Comments on Competing Applications for Additional Acute Care Beds and Operating Rooms in Wake County

October 3, 2022

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submitted by

Rex Hospital, Inc.

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Rex Hospital, Inc. d/b/a UNC Health Rex Hospital (Rex) hereby submits the following comments related to competing applications to develop additional acute care beds and operating rooms to meet the need identified in the *2022 State Medical Facilities Plan* (*2022 SMFP*) for 45 additional acute care beds and two additional operating rooms (ORs) in Wake County. 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, Rex has organized its discussion by issue, noting some of the general Certificate of Need (CON) statutory review criteria and specific regulatory criteria creating the non-conformity on the application. Rex's comments relate to the following applications:

- **WakeMed Garner Hospital (WakeMed Garner), Develop a new hospital by relocating 22 beds, adding 9 beds and 2 ORs, Project ID # J-12264-22**
- **Duke Raleigh Hospital (DRAH), Add 45 acute care beds, Project ID # J-12263-22**
- **Oakview ASC (Oakview), LLC, Develop a single-specialty ophthalmic ASC with one OR, Project ID # J-12252-22**
- **Triangle Vascular Care (TVC), Develop a single-specialty ASF with one OR, Project ID # J-12253-22**
- **Duke Health Green Level Ambulatory Surgical Center (DHGL), Add two ORs, Project ID # J-12261-22**
- **KM Surgery Center (KMSC), Develop a multi-specialty ASF with one OR, Project ID # J-12248-22**

As detailed above, this review includes a mix of proposals for acute care beds, hospital-based operating rooms and ambulatory surgical facilities (ASFs). Moreover, given the number of applications and proposed acute care beds and operating rooms, all the applications cannot be approved. Rex's detailed comments include general comments about the competing applications as well as application-specific comments related to each competing application and a comparative analysis related to its applications.

Rex has a long-standing, demonstrated commitment to developing projects that increase geographic and financial access to healthcare services, feature physician collaboration, and provide cost effective and efficient options for patient care. As detailed in its applications, Rex believes that the most appropriate way to meet the need for two additional operating rooms and 45 acute care beds in Wake County identified in the *2022 SMFP* is to develop two additional operating rooms and 36 acute care beds at UNC Heath Rex Hospital, and nine acute care beds at UNC Health Rex Holly Springs Hospital. The Rex applications are the result of prudent healthcare planning to provide greater access to hospital-based

[1] Rex is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to the applications filed on August 15, 2022 by Rex (Project ID # J-1258-22, Project ID # J-12260-22, and Project ID # J-1212259-22).

operating rooms and tertiary acute care beds in Wake County, while also increasing geographic access to acute care beds.

GENERAL COMMENTS

As noted above, four applications in this review propose to develop only ORs, three of which propose new ASFs; three applications propose to develop acute care beds (DRAH, UNC Health Rex Hospital and UNC Health Rex Holly Springs Hospital) and one application (WakeMed Garner) proposes to develop both beds and ORs. Rex believes it has presented the most compelling applications to develop additional acute care beds and OR capacity. In addition to the many reasons included in its applications, the following factors show that Rex is the most effective applicant:

- Agency Analysis and Recommendations
- Hospital OR Capacity Constraints
- Scope of Services
- Geographic Accessibility

Each of these factors is discussed in turn below.

Agency Analysis and Recommendations

At the outset, it is important to note that the *2022 SMFP* OR need determination was a direct result of a special need petition submitted by Rex to add six ORs specifically designated for existing licensed acute care hospitals in the Wake County service area. The Agency's report (see Attachment A) analyzed relevant Wake County data and found the following significant implications:

- Ambulatory case times in Wake County have increased at a greater rate in hospitals than ASFs, suggesting an increase in higher acuity/complex cases in the service area
- Overall Wake County hospitals are approaching the 75% threshold with Rex and Duke Raleigh having the highest percent of total OR hours per OR, 96% and 111% respectively
- OR utilization growth in Wake County hospitals has mirrored and in the case of Rex (6.6% growth) exceeded Wake County population growth rates (1.9%)
- On average Wake County hospitals have experienced a deficit of 2.30 ORs with Rex having a deficit of 4.37 ORs

The Agency notes in its conclusion,

"*the impetus for this [Rex's] petition is a trend of CONs for ORs being awarded to AMSU facilities despite high utilization trends in hospitals. A review of Wake County hospital and AMSU OR data suggests that hospital ORs may be experiencing growth in utilization due to a higher concentration of more complex ambulatory surgical cases*." (emphasis added)

Ultimately the Agency recommended adding a need determination for two ORs in the Wake County service area in the *2022 SMFP,* and although the Agency does not specifically support designating OR need determinations for a particular type of facility, it is self-evident from the data presented in the Agency's report that the current Wake County OR need exists in hospital based ORs rather than ASFs. As such, for the CON Section to remain consistent with the recommendations set forth by the Healthcare Planning

Section and subsequently adopted by the SHCC, approval for the two ORs should be for a hospital-based proposal providing the widest scope of services to the greatest number of patients rather than ASFs. While the Agency has sometimes previously analyzed the percentage of ambulatory cases performed in a county compared to the number of ASF-based operating rooms, as the petition and the Agency's analysis demonstrated, despite the growth in the number of approved ASF-based operating rooms in Wake County, there is a need for additional hospital-based operating room capacity for ambulatory cases as well as inpatient cases. Thus, based on the Agency recommendation and subsequent adoption by the SHCC, UNC Health Rex Hospital is the most effective alternative for the development of ORs in Wake County.

The Agency also recently released another recommendation pertinent to the current review of proposals to develop ORs in Wake County pursuant to the 2022 need determination in response to a request to add a single specialty vascular access OR need determination in Nash County. This will be discussed later in issue-specific comments.

Hospital OR Capacity Constraints

Rex believes that a simple analysis that compares ambulatory surgical cases to the number of dedicated ambulatory operating rooms fails to consider the need for a considerable number of outpatient cases to be performed in hospital-based operating rooms. As described in the application, based on internal data for partial State Fiscal Year (SFY) 2021, 34 percent of surgical cases performed at Rex were classified as inpatient. However, 58 percent of surgical cases performed at Rex were either inpatient or were classified as outpatient or observation but involved an overnight stay, which demonstrates that not all cases classified as outpatient are actually appropriate for an ASF setting. Most ASFs are not currently equipped or staffed to accommodate these patients, and with the severe staffing shortages faced in healthcare today, it would not be prudent to staff most ASFs through the night for the occasional patient who requires it, particularly when staff are already available in a hospital setting to provide 24/7 coverage. Also of note, Rex performs a number of outpatient surgical cases on patients who do not require an overnight stay, but who have advanced needs that require hospital resources commensurate with an inpatient case.

The application also describes the complicating factor for hospitals regarding the current situation with diversion status. In the past, when a hospital was experiencing an acute strain on capacity, Wake County Emergency Medical Services (EMS) would divert patients to other hospitals in the county to relieve some of the strain. At present, every Wake County hospital is regularly reporting capacity constraints, and Wake County EMS is unable to accommodate diversions. Certainly, contributing to this phenomenon is insufficient OR capacity in existing Wake County hospitals. For example, when a patient presents to a hospital emergency department via Wake County EMS and requires surgery, the hospital is unable to move that patient from the emergency department to the OR until an OR becomes available. This excessive demand on hospital providers in Wake County results in inpatient backlogs, long turnaround times, and more time in the hospital – all of which are detrimental to patient care.

Of note, mechanisms are in place to provide hospitals experiencing a strain on acute care bed capacity temporary relief when needed in the form of temporary bed overflow approval. This past year, Rex had additional inpatient bed capacity through the COVID-19 waiver which allowed it to adjust its bed capacity when necessary. In prior years, Rex has been approved for temporary bed overflow status; however, there is no similar mechanism that allows a hospital to temporarily increase its OR capacity. While additional bed capacity afforded by the COVID-19 waiver and temporary bed overflow status is critical, it

also further strains Rex's OR capacity absent any corresponding flexibility to expand its OR capacity as demand dictates.

For these reasons, Rex's proposal to develop two hospital-based ORs is the most effective alternative, given that it is only one of two proposals to develop hospital-based ORs, and it is the only hospital OR applicant that provides tertiary services.

Scope of Services

Because UNC Health Rex Hospital is the only proposal that seeks to develop shared operating rooms which will serve both inpatients and outpatients in a tertiary care setting, its proposed project to develop two additional ORs enables the development of surgical capacity that will serve a full scope of surgical services that will serve to meet the growing need for both inpatient and outpatient surgical capacity in Wake County. As shown in the Rex OR application and excerpted below, hospitals in Wake County experienced significantly higher utilization than ASFs.

FFY 2021 Wake County Operating Room Utilization by Site of Care

Site	*Total Surgical Hours**	*Standard OR Hours Total^*	*Percent Capacity*
Freestanding ASF	31,421	40,672	77%
Hospital	151,694	137,265	111%

Source: *Proposed 2023 SMFP.*

*Total Surgical Hours for Grouping per Table 6A in *Proposed 2023 SMFP.*

^Standard Hours per OR per Year x OR inventory per Table 6A in *Proposed 2023 SMFP* excluding any CON adjustments for future projects in order to accurately determine actual utilization.

As noted in the table above, the capacity shown does not reflect any of the ASF capacity approved in recent years that has not been developed. This additional undeveloped capacity which is shown below can only be expected to further decrease ASF capacity.

Site	*Undeveloped ORs*	*Standard OR Capacity**
Duke Health Garner ASC	1	1,312
Duke Health Green Level ASC	1	1,312
Raleigh Orthopaedic Surgery Center	1	1,312
Orthopaedic Surgery Center of Garner	1	1,312
WakeMed Surgery Center-Cary^	1	1,312
Ortho NC ASC	1	1,312
Valleygate Surgery Center	1	1,312
Triangle Surgery Center	1	1,312
Wake Spine and Specialty Surgery Center	1	1,312
Total	**9**	**11,808**

Source: *Proposed 2023 SMFP.*

*Standard Hours per OR per Year for Group 5 and 6 ASFs per Table 6A in the *Proposed 2023 SMFP.*

^WakeMed was approved through settlement to develop two new ASFs; however, only one included a new (additional) operating room and the other will be developed through a transfer of a hospital-based operating room.

Please note that the table above does not include ASF operating rooms that will be developed through the transfer of hospital operating rooms. As previously discussed, while there are significant benefits to the provision of outpatient surgery in an ASF setting in terms of quality and cost, the benefits of increased access to ASFs must be balanced with the need for adequate hospital-based operating room capacity for inpatient surgical cases and outpatient cases that can only be performed in hospital settings. According to analysis performed by the Healthcare Planning and Certificate of Need Section, hospitals in Wake County receive a substantially smaller percentage of new ORs than other counties in CON reviews, even though hospital utilization is most often responsible for the need determinations.[2] Given the small number of operating rooms allocated in the *2022 SMFP* compared with the number of approved but undeveloped ASF-based operating rooms, Rex believes that it is vital to expand access to hospital-based operating rooms in Wake County.

Not only is it important that surgical access be expanded in the hospital-based setting, but it is also equally important that the surgical services be provided in a tertiary care hospital with adequate acute care bed capacity. As a tertiary care hospital Rex is equipped to serve high acuity patients by providing highly specialized medical care involving advanced and complex surgical procedures. No other provider proposes to develop surgical capacity that will serve patients in a tertiary care setting: WakeMed proposes to develop ORs in a community hospital-based setting and the other four OR applicants (DHGL, TVC, KM Surgery Center, Oakview ASC) all propose to develop ASF-based dedicated ambulatory ORs. Notably, two of the four OR applicants (Oakview and TVC) are proposals for single-specialty ASFs and the WakeMed proposal specifically states in the methodology that they propose to serve non-tertiary patients.

Recognizing the need to support access to both ORs and acute care beds designed to serve high acuity patients, Rex has submitted two applications to expand both acute care bed capacity by adding 36 acute care beds and two ORs at Rex Hospital. Additionally, through its prudent and strategic healthcare planning Rex also recognized the need for additional community hospital bed capacity in southern Wake County and submitted an application to add nine acute care beds at UNC Health Rex Holly Springs Hospital.

As such, the applications submitted by UNC Health Rex best meet the need identified it the SMFP. Specifically, approval of UNC Health Rex Hospital for two ORs and 36 acute care beds will allow the development of surgical capacity for both inpatient and outpatient surgical patients with the greatest scope of services in Wake County and approval for nine additional beds at UNC Health Rex Holly Springs Hospital will enhance geographic accessibility.

[2] Accessed at https://info.ncdhhs.gov/dhsr/mfp/pdf/2022/acsc/12_OR-Apps-2018-2021.pdf.

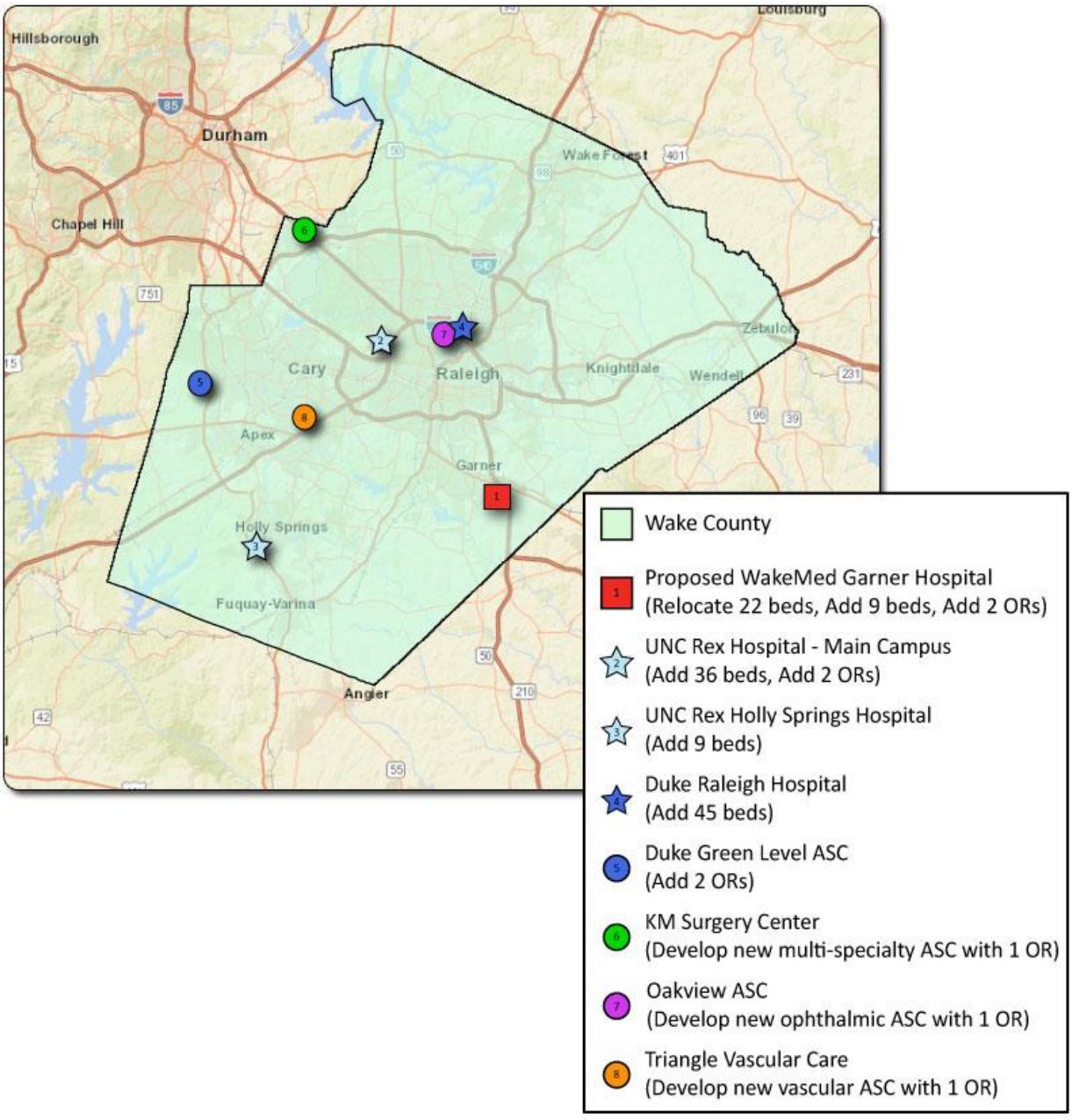
Geographic Accessibility

As noted previously, Rex is submitting three concurrent and complementary applications to meet the need for the 45 additional acute care beds and two ORs identified for Wake County in the *2022 SMFP*. Two applications filed by Rex propose to develop 36 additional acute care beds and two ORs at UNC Health Rex Hospital. A third application proposes to develop nine additional acute care beds and 15 unlicensed observation beds at UNC Health Rex Holly Springs Hospital. The need for each respective project is based on similar concepts, but ultimately each is proposing to serve a patient population with a distinct need for the proposed project. UNC Health Rex Hospital is a centrally located tertiary care hospital designed to serve patients from Wake and surrounding counties with high acuity needs; UNC Health Rex Holly Springs Hospital by contrast is a community hospital in southern Wake County serving non-tertiary care patients. All the other applicants except for DRAH and DHGL propose to develop a new site of care for acute care beds or ORs. Duke Raleigh proposes to add acute care beds in central Wake County and Duke Health Green Level proposes to add two ORs in southwest Wake County. While WakeMed proposes to develop a complement of both acute care beds and ORs with a new hospital located in eastern Wake County, a vast majority of the beds in the new hospital would be a result of relocating acute care beds from its main campus in central Wake County, which does not increase capacity. Additionally, the proposed site location for the WakeMed Garner Hospital at the intersection of White Oak Road and Timber Drive East in Garner is only 8.7 miles[3] from UNC Health Johnston-Clayton, an existing community hospital.

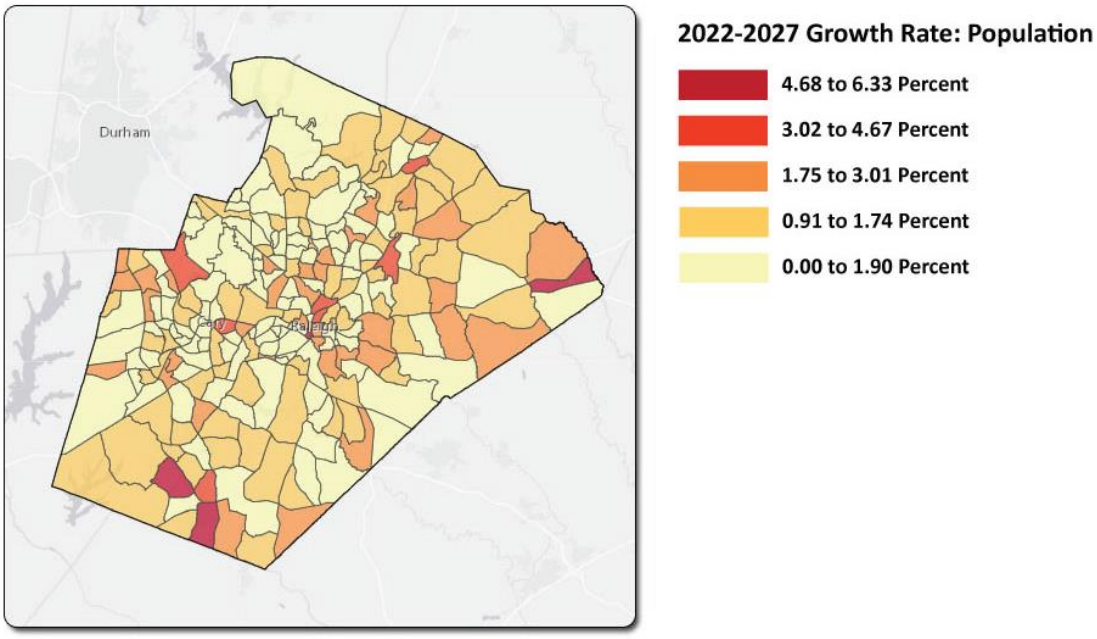
None of the applicants (besides UNC Health Rex) collectively or singularly propose projects covering both central Wake County and southern Wake County, where, as discussed in the respective Rex applications, the population growth and need is greatest. The location and service components of each project submitted by Rex serve to geographically complement the other two applications submitted by Rex. Together, the proposed projects will enhance geographic access to both acute care beds and ORs for patients across Wake County.

The two maps below illustrate how the three applications submitted by Rex collectively present the most effective solution to meet the needs of Wake County in consideration of population growth factors. The first map shows all the projects under review and the second map shows the proposed projects under consideration and the population growth rate for Wake County. As shown below, the applications submitted by Rex are all located in or near the highest population growth areas of Wake County.

[3] Accessed at: https://www.google.com/maps/dir/Johnston+Health+Clayton,+2138+NC-42+W,+Clayton,+NC+27520/White+Oak+Rd+%26+Timber+Drive+East,+North+Carolina+27529/@35.6568126,-78.573364,13z/data=!3m1!4b1!4m13!4m12!1m5!1m1!1s0x89ac66741757de6d:0xbcd6e9407ced051a!2m2!1d-78.5034071!2d35.6311617!1m5!1m1!1s0x89ac60c4669030a3:0xfc97bbdb1ee1c4b!2m2!1d-78.5820642!2d35.6893801


Hillsborough
Louisburg
Durham
Wake Forest
Chapel Hill
Cary
Raleigh
Knightdale
Wendell
Zebulon
Apex
Garner
Holly Springs
Fuquay-Varina
Angier
Wake County
Proposed WakeMed Garner Hospital
(Relocate 22 beds, Add 9 beds, Add 2 ORs)
UNC Rex Hospital - Main Campus
(Add 36 beds, Add 2 ORs)
UNC Rex Holly Springs Hospital
(Add 9 beds)
Duke Raleigh Hospital
(Add 45 beds)
Duke Green Level ASC
(Add 2 ORs)
KM Surgery Center
(Develop new multi-specialty ASC with 1 OR)
Oakview ASC
(Develop new ophthalmic ASC with 1 OR)
Triangle Vascular Care
(Develop new vascular ASC with 1 OR)

Source: Esri



Source: Esri

For these reasons, approval of Rex for two ORs and 36 acute care beds at UNC Health Rex Hospital as well as the approval of nine acute care beds at UNC Health Rex Holly Springs Hospital will provide the greatest geographic access to services where they are most needed.

