Comments on Competing Applications for Additional Operating Rooms in Wake County

submitted by

Rex Hospital, Inc.

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Rex Hospital, Inc. d/b/a UNC REX Hospital, ("UNC REX" or "Rex") submits the following comments related to competing applications to develop additional operating rooms in Wake County. UNC REX's comments on these competing applications include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*[1]." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, UNC REX has organized its discussion by issue, noting some of the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity on the following applications:

- **Triangle Orthopaedics Surgery Center ("TOSC"), Project ID # J-11752-19**
- **Duke Health Green Level Ambulatory Surgical Center ("Duke"), Project ID # J-11753-19**
- **WakeMed Cary Hospital ("WakeMed"), Project ID # J-11759-19**

General Comments

Given the number of applications and proposed operating rooms, all the applications cannot be approved. This review includes a mix of proposals for ambulatory surgical facilities (ASFs) and hospital-based operating rooms. While ASFs clearly provide certain benefits, including the potential for expanded geographic accessibility and lower costs and charge structures, they cannot serve higher acuity outpatient and inpatient cases that require hospital-based care. Further, following the 2018 Wake County OR review and subsequent settlement of appeals, the Agency approved the development of five new ASFs, the most that have ever been approved in a single county in a given year. While these facilities will take time to be developed, they will provide additional options for patients around the county. As described in UNC REX's application, Wake County's existing hospital-based operating rooms are experiencing much higher utilization, on average, compared with ASFs. At the same time, the number of ORs in hospitals has not increased to meet this need. Hospital-based operating rooms are more versatile, providing broader access to surgical services, with higher capacity per room based on typically longer hours of operation each day and more days of operation each week and greater ability to care for more highly acute patients. Given these factors and the circumstances of this review, UNC REX believes that its proposed project to meet the need for additional hospital-based OR capacity should be approved. The comments below include substantial issues that UNC REX believes renders the applications listed above non-conforming with applicable statutory and regulatory criteria. However, as presented at the end of these comments, even if all these applications were conforming, the application filed by UNC REX is comparatively superior to the others and represents the most effective alternative for expanding access to surgical services in Wake County.

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[1] UNC REX is providing comments consistent this statute; as such, none of the comments should be interpreted as an amendment to its application as filed August 15, 2019.

COMMENTS ON TRIANGLE ORTHOPAEDICS SURGERY CENTER

General Comments

The need determination in the *2019 SMFP* is based on the sum of the need generated by the existing facilities in Wake County that are included in Table 6B. While the cases reported by TOSC are included in Table 6B, they are excluded from the calculation in the methodology. This fact is explained in the statement following the triple asterisk below the table. Thus, the standard methodology shows no need for additional operating rooms at TOSC, and its volume in no way contributes to the need determination for two additional operating rooms. While this may not prevent TOSC or any person from applying pursuant to the need determination, as a practical matter, approval of TOSC will not meet the need generated by facilities with a deficit of operating rooms in the *2019 SMFP*. However, the Acute Care Services Committee of the State Health Coordinating Council did vote on September 17, 2019 to follow the Agency's recommendation to include the utilization for TOSC and the other single-specialty demonstration projects in future *SMFP*s, including the *2020 SMFP*. As such, as an existing licensed facility, it would be prudent to wait until TOSC is part of the need methodology calculations before considering approval of additional operating rooms.

Moreover, as noted in its application, TOSC is in the process of expanding its ASF to develop two new procedure rooms and additional support space. As explained on its exemption notice of April 23, 2019, this expansion will "increase the facility capacity…enhance staff productivity and reduce the frequency of having to extend hours of surgery."

UNC REX believes the TOSC application should be denied, based on the reasons noted above, as well as the specific issues outlined below.

Issue-Specific Comments

1. <u>TOSC fails to demonstrate the need patients have for the proposed project</u>.

   TOSC's proposed project includes the development of two additional operating rooms and the conversion to a multispecialty facility. Both of these components are predicated on the addition of services and utilization that TOSC has historically not provided. Given these facts, TOSC must demonstrate that the patients it proposes to serve have a need for its project. Despite this burden, TOSC fails to mention any issues that prevent the proposed patient population from being served at other ASFs, many of which provide these specialties (discussed below) and some of which have available capacity. In particular, TOSC fails to discuss any issues with the facilities at which the surgeons supporting the project currently practice, nor does the application even mention which facilities they are. Since the proposal includes a shift of cases performed by these surgeons from other facilities to TOSC, the application must demonstrate why the patients currently served at these other facilities need instead to be served at TOSC. As noted in UNC REX's application, in addition to the existing ASFs in Wake County, several additional ASFs have recently been approved, including at least three that are multispecialty. None of the approved ASFs have indicated an intent to maintain a closed medical staff. In addition, some of the proposed surgeons have privileges at existing ASFs in Wake County. Dr. Zenn, for instance, has privileges at Rex Surgery Center of Cary and

