COMPETITIVE COMMENTS ON WAKE COUNTY

2020 WAKE COUNTY OR NEED DETERMINATION

SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

Duke University Health System, Inc. (DUHS) submitted two CON applications pursuant to the 2020 SMFP need determination for three additional ORs in Wake County: CON Project ID# J-011966-20 Duke Health Garner Ambulatory Surgical Center (Duke Health Garner ASC) and J-011967-20 Green Level Ambulatory Surgical Center (Duke Health Green Level ASC). Four additional applications were submitted in response to the need determination:

These comments are submitted by DUHS in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the applications, including a comparative analysis and a discussion of the most significant issues regarding the applicants' conformity with the statutory and regulatory review criteria ("the Criteria") in N.C. Gen. Stat. §131E-183(a) and (b). Other non-conformities in the competing applications may exist.

COMPARATIVE COMMENTS

The Healthcare Planning and Certificate of Need Section developed a list of suggested comparative factors for competitive batch reviews. The following factors are suggested for all reviews regardless of type of services or equipment proposed:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Access by Underserved Groups: Charity Care

- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per Case
- Projected Average Total Operating Cost per Case
- Patient Access to Lower Cost Surgical Services
- Multispecialty versus Specialty (ASFs only)

The following summarizes the competing applications relative to the suggested comparative factors.

Conformity to CON Review Criteria

Six CON applications have been submitted seeking to develop ORs in Wake County. The applicants each propose to develop one or two ORs. Based on the 2020 SMFP's need determination, only three ORs can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the applications submitted by DUHS demonstrate conformity to all Criteria:

Conformity of Applicants

Applicant	Project I.D.	Conforming/ Non-Conforming
WakeMed Cary Hospital	J-011960-20	No
Valleygate Surgery Center	J-011961-20	No
Orthopaedic Surgery Center of Garner	J-011962-20	No
Rex Hospital	J-011963-20	No
Duke Health Garner ASC	J-011966-20	**Yes**
Duke Health Green Level ASC	J-011967-20	**Yes**

The DUHS applications are based on reasonable and supported volume projections and adequate projections of cost and revenues. As discussed below, the competing applications contain errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the DUHS applications are the most effective alternatives on conformity with the Criteria.

Scope of Services

Historically the Agency has considered the application proposing to provide the greatest scope of services is the more effective alternative regarding this comparative factor. However, this comparison is only relevant between the same kinds of facilities, that is, between hospitals, or between ambulatory surgery facilities. As between the competing ASC applications, Duke Health Green Level ASC and Duke Health Garner ASC are more effective with respect to scope of services, i.e., surgical specialties.

The following table shows each applicant's projected scope of services (surgical specialties) to be provided at the proposed facilities. Generally, the application proposing to provide the greatest scope of services is the more effective alternative regarding this comparative factor.

Facility Type:	**ASC**	**ASC**	**ASC**	**ASC**
Surgical Specialty	**Duke Health Green Level ASC**	**Duke Health Garner ASC**	**OSCG**	**Valleygate**
Cardiothoracic				
Cardiovascular				
Gastroenterology				
General Surgery	X	X		
Gynecology	X	X		
Obstetrics				
Open Heart				
Ophthalmology	X	X		X
Oral Surgery				X
Orthopedic	X	X	X	
Otolaryngology	X	X		X
Neurology/Spine	X			
Pain Management				
Pediatrics				
Plastic Surgery	X	X		X
Podiatry	X			
Pulmonary				
Thoracic				
Urology	X	X		
Vascular	X			

DUHS notes that even though Valleygate proposes a "multispecialty" ASC, its focus is still narrow, limited to dental and related head and neck procedures. Therefore, the two DUHS facilities are the only

comprehensive multispecialty ASC proposals. In a service area that already has a plethora of single specialty or narrowly focused ASCs, especially orthopedic-focused facilities, the DUHS facilities therefore better serve the needs of the patient population as a whole.

Historical Utilization

WakeMed Cary and UNC Rex each provided surgical services in Wake County during FFY2019. While Duke Health Green Level ASC and Duke Health Garner ASC are not existing health service facilities (Duke Health Green Level ASC is approved but not developed), Duke Raleigh Hospital (DRAH) provided surgical services in Wake County during FFY2019. Similarly, OSCG is wholly owned by Rex Orthopedic Ventures, LLC which is wholly owned by Rex Healthcare, Inc., which is the parent of Rex Hospital, Inc.

The following table illustrates historical utilization of the respective providers/applicants as provided in the Proposed 2021 SMFP representing FY2019 reported utilization.

Applicants Providing Wake County Surgical Services
Proposed 2021 SMFP Based on FY2019 Data

Provider	IP Cases	OP Cases	Total Adjusted Estimated Surgical Hours	Standard Hours per OR / Year	ORs Required Based on Surgical Hours	Adjusted Planning Inventory	OR Deficit/ (Surplus)
Duke Raleigh Hospital	3,568	7,415	29,103	1,755	16.6	15	1.6
UNC Rex Hospital	8,334	11,942	52,686	1,950	27.0	24	3.0
WakeMed Cary Hospital	3,142	3,740	9,372	1,950	4.8	10	-5.2

Source: 2021 Proposed SMFP, Table 6A & 6B

DUHS and UNC Rex each demonstrate need for additional OR capacity based solely on FY2019 surgical utilization. WakeMed Cary demonstrates a surplus of over 5 ORs based on its FY2019 surgical utilization. Valleygate does not have a history providing surgical services to Wake County patients.

Geographic Accessibility

The following table identifies the existing and approved Wake County operating rooms by location, facility name, and type of operating room.

