are SFYs 2025- 2027. Because the methodology is the same and UNC Health simply rolls its projections forward one year for the UNC Rex application, the flaws and discrepancies below apply to both the UNC Rex and the OSCR applications. The analyses below will be provided through SFY 2027 to encompass the projected utilization for both UNC Rex and OSCR. At times, the collective entities may be referred to as UNC Health.

UNC Health System Historical Growth Rate is Incorrect as Presented (Form C Assumptions, Page 2)

On page 55 of the UNC Rex application and again on page 2 of the Form C Utilization Assumptions for both the UNC Rex and OSCR CON applications, the following information is presented:

² <https://www.healthleadersmedia.com/clinical-care/hospital-service-volumes-expected-rebound-survey-finds>

³ While the NC SHCC made adjustments to the acute care bed methodology in the Proposed 2022 SMFP based on FFY2020 data impacted by COVID, no such adjustment was made to the OR methodology.

UNC Health System Facilities Operating Room Utilization*

	SFY15	SFY16	SFY17	SFY18	SFY19	SFY20	SFY21	SFY15 to SFY19 CAGR [^]	SFY19 to SFY21 CAGR
Inpatient Cases	7,907	8,502	8,668	8,418	8,624	7,643	7,204	2.2%	-8.6%
Outpatient Cases ^{^^}	18,260	18,146	17,619	21,507	21,660	21,766	23,522	4.4%	4.2%
Total Cases	26,167	26,648	26,287	29,925	30,284	29,409	30,726	3.7%	0.7%

Source: UNC Health internal data.

*Includes UNC REX Hospital, REX Surgery Center of Cary, REX Surgery Center of Wakefield, and Raleigh Orthopaedic Surgery Center.

[^]Compound annual growth rate.

^{^^}Raleigh Orthopaedic Surgery Center SFY 2018, 2019, and 2020 cases are adjusted to reflect only those cases performed in its operating rooms according to Raleigh Orthopaedic Surgery Center internal data.

This analysis is flawed for the following reasons:

- UNC Health appears to inadvertently omit OSCR’s outpatient case volume in SFYs 2015- 2017. See **Figure 6** below. This inappropriately inflates the overall outpatient growth rates for UNC Health. This can be determined by reconciling the total UNC Health outpatient volume.

**Figure 6
Reconciliation of UNC Health Outpatient Data**

	SFY 2015	SFY 2016	SFY 2017	SFY 2018	SFY 2019	SFY 2020	SFY 2021
Total Outpatient UNC Health	18,260	18,146	17,619	21,507	21,660	21,766	23,522
UNC Rex Outpatient	11,431	11,259	10,720	10,898	11,705	10,901	12,892
Rex Surgery Center Cary	5,274	4,918	4,901	4,727	4,501	4,060	3,697
Rex Surgery Center of Wakefield	1,555	1,969	1,998	1,356	1,530	2,468	2,704
Total without OSCR	18,260	18,146	17,619	16,981	17,736	17,429	19,293
Difference (assumed to be OSCR) *	-	-	-	4,526	3,924	4,337	4,229

Source: UNC Rex CON application, Form C Assumptions

*SFY 2021 Volume left to be attributed to OSCR in the table above (4,229) is incorrect. OSCR’s OR volume in SFY 2021 is 3,427 as presented in Form C Assumptions, Page 15.

- When the outpatient volumes are corrected based on historical volumes presented in Form C Utilization Assumptions, UNC Health’s outpatient growth rate and total growth rate are significantly lower than presented. See **Figure 7**.

**Figure 7
Corrected UNC Health System Facilities Operating Room Utilization**

	SFY 2015	SFY 2016	SFY 2017	SFY 2018	SFY 2019	SFY 2020	SFY 2021	CAGR SFY 2015 - 2019	CAGR SFY 2019 - 2021
Inpatient Cases	7,907	8,502	8,668	8,418	8,624	7,643	7,204	2.2%	-8.6%
Outpatient Cases	21,926	22,016	21,968	21,507	21,660	21,766	22,720	-0.3%	2.4%
Total Cases	29,833	30,518	30,636	29,925	30,284	29,409	29,924	0.4%	-0.6%

Source: UNC Rex CON application, Form C Assumptions

UNC Rex Hospital's Historical Growth Rates are Questionable (Form C Assumptions, Page 3)

UNC Rex presents its hospital surgical utilization from SFY 2015 to SFY 2021 on page 3 of its Form C Utilization Assumptions:

	SFY15	SFY16	SFY17	SFY18	SFY19	SFY20	SFY21	SFY15 to SFY19 CAGR	SFY19 to SFY21 CAGR
Inpatient Cases	7,907	8,502	8,668	8,418	8,624	7,643	7,204	2.2%	-8.6%
Outpatient Cases*	11,431	11,259	10,720	10,898	11,705	10,901	12,892	0.6%	4.9%
Total Cases	19,338	19,761	19,388	19,316	20,329	18,544	20,096	1.3%	-0.6%

Source: UNC REX Hospital internal data.

*Excludes REX Surgery Center of Wakefield.

Source: UNC Rex CON application, Form C Utilization Assumptions, Page 3

Figure 8 provides the UNC Rex Hospital trend in surgical utilization from FFY 2015 to FFY 2020 based on UNC Rex's LRAs.

Figure 8
UNC Rex OR Utilization Trend Based on FFY

	FFY 2015	FFY 2016	FFY 2017	FFY 2018	FFY 2019	FFY 2020	CAGR FFY 2015 - 2019	CAGR FFY 2015 - 2020
UNC Rex Inpatient	7,984	8,557	8,453	8,366	8,334	7,631	1.1%	-0.9%
UNC Rex Outpatient	11,577	11,062	10,681	11,047	11,942	10,839	0.8%	-1.3%
Total UNC Rex	19,561	19,619	19,134	19,413	20,276	18,470	0.9%	-1.1%

Source: UNC Rex LRAs

The issues with the tables above are as follows:

- UNC Rex's SFY data cannot be replicated based on publicly available data provided in the LRAs
- The difference between SFY (July to June) and FFY (October to September) is only one quarter of data.
- The significant difference between the CAGR for FFY 2015-2019 as reported on UNC Rex's LRAs and SFY 2015-2019 as provided in UNC Rex's CON application is concerning and calls into question the validity of UNC Rex's presentation of its historical trend in OR utilization. See **Figure 9**.
- Because: (1) UNC Rex relies on SFY 2015-2019 growth rates for its projections, (2) SFY 2015-2019 growth rates which cannot be verified, are very different from FFY 2015-2019 growth rates which can be verified, and (3) UNC Rex has presented inaccurate historical utilization elsewhere in its application, the validity of UNC Rex's projected utilization based on historical growth rates is questionable.

Figure 9
Comparison of UNC Rex OR Utilization CAGRs: SFY vs. FFY

	CAGR SFY 2015 - 2019*	CAGR FFY 2015 - 2019
Inpatient OR Cases	2.2%	1.1%
Outpatient OR Cases	-0.3%	0.8%
Total	0.4%	0.9%

*Based on corrected data as presented in Figure 7.

Figure 10 provides the projected utilization and OR need when UNC Rex’s growth rates are adjusted to align with the FFY 2015-2019 growth rates which are verifiable based on publicly available data.

Figure 10
UNC Rex Utilization and OR Need Based on FFY 2015-2019 Growth Rates

Projected UNC REX Hospital Surgical Utilization after Shifts

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
Inpatient Cases	7,282	7,360	7,440	7,520	7,601	7,683
Outpatient Cases	12,992	13,094	13,196	13,298	13,402	13,506
Inpatient Cases Shifted to UNC REX Holly Springs Hospital	-269	-556	-766	-774	-783	-791
Outpatient Cases Shifted to UNC REX Holly Springs Hospital	-473	-1,007	-1,400	-1,412	-1,423	-1,434
Inpatient Cases After Shifts	7,013	6,804	6,674	6,746	6,818	6,892
Outpatient Cases After Shifts	12,520	12,087	11,795	11,887	11,979	12,072

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
Inpatient Cases	7,013	6,804	6,674	6,746	6,818	6,892
Outpatient Cases	12,520	12,087	11,795	11,887	11,979	12,072
Final Inpatient Case Time	183.0	183.0	183.0	183.0	183.0	183.0
Final Outpatient Case Time	137.0	137.0	137.0	137.0	137.0	137.0
Total Surgical Hours	49,975.6	48,350	47,287	47,716	48,149	48,585

Projected UNC REX Hospital Surgical Utilization

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
Total Surgical hours	49,976	48,350	47,287	47,716	48,149	48,585
Standard Hours per OR per Year	1,950	1,950	1,950	1,950	1,950	1,950
Total Surgical Hours / Standard Hours per OR per Year	25.6	24.8	24.2	24.5	24.7	24.9
Existing and Approved OR Capacity	24	24	24	24	24	24
OR Deficit/(Surplus)	1.6	0.8	0.2	0.5	0.7	0.9

Growth Rate Applied to Rex Surgery Center of Wakefield is Flawed (Form C Assumptions, Page 11)

UNC Health uses an inappropriate and flawed use rate to project volume for Rex Surgery Center of Wakefield.