Rex Surgery Center of Wakefield. Dr. Elizabeth Bagsby has privileges at Capital City Surgery Center. Other surgeons certainly either have privileges at ASFs or have the opportunity to obtain them. No discussion is given as to whether the surgeons relied upon by TOSC intend to shift all or just a portion of their case volume from these facilities, nor is there any discussion of the impact that may have on patients currently having their surgery performed elsewhere. Clearly, TOSC fails to demonstrate why there is a patient-based need for the project is proposes.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 8 and 18a, as well as the performance standards at 10A NCAC 14C .2103.

2. TOSC cannot convert to a multispecialty ASF as proposed.

TOSC was initially approved as part of a special need determination created by the State Health Coordinating Council for a demonstration project for a single-specialty demonstration project. Indeed, one of the conditions of its CON was that it "shall develop a single specialty (orthopaedic) ambulatory surgical facility." As part of the instant application, TOSC proposes "to convert TOSC from a single specialty to a multispecialty ASF." See the application at page 18. TOSC also responds to the administrative rules at 10A NCAC 14C .2103(d), which require an applicant proposing to convert from a "specialty ambulatory surgical program to a multispecialty ambulatory surgical program" to meet certain criteria. As demonstrated in the discussion below, TOSC is not a "specialty ambulatory surgical program" and thus cannot convert to a multispecialty ambulatory surgical program; further, even if TOSC could convert as it proposes, it fails to adequately respond to the rules or demonstrate conformity with the rules.

According to NCGS §131E-176(24f) a "specialty ambulatory surgical program" is *"… a formal program for providing on a same-day basis surgical procedures for only the specialty areas identified on the ambulatory surgical facility's 1993 Application for Licensure as an Ambulatory Surgical Center and authorized by its certificate of need…."* Since TOSC was not licensed in 1993, it is not a specialty ambulatory surgical program, and therefore, it cannot convert from a specialty ambulatory surgical program to a multispecialty ambulatory surgical program.

Even if TOSC could convert to a multispecialty ambulatory surgical program as proposed, it fails to meet the required performance standards in the rule relating to such a conversion. The language of the rule at 10A NCAC 14C .2103(d)(1) states,

> "*provide documentation to show that each existing ambulatory surgical program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,312.5 hours per operating room per year....*" (emphasis added)

In response to this rule, TOSC provided information for two of the existing ambulatory surgical programs in the service area that provide orthopaedic surgery only; however, that response is incomplete and the application is fatally flawed. The rule refers to each program that performs ambulatory surgery "in the same specialty area as proposed in the application." The application proposes orthopaedics as well as plastic surgery and general

surgery, all of which are included in the list of defined specialty areas per 10A NCAC 14C .2101(15). Thus, to be conforming with the rule, **TOSC must demonstrate that each facility that performs ambulatory surgery in orthopaedic, plastic and general surgery are currently utilized at the minimum threshold**. The actual requirements of the rule are much more sensible than the way in which TOSC responded to it, because the rule requires an applicant wanting to expand into new specialties to demonstrate that facilities providing the same specialties it wishes to offer are well utilized. It would not make sense to look only at the facilities that are also limited to the same surgical specialty already offered by the applicant, when the applicant is proposing to add specialties. Without this requirement, an applicant could merely shift surgical volume from one facility to another, even though the existing facility has capacity to provide the volume, resulting in unnecessary duplication of existing resources.

The correct and complete analysis required by this rule includes all of the existing facilities that perform ambulatory surgery in orthopaedic, plastic and general surgery. The table below shows these facilities, including FFY 2018 total utilization, utilization by specialty and number of licensed operating rooms reported in their 2019 License Renewal Applications and total surgical hours shown in the *Proposed 2020 SMFP*.