Existing and Approved Wake County Operating Rooms

Location	Facility	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjust-ments	Total ORs
Holly Springs	Rex Hospital Holly Springs	0	0	0	0	3	**3**
Holly Springs	Holly Springs Surgery Center	0	0	0	0	3	**3**
Cary/Apex	Duke Health Green Level ASC	0	0	0	0	1	**1**
Cary	Rex Surgery Center of Cary	0	4	0	0	0	**4**
Cary	Raleigh Ortho Surgery-West Cary	0	0	0	0	1	**1**
Cary	WakeMed Cary Hospital	2	0	9	-2	1	**10**
Cary	WakeMed Surgery Center-Cary	0	0	0	0	1	**1**
Raleigh	Rex Hospital	3	0	24	-3	-2	**24**
Raleigh	RAC Surgery Center	0	0	0	0	1	**1**
Raleigh	Raleigh Orthopedic Surgery Center	0	4	0	0	-1	**3**
Raleigh	Capital City Surgery Center	0	8	0	0	-1	**7**
Raleigh	WakeMed	7	0	16	-5	-1	**15**
Raleigh	Blue Ridge Surgery Center	0	6	0	0	0	**6**
Raleigh	Raleigh Plastic Surgery Center	0	1	0	0	0	**1**
Raleigh	Triangle Ortho Surgery Center	0	2	0	0	1	**3**
Raleigh	Duke Raleigh Hospital	0	0	15	0	0	**15**
Raleigh	Surgical Center for Dental Prof.	0	0	0	0	2	**2**
North Raleigh	WakeMed North Hospital	1	0	4	-1	0	**4**
North Raleigh	Rex Surgery Center of Wakefield	0	0	0	0	2	**2**
North Raleigh	WakeMed Surgery Center-N. Raleigh	0	0	0	0	1	**1**
North Raleigh	OrthoNC Ambulatory Surgery Center	0	0	0	0	1	**1**
North Raleigh	Wake Spine & Specialty Surgery Ctr.	0	0	0	0	1	**1**

*Includes ambulatory surgery facilities and ORs that were approved pursuant to the need determination for two additional operating rooms in the 2019 SMFP. Also includes one operating room to be relocated from Capital City Surgery Center to WakeMed Surgery Center-North Raleigh.

As the previous table shows, the existing and approved Wake County operating rooms are located in Raleigh, North Raleigh, Cary, and Holly Springs. The following table summarizes the number of facilities and ORs within these geographic locations.

Geographic Distribution of Wake County ORs

Location	No. of Facilities	No. of ORs
Holly Springs	2	6
Cary	5	17
Raleigh	10	77
North Raleigh	5	9
Garner	***0***	***0***

As summarized in the previous table, there are no existing or approved ORs located in Garner or southeast Wake County. Garner is the largest Wake County Municipality (by population) without local access to ORs.

Estimates of the Total Population of Wake County Municipalities for July 1, 2018, Certified Population Estimates

Municipality	Population	ORs
Raleigh	464,453	77
Cary	162,341	16
Apex	52,909	1*
Wake Forest	37,279	9
Holly Springs	34,071	6
Garner	**30,787**	**0**
Fuquay-Varina	26,936	
Morrisville	26,041	
Knightdale	15,305	
Wendell	7,132	
Rolesville	6,638	
Angier	5,213	
Zebulon	4,986	

Source: North Carolina OSBM, Certified Population Estimates, Vintage 2018
* Although the approved Duke Health Green Level ASC facility has a Cary address, the site is in fact located within the Town of Cary extra-territorial jurisdiction (ETJ) and not in the town of Cary itself. The approved location is less than one mile from Apex zip code 27523. From a practical perspective, the approved facility is most proximate to the town of Apex and not to Cary.

Three applicants propose to develop new ORs in Garner: Duke Health Garner ASC, OSCG, and Valleygate. Therefore, the respective applications of Duke Health Garner ASC, OSCG, and Valleygate are the most

effective alternatives with respect to geographic access. However, OSCG and Valleygate do not conform to all statutory review criteria and, therefore, cannot be approved. In addition, OSCG and Valleygate propose a narrow scope of services, and therefore do not expand geographic access to all patients needing ambulatory surgery services. Thus, Duke Health Garner ASC is the most effective alternative regarding improving geographic access.

Duke Health Green Level ASC will also enhance geographic access because Apex has comparatively fewer population per OR compared to Raleigh, Wake Forest and Holly Springs. UNC Rex is the least effective alternative with respect to improving geographic access to surgical services.

Access By Service Area Residents

On page 52, the 2020 SMFP states, "The SMFP contains two types of operating room service areas: single county and multicounty. Counties with at least one facility having a licensed operating room that are not grouped with another county are single county service areas." Wake County host several facilities with licensed ORs; thus, Wake County is the applicable OR service area. Facilities may also serve residents of counties not included in their service area.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

	Duke Health Green Level ASC	Duke Health Garner ASC	OSCG	UNC REX	Valleygate	WakeMed Cary
Access by Service Area Residents (# of Wake County Patients)	1,746	700	1,371	13,008	365	6,188
Access by Service Area Residents (% of Wake County Patients)	51%	51%	68%	62%	48%	70%

In the 2019 Mecklenburg OR Review, the Agency determined the "Access by Service Area Residents" factor to be of "little value." The Agency stated, "the Operating Room Need Determination in the 2019 SMFP is based on the total number of surgical hours provided to patients and not based on anything related to Mecklenburg County-specific patients." Similarly, the Wake County OR need determination is premised on the total number of surgical hours provided to patients and not based on anything related to Wake County-specific patients. Wake County is a large urban county with over one million residents, four large health systems plus other smaller healthcare groups.

For statistical purposes, the United States Office of Management and Budget (US OMB) delineates Metropolitan Statistical Areas (MSAs) when using Census Bureau data. The US Census Bureau states the following about MSAs: "The general concept of a metropolitan or micropolitan statistical area is that of a core area containing a substantial population nucleus, together with adjacent communities having a high degree of economic and social integration with that core."

Today, the Raleigh-Durham-Cary MSA is comprised of eight North Carolina counties, and as of July 1, 2018 had an estimated population of more than 2 million residents.

Considering these facts and the Agency's determination in the 2019 Mecklenburg County OR Review, DUHS believes that in this specific review, comparing the applicants based on the projected OR access of Wake County residents has little value.

Competition (Patient Access to a New or Alternative Provider)

Generally, the application proposing to increase competition in the service area is the more effective alternative regarding this comparative factor. The following table identifies the adjusted planning inventory of operating rooms for each applicant as a percent of the total existing and approved Wake County operating rooms, based on Table 6B of the Proposed 2021SMFP. Table 6B shows a total of 109 existing and approved operating rooms in Wake County, excluding the need determination for three operating rooms in the 2020 SMFP.