Nonetheless, as demonstrated below, Rex believes that it is the only applicant that has demonstrated conformity with the statutory and regulatory review criteria. The following sections provide detailed comments on each competing application as well as a more detailed comparative analysis.

ISSUE-SPECIFIC COMMENTS ON WAKEMED GARNER HOSPITAL

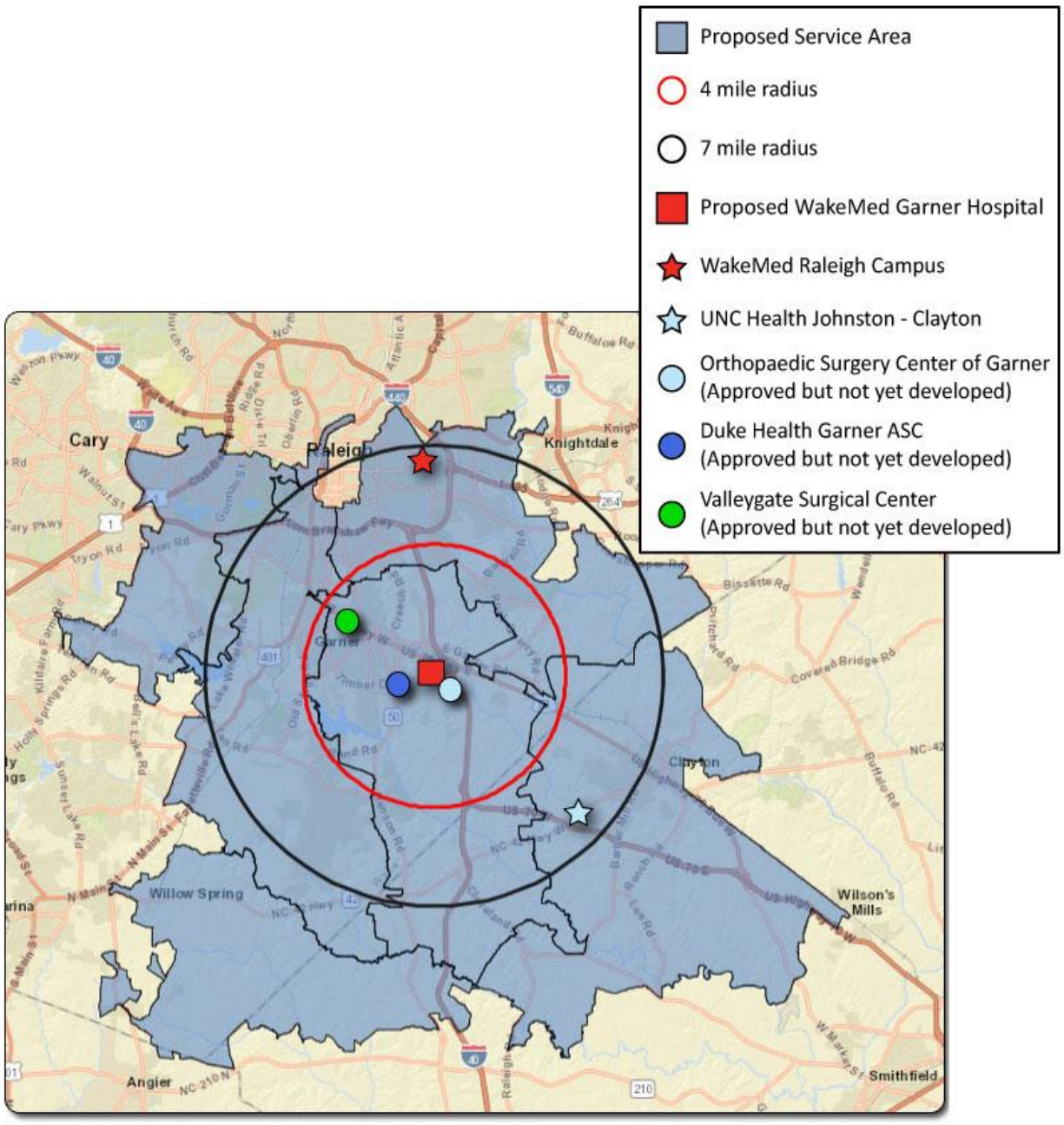
WakeMed's application to develop a new hospital by relocating 22 beds, adding 9 beds, and adding two ORs should not be approved. WakeMed's application contains numerous errors, overstatements, and inconsistencies as well as insufficient responses to the Certificate of Need application form. The information in the application as submitted is insufficient to make a determination of conformity with the statutory review criteria and specific regulatory criteria and standards. Rex has grouped the errors, overstatements, inconsistencies, and insufficiencies by issue, each of which contributes to WakeMed's non-conformity:

(1) Failure to demonstrate need for the project
(2) Failure to demonstrate the reasonableness of projected utilization
(3) Failure to demonstrate that the least costly or most effective alternative has been proposed
(4) Failure to demonstrate financial feasibility
(5) Failure to demonstrate that its proposal will not result in the unnecessary duplication of services
(6) Failure to demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative

Each of the issues listed above is discussed in turn. Please note that relative to each issue, Rex has identified the statutory review criteria and specific regulatory criteria and standards creating the non-conformity.

1. <u>The WakeMed Garner Hospital application fails to demonstrate need or support for the project.</u>

   Throughout the WakeMed Garner Hospital application, WakeMed discusses the lack of acute care beds and ORs for the volume of patients currently treated at the WakeMed freestanding emergency department on its WakeMed Garner Healthplex campus. On page 130, WakeMed discusses how its application is in response to the need determination in the *2022 SMFP* and how WakeMed has the largest need for ORs in both the *2022* and *Proposed 2023 SMFP*s and the largest need for acute care beds in the *2022 SMFP*. However, WakeMed fails to acknowledge that the deficits are specific to the WakeMed Raleigh campus, which according to the *2022 SMFP* has a deficit of four acute care beds and four ORs. Deficits at one facility do not translate to a need for developing an entirely new hospital campus in another part of the county, particularly when ORs and acute care bed capacity either exists or is under development. WakeMed makes no mention of the additional OR capacity being developed at Valleygate Surgery Center, Orthopaedic Surgery Center of Garner and Duke Health Garner ASC, all of which fall within a 4-mile radius of the proposed site. WakeMed does acknowledge the existence of UNC Health Johnston-Clayton with two ORs; however, it fails to mention that according to the *2022 SMFP,* UNC Health Johnston-Clayton, has available acute care bed and operating room capacity and falls within a 7-mile radius of the proposed WakeMed Garner site. See the map below for details regarding the location of existing and CON approved ORs under development.



Source: Esri

As shown in the map above, not only are there two hospitals within a seven-mile radius of the proposed site, there are multiple ASFs currently under development.

Furthermore, WakeMed fails to provide any provider support for the relocation of 22 beds from the WakeMed Raleigh campus or for any new components of the proposed WakeMed Garner Hospital. While the application does include a single support letter from the Mayor of Garner voicing his support for the project, there is no documentation in the application of any physician or medical community support for the acute care beds, surgical services, or the hospital.

Obviously, a hospital without physician support is not feasible. WakeMed's methodology for beds and operating rooms relies on shifting volume that would otherwise be performed at its other facilities to Garner, including surgical volume. Such a shift requires admission by physicians with privileges at the proposed facility, and as such, it requires a tremendous commitment from medical staff members willing to obtain privileges at a new facility and take on the associated responsibilities, such as emergency call coverage and performing surgical cases at another location. By failing to provide a single letter from any physician documenting a commitment to admit patients or perform surgery at the proposed facility, or even in support of the project, WakeMed has failed to demonstrate that the project is needed or that it can reasonably achieve the utilization by shifting cases admitted by its physicians to other facilities, particularly when—physicians have indicated no support for the proposed project or any intention to shift their patients.

As such, the WakeMed Garner Hospital application is **non-conforming with Criteria 1, 3, 4, 5, 6, and 18a, and the performance standards for Acute Care Beds (10A NCAC 14C .3803) and Operating Rooms (10A NCAC 14C .2103).**

2. <u>The WakeMed Garner Hospital application fails to demonstrate the reasonableness of its projected operating room utilization.</u>

In Section Q, pages 188 and 198 and as shown in the excerpts below, WakeMed provides the methodology for inpatient admission shifts and OR case shifts.

> **e. Projected Shift of Inpatient Admissions to WakeMed Garner Hospital**
>
> WakeMed expects that a percentage of its non-tertiary inpatients originating in the proposed service area will shift to WakeMed Garner Hospital, based on proximity of the new hospital to the service area population. This shift was estimated based on the drive-time comparison for each ZIP Code and drive-time contours from the proposed site as presented in Section C. A higher percentage of patients located in ZIP Codes closer to Garner Hospital will shift to the new hospital. The projected shifts of non-tertiary patients by ZIP Code are shown in **Table Q-1e**. The percentage shift is applied to the FY2027-FY2029 patient volume for each ZIP Code and hospital shown in **Table Q-1d** above. For example, WakeMed Raleigh projected ZIP Code 27529 for FY 2027 without WakeMed Garner is 1,200 patients x 45% shift = a shift of 540 patients.

> **f. Projected Shift of Outpatient Surgery Cases in the Proposed Service Area to WakeMed Garner Hospital**
>
> WakeMed expects that, based on proximity, a percentage of outpatient surgery cases from the proposed service area will shift from existing facilities to WakeMed Garner Hospital. This shift was estimated based on the drive-time comparison for each ZIP code and drive-time contours from the proposed site as presented in Section C. For example, patients in a ZIP code closer to Garner than to the other WakeMed facilities/campuses will shift at a higher rate. The projected shifts of outpatient surgery cases by facility by ZIP code are provided in **Table Q-4f**.

Despite virtually identical assumptions for the two service components, as illustrated in the table below, the shift percentages do not match and in some instances differ by as much as 50 percent.

Therefore, the service component shifts are unsupported and thereby result in utilization projection errors discussed below.

ZIP Code	***Acute Care Bed Shift Percentage***			***OR Shift Percentage***		
	FY 27	***FY 28***	***FY 29***	***FY 27***	***FY 28***	***FY 29***
27529 (Garner)	45.0%	50.0%	55.0%	55.0%	65.0%	70.0%
27603 (Raleigh)	45.0%	50.0%	55.0%	65.0%	75.0%	80.0%
27520 (Clayton)	45.0%	50.0%	55.0%	65.0%	75.0%	80.0%
27592 (Willow Spring)	45.0%	50.0%	55.0%	65.0%	75.0%	80.0%
27606 (Raleigh)	15.0%	20.0%	25.0%	25.0%	30.0%	35.0%
27610 (Raleigh)	5.0%	7.5%	10.0%	5.0%	7.5%	10.0%

WakeMed fails to demonstrate that either of its shift percentages are reasonable, based on the basis provided for the percentages given that the rationale is the same (proximity and drive times), but the percentages are significantly different. The unreasonableness of these differences is also highlighted by the absence of physician support for the project, which demonstrates the complete lack of basis in WakeMed's assumed shift percentages. In particular, without support from surgeons that will perform cases at the new hospital, WakeMed has provided no basis for its assumed *higher* shift in operating room case volume, which is necessarily dependent on the provider performing the case.

Moreover, as shown in the excerpts below, WakeMed presents total system OR utilization in two places in the application with dramatically different projections for total system OR cases.

OR utilization presented on page 104:

Figure 32

Projected WakeMed Health & Hospitals OR Utilization and Need

WakeMed Health and Hospitals - Projected OR Cases

	FY 2027	FY 2028	FY 2029
Hospital-Based ORs			
WakeMed Raleigh Campus*			
Inpatient	7,609	7,641	7,671
Outpatient	10,770	10,712	10,713
WakeMed North Campus*			
Inpatient	625	630	635
Outpatient	2,776	2,794	2,808
WakeMed Garner Hospital*			
Inpatient	377	447	519
Outpatient	1,477	1,747	1,980
WakeMed License (Raleigh Campus + North Campus + Garner Campus)			
Inpatient	8,611	8,718	8,825
Outpatient	15,023	15,253	15,502
WakeMed Cary Hospital			
Inpatient	2,601	2,557	2,521
Outpatient	6,130	6,151	6,151
Ambulatory Surgery ORs			
Capital City Surgery Center	9,530	9,626	9,723
WakeMed Surgery Center - North Raleigh	1,839	1,858	1,877
WakeMed Surgery Center - Cary	1,594	1,562	1,578
Total WakeMed OR Cases	45,327	45,725	46,176

OR utilization presented on page 205:

Table Q-5e

Projected Total WakeMed System OR Utilization – Including WakeMed Garner

	Status Quo w/o Garner			Projected Years w/ Garner			Shifts to Garner		
	FY 2027	FY 2028	FY 2029	FY 2027	FY 2028	FY 2029	FY 2027	FY 2028	FY 2029
Hospital-Based ORs									
WakeMed Raleigh Campus	**20,299**	**20,670**	**21,048**	**19,188**	**19,335**	**19,546**	**(1,111)**	**(1,335)**	**(1,502)**
Inpatient	7,881	7,960	8,040	7,609	7,641	7,671	(271)	(320)	(370)
Outpatient	12,419	12,710	13,007	11,579	11,695	11,875	(840)	(1,015)	(1,132)
WakeMed North Campus	**3,729**	**3,808**	**3,889**	**3,655**	**3,722**	**3,787**	**(74)**	**(86)**	**(102)**
Inpatient	629	636	642	625	630	635	(5)	(6)	(7)
Outpatient	3,100	3,172	3,247	3,030	3,092	3,152	(70)	(80)	(95)
WakeMed Garner Hospital				**1,854**	**2,194**	**2,499**			
Inpatient				377	447	519			
Outpatient				1,477	1,747	1,980			
WakeMed Raleigh License - All Campuses	**24,028**	**24,478**	**24,936**	**24,697**	**25,251**	**25,832**	**(1,186)**	**(1,420)**	**(1,604)**
Inpatient	8,510	8,596	8,682	8,611	8,718	8,825	(276)	(325)	(377)
Outpatient	15,518	15,882	16,254	16,086	16,533	17,007	(910)	(1,095)	(1,227)
WakeMed Cary Hospital	**9,850**	**10,041**	**10,237**	**9,187**	**9,262**	**9,326**	**(663)**	**(779)**	**(911)**
Inpatient	2,918	2,947	2,977	2,601	2,557	2,521	(317)	(390)	(455)
Outpatient	6,932	7,094	7,261	6,586	6,705	6,805	(346)	(390)	(456)
Total Hospital-Based OR Cases	**33,878**	**34,519**	**35,174**	**33,883**	**34,513**	**35,158**			
Ambulatory Surgery ORs									
Capital City Surgery Center	10,196	10,435	10,679	10,196	10,435	10,679			
WakeMed Surgery Center - North Raleigh	1,839	1,858	1,877	1,839	1,858	1,877			
WakeMed Surgery Center - Cary	1,547	1,562	1,578	1,594	1,562	1,578			
Total Ambulatory Surgery Center OR Cases	**13,582**	**13,855**	**14,134**	**13,629**	**13,855**	**14,134**			
Total WakeMed OR Cases	**47,460**	**48,374**	**49,307**	**47,513**	**48,368**	**49,292**			

The two tables shown above provide inconsistent projections for total system OR cases; thus, the basis for the need for WakeMed's proposed two additional operating rooms is unclear. In particular, on page 205, WakeMed states that the system as a whole is projected to have a deficit of 12.76 ORs in FY2029, which does not comport with the numbers found in the table on page 105. Given these unexplained inconsistencies, both of which cannot be correct, WakeMed has failed to demonstrate that its conflicting utilization projections are reasonable.

Most importantly, in calculating OR hours, WakeMed uses the incorrect methodology. 10A NCAC 14.C .2103, which is included on page 103 of the WakeMed application, states the following:

> "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."
>
> (Emphasis added)

Step 4a of the *2022 SMFP* then provides the following instruction:

> "…for Groups 2 through 6, use the Adjusted Case Time from Step 2 to calculate the average (mean) inpatient and ambulatory case times for each group."

WakeMed fails to follow these required and critical steps in its methodology, and for both WakeMed Raleigh and WakeMed Cary, the application uses surgical hours in excess of case times in the *2022 SMFP*. Furthermore, WakeMed utilizes different surgical hours for WakeMed Raleigh Campus, WakeMed North Campus, and WakeMed Garner Hospital despite all three being on the same license. The WakeMed License surgical hours were calculated in Figure 32 on pages 104-105 of the application and are shown below.

Project Year 3	***WakeMed Raleigh Campus***	***WakeMed North Campus***	***WakeMed Garner Campus***	***WakeMed License***
IP Cases	7,671	635	519	8,825
OP Cases	10,713	2,808	1,980	15,502
IP Hours	24,147	1,619	1,146	26,911
OP Hours	25,043	5,971	3,200	34,214
IP Case Time	188.87	152.96	132.44	**182.97**
OP Case Time	140.26	127.58	96.96	**132.43**

As shown above, the average IP case time was 182.97 minutes, and the average outpatient case time was 132.43 minutes. According to the *2022 SMFP* Table 6B, the final inpatient case time was 182.6 minutes, and the final ambulatory case time was 124.9 minutes for WakeMed.

Project Year 3	*WakeMed License As Calculated*	*Adjusted for 2022 SMFP Case Times*	*Difference*
IP Cases	8,825	8,825	
OP Cases	15,502	15,502	
IP Case Time	182.97	182.6	
OP Case Time	132.43	124.9	
IP Hours	26,911	26,857	(54)
OP Hours	34,214	32,268	(1,945)

By overstating WakeMed License blended case times, WakeMed overstates OR hours by 1,999 hours. This overstatement is greater than one OR for the license.

Similarly, WakeMed uses incorrect case times for WakeMed Cary Hospital. According to Figure 32, IP case times are 150 minutes and OP case times are 107 minutes. According to the *2022 SMFP* Table 6B, the final inpatient case time was 124.0 minutes and the final ambulatory case time was 61.2 minutes for WakeMed Cary Hospital. The impact of using incorrect case times is shown below.

Project Year 3	*WakeMed Cary As Calculated*	*Adjusted for 2022 SMFP Case Times*	*Difference*
IP Cases	2,521	2,521	
OP Cases	6,151	6,151	
IP Case Time	150.0	124.0	
OP Case Time	107.0	61.2	
IP Hours	6,303	5,210	(1,092)
OP Hours	10,969	6,274	(4,695)

The WakeMed Cary Hospital surgical hours are overstated by 5,787 hours by not following Step 4a of the *2022 SMFP* need methodology. With standard hours of 1,500 per OR, this overstatement equates to 3.86 ORs in project year 3. WakeMed Cary Hospital when correctly calculated has a **surplus** of 2.34 ORs instead of the presented deficit of 1.51 ORs as incorrectly calculated in the application.

In conclusion, WakeMed does not follow the need methodology as outlined in the performance standards, overstates its projected number of surgical hours, and therefore fails to meet the **performance standards for Operating Rooms (10A NCAC 14C .2103).**

Based on the numerous points made above WakeMed's projected OR utilization is unsupported and unreasonable. As such, the WakeMed Garner Hospital application is **non-conforming with Criteria 1, 3, 4, 5, 6, and 18a, and the performance standards for Operating Rooms (10A NCAC 14C .2103).**

3. WakeMed fails to demonstrate the reasonableness of its acute care bed and other utilization projections.

First, as noted above, WakeMed provides similar assumptions for its projected volume shifts for acute care beds and surgical cases. However, WakeMed does not explain why it is reasonable for these percentages to be similar, and for the same ZIP codes it projects different percentage shifts for each service. As such, its projected shift percentages are unsupported and not reasonable.

Next, WakeMed's projected acute care days are based on unsupported assumptions. Specifically, Step 1.f of its acute care bed methodology assumes an average length of stay of 3.00 days. WakeMed states that this assumption is conservative compared to its other community hospitals and other approved acute care hospitals in the state. However, the basis of WakeMed's methodology is the patient population it has historically served from the service area, using internal data pulled for the appropriate DRGs it intends to serve. Given the availability of these specific patient data, the reasonable and adequately supported approach would have been to use the data for these actual patients. Moreover, WakeMed's reliance on the methodology of other recently approved hospitals is misplaced, given that the services proposed, the service areas, and the sizes of the other recently approved hospitals were considerably different than what WakeMed proposes for the Garner hospital. For example, in its Durham County hospital application (UNC Hospitals-RTP), UNC Health proposed obstetrics, whereas WakeMed does not; Duke Green Level also included obstetrics patients. The number of ICU beds and patients also differs considerably across the applications. Further, Duke Green Level and UNC Hospitals-RTP calculated actual lengths of stay from the analyzed patient data, which WakeMed could have also done.

WakeMed also provides conflicting assumptions regarding its ED utilization. On page 213, WakeMed states that it assumes that ED volume will grow by the population growth rate of 2.97 percent. Contrary to this assumption, WakeMed grows ED volume in FY2026 (40,639) by 10%, resulting in overstated ED projections in Table Q.9b for FY2027 (44,703). The subsequent years, FY2028 and FY2029, are also thereby inflated, resulting in significantly overstated ED volumes in all three project years.

Finally, WakeMed fails to demonstrate that it can serve the projected observation patients. Specifically, Step 10 on page 214 projects 18.7 patients per day to be served in only 14 observation beds. While the application states that observation patients stay a full day, it is Rex's experience (as well as DUHS', according to its application), that some stay longer than a day. Further, WakeMed admits that its projected utilization does not include same day surgery patients who may also use these beds, in which case they would be unavailable for other observation patients. Without sufficient capacity for these patients, they will have to be transferred to other facilities, and their inclusion in WakeMed's utilization and financial projections inappropriately inflate the projected net income.