Facility	***Operating Rooms***	***Total Surgical Hours***	***Surgical Hours/ Operating Room***	***Relevant Specialties***
Rex Surgery Center of Cary	4	5043.5	1260.9	General, Orthopaedic, Plastic
Raleigh Orthopaedic Surgery Center	4	7362.1	1840.5	Orthopaedic
Rex Surgery Center of Wakefield	2	1754.3	877.2	General, Orthopaedic, Plastic
Capital City Surgery Center	8	3637.6	454.7	General, Orthopaedic
Blue Ridge Surgery Center	6	8390.9	1398.5	General, Orthopaedic, Plastic
Raleigh Plastic Surgery Center	1	850.0	850.0	Plastic
Triangle Orthopaedic Surgery Center	2	4525.7	2262.9	Orthopaedic
Holly Springs Surgery Center	3	1887.9	629.3	Orthopaedic

Sources: License Renewal Applications, *Proposed 2020 SMFP*; note that data for Rex Surgery Center of Wakefield was calculated using the LRA for UNC REX Hospital for the time period it was licensed as part of that hospital (using data reported specifically for Wakefield) and the LRA for the facility once it was separately licensed, to provide the most complete data for all of FFY 2018.

As shown by the highlighted rows in the table above, five existing ASF's performing cases in the specialties proposed by TOSC did not perform 1,312.5 hours per operating room in the most recent year, which is the most current data publicly available. Not included in these data are the four existing licensed hospitals, all of which perform ambulatory

surgical cases in these three specialties. Based on the data shown above, **TOSC's application clearly fails to meet the performance standard in the rule noted above**.

Even if this rule did not exist, these data demonstrate that the TOSC application should not be approved. The surgeons TOSC expects to perform cases in the additional specialties are all identified by name, and it is clear that they are already performing surgery at existing facilities in the area. The application fails to identify from which facility these surgeons will shift these cases, and therefore also fails to demonstrate the need these surgeons have for the proposed project. Given the available capacity at other facilities that perform these cases in the county, much less the broader Triangle region, TOSC fails to demonstrate the need to add these specialties and to expand its facility as proposed.

The discussion in the TOSC application regarding the need for another multispecialty ASF in Wake County also fails to demonstrate the need for the project. See the application at pages 36 to 41. While the application notes that approximately one-third of the operating room capacity in ASFs are dedicated to single specialty, it fails to note that these facilities are among the most highly utilized in the county. Further, it follows that the remaining two-thirds are in multispecialty ASFs, and as shown in the table above, the two least utilized ASFs in Wake County in terms of operating hours per operating room, Holly Springs Surgery Center and Capital City Surgery Center, are both multispecialty ASFs. As noted in UNC REX's application, there are a number of ASFs that have been approved in the last year, including three multispecialty ASFs. Given the available capacity in ASFs, including multispecialty, TOSC fails to demonstrate why another multispecialty ASF is needed, particularly given the other issues with its application documented in these comments.

The TOSC application also makes statements which, at best, are misleading regarding the existing ASFs in Wake County. On pages 36 through 38, TOSC presents data and implies that existing ASFs that are assigned as part of larger health systems in the service area are somehow deficient compared to those that are not. TOSC ignores and omits from its analysis that many, if not all of these facilities, include physician owners, who are an important part of the governance of the facility. Further, physicians with ownership at ASFs that are part of the UNC Health Care System are able to choose at what hospitals they maintain privileges and where they admit their patients. To suggest otherwise as TOSC does is disingenuous, and the idea that a need for TOSC's project derives from this issue is simply false.

Finally, UNC REX does not believe that it should be assumed that TOSC can or should be able to convert to a multispecialty ASF. TOSC obtained its original CON as part of a special need determination for a single-specialty ASF. In its original application (J-8616-10), it asserted the benefits of a single-specialty ASF compared with multispecialty ASFs, particularly with regard to quality and safety. The basis of its creation and existence was not the need for a multispecialty ASF, but solely for a single specialty ASF. As such, the desire of TOSC's owners to convert to a multispecialty ASF should not be considered a mere matter of course for the facility, given its history and the need upon which its development was predicated.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 5, 6, and 18a, as well as the performance standards at 10A NCAC 14C .2103.

3. TOSC provides unreasonable utilization projections.

Orthopaedic cases

On pages 99 through 102 of the application, TOSC states its assumption for Step 4 regarding market share increases. The application projects market share to increase by one percent per year, from 13 percent in the last interim year to 16 percent in the third project year. The application narrative presents this growth as "modest," but ultimately provides no basis for this assumption compared to the historical growth rate. The application shows that the historical market share of 12 percent in 2018 is projected to grow to 13 percent, a growth of one percent, by 2020, a two-year period. For the next three years, it projects a market share growth of one percent in each year. The application provides no support for this growth, apart from the same few factors that it lists for each of the previous years. However, it is unreasonable to believe that those same factors could drive growth of one percent per year in the project years, but an average of one-half that growth in the previous years.

TOSC's orthopaedic case projections are also unreasonable because they fail to consider other ASFs that are under development, particularly Raleigh Orthopaedic Surgery Center-West Cary and OrthoNC ASC. Since neither of these facilities have been developed yet, they had no impact on TOSC's historical utilization; however, they are under development and should thus be reasonably expected to impact its future utilization. As such, it is more reasonable to assume that TOSC's future growth will be lower, not higher than it has historically experienced.