Applicants' Existing and Approved Wake County Operating Rooms as Percent of Total

	Adjusted OR Planning Inventory	Applicants' ORs as a Percent of Total Wake County ORs
Rex Hospital Holly Springs	3	
Rex Surgery Center of Wakefield	2	
Rex Surgery Center of Cary	4	
Rex Hospital	24	
Raleigh Orthopedic Surgery Center	3	
Raleigh Orthopedic Surgery-West Cary	1	
UNC REX Health System	37	**33.9%**
WakeMed Surgery Center-Cary	1	
Capital City Surgery Center	8	
WakeMed	22	
WakeMed Cary Hospital	10	
WakeMed Health System	41	**37.6%**
Duke Green Level Ambulatory Surgery Center	1	
Duke Raleigh Hospital	15	
Duke University Health System	16	**14.7%**

As shown in the table above, the WakeMed Health System controls 37.6 percent of the existing and approved operating rooms in Wake County, the UNC REX Health System controls 32.7 percent, and the Duke Health System controls 14.2 percent. Valleygate does not control existing or approved ORs in Wake County. Therefore, regarding increasing competition for surgical services in Wake County, the

applications submitted by DUHS and Valleygate are more effective alternatives. However, the application submitted by Valleygate does not conform to all statutory review criteria. Thus, Duke Health Green Level ASC and Duke Health Garner ASC are the most effective alternatives for this comparative.

Patient Access By Lower Cost Surgical Services

The following table identifies the existing and approved inpatient (IP), outpatient (OP) and shared inpatient/outpatient ORs in Wake County.

	Total ORs*	IP ORs	% IP of Total ORs	OP ORs**	% OP of Total ORs	Shared ORs	% Shared of Total ORs
Wake County Operating Rooms	110	3	2.7%	36	32.7%	71	64.5%

Source: 2020 SMFP
*Total operating rooms includes existing and approved operating rooms and excludes dedicated C-Section and designated trauma operating rooms.
**Includes two single-specialty demonstration project operating rooms at Triangle Orthopaedics Surgery Center.

The table below shows the percentage of total Wake County surgical cases that were ambulatory surgeries in FY2019, based on data reported in the Proposed 2021 SMFP.

Ambulatory Surgical Cases as Percent of Total Wake County Surgical Cases

Wake County Surgical Facility	Type of ORs	IP Cases	OP Cases	Total Cases	Percent Ambulatory
Blue Ridge Surgery Center	ASC	-	5,923	5,923	100%
Raleigh Plastic Surgery	ASC	-	340	340	100%
Raleigh Orthopedic Surgery	ASC	-	5,416	5,416	100%
Rex Surgery Center Wakefield	ASC	-	41	41	100%
Rex Surgery Center Cary	ASC	-	4,585	4,585	100%
Rex Hospital	Hospital Shared	8,366	12,019	20,385	59%
Capital City Surgery Center	ASC	-	6,712	6,712	100%
WakeMed	Hospital Shared	7,810	8,449	16,259	52%
WakeMed North Hospital	Hospital Shared	131	2,740	2,871	95%
WakeMed Cary Hospital	Hospital Shared	2,973	4,956	7,929	63%
Holly Springs Surgery Center	ASC	-	1,827	1,827	100%
Triangle Orthopedic Surgery	ASC	-	2,403	2,403	100%
Duke Raleigh Hospital	Hospital Shared	3,328	7,474	10,802	69%
Totals		22,608	62,885	85,493	74%

Source: 2020 SMFP, Table 6B

As the table above shows, 74% of the total Wake County surgical cases in FY2018 were performed as ambulatory surgeries. Wake County currently has fifteen existing and approved ASCs. Based on the fact that 74 percent of Wake County's FY2018 surgical cases were ambulatory surgery cases and that ASC operating rooms represent 33 percent of the total existing and approved Wake County operating rooms, projects proposing the development of ASC operating rooms would represent more effective alternatives.

Therefore, the applications submitted by Duke Health Green Level ASC, Duke Health Garner ASC, OSCG, and Valleygate are the more effective proposals with respect to this comparative factor. The WakeMed Cary Hospital and UNC Rex applications are less effective with respect to this comparative factor. Further, OSCG and Valleygate do not conform to all statutory review criteria and cannot be approved. Thus, the proposals by Duke Health Green Level ASC and Duke Health Garner ASC are the most effective alternatives.

Access By Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

"Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority."

For access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid admissions as a percentage of total patients
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total gross or net revenues
- Charity care, Medicare or Medicaid cases per OR

Which of the above metrics the Agency uses is determined by whether or not the applications included in the review provide data that can be compared as presented above and whether or not such a comparison would be of value in evaluating the alternative factors.

Projected Charity Care

The following table compares projected charity care in the third full fiscal year following project completion for all the applicants.

Provider	Duke Health Green Level ASC	Duke Health Garner ASC	OSCG	UNC REX	Valleygate	WakeMed Cary
Charity Care Surgical Cases	68	22	16	565	31	197
Charity Care Surgical Cases as a % of Total Surgical Cases	2.0%	1.6%	0.8%	2.7%	4.1%	2.2%
Charity Care Surgical Cases Per OR	23	22	8	23	31	18
Charity Care Deduction From Revenue	$440,193	$489,522	$376,433	$14,074,985	$94,371	$65,331,555
Charity Care Deduction From Revenue as a % of Total Gross Revenue	3.3%	3.3%	0.6%	2.1%	2.0%	5.9%
Charity Care Deduction From Revenue as a % of total Net Revenue	9.1%	10.1%	3.2%	6.2%	7.5%	24.5%

Due to significant differences in the types of surgical services proposed by hospitals vs ASCs which naturally serve varying patient populations by age, it is not possible to make conclusive comparisons regarding percentage of charity care access.

As among the competing ASC applications, Duke Health Green Level ASC is the most effective with respect to number of charity care surgical cases, charity care deductions from revenue, charity care deduction from revenue as a percent of total gross revenue. Duke Health Garner ASC is the most effective with respect to charity care deduction from revenue as a percent of total net revenue.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for all the applicants in the review.