- UNC Health applied the 4.4 percent outpatient surgical growth rate to Rex Surgery Center of Wakefield. As shown above, this rate is flawed due to the fact that it does not include OSCR’s OR volume for SFY 2015-2017.
- Not only is the outpatient growth rate fundamentally incorrect, but it also includes UNC Rex Hospital’s outpatient OR volume, which is inappropriate to apply to an ASF.
- Because the projections are presented based on SFY and UNC Health never provides OSCR’s OR utilization for SFYs 2015-2017, it is impossible to accurately determine the trend in OSCR’s OR volume based on SFY.

Accordingly, WakeMed recalculated and corrected the ASF growth rates for UNC Rex-affiliated ASFs as follows:

- First, UNC Rex’s outpatient volume was removed, as it is not relevant to ASF growth rates.
- Next, the OSCR’s utilization was corrected by including its SFY 2015-2017 volumes, which were not included in the table on Form C, page 2 as discussed above. Note that OSCR’s OR and procedure room volume is included in **Figure 11** below, because OR-only data is not provided.
- The OSCR growth rate presented in **Figure 11** (6.8 percent) is *very* generous, considering that OSCR’s annual growth rate in OR utilization from FFY 2015-2019 (only one quarter different from SFY 2015-2019) is only 1 percent. See **Figure 5** above. It is more likely that the overall ASF (OR only) volume for UNC Health-affiliated facilities in Wake County is declining.

Figure 11
UNC Health-Affiliated ASF Utilization in Wake County

	SFY 2015	SFY 2016	SFY 2017	SFY 2018	SFY 2019	CAGR SFY 2015 - 2019
REX Surgery Center of Cary	5,274	4,918	4,901	4,727	4,501	-3.9%
Raleigh Orthopaedic Surgery Center*	4,163	4,285	4,746	5,536	5,414	6.8%
REX Surgery Center of Wakefield	1,555	1,969	1,998	1,356	1,530	-0.4%
Total ASF Volume	10,992	11,172	11,645	11,619	11,445	1.0%

Source: UNC Health Form C Utilization

*Includes both OR and procedure room cases because OR only data is not presented in the application

WakeMed applied this “corrected” growth rate for UNC Health-affiliated ASFs to Rex Surgery Center of Wakefield’s historical utilization. See **Figure 12**.

Figure 12
Corrected Rex Surgery Center of Wakefield Projected Utilization
Assuming 1 Percent CAGR

SFY22	SFY23	SFY24	SFY25	SFY26	SFY27	CAGR
2,731	2,759	2,787	2,815	2,844	2,873	1.0%

Figure 13 provides the resulting operating room utilization for Rex Surgery Center of Wakefield.

Figure 13
Corrected Rex Surgery Center of Wakefield OR Need

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
Total Operating Room Cases	2,731	2,759	2,787	2,815	2,844	2,873
Assumed Case Times	59.4	59.4	59.4	59.4	59.4	59.4
Total Surgical Hours	2,704	2,732	2,759	2,787	2,816	2,844
Standard Hours per Or per Year	1,312	1,312	1,312	1,312	1,312	1,312
Total Surgical Hours / Standard Hours per OR per Year	2.1	2.1	2.1	2.1	2.1	2.2
OR Capacity	2	2	2	2	2	2
OR Deficit/(Surplus)	0.1	0.1	0.1	0.1	0.1	0.2

OSCR's Inventory of Rooms is Misleading and Projected Utilization is Flawed (Form C Assumptions, Pages 13-21)

OSCR's projections are intricate, involving operating room and procedure room volume as well as shifts to approved but not yet implemented ASFs. There are several issues that WakeMed identified related to OSCR's inventory of rooms and projected utilization that will be detailed by issue below.

Issue #1 - OSCR is Proposing to Simply Negate the Shift of OR Capacity to West Cary

In Project No. J-1161-16, UNC Rex and ROC were approved to develop West Cary as an ASF through a shift of one OR from OSCR. According to UNC Health, West Cary opened 9/21/2020, and OSCR purportedly shifted one OR to West Cary as of 9/24/2020 (SFY2021) as shown in OSCR's 2021 LRA:

2021 License Renewal Application for Ambulatory Surgical Facility:
Raleigh Orthopaedic Surgery Center
All responses should pertain to October 1, 2019 *thru* September 30, 2020.

License No: **AS0143**
Facility ID: **080609**

A. **Total Existing Licensed Surgical Operating Rooms:** # 43 - Effective 9/24/2020 (4 OR was allowed to ASO171)

A Surgical Operating Room is defined as a room "used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room" (G.S. §131E-146(1c)). Do not include unlicensed procedure rooms or GI endoscopy rooms listed in Part B. or C., which follow.

OSCR then reclassified this vacated OR as a procedure room, as evidenced by the notations on the procedure room section of OSCR's originally submitted 2021 LRA, which notes an additional procedure room effective on the same date as the OR was shifted to West Cary (9/24/2020):

C. **Procedure Rooms (Excluding Operating Rooms and Gastrointestinal Endoscopy Rooms)**
Report rooms, which are not licensed as operating rooms or GI endoscopy rooms, but that are used for performance of surgical procedures other than Gastrointestinal Endoscopy procedures.

Total Procedure Rooms: # 4 / 5 effective 9/24/2020 AMC 12/15/2020

D. **Total recovery room beds:** # 17

In other words, OSCR simply continued to use this "procedure room" for OR cases. In its CON application, OSCR refers to these cases as "procedure room cases appropriate for an OR". in reality, OSCR simply shifted volume appropriate for the OR to an unlicensed procedure room in order to continue to do business as though the "shifted OR" was never removed from OSCR's capacity. With the proposed project, OSCR intends to reconstitute the OR it recently relocated to West Cary. This would essentially negate the effect of the agreed upon shift of one OR to West Cary.

It is also unclear whether OSCR actually operates four or five procedure rooms. OSCR's CON claims that it operates four procedure rooms, using the one additional procedure room for storage, but as shown above, the originally submitted 2021 LRA indicates otherwise. If OSCR has so much volume that it is operating unlicensed procedure rooms as ORs, then it is unclear why OSCR would bring a fifth procedure room online in September of 2020 and convert it to storage less than a year later. OSCR submitted a revised LRA on August 10, 2021, immediately before the submission of Project No. J-12119-21, in which it reduce its procedure room inventory from five to four, although this is never mentioned in the cover letter to Azzie Conley documenting why the corrected LRA was submitted. See OSCR's **Exhibit C.4-1**.

As **Figure 14** shows, prior to West Cary, OSCR operated 8 total rooms (operating rooms and procedure rooms) at its facility on Macon Pond Road in Raleigh. With the implementation of West Cary, the rooms were simply reclassified and with the proposed project, OSCR proposes to “make itself whole” back to 4 ORs and 4 procedure rooms.

Figure 14
OSCR OR and Procedure Room Inventory

	Pre-West Cary	Post-West Cary	The Proposed Project
ORs	4	3	4
Procedure Rooms	4	5	4
Total Rooms	8	8	8

While the State does not regulate procedure rooms, the Agency makes it explicitly clear that OR volume is meant to be performed in an OR, not in a procedure room. Despite its admission that it continues to operate the unlicensed procedure room “built to OR standards” in the same (or similar) capacity as an OR, UNC Health and its affiliates are well aware of the fact that this is not acceptable. When OSCR was approved in Project No. J-8496-10 for a cost overrun and change in scope for Project No. J-8170-08, the Condition 3 stated:

The minor procedure rooms shall be used only for minor procedures that are not required to be performed in an operating room, based on current standards of practice as enforced by the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation.

OSCR has clearly violated this Condition of Approval and should not be awarded a CON for additional ORs.

Based on UNC Rex’s comments in opposition to WakeMed Cary’s CON application in the 2020 OR Review Cycle, it would appear that UNC Rex agrees with WakeMed’s contention concerning cases performed outside of the OR. See the excerpt from UNC Rex’s comments below:

*WakeMed’s utilization projections are based on erroneous data, as they improperly include non-surgical cases as a basis for projecting future operating room utilization. Of note, it is unclear whether these cases were historically performed in operating rooms or not; however, that is irrelevant, as the rules require applicants to base their projections on the methodology in the 2020 SMFP. The 2020 SMFP methodology uses data reported on LRAs and projects surgical volume forward to determine future need for operating rooms. The methodology uses only those data which are reported as surgical cases performed in licensed operating rooms. **No other cases, including non-surgical cases performed in licensed operating rooms or surgical cases performed outside of a licensed operating room, are included in the methodology. WakeMed’s erroneous inclusion of non-surgical cases does not comport with the SMFP methodology, and it is therefore not in compliance with the operating room rules.***

- UNC Rex’s Comments on Competing Applications for Additional Operating Rooms in Wake County, Page 6

UNC Rex cannot have it both ways, accusing and condemning other applicants for doing what it proposes to do itself.