Given these issues, the WakeMed Garner Hospital application is **non-conforming with Criteria 1, 3, 4, 5, 6, and 18a, and the performance standards for Acute Care Beds (10A NCAC 14C .3803).**

4. The WakeMed Garner Hospital application fails to demonstrate that the needs of the population will be met adequately by the reduction of acute care beds at the WakeMed Raleigh Campus.

   As detailed in the WakeMed Garner Hospital application, the proposed project involves the relocation of 22 beds from WakeMed Raleigh to the proposed WakeMed Garner Hospital; therefore, Criterion 3a applies. In Section D.2b, WakeMed discusses how the proposed relocated beds can be better utilized by converting semi-private rooms to private rooms and delicensing three post-partum beds for use as med/surg beds at the WakeMed Garner Hospital. The discussion completely ignores how the needs of the current population being served in Raleigh will be adequately met when there is already an existing deficit of acute care beds at the WakeMed Raleigh campus. Additionally, there is no acknowledgement of the 41-bed deficit of acute care beds at the WakeMed Raleigh campus in the *Proposed 2023 SMFP.* Regardless of how the beds will be utilized at another location, reducing the acute care bed at the WakeMed Raleigh campus only serves to increase the deficit of 41 acute care beds.

   Further, as WakeMed acknowledges in its application, the proposed WakeMed Garner hospital will not provide the same services as those provided at WakeMed Raleigh; thus, the application fails to demonstrate that patients currently being served in the beds to be relocated will be adequately served following the development of the proposed project. This issue is highlighted by the data presented in the application. On pages 81 and 82, WakeMed shows that the vast majority of patients admitted to a WakeMed facility from the service area are served at WakeMed Raleigh, which provides numerous services that the proposed facility will not, including trauma, obstetrics, pediatrics, and tertiary services.

   In Section D.2b.3., regarding the effect of the relocation on underserved groups, the applicant opines that relocation of the beds will offer enhanced access to comprehensive inpatient and outpatient healthcare services not provided in Garner. While it may be true that the town of Garner lacks acute care beds, it is not true that they lack access to acute care beds given that both WakeMed Raleigh and UNC Health Johnston-Clayton campuses are located within a seven-mile radius of the proposed site. Additionally, it must be noted that the WakeMed Raleigh campus where beds are being relocated from is centrally located and therefore has more public transportation and support services available to enhance access. Reducing the number of acute care beds at WakeMed Raleigh could reduce access to care due to the lack of public transportation and other services in and around the proposed site.

   Based on the discussion above, it is clear that WakeMed fails to demonstrate how the needs of the population presently served will be met adequately by the proposed relocation in accordance with Criterion 3a. As such, the WakeMed application is non-conforming with Criteria 1, 3, and 3a.

5. The WakeMed Garner Hospital application fails to demonstrate that the cost, design and means of construction proposed represent the most reasonable alternative.

   WakeMed fails to answer the application questions related to the zoning of the proposed site. In response to Section K.4.c regarding zoning, WakeMed states only that the seller's representative does not have concerns with receiving the required zoning changes. That response, however, does not answer the application questions, which include describing the current zoning, explaining

whether rezoning is required, and how the applicant intends to pursue that. None of those questions were answered by WakeMed. Further, despite WakeMed's statements, the LOI in Exhibit K.4 does not support its claim about the development company's position on zoning.

Given these issues, WakeMed fails to demonstrate that the cost, design and means of construction proposed represent the most reasonable alternative. As such, the WakeMed application is non-conforming with Criterion12.

6. The financial information and statements in the application contain multiple errors, omissions and inconsistencies.

Section F.4b. of the CON application form instructs the applicant to complete Form F.3b Projected Operating Costs, and hospitals are instructed to complete the form for each hospital service included in the proposal. While WakeMed provides Forms F.2b (Projected Revenues and Net Income) for Inpatient Services, Outpatient Surgical Services, Emergency Department, Outpatient Observations, and Outpatient GI Endoscopy, it fails to provide projected operating costs for any of the service components and only provides Form F.3b for the entire facility. The WakeMed application should be found non-conforming because it fails to provide the information requested by the Agency to allow a complete review of the application.

The expenses that WakeMed does include are significantly understated, specifically Salary Expense as shown on Form H. As shown in the excerpt below a significant number of total salaries shown in columns G, J and M are not accurate based on the numbers for FTEs and average annual salary shown in the previous columns. For example, the position of "Mgr Nursing Unit" in the 1st Full FY shows an FTE value of 4.94 and an average annual salary of $211,597 which results in a total salary of $1,045,289. WakeMed lists the total salary in column G as $532,129, which is an understatement of $513,160 in expenses for just one position. Numerous similar errors exist in Form H, including for "Patient Educator RN," "Clinical Nurses," "Nurse Aide/Clin Secretary," and many others, resulting in millions of dollars of understated staffing expenses.

Another example of understated expenses is the calculation of interest expense. In Section Q, page 226, Form F.3.b and Form H Assumptions, WakeMed states it assumes a 4.5 percent interest rate for the $214 million bond it will use to finance the project. As shown in the table below, WakeMed's calculation of interest expense shown in Form F.3b is understated by over $1.6 million dollars. This results in understated expenses and overstated net income.

	WakeMed*	***Calculated****	***Difference***
FY2027	$9,085,190	$9,491,816	$406,626
FY2028	$8,630,930	$9,181,510	$550,580
FY2029	$8,176,671	$8,856,948	$680,277
Total			**$1,637,483**

*From Form F.3b

**Calculated using 4.5%

Since the only source of capital for the proposed project is bonds, upon which WakeMed will have to pay interest, the interest cost on these bonds is clearly understated.

Additionally, WakeMed appears to have overstated the outpatient observation charges on Forms F.2b, as shown in the table below.

	Inpatient Services Revenue	*Outpatient Observation Revenue*
Gross Revenue	$127,319,697	$125,883,361
Patient Days (Forms C.1b, C.4b)	8,637	6,827
Revenue/Pt. Day	$14,741	$18,439

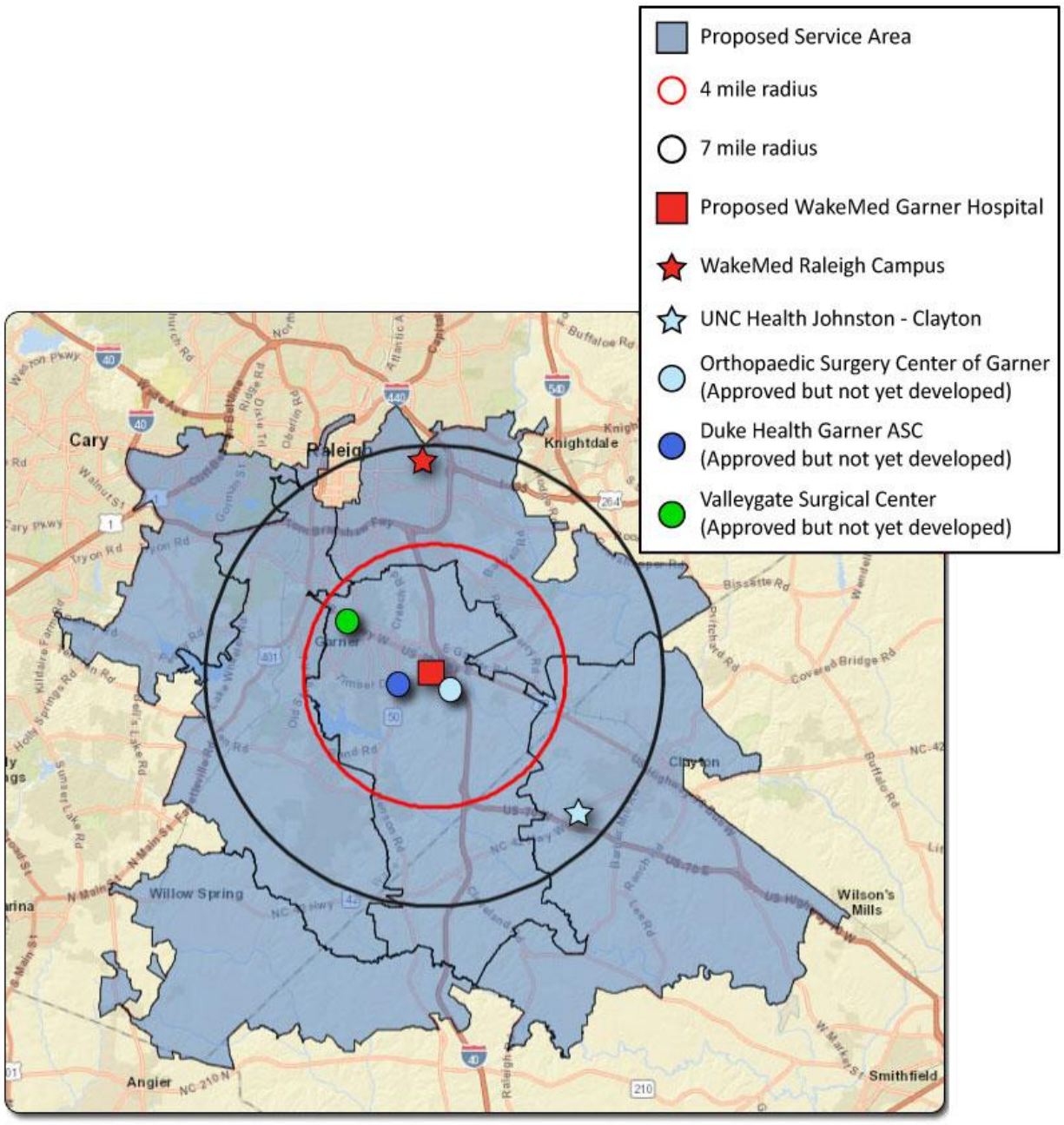
As shown, the projected revenue per patient day is substantially higher for observation patients, and, indeed the total revenue is nearly equal despite the much lower volume for observation patients, which does not appear to be reasonable, given the general lower acuity and shorter lengths of stay for observation patients.

Based on the numerous issues discussed above, it is clear that the WakeMed Garner Hospital application has failed to demonstrate financial feasibility and that the projections of costs and charges are reasonable. As such, the application should be found non-conforming with Criterion 5.

7. The WakeMed Garner Hospital application fails to demonstrate that its proposal will not result in the unnecessary duplication of services.

As noted previously, the proposed service area for the WakeMed Garner Hospital has an abundance of accessible and existing/approved ORs and acute care beds. On page 130, WakeMed discusses how its application is in response to the need determination in the *2022 SMFP* and how the WakeMed has the largest need for ORs in both the *2022* and *Proposed 2023 SMFP*s and the largest need for acute care beds in the *2022 SMFP*. However, WakeMed fails to acknowledge that the deficits are specific to the WakeMed Raleigh campus, which according to the *2022 SMFP* has a deficit of four acute care beds and four ORs. Deficits at one facility do not translate to a need for developing an entirely new hospital campus in another part of the county, particularly when ORs and acute care bed capacity either exists or is under development. The methodology encourages hospitals with multiple sites of care to be efficient and allocate their resources across these sites in a way that best serves patients. To ignore the deficit at main campus and allow expansion elsewhere would encourage WakeMed's inefficiency and would not meet the need identified in the SMFP.

WakeMed makes no mention of the additional OR capacity being developed at Valleygate Surgery Center, Orthopaedic Surgery Center of Garner or Duke Health Garner ASC, all of which fall within a 4-mile radius of the proposed site. While WakeMed does acknowledge that UNC Health Johnston operates two ORs, it fails to mention that according to the *2022 SMFP,* a 1.65 OR surplus and 33 acute care bed surplus exists at Johnston Health, which falls within a 7-mile radius of the proposed WakeMed Garner site. See the map below for details regarding the location of existing and CON approved ORs under development.



Source: Esri

Given the close proximity of existing OR and acute care bed resources in addition to those under development, WakeMed's proposal would serve to duplicate services and is counter to the basic tenets of the CON law which states that government regulation is necessary *"…to control costs, utilization, and distribution of new health service facilities and the bed complements of these health service facilities*."

In summary, WakeMed has failed to demonstrate that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and that the project is needed, and the WakeMed Garner Hospital 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 .2100 and at 10A NCAC 14C .3800. The WakeMed Garner Hospital application should not be approved.

ISSUE-SPECIFIC COMMENTS ON DUKE RALEIGH HOSPITAL

1. The Duke Raleigh Hospital application to add 45 acute care beds should not be approved, as it is incomplete and fails to include all information necessary for the Agency to conduct the review pursuant to N.C. GEN. STAT. § 131E-182(b).

   Specifically, DUHS fails to provide all requested information required in response to the CON application form as it fails to identify all related entities in response to Form O Facilities and the performance standards.

   As defined in 10A NCAC 14C .0202(10) as well as the definition portion of the CON application form (page 14), when used in the application form, the term "related entity" means "a person that:

   (a) Shares the same parent corporation or holding company with the applicant;
   (b) Is a subsidiary of the same parent corporation or holding company as the applicant; or
   (c) **Participates with the applicant in a joint venture that provides the same type of health services proposed in the application**."

   [**emphasis added**]

   Section O.1 of the CON application form requires an applicant to "[i]*dentify all existing and approved facilities providing the same service components included in this proposal* ***that are owned, operated or managed by the applicant or a related entity*** *in North Carolina by completing* ***Form O Facilities****, which is found in Section Q*." [**emphasis added**]. However, while DUHS identifies James E. Davis Ambulatory Surgical Center, Arringdon ASC, Duke University Hospital, Duke Regional Hospital, Duke Health Green Level ASC, Duke Health Raleigh ASC, Duke Health Garner ASC, Duke Raleigh Hospital, Duke Health Orange ASC, and Same Day Surgery Center in response to Form O Facilities (see page 116 of the Duke Raleigh Hospital application), it fails to identify all the Duke LifePoint entities which offer acute care services. According to the Duke LifePoint website[4] and as shown in Attachment B, Duke LifePoint Healthcare is a joint venture of DUHS and LifePoint Health and includes several acute care facilities in North Carolina. As such, the DUHS application fails to identify all related entities in response to Form O Facilities. Further, other questions in Section O of the CON application form – specifically, Questions 4 and 5 – require an applicant to provide information regarding the facilities identified in Form O Facilities. As DUHS' response to Form O Facilities is incomplete, likewise, its responses to Section O.4 and O.5 are incomplete. Further, all of DUHS' related entities should be considered in the Agency's quality review under Criterion 20, not just the partial list included in Duke's application.

2. The Duke Raleigh Hospital acute care bed application fails to demonstrate that the needs of the population will be met adequately by the proposed elimination of services (observation beds) and that the cost, design, and means of construction proposed represent the most reasonable alternative.

[4] Accessed at http://www.dukelifepointhealthcare.com/about_us.aspx

Duke Raleigh Hospital proposes to develop 45 additional medical/surgical acute care beds by converting existing observation beds in the "new South Pavilion and/or the North Pavilion at DRAH." While this on the surface appears to be a quick and fast remedy to the acute care bed deficit in Wake County, DUHS fails to demonstrate that it needs to convert the number of observation beds to acute care beds as proposed. In particular, on page 103, the application projects an observation ADC of 33 patients in Year 3 (12,018 ÷ 365 = 33), with only 25 remaining observation beds. Clearly, this number of patients cannot be accommodated in the observation beds that will remain after development of the proposed project.

In Section D, DUHS states that observation patients can be accommodated in licensed acute care beds; however, the more reasonable solution would be to develop fewer additional acute care beds. For example, if DUHS developed 10 fewer acute care beds, or 35, its projected occupancy rate in Year 3 would still be lower than it is currently (75.3% versus 80.0%), and its projected observation patients could be accommodated, albeit at a high occupancy rate. While it may be true that observation patients can be placed in licensed acute care beds, since DUHS' proposed project must demonstrate both need for the acute care beds and that its patients served by the service to be reduced (observation beds) will have adequate access to services, the most reasonable approach for the proposed project is to convert fewer observation beds to licensed acute care beds.

Given these issues, DUHS fails to demonstrate conformity with Criteria 1, 3, 3a, 4, 5, 6, 12 and 18a.

3. <u>The Duke Raleigh Hospital application fails to adequately demonstrate that the financial and operational projections are based on reasonable assumptions and therefore fails to demonstrate the immediate and long-term financial feasibility of its proposal.</u>

DUHS fails to accurately account for expenses associated with salaries as shown in Form H on page 115 of the application. On page 72, DUHS states that there will be salary adjustments totaling 4 percent in FY2023, yet Form H only includes a 3.5% adjustment for wages. Additionally, Form H is inconsistent with what is stated on page 72 regarding DUHS' minimum wage of $17.00 per hour effective July 1, 2022. This minimum wage calculates to a minimum annual salary of $35,360 per year; yet, on Form H DUHS provides a salary for approximately one-quarter of its staff (Certified Nurse Aides/Nursing Assistant) that is nearly 10 percent lower than this amount. The understatement of salaries creates an inaccurate basis upon which to evaluate operational costs and the inability to demonstrate financial feasibility.

Further, DUHS' projected total staffing expense is unreasonable and unsupported. On page 114, Salaries in Year 3 are projected to exceed $81 million, while on Form H, they are projected to be $34 million. DUHS acknowledges this difference on page 118 of its assumptions; however, the explanation is wrong. First, DUHS states that the two numbers do not tie because the cost on Form F.3 includes both salary and fringe expenses; however, this is not correct, because taxes and fringe benefits are shown on a separate line below the salary line. DUHS' second explanation is that the salary costs on Form F.3 include salaries for staff providing other services to acute care patients beyond those listed on Form H. While that statement may be factual, it does not explain why it is reasonable for the two forms to be inconsistent, given that they are stated to be for the same service (acute care beds), and since Form F.3 specifically states that salary expenses should come from Form H Staffing. Without the staffing detail provided on Form H, the Agency cannot

determine whether the projected staffing expense is reasonable for the proposed service, and given the understated costs for those positions that are provided, as noted above, the projected costs cannot be determined to be reasonable.

Additionally, DUHS fails to provide reasonable assumptions for its projected change in payor mix. The application states that there was an adjustment for the facility-wide payor mix between insurance (lower) and Medicare (higher); however, that adjustment appears for the acute care bed component, while the facility payor mix is different across most payors, without explanation. Thus, the payor mix for acute care beds is not consistent with the 2022 acute care payor mix, as the application states, and for the facility wide payor mix, several unexplained and unsupported adjustments are made.

Based on the discussion above, it is clear that the Duke Raleigh Hospital bed application is non-conforming with Criteria 5, 7, and 13(c).

In summary, DUHS has failed to demonstrate that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and the Duke Raleigh Hospital application should be found non-conforming with Criteria 1, 3, 3a, 5, 6, 7, 12, 13 (c)and 18(a). The Duke Raleigh Hospital application should not be approved.

ISSUE-SPECIFIC COMMENTS ON OAKVIEW ASC

1. The application fails to reasonably identify the patient population to be served.

   On pages 42 and 43, the applicant provides projected patient origin, stating that it expects it to reflect the patient origin for Dr. Michael Kelly's surgical patients in CY 2021 limited to patients who receive care at Blue Ridge Surgery Center, UNC REX Wakefield, and Maria Parham Medical Center, the facilities from which Dr. Kelly is expected to shift cases. However, while the methodology does assume that many of the cases at the ASF will shift from three geographically different sites, it is not reasonable to assume that an ASF located at 3700 Barrett Drive in Raleigh will serve the identical patient population as those served at Maria Parham Medical Center located 44.7 miles north in Henderson, NC or even UNC REX Wakefield in northern Wake County, and assuming that the patient origin for the proposed ASF will be the same as Dr. Kelly's experience at these other facilities is inconsistent with the basis of its utilization projections . Specifically, the application provides as one of its supporting factors for the utilization projections the "enhanced geographic access" and "convenient location" of the ASF (pages 73 to 76). However, for patients that would be closer to Maria Parham Medical Center or UNC REX Wakefield, such as residents of Vance County, Franklin County or northern Wake County, the proposed location will not reduce their travel burden, and in fact, those patients would travel farther to access the proposed facility than they would the existing ASF at UNC REX Wakefield; thus, the application fails to demonstrate that the proposed project would attract these patients and have the same patient origin based on "geographic access" or a "convenient location."

   While the application states that patients have the right to be treated where they wish, the application fails to provide a single letter from a patient living in Vance or Warren counties, for example, that indicate they would travel to Wake County for the proposed service. Moreover, the application states that it expects that many other physicians in addition to Dr. Kelly will use the proposed facility and to that end, the application names 12 other eye surgeons, including 10 from Raleigh Eye Center and a 13th unnamed surgeon as well. There are no data provided to suggest that these surgeons' patient origin is or will be identical to Dr. Kelly's. To the contrary, the discussion on page 153 of the methodology refers to patients treated by the other surgeons at facilities in Wake County, which would certainly have patient origins that differ from Dr. Kelly's. The methodology on page 155 shows that cases from physicians other than Dr. Kelly comprise more than 60 percent of the projected volume (3,011 of the projected 4,990 cases), yet the application fails to provide a reasonable basis for projecting patient origin for the majority of its cases. Since it is unlikely that patients (especially those outside of Wake County) would bypass other ASFs including ones at which Dr. Kelly and other eye surgeons already have privileges to access care at the proposed facility, the application's utilization projections based on this patient population are similarly unreasonable**. For these reasons, the application should be found non-conforming with Criterion 3 and the performance standards at 10A NCAC 14C .2103**.

2. The Oakview ASC application's need arguments are not based on reasonable and adequately supported assumptions.

   Oakview ASC proposes to develop a newly licensed single-specialty ASF with one operating room and one procedure room for the performance of ophthalmic surgical procedures as well as an additional room to house laser equipment. In support of need, the applicant states on pages 39 and 54 of the application that Oakview will be Wake County's first single-specialty ophthalmic

ASF. However, this is simply not true. Southern Eye Associates operated an ophthalmic ASF in Wake County for several years; it was considered "chronically underutilized" in the previous operating room methodology in the *SMFP* due to its ongoing low utilization, and eventually the operating rooms were purchased by WakeMed. See Attachment C for the notice of acquisition and the Agency's exempt from review determination.