Provider	Duke Health Green Level ASC	Duke Health Garner ASC	OSCG	UNC REX	Valleygate	WakeMed Cary
Medicare Surgical Cases	1,503	646	402	8,783	159	4,215
Medicare Surgical Cases as a % of Total Surgical Cases	44.0%	47.2%	19.8%	42.0%	20.9%	47.9%
Medicare Surgical Cases per OR	501	646	201	351	159	383
Medicare Gross Revenue	$6,021,378	$6,772,886	$11,966,963	$280,184,372	$985,544	$499,625,339
Medicare Gross Revenue as a Percentage of Total Gross Revenue	45.2%	45.1%	20.2%	42.0%	20.6%	45.4%
Medicare Gross Revenue per OR	$2,007,126	$6,772,886	$5,983,482	$11,207,375	$985,544	$45,420,485

Due to significant differences in the types of surgical services proposed by hospitals vs ASCs which naturally serve varying patient populations by age, it is not possible to make conclusive comparisons regarding percentage of Medicare access.

As among the competing ASC applications, Duke Health Green Level ASC is the most effective alternative with respect to number of Medicare care surgical cases and Medicare Gross Revenue as a Percentage of Total Gross Revenue. Duke Health Garner ASC is the most effective with respect to Medicare surgical cases as a percent of total surgical cases, Medicare surgical cases per OR, and Medicare Gross Revenue per OR.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants in the review.

Provider	Duke Health Green Level ASC	Duke Health Garner ASC	OSCG	UNC REX	Valleygate	WakeMed Cary
Medicaid Surgical Cases	181	48	26	816	418	332
Medicaid Surgical Cases as a % of Total Surgical Cases	5.3%	3.5%	1.3%	3.9%	55.1%	3.8%
Medicaid Surgical Cases per OR	60	48	13	33	418	30
Medicaid Gross Revenue	$1,421,010	$1,598,361	$781,140	$25,823,444	$2,597,742	$61,223,236
Medicaid Gross Revenue as a Percentage of Total Gross Revenue	10.7%	10.7%	1.3%	3.9%	54.4%	5.6%
Medicaid Gross Revenue per OR	$473,670	$1,598,361	$390,570	$1,032,938	$2,597,742	$5,565,749

Due to significant differences in the types of surgical services proposed by hospitals vs ASCs which naturally serve varying patient populations by age, it is not possible to make conclusive comparisons regarding percentage of Medicaid access.

As among the competing ASC applications, Duke Health Green Level ASC and Duke Health Garner ASC are more effective with respect to Medicaid access compared to OSCG. Valleygate projects the highest Medicaid access; however, the Valleygate application does not conform to all statutory review criteria. Therefore, as between the competing ASC applications, Duke Health Green Level ASC and Duke Health Garner ASC are the most effective alternatives.

Projected Average Net Revenue

The following table shows the projected average net surgical revenue per OR and per surgical case in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Provider	Duke Health Green Level ASC	Duke Health Garner ASC	OSCG	UNC REX	Valleygate	WakeMed Cary
Surgical Cases	3,417	1,369	2,031	20,913	759	8,802
Net Revenue	$4,833,637	$4,833,637	$11,638,953	$228,089,339	$1,263,889	$266,489,277
Net Revenue Per Surgical Case	$1,415	$3,531	$5,731	$10,907	$1,665	$30,276

As shown in the table above, Duke Health Green Level ASC projects the lowest net revenue per surgical case in the third operating year. Therefore, the application submitted Duke Health Green Level ASC is the most effective applications with respect to net revenue per surgical case.

Projected Average Operating Expense per Case

The following table compares the projected average operating expense per patient day and per admission for the third year of operation following project completion for all the applicants, based on the information provided in the applicants' pro forma financial statements (Section Q).

	Duke Health Green Level ASC	Duke Health Garner ASC	OSCG	UNC REX	Valleygate	WakeMed Cary
Surgical Cases	3,417	1,369	2,031	20,913	759	8,802
Operating Costs	$4,588,340	$3,961,399	$8,673,441	$192,639,806	$1,066,626	$193,486,744
Cost Per Surgical Case	$1,343	$2,894	$4,271	$9,211	$1,405	$21,982

As shown in the table above, Duke Health Green Level ASC projects the lowest operating expense per surgical case in the third operating year. Therefore, the application submitted Duke Health Green Level ASC is the most effective applications with respect to operating expense per surgical case.

Summary

For each of the comparative factors previously discussed, Duke Health Green Level ACS's application is determined to be the most or more effective alternative for the following factors:

- Conformity with Review Criteria
- Scope of Services
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Net Revenue per Surgical Case
- Operating Costs per Surgical Case

Duke Health Garner ACS's application is determined to be the most or more effective alternative for the following factors:

- Conformity with Review Criteria
- Scope of Services
- Geographic Accessibility (Location within the Service Area)
- Competition (Access to a New or Alternate Provider)
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare

COMMENTS SPECIFIC TO WAKEMED CARY HOSPITAL (WakeMed Cary)
PROJECT ID No. J-011960-20

General Comments

WakeMed has the greatest number of ORs in the Wake County OR service area [(10 inpatient + 29 shared = 39 ORs) + 8 ambulatory ORs (Capital City Surgery Center) = 47 ORs].[1] With this vast inventory of ORs, the 2020 SMFP projects a surplus of ORs for WakeMed. Data from Table 6B of the 2020 SMFP is provided below for reference.

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

Facility	2021 Projected OR Deficit (Surplus)
WakeMed Surgery Center-Cary	-1.00
WakeMed Surgery Center-North Raleigh	-1.00
Capital City Surgery Center	-1.37
WakeMed	5.14
WakeMed Cary	-3.27
WakeMed Total	***-1.50***

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

Criterion 1 *"The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which shall constitute a determinative limitation on the provision of any health services, health service facility, health service beds, dialysis stations, operating rooms, or home health offices that may be approved."*

POLICY GEN-3: BASIC PRINCIPLES states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

WakeMed Cary fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective

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

alternative to meet the need. See discussion regarding criteria 3, 4, 5, 6, and 18a. Therefore, the application is not conforming to this criterion and cannot be approved.