Issue #2 - OSCR Uses Volume to Be Shifted to West Cary to Justify Recapturing its OR Volume

While an OR was shifted from OSCR to West Cary in September 2020, supposedly the OR volume did not shift at the same time due to COVID. OSCR now uses this volume, which was supposed to shift, to justify a new OR at OSCR. By delaying the shift of cases to West Cary, OSCR manufactures need that does not truly exist. OSCR appears to have simply continued to use the purportedly “shifted OR” in the same capacity it historically had while relabeling it a “procedure room” as shown below in **Figure 15** below and discussed in Issue #1 above.

Figure 15
OSCR OR and Procedure Room Utilization SFY 2019 – SFY 2021

	SFY19	SFY20	SFY21
ORs	4	4	3
Operating Room Cases	3,924	4,337	3,427
Procedure Rooms	4	4	5
Procedure Room Procedures	1,490	1,819	3,225

Source: OSCR CON application, Form C Utilization Assumptions, Page 15

The reliance on procedure room cases claimed as OR cases for its projections is inappropriate and leads to a cycle of adding unregulated procedure rooms, filling them with OR cases, then using the OR cases to justify the need for more ORs. OSCR should not be rewarded for this, as it is in direct non-compliance of the conditions of their CON application. See Issue #1.

Importantly, the justification of the West Cary ASF relies 100 percent on the shift of volume from OSCR. OSCR now uses the “not yet shifted volume” of 811 cases in West Cary’s Year 1 of its operation as the historical basis (SFY 2021) for its projected utilization moving forward, thus overstating the need.

Issue #3 - OSCR’s OR Growth Rate is Flawed

OSCR uses the growth rate for “Total Operating Room Cases + Potential Operating Room Cases” from SFY 2019-2021 to project its utilization moving forward. Most importantly, OSCR’s growth rates are inaccurately inflated by aggregating OR and procedure room volumes, which clearly incorporates OR cases inappropriately being performed in a former OR now described as a “procedure room”. See Issue #1.

Figure 16 provides the historical utilization for OSCR’s ORs based on its LRAs. The annual growth rate for OR volume from FFY 2015-2019 is only 1 percent. By comparison, when OSCR’s OR and procedure room utilization are added together, OSCR claims a 6.8 percent annual increase in utilization from SFY 2015 -2019. See Form C Utilization Assumptions, page 13.

Figure 16
Raleigh Orthopaedic Surgery Center OR Utilization

FFY 2015	FFY 2016	FFY 2017	FFY 2018	FFY 2019	FFY 2020	CAGR FFY 2015 - FFY 2019	CAGR FFY 2015 - FFY 2020
3,739	3,766	4,384	5,416	3,897	4,126	1.0%	2.0%

Source: Raleigh Orthopaedic Surgery Center LRAs

The table below from page 15 of Form C Utilization Assumptions is flawed based on the aggregation of procedure room and OR volume as described above, as well as multiple other issues.

Raleigh Orthopaedic Surgery Center Historical and Potential Operating Room Volume

	<i>SFY19</i>	<i>SFY20</i>	<i>SFY21</i>	<i>CAGR</i>
Operating Room Cases	3,924	4,337	3,427	
Procedure Room Procedures	1,490	1,819	3,225	
Potential Operating Room Cases*	1,260	1,572	2,132	
Total Operating Room Cases + Potential Operating Room Cases**	5,184	5,909	5,559	3.6%
Remaining Procedure Room Procedures [^]	230	247	1,093	118.0%
Total	5,414	6,156	6,652	10.8%

Source: Raleigh Orthopaedic Surgery Center internal data.

*Potential Operating Room Cases are cases performed in a procedure room that would be performed in an operating room with sufficient capacity.

**Total Operating Room Cases = Operating Room Cases + Potential Operating Room Cases.

[^]Remaining Procedure Room Procedures = Procedure Room Procedures – Potential Operating Room Cases.

The additional issues with the table above are:

- OSCR’s reliance on SFY 2019-2021 data is inconsistent with the projections for UNC Health’s other affiliated ORs which rely on SFY 2015-2019 growth rates. UNC Health cannot pick and choose, acknowledging more recent data only when it works in their favor and ignoring it when it does not.
- OSCR relies on its SFY 21 procedure room volume as the basis for its procedure room projections and “Potential Operating Room Cases”. This volume is completely inconsistent with OSCR’s historical procedure room volume in SFYs 2019 and 2020, as well as historical FFY years reported on its LRAs.
- The 77.2 percent “growth” in procedure room volume from SFY 2020 to 2021 (1,819 cases in SFY 2020 and 3,225 cases in SFY 2021) cannot be verified and is likely an artifact of OSCR’s “reclassification” of the shifted OR to a procedure room. See Issues #1 and #2.
- OSCR’s growth rate of 3.6 percent is dependent upon an unverifiable combination of total OR cases and some procedure room volume, which includes cases that should have shifted to West Cary, when the OR relocated in 2020. This analysis is wrong for three reasons:
 - It gives OSCR credit for OR volume performed in a procedure room, which is a violation of the Condition of Approval for Project No. J-8496-10. See Issue #1.
 - It treats procedure room and OR volume as equal, growing both at the same rate despite vast differences in OR-appropriate volume and procedure room appropriate volume.
 - It is inappropriate to use volume designated for West Cary as a basis for need at OSCR. See Issue #2.
- OSCR should not be permitted to use the OR cases that should have been shifted to West Cary and that are being performed in a procedure room to justify the growth rate for projected OSCR utilization. When the volume that OSCR identified as designated for the West Cary ORs are removed from OSCR’s SFY 2021 volume, the remaining OR Cases + “Potential Operating Room Cases” at OSCR actually declines at annual rate of 4.3 percent, as shown in **Figure 17**.

Figure 17
Raleigh Orthopaedic Surgery Center Corrected OR Utilization Trend

	SFY19	SFY20	SFY21	CAGR
Operating Room Cases	3,924	4,337	3,427	
Potential Operating Room Cases*	1,260	1,572	2,132	
Cases Designated for West Cary			811	
Total Operating Room Cases + Potential Operating Room Cases**	5,184	5,909	4,748	-4.3%

Source: Raleigh Orthopaedic Surgery Center internal data.

*Potential Operating Room Cases are cases performed in a procedure room that would be performed in an operating room with sufficient capacity.

**Total Operating Room Cases = Operating Room Cases + Potential Operating Room Cases - Less Cases Designated for West Cary.

Note: In its CON application, OSCR projects 811 cases to be shifted from OSCR to West Cary in Year 1. There is no logical rationale to subtract the 9 cases performed in SFY2021.

Issue #4 –West Cary Projected Utilization Which is Based in Shift from OSCR is Unrealistic

UNC Health projects that 100 percent of the OR volume performed at the approved West Cary ASF (beginning in SFY 2021) and Garner ASF (beginning in SFY 2024) would be volume shifted from OSCR. UNC Health projected an increase in Garner’s projected volume from SFY 2024 - 2027⁴ (and therefore an increase in shift of volume from OSCR). The growth in Garner’s volume through SFY 2027 is based on same annual growth rate found in the original CON application. See the table below from UNC Rex Form C Utilization Assumptions, page 16.

Projected Orthopaedic Surgery Center of Garner Utilization

	SFY24	SFY25	SFY26	SFY27*
Operating Room Volume	1,634	1,830	2,031	2,067
Procedure Room Volume	209	234	260	264

*SFY27 was not included in the original Garner application but was included here to comply with performance standards in the Criteria and Standards for Surgical Services and Operating Rooms at 10A NCAC 14C .2103 by showing utilization in the third project year of the proposed UNC REX Hospital project. SFY27 volume was projected using the same annual growth rate assumed in Project ID # J-11962-20.

Contrarily, the OR volume at West Cary was projected to grow at a rate of 4 percent in the original CON application. UNC Rex increased its projections at 4 percent per year through SFY 2023 but held the projected utilization (or the shift out of OSCR to West Cary) constant at 1,136 cases after SFY 2023. See the table from Form C Utilization Assumptions, Page 17 below.⁵

⁴ UNC Health projects that the first three full fiscal years of operation for UNC Rex are SFY 2025, SFY 2026, and SFY 2027. UNC Health projects that the full fiscal years of operation for OSCR are SFY 2024, SFY 2026, and SFY 2026

⁵ In the original application for West Cary, the projected utilization for PY1 was 1,050 based on the projected 800 OR cases shifted from OSCR and 250 OR cases to be performed by UNC orthopaedic surgeons. This additional 200+ OR cases from UNC orthopaedic surgeons in PY 1 (or in this case SFY 2021) is not acknowledged anywhere in UNC Health’ complimentary CON Applications.

