COMMENTS REGARDING CERTIFICATE OF NEED APPLICATIONS FILED FOR OPERATING ROOMS IN 2020 WAKE COUNTY SERVICE AREA

Submitted by WakeMed Health & Hospitals November 2, 2020

A total of six CON applications were filed for the October 1, 2020 review cycle requesting operating rooms in the Wake County service area, all pursuant to the need determination for three operating rooms identified in the 2020 State Medical Facilities Plan (SMFP):

- WakeMed Cary Hospital ("WakeMed Cary") (Project No. J-11960-20): Develop one additional shared OR at its existing campus at 1900 Kildaire Farm Road in Cary. Total project cost: \$2,265,178.
- <u>Valleygate Surgery Center ("Valleygate") (J-11961-20)</u>: Develop a new ambulatory surgical facility (ASF) with 1 OR and 3 procedure rooms in Garner. Total project cost: \$2,341,977.
- Orthopaedic Surgery Center of Garner ("OSCG") (J-11962-20): Develop a new ASF with 2 ORs and 2 procedure rooms in Garner. Total project cost: \$14,056,934.
- Rex Hospital ("Rex") (J-11963-20): Develop 1 additional OR at its existing main campus at 4420 Lake Boone Trail in Raleigh. Total project cost: \$407,588.
- <u>Duke Health Garner Ambulatory Surgery Center ("Duke-Garner") (J-11966-20)</u>: Develop a new ASF with 1 OR and 2 procedure rooms in Garner. Total project cost: \$11,700,000.
- <u>Duke Health Green Level Ambulatory Surgery Center ("Duke-Green Level") (J-11967-20)</u>: Add 1
 OR to an approved ASF proposed for 3208 Green Level West Road in Garner. Total project cost: \$6,000,000.

The six applicants in the review propose a total of 7 operating rooms. Because the Agency can approve no more than three operating rooms in this review, per the 2020 SMFP allocation, not all of the applications can be approved. The applicants in this review are in agreement on the need for additional operating room capacity in Wake County. The decision before the Agency is how these additional resources can be most effectively deployed in meeting the needs of Wake County residents and patients from outside Wake County who utilize Wake County facilities. WakeMed appreciates the challenging task ahead for the Agency, and has opted to keep its competitive remarks as concise as possible.

The WakeMed Cary application, proposing to add one additional OR at its existing campus, is comparatively superior to the other applications in this review. In addition, there are deficiencies in the other proposals that render them non-conforming with applicable CON review criteria. The details for these conclusions are set forth below.

Maximize Geographic Access to Surgical Services

The applications filed in this review propose to develop operating rooms at new and existing locations throughout Wake County. Two applications seek to add new operating rooms at existing acute care hospitals (WakeMed Cary and Rex). Three applications seek to develop new ASCs in Garner (Valleygate, OSCG and Duke-Garner). One application seeks to add OR capacity at an ASC scheduled for development (Duke-Green Level). Aside from new locations, no applicant proposes to serve a unique patient population.

The WakeMed Cary application stands apart as it seeks to added shared OR capacity at the only acute care hospital currently operational in southwestern Wake County, where the county's population is growing most rapidly. WakeMed Cary recently increased its acute care bed complement by 22 beds, and plans to open 30 additional beds in Calendar Year 2021. The growth in acute care capacity, in addition to other factors, necessitates this request for new OR capacity.

Freestanding vs. Hospital-Based Surgical Operating Rooms

Most of the applicants in the review propose to develop operating rooms in freestanding ASFs. Two applicants, WakeMed Cary (J-11960-20) and Rex (J-11763-20) seek to add hospital-based operating rooms at existing campuses. While the majority of ORs in Wake County are in acute care hospitals, most of these recently-approved ORs in Wake County were awarded to new ASFs. In the 2018 Wake County Operating Room review, 4 of the six allocated ORs were awarded to new ASFs; the remaining 2 were awarded to Rex Hospital. In the 2019 Wake County Operating Room review, the 2 allocated ORs were awarded to freestanding ASFs.

WakeMed understands that both freestanding ASFs and hospital-based ORs are important components in the healthcare continuum, and that each setting offers significant benefits for patient care. Freestanding ASFs can usually provide outpatient surgery at a much lower cost than comparable cases performed in a hospital setting; however, an adequate supply of hospital-based ORs are still necessary to allow for more complex inpatient and outpatient surgical cases to be performed.

For the 2020 Wake County OR review, there is an opportunity for the Agency to approve applicants seeking both freestanding and hospital-based operating rooms.

WakeMed Cary Hospital Application

Several factors point toward the WakeMed Cary application being the most effective alternative in this review. Specifically:

WakeMed Cary Is the only acute care hospital currently operational in southwestern Wake
County, the region of Wake County where population growth is highest, home to approximately
500,000 residents and growing at a rate of 2.5 percent per year.

- WakeMed Cary recently increased its acute care bed capacity from 156 to 178 beds, and capacity will increase to 208 beds in 2021. This is a significant expansion in beds that will enhance demand for surgical services.
- From FY 2015-2019, WakeMed Cary's inpatient surgery cases grew at a rate of 4.61 percent per year, and outpatient surgery increased 0.54 percent per year, despite the approval of several new ASFs in Wake County.
- Average surgical case times for inpatient and outpatient surgery at WakeMed Cary increased 83
 percent and 105 percent, respectively, from 2015 to 2019, a function of higher patient acuities
 and expanded surgical capabilities. The increase in surgical case times are, in some ways, more
 illustrative of the need for additional OR capacity than increases in case volumes.

Valleygate Surgery Center – Develop Freestanding Ambulatory Surgical Facility with One OR Project No. J-11963-20

The Valleygate application seeks to develop a freestanding ASF with 1 OR and 2 procedure rooms at a location in Garner. The application is nonconforming with several CON Review Criteria, as evidenced below.

Review 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.

Valleygate would be a new freestanding ASF location. Although the new ASF would be multi-specialty, there will be an emphasis on dental and oral surgery, which Valleygate claims are desperately needed in Wake County.