Criterion 3 *"The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed."*

WakeMed Cary does not demonstrate the need for an additional OR.

WakeMed Cary recently developed incremental surgical capacity. During FY2020, WakeMed relocated one OR from WakeMed Raleigh to WakeMed Cary, per CON Project I.D. #J-11428-17. Thus, additional surgical capacity is not needed, especially in consideration of the current and projected surplus of ORs at WakeMed Cary.

WakeMed also has approved incremental surgical capacity in the system it has yet to develop. In 2018, WakeMed submitted Project Nos. J-11564-18 and J-11565-18 to develop new freestanding ASFs in Cary and North Raleigh, respectively, in response to the need determination for the Wake County service area in the 2018 SMFP. Following the appeal of the State's decision, the following WakeMed projects were approved in Settlement:

- WakeMed Surgery Center-North Raleigh (Project No. J-11564-18) was approved to develop an ASF with 1 operating room, to be relocated from Capital City Surgery Center, and 3 procedure rooms;
- WakeMed Surgery Center-Cary (Project No. J-11565-18) was approved to develop an ASF with 1 operating room, from the 2018 SMFP Wake County OR allocation, and 3 procedure rooms

WakeMed anticipates these approved ASCs will open during FY2022. Thus, WakeMed will soon have additional OR capacity available to which WakeMed Cary can decant outpatient surgical volume. This will allow WakeMed Cary to accommodate its stated growth in inpatient surgical cases.

Regarding the shift of ambulatory surgical cases to the approved ASCs, Step 3 of WakeMed Cary's methodology provides no assumptions or methodology to substantiate shifts of outpatient surgical cases from WakeMed Cary, WakeMed, and Capital City Surgery Center to WakeMed Surgery Center-North Raleigh (WSCNR) and WakeMed Surgery Center-Cary (WSCC), respectively. There is no discussion of the rationale the Applicant used to determine which and how many surgical cases are appropriate to shift to WSCNR or WSCC. Notably, the applicant projects to shift 1,175 patients from WakeMed Raleigh to WSCC and only 404 patients from WakeMed Cary to WSCC. The Applicant provides no rationale to explain why such a small number of ambulatory surgery patients will shift from WakeMed Cary to WSCC. Presumably, a large portion of WakeMed Cary ambulatory surgical patients could benefit from access to lower cost ambulatory surgical services at a comparable geographic location. It appears that WakeMed is attempting to bolster projected surgical volume at WakeMed Cary simply to avoid further inflating the surplus of ORs at the facility.

Separately and more importantly, WakeMed Cary's projected surgical utilization results in a **surplus** of 3.66 ORs at the facility during the third project year. How can WakeMed Cary demonstrate the need it has for an additional OR when the facility currently has a surplus of 3.3 ORs (see Proposed 2021 SMFP, Table 6B) and is projected to have a surplus of ORs of 3.66 ORs upon completion of the proposed project (see Form C and Table Q.11A, Project I.D. J-11960-20)?

Section Q, page 122 includes Table Q. 11A which projects OR surplus of 3.66 ORs at WakeMed Cary Hospital based on the OR methodology set forth in the 2020 SMFP. Form C, page 127 similarly projects a surplus of 3.66 ORs during the third project year. Table Q. 11A and Form C clearly show WakeMed Cary Hospital is projected to have a surplus of 3.66 (rounded to 4) ORs during Project Year 3. The applicant attempts to provide a revised Table Q 11B utilizing average case times from its LRAs and subtracting one OR from its inventory based on its recent designation as a Level III Trauma Center. However, 10A NCAC 14C .2103(a) states the OR Methodology in the 2019 SMFP must be applied, and the OR Methodology in the 2019 SMFP utilizes adjusted case times. Furthermore, the OR Methodology in the 2019 SMFP excludes one OR for each Level I and Level II Trauma Center. WakeMed Cary Hospital is designated as a Level III Trauma Center; thus, it is not appropriate to exclude one OR from its inventory when evaluating need vis a vis Criterion 3.

DUHS acknowledges 10A NCAC 14C .2103(a) states an applicant 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; however, the applicant bears the burden to demonstrate conformity to Criterion 3. Criterion 3 requires an applicant to demonstrate the need the population has for the services proposed, i.e., one additional OR at WakeMed Cary Hospital. The applicant fails to demonstrate why WakeMed Cary's existing complement of ORs is insufficient to accommodate projected surgical utilization. Further, WakeMed Cary did not demonstrate that the proposed additional OR would not duplicate the services provided by its existing ORs given the current and projected surplus of ORs at the facility.

For these reasons, the WakeMed Cary application does not conform to Criterion 3.

Criterion 4 *"Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed."*

The WakeMed application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. An application that cannot be approved cannot be an effective alternative.

The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion and cannot be approved. See discussion regarding criteria 1, 3, 6, and 18a.

Criterion 5 *"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."*

Based on the facts described in these written comments specific to Criterion 3 (incorporated herein by reference), these same facts result in the WakeMed Cary application being non-conforming to Criterion 5.

Criterion 6 "The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."

WakeMed Cary did not demonstrate that the proposed additional OR would not duplicate services provided by its existing ORs given the current and projected surplus of ORs at the facility and in the system. See discussion regarding Criterion 3.

Criterion 18a *"The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact."*

Based on the facts which result in WakeMed Cary being non-conforming with Criteria 1, 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a.

Comments Regarding Comparative Analysis

Costs & Revenues

As compared to DUHS's applications, WakeMed Cary's proposal is inferior with respect to costs and revenues. WakeMed Cary projects comparatively higher average costs and revenues per surgical case than Duke Health Green Level ASC and Duke Health Garner ASC.

Geography

As compared to Duke Health Garner ASC's application, WakeMed Cary's proposal is inferior with respect to geographic access.

Medically Underserved Access: Medicaid

As compared to DUHS's applications, WakeMed Cary's proposal is inferior with respect to Medicaid access. WakeMed Cary projects comparatively lower Medicaid access (Medicaid surgical cases as a % of total surgical cases, Medicaid surgical cases per OR) than Duke Health Green Level ASC. WakeMed Cary

projects comparatively lower Medicaid access (Medicaid surgical cases per OR) than Duke Health Garner ASC.