General and plastic cases

For these cases, TOSC projects utilization based on the letters of support. The application states that volume for the first year is based on the low estimate, while the third year is based on the high estimate and the second year is based on the average of the two. This assumption is unreasonable because it assumes that year three volume will equate the highest estimate from each of the surgeon letters. Even if the surgeons' volume were to fall in the range of estimated volume, it is unlikely that they will each perform the highest number of cases in the third year.

In addition, as noted above, UNC REX does not believe that TOSC can or should be approved be a multispecialty surgical program. As such, these cases cannot and should not be performed at the ASF.

Pain management cases

TOSC projects that these cases will comprise, by far, its highest number of non-orthopaedic cases. In year three, these cases are projected to be 67 percent, or two-thirds of its non-orthopaedic cases and 20 percent of its total cases. In other words, one in every five cases performed at the ASF are projected to be pain management cases. **However,**

these cases are not surgical cases. This fact is made clear in several ways. On page 18, the application explains that they include "injections, ablation cases, implant cases, and nerve blocks." These types of procedures do not require an operating room but can be performed in procedure rooms in any facility, including a physician office. While they do typically involve image guidance, they do not need to be performed in an operating room. Further, it is clear that these procedures are not surgery because they are not performed by surgeons, but by physiatrists. A simple internet search confirms that physiatry is non-surgical in nature[2].

This distinction is critical, because the administrative rules require applications to demonstrate their ability to meet the performance standards based on the methodology in the *2019 SMFP*. Chapter 6 of the *2019 SMFP* presents the operating room methodology, and the section entitled "Sources of Data" indicates that they are the License Renewal Applications ("LRAs"). The 2018 LRAs, which contain the data used in the *2019 SMFP*, include a table for surgical utilization and one for non-surgical utilization. The first row in the non-surgical table is "pain management," as these cases are not surgical. Therefore, they are not used in the *SMFP* methodology for operating room need, and they cannot be used to demonstrate conformity with the performance standards in the rules.

TOSC also fails to demonstrate the need for additional operating rooms, when one-fifth of the cases it projects to perform are non-surgical and do not need to be performed in an operating room. While the application suggests in Section E that TOSC is unable to expand to accommodate a procedure room in addition to the two proposed operating rooms, this points to an issue with TOSC's planning and design, not an issue driven by patient need. In a large and growing county with thousands of new residents each year, new operating rooms should be approved for those that intend to use them for surgical cases, not procedures that can be performed by non-surgical physicians in multiple settings.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18a, as well as the performance standards at 10A NCAC 14C .2103, and the TOSC application should not be approved.

[2] See, e.g. https://www.spineuniverse.com/treatments/what-physiatrist

COMMENTS ON DUKE HEALTH GREEN LEVEL AMBULATORY SURGICAL CENTER

General Comments

As the Agency is aware, Duke Raleigh Hospital submitted a letter to the Agency in early 2019 to inform it of reporting errors on its Hospital License Renewal Application (HLRA), which resulted in the inclusion of thousands of cases performed in procedure rooms in its operating room volume. This error is important context to the Duke application in this review, as it primarily proposes to take cases done historically in procedure rooms, and shift them to a *higher* level of care, namely operating rooms it proposes to develop in its recently-approved ASF. Not only is this proposal illogical from a health planning and clinical/operational perspective, but it gives rise to more serious questions regarding Duke's proposed project and its alleged need for additional operating room capacity.

Issue-Specific Comments

1. <u>The application fails to demonstrate the need for the proposed operating rooms.</u>

   Central to its proposal is Duke's statement regarding the current provision of surgical cases in its procedure rooms:

   > *"Therefore, DRAH has accommodated a portion of its growing surgical volume in recent years in its procedure rooms. The majority of these surgical cases performed in a procedure room are appropriate for an ASC setting (based on acuity, anesthesia and other coverage needs, and procedure type; see Section Q for a discussion of the criteria used to determine ASC-appropriate cases). Therefore, it would be beneficial beneficial [sic] to patients and payors from a cost perspective to have such surgical procedures performed in an ASC rather than in a hospital setting. Indeed, the proposed additional ORs to be developed at Green Level ASC would increase access to cost effective, dedicated-ambulatory surgical services for many of the patients whose surgical cases would otherwise be performed in DRAH's procedure rooms, similar to those whose cases would be performed in a licensed hospital operating room."*

   See Duke application at page 22.