The application also asserts need is based on scheduling delays that persist despite *SMFP*-reported OR capacity and the need for enhanced geographic access. These two claims are unfounded and unsupported based on information presented elsewhere in the application as well as information found in public sources such as the *SMFP* and Google Maps. Information gathered from the proposed *2023 SMFP* as well as Agency findings show more than adequate outpatient surgical capacity at both Blue Ridge Surgery Center and Duke Raleigh Hospital, both of which are near the proposed location of the Oakview ASC. Duke Raleigh Hospital which is located 1.5 miles away and is a five-minute drive[5] from the proposed location of Oakview ASC received CON approval (Project ID # J-12212-22) in July 2022 to develop a freestanding ASF on the hospital campus, where it proposes to provide ophthalmology surgery. Blue Ridge Surgery Center where Dr. Kelly currently performs 67% of his surgeries is located less than five miles and shorter than a 10-minute drive[6] from the proposed Oakview site; according to the *Proposed 2023 SMFP*, it has a surplus of more than 2.5 ORs. Geographical access will be duplicated rather than enhanced with the proposed location of Oakview ASC being proximate to two existing/approved freestanding ASFs with more than adequate surgical capacity. **Therefore, based on the information presented above the need for a single specialty ophthalmic ASF in the location proposed by Oakview is not adequately supported. As such, the application should be found non-conforming with Criteria 3, 4 and 6.**

3. <u>The Oakview ASC application's utilization projections and assumptions are unreasonable.</u>

In Section Q, Form C.3b, the applicant provides its utilization projections, methodology and assumptions for OR utilization. These projections include inconsistent and unreasonable data and assumptions and are therefore unreliable, as discussed below.

The methodology on pages 152 to 155 applies a 5.1 percent annual growth rate to the total case volume expected to shift to the proposed Oakview ASC from Dr. Kelly, other existing area physicians and a newly recruited ophthalmic surgeon. The applicant explains that the 5.1 percent

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[5] Accessed at: https://www.google.com/maps/dir/Duke+Raleigh+Hospital,+3400+Wake+Forest+Rd,+Raleigh,+NC+27609/3700+Barrett+Dr,+Raleigh,+NC+27609/@35.82492,-78.6306901,16z/data=!3m1!4b1!4m13!4m12!1m5!1m1!1s0x89ac58dde98dfcb1:0x14a133e7ca7d93ca!2m2!1d-78.618179!2d35.8282966!1m5!1m1!1s0x89ac58c08fdec6c5:0xad16a702558e9825!2m2!1d-78.6333573!2d35.8278396

[6] Accessed at: https://www.google.com/maps/dir/Blue+Ridge+Surgery+Center,+2308+Wesvill+Ct,+Raleigh,+NC+27607/3700+Barrett+Dr,+Raleigh,+NC+27609/@35.8259915,-78.6821799,14z/data=!3m1!4b1!4m13!4m12!1m5!1m1!1s0x89acf5d61f4acd51:0xd2d973c917c1d0f4!2m2!1d-78.6952424!2d35.8151558!1m5!1m1!1s0x89ac58c08fdec6c5:0xad16a702558e9825!2m2!1d-78.6333573!2d35.8278396

growth rate is based on the CAGR for the 65+ population in Wake County. The application fails, however, to demonstrate that the future growth in these cases can reasonably be based on the growth of the 65 and older population in Wake County. The applicant projects that more than 30 percent of its patients will come from outside Wake County; these smaller, rural counties have substantially lower population growth rates. Further, this growth rate is unreasonable based on the experience of Dr. Kelly, who will account for a significant portion of the utilization. As shown on page 149, Dr. Kelly's volume growth has been flat or slightly down, even prior to the pandemic, and his 2017 to 2021 CAGR is negative (-2.53 percent). Thus, the projected volume growth is not based on a reasonable assumption.

The utilization projections are also unreasonable based on the assumption that Dr. Kelly will perform a significant and growing number of surgical cases. According to public data, Dr. Kelly is currently 65 years old, and the applicant projects that he will continue to perform an increasing number of surgical cases through at least 2027. The applicant fails to document how Dr. Kelly's volume will continue to be sustained and grow as he approaches retirement.

Additionally, the total projected Oakview ASC volumes are unreasonable based on information presented in the chart at the top of page 48 of the application showing the Wake County ASF ophthalmic cases performed in ORs by FFY. The chart shows a total of 3,762 ASF ophthalmic cases were performed in Wake County in FY 2021 as reported in data retrieved from LRAs. On page 155, the applicant provides total surgical volume projections based on the combined volumes of Dr. Kelly and other physicians expected to practice at Oakview and projects that in project year 1 (2025), the total surgical case volume at Oakview ASC will be 4,519 ophthalmic surgery cases. These projections are unreasonable when compared to the total Wake County ASF ophthalmic case volume from page 48 of the application. Even if one applies the same growth rate assumed by Oakview (5.1 percent) to total 2021 Wake County ASF ophthalmic case volume, the result is 4,590 cases performed in **all Wake County ASFs** in 2025, which is only 71 cases more than the total volume projected at Oakview ASC in the same year. Said another way, Oakview ASC is projecting to perform over 98% of the total Wake County ASF ophthalmic case volume not only in 2025 but also in 2026 and 2027. The table below illustrates the projected volumes at Oakview relative to Wake County ASF ophthalmic cases when the same growth rate of 5.1 percent is applied.

	2025	***2026***	***2027***
Oakview ASC projected case volume*	4,519	4,748	4,990
Wake County ASC ophthalmic cases**	4,590	4,824	5,070
Oakview cases as a % of total Wake County cases	98.5%	98.4%	98.4%

*From Section Q page 155 of Oakview application

**2021 data from chart on page 48 of Oakview application with 5.1% growth rate applied each year

As shown above, Oakview ASC projects to consistently perform over 98% of total Wake County ASF volume in project years 1 to 3 (2025-2027). These volume projections and the calculated market share are simply unreasonable especially given that the applicant reports on page 153 that there are a total of 81 active ophthalmic physicians in Wake County and 91 additional ophthalmic surgeons live in the Triangle area in Durham County; the projected 14 surgeons would comprise only 17 percent (14 ÷ 81 = 0.17) of the ophthalmologists in Wake County, yet the application

unreasonably projects them to perform over 98 percent of the eye surgeries performed in Wake County ASFs.

Yet another factor demonstrating that the OR projections are unreasonable is that Oakview clearly overstates its surgical case volume for the proposed number of hours it will operate. The application states on page 151 that the facility will be open Monday through Thursday except for federal holidays; that equates to approximately 200 days per year (4 x 52 = 208 – 8 federal holidays = 200). The same page states that surgeries will be scheduled for eight hours, from 7:30 to 3:30, which equates to a total of 1,600 operating hours per year (200 x 8 = 1,600). Yet on page 146, Form C.3b, the application projects a total of 1,671.65 surgical hours in Year 3, which is clearly higher than the number of hours available, based on its stated hours of operation. Clearly, the applicant cannot provide a higher amount of surgical volume than it has capacity to provide, and its utilization projections are overstated. Of note, this volume is in addition to the cases projected for the procedure room, which has the same issue regarding lack of capacity, since the volume is assumed to be split evenly between the two rooms.

Furthermore, Dr. Kelly's self-reported surgical case rates upon which the projections are based appear questionable. In Section Q, pages 149-150, the applicant begins projections by providing Dr. Kelly's historical cataract cases from 2017-2021 as shown in the table below.

Dr. Kelly's Historical Cataract Surgical Cases

2017	2018	2019*	2020	2021
2,442	2,239	2,436	1,644	2,204

*Source: Dr. Kelly's Internal Practice Data *Dr. Kelly's practice changed medical record systems in 2019. A complete year of data is not available. The number reported for 2019 is five months of data (August-December), annualized: 1,015 cases divided by 5 and multiplied by 12.*

On page 150, the applicant provides Dr. Kelly's cataract surgical cases by facility in 2021 as shown in the table below.

Dr. Kelly's Cataract Surgical Cases by Facility, 2021

Location	2021 Cases
Blue Ridge Surgery Center	1,474
Maria Parham Medical Center	239
Rex Hospital	100
Rex Wakefield	391
Grand Total	**2,204**

Source: Dr. Kelly's Internal Practice Data

The 2022 LRA data (FY2021) for Blue Ridge Surgery Center combined with Dr. Kelly's self-reported numbers above indicates that out of 25 ophthalmologists credentialed to perform surgeries at Blue Ridge Surgery Center, Dr. Kelly alone performed 61.6 percent (1,474 ÷ 2,391 = 0.616) of all the cataract procedures performed in FY 2021. This percentage is unreasonable considering the number of ophthalmologists on staff at Blue Ridge Surgery Center[7] and the fact that many of these surgeons are with Raleigh Eye Center, which states in its support letter (Exhibit C-5.2) that they

[7] https://blueridgesurgerycenter.com/physicians/ophthalmology/

performed over 1,700 cases in Wake County in 2021. These numbers are an extremely high proportion of the total number of cataract surgeries performed at this facility particularly when the application asserts that Dr. Kelly has difficulties in scheduling at Blue Ridge Surgery Center.

Finally, while the application refers to purported limitations in availability at some facilities, it fails to demonstrate that the supporting surgeons have made any effort to utilize existing or approved ASFs in Wake County. As noted above, DUHS was recently approved to develop a new ASF on its campus in Raleigh, and it proposed to perform eye surgery there. Valleygate Surgery Center was approved to develop a new ASF in Garner, which includes the provision of eye surgery, yet the application provides no evidence of an attempt to reach out to that provider regarding the potential to perform cases there. The application also notes that Rex's Cary ASC performs ophthalmic surgery. In fact, Rex values its relationship with Dr. Kelly and would gladly discuss the option of performing cases at its Cary ASC, particularly given the available capacity there. That facility also provides the opportunity for physician ownership. Rex believes that the lack of adequate consideration of the available capacity at existing and approved ASFs in Wake County is another flaw in the Oakview application, particularly given the analysis performed in the Rex application and by the Agency regarding the utilization rates of ASF ORs compared with hospital ORs, cited previously.

Based on these errors and unreasonable assumptions, the application fails to demonstrate the need for the single-specialty ophthalmic operating room proposed by Oakview ASC. As such, the application should be found non-conforming with Criterion 1, 3, 4, 5, 6, 18A and the performance standards at 10A NCAC 14C .2103.

ISSUE-SPECIFIC COMMENTS ON TRIANGLE VASCULAR CARE

1. The Triangle Vascular Care application provides unreasonable utilization assumptions.

In Section Q, Triangle Vascular Care provides its methodology for projecting operating room and procedure room volume for the proposed project. Triangle Vascular Care's operating room utilization projections are based on erroneous assumptions, as it improperly includes a large number of procedures that do not require an operating room and can be performed in a procedure room. As stated on page 135 of its utilization methodology, fistula creations, ESRD stents, and ESRD thrombectomy cases will be performed in the operating room and all other procedures will be performed in the procedure rooms. However, the applicant notes on page 135 that a fistula creation is the only type of case that currently cannot be done in an office based vascular access center. In other words, only fistula creation requires an operating room. The methodology projects a total of 122 fistula creations being performed in 2026, Triangle Vascular Care's third full year of operation. ESRD stent procedures and ESRD thrombectomy cases are projected to be 559 and 48, respectively, in the third project year, and as noted above, these cases have historically been performed in an office based vascular access center and do not require an operating room. The table below summarizes the difference between the projections of operating room utilization when the ESRD stent and ESRD thrombectomy cases are appropriately removed.

	FY 2024	***FY 2025***	***FY 2026***
Triangle Vascular Care Application			
Total OP Surgery Cases	645	687	729
Surgical Hours*	754	803	851
ORs Needed**	0.57	0.61	0.65
Removal of Stent and Thrombectomy Cases			
Total OP Surgery Cases	120	122	122
Surgical Hours*	140	143	143
ORs Needed**	0.11	0.11	0.11

*Based on 2022 SMFP methodology case time of 70.1 minutes (1.168 hours) and standard hours of 1,312/OR
** Based on 2022 SMFP methodology standard hours of 1,312/OR for Group 6

Triangle Vascular Care is clearly including cases appropriate for a procedure room 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 annual 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* only includes surgical cases performed in operating rooms. Therefore, the basis of Triangle Vascular Care's utilization projections and attempt to demonstrate conformity with this rule are erroneous.

Furthermore, Agency findings from the 2021 Durham/Caswell Acute Care Bed and Durham OR Review show that procedure room volumes and shifts cannot be used to support projected utilization and the need for additional ORs. Specifically, on page 15 of the 2021 Durham/Caswell Acute Care Bed and Durham OR Review, the Agency states the following:

> "However, as the applicant's projected utilization methodology shows, in Step 2 above, the applicant proposes to shift procedure room cases from NCSH to be performed at SSC. **This does not support the need for additional ORs** at SSC. It would in fact support the need to maintain procedure room capacity at SSC, as opposed to converting all four of them to ORs. Furthermore, removing the PR cases being shifted to SSC leaves a total of the following OR cases being projected at SSC, per the applicant's methodology."
> [**emphasis added**]

Since these cases are currently being performed in a physician office setting, the applicant has similarly failed to demonstrate the need to shift the cases to an operating room.

Because of this issue, the Triangle Vascular Care application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18(a), as well as the performance standards at 10A NCAC 14C .2103. The Triangle Vascular Care application should not be approved.

2. The approval of Triangle Vascular Care's ASF would result in an unnecessary duplication of services.

The approval of Triangle Vascular Care's application would result in an unnecessary duplication of services in Wake County. Wake County is home to RAC Surgery Center, a freestanding ASF with one operating room and two procedure rooms that is solely dedicated to providing ASF capacity for the provision of vascular access procedures. RAC Surgery Center (RAC) is just ending its first year of operation and volume at RAC is still ramping up. According to the *Proposed 2023 SMFP*, only 134 cases were performed in the one operating room at RAC in Federal Fiscal Year (FFY) 2021. In addition, RAC has two licensed procedure rooms that, according to RAC's 2022 LRA, were used to perform 482 procedures in FFY 2021. Although these numbers only represent four months of utilization, the annualized numbers of both the operating room and procedure rooms at RAC are far below the project year one projections of 1,329 surgical cases and 4,491 procedure room cases found on page 79 of its application (Project ID # J-11551-18). Additionally, according to the 2022 RAC LRA, the facility is open only two days a week for eight hours each day, which is additional evidence of available vascular access OR capacity in Wake County.

RAC is also owned by the same owner as the proposed facility, as noted in the application, including on Form O (page 152). The application to develop RAC, cited above, included volume for the physicians who intend to use the proposed Triangle Vascular Care ASF. While the application provides projected utilization for RAC (pages 140 and 141), that utilization is far below the utilization projected in its original application. In fact, all of the projected fistula creations at TVC can be performed in the operating room at RAC, and the operating room volume would still

remain lower than what was projected in the RAC application. While the application attempts to explain the need for TVC based on the drive time between RAC and the proposed facility, TVC projects that most of its operating room patients will come from Cumberland County, as well as areas east of Wake County. Thus, the drive time between Cary and Raleigh is irrelevant for these patients, many of whom are closer to the existing RAC location.

Furthermore, as demonstrated on page 137 of its utilization methodology, Triangle Vascular Care assumes that in 2026, its third full year of operation, 76 percent of the total projected surgical cases will be performed in procedure rooms (76 percent = 2,247 procedure room cases / 2,975 total projected cases). Clearly, a significant portion of the cases projected to be performed at Triangle Vascular Care can be done safely and effectively in a procedure room, and there is plenty of excess capacity in RAC's procedure rooms. Even if a vascular access case requires an operating room, RAC Surgery Center has more than sufficient capacity to accommodate, as noted above.

It is important to note that the SHCC recently considered a petition to add one vascular access operating room in Nash County. The Agency recommended denial of the petition and alternatively recommended,

> "Approval of one dedicated ambulatory VA ORs in each of the six HSAs in the state, for a total of six VA ORs. VA ORs proposed pursuant to this need determination **cannot be located in either Mecklenburg or Wake counties** in light of the fact that there is a dedicated VA ASC with one OR in each of these counties."
>
> [**emphasis added**]

The recommendation of the Acute Care Services Committee to approve the Agency's recommendation as shown in Attachment D was approved by the SHCC on Wednesday, September 28, 2022. It is reasonable to surmise that the Agency's recommendation is based on preventing the duplication of vascular operating rooms in Wake and Mecklenburg counties, which is consistent with CON law. Therefore, given the SHCC's recent adoption of the Agency's recommendation to not allow another need determination for a vascular access OR in Wake County, the Agency and the SHCC clearly agree that sufficient vascular access capacity already exists in Wake County, and the Oakview ASC should be denied.

In consideration of the factors discussed above, it is clear that the approval of Triangle Vascular Care would result in an unnecessary duplication of services in Wake County and that its application **is non-conforming with Criteria 1, 3, and 6 and the performance standards at 10A NCAC 14C .2103.** Therefore, the Agency should deny this application.

3. Triangle Vascular Care fails to demonstrate the need patients have for the proposed project.

Triangle Vascular Care fails to mention any reasonable issues that prevent the proposed patient population from being served at other ASFs in Wake County, including RAC Surgery Center, or even hospitals in the county, many of which provide the specialty proposed and some of which have available capacity. In particular, Triangle Vascular Care fails to discuss any issues with the facilities at which the surgeons supporting the project currently practice, nor does the application even mention at which facilities they currently practice.

The vast majority of the patient population proposed to be served at the Triangle Vascular Care facility already has safe and effective access to care in a non-hospital setting. As demonstrated on page 133 of the application, Triangle Vascular Access is already performing over 3,000 cases/procedures annually in its existing vascular access center in Cary. These patients already have access to the office-based setting, which Triangle Vascular Center presumably believes to be safe for these patients. The application fails to demonstrate why these patients need to be treated in an ASF, which would actually increase the cost of care, including expenses and actual charges to the patients, by adding a facility fee and costs for the development of the ASF that do not currently exist. Moreover, the application fails to demonstrate that any attempts were made to join the medical staff of the existing ASFs in the county, as suggested by the Agency in its analysis of the *SMFP* petitions, which would allow any cases that had to be performed in an ASF setting (as opposed to office-based), if any, to be performed there without necessitating the development of the proposed project.

The only cases that apparently cannot currently be provided in the office-based setting are the fistula creations, which total only 122 projected cases in project year 3. This represents less than five percent of the total cases/procedures projected in the ASF[8]. The application fails to demonstrate that there is insufficient capacity in an existing licensed facility in Wake County or elsewhere to accommodate this small number of cases. Specifically, the proposed Triangle Vascular Center location is located less than 15 miles from RAC, which has more than adequate capacity for these cases as noted previously.

Additionally, the application provides no discussion regarding the fate of patients currently receiving these treatments in an office-based setting, but who would be subject to higher costs and charges in the proposed ASF. Subjecting patients to higher costs for the same care is fundamentally contrary to the purposes of the CON law. Given the high percentage of Medicare and dually-eligible Medicaid dialysis patients who this change would likely disproportionally impact, the application fails to show that these patients would not have diminished access following the development of the proposed project.

For these reasons, the application should be found non-conforming with Criteria 3, 4 and 6.

4. Triangle Vascular Care fails to demonstrate that it maximizes healthcare value

In Section N of its application, TVC argues that the project will lower cost for vascular access surgeries as patients who receive these procedures in hospital EDs will have more cost-effective access to vascular access procedures on a timely basis. However, TVC's projected utilization contradicts this statement. According to utilization step 2, 85 percent of the volume that is currently performed in an office setting will shift to an ASF setting. The only incremental volume will result from fistula creations as they cannot be performed in office-based settings.

While TVC contends that an ASF is a lower cost setting, the majority of its volume (almost 90 percent) is being shifted from an office-based location to a licensed ASF. This, in fact, is shifting patients from a low-cost office setting to a *higher* cost ambulatory surgery setting. According to page 76 of its application,

[8] See discussion below regarding the inconsistent utilization projections.

> "*Although office-based vascular access centers have been a practical location for providing such services, these centers are at risk because beginning in 2017, the Centers for Medicare and Medicaid Services (CMS) began effectively reducing Medicare payments of these centers. Medicare is the primary payor for ESRD patient services. Medicare pays less for vascular access services in an office-based center, and with the Medicare payment reductions, which have reduced payment by 39 percent since 2017, the office-based reimbursement is not covering costs*."

As described above, the reimbursement for office-based treatment is lower than an ASF setting. As a result, TVC plans to shift its office-based volume to a higher reimbursing ambulatory surgery facility. ***This shift will increase reimbursement for the same procedures.*** The only procedures this does not apply to are the fistula creations (a small subset of TVA's total volume) that TVA is unable to perform in an office-based setting. Increasing reimbursement by moving office-based procedures to an ASF does not maximize healthcare value; it simply increases consumer healthcare cost. As such, this application should be denied.

5. Triangle Vascular Care's initial operating expenses are understated.

TVC calculates its initial operating expenses (IOE) of $125,057 on page 151 in its financial assumptions. It assumes that the initial operating expenses will maximize after the initial six-month period.