Competition/Access to a New Provider

As described previously, the WakeMed Health System controls 37.6 percent of the existing and approved ORs in Wake County, the highest of any health system in Wake County. WakeMed Cary is the least effective alternative with respect to competition. DUHS controls only 14.7% of the existing and approved ORs in Wake County. Thus, Duke Health Green Level ASC and Duke Health Garner ASC are more effective alternatives for this comparative.

COMMENTS SPECIFIC TO VALLEYGATE SURGERY CENTER (Valleygate)
PROJECT ID No. J-011961-20

Criterion 1 *"The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which shall constitute a determinative limitation on the provision of any health services, health service facility, health service beds, dialysis stations, operating rooms, or home health offices that may be approved."*

POLICY GEN-3: BASIC PRINCIPLES states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

Valleygate fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding criteria 3, 4, 5, 6, and 18a. Therefore, the application is not conforming to this criterion and cannot be approved.

Criterion 3 *"The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed."*

The Valleygate proposal is not effective to meet the identified need. The project as defined is not the most effective alternative nor are its financial projections based on reasonable projections of utilization.

Valleygate's market share projections are unreasonable and not supported. Valleygate assumes a census tract service area that will encompass more than 240,000 people in 2025 for each specialty except for dental; for dental services, its projected service area includes all of Wake County. Valleygate then projects the following aggressive share percentages by surgical specialty during the first three project years.

Valleygate Market Share Projections			
Specialty	**PY1**	**PY2**	**PY3**
Oral/Dental	37.5%	40.0%	50.0%
ENT	32.5%	48.8%	65.0%
Ophthalmology	12.0%	21.0%	30.0%
Plastic	32.5%	48.8%	65.0%

Valleygate has limited physician support to substantiate these aggressive market share projections it projects to attain in its proposed service area. The following table was obtained from Exhibit I.3 of the Valleygate application and summarizes the physician referral support for the project.

First Name	Last Name	Suffix Specialty	Low	High
Vinod	Jihdal	MD Ophthalmology	60	60
Nazir	Ahmad	DDS Oral Surgery	15	15
Raymond	Tseng	DDS Oral Surgery	10	10
Bryan	Dunston	DDS Oral Surgery	20	20
Boo	Lee	DDS Pediatric Dentistry	6	6
E. LaRee	Johnson	DDS, MS,FAA Pediatric Dentistry	16	16
Mark	Herring	DMD Pediatric Dentistry	10	10
David	Olson	DDS Pediatric Dentistry	3	3
Burton	Horwitz	DDS Pediatric Dentistry	16	16
Shamik	Vakil	DDS Pediatric Dentistry	10	10
Harpreet	Wasson	DDS Pediatric Dentistry	12	12
Vinod	Jihdal	MD Plastics	30	30

Source: Valleygate Surgery Center Wake County 2020 OR CON, Exhibit I.3

As shown in the previous table, Valleygate received physician support from only one ophthalmologist. It is unreasonable to assert that the single, unaffiliated physician can attract 30 percent share of projected ophthalmic surgical cases for a service area spreading over three counties and including more than 240,000 residents during 2025. The only rationale Valleygate provides to support the projected market share assumption is found on page 130, which states "Market shares presume that Valleygate will be sufficiently organized to serve most of the unmet need, while leaving cases for other providers to serve." This is woefully insufficient to support such a robust market share to be fulfilled by only one ophthalmologist. Absent any rationale provided in Valleygate's application, the projected ophthalmic market shares are unsubstantiated and not supported. Therefore, the resulting ophthalmic surgical cases are unreasonable and not supported.

Similarly, Valleygate documented physician support from only one plastic surgeon. It is unreasonable to assert that the single, unaffiliated physician can attain 65 percent market share of projected plastic surgery cases for a service area comprised of three counties and over 240,000 residents during 2025. Again, the only rationale Valleygate provides to support the projected market share assumption is found

on page 130, which states "Market shares presume that Valleygate will be sufficiently organized to serve most of the unmet need, while leaving cases for other providers to serve." This is woefully insufficient to support such a robust market share to be fulfilled by only one plastic surgeon. (Notably, Valleygate projects higher market share in plastic surgery (65%) with only one plastic surgeon compared to its projected market share for oral/dental (50%) which is supported by 10 surgeons.) Absent any rationale provided in Valleygate's application, the projected plastic surgery market shares are unsubstantiated and not supported. Therefore, the resulting plastic surgery cases are unreasonable and not supported.

Unlike the need/utilization methodology for the ENT, ophthalmology, and plastic, Valleygate uses a different service area in its calculation for dental/oral surgery cases. Valleygate uses all of Wake County as its service area to forecast dental/oral surgery need and utilization.

Valleygate applies the 2018 NC ambulatory surgical case use rate to calculate the population need for dental/oral surgery cases in the service area for future years, 2020 through 2025. However, the applicant failed to demonstrate how the statewide overall ambulatory surgical use rate is a comparable proxy to project demand for a single surgical specialty, i.e., dental/oral surgery, especially one that is often done predominantly in an unlicensed office setting. On page 135, Valleygate claims the state use rate reasonably reflects the current utilization of ambulatory surgery at all state facilities. However, on the same page Valleygate also states, "There are 169 freestanding ASFs, only 13 of those offer dental/oral surgery. Of those 13 ASFs, only one is in Wake County." Therefore, based on Valleygate's own admissions, dental/oral surgery would comprise a minute portion of the surgical utilization used to determine the statewide ambulatory surgical use rate. Therefore, application of a statewide ambulatory surgical use rate grossly over projects demand for a single specialty, i.e., dental/oral surgery. As a result, application of Valleygate's projected oral/dental market shares result in overstated and unreasonable projected dental/oral surgical cases.