   While there is no dispute that patients with cases appropriate for an ASF can benefit from having them performed there over a hospital-based setting, what Duke proposes is not so simple. It has purportedly identified cases that are a) procedure room appropriate, as they are currently being performed there; and, b) ASF-appropriate, but rather than proposing to shift these cases to the procedure rooms in its approved ASF, it proposes instead to spend millions in additional capital to develop licensed operating rooms at the ASF, to perform cases that it has already deemed entirely appropriate for procedure rooms.

   The only merit of this proposal is to provide Duke a remedy for its HLRA reporting issues and a way to project sufficient surgical volume in its proposed operating rooms to attempt

to meet the performance standards in the administrative rules. No other operational, clinical or patient-focused reason is provided in the application, and UNC REX believes that none exist.

The data provided in the application actually support the status quo, or at best, the development of additional procedure rooms. As shown, for example, in the table on page 61 of the application, Duke's most significant growth has been in outpatient cases performed in procedure rooms. The most effective and least costly alternative, therefore, would be to proceed with the development of its ASF in Apex, which is already approved for five procedure rooms.

This absurdity is also apparent on the Form C Utilization table, which shows five approved procedure rooms with a total projected volume of 819 cases in Year 3, or 168 cases per room per year. Since these cases are already appropriate for this setting, using these approved procedure rooms instead of developing additional operating rooms is a more appropriate option, and the development of the proposed operating rooms at the facility is unwarranted. In a fast-growing area like Wake County, with multiple successive need determinations for operating rooms, clearly these operating rooms do not need to be used to perform cases that can be—and currently are being—performed in procedure rooms.

Based on these issues, the application fails to demonstrate that the project is needed or that it is the most effective or least costly alternative. As such, the application **should be found non-conforming with Criteria 1, 3, 4, 5, 6, 12 and 18(a) and the performance standards at 10A NCAC 14C .2103**.

2. <u>The application fails to demonstrate that its utilization projections are based on reasonable assumptions</u>.

Throughout the need methodology presented in Section Q, Duke includes surgical cases performed in procedure rooms. While there is no issue with Duke performing surgical cases in procedure rooms, as clinically appropriate, its methodology masks the fact that it projects to shift many of these cases to fill its operating rooms and to meet the performance standards in the operating room rules. The fact that these procedure-room cases are added into the methodology is shown clearly between the table in Step 3 on page 127, which shows 7,365 total ambulatory surgical cases performed in operating rooms in FY 2019 , and the table in Step 5 on page 129, which reports 8.412 total ambulatory cases in FY 2019 that are appropriate for an ASF. Obviously more than 1,000 of these cases, and likely more, have historically been performed in procedure rooms. In fact, as shown in Exhibit Q, of a total of 22,839 cases in FY 2018-2019, 8,005 were performed in procedure rooms.

Exhibit Q also shows that more than one-third of the total cases Duke proposes to serve in its proposed operating rooms have historically been performed in procedure rooms. In the Attachment for Step 10, the table shows the following number of cases to be shifted from Duke Raleigh Hospital to the ASF and the historical venue for these cases (OR or procedure room):

FY23			FY 24			FY 25		
OR	*Procedure*	*Total*	*OR*	*Procedure*	*Total*	*OR*	*Procedure*	*Total*
807	473	1,280	1,429	827	2,256	1,872	1,004	2,876

Note that the totals in each year match the total projected volume for the operating rooms proposed at Duke's ASF. Thus, Duke proposes to spend $6 million to add operating rooms to an approved ASF, when that ASF is already approved to develop five procedure rooms which have more than sufficient capacity to accommodate, at a minimum, the cases that have historically been performed in procedure rooms.

Duke has failed to demonstrate the need for the proposed operating rooms to perform cases that have historically been performed in procedure rooms, and the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 12, 18(a) and the performance standards at 10A NCAC 14C .2103. The Duke application should not be approved.

COMMENTS ON WAKEMED CARY HOSPITAL

General Comments

According to the *2019 SMFP*, **the WakeMed system has the highest projected operating room surplus of any system or single facility in Wake County**. WakeMed Cary, the location of the proposed operating room in this application, shows the second highest facility-specific surplus of operating rooms of any licensed facility in Wake County, which is surpassed only by Capital City Surgery Center, also part of the WakeMed system. This surplus is projected to continue according to the September 17, 2019 Draft Table 6B, which shows that **WakeMed Cary is projected to have the highest operating room surplus of any licensed facility in the county**. While the application argues that the *SMFP* methodology inappropriately limits its growth in case time, the same is true for any other applicant experiencing case time growth, including UNC REX. Therefore, WakeMed is not being treated any differently than other applicants with existing facilities. As explained in the comments to follow, WakeMed Cary's application is also non-conforming with review criteria and should not be approved.