Projected Raleigh Orthopaedic Surgery Center-West Cary Operating Room Utilization

	SFY21	SFY22	SFY23	SFY24	SFY25*	SFY26*	SFY27*
Operating Room Volume	811	1,092	1,136	1,136	1,136	1,136	1,136
Procedure Room Volume	138	143	148	153	159	164	170

Source: Project ID # J-11161-16.

*SFY25 through SFY27 were not included in the original West Cary application but are included here to comply with performance standards in the Criteria and Standards for Surgical Services and Operating Rooms at 10A NCAC 14C .2103 by showing utilization in the third project year of the proposed UNC REX Hospital project.

There are several issues with UNC Health’s decision to hold the shift from OSCR to West Cary constant during SFYs 2023 and 2024:

- It does not align with UNC Health’s approach to Garner’s projections. While UNC Health is not necessarily required to use the same method, its assumptions must be reasonable. UNC Health provides no explanation for why it takes a different approach for its West Cary projections, despite the fact that both ASFs are projected to shift volume from OSCR.
- It is completely contradictory with UNC Health presentation of growth in orthopaedic surgery cases (see OSCR application, Page 48) and its projected increase in volume at Garner during the same time period (see UNC Rex Form C Utilization Assumptions, Page 16).
- UNC Health’s decision to hold the projections for West Cary constant for five years from SFY 2023 - 2027 is not based in any logic and creates a false need at OSCR.

Accordingly, WakeMed updated West Cary’s projected utilization to show a 1 percent annual increase in projected volume (shifted from OSCR) from SFY 2023-2027, consistent with the growth rate for UNC Health-affiliated ASFs as shown in **Figure 16** above. This growth rate is very conservative, considering that UNC Health reports a 4 percent projected annual growth rate in the shift from OSCR to West Cary in the original CON application. **Figure 18** provides the resulting corrected projected utilization for Raleigh Orthopaedic Surgery Center – West Cary.

Figure 18

Corrected Shifts: OSCR to Raleigh Orthopaedic Surgery Center – West Cary

Projected Raleigh Orthopaedic Surgery Center-West Cary Operating and Procedure Room Utilization

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
Operating Room Volume	1,092	1,136	1,148	1,159	1,171	1,183
Procedure Room Volume	143	148	153	159	164	170

Raleigh Orthopaedic Surgery Center-West Cary Operating Room Utilization

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
Outpatient Cases	1,092	1,136	1,148	1,159	1,171	1,183
Outpatient Case Time	69.5	69.5	69.5	69.5	69.5	69.5
Total Surgical Hours	1,265	1,316	1,329	1,343	1,356	1,370
Standard Hours per OR per Year	1,312	1,312	1,312	1,312	1,312	1,312
Total Surgical Hours / Standard Hours per OR per Year	1.0	1.0	1.0	1.0	1.0	1.0
OR Capacity	1	1	1	1	1	1
OR Deficit/(Surplus)	(0.0)	0.0	0.0	0.0	0.0	0.0

Issue #5 – OSCR and West Cary Should Have Been Modeled Together to Avoid Duplication of Cases

While OSCR projects a shift in cases to both West Cary and Garner ASFs, West Cary and has been operational since September 2020. UNC Health shows a delay in its projected shift from OSCR to West Cary, despite the fact that the OR was supposedly relocated to West Cary in 2020. UNC Health still counts

the volume that was projected to shift with the OR as volume performed at OSCR and uses this as a basis for its projections for OSCR moving forward. The projected utilization for OSCR and West Cary could have been modeled together to prevent double-counting OR cases designated for West Cary in the OSCR projections, See **Figure 19** below. In this corrected model:

- OSCR’s OR cases were projected based on this historical trend from FFY 2015-2020 as shown above in **Figure 16**. This assumption is generous considering that:
 - UNC Rex uses the 2015-2019 growth rates to project the utilization of most of its facilities. The below analysis uses OSCR’s FFY 2015-2020 annual growth rate of 2 percent which is higher than the FFY 2015-2019 growth rate of 1 percent per year.
 - The analysis in **Figure 19** below generously includes OR volume and “potential OR cases” performed in procedure rooms.
- The analysis below aligns the case volume with the ORs when it was transferred to West Cary and should be designated as such. Accordingly, West Cary’s designated cases were subtracted beginning in SFY 2021, when the OR actually opened, and the cases should have shifted out of OSCR’s case volume.

Figure 19
Corrected OSCR Projections with Designated Case Shift to West Cary

	SFY21	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27	CAGR
Operating Room Cases +								
Potential Operating Room Cases*	5,559	5,670	5,782	5,897	6,015	6,134	6,256	2.0%
Cases Designated for West Cary**	811	1,092	1,136	1,148	1,159	1,171	1,183	1.0%
Total OSCR Cases Remaining	4,748	4,578	4,646	4,750	4,856	4,963	5,074	1.1%

*Total Operating Room Cases = Operating Room Cases + Potential Operating Room Cases - Projected to grow based on OR case growth FFY2015-2020

**Cases designated for West Cary but not yet shifted, then shifted in SFY21. Projected to grow at 1 percent beginning in SFY 2024 (2020 CON holds West Cary constant after 2022; 2016 CON for West Cary showed an annual growth rate of 4%).

Even this calculation is generous, given the inability to validate the purported OR cases performed inappropriately in procedure rooms and the inappropriate use of procedure rooms to perform OR cases blatantly reported when one OR was shifted to West Cary.

Next, the cases remaining at OSCR can be projected, factoring in the shift of cases from OSCR to Garner. See **Figure 20**.

Figure 20
Corrected Projected Raleigh Orthopaedic Surgery Center OR Utilization after Shifts

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
OSCR Cases After West Cary Shift	4,578	4,646	4,750	4,856	4,963	5,074
Operating Room Cases to Shift to Garner			-1,634	-1,830	-2,031	-2,067
Raleigh Orthopaedic Surgery Center Operating Room Cases	4,578	4,646	3,116	3,026	2,932	3,007

Issue #6 – OSCR’s Projected Procedure Room Volume is not Realistic

As previously established in Issue #1, OSCR claims it currently operates four procedure rooms; however, its originally submitted 2021 LRA reports that it just recently opened a fifth procedure room, effective 9/24/2020. This procedure room was discretely removed from inventory on paper in OSCR’s Revised 2021 LRA, submitted right before its CON application. In its drawings found in Exhibit C.1, this procedure room appears to be labeled as storage. While it is unclear whether OSCR actually operates this additional fifth

procedure room that it indicates is built to OR standards or just uses it for “storage”, OSCR does not prove that its existing procedure rooms are justified. WakeMed understands that procedure rooms are not regulated by the Agency; however, the justification for OSCR’s proposed OR is heavily reliant on the volume it currently performed in its procedure rooms. Thus, WakeMed contends that OSCR had the burden to prove that the proposed OR is needed *in addition to* its existing inventory. **Figure 21** provides the projected OSCR procedure room utilization after shifts to West Cary and Garner.

As it relates to its procedure room projections:

- OSCR projects to move over 2,200 cases (more than 60 percent of its total procedure room volume) out of its procedure rooms, designating them as “potential OR cases”.
- OSCR inflates its projected procedure room cases, growing them by 3.6 percent per year, which is inconsistent with historical growth rates.
- OSCR then projects a relatively minor shift of its procedure room volume to Garner and West Cary.

The table below provides the projected utilization of OSCR’s procedure rooms based on its own data. **Figure 21** makes no adjustments to OSCR’s projected procedure room utilization based on the issues discussed herein. According to its own (flawed) projections, OSCR claims it will perform less than 1 procedure per day in its four procedure rooms, assuming 250 days of operation per year.

Figure 21
Projected Raleigh Orthopaedic Surgery Center Procedure Room Utilization after Shifts

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
Total Procedure Room Procedures Prior to Shifts	1,132	1,172	1,214	1,257	1,302	1,348
Procedure Room Procedures to Shift to Garner			-209	-234	-260	-264
Procedure Room Procedures to Shift to West Cary	-138	-143	-148	-153	-159	-164
Raleigh Orthopaedic Surgery Center Procedure Room Procedures	994	1,029	857	870	883	920
Projected Rooms	4	4	4	4	4	4
Cases per Room	248	257	214	217	221	230
Cases per Day Assuming 250 Operating Days per Year	0.99	1.03	0.86	0.87	0.88	0.92

Source: UNC Health Form C Utilization Assumptions

This analysis is important because it reveals the true intentions of OSCR. It is not realistic to believe that OSCR would have at least six rooms, all built to OR standards and labeled as operating rooms and two procedure rooms in its line drawings (see Exhibit C.1), and then operate four of those rooms as procedure rooms to accommodate *less than one minor procedure room case per day*. By its own admission, OSCR has historically operated all of these rooms as *de facto* ORs and likely will continue to do so if approved. OSCR should not be awarded for subverting the system and operating more ORs than it is licensed to operate.