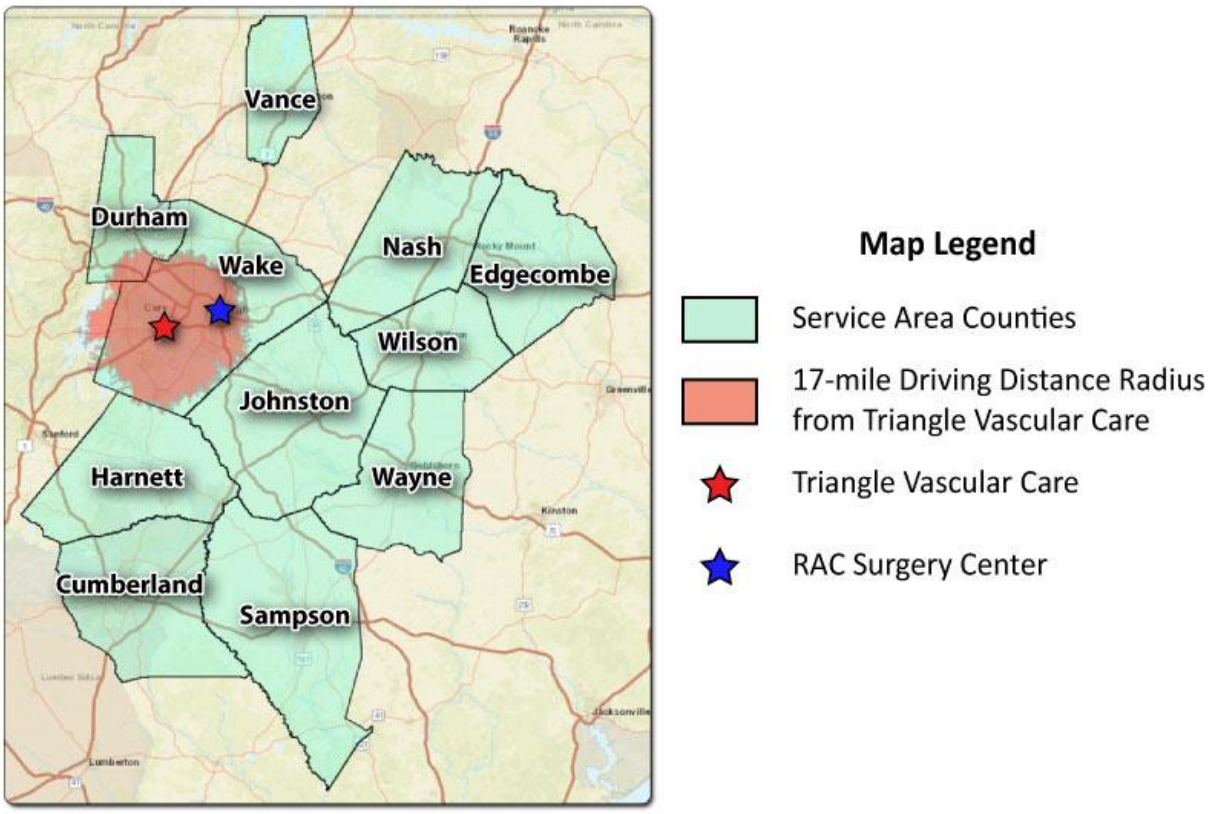
According to the initial operating expenses information, the average monthly expense is $501,584 ($6,019,018 / 12 months). Per Section P milestone 15, TVC will not have Medicare or Medicaid certification until February 1, 2024, one month after it begins operations. Given that the majority of the facility's charges are Medicare, TVC will receive little to no reimbursement during at least the first month. At a minimum, IOE will represent one month of expenses (or $501,584). Conservatively, it will take at least another 30 days before receiving Medicare payments. TVC will likely have at least two months of expenses with little to no reimbursement. This would generate initial operating expenses in excess of $1 million, for which TVC has provided no documentation of funding.

TVC's calculation of initial operating expenses is understated, and it fails to demonstrate the availability of funds to offset these expenses. Thus, **Triangle Vascular Care fails to reasonably demonstrate financial feasibility and its application is non-conforming with Criterion 5.**

6. Triangle Vascular Care's proposed service area is unreasonable and unsupported.

Triangle Vascular Care's application lists improved geographic access to vascular access / treatment within Wake County as support for need. On page 55, TVC measures drive time from TVC to RAC. The analysis focuses exclusively on drive times from Cary to RAC and ignores the rest of TVC's service area. According to the patient origin tables on page 37, 16.97 percent of OR and 25.8 percent of procedure room procedures are expected to originate from Wake County. The population of Cary is a small subset (about 15%) of the Wake County population. TVC does not demonstrate how the proposed location will impact drive times for the rest of Wake County or other counties within its primary service area. Further, on page 55, TVC lists a 17-mile drive from Cary to RAC as support for the project and implies traveling this distance is too far for patients.

However, TVC's patients are expected to travel significantly further than 17 miles to receive service. The map below shows a 17-mile drive time relative to TVC's patient origin.



Source: Esri

As shown above, only a portion of Wake County is within 17 miles of the proposed TVC location. Patients from the rest of the service area are expected to travel significantly further distances. TVC does not discuss how it will improve access for these patients nor why it is reasonable for patients to travel such distances to access care at TVC, but not to the existing option of RAC Surgery Center. The table below calculates driving distance and drive time from major cities and towns in each county, with the closer facility highlighted for each county.

City	*County*	*Miles / Minutes*	
		TVC	*RAC*
Fayetteville	Cumberland	71.7 / 1:10	63.3 / 1:02
Wilson	Wilson	58.3 / 0:59	44.8 / 0:45
Goldsboro	Wayne	63.0 / 1:03	55.1 / 0:55
Tarboro	Edgecombe	82.1 / 1:15	68.6 / 1:01
Rocky Mount	Nash	67.6 / 1:04	54.1 / 0:51
Henderson	Vance	62.9 / 0:59	42.7 / 0:57
Durham	Durham	25.1 / 0:30	30.2 / 0:34

Smithfield	Johnston	38.1 / 0:42	30.2 / 0:33
Clinton	Sampson	71.1 / 1:12	63.3 / 1:04
Lillington	Harnett	30.4 / 0:43	36.6 / 0:45

Source: Google Maps based on time

Based on the drive time analysis above, patients in eight of the ten service area counties have a shorter drive time to RAC than TVC. The two exceptions are Durham and Lillington which save patients four and two minutes in drive time, respectively. Within Wake County, RAC is located in Raleigh and TVC plans to be located in Cary. Patients located in Morrisville, Apex, Holly Springs, and Cary will likely be closer to TVC. Patients located in Raleigh, Garner, Wake Forest and Knightdale will be closer to RAC. Only patients located in a subset of Wake County will experience improved drive times with the proposed facility. Based on the table above, TVC does not improve geographic accessibility to vascular access patients within its self-defined service area as most patients will continue to have shorter drive times to the existing facility under common ownership, RAC. The patient origin projections and service area definition show that TVC expects patients to travel from up to several counties away, as far as Edgecombe and Cumberland counties, to access services at the ASF, yet it states that patients from Cary cannot access a facility in Raleigh. Clearly, the application fails to demonstrate the need for a proposed second vascular access ASF in Wake County.

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

ISSUE-SPECIFIC COMMENTS ON DUKE HEALTH GREEN LEVEL AMBULATORY SURGICAL CENTER

1. The application fails to reasonably identify the patient population to be served.

   On pages 33-36, the Duke Health Green Level ASC application provides projected patient origin, stating that it expects it to reflect the patient origin at Duke Raleigh Hospital. However, while the methodology does assume that many of the cases at the ASF will shift from DRAH, it is not reasonable to assume that the patient origin at a facility in Apex will be the same as the hospital in North Raleigh, for several reasons. First, the application provides as one of its supporting factors for the utilization projections the "reduced travel burden" and "convenient location" of the ASF (page 139). However, for patients that would be closer to DRAH, such as residents north or east of DRAH, the proposed location will not reduce their travel burden. In addition, Duke University Health System previously proposed to develop an ASF in Morrisville in Durham County, Arringdon ASC (Project ID # J-11508-18), which would be a more convenient location for patients from areas north and west of DRAH than would Green Level. Moreover, DRAH was recently approved to develop an ASF on the campus of DRAH and given its location on the same campus where patients are currently seeking these services, it is reasonable to assume that many would prefer to access care at the approved ASF there, rather than traveling to Green Level.

   In fact, as shown on page 138 of the Green Level application, patients are projected to be shifted from Duke Raleigh Hospital to the Arringdon ASC. Given its location, it is more reasonable that the patients north or west of DRAH would shift to Arringdon as opposed to a more distant location in Apex in southern Wake County. Second, the methodology assumes that more than 400 patients at the proposed ASF would shift from Duke University Hospital, which has a different patient origin than Duke Raleigh Hospital; the patient origin assumptions fail to account for the impact of these shifts. Third, given the specificity with which the application attempts to quantify the volume shifts by specialty, the data regarding patient origin for the cases to be shifted were surely available to allow the application to exclude patients who would more likely be treated at another facility, including Arringdon.

   Since it is unlikely that patients, especially those outside Wake County, would bypass other ASFs, particularly other Duke-owned ASFs, to access care at the proposed facility, the application's utilization projections based on this patient population are similarly unreasonable**. For these reasons, the application should be found non-conforming with Criterion 3 and the performance standards at 10A NCAC 14C .2103**.

2. The Duke Health Green Level ASC application fails to demonstrate need for the proposed project.

   In Section Q, DUHS provides its methodology for projecting utilization for the proposed project and for some of the other facilities in its system. In Steps 10 and 11 of its methodology (see pages 141-144 of the Duke Health Green Level application), DUHS states that it projects to shift OR cases from DUHS (Step 10, page 141) as well as outpatient OR and outpatient procedure room cases at DRAH (Step 11, pages 143-144) to Duke Health Green Level. The table below shows the total projected OR volume at Duke Health Green Level ASC as represented in Steps 10 and 11 of the methodology and found in Form C.3b of the Duke Health Green Level ASC application.

Total Surgical Cases Shifting to Duke Health Green Level

	FY 2027	*FY 2028*	*FY 2029*
OP OR Cases Shifted from DRAH*	973	1,527	2,096
OP Procedure Room Cases Shifted from DRAH*	358	556	763
Shift from DUH**	200	291	420
Total Duke Health Green Level OR Volume* **	**1,532**	**2,374**	**3,279**

*Table showing DRAH surgical cases that will shift to Duke Health Green Level ASC on the bottom of application page 143.
**Application page 141. No information is provided to differentiate between OR and procedure room cases to be shifted.
***Matches Form C.3b

Agency findings from the 2021 Durham/Caswell Acute Care Bed and Durham OR Review show that procedure room volumes and shifts do not necessarily support projected utilization and the need for additional ORs. Specifically, on page 15 of the Findings for the 2021 Durham/Caswell Acute Care Bed and Durham OR Review, the Agency states the following:

> "*However, as the applicant's projected utilization methodology shows, in Step 2 above, the applicant proposes to shift procedure room cases from NCSH to be performed at SSC.* ***This does not support the need for additional ORs*** *at SSC. It would in fact support the need to maintain procedure room capacity at SSC, as opposed to converting all four of them to ORs. Furthermore, removing the PR cases being shifted to SSC leaves a total of the following OR cases being projected at SSC, per the applicant's methodology*."
> [**emphasis added**]

The Agency then recalculates the total OR need without the inclusion of the shifted procedure room cases and concludes that the total number of projected OR cases for SSC does not support the need for six total ORs. Furthermore, on page 16 of those findings, the Agency finds the projected utilization not reasonable and adequately supported for the following reasons:

- *"The applicant counted the projected shift of procedure room cases from NCSH to SSC as projected OR cases. Cases that can be performed in procedure rooms do not support the need for adding the proposed number of ORs and eliminating all existing procedure rooms.*
- *Without the procedure room cases, the applicant does not show a need for the proposed four additional ORs.*
- *The applicant's projected utilization of OR surgical cases does not meet the performance standard promulgated in 10A NCAC 14C .2013(a)."*

The table below uses the projected OR volume at Duke Health Green Level less the procedure room cases shifted from DRAH and applies the Agency's process found on page 15 of the 2021 Durham/Caswell Acute Care Bed and Durham OR Review used for analyzing the SSC application.

	FY 2027	*FY 2028*	*FY 2029*
Total OR Cases (Form C.3b)	1,532	2,374	3,279
Less the Procedure Room Cases Shifted from DRAH (page 143)	358	556	763
Total OR Cases	1,174	1,818	2,516
Average Case Time	70.1	70.1	70.1
Total Annual Surgical Hours	1,372	2,124	2,940
Standard Surgical Hours per OR (Group 6)	1,312	1,312	1,312
Total ORs Needed	**1.05**	**1.62**	**2.24**
OR Deficit / (Surplus)	**(1.95)**	**(1.38)**	**(0.76)**

As illustrated in the table above, if procedure room volume is removed from the OR volume projections, Duke Health Green Level ASC has a surplus of 1.95 ORs in project year 1 and 0.76 ORs in project year 3. Cases that can be performed in procedure rooms do not support the need for adding the proposed number of ORs and reducing the number of procedure rooms. Without shifting the procedure room cases to an OR, the applicant does not show a need for the proposed two additional ORs. This issue is particularly pertinent to DUHS' application, since it is already approved for the procedure rooms it proposes to supplant with operating rooms, and since it has historically performed these same cases in procedure rooms and has presumably determined it is safe to continue that practice.

In conclusion, the applicant's projected utilization of OR surgical cases does not meet the performance standard promulgated in 10A NCAC 14C .2103 and its application should be found non-conforming with the rules and with Criterion 3.

3. <u>The DUHS application does not meet performance standards pursuant to 10A NCAC 14C .2103.</u>

According to Rule 10A NCAC 14C .2103 which DUHS includes on page 63:

(a) 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.

(b) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule*.

DUHS fails to meet this Rule in two distinct ways. First, DUHS provides incomplete projections for two approved facilities. Second, DUHS does not demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms as the need is generated by shifting procedure room cases at DRAH to operating room cases at other facilities.

DUHS provides incomplete projections for Duke Health Garner ASC and Duke Green Level Hospital. In Step 4, page 133, DUHS projects shifted IP and OP cases from DRAH to Duke Green Level Hospital. In project year 3, 228 IP cases are shifted. In Step 8 for Project Year 3, DUHS shifts 1,015 outpatient cases from DRAH to Duke Health Garner ASC. No additional case volumes are discussed or projected for either facility (Duke Green Level Hospital or Duke Health Garner ASC). Form C.3b projects 585 IP cases (compared to 228 shifted from DRAH) and 1,369 OP cases for Duke Health Garner ASC (compared to 1,015 shifted from DRAH).

	Cases Shifted from DRAH	***Form C.3b Projections***	***Overstated/ Unexplained Volume***
DGLH IP Cases	228	585	357
Duke Health Garner ASC Cases	1,015	1,369	354

Thus, the Duke Green Level Hospital IP cases and the Duke Health Garner ASC OP cases are overstated relative to the methodology in the application. In both instances, the total volume projections are purportedly based on a shift of cases, but DUHS failed to include the source of the shift or any other discussion of the missing volume noted in the table above. Since DUHS cannot amend its application by providing additional information, the methodology is incomplete, the projections are not reasonable and adequately supported, and DUHS should be found non-conforming.

As previously discussed, DUHS improperly relies on procedure room shifts from DRAH to operating rooms in other facilities to meet performance standards. In addition to shifting procedure room cases to Duke Health Green Level ASC as previously discussed, DUHS shifts procedure room cases at DRAH to Duke Green Level Hospital, Duke Health Garner ASC, and Duke Health Raleigh ASC. According to the table on the top of page 143, DRAH shifts 2,955 OP procedure room cases to a combination of these three facilities and Arringdon ASC. The impact of these shifts is presented in the table below.

	Duke Green Level Hospital	***Duke Health Garner ASC***	***Duke Health Raleigh ASC***	***Total***
Procedure Room Cases*	447	459	1,731	2,637
OP Case Time (Minutes)	72.7	70.1	39.9	N/A
Surgical Hours	541.6	536.3	1,151	2,228.9
Standard Hours per OR	1,500	1,312	1,312	N/A
FY 2029 Need Impact	**(0.36)**	**(0.41)**	**(0.88)**	**(1.65)**

* While page 143 did not provide additional details, a review of the previous applications identified the quantity of procedure room cases shifted from DRAH for each facility.

After procedure room adjustments, three DUHS facilities, Duke Health Garner ASC, Duke Health Raleigh ASC and Duke Green Level Hospital, all located in Wake County, have a surplus of operating rooms. In addition, as shown in the table below, DUHS facilities fail to meet performance standards in total for the service area.

	FY 29 OR Need	*FY 29 ORs*	*Deficit / (Surplus)*
Duke Health Green Level ASC	2.9	3	(0.1)
Duke Raleigh Hospital	13.5	12	1.5
Duke Green Level Hospital	1.7	2	(0.3)
Duke Health Garner ASC	1.2	1	0.2
Duke Health Raleigh ASC	1.1	1	0.1
Total Wake County DUHS	**20.4**	**19**	**1.4**
Duke Health Green Level ASC Adjustment	(0.8)		(0.8)
Duke Green Level Hospital Adjustment	(0.4)		(0.4)
Duke Health Garner ASC Adjustment	(0.4)		(0.4)
Duke Health Raleigh ASC Adjustment	(0.9)		(0.9)
Adjusted Total Wake County DUHS	**17.9**	**19**	**(1.1)**

In conclusion, the applicant's projected utilization of OR surgical cases shows a surplus of ORs and not a deficit. It does not demonstrate need and does not meet the performance standard, and thus should be found non-conforming.

4. <u>The DUHS application overstates procedure room volume</u>.

The procedure room volume at Duke Health Green Level ASC is based on the projections from its 2018 CON application. The volumes have not been updated.

In its 2021 Duke Health Raleigh ASC application, DUHS shifts 10 percent of pain management volume and 50 percent of the cystoscopy volume from DRAH. DUHS goes on to state that, "DRAH will continue to operate existing cystoscopy and pain management procedure areas within the hospital to accommodate remaining hospital-based volumes, which are projected to remain constant ***after the shift of procedures to the ASC"*** (emphasis added). DUHS has continually allocated this same volume to its four approved facilities in Wake County as shown below.

	*Duke Health Green Level ASC**	*Duke Green Level Hospital***	*Duke Health Garner ASC*	*Duke Health Raleigh ASC*	*Total*
Pain Management Procedures	821	180	154	141	1,296
Cystoscopy Procedures	194	70	43	275	582
Total from DRAH	**1,015**	**250**	**197**	**416**	**1,878**

*Based on 2018 application where the current procedure room volumes were originally calculated

**Given 100% of outpatient volume is shifted from DRAH, it is assumed procedure room volume will also shift from DRAH. The application did not break down the proportion of pain management and cystoscopy so the FY 2021 LRA percentage for DRAH was used.

As shown in the table above, between the four Wake County facilities, DUHS is expecting to shift 1,296 pain management procedures and 582 cystoscopy procedures. According to its 2022

License Renewal Application, DRAH performed 1,412 pain management procedures and 550 cystoscopy procedures in FFY 2021. With its failure to update Duke Health Green Level ASC procedure room volumes, DUHS is now shifting more cystoscopy procedures from DRAH than it currently performs. In addition, DUHS is shifting 96 percent of these two types of cases in total. This is contradictory to what DUHS stated in its approved Duke Health Raleigh ASC application (Project ID # J-12212-22) that DRAH volume would remain constant after the shift of patients to Duke Health Raleigh ASC.

While DUHS may contend that procedure rooms are not regulated by CON and that volumes do not need to be updated, as explained above the Agency findings from the 2021 Durham/Caswell Acute Care Bed and Durham OR Review show that procedure room volumes and shifts do not automatically support projected OR utilization and the need for additional ORs.

In summary, DUHS fails to demonstrate that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and that the project is needed, and the Duke Health Green Level ASC application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18(a) and the performance standards at 10A NCAC 14C .2100 et seq. The Duke Health Green Level ASC application should not be approved.

5. The Duke Health Green Level ASC application fails to demonstrate financial feasibility and reasonable financial assumptions.

   As noted above with regard to Criterion 3, the Duke Health Green Level ASC application includes unreasonable and unsupported utilization projections; as such, the projected financials are based on unreasonable and unsupported assumptions. DUHS is required to provide projected revenues and expenses for the entire facility in Forms F.2b and F.3b. Based on the projected utilization analysis above, DUHS' operating room volume projections are overstated and therefore result in overstated revenues and questionable operating expenses.

   As a result, the Duke Health Green Level ASC application should be found non-conforming with Criterion 5.

6. The Duke Health Green Level ASC application cannot be approved as submitted, as it is incomplete and fails to include all information necessary for the Agency to conduct the review pursuant to N.C. GEN. STAT. § 131E-182(b).

   Specifically, DUHS fails to provide all requested information required in response to the CON application form as it fails to identify all related entities in response to Form O Facilities and the performance standards.

   As defined in 10A NCAC 14C .0202(10) as well as the definition portion of the CON application form (page 14), when used in the application form, the term "related entity" means "a person that:

   (d) Shares the same parent corporation or holding company with the applicant;
   (e) Is a subsidiary of the same parent corporation or holding company as the applicant; or

(f) **Participates with the applicant in a joint venture that provides the same type of health services proposed in the application**."

[**emphasis added**]

Section O.1 of the CON application form requires an applicant to "[i]*dentify all existing and approved facilities providing the same service components included in this proposal* ***that are owned, operated or managed by the applicant or a related entity*** *in North Carolina by completing* ***Form O Facilities****, which is found in Section Q*." [**emphasis added**]. However, while DUHS identifies James E. Davis Ambulatory Surgical Center, Arringdon ASC, Duke University Hospital, Duke Regional Hospital, Duke Health Green Level ASC, Duke Health Raleigh ASC, Duke Health Garner ASC, Duke Raleigh Hospital, Duke Health Orange ASC, and Same Day surgery Center in response to Form O Facilities (see page 152 of the Duke Health Green Level ASC application), it fails to identify all the Duke LifePoint entities which offer surgical services. According to the Duke LifePoint website[9] and shown in Attachment B Duke LifePoint Healthcare is a joint venture of DUHS and LifePoint Health and includes several facilities such as Central Carolina Hospital in Lee County, which according the *2022 SMFP* has six ORs. As such, the DUHS application fails to identify all related entities in response to Form O Facilities.

In summary, DUHS has failed to demonstrate that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and that the project is needed, and the Duke Health Green Level ASC application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18(a) and the performance standards at 10A NCAC 14C .2100 et seq. The Duke Health Green Level ASC application should not be approved.