Issue-Specific Comments

1. The application fails to demonstrate the need for an additional OR at WakeMed Cary.

   While the specific issues with the application's utilization methodology will be addressed below, the application simply fails to demonstrate why another operating room is needed at WakeMed Cary. Although the application references some growth and historical and expected physician recruitment, it has a sufficient number of operating rooms to meet its current and projected utilization, even if the latter is assumed to be accurate. As shown in the utilization table on page 127, WakeMed Cary will develop its 10th non-C-Section OR in FY 2020. Utilization projections for FY 2023 show a need for only 7.12 operating rooms. As such, there is simply no need for WakeMed Cary to be approved for another operating room.

   Moreover, the application includes non-surgical volume to project need, which clearly can be performed outside of an operating room, further lessening the need for additional capacity. While the application also speaks to issues it has with the methodology, the time to petition the SHCC to change the methodology for this review has long past, and since the OR rules require applicants to demonstrate need consistent with the *SMFP* methodology, such issues are irrelevant in this review.

   Because of this issue, the application should be found non-conforming with Criterion 1, 3, 4, 5, 6, and 18(a).

2. The application provides unreasonable utilization assumptions.

   Unreasonable growth rate assumptions

   In Section Q, WakeMed provides its methodology for projecting utilization for the proposed project and for some of the other facilities in its system. In Step 4, WakeMed calculates the Compound Annual Growth Rate (CAGR) for its existing facilities. This step

contains multiple errors and unreasonable assumptions. First, the data for FY 2019 is stated to be annualized based on nine months of actual data. The application fails to state how that calculation was made, but absent any other explanation, it is reasonable to assume that WakeMed divided the surgical cases for the first nine months of the year by nine, then multiplied that number by 12. This calculation can reasonably be expected to overstate the surgical volume for the year, as it assumes the same average volume during the summer months (July, August and September), the last three months of the federal fiscal year, as in each of the preceding months. These summer months traditionally experience lower volume than the rest of the year, particularly for surgical cases, as surgeons and patients take vacations. By failing to adjust for this seasonality, the data for FY 2019 is overstated. The Agency can and should review the HLRA data submitted by WakeMed for FY 2019 during the review to confirm that WakeMed failed to make this adjustment. Since the calculation of the CAGR includes this annualized number, if it is inaccurate, then the projected utilization is based on unreliable data and is unreasonable.

Next, WakeMed calculates the CAGR for Capital City Surgery Center for 2015 to 2019, even though it states on page 119 that "Capital City's case volumes have been significantly underreported. This underreporting has likely occurred for a number of years. To remedy this error, Capital City resubmitted its 2019 LRA to more accurately reflect actual FY 2018 volume." In other words, WakeMed used upwardly-adjusted volume for 2019 to calculate the CAGR, while making no attempt to adjust the data for 2015 (or any other year), which is also used in calculating the CAGR and which it admits is "significantly underreported." This has the effect of artificially inflating the CAGR and making it appear that Capital City has a higher growth rate than it actually does. Given the lack of correct data for 2015-2017 and the issue with annualization for 2019 noted above, there is no way of knowing what the correct historical volume has been or whether the volume trend at Capital City is actually positive. As such, WakeMed's failure to correct the historical data for other years results in erroneous, overstated and unreasonable volume projections.

WakeMed's utilization projections are also 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 *2019 SMFP*. The *2019 SMFP* methodology uses data reported on License Renewal Applications (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. Further, its methodology, based on this improper data, is therefore also flawed.

As an example of this issue, the following figures compare the data on WakeMed Cary's LRA with data reported in the SMFP and finally with data reported in the application in Table Q.5 on page 117.

Table 8.d from the WakeMed Cary LRA, page 12

WakeMed Cary Hospital Facility ID: **990332**

All responses should pertain to **October 1, 2014 through September 30, 2015.**

8. Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures *(continued)*

(Campus – *If multiple sites*: _____**)**

d) Surgical Cases by Specialty Area Table

Enter the number of surgical cases performed only in licensed operating rooms by surgical specialty area in the table below. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases performed only in licensed operating rooms. The total number of surgical cases should match the total number of patients listed in the Patient Origin Tables on pages 26 and 27.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)	23	0
Open Heart Surgery (from 7.(b) 4.)	0	
General Surgery	1,451	1,626
Neurosurgery	0	0
Obstetrics and GYN (excluding C-Sections)	94	629
Ophthalmology	2	658
Oral Surgery	0	7
Orthopedics	905	493
Otolaryngology	7	91
Plastic Surgery	6	155
Urology	70	493
Vascular	0	0
Other Surgeries (specify) Podiatry	2	76
Other Surgeries (specify)		
Number of C-Section's Performed in Dedicated C-Section ORs	720	
Number of C-Section's Performed in Other ORs	0	
Total Surgical Cases Performed Only in Licensed ORs	3,280	4,228