OSCR’s Corrected Projected Utilization based on Issue #1 through Issue #6

Based on the issues discussed above, WakeMed made the following corrections to OSCR’s projected utilization:

- The growth rate for OSCR’s OR cases was adjusted to 2 percent based on historical growth rates. See Issue #3.
- The shift from OSCR to West Cary is projected to grow by 1 percent from SFY 2023 - 2027. See Issue #4.

- The shift of cases from OSCR to West Cary is projected to begin in SFY 2021 when the ASF opened and the OR was relocated, to avoid duplication of case volume in the OSCR projections. See Issue #5.

See **Figure 22** for the resulting corrected projected utilization and OR need for OSCR. Note that OSCR currently operates 3 ORs and shows a need for 3.1 ORs in SFY 2026 (the third full fiscal year of operation for OSCR).⁶ Thus, there is no need for the additional OR proposed at OSCR.

Figure 22
OSCR Projected Utilization After Corrections

Projected Raleigh Orthopaedic Surgery Center Surgical Utilization after Shifts

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
Outpatient Cases	4,578	4,646	3,116	3,026	2,932	3,007
Final Outpatient Case Time	82	82	82	82	82	82
Total Surgical Hours	6,256	6,350	4,258	4,135	4,008	4,109

Projected Raleigh Orthopaedic Surgery Center Surgical Utilization

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
Total Surgical Hours	6,256	6,350	4,258	4,135	4,008	4,109
Standard Hours per OR per Year	1,312	1,312	1,312	1,312	1,312	1,312
Total Surgical Hours / Standard Hours per OR per Year	4.8	4.8	3.2	3.2	3.1	3.1
Existing and Approved OR Capacity	3	3	3	3	3	3
OR Deficit/(Surplus)	1.8	1.8	0.2	0.2	0.1	0.1

UNC Rex and OSCR Do Not Meet the OR Performance Standards

The UNC Rex and OSCR applications are required to meet 10A NCAC 14C .2103(a), which 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 annual State Medical Facilities Plan.** The applicant is not required to use the population growth factor.*

Based on the information presented above, WakeMed made the following adjustments to UNC Health's projections:

- Updated the Rex Surgery Center of Wakefield's growth rate to the ASF growth rate of 1 percent per year, based on historical trends.
- Updated OSCR's projected utilization as shown in **Figure 22** above.

When the appropriate aforementioned corrections are made, UNC Rex does not meet the Performance Standards

⁶ In accordance with the complementary nature of the UNC Rex and OSCR CON applications, the OR projections and need for OSCR are provided through SFY 2027, the third full fiscal year of operation for the UNC Rex CON application.

Figure 23 provides the adjusted OR need for all UNC Health-affiliated ORs in Wake County through SFY 2027. The third full fiscal year for the proposed project at OSCR is SFY 2026. OSCR shows a need for 0.1 OR in SFY 2026, which does not support the need for the project. The third full fiscal year for the proposed project at UNC Rex is SFY 2027. While UNC Rex shows a need for 1.5 ORs in SFY 2027, the overall UNC Health system need in Wake County is only 1.1 ORs. Thus, UNC Health does not demonstrate the need for the number of proposed operating rooms in either project, as shown in the table below,

Figure 23
UNC Health System Corrected OR Need in Wake County

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
UNC Rex Holly Springs	(1.9)	(0.7)	0.2	0.2	0.2	0.3
UNC REX Hospital	1.7	1.0	0.6	0.9	1.2	1.5
REX Surgery Center of Wakefield (See Figure 13)	0.1	0.1	0.1	0.1	0.1	0.2
REX Surgery Center of Cary	(1.0)	(1.1)	(1.2)	(1.4)	(1.5)	(1.6)
Raleigh Orthopaedic Surgery Center (See Figure 22)	1.8	1.8	0.2	0.2	0.1	0.1
Raleigh Orthopaedic Surgery Center-West Cary	(0.0)	0.0	0.0	0.0	0.0	0.0
Orthopaedic Surgery Center of Garner			0.4	0.6	0.8	0.8
Total OR Deficit/Surplus	0.6	1.1	0.3	0.6	1.0	1.4

Note: Facilities whose OR need changed as a result of projected utilization adjustments are highlighted in the table above.

Figure 23 assumes that UNC Rex Hospital’s SFY growth rates from SFY 2015-2019 are accurate despite the discrepancies between SFY and FFY growth rates for UNC Rex described above. If UNC Rex’s growth rate was updated to align with its FFY 2015-2019 growth rate, UNC Rex would only show a need for 0.9 OR and the UNC Health System would only show an overall need for 0.5 OR in Wake County. See **Figure 24**. Clearly, neither UNC Rex nor OSCR meet the Performance Standards.

Figure 24
UNC Health System Corrected OR Need in Wake County (UNC Rex Growth Rates Adjusted)

	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27
UNC Rex Holly Springs	(1.9)	(0.7)	0.2	0.2	0.2	0.2
UNC REX Hospital (See Figure 10)	1.6	0.8	0.2	0.5	0.7	0.9
REX Surgery Center of Wakefield (See Figure 13)	0.0	0.0	0.0	-0.1	-0.1	-0.1
REX Surgery Center of Cary	(1.0)	(1.1)	(1.2)	(1.4)	(1.5)	(1.6)
Raleigh Orthopaedic Surgery Center (See Figure 22)	-0.5	-0.5	0.2	0.2	0.1	0.1
Raleigh Orthopaedic Surgery Center-West Cary	(0.0)	0.0	0.0	0.0	0.0	0.0
Orthopaedic Surgery Center of Garner	-	-	0.4	0.6	0.8	0.8
Total OR Deficit/Surplus	(1.8)	(1.5)	(0.2)	0.0	0.2	0.5

Note: Facilities whose OR need changed as a result of projected utilization adjustments are highlighted in the table above.

UNC Rex and OSCR fail to demonstrate the need for both proposed projects as required by Criterion (3) for several reasons, including unsupported, flawed, and/or unrealistic utilization projections as detailed

above. Recall that both UNC Rex and OSCR use the same methodology for their projected utilization and the Performance Standards require the Applicant to show a OR need for all affiliates in Wake County. Thus, if the Agency finds that one application fails to show a need across the health system and thereby fails to meet the performance standards, then both applications must be denied.

Criterion (4)

The UNC Rex and OSCR applications dismissed the most obvious cost-effective alternative to the proposed projects – maintain the status quo. UNC Rex and OSCR each claim that they cannot maintain the status quo because there is a projected need for additional operating room capacity at UNC Rex and OSCR. However, as established in WakeMed’s comments provided above concerning Criterion (3), both UNC Rex and OSCR fail to establish a need for their respective proposed projects.

UNC Rex and OSCR do not effectively establish that the alternatives proposed in both applications are the most effective alternatives to meet the identified need, because both applications fails to adequately support the respective projected utilization or financial feasibility for the proposed projects as documented in other sections of this document. Based on these issues, UNC Rex and OSCR should be found non-conforming with Criterion (4).

Criterion (5)

As previously discussed, both UNC Rex’s and OSCR’s utilization projections are unsupported, and their assumptions are flawed and/or not reasonably documented. This calls into question the reasonableness of UNC Rex’s and OSCR’s utilization projections, which in turn raises concerns about the reasonability of UNC Rex’s and OSCR’s financial projections. Additionally:

Form F.1a Capital Cost: UNC Rex projects \$1.1 million in medical equipment but provides no vendor quotes. OSCR’s project costs are 90 percent medical equipment (\$382,260). Yet, neither application provides specific information regarding medical equipment over \$10,000.

Form H Staffing: Both UNC Rex and OSCR project a reduction in staffing on Form H in comparison to current staffing despite adding additional ORs. This issue is discussed further in WakeMed’s comments related to Criterion (7).

Based on these issues, UNC Rex and OSCR should be found non-conforming with Criterion (5).

Criterion (6)

As described above in response to Criterion (3), the projects proposed by UNC Rex and OSCR will inevitably result in unnecessary duplication of existing health service capabilities. UNC Health facilities in have been awarded additional OR capacity both in the hospital and ASF settings in recent Wake County CON Review Cycles. Further, despite UNC Health’s claims otherwise, its system OR utilization is not growing. This is important because UNC Rex and OSCR purport the need for their respective projects is based primarily on an increase in OR utilization within the system.

UNC Rex and OSCR do not adequately demonstrate that the three additional ORs proposed are needed in addition to the existing and approved ORs in Wake County operated by UNC Health based on reasonable assumptions. Additionally, neither applicant proves the individual need for the proposed projects. Thus, it is clear that both UNC Rex’s and OSCR’s projects result in duplication of existing services and should be found non-conforming with Criterion (6).