[9] Accessed at http://www.dukelifepointhealthcare.com/about_us.aspx

ISSUE-SPECIFIC COMMENTS ON KM SURGERY CENTER

1. KM Surgery Center fails to demonstrate the need patients have for the proposed project.

   KM Surgery Center proposes to develop a new ASF with one OR and two unlicensed procedure rooms in northern Wake County. KM Surgery Center fails to mention any issues that prevent the proposed patient population from being served at other ASFs in Wake County, or even hospitals in the county, many of which provide the specialties proposed and some of which have available capacity. In particular, KM Surgery Center fails to discuss any issues with the facilities at which the surgeons supporting the project currently practice, nor does the application even mention at which facilities they practice. Furthermore, on page 18 of the application, KM Surgery Center states the specialties to be offered at the proposed ASF will be otolaryngology (ENT), plastic surgery, general surgery, ophthalmology, and urology as well as pain management services; however, Section Q of the application shows the proposed facility will have a special focus on urology services with the need for a freestanding ASF operating room specifically for urology surgery. In fact, Section C.4 mentions very little about the need for ASF operating room capacity for the provision of ENT, ophthalmology, and/or plastic surgery procedures. Instead, KM Surgery Center's application focuses heavily on the need for an ASF operating room specifically for the provision of urologic procedures and continually fails to acknowledge the available capacity at existing ASFs and area hospitals. Clearly, KM Surgery Center fails to demonstrate why there is a patient-based need for the project it proposes.

   Based on the discussion above, KM Surgery Center fails to demonstrate the need for the proposed project in accordance with Criterion 3. As such, the KM Surgery Center application is non-conforming with Criteria 1 and 3.

2. The KM Surgery Center application fails to identify the population to be served.

   In Section C, KM Surgery Center provides projected patient origin for the proposed operating room and procedure rooms stating that the patient origin is based on ambulatory patients treated by surgeons at local ASFs or hospitals. However, the application provides no data or other documentation to support its patient origin, nor does it attempt to reconcile the projected patients with a particular specialty or surgeon, other than for urology cases. Based on these issues, the KM Surgery Center application fails to reasonably identify the population to be served by the proposed project in conformance with Criterion 3. As such, **the application should be found non-conforming with Criterion 3**.

3. The KM Surgery Center application fails to demonstrate the reasonableness of its projected utilization.

   The application presents the proposed facility as having a "special focus" on urology procedures, and most of the support letters and projected utilization are for urology cases. As noted above, the application provides little information regarding other specialties, but the information for urology cases in Section C.1 focuses on the urologic treatment of kidney stones. On page 38, the application presents the common treatment used to minimize the need for narcotics, specifically ureteroscopy. However, a ureteroscopy is not a surgical case, and the application actually notes that it is performed "without making any cuts by directing the instrument through the urethra…." As stated in NCGS 131E-176 (18c), an operating room is for the "performance of surgical

procedures requiring one or more incisions….” Since the ureteroscopy procedures, by admission of the applicant, do not require incisions, they are not surgical cases. This is similar to GI endoscopy procedures, which also use an existing orifice to perform the procedure, and while they may be performed in operating rooms, they are not considered “surgical” cases. While these procedures can be performed in operating rooms or procedure rooms, they cannot be counted in the utilization required by the performance standards. Specifically, the performance standards refer to the *SMFP* need methodology, which refers to case volume from License Renewal Applications (LRAs). LRAs include only surgical cases performed in licensed operating rooms, not non-surgical cases or even surgical cases performed in procedure rooms. As such, the non-surgical urology cases projected by KM Surgery Center cannot be used to demonstrate need for operating rooms or conformity with the OR rules.

Additionally, in a contested case, the Agency has previously confirmed that non-surgical cases—while permitted to be performed in an operating room—cannot be included in demonstrating conformity with the performance standards for operating rooms. Specifically, in a contested case hearing conducted in January 2018 (17-DHR-06745 and 17-DHR-06576), Ms. Martha Frisone, then Section Chief, testified that the inclusion of non-surgical cases (in that case, GI endoscopy cases) performed in operating rooms was not permitted for demonstrating conformity with the operating room performance standards. The following excerpt includes Ms. Frisone’s testimony in that case (see responses preceded with “A” below):

SCW v. NCDHHS_DHSR_HPCON and SurgCare - Vol. 6, (Pages 1208:22 to 1210:10)

1208

Q Okay.
A While you can't do--GI endoscopy rooms are limited to GI endoscopy procedures by definition. Operating rooms-- you can do nonsurgical cases in an operating room.

1209

Q And you would consider a GI endoscopy procedure done in an operating room to be a nonsurgical case?
A Yes. That's why we backed it out when we looked at the--whether SurgCare demonstrated the need for three additional ORs. And we mathematically showed that yes, even when you back out those GI endo cases, yes, they still show a need for three additional ORs.
Q Okay. So the number that was for the performance standard that you believe--because the Agency's decision included the performance standard calculation including the GI endoscopy room or GI endoscopy cases as OR cases. And then there was a second analysis that removed those. Do you remember that from the decision?
A I wouldn't call it a second analysis. I would call it a continuation of the analysis, that if you look at the total procedures to be done in the ORs, this is the result you get. But backing the GI endo cases out, you still show a need for three additional ORs.
Q So let me restate that, then. There was a chart included in the decision that showed the performance standard

calculated with the GI endoscopy procedures included.
A Correct.
Q And then there was a second chart that showed the performance standard without the GI endoscopy procedures included.

1210

A Correct.
Q And so it's the Agency's position in terms of SurgCare meeting or not meeting the performance standard that the one that they viewed, the one that the Agency views, is the one that did not include the GI endoscopy procedures?
A In order to meet the rule you have to back out the GI endoscopy cases.
Q So the answer to my question is yes, it's the one without the GI endoscopy procedures?
A Well, I didn't really--yes.

(Emphasis added.)

Thus, the non-surgical urology cases projected by KM Surgery Center, which appears to be all of the urology cases, must be "backed out," and cannot be used to demonstrate conformity with the OR rules.

Regarding non-urology cases, KM Surgery Center bases its utilization assumptions on letters from physicians provided in Exhibit C.4. In Section Q, the applicant projects case volume for urology and "other specialties" and states in Step 2 that OR cases are projected to increase annually. No assumptions are provided for the number of cases in the "other" specialty category. The totals are provided in tables excerpted below.

Operating Room			
Specialty	**2024**	**2025**	**2026**
Urology %	40.0%	45.0%	50.0%
Urology Cases	648	729	810
Other Specialties %	20.0%	30.0%	40.0%
Other Specialties Cases	177	266	354
Total	**825**	**994**	**1,164**

Procedure Rooms			
Specialty	**2024**	**2025**	**2026**
Urology %	80.0%	90.0%	100.0%
Urology Cases	1,865	2,098	2,331
Other Specialties %	20.0%	30.0%	40.0%
Other Specialties Cases	294	441	588
Total	**2,159**	**2,539**	**2,919**

The lack of any breakdown of cases among the other specialties is problematic. On page 44 of the application, the table shows five other specialties for which the application has support letters.

These specialties have a wide range of procedures and reimbursement for those procedures, as well as payors. For example, ophthalmology cases are largely Medicare patients with relatively low reimbursement, while ENT cases often include a portion of Medicaid patients, and plastic surgery is often self-pay. Without any assumptions regarding the number of each type of cases that will comprise the "other" category, it is impossible to conclude that each of the specialties will actually be performed at the facility, and how many cases of each will be performed. For example, with 942 projected "other" specialty cases in total, they could be comprised of just pain management cases, or only pain management and general surgery, or some other mix of cases. Without these assumptions, the projected utilization, specialty mix (and multispecialty status), and payor mix cannot be reasonably determined.

Further, without a breakdown of cases by specialty, the financial projections are not reasonable. The assumptions to Form F.2 state that the revenue was calculated using the "projected average gross charge by specialty (urology or other specialties)," but the charges for other specialties varies widely, and without a breakdown by specialty, cannot reasonably be determined. Similarly, variable expenses differ considerably by specialty and cannot be accurately estimated without the breakdown by specialty.

It is also highly improbable that KM Surgery Center can develop and operationalize the project as proposed. Specifically, while the applicant states that it will be a multispecialty ASF, given the need for different types of surgical equipment and staff training, as well as the practical issues with scheduling five different surgical specialties plus pain management in only a single operating room, it is unlikely that all of the listed specialties will actually be offered.

Based on these issues, KM Surgery Center is non-conforming with Criteria 1, 3, 4, 5, 6, and 18a, and the performance standards for Operating Rooms (10A NCAC 14C .2103).

The issue-specific comments above include substantial issues that Rex believes render the competing applications listed above non-conforming with applicable statutory and regulatory criteria. However, as presented in the following section, even if all these applications were conforming, the applications filed by Rex are comparatively superior to the others and represent the most effective alternative for expanding access to acute care beds and hospital-based surgical services in Wake County.

COMPARATIVE ANALYSIS FOR OPERATING ROOMS

The UNC Health Rex Hospital OR application (Project ID # J-12260-22), the WakeMed Garner Hospital application (Project ID # J-12264-22), the Duke Health Green Level ASC application (Project ID # J-12261-22), the Oakview ASC application (Project ID # J-12252-22), the Triangle Vascular Care application (Project ID # J-12253-22), and the KM Surgery Center application (Project ID # J-12248-22) each propose to develop operating rooms in response to the *2022 SMFP* need determination for Wake County. Given that multiple applicants propose to meet all or part of the need for the two additional operating rooms in Wake County, not all can be approved. To determine the comparative factors that are applicable in this review, Rex examined recent Agency findings for competitive operating room reviews. Based on that examination and the facts and circumstances of the competing applications in this review, Rex considered the following comparative factors:

- Conformity with Review Criteria
- Historical Utilization
- Geographic Accessibility
- Provider Support
- Patient Access to Lower Cost Services
- Scope of Services/Patient Access to Multiple Surgical Services
- Access by Underserved Groups
    - Projected Charity Care
    - Projected Medicare
    - Projected Medicaid
- Projected Average Net Revenue per Case
- Projected Average Operating Expense per Case

Rex believes that the factors presented above and discussed in turn below should be used by the Project Analyst in reviewing the competing applications.

Conformity with Applicable Statutory and Regulatory Review Criteria

As discussed in the application-specific comments above, the Triangle Vascular Care application, the Duke Health Green Level ASC application, the Oakview application, the WakeMed Garner application and the KM Surgery Center application are all non-conforming with multiple statutory and regulatory review criteria. In contrast, the UNC Health Rex Hospital application is conforming with all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with statutory and regulatory review criteria, the UNC Health Rex Hospital application is the most effective alternative.

Historical Utilization

The following table shows projected operating room surplus or deficit for the existing providers of surgical services in Wake County who have submitted applications in this review. The projected operating room deficit (surplus), from the *2022 SMFP*, Table 6B, Projected Operating Room Need for 2024, are based on the historical utilization of existing providers of surgical services in the service area.

Projected 2024 Operating Room Need for Wake County by Health System

	Adjusted OR Planning Inventory	***Projected OR Deficit / (Surplus) 2024***
UNC Health System	37	(1.69)
Duke University Health System	17	(0.10)
WakeMed System	41	(2.64)

*Source: *2022 SMFP*, Table 6B.

As the table above shows, based on the operating room need methodology for Wake County in the *2022 SMFP*, the WakeMed System is projected to have the highest operating room surplus in 2024 and while the Duke University Health System has the lowest surplus, it has submitted an application to develop two ORs at an ASF still under development. Therefore, based on the Agency's past position on this comparative factor – that applications proposing to develop additional operating rooms in the health systems with the highest projected operating room deficits are the most effective alternatives – the UNC Health Rex Hospital application submitted by Rex and the Duke Health Green Level ASC application are more effective proposals than the WakeMed Garner application with respect to this comparative factor. Given that the UNC Health Rex Hospital application is the only one conforming to all statutory and regulatory review criteria, it is the most effective alternative with regard to historical utilization.

Geographic Accessibility (Location within the Service Area)

Rex proposes to develop two ORs at an existing tertiary care hospital, centrally located in Wake County. All the other applicants propose to develop OR capacity at ASFs and hospitals that have not yet been developed or are CON approved. While the Oakview ASC and TVC proposals are also for locations centrally located in Wake County, neither will offer inpatient acute care services and as previously discussed neither application is conforming to all applicable statutory and regulatory review criteria. Duke Health Green Level ASC is a CON approved but not yet developed ASF to be located in western Wake County and as discussed above does not conform with statutory and regulatory review criteria. The proposed location for KM Surgery Center is northern Wake County; however, along with the WakeMed Garner Hospital, it does not demonstrate conformity with statutory and regulatory review criteria. While the WakeMed Garner application proposes to offer inpatient acute care services at a location in southern Wake County, the inpatient acute care services are limited to non-tertiary care patients. As a centrally located tertiary care hospital, UNC Health Rex Hospital serves patients, many of whom require care that cannot be provided at an ASF or community hospital, from all over Wake County., Given the factors described above, with regard to geographic accessibility, the Rex application is the most effective.

Provider Support

The three Rex applications each provide **442** letters of physician support for each of the three Rex proposals. Meanwhile, DUHS provides 15 physician letters and 2 general letters of support for the Duke Green Level Hospital application and 25 physician letters and 1 general letter of support for the Duke Raleigh Hospital application. The TVC application provides 2 physician letters of support and the Oakview ASC application includes 5 letters of support from optometrists, 13 from patients and 5 letters from physicians. KM Surgery Center provides 22 physician letters of support, yet the proportion of physician specialties is inconsistent with the projections by specialty found in Section Q Utilization Assumptions and Calculations Step 2. As noted in the application-specific comments, WakeMed provides a single letter from the Mayor of Garner voicing his support for the project but fails to document any physician support for its acute care beds, surgical services or any other service components.

In the 2011 Wake County Acute Care Bed review, which was the most recent Wake County review involving acute care beds, the Agency found an applicant non-conforming with Criterion 3 due to the applicant failing to demonstrate the need for the proposed services. Specifically, on page 131 the Agency states,

> "*Also the applicant's acute care bed utilization projections are based on the projection that 2,314 of 12,955 acute care patient days in the third year of operation, or approximately 18% of total acute care patient days, will be provided to obstetrical patients. Based on the lack of documentation of physician support from obstetricians within its proposed service area, the applicant's market share assumptions for obstetrical services are not supported. Therefore, the applicant's utilization projections for the proposed acute care beds are not supported or reliable. Therefore, the applicant did not adequately demonstrate the need for the acute care beds*."

Understandably, physician support is critical to the development of acute care beds and operating rooms. Without physician support, need is not demonstrated, and utilization projections are not reasonable or adequately supported as required by both Criterion 3 and the performance standards found in 10A NCAC 14C .2103. While WakeMed clearly fails to meet these standards in many ways, not providing any indication of support from the medical community is a glaring omission.

With respect to provider support, Rex clearly is comparatively superior to the other applications. Regardless, Rex is the only applicant that is conforming with all statutory and regulatory review criteria for all applications proposing to develop ORs. Therefore, UNC Health Rex Hospital is the most effective alternative with regard to provider support[10].

Patient Access to Lower Cost Services

Historically, the Agency has prioritized ASFs over hospital-based ORs as the cost for the same service will often be higher in a hospital licensed operating room than if received in a non-hospital licensed operating

[10] While not used in every competitive review, there have been numerous reviews recently in which provider support has been used as comparative factor, including the 2019 Orange County Operating Rooms Review and, in 2018, the Orange County Operating Rooms Review, the Mecklenburg County Operating Rooms Review, the Durham County Operating Rooms Review, the Wake County Operating Rooms Review, the Buncombe County Operating Rooms Review, and the Forsyth County Operating Rooms Review.

room in an ASF. The typical analysis compares the percentage of outpatient surgical cases to the percentage of ASF operating rooms in the service area. However, in this specific instance, Rex believes the Agency needs to prioritize hospital-based ORs over ASFs, and, as noted previously, the Agency's analysis stemming from Rex's 2021 SHCC petition determined that Wake County in particular has had a disproportionate number of ASF-based ORs approved compared to the need for hospital-based ORs.

As previously discussed, despite the growth in the number of ASFs that have been developed in Wake County through OR need determinations or reorganized/relocated hospital ORs, hospitals continue to drive much of the need for additional ORs given the inherently higher utilization of hospitals versus freestanding facilities. Hospitals are generally highly utilized due to the essential flexibility and capacity they provide. Specifically, while ASF ORs can treat many outpatient surgical cases, even with continuing improvements in technology and growing cost pressures, the need for some outpatient cases to be performed in a hospital setting is likely to persist for the foreseeable future.

Scope of Services/Patient Access to Multiple Surgical Services

UNC Health Rex Hospital and WakeMed Garner are the only proposals that seek to develop shared operating rooms which will serve both inpatients and outpatients. The proposed projects enable the development of surgical capacity that will serve a full scope of surgical services to meet the growing need for both inpatient and outpatient surgical capacity in Wake County. As shown in the UNC Health Rex OR application and excerpted below, Rex is one of the largest providers of surgical services in Wake County with more than 21,000 inpatient and outpatient cases. It is second only to WakeMed whose combined total including WakeMed North is only slightly higher at 21,587 cases. WakeMed proposes to add two ORs to its proposed Garner hospital with approximately 20 percent of surgical capacity being allotted to inpatient cases and 80 percent to outpatient cases. Alternatively, UNC Health Rex Hospital proposes to relieve capacity constraints at its existing hospital facility by adding two ORs and projects 30 percent of cases will be inpatient and 70 percent will be outpatient cases.

FFY 2021 Wake County Total Surgical Volume by Licensed Facility

	*FFY 2021 Total Cases**
WakeMed^	21,587
UNC REX Hospital	21,034
Duke Raleigh Hospital	10,102
Capital City Surgery Center	7,177
WakeMed Cary	7,176
Blue Ridge Surgery Center	5,304
REX Surgery Center of Cary	3,522
Raleigh Orthopaedic Surgery Center	3,008
REX Surgery Center of Wakefield	2,928
Triangle Surgery Center	2,821
Holly Springs Surgery Center	2,546
Surgery Center for Dental Professionals of NC	1,134
Raleigh Plastic Surgery Center	336
RAC Surgery Center LLC	134
Raleigh Orthopaedic Surgery Center-West Cary	33
Total	**88,842**

Source: *Proposed 2023 SMFP.*
*FFY 2021 (October to September).
^Includes WakeMed and WakeMed North.

Rex is the provider proposing to develop capacity to serve the largest number of inpatients with the broadest range of specialties, including tertiary services. WakeMed proposes to provide limited, community hospital (non-tertiary) services. TVC, Oakview, KM Surgery Center, and Duke Health Green Level ASC all propose to develop ASF-based dedicated ambulatory ORs. As such, approval of the Rex application will allow the development of surgical capacity for both inpatient and outpatient surgical patients in Wake County. Further, because WakeMed Garner, TVC, Oakview, Duke Health Green Level ASC and KM Surgery Center are not conforming with statutory and regulatory review criteria, they cannot be approved. Therefore, with regard to scope of services, UNC Health Rex Hospital is the most effective alternative.

Access by Underserved Groups

The following table shows projected operating room cases to be provided to Self Pay/Indigent/Charity Care, Medicare, and Medicaid recipients in the third project year following completion of the project, based on the information provided in Section L.3(a) of each application discussed in these comments.

Self Pay/Indigent/Charity, Medicare, and Medicaid Surgical Cases – Project Year 3

Applicant	*Self Pay/ Indigent/Charity as % of Total*	*Medicare % of Total*	*Medicaid % of Total*	*Total*
WakeMed Garner Hospital^	7.77%	41.00%	14.02%	62.79%
UNC Health Rex Hospital	3.1%	40.9%	4.3%	48.3%
Oakview ASC	3.0%	72.3%	0.5%	75.8%
TVC	2.5%	69.44%	4.52%	76.46%
Duke Health Green Level ASC	2.0%	40.9%	6.0%	48.9%
KM Surgery Center	1.8%	29.5%	1.9%	33.2%

Source: Section L.3(a) of the respective applications.

^ Application only provided % for OP Surgery; IP surgery % not provided

As shown in the table above, relative to the six applicants discussed in these comments, WakeMed Garner projects the highest percentage of Medicaid and Self Pay/Indigent/Charity patients; however, as noted above, the WakeMed Garner application does not provide a projected payor mix for both IP and OP surgery services. Oakview ASC projects the highest number of Medicare patients but is limited to ophthalmology patients; similarly, TVC proposes to serve only vascular access patients. However, the WakeMed Garner and Oakview applications do not adequately demonstrate that their proposals are conforming to all applicable statutory and regulatory review criteria and cannot be approved. Additionally, the TVC, KM Surgery Center and Duke Health Green Level ASC applications are not conforming to all applicable statutory and regulatory review criteria and cannot be approved. As such, the UNC Health Rex Hospital application represents a more effective alternative with regard to this comparative factor. Further, each of the applicants proposes a different mix of services and patients; therefore, it is unlikely that any conclusions can be drawn from this analysis.

Projected Average Revenue per Case

The following table shows the projected gross revenue per operating room case in the third year of operation based on the information provided in each applicant's pro forma financial statements (Form F.2). It is important to note that WakeMed only provided outpatient surgical cases separately as inpatient cases were included in the inpatient services component of the proposed hospital's pro forma financial statements and are not separately stated. As a result, the WakeMed Garner Hospital average gross revenue per case only reflects outpatient cases.

Applicant	*Cases*	*Gross Revenue*	*Average Gross Revenue Per Case*
WakeMed Garner Hospital	1,980	$73,022,253	$36,880
UNC Health Rex Hospital	22,776	$772,325,837	$33,910
Duke Green Level ASC	3,279	$41,177,459	$12,558
KM Surgery Center	1,164	$24,503,292	$21,051
Oakview ASC	2,495	$5,157,285	$2,067
Triangle Vascular Care	729	$13,278,366	$18,214

Source: Forms C and F.2 of the respective applications.