The data reported in the table above, per the instructions above the table, include only surgical cases performed in licensed operating rooms. To determine the case numbers in the table below, C-Sections performed in Dedicated C-Section ORs are subtracted from the inpatient total, in this case 720. Thus, 3,280 total inpatient cases minus 720 C-Sections equals 2,560 inpatient cases. The case numbers for ambulatory cases transfer directly.

Table 6A from the 2017 SMFP

Case Data for 10/1/2014 through 9/30/2015 as reported on the 2016 Hospital and Ambulatory Surgical Facility License Renewal Applications

County	License	Facility Name	Inpatient Cases (Dedicated C-Section Cases Excluded)	Ambulatory Cases	Inpatient ORs	Ambulatory ORs	Shared ORs	Excluded C-Section ORs	Excluded Trauma/ Burn ORs	CON Adjust-ments	CON Adjustments for Dedicated C-Section
Wake	H0276	WakeMed Cary Hospital	2,560	4,228	2	0	9	-2	0	0	0

The historical data provided in WakeMed's application is reported to emanate from its LRA, but it clearly includes additional cases that the methodology does not include, as the numbers are much larger, shown below.

Table Q.5A from the WakeMed Cary Application, page 117

Facility	2015		
	IP	OP	Total
WakeMed Cary Hospital	2,769	4,815	7,584

The difference between the SMFP methodology and WakeMed's contrived methodology is shown below:

	IP	*OP*
Application	2,769	4,815
HLRA/*SMFP*	2,560	4,228
Difference	209	587

The source of this difference is apparent when reviewing the following table from WakeMed's LRA.

e) Non-Surgical Cases by Category Table

Enter the number of non-surgical cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category – the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location, *except* do not count cases having endoscopies in GI Endoscopy rooms. Report cases having endoscopies in GI Endoscopy Rooms on page 10.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Pain Management	0	0
Cystoscopy	207	339
Non-GI Endoscopies *(not reported in 8. c)*	0	0
GI Endoscopies *(not reported in 8. c)*	0	0
YAG Laser	0	86
Other (specify) Dental	2	162
Other (specify)	0	0
Other (specify)	0	0
Total Non-Surgical Cases	209	587

WakeMed is clearly including non-surgical cases in its utilization methodology, which is inconsistent with the operating room rules. Specifically, the performance standards at 10A NCAC 14C .2103 state,

> *"An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need*

for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor."

Emphasis added.

The Operating Room Need Methodology in the SMFP does not include non-surgical cases. Therefore, the basis of WakeMed's utilization projections and attempt to demonstrate conformity with this rule are erroneous.

The same error is repeated throughout this step, for FY 2016 and 2017. For brevity, the table below summarizes the difference between the correct data and WakeMed's application data, but the sources are the same (i.e. LRA, *SMFP*, application Table Q.5).

	Application		***HLRA/SMFP***		***Difference***	
	IP	***OP***	***IP***	***OP***	***IP***	***OP***
FY 2016	3,037	4,820	2,914	4,132	123	688
FY 2017	3,162	5,242	3,041	4,663	121	579

Of note, the errors are consistently in WakeMed's favor, inflating its surgical utilization by thousands of hours each year. While WakeMed states that its FY 2019 volume is based on nine months of annualized data, given these errors, those data certainly cannot be relied upon. Since these errors are included in the foundational data for WakeMed's utilization methodology, the resulting projections are therefore also unreliable.

In Step 5, WakeMed states that it projects to shift cases from various existing facilities to its approved ASFs in Cary and North Raleigh and provides the number of cases it projects to shift. The application fails completely to provide any methodology or rationale for the projected shifts, however; as such, they cannot be determined to be reasonable. Without any methodology or explanation, the case volume for these facilities cannot be relied upon to demonstrate conformity with the operating room rules.

In Step 7, WakeMed makes two incredible assumptions. First, it believes the methodology unfairly suppresses the need by limiting the actual case time growth. It should be noted that this function impacts all providers whose case time is growing more than 10 percent per year, including UNC REX, which has been negatively impacted by this function multiple times since its inception. Second, WakeMed believes it should exclude an operating room on the basis of its Level III Trauma status, even though it admits this is also not part of the SMFP methodology's assumptions[3]. When these assumptions are applied to WakeMed Cary's projected utilization, only then is there a projected deficit of an operating room in Year 3. When the *SMFP* methodology is applied, as required by the operating room rules,

[3] The SMFP methodology subtracts an operating room for Level II and Level I Trauma Centers, based on their specific requirements for surgical availability. Level III Trauma Centers do not have the same expectations.