Criterion (7)

UNC Rex projects a decrease of staffing (a decrease of 9.4 FTEs) within their ORs, despite proposing additional OR capacity. See UNC Rex Form H Staffing. UNC Rex proposes to place the additional ORs in its Heart & Vascular tower “in close proximity” to the existing ORs (see UNC Rex application, Page 35) and proposes no additional support space. The disjointed physical layout of the existing and proposed ORs alone would merit additional staffing or at the least the same level of staffing as currently available. The proposed project will not benefit from any economies of scale that perhaps could justify less staff if the proposed two additional ORs were in the existing surgical suite and support space (i.e. nurse stations, pre- and post-op beds, etc.).

OSCR proposes a decrease of 6 FTEs in comparison to current staffing. See OSCR Form H Staffing. OSCR is already operating a procedure room as if it were an operating room and simply proposes to turn this procedure room into a licensed operating room on paper. If OSCR is as highly utilized as it claims to be (i.e. exceeding the total OR standard hours per OR), then it is unclear how OSCR can justify less staff to support the existing and proposed ORs.

Figure 25 shows that after all of the proposed volume shifts between facilities:

- UNC Rex only projects a slight overall decrease in its OR cases from the most recent year (SFY 2021) to the project’s third full fiscal year (SFY 2027).
- OSCR projects an overall increase in its OR case volume from the most recent year (SFY 2021) to the project’s third full fiscal year of operation (SFY 2026).
- For both UNC Rex and OSCR, the difference between historical volume performed in SFY 2021 and the associated staffing to support and the volume projected in the respective projects’ first three full fiscal years of operation does not justify a projected reduction in staffing.

Figure 25
SFY 2021 – SFY 2027 OR Utilization – UNC Rex and OSCR

	SFY21	SFY22	SFY23	SFY24	SFY25	SFY26	SFY27	CAGR
UNC Rex Hospital								
IP OR Cases	7,204	7,093	6,967	6,923	7,075	7,230	7,388	0.4%
OP OR Cases	12,892	12,496	12,038	11,723	11,792	11,862	11,933	-1.3%
Total OR Cases	20,096	19,589	19,006	18,645	18,867	19,092	19,321	-0.7%
Raleigh Orthopaedic Surgery Center								
Total OR Cases	3,427	2,747	2,539	3,403	3,426	3,453		0.1%

Source: Form C Utilization Assumptions

Based on these issues, UNC Rex and OSCR both should be found non-conforming with Criterion (7).

Criterion (12)

The line drawings for UNC Rex's proposed hospital OR project note expansion of OR capacity but proposes no additional support space, despite the proposal to place the two additional ORs (with no additional support space) in a separate tower away from the existing surgical suite and its associated support space. The lack of additional support space within construction design and no explanation means that the proposed project is not the most reasonable alternative. UNC Rex should be found non-conforming with Criterion (12).

Criterion (18a)

For the same reasons established in WakeMed's comments related to Criterion (1), (3), (4), (5), (6), and (7) for both the UNC Rex and OSCR CON applications and additionally Criterion (12) for the UNC Rex application, neither UNC Rex nor OSCR will not enhance competition in the service area, nor will they have a positive impact upon cost-effectiveness, quality, and access.

Based on these issues, both applications should be found non-conforming with Criterion (18a).

Summary of Non-Conformity with Review Criteria

Both of the UNC Rex and OSCR applications are non-conforming with several review criteria as described above. Because the UNC Rex and OSCR projects are:

- Complimentary;
- Submitted by affiliated entities;
- Make some of the same arguments; and
- Based on the same flawed projected utilization methodology,

There is significant overlap between the two projects and therefore significant overlap between the WakeMed's comments related to non-conformity with review criteria. The table on the following page provides a summary of the comments provided within this document related to UNC Rex and OSCR's non-conformity with specific review criteria.

Summary of UNC Rex and OSCR Projects' Non-Conformity with Review Criteria

Criteria	OSCR / Raleigh Orthopedic Surgery Center	UNC Rex
<i>Criterion (1) / Policy GEN-3</i>	NON-CONFORMING See Criteria (3) and (5)	NON-CONFORMING See Criteria (3) and (5)
<i>Criterion (3)</i>	NON-CONFORMING based on: <ul style="list-style-type: none"> • Significant ASF capacity is available to UNC Health • Orthopaedic specific ASF capacity is available • ASF utilization has not been growing rapidly • Inconsistently relies on 2020-2021 data • Relies on OR cases inappropriately performed in procedure room (the room shifted to West Cary) • Relies on cases that should have shifted to West Cary to overstate growth and misrepresent need • System-wide OR projections are flawed • Corrected projections do not show a need 	NON-CONFORMING based on: <ul style="list-style-type: none"> • No documentation of capacity constraints • Misleading case mix index analysis • BCBS "Blue Premier" Model is not unique • Failure to consider 2020 and 2021 utilization • Current data does not show an OR need • System-wide OR projections are flawed • Corrected projections do not show a need
<i>OR Performance Standards</i>	NON-CONFORMING based on: <ul style="list-style-type: none"> • System-wide OR projections are flawed • Corrected projections do not meet required performance standards 	NON-CONFORMING based on: <ul style="list-style-type: none"> • System-wide OR projections are flawed • Corrected projections do not meet required performance standards
<i>Criterion (4)</i>	NON-CONFORMING See Criteria (3) discussion	NON-CONFORMING See Criteria (3) discussion
<i>Criterion (5)</i>	NON-CONFORMING based on: <ul style="list-style-type: none"> • No documentation to support \$380,00+ equipment costs • See Criterion (3) discussion of utilization projections • See Criterion (7) of declining staffing 	NON-CONFORMING based on: <ul style="list-style-type: none"> • No documentation to support \$1.1M equipment costs • See Criterion (3) discussion of utilization projections • See Criterion (7) of declining staffing
<i>Criterion (6)</i>	NON-CONFORMING See Criteria (3) discussion	NON-CONFORMING See Criteria (3) discussion
<i>Criterion (7)</i>	NON-CONFORMING based on: <ul style="list-style-type: none"> • Projected staffing reduction is inconsistent with flat volume projections 	NON-CONFORMING based on: <ul style="list-style-type: none"> • Projected staffing reduction is inconsistent with volume projections • Projected staffing reduction is inconsistent with coverage for a new physical OR
<i>Criterion (12)</i>	Not applicable.	NON-CONFORMING based on: <ul style="list-style-type: none"> • No support space added to support new OR in remote location.
<i>Criterion (18a)</i>	NON-CONFORMING See Criteria (3), (4), (5), (6), and (7) discussion	NON-CONFORMING See Criteria (3), (4), (5), (6), (7), and (12) discussion

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2021 SMFP, there is a need for three additional ORs in Wake County; thus, although there are four identified applicants, not all applicants can be approved. It is clear that the applications filed by UNC Rex and OSCR contain major flaws, particularly with respect to Criterion (3), that should result in denial of both applications. Therefore, there should be no need for a comparative review. Nonetheless, WakeMed has provided the following comparative review between the four applicants. Each applicant is ranked based on effectiveness with respect to each comparative factor; the most effective applicant is ranked 1 and the least effective ranked 4. A summary table can be found on Page 34 of this document, demonstrating the cumulative score of each applicant.

Project Timeline

The table below identifies the date in which the proposed services will be offered by each applicant.

Rank	Applicant	Date
1	OSCR	8/1/2022
2	WakeMed Raleigh Campus	10/1/2022
3	WakeMed North Hospital	10/1/2023
3	UNC REX Hospital	10/1/2023

Source: CON Applications, Section P

As shown in the table above, OSCR proposes to offer services at the earliest date (August 2022), in large part due to the ease of converting an existing procedure room that is already configured to OR standards to a licensed operating room. Similarly, WakeMed Raleigh's proposal seeks to renovate a previously decommissioned OR in a relatively fast timeline, only 2 months after OSCR's proposed opening date. WakeMed North and UNC Rex, by comparison, will offer services approximately one year after OSCR and WakeMed Raleigh Campus. The project timeline for WakeMed North is dependent on new construction for additional OR capacity and related support space. In this regard, OSCR and WakeMed Raleigh are the more effective alternatives, and WakeMed North and UNC Rex the less effective alternatives.

Geographic Accessibility (Location Within the Service Area)

Enhanced timely access to healthcare services is largely dependent on the geographical distribution of surgical facilities. The table below identifies the existing and approved Wake County operating rooms by location, facility name, and type of operating room. As shown, the operating rooms in Wake County are primarily located in Raleigh, Cary, and North Raleigh. These areas have a significantly growing and aging population, which results in the consequent increase in the demand for surgical services.