As shown above, Oakview ASC projects the lowest gross revenue per surgical case in the third operating year; however, the Oakview ASC application is not conforming to all applicable statutory and regulatory review criteria and cannot be approved. Of the two hospital applicants, UNC Health Rex Hospital's gross charge per case is significantly lower than WakeMed Garner's even though WakeMed Garner's application does not include inpatient cases. Moreover, the WakeMed Garner application is not conforming to all applicable statutory and regulatory review criteria and cannot be approved. Therefore, the application submitted by UNC Health Rex Hospital is the more effective alternative with respect to hospital applicants.

The following table shows the projected net revenue per operating room case in the third year of operation based on the information provided in each applicant's pro forma financial statements (Form F.2). It is important to note again that WakeMed only provided outpatient surgical cases separately as inpatient cases were included in the inpatient services component and are not separately stated. As a result, the WakeMed Garner Hospital average net revenue per case only reflects outpatient cases.

Applicant	*Cases*	*Net Revenue*	*Average Net Revenue Per Case*
UNC Health Rex Hospital	22,776	$252,596,640	$11,090
WakeMed Garner Hospital	1,980	$16,377,138	$8,271
DUHS Green Level ASC	3,279	$15,663,253	$4,777
KM Surgery Center	1,164	$7,074,418	$6,078
Oakview ASC	2,495	$2,722,058	$1,091
Triangle Vascular Care	729	$4,226,955	$5,798

Source: Forms C and F.2 of the respective applications.

Similar to net revenue per case, as shown above, Oakview ASC projects the lowest net revenue per surgical case in the third operating year, but its application cannot be approved. Of the two hospital applicants, UNC Health Rex Hospital's net revenue per case is slightly higher than WakeMed Garner Hospital's. However, Rex's net revenue per case reflects both inpatient and outpatient cases where WakeMed Garner Hospital's reflects only outpatient cases making these figures incomparable. Further, Rex proposes to provide more services, including higher acuity services, than WakeMed Garner Hospital. Moreover, the WakeMed Garner Hospital application cannot be approved.

Differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary hospital, and inpatient vs. ambulatory cases) at each facility, and the number and types of surgical services proposed by each of the facilities impacts the averages shown in the tables above. Thus, the result of this analysis must be inconclusive. This conclusion is consistent with the Agency's Findings in the 2021 Durham/Caswell Acute Care Bed and Durham OR Review (page 134) which also had multiple hospitals and ASFs competing for OR resources.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per case/procedure in the third year of operation for each of the applicants, based on the information provided in applicants' pro forma financial statements (Form F.3). Once again, WakeMed only provided outpatient surgical cases separately as inpatient cases were included in the inpatient services component and are not separately stated. As a result, the WakeMed Garner Hospital average expense per case only reflects outpatient cases.

Applicant	*Cases*	*Operating Expenses*	*Average Operating Expense Per Case*
UNC Health Rex Hospital	22,776	$205,748,067	$9,033
WakeMed Garner Hospital	1,980	$16,923,587	$8,547
DUHS Green Level ASC	3,279	$11,289,982	$3,443
KM Surgery Center	1,164	$5,067,781	$4,354
Oakview ASC	2,495	$2,452,508	$983
Triangle Vascular Care	729	$2,149,140	$2,948

Source: Forms C and F.3 of the respective applications.

As shown in the table above, Oakview ASC projects the lowest operating expense per surgical case in the third operating year; however, the Oakview ASC application is not conforming to all applicable statutory and regulatory review criteria and cannot be approved. Of the two hospital applicants, UNC Health Rex Hospital's operating expense per case is slightly higher than WakeMed Garner Hospital's. However, Rex's operating expense per case reflects both inpatient and outpatient cases where WakeMed Garner Hospital's reflects only outpatient cases making these figures incomparable. Further, Rex proposes to provide more services, including higher acuity services, than WakeMed Garner Hospital. Moreover, the WakeMed Garner Hospital application cannot be approved.

Differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary hospital, and inpatient vs. ambulatory cases) at each facility, and the number and types of surgical services proposed by each of the facilities impacts the averages shown in the tables above. Thus, the result of this analysis must be inconclusive. This conclusion is consistent with the Agency's Findings in the 2021 Durham/Caswell Acute Care Bed and Durham OR Review (page 135) which also had multiple hospitals and ASFs competing for OR resources.

SUMMARY

To assess the most effective alternatives for these operating rooms, the following table summarizes the comparative analysis shown above.

Comparative Factor	*UNC Health Rex Hospital*	*WakeMed Garner Hospital*	*Duke Green Level ASC*	*KM Surgery Center*	*Oakview ASC*	*Triangle Vascular Care*
Conformity with Applicable Statutory and Regulatory Review Criteria	Yes	No	No	No	No	No
Historical Utilization	More Effective	Less Effective	More Effective, But Not Approvable	Less Effective	Less Effective	Less Effective
Geographic Accessibility	Effective	More Effective, But Not Approvable	Less Effective	More Effective, But Not Approvable	Less Effective	Less Effective
Provider Support	Most Effective	Less Effective	Less Effective	Less Effective	Less Effective	Less Effective
Patient Access to Lower Cost Surgical Services	Effective	Not Approvable	Not Approvable	Not Approvable	Not Approvable	Not Approvable
Scope of Services	Most Effective	Less Effective	Less Effective	Less Effective	Less Effective	Less Effective
Access by Underserved Groups	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Revenue/Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense/Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive

In summary, Rex's application to develop two additional ORs at UNC Health Rex Hospital is the only OR application conforming to all applicable statutory and regulatory review criteria. As previously discussed, the WakeMed Garner Hospital, Duke Green Level ASC, KM Surgery Center, Oakview and Triangle Vascular Care applications are all non-conforming with several statutory and regulatory review criteria and cannot be approved. However, even assuming that all the applications were conforming, the Rex application that proposes to develop two additional ORs at UNC Health Rex Hospital is the most effective alternative for the following reasons:

<u>UNC Health Rex Hospital</u>:

- Is conforming with all statutory and regulatory requirements;
- Provides essential access to hospital-based surgery;
- Provides the greater depth of services (tertiary facility);
  Provides access to acute care services in a centrally located part of the county; and,
  Between the hospital-based applications, projects the lowest gross revenue per case.

COMPARATIVE ANALYSIS FOR ACUTE CARE BEDS

The UNC Health Rex Hospital (Project ID # J-12258-22), the UNC Health Rex Holly Springs Hospital (Project ID # J-12259-22), the Duke Raleigh Hospital (Project ID # J-12263-22) and the WakeMed Garner Hospital (Project ID # J-12264-22) applications each propose to develop acute care beds in response to the *2022 SMFP* need determination for Wake County. Given that multiple applicants propose to meet all or part of the need for the 45 additional acute care beds in Wake County, not all can be approved. To determine the comparative factors that are applicable in this review, Rex examined recent Agency findings for competitive acute care bed reviews. Based on that examination and the facts and circumstances of the competing applications in this review, Rex considered the following comparative factors:

- Conformity with Review Criteria
- Geographic Accessibility
- Provider Support
- Competition (Patient Access to a New Provider)
- Access by Underserved Groups
    - Projected Charity Care
    - Projected Medicare
    - Projected Medicaid
- Projected Average Net Revenue per Case
- Projected Average Operating Expense per Case

Rex believes that the factors presented above and discussed in turn below should be used by the Project Analyst in reviewing the competing applications.

Conformity with Applicable Statutory and Regulatory Review Criteria

As discussed in the application-specific comments above, the Duke Raleigh Hospital application and the WakeMed Garner Hospital application are non-conforming with multiple statutory and regulatory review criteria. In contrast, the UNC Health Rex Hospital and UNC Health Rex Holly Springs Hospital applications are conforming with all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with statutory and regulatory review criteria, the UNC Health Rex Hospital and UNC Health Rex Holly Springs applications are the most effective alternatives.

Geographic Accessibility

UNC Health Rex Hospital, UNC Health Rex Holly Springs Hospital, Duke Raleigh Hospital and WakeMed Garner Hospital each propose to develop the acute care beds in Wake County. UNC Health Rex Hospital, UNC Health Rex Holly Springs Hospital, and Duke Raleigh Hospital all propose to add the acute care beds to their respective existing facilities in Wake County. The application submitted by WakeMed Garner proposes to develop a new site of care for acute care beds. Both the UNC Health Rex Hospital application and the Duke Raleigh Hospital application propose to add beds to facilities located in central Wake County. UNC Health Rex Hospital is a tertiary care facility proposing to add 36 of the 45 acute care beds in the need determination while Duke Raleigh Hospital is a community hospital and proposes to add 45 acute care beds at its existing facility. The UNC Health Rex Holly Springs application proposes to add nine acute care beds, a small portion of the full need determination, to the facility located in Southern Wake County. The proposed WakeMed Garner Hospital site is located in southeastern Wake County less than 10 miles from WakeMed Raleigh, an

existing tertiary care and trauma hospital and UNC Health Johnston-Clayton, an existing community hospital. Therefore, with regard to geographic accessibility, the Rex applications collectively propose to provide the greatest geographical coverage with the acute care bed resources allotted in the need determination and are the most effective alternatives.

Provider Support

As noted in the application-specific comments and the comparative analysis for ORs, WakeMed fails to document physician support for its proposed hospital in Garner, including for acute care beds. The remaining applications proposing acute care beds each appear to document adequate provider support for their proposed project. Regardless, UNC Health Rex is the only applicant that is conforming with all statutory and regulatory review criteria and therefore, the UNC Health Rex Hospital and UNC Health Rex Holly Springs Hospital applications are the most effective alternatives with regard to provider support.

Competition (Patient Access to a New Provider)

Rex, WakeMed and DUHS, which operates Duke Raleigh Hospital and is approved to develop Duke Green Level Hospital, are three existing, mature, and well-established acute care service providers in Wake County. As such, none of the three applicants would qualify as a "new or alternative provider" under the Agency's historical reasoning of the "Competition (Patient Access to a New or Alternative Provider)" comparative factor in competitive reviews over the last decade.

Based on the Agency's past position on this comparative factor – that the expansion of an existing provider that currently controls fewer acute care beds than another provider would represent the most effective alternative –Rex compared the percent of beds under control by each facility. Of note, Rex does not necessarily believe this to be a useful factor as applied by the Agency; nonetheless, the analysis below shows the result of this factor if the Agency applies it the same way it has historically.

There are 1,431 existing and approved acute care beds in Wake County. Duke Raleigh Hospital and Duke Green Level Hospital are affiliated with DUHS, which currently controls 186 of the 1,547 existing and approved acute care beds in Wake County, or 12 percent. However, DUHS also controls 1,364 beds in contiguous Durham County, and DUHS has previously asserted that the number of beds controlled by related entities in contiguous counties should be considered by the Agency. WakeMed currently controls 872 acute care beds in Wake County, or 64 percent. Rex controls 489 acute care beds, representing 36 percent.

Specifically, the Agency has stated in numerous competitive reviews over the last five years that an applicant proposing to increase access to a "new provider" is a more effective alternative with regard to "Competition/Patient Access to a New or Alternative Provider." In the 2020 Forsyth County Acute Care Bed review, the Agency specifically noted with regard to the two applicants that are well-established providers in Forsyth County (North Carolina Baptist and Novant Health):

> *"Both applicants and/or related entities provide acute care bed services in the service area of Forsyth County; and each has over 45% of the beds in Forsyth County. Therefore, regarding this comparative factor, both applicants are equally effective alternatives." See Findings, p. 61*

Likewise, Rex, WakeMed and DUHS all provide acute care services in the Wake County service area. None of these three systems qualify as a new or alternative provider of acute care services in Wake County. In addition, Rex has documented in its applications the negative impact not having sufficient bed capacity has on patients that are seeking admission at its facilities, including extensive delays waiting for bed placement and the necessity of turning away some patients for inpatient admission because of the lack of bed capacity. Without sufficient bed capacity, Rex's ability to accommodate the growing number of patients who not only **choose** Rex facilities and physicians for their care but also require the acuity level offered by Rex continues to be restricted. Clearly, the most effective choice to enhance competition for all acute care patients, including tertiary patients that cannot be served by either DUHS' or WakeMed's proposed projects, more capacity is needed at UNC Health Rex Hospital. Further, as discussed in the UNC Health Rex Holly Springs Hospital application, the need for community hospital beds is greatest in the southern part of Wake County where growth is greatest. Therefore, with regard to competition, the applications submitted by Rex to add 36 acute care beds at UNC Health Rex Hospital and nine acute care beds at UNC Health Rex Holly Springs Hospital are the more effective alternatives with regard to this factor.

Access by Underserved Groups

The following table shows projected acute care bed percentages provided to Self Pay/Indigent/Charity Care, Medicare, and Medicaid recipients in the third project year following completion of the project, based on the information provided in Section L.3(a) of each application discussed in these comments.

Self Pay/Indigent/Charity, Medicare, and Medicaid Patient Days – Project Year 3

Applicant	*Self Pay/ Indigent/Charity as % of Total*	*Medicare % of Total*	*Medicaid % of Total*	*Total*
UNC Health Rex Hospital	3.4%	58.3%	10.3%	72.0%
UNC Health Rex Holly Springs Hospital	2.6%	57.9%	9.5%	70.0%
WakeMed Garner Hospital	7.1%	45.2%	17.7%	70.1%
Duke Raleigh Hospital	5.8%	60.1%	8.8%	74.7%

Source: Section L.3(a) of the respective applications.

On page 84, DUHS states that the projected Medicare payor mix for acute care beds is based on the FY 2022 payor mix and adjusted 3.2% to reflect the anticipated aging of the population; if such a change impacts the percentage of Medicare patients, it is likely to impact all applicants, not just DUHS. Further, given the analysis above, all four applicants project to serve 70 to 75 percent of patients that are Self Pay/Indigent/Charity Care, Medicare, or Medicaid recipients. Rex also notes that the services proposed by the various applicants are significantly different, particularly as UNC Health Rex Hospital is the only tertiary care provider among the applicants. If the Agency believes a comparison is of value, it appears that all four applications are equally effective.

Projected Average Revenue per Case

The following table shows the projected gross revenue per patient day in the third year of operation based on the information provided in each applicant's pro forma financial statements (Form F.2).

Applicant	*Patient Days*	*Gross Revenue*	*Average Gross Revenue Per Day*
WakeMed Garner Hospital	8,637	$127,319,698	$14,741
Duke Raleigh Hospital	60,796	$594,905,602	$9,785
UNC Rex Holly Springs Hospital	4,277	$29,541,611	$6,907
UNC Health Rex Hospital	141,863	$258,600,396	$1,822

Source: Forms C and F.2 of the respective applications.

As shown above, UNC Health Rex Hospital projects the lowest gross revenue per patient day in the third operating year and is the most effective alternative. UNC Health Rex Holly Springs Hospital has the second lowest average gross revenue per patient day and is more effective than the other two alternatives.

The following table shows the projected net revenue per patient day in the third year of operation based on the information provided in each applicant's pro forma financial statements (Form F.2).

Applicant	*Patient Days*	*Net Revenue*	*Average Net Revenue Per Day*
WakeMed Garner Hospital	8,637	$38,508,532	$4,458
Duke Raleigh Hospital	60,796	$181,882,640	$2,991
UNC Health Rex Holly Springs Hospital	4,277	$9,630,154	$2,252
UNC Health Rex Hospital	141,863	$84,577,799	$596

Source: Forms C and F.2 of the respective applications.

As shown above, UNC Health Rex Hospital projects the lowest net revenue per patient in the third operating year and is the most effective. UNC Health Rex Holly Springs Hospital has the second lowest average net revenue per patient day and is more effective than the other two applications.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per patient day in the third year of operation for each of the applicants, based on the information provided in applicants' pro forma financial statements (Form F.3).

Applicant	*Patient Days*	*Operating Expenses*	*Average Op Expense Per Day*
UNC Health Rex Hospital	141,863	$183,809,070	$1,295
WakeMed Garner Hospital	8,637	$25,847,201	$2,993
UNC Health Rex Holly Springs Hospital	4,277	$13,965,702	$3,265
Duke Raleigh Hospital	60,796	$260,610,772	$4,287

Source: Forms C and F.3 of the respective applications.

As shown above, UNC Rex Hospital projects the lowest operating expense per patient in the third operating year and is the most effective alternative. Among the community (non-tertiary) providers, UNC Health Rex Holly Springs Hospital is the second most effective alternative.

Summary of Comparative Analysis – Acute Care Beds

The following table summarizes the comparative analysis for acute care beds.

Comparative Factor	*UNC Health Rex Hospital*	*UNC Health Rex Holly Springs Hospital*	*Duke Raleigh Hospital*	*WakeMed Garner Hospital*
Conformity with Review Criteria	Yes	Yes	No	No
Geographic Accessibility	Effective	More Effective	Less Effective, But Not Approvable	More Effective, But Not Approvable
Provider Support	Equally Effective	Equally Effective	Equally Effective, But Not Approvable	Less Effective
Competition (Patient Access to a new provider)	More Effective	More Effective	Not Approvable	Less Effective
Access by Underserved Groups	Equally Effective	Equally Effective	Equally Effective, But Not Approvable	Equally Effective, But Not Approvable
Average Net Revenue per Day	Most Effective	Effective	Less Effective	Less Effective
Average Expense per Day	Most Effective	Effective	Less Effective	Effective

To summarize the comparative reviews for ORs and for acute care beds, Rex believes that its three complementary applications are clearly the most effective alternatives for two additional operating rooms and 45 acute care beds needed in Wake County. They are also fully conforming to all applicable statutory and regulatory review criteria and comparatively superior on the relevant factors in this review. As such, the three proposals by Rex should be approved.

Please note that in no way does Rex intend for these comments to change or amend its three applications filed on August 15, 2022. If the Agency considers any of these comments to be amending Rex's applications, those responses should not be considered.

Attachment A

Acute Care Committee Agency Report
Adjusted Need Petition
for the Wake Operating Room Service Area
in the 2022 State Medical Facilities Plan

Petitioner:
Rex Hospital, Inc.
4420 Lake Boone Trail
Raleigh, North Carolina 27607

Contact:
Elizabeth Runyon
UNC HCS, Hendrick Building
211 Friday Center Drive, Suite G104
Chapel Hill, North Carolina 27517
(919)215-3622
Elizabeth.runyon@unchealth.unc.edu

Request:
Rex Hospital, Inc. (UNC Rex) requests a special need determination for six ORs specifically designated for existing licensed acute care hospitals in the Wake County service area in the *2022 State Medical Facilities Plan* (*SMFP* or *"Plan"*).

Background Information:
Chapter Two of the *SMFP* provides that "[a]nyone who finds that the *North Carolina State Medical Facilities Plan* policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections." The annual planning process and timeline allow for submission of petitions requesting adjustments to need projections during the comment period for the proposed SMFP in the summer. This includes petitions for adjustments based on a belief that "unique or special attributes of a particular geographic area or institution give rise to resource requirements that differ from those provided by application of the standard planning procedures and policies…." It should be noted that any person may submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the Petitioner would be the approved applicant.

The current OR need determination methodology was enacted within the *2018 SMFP*. The previous methodology calculated need determinations using service area-level data. The current methodology utilizes facility-level data to project need. It calculates service area need determinations by first subtracting each facility's adjusted planning inventory from its projected number of ORs required to determine the facility's surplus or deficit. Next, the deficits and

surpluses of each facility within the system are totaled to obtain the projected number of ORs for the health system. Each health system's total is rounded according to the number of ORs in the health system. Finally, all health system deficits are added together, and placeholders for need determinations from previous Plans are deducted to arrive at the service area need. None of the methodology's calculations were adjusted to account for potential impacts on OR utilization during 2020 caused by the COVID-19 pandemic.

The Wake County service area has four hospitals: Duke Raleigh, operated by Duke University Health System; Rex Hospital, operated by UNC Health; WakeMed Hospital and WakeMed Cary Hospital, both operated by WakeMed Health & Hospitals. These hospitals operate 82 of 114 total licensed ORs in the service area. The *2021 SMFP* showed a need determination for 3 ORs in Wake County. According to the OR need determination methodology in the *Proposed 2022 SMFP*, there is not a projected need for ORs in Wake County.

Analysis/Implications:
According to the Petitioner, the practice of shifting outpatient surgical cases to ambulatory surgical center (AMSU) settings in Wake County has resulted in higher concentrations of complex outpatient cases at hospitals, and consequently, highly utilized ORs. The Petitioner states that while OR utilization in hospitals has been responsible for creating need determinations in Wake County, the CON review process usually favors AMSUs over hospitals, partly because of their lower cost. Since the new methodology was first used in the *2018 SMFP*, there have been need determinations for a total of 11 ORs in Wake County. Each OR was initially awarded to AMSUs, although two ORs were later awarded to UNC Rex in a settlement agreement. UNC Rex licensed these two ORs in March 2021.

Agency staff examined the total case times reported by hospitals and AMSUs in the service area for the 2016 through 2019 data reporting years. As shown in Table 1, based on the median of average reported case times, even as AMSUs experienced slight increases, ambulatory case times have increased at a greater rate in hospitals. The Agency has no data on the acuity or complexity of cases, although it is logical that higher acuity/complexity cases would be performed at hospitals.

Table 1. Wake County ORs, Median of Average Reported Case Times, Data Years 2016 – 2019*

Facility Type	Surgical Type	2016	2017	2018	2019	% change	CAGR
AMSUs	Ambulatory	73.0	71.6	73.8	74.0	1.4	0.4
Hospitals	Inpatient	172.8	185.7	188.9	188.0	8.5	2.8
	Ambulatory	116.0	115.3	128.2	129.2	11.3	3.6

**Includes four AMSUs that operated for the entire period of 2016-2019.*

The OR need methodology projects need under the assumption that the average OR will be staffed at least 75% of its available time. On this basis, the methodology calculates a number of "Standard Operating Room Hours Per OR" for each facility according to the facility's type. In light of the potential impacts of the COVID pandemic on OR utilization, Agency staff examined 2019 total adjusted surgical hours based on surgical case times reported on Wake County's 2020 Hospital

LRAs. Table 2 shows that Wake County hospitals overall are approaching the 75% utilization threshold. In particular, Duke Raleigh, Rex and WakeMed's operating room hours either exceeded or approached the thresholds for their facility types.