Valleygate's projections of in-migration for dental/oral are also unreasonable. On page 142, Valleygate projects 58.6% of dental/oral surgery cases will originate from outside Wake County. Valleygate premises this assumption on its patient origin data at Valleygate freestanding facilities in Fayetteville, Charlotte, and Greensboro. However, these facilities are single-specialty ASCs and not multi-specialty ASCs as proposed in this Wake County batch review. Moreover, those other facilities are the sole dental ASCs in their respective areas; Wake County already has a dental ASC. This is not an apples to apples comparison. An assumption of 58.6% in-migration is likely a strategy to artificially inflate surgical utilization at the proposed facility to project greater surgical hours, i.e., need.

For these reasons, the Valleygate application does not conform to Criterion 3.

Criterion 4 *"Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed."*

The Valleygate application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. An application that cannot be approved cannot be an effective alternative.

The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion and cannot be approved. See discussion regarding criteria 1, 3, 5, 6, and 18a.

Criterion 5 *"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."*

Based on the facts described in these written comments specific to Criterion 3 (incorporated herein by reference), these same facts result in the Valleygate application being non-conforming to Criterion 5.

Also, Valleygate did not include financing costs in Form F.1a Capital Costs. In Section F, Valleygate states it will fund the project via loan from First Citizens Bank; however, no financing costs are reflected in Form F.1a.

Criterion 6 "The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."

Based on the facts described in these written comments specific to Criterion 3 (incorporated herein by reference), these same facts result in the Valleygate application being non-conforming to Criterion 6.

Criterion 18a *"The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact."*

Based on the facts which result in Valleygate being non-conforming with Criteria 1, 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a.

Comments Regarding Comparative Analysis

Costs & Revenues

As compared to the Duke Health Green Level ASC application, Valleygate's proposal is inferior with respect to costs and revenues. Valleygate projects comparatively higher average costs and revenues per surgical case than Duke Health Green Level ASC.

Scope of Services

As compared to DUHS's applications, Valleygate's is inferior with respect to scope of services. Valleygate proposes comparatively fewer surgical specialties than Duke Health Green Level ASC and Duke Health Garner ASC.

Medically Underserved Access: Charity Care

As compared to the DUHS applications, Valleygate's proposal is inferior with respect to charity care access. Valleygate projects comparatively lower charity care access (total charity care surgical cases and charity care deduction from revenue as a % of total gross and net revenue) than Duke Health Green Level ASC.

Valleygate projects comparatively lower charity care access (charity care deduction from revenue as a % of total gross and net revenue) than Duke Health Garner ASC.

Medically Underserved Access: Medicare

As compared to the DUHS applications, Valleygate's proposal is inferior with respect to Medicare access. Valleygate projects comparatively lower Medicare access (total Medicare surgical cases, Medicare surgical cases as a % of total cases, Medicare surgical cases per OR, Medicare revenue as a % of total gross revenue, Medicare revenue per OR) than Duke Health Green Level ASC and Duke Health Garner ASC.

COMMENTS SPECIFIC TO ORTHOPAEDIC SURGERY CENTER OF GARNER (OSCG)
Project ID No. J-011962-20

General Comments

There are already seven existing and approved single-specialty ASCs in Wake County: Triangle Orthopaedics Surgery Center (orthopaedics),[2] Raleigh Orthopaedic Surgery Center (orthopaedics), Raleigh Orthopaedic Surgery Center-West Cary (orthopaedics), Raleigh Plastic Surgery Center (plastic surgery), Surgical Center for Dental Professionals of NC (dental), as well as the OrthoNC ASC (orthopaedics) and RAC Surgery Center ASC (vascular) facilities approved in the 2018 Wake County Operating Room batch review. Approximately one-third of Wake County's OR capacity is allocated to single-specialty ASFs (existing and approved), and a majority of those are orthopaedics-focused. Therefore, Wake County residents already have adequate access to single-specialty ORs.

UNC Rex proposes to develop a third franchise of its single-specialty orthopaedic ASCs, further diluting the marketplace with a fifth single-specialty orthopaedic ASC in Wake County. Thus, the OSCG proposal is not an effective alternative in this batch review for enhancing access to surgical services.

Criterion 1 *"The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which shall constitute a determinative limitation on the provision of any health services, health service facility, health service beds, dialysis stations, operating rooms, or home health offices that may be approved."*

POLICY GEN-3: BASIC PRINCIPLES states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

OSCG fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The application does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding criteria 3, 4, 5, 6, and 18a. Therefore, the application is not conforming to this criterion and cannot be approved.

[2] This facility recently received approval to become a multi-specialty ASC; however, its projected procedures are overwhelming orthopedic and therefore it remains an orthopedic-focused facility.

Criterion 3 *"The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed."*

As described in the assumptions and methodology used to project surgical cases in Section Q, OSCG identifies "Potential Operating Room Cases" as surgical cases historically performed in procedure rooms at another existing ASC, Raleigh Orthopaedic Surgery Center. While DUHS does not dispute that some surgical cases can safely be performed in procedure rooms, it is unclear why additional ASC OR capacity is needed to accommodate cases that are already performed in ASC procedure rooms. While DUHS's proposed of shift patients from hospital-based procedure rooms to ASC ORs will lower the cost of surgical services for patients, the identified procedure room patients to be served by OSCG's ORs are already receiving services at an ASC and would not see any change in their charges as a result. OSCG does not document any capacity constraints in Raleigh Orthopaedic Surgery Center's procedure rooms or other limitations that would drive the need to shift patients across Wake County from an existing ASC to the proposed ORs at OSCG.

Additionally, OSCG projects to shift 60% of the total potential OR cases projected for surgeons expected to practice at OSCG. This is incredibly aggressive and assumes that more than half of the surgeons' patients would prefer to travel to Garner/southeast Wake County for ambulatory surgery despite existing access to the very same kind of facility in Raleigh and Cary. OSCG failed to provide any historical patient origin for the surgeons expected to practice at OSCG to substantiate this robust projection.

The applicant fails to demonstrate why Raleigh Orthopedic Surgery Center's existing complement of ORs and procedure rooms are insufficient to accommodate projected surgical utilization. Further, OSCG did not demonstrate that the proposed additional ORs would not duplicate the surgical services provided by its existing ORs and procedure rooms at other facilities.

For these reasons, the OSCG application does not conform to Criterion 3.