Wake County Existing and Approved Operating Rooms by Location

Location	Facility	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjustments	Total ORs
Cary	Duke Health Green Level ASC	0	0	0	0	1	1
Cary	Raleigh Orthopaedic Surgery Center-West Cary	0	0	0	0	1	1
Cary	Rex Surgery Center of Cary	0	4	0	0	0	4
Cary	WakeMed Surgery Center-Cary	0	0	0	0	1	1
Cary	WakeMed Cary Hospital	2	0	9	-2	1	10
North Raleigh	WakeMed North*	1	0	4	-1	0	4
North Raleigh	Rex Surgery Center of Wakefield	0	2	0	0	0	2
North Raleigh	WakeMed Surgery Center-North Raleigh	0	0	0	0	1	1
North Raleigh	Ortho NC ASC	0	0	0	0	1	1
Holly Springs	Holly Springs Surgery Center	0	3	0	0	0	3
Raleigh	Duke Raleigh Hospital	0	0	15	0	0	15
Raleigh	Raleigh Orthopaedic Surgery Center	0	4	0	0	-1	3
Raleigh	Rex Hospital	3	0	25	-3	2	27
Raleigh	Capital City Surgery Center	0	8	0	0	-1	7
Raleigh	WakeMed (Raleigh Campus)*	7	0	16	-4	-1	18
Raleigh	RAC Surgery Center	0	0	0	0	1	1
Raleigh	Surgical Center for Dental Professionals of NC	0	2	0	0	0	2
Raleigh	Blue Ridge Surgery Center	0	6	0	0	0	6
Raleigh	Raleigh Plastic Surgery Center	0	1	0	0	0	1
Raleigh	Triangle Orthopaedics Surgery Center	0	2	0	0	1	3
Raleigh	Wake Spine and Specialty Surgery Center	0	0	0	0	1	1
Garner	Valleygate Surgery Center	0	0	0	0	1	1
Garner	Duke Health Garner ASC	0	0	0	0	1	1
Garner	Orthopaedic Surgery Center of Garner	0	4	0	0	0	4

Source: 2021 SMFP, Table 6A; WakeMed 2020 LRA; recent Agency decisions regarding 2020 Wake County OR Need Determination

*WakeMed Raleigh Campus and WakeMed North are both on the WakeMed License.

Cognizant of such trends, all applicants in this review cycle seeks to develop the additional operating rooms at existing surgical facilities at Raleigh within an approximate 13-mile radius. With respect to this comparative factor, all applicants are equally effective.

Competition

In past Review Cycles, the Agency used this comparative factor to assess which applicant is the most effective in enhancing the competition in the service area. The introduction of a new provider in the service area would be the most effective alternative, based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, all applicants in this review cycle are existing surgical providers in Wake County. Therefore, with regard to increasing competition for surgical services in Wake County, all applications in this review cycle are equally effective.

Historical Utilization

The following table identifies the projected operating room deficit and surplus for 2023 and 2024 as identified in the 2021 and draft 2022 SMFP. The operating deficit and surplus are based on each facility’s historical utilization. Generally, the applicant that demonstrates the highest operating room deficit is the most effective alternative with respect to this comparative factor.

Projected 2023 and 2024 Operating Room Need for Wake County by Facility

Rank	Facility	Adjusted Operating Room Planning Inventory	Projected Operating Room Deficit (Surplus) 2023	Projected Operating Room Deficit (Surplus) 2024
	Capital City Surgery Center	7	(1.37)	(1.58)
1*	WakeMed	22	5.14	4.04
	WakeMed Cary Hospital	10	(3.27)	(3.10)
	WakeMed Surgery Center - Cary	1	(1.00)	(1.00)
	WakeMed Surgery Center - North Raleigh	1	(1.00)	(1.00)
	WakeMed Health and Hospitals	41	(1.50)	(2.64)
2	Raleigh Orthopaedic Surgery Center	3	3.19	2.60
	Raleigh Orthopaedic Surgery Center - West Cary	1	(1.00)	(2.00)
3	Rex Hospital	27	2.11	(1.77)
	Rex Surgery Center of Cary	4	0.14	(0.59)
	Rex Surgery Center of Wakefield	2	(0.27)	0.06
	Rex Surgery Center of Garner	2	(2.00)	(2.00)
	UNC Health System	39	2.17	(3.70)

Source: 2021 and Proposed 2022 SMFP, Table 6B

*Since WakeMed Raleigh and WakeMed North are under WakeMed License, both Applicants are equally effective.

As the table above shows, WakeMed, which encompasses both WakeMed Raleigh and WakeMed North, demonstrates operating room deficits that are significantly higher than both UNC Rex and OSCR for project years 2023 and 2024. Moreover, it should be noted that UNC Rex shows a surplus of 1.77 operating rooms for calendar year 2024 as projected in the Proposed 2022 SMFP. WakeMed Raleigh and WakeMed North are equally the most effective applicants, and OSCR and UNC Rex are less effective with respect to this comparative factor.

Physician Support

All applicants document adequate physician support for their proposed projects. Therefore, with regard to the demonstration of physician support, all proposals are equally effective.

Patient Access to Multiple Services

The following table illustrates the surgical specialties (as defined on the North Carolina Hospital License Renewal Application) that the individual applicants in this review propose to provide:

Proposed Services to be Offered

Surgical Specialty	WakeMed Raleigh Campus	WakeMed North Hospital	UNC Rex Hospital	OSCR
Cardiothoracic (excluding Open Heart Surgery)	X		X	
Open Heart Surgery	X			
General Surgery	X	X	X	
Neurosurgery	X		X	
Obstetrics and GYN (excluding C-Sections)	X	X	X	
Ophthalmology	X	X		
Oral Surgery/Dental	X			
Orthopaedics	X	X	X	X
Otolaryngology	X	X	X	
Plastic Surgery	X	X	X	
Podiatry	X	X	X	
Urology	X		X	
Vascular	X	X	X	
Rank	1	1	1	2

Source: 2021 LRAs, page 12

WakeMed Raleigh, WakeMed North, and UNC Rex are existing acute care hospitals offering a full continuum of care and a broad range of clinical specialties, and all offer inpatient and outpatient surgery. Moreover, WakeMed Raleigh is the only designated Level I Trauma Center in Wake County and offers highly complex and more intensive level of care. By contrast, OSCR is an outpatient surgical facility with sole specialty in orthopedics. In this regard, OSCR is the least effective alternative, with the rest of the applicants being equally effective with respect to this comparative factor.

Access by Underserved Groups

WakeMed Raleigh and WakeMed North have historically assumed a major role in the provision of comprehensive services to the medically underserved population in Wake County. Considered safety-net hospitals, both facilities organize and deliver a significant level of health care and other health-related services to uninsured and underinsured patients, low-income populations, and the elderly, as discussed in turn below. It should be noted that for all subsequent analysis in this section, all relevant data include the financial projections for the third full fiscal year of operations following project completion (“Project Year 3” or “PY 3”) as presented in Section Q of individual applications.

Projected Charity Care

The following table identifies the charity care revenue and total surgical net revenue as projected by the Applicants for PY 3.

Services to Charity Care Patients - Project Year 3

Rank	Applicant	Charity Care Revenue	Total Surgical Net Revenue	Charity % of Total Net Surgical Revenue
1	WakeMed Raleigh Campus	\$ 101,616,445	\$ 307,085,870	33.1%
2	WakeMed North Hospital	\$ 19,068,852	\$ 75,008,160	25.4%
3	UNC Rex	\$ 14,683,220	\$ 226,972,630	6.5%
4	OSCR	\$ 597,610	\$ 21,499,015	2.8%

Source: Section Q, Form F2.b

As shown in the table above, WakeMed Raleigh and WakeMed North project significantly high amounts of charity care in PY 3, accounting for 33.1 and 25.4 percent of total net surgical revenue, respectively. By comparison, UNC Rex and OSCR’s projected charity care revenue comprise only 6.5 and 2.8 percent, respectively, of their total net surgical revenue by PY 3. In this regard, the proposals submitted by WakeMed Raleigh and WakeMed North are the most effective alternatives with respect to this comparative factor.

Projected Self-Pay

The following table identifies the self-pay revenue and the total gross revenue as projected by each Applicant for PY 3.

Services to Self-Pay Patients - Project Year 3

Rank	Applicant	Self-Pay Revenue	Total Gross Revenue	Self-Pay % of Total Gross Revenue
1	WakeMed Raleigh Campus	\$ 84,029,992	\$ 1,429,358,207	5.9%
2	WakeMed North Hospital	\$ 8,663,774	\$ 274,642,269	3.2%
3	UNC Rex	\$ 15,071,324	\$ 668,480,841	2.3%
4	OSCR	\$ 998,183	\$ 108,999,420	0.9%

Source: Form F2.b

As shown in the table above, WakeMed Raleigh and WakeMed North project the highest self-pay revenue as a percentage of the total gross revenue (5.9 and 3.2 percent, respectively). By contrast, UNC Rex and OSCR projects the lowest self-pay revenue as a percentage of total gross revenue (2.3 and 0.9 percent, respectively). In this regard, the applications submitted by WakeMed Raleigh and WakeMed North provide the most effective alternatives with respect to this comparative factor.