WakeMed Cary shows a surplus of four operating rooms in Year 3, as shown in table Q.14A.

In the same step, WakeMed projects a deficit of more than five operating rooms at WakeMed's New Bern campus, but states that "WakeMed executive leadership are confident that its current and proposed OR complement will be adequate for the next several years." Somehow, WakeMed Cary, with a projected surplus of four operating rooms needs an operating room, but WakeMed's purported five-OR deficit is "adequate." Clearly, WakeMed has not demonstrated its projections and proposal to be based on reasonable assumptions.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6 and 18(a), as well as the performance standards in the administrative rules, and the WakeMed Cary application should be denied.

COMPARATIVE ANALYSIS

Given that the multiple applicants propose to meet all or part of the need for the two new operating rooms in Wake County, not all can be approved as proposed. To determine the comparative factors that are applicable in this review, UNC REX examined recent Agency findings for competitive OR reviews. Based on that examination and the facts and circumstances of the competing applications in this review, UNC REX considered the following factors:

- Conformity with Rules and Criteria
- Geographic Accessibility
- Patient Access to Low Cost Outpatient Surgical Services
- Patient Access to Surgical Specialties
- Access by Underserved Groups
- Projected Average Revenue per Case
- Projected Average Operating Expense per Case

Conformity with Applicable Statutory and Regulatory Review Criteria

As discussed in the application-specific comments above, the TOSC application, the Duke application, and the WakeMed application are non-conforming with multiple statutory and regulatory review criteria. In contrast, the UNC REX application is conforming with all applicable statutory and regulatory review criteria. Therefore, with regard to statutory and regulatory review criteria, the UNC REX application is the most effective alternative.

Geographic Accessibility

All of the applications propose developing the ORs in or near locations where surgical services are already available or approved. Thus, no one propose to expand geographic accessibility.

Patient Access to Low Cost Outpatient Surgical Services

UNC REX understands that this factor has been used in the past, particularly in areas without sufficient access to freestanding ASFs. As discussed previously, Wake County has numerous existing and approved ASFs in many locations throughout the county. In fact, six new ASFs are approved/under development, five of which were approved in 2019. As explained in UNC REX's application, most of the existing and operational ASFs have additional capacity to serve more patients. As such, given the available access to freestanding ASFs in Wake County, UNC REX does not believe that this factor is meaningful or appropriate in this review.

Patient Access to Surgical Specialties

In general, ASFs, whether single specialty or multispecialty, provide access to a lower number of specialties than hospitals. This is especially true for hospitals like UNC REX, which provides tertiary-level care to patients in Wake County. As shown on its HLRA, UNC REX provides care in numerous specialties, such as cardiothoracic surgery, open heart surgery and neurosurgery, along with many other inpatient and some outpatient cases that can only be performed in a hospital setting. As one of only two hospital applicants and the only tertiary surgical provider in this review,

UNC REX believes that it clearly is the most effective alternative regarding access to surgical specialities.

Access by Underserved Groups

In recent reviews, the Agency has determined that a comparison using this factor is not conclusive. In this review, it appears that most applicants project comparable amounts of care to Medicare and Medicaid patients, with the exception of TOSC, which projects a significantly lower amount of Medicare. UNC REX believes that if these factors are found to be conclusive, the Agency should consider the history of the facility in actually providing care to the underserved as projected, as well as the services provided. UNC REX is the most comprehensive surgical provider among the applicants, providing services that cannot be accessed through any of the other applications. For these reasons, UNC REX believes it is an effective alternative for providing access to underserved groups.

Projected Average Revenue per Case

UNC REX recognizes that differences among types of surgical cases and facilities drive different revenue per case statistics. However, it should be noted that UNC REX's gross and net revenue per case statistics are significantly lower than WakeMed, its only hospital-based competitor. As such, and given the need for additional hospital-based OR capacity in Wake County, UNC REX believes it is the most effective alternative regarding this factor.

Projected Average Operating Expense per Case

As with revenue per case, UNC REX understands that the types of surgical cases performed drive the expense per case. As noted previously, UNC REX provides tertiary surgical services, which by their nature demand more resources than other types of cases, yet they are still needed by patients. UNC REX believes it is an effective alternative regarding operating expenses per case.