Criterion 4 *"Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed."*

The OSCG Application is not conforming to Criterion 4. OSCG does not adequately demonstrate that the alternative proposed in its Application is the most effective alternative to meet the need because the Application is not conforming to all statutory and regulatory review criteria. See discussion regarding criteria 3, 5, 6, and 18a. An application that cannot be approved cannot be the most effective alternative.

Criterion 5 *"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."*

Based on the facts described in these written comments specific to Criterion 3 (incorporated herein by reference), these same facts result in the OSCG application being non-conforming to Criterion 5.

Criterion 6 "The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."

OSCG did not demonstrate that the proposed ORs would not duplicate services provided by Raleigh Orthopaedic Surgery Centers existing ORs and procedure rooms. See discussion regarding Criterion 3.

Criterion 18a *"The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact."*

Based on the facts which result OSCG being non-conforming with Criteria 1, 3, 4, and 6, it should also be found non-conforming with Criterion 18a.

Comments Regarding Comparative Analysis

Costs & Revenues

As compared to DUHS's applications, OSCG's proposal is inferior with respect to costs and revenues. OSCG projects comparatively higher average costs and revenues per surgical case than Duke Health Green Level ASC and Duke Health Garner ASC.

Scope of Services

As compared to DUHS's applications, OSCG is inferior with respect to scope of services. OSCG proposes comparatively fewer surgical specialties than Duke Health Green Level ASC and Duke Health Garner ASC.

Medically Underserved Access: Medicaid

As compared to DUHS's application, OSCG's proposal is inferior with respect to Medicaid access. OSCG projects comparatively lower Medicaid access Duke Health Green Level ASC and Duke Health Garner ASC.

Medically Underserved Access: Charity Care

As compared to DUHS's applications, OSCG's proposal is inferior with respect to charity care access. OSCG projects comparatively lower charity care access than Duke Health Green Level ASC and Duke Health Garner ASC.

Medically Underserved Access: Medicare

As compared to DUHS's applications, OSCG's proposal is inferior with respect to Medicare access. OSCG projects comparatively lower Medicare access than Duke Health Green Level ASC and Duke Health Garner ASC.

Competition/Access to a New Provider

As described previously, the UNC System controls 33.9 percent of the existing and approved ORs in Wake County, which is the second highest market share of ORs in Wake County. Also, UNC Rex proposes to develop a third franchise of its single-specialty orthopaedic ASCs via the OSCG proposal. Therefore, OSCG is a less effective alternative with respect to competition. DUHS controls only 14.7% of the existing and approved ORs in Wake County. Thus, Duke Health Green Level ASC and Duke Health Garner ASC are more effective alternatives for this comparative.

COMMENTS SPECIFIC TO UNC REX HOSPITAL (UNC Rex)
PROJECT ID No. J-011963-20

Criterion 1 *"The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which shall constitute a determinative limitation on the provision of any health services, health service facility, health service beds, dialysis stations, operating rooms, or home health offices that may be approved."*

POLICY GEN-3: BASIC PRINCIPLES states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

Adoration fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding criteria 3, 5, 6, and 18a. Therefore, the application is not conforming to this criterion and cannot be approved.

Criterion 3 *"The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed."*

UNC REX states it needs to replace the lost OR capacity resulting from the pending relocation of three ORs to UNC REX Holly Springs Hospital when it opens in State Fiscal Year (SFY) 2022. However, the three ORs have already been replaced via recently approved projects. Specifically,

- UNC Rex states in Section Q, page 12 "*UNC REX Hospital was approved to relocate one of Rex Surgery Center of Wakefield's three operating rooms to UNC REX Hospital's main campus (Project ID # J-11198-16). That operating room was relocated on July 1, 2017.*" Please see Attachment 1 which contains pages from UNC Rex License Renewal Applications documenting the net increase in ORs at UNC Rex's main hospital facility as a result of Project ID J-11198-16. Therefore, Project ID J-11198-16 effectively replaces one of the UNC Rex main hospital ORs that will be relocated to Holly Springs.

- As stated on page 17 of its CON application, "*Following the settlement of the 2018 Wake County Operating Room Review, UNC REX Hospital was approved to develop two additional operating rooms at its main hospital facility, one of which became operational on August 22, 2020.*" Therefore, the settlement of the 2018 Wake County OR review effectively replaces two of the UNC Rex main hospital ORs that will be relocated to Holly Springs.

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

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

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

Criterion 4 *"Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed."*

The Adoration application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. An application that cannot be approved cannot be an effective alternative.

The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion and cannot be approved. See discussion regarding criteria 3, 5, 8, and 13c.

Criterion 5 *"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."*

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

Criterion 6 "The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."

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

Criterion 18a *"The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact."*

Based on the facts which result UNC Rex being non-conforming with Criteria 1, 3, 4, and 6, it should also be found non-conforming with Criterion 18a.

Comments Regarding Comparative Analysis

Costs & Revenues

As compared to DUHS's applications, UNC Rex proposal is inferior with respect to costs and revenues. UNC Rex projects comparatively higher average costs and revenues per surgical case than Duke Health Green Level ASC and Duke Health Garner ASC.

Medically Underserved Access: Medicaid

As compared to DUHS's application, UNC Rex's proposal is inferior with respect to Medicaid access. UNC Rex projects comparatively lower Medicaid access Duke Health Green Level ASC and Duke Health Garner ASC.

Medically Underserved Access: Charity Care

As compared to DUHS's applications, OSCG's proposal is inferior with respect to charity care access. OSCG projects comparatively lower charity care access than Duke Health Green Level ASC and Duke Health Garner ASC.

Medically Underserved Access: Medicare

As compared to DUHS's applications, OSCG's proposal is inferior with respect to Medicare access. OSCG projects comparatively lower Medicare access than Duke Health Green Level ASC and Duke Health Garner ASC.

Competition/Access to a New Provider

As described previously, the UNC System controls 33.9 percent of the existing and approved ORs in Wake County, which is the second highest market share of ORs in Wake County. Therefore, UNC Rex is a less effective alternative with respect to competition. DUHS controls only 14.7% of the existing and approved ORs in Wake County. Thus, Duke Health Green Level ASC and Duke Health Garner ASC are more effective alternatives for this comparative.