Projected Medicare

The following table identifies the Medicare revenue and total gross revenue as projected by each Applicant for PY 3.

Services to Medicare Patients - Project Year 3

Rank	Applicant	Medicare Gross Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
1	UNC Rex	\$ 276,064,431	\$ 668,480,841	41.3%
2	WakeMed Raleigh Campus	\$ 575,177,700	\$ 1,429,358,207	40.2%
3	WakeMed North Hospital	\$ 91,605,685	\$ 274,642,269	33.4%
4	OSCR	\$ 21,154,609	\$ 108,999,420	19.4%

Source: Section Q, Form F2.b

As demonstrated in the table above, UNC Rex projects the highest Medicare gross revenue as a percentage of total gross revenue for PY 3 at 41.3 percent. WakeMed Raleigh and WakeMed North projects the next highest at 40.2 and 33.4 percent, respectively, with OSCR projecting the lowest percentage of Medicare gross revenue at 19.4 percent. However, WakeMed collectively projects a significantly higher amount of Medicare gross revenue at approximately \$660 million, which is more than double the projected Medicare gross revenue by UNC Health system (approximately \$297 million). Moreover, both UNC Rex and OSCR

demonstrated significant flaws in their utilization projection, inevitably calling into question their financial projections (see discussion on Criterion 3).

Projected Medicaid

The following table identifies the Medicaid revenue and total gross revenue as projected by each Applicant for PY 3.

Services to Medicaid Patients - Project Year 3

Rank	Applicant	Medicaid Gross Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
1	WakeMed Raleigh Campus	\$ 250,038,568	\$ 1,429,358,207	17.5%
2	WakeMed North Hospital	\$ 15,362,579	\$ 274,642,269	5.6%
3	UNC Rex	\$ 28,817,517	\$ 668,480,841	4.3%
4	OSCR	\$ 1,481,214	\$ 108,999,420	1.4%

Source: Section Q, Form F2.b

As shown in the table above, WakeMed Raleigh projects the highest Medicaid gross revenue as a percent of its total gross revenue for PY3 (17.5 percent) by a wide margin compared with the rest of the applicants. WakeMed North projects the second highest proportion of total revenue at 5.6 percent, followed by UNC Rex and OSCR at 4.3 and 1.4 percent, respectively. In this regard, both applications submitted by WakeMed are the most effective alternatives with respect to this comparative factor.

Projected Average Net Revenue per Case

The following table shows the projected average net surgical revenue per OR and per surgical case in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements. In general, the Agency finds that the application proposing the lowest average net revenue per case is the more effective alternative with regard to this comparative factor.

Net Revenue per Surgical Case - Project Year 3

Rank	Applicant	Net Revenue	# of Cases	Net Revenue per Case
1	OSCR	\$ 21,499,015	3,453	\$ 6,226
2	UNC Rex	\$ 226,972,630	19,321	\$ 11,747
3	WakeMed North Hospital	\$ 75,008,160	4,441	\$ 16,890
4	WakeMed Raleigh Campus	\$ 307,085,870	16,007	\$ 19,184

Source: Section Q, Form F2.b and Form C3.b

As previously stated, the inpatient Prospective Payment System was introduced to incentivize hospitals and physicians to provide more patient care in the outpatient setting enabled ASCs to effectively reduce the overall costs of perioperative surgery. The Agency has remained consistent with this concept based on the findings for the previous OR review cycles.

As shown in the table above, OSCR projects the lowest net revenue per case at approximately \$6,226, followed by UNC Rex at \$11,747. WakeMed North and WakeMed Raleigh have the higher projected net revenue per case at \$16,890 and \$19,184, respectively. In this regard, OSCR is the most effective alternative with respect to this comparative factor. However, several caveats must be considered:

- While ASCs such as OSCR often present as more cost-effective settings of care for some patients, outpatient facilities are not alternatives to hospitals. While ASCs perform elective outpatient surgeries, unlike acute care hospitals they do not treat inpatient or emergent cases, and do not perform cases during nights and weekends.
- On Page 55 of its application, UNC Rex presents an exhibit demonstrating its higher case mix index (CMI) as compared to other existing surgical providers in the County. The Centers for Medicare and Medicaid Services (CMS) utilize CMI data to determine hospital reimbursement rates for Medicare and Medicaid beneficiaries. By this logic, a higher CMI should result in higher reimbursement pay rates and consequently, higher net revenue per case. UNC Rex’s significantly lower net revenue per case, approximately 60-70 percent of WakeMed Raleigh and WakeMed North’s projected net revenue per case, calls into question the reasonableness and credibility of its financial projection. This is further compounded by the numerous, significant errors presented in their utilization projection methodology (see discussions on Criterion 3).
- As previously discussed, both OSCR and UNC Rex project to serve significantly less charity, self-pay, Medicare, and Medicaid patients than WakeMed Raleigh and WakeMed North. With this in mind, it is unclear how the UNC Rex’s project shows markedly lower projected net revenues.

Projected Average Operating Expense per Case

The following table compares the projected average operating expense in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements. Generally, the application proposing the lowest average operating expense is the more effective alternative with regard to this comparative factor.

Operating Expense per Surgical Case - Project Year 3

Rank	Applicant	Operating Expense	# of Cases	Operating Expense per Surgical Case
1	OSCR	\$ 18,250,375	3,453	\$ 5,285
2	WakeMed Raleigh Campus	\$ 133,778,567	16,007	\$ 8,358
3	WakeMed North Hospital	\$ 40,648,547	4,441	\$ 9,153
4	UNC Rex	\$ 200,739,284	19,321	\$ 10,390

Source: Section Q, Form F2.b and Form C3.b

As shown in the table above, OSCR presents the lowest operating expense per case for PY 3, followed by WakeMed Raleigh, WakeMed North, and UNC Rex at \$8,358, \$9,153, and \$10,390, respectively. At first glance, OSCR represents the most effective alternative with respect to this comparative factor; however, ASCs typically demonstrate lower operating expense as a result of their smaller physical footprint, lower upkeep and maintenance, and lower overhead as compared to hospitals. For the sake of this comparative factor, however, OSCR provides the best alternative.

Summary of Comparative Analysis

The following is a summary of the comparative analysis performed on the proposed projects, ranking the proposals based on effectiveness for each comparative factor herein. As discussed at length throughout the written comments in opposition, WakeMed contends that neither OSCR nor UNC Rex are conforming with all applicable Review Criteria. Thus, the aforementioned comparative factors do not apply to the UNC Rex and OSCR, and both proposals submitted by WakeMed are the most effective alternatives. Further, due to significant differences in the types of surgical facilities (one single-specialty ASC, two tertiary hospitals,

and one community hospital) in this Review Cycle, certain comparative factors driven by financial data may be of less value than if all applications were for like facilities proposing like services.

WakeMed has provided the following summary of the comparative factors for all applicants. A ranking of “1” denotes the most effective alternative, with higher numbers indicating less effective alternatives, so the applicant with the lowest score is the most effective alternative. Accordingly, the WakeMed Raleigh and the WakeMed North projects are the most effective alternatives in this review.

Comparative Factor	WakeMed Raleigh	WakeMed North	UNC Rex	OSCR
Conformity with Review Criteria	Yes	Yes	No	No
Project Timeline	2	3	3	1
Geographic Accessibility	1	1	1	1
Competition	1	1	1	1
Historical Utilization	1	1	3	2
Physician Support	1	1	1	1
Patient Access to Multiple Services	1	1	1	2
Access by Underserved Groups: Charity Care	1	2	3	4
Access by Underserved Groups: Medicare	2	3	1	4
Access by Underserved Groups: Medicaid	1	2	3	4
Access by Underserved Groups: Self-Pay	1	2	3	4
Projected Average Net Revenue per Case	4	3	2	1
Projected Average Operating Expense per Case	2	3	4	1
Total	18	23	26	26

CONCLUSION

The application submitted by UNC Rex should not be approved due to non-conformity with Review Criteria (1), (3), (4), (5), (6), (7), (12), and (18a). The application submitted by OSCR should not be approved due to non-conformity with Review Criteria (1), (3), (4), (5), (6), (7), and (18a). WakeMed Raleigh’s and WakeMed North’s applications, by comparison, are conforming with all applicable Review Criteria and Performance Standards for operating rooms. In addition, for each of the comparative analysis factors provided in this analysis, WakeMed Raleigh’s and WakeMed North’s applications are determined to be the superior applicants (see Summary table above).

Regardless of the comparative factors, only the applications submitted by WakeMed meet all CON Review Criteria and the Performance Standards for operating rooms, presenting clear and reasonable documentation throughout its application. WakeMed Raleigh and WakeMed North are the most effective applicants on a comparative basis to ensure enhanced access to high quality surgical care for the residents of Wake County. Thus, both proposals submitted by WakeMed should be approved.