Table 2. Wake County Hospitals' OR Utilization, Data Year 2019

Hospital	Number of Licensed ORs	Total Operating Room Hours	Operating Room Hours Per OR	Standard Operating Room Hours Per OR (75% Utilization)	% Total OR Hours of Standard Hours per OR
Duke Raleigh	15	29,103	1,940	1,755	111%
Rex	28	52,686	1,882	1,950	96%
WakeMed	28	49,129	1,755	1,950	90%
WakeMed Cary	11	9,372	852	1,500	57%
TOTALS	**82**	**140,290**	**6,428**	**7,155**	**90%**

Source: *2021 SMFP*

Despite WakeMed Cary's relatively low utilization rate in FY 2019, its pre-COVID utilization trends indicate strong growth in OR utilization (Table 3). OR utilization growth in Wake's hospitals overall mirrors the population growth rate of the Wake County service area (CAGR = 1.9%).

Table 3. Wake County Hospitals' Total OR Hours per OR, Data Years 2016 – 2019

Hospital	FY 2016	FY 2017	FY 2018	FY 2019	CAGR
Duke Raleigh	2,343	2,321	1,818	1,940	-6.0%
Rex	1,552	1,670	1,894	1,882	6.6%
WakeMed	1,696	1,572	1,711	1,755	1.1%
WakeMed Cary	636	754	841	852	10.2%
TOTALS	**6,227**	**6,317**	**6,264**	**6,428**	**1.1%**

Source: *2021 SMFP*

The Petitioner asserts that a need adjustment for six ORs in Wake County is appropriate because of the outcomes of the need methodology calculation in the *2021 SMFP*. As a point of clarification to assertions made in the Petition, the *2021 SMFP* did not reflect a need for six additional ORs. Rather, it indicated a *deficit* of six ORs, based on utilization. The deficit was driven by a 1.86 OR deficit the Duke University Health System, a 4.17 OR deficit in UNC Health and a 0.27 OR deficit at an AMSU. The calculated deficit was offset by a prior need determination of three ORs in the *2020 SMFP*, leading to a need determination for three ORs in the *2021 SMFP*. Also, in the *2021 SMFP*, OR surpluses were calculated for WakeMed facilities (1.50 ORs) and for almost all the AMSU facilities unaffiliated with a health system. However, as noted above, the methodology only accounts for deficits when determining a service area's need.

Agency staff reviewed the OR deficits and surpluses of Wake County's hospitals since the implementation of the current OR need determination methodology. On average, these hospitals have experienced a deficit of 2.30 ORs (Table 4).

Table 4. Wake Hospital OR Surpluses and Deficits, 2018 -2021 SMFPs*

	2018 SMFP	2019 SMFP	2020 SMFP	2021 SMFP	Average OR Deficit (+) /Surplus (-)
Duke Raleigh Hospital	6.77	6.56	1.86	2.86	4.51
Rex Hospital	3.95	5.93	5.50	2.11	4.37
WakeMed	3.47	1.53	4.66	5.14	3.70
WakeMed Cary Hospital	-3.93	-2.99	-3.30	-3.27	-3.37
				Group Mean	**2.30**

*Corresponds to Data Years 2017 - 2019

Agency Recommendation:

UNC Health requests a need determination for six ORs in the Wake County service area designated specifically for existing licensed hospitals. The impetus for this Petition is a trend of CONs for ORs being awarded to AMSU facilities despite high utilization in hospitals. A review of Wake County hospital and AMSU OR data suggests that hospital ORs may be experiencing growth in utilization due to a higher concentration of more complex ambulatory surgical cases. The Agency does not support specifically designating OR need determinations for a particular type of facility. Thus, given available information and comments submitted by the August 11, 2021 deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition to include a need determination for six ORs to be designated for existing licensed hospitals in the Wake County service area. Rather, the Agency recommends adding a need determination for two ORs in the Wake County service area in the *2022 SMFP*.

Attachment B

Duke LIFEPOINT HEALTHCARE

go

HOME | ABOUT US | WHY PARTNER? | OUR LOCATIONS | CONTACT US

Home > About Us

- Our Vision
- Quality Initiative

About Us

An Unparalleled Partner

Duke LifePoint Healthcare is a joint venture of Duke University Health System, one of the country's leading academic health systems, and LifePoint Health, a leading healthcare company dedicated to Making Communities Healthier. We joined forces because we share an interest in collaborating with hospitals, healthcare providers and patients to bring high quality, innovative healthcare services to communities.

Duke LifePoint combines Duke's unparalleled expertise in clinical excellence and quality care with LifePoint's extensive resources and knowledge and experience operating community hospitals and healthcare organizations.

We are working to strengthen and improve healthcare delivery. Together, we are making communities healthier.

330 Seven Springs Way
Brentwood, TN 37027

Attachment C

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center • Raleigh, North Carolina 27699-2704
http://www.ncdhhs.gov/dhsr/

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

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Phone: (919) 855-3873
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March 16, 2012

Terrill Johnson Harris
Smith, Moore, Leatherwood, LLP
300 N. Greene Street
Suite 1400
Greensboro, NC 27401

RE: Exempt from Review / Acquisition of Southern Eye Associates Ophthalmic Surgery Center by WakeMed / Wake County
FID #: 943462

Dear Ms. Harris:

In response to your letter of March 8, 2012, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(8). Therefore, WakeMed may proceed to acquire the above referenced health service facility without first obtaining a certificate of need. However, you need to contact the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation to obtain instructions for changing ownership of the existing facility. Note that pursuant to N.C.G.S. §131E-181(b): "*A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.*"

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Michael J. McKillip
Project Analyst

Craig R. Smith, Chief
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR

mike

SMITH MOORE LEATHERWOOD

March 8, 2012

Mr. Craig R. Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Notice of Exempt Acquisition by WakeMed of Southern Eye Associates Ophthalmic Surgery Center, Wake County

Dear Mr. Smith:

This letter provides prior written notice that WakeMed plans to acquire from Southern Eye Associates, P.A. the existing, licensed ambulatory surgical facility in operation under the name Southern Eye Associates Ophthalmic Surgery Center at 2801 Blue Ridge Road, Suite 200, Raleigh, North Carolina, and all equipment associated with the ambulatory surgical facility.

The acquisition of "an existing health service facility, including equipment owned by the health service facility at the time of acquisition" is exempt from certificate of need review. N.C. Gen. Stat. § 131E-184(a)(8). As you know, "health service facility" is defined to include an "ambulatory surgical facility." N.C. Gen. Stat. § 131E-176(9b).

Please confirm that WakeMed's acquisition of Southern Eye Associates Ophthalmic Surgery Center is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(8). We look forward to receiving your confirmation as soon as possible. Please let us know if you have any questions or need additional information.

With kindest regards, I am

Very truly yours,

SMITH MOORE LEATHERWOOD LLP

Terri Harris

Terrill Johnson Harris

cc: W. Stan Taylor, WakeMed

WakeMed Acq Southern Eye Assoc Ex 12

Attachment D

Acute Care Committee Agency Report
Adjusted Need Petition
for the Nash County Operating Room Service Area
in the 2023 State Medical Facilities Plan

Petitioner:
Carolina Vascular Care, PLLC
PO Box 1276
Morrisville, NC 27560

Contact:
Karn Gupta, MD
guptakarn@gmail.com
(252) 220-5470

Request:
Carolina Vascular Care requests a special need determination for one a single specialty ambulatory surgical center (ASC) with one operating room (OR) dedicated to vascular access (VA) in the Nash County service area in the *2023 State Medical Facilities Plan* (*SMFP*).

Background Information:
Chapter Two of the SMFP notes that during the summer, the Agency accepts petitions that "involve requests for adjustments to need determinations in the Proposed SMFP. Petitioners may submit a written petition requesting an adjustment to the need determination in the Proposed SMFP if they believe that special attributes of a service area or institution give rise to resource requirements that differ from those provided by the standard methodologies and policies." It should be noted that any person might submit a certificate of need (CON) application for a need determination in the SMFP. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

The methodology uses growth in surgical procedures at a facility and service area population to determine needs. The Petitioner is correct that the Nash County service area is not likely to have a standard OR need determination in the foreseeable future due to both a stable population and the lack of substantial growth in procedures performed in Nash County. The only ORs in the service area are at Nash General Hospital, which has 13 shared ORs and one dedicated C-Section OR. The hospital has a surplus of 5.21 ORs in the Proposed 2023 SMFP. Even though the Petitioner proposes to locate in Nash County, they intend to serve a larger area. The Petition specifically mentions Edgecombe, Halifax, Northampton and Wilson, in addition to Nash. Taken together, these four service areas have a surplus of 23.39 ORs. (Halifax and Northampton comprise a multicounty service area because Northampton has no licensed ORs.)

The SHCC first received a petition regarding VA centers in 2017 with a request to exclude VA ASCs from the methodology; the petition was denied. The same petitioners submitted a summer petition in 2017 for a demonstration project. The petition proposed two centers in each of the six health service areas (HSA) (see Appendix A of the SMFP for a listing of HSAs). The decline in reimbursement for VA procedures performed in physician-office-based laboratories (OBL) was a major basis for the petition. The petitioners argued that ASCs were the only viable option for continued non-hospital VA care. Based on the data available at that time, it did not appear that the number of patients could support 12 VA centers. Additionally, the SHCC opined that the appropriateness and efficacy of providing VA procedures in an outpatient setting was not in question, and thus did not need to be demonstrated. The SHCC received a third petition in 2018 requesting an adjusted need determination for one VA ASC in the Pitt/Greene/Hyde/Tyrrell service area. The petitioner again cited reductions in OBL reimbursement as a basis for the request. The Agency observed that reimbursements were in flux and it was unclear that rates were consistently being reduced in OBLs. The SHCC denied the petition and recommended that those interested in developing VA centers apply for ORs based on standard need determinations.

Certificates of need were subsequently issued to two VA ASCs in response to need determinations in the 2018 SMFP. Metrolina Vascular Access Care in Mecklenburg County was licensed on April 29, 2022. RAC Surgery Center in Wake County was licensed on March 19, 2021. Each ASC has one OR. Neither facility has been in operation long enough to provide a full year of data.

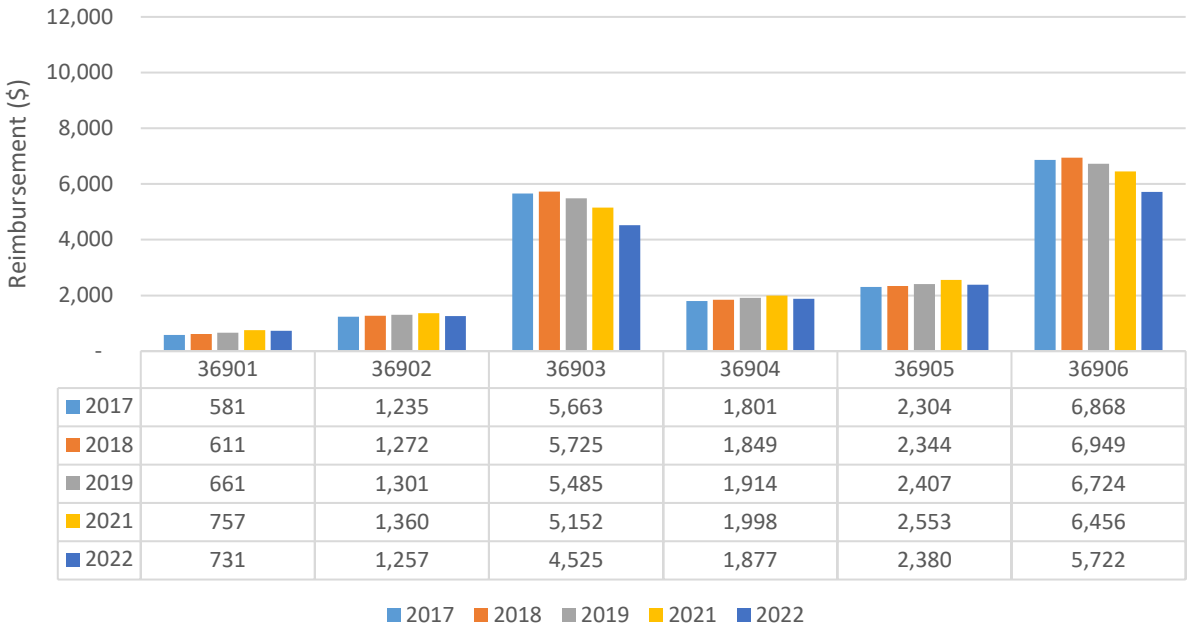
Analysis/Implications:
Like previous petitions, the current Petition cites reductions OBL reimbursements as a main motivation for the request. These changes began in 2017 when the Centers for Medicare and Medicaid Services (CMS) established requirements for procedures billed together more than 75% of the time to be bundled. As a result, commonly performed VA procedures experienced significant Medicare reimbursement cuts.[1] With these reductions have come increases in reimbursement for VA procedures at ASCs. These changes, however, were not consistent.

Figures 1 and 2 show changes in annual OBL reimbursement rates since 2017.[2] Rates for 2020 were not readily available. The first row of numbers below each chart shows the Healthcare Common Procedure Coding System (HCPCS) codes. The remaining rows are reported to be global national reimbursement rates for each procedure for each year. OBL reimbursement rates have remained relatively stable for most procedures. However, rates for the codes with the highest reimbursements, 36903 and 36906, have decreased by 20% and 17%, respectively. In contrast, rates for all ASC procedures except 36901 have fluctuated over this same time period. ASC reimbursement for 36903 and 36906 increased 39% and 16%, respectively.

[1] McGuireWoods (August 23, 2018). Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers. Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers | McGuireWoods (accessed August 7, 2022).

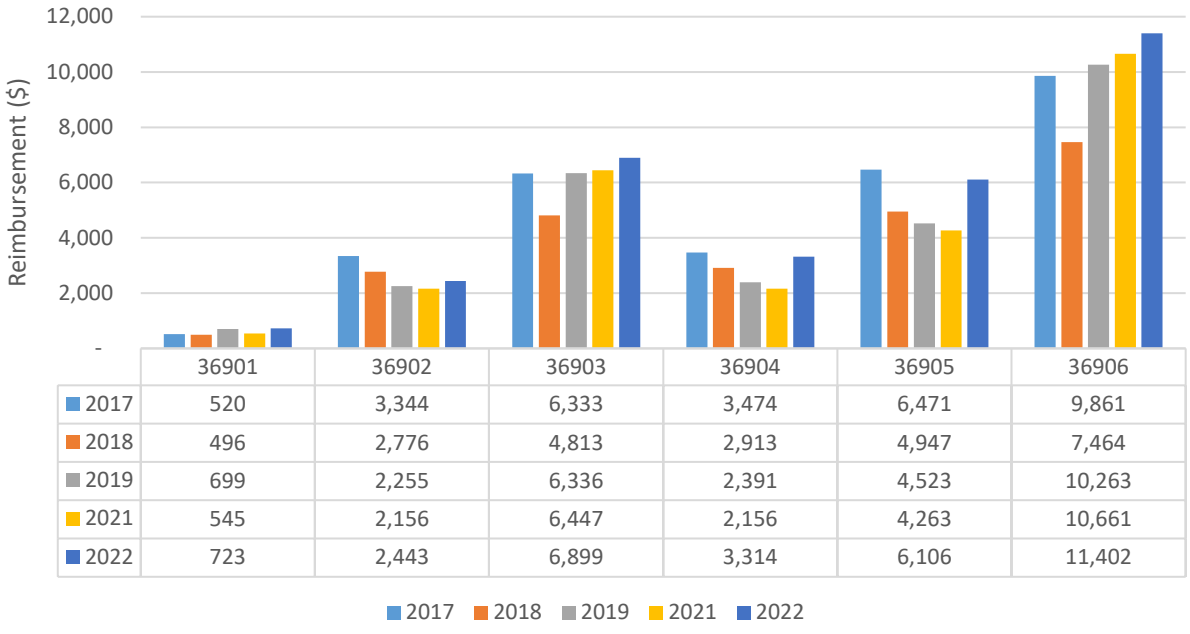
[2] *2017 and 2018 rates:* McGuireWoods (August 23, 2018). Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers. Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers | McGuireWoods (accessed August 7, 2022). *2019 rates:* Litchfield, Terry (June 2019). Dialysis Access Coding Essentials, Recent Changes and Location Distinctions. *Endovascular Today* (18:6). Dialysis Access Coding Essentials, Recent Changes, and Location Distinctions - Endovascular Today (evtoday.com) (accessed August 7, 2022). *2021 rates:* Greis, Jason S., Downing, Scott O., & Cilek, Jake A. (August 2021). CMS Proposes Steep Cuts to Office-Based Dialysis Vascular Access Reimbursement …Again! Bensch Healthcare+:Health Care & Life Sciences Client Bulletin. (accessed August 7, 2022). *2022 rates:* Petition.

Figure 1. OBL Reimbursement



	36901	36902	36903	36904	36905	36906
2017	581	1,235	5,663	1,801	2,304	6,868
2018	611	1,272	5,725	1,849	2,344	6,949
2019	661	1,301	5,485	1,914	2,407	6,724
2021	757	1,360	5,152	1,998	2,553	6,456
2022	731	1,257	4,525	1,877	2,380	5,722

Figure 2. ASC Reimbursement



	36901	36902	36903	36904	36905	36906
2017	520	3,344	6,333	3,474	6,471	9,861
2018	496	2,776	4,813	2,913	4,947	7,464
2019	699	2,255	6,336	2,391	4,523	10,263
2021	545	2,156	6,447	2,156	4,263	10,661
2022	723	2,443	6,899	3,314	6,106	11,402

HCPCS	Description
36901	Angiogram of Access (Fistulagram)
36902	Angiogram with Angioplasty
36903	Angiogram with Stent

HCPCS	Description
36904	Thrombectomy
36905	Thrombectomy with Angioplasty
36906	Thrombectomy with Stent

Litchfield (2019)[3] noted that

> The cut in the physician office payment was a combination of items, but the primary driver was the time for the procedure, which was significantly less than in the older codes. When the new codes came into the physician office fee schedule, it reflected that new value for the new codes. The valuation method for the ambulatory surgery center (ASC) and hospital outpatient department (HOPD) is different from that for the Physician Fee Schedule. For the HOPD, the procedures are assigned ambulatory payment classifications that are groupings of similar codes for endovascular procedures. The ASC payment is cross walked from the HOPD rate and discounted. This valuation methodology difference is why the new codes are paid very differently, and the rate increase is consistent with CMS methodology. Despite some concerns about growing utilization, this was not a signal from CMS to create ASCs nor was it a penalty for physician office surgery centers, but merely the way CMS prices new code.

Regardless of the rationale for the changes in reimbursement, the changes have, in fact, occurred. Many segments of medical care have experienced reductions in CMS reimbursement rates. It is unknown whether OBL VA procedures have received comparatively steeper reductions.

Anecdotal information claims that OBLs can no longer afford to operate. The American Society of Diagnostic and Interventional Nephrology (ASDIN) reported that nearly 20% of OBLs closed as a result of the 2017 rate reductions.[4] The Agency attempted to verify this data but could not do so. The 20% figure appears to be based on a survey of ASDIN members. It is unknown what proportion of OBLs in the country are represented in the ASDIN membership. It is also unknown what proportion of survey recipients responded to the survey. The Agency could not locate more recent data on subsequent closures.

The Agency acknowledges that access to VA services is needed throughout the state. Health Service Areas II through VI have about 3,400 dialysis patients residing in each HSA, while HSA I has about 2,000 patients.

The Agency also acknowledges that that OBLs may be at continued financial risk. However, the Agency does not recommend approval of a dedicated VA OR in Nash County in the absence of evidence of a need. Specifically, the SMFP does not have a need determination methodology for ASCs. Rather, need determinations in the SMFP are for ORs. CON applications specify the location of the proposed ORs (hospitals or ASC). The Petition does not indicate that Petitioner discussed access to VA services with any of the providers in the service areas they propose to serve, all of which have a surplus of ORs. We note that such a discussion does not necessarily imply that services would be provided in the manner that VA patients are currently normally seen in a hospital. Rather, a hospital may consider relocating an OR to an ASC in partnership with the Petitioner.

In considering alternatives to the Petitioner's request, the Agency investigated the potential utilization of dedicated VA ORs. In CY 2021, dialysis providers reported serving 19,302 patients. If we assume that each patient will need two VA procedures annually, NC patients will need a

[3] Litchfield, Terry. June 2019. Dialysis Access Coding Essentials, Recent Changes, and Location Distinctions. *Endovascular Today*. 18:6.
[4] Litchfield, 2019.

total of 38,604 procedures. This number of procedures calculates to 19,302 surgical hours, based on RAC Surgery Center's reported average case time of 30 minutes. The SMFP methodology anticipates that the average OR will be staffed and utilized at least 75% of the available time, for a total of 1,312 hours annually. Using this standard, it is possible that the state could potentially support 15 VA ORs (19,302/1,312 = 14.71), if **all** procedures were performed in dedicated VA ORs. This situation is highly unlikely, though, because there will always be areas where a hospital or OBL is the best or perhaps only reasonably accessible option.

Agency Recommendation:
Given available information and comments submitted by the August 11, 2021 deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition to include a need determination for one VA ASC in Nash County in the *2023 SMFP*.

As an alternative to the submission of *ad hoc* petitions for VA ORs in specific service areas, the Agency recommends consideration of the following:

- Approval of one dedicated ambulatory VA OR in each of the six HSAs in the state, for a total of six VA ORs. VA ORs proposed pursuant to this need determination cannot be located in either Mecklenburg or Wake counties in light of the fact that there is a dedicated VA ASC with one OR in each of these counties. The VA OR can be located at an existing ASC, a proposed ASC, or on a hospital campus. If the OR is to be located at a hospital, it must be a dedicated ambulatory OR (i.e., in a hospital outpatient surgery department [HOPD]); and
- The VA ORs will be limited to serving dialysis patients; and
- CON-approved VA ORs and their procedures will be included in the standard OR planning inventory and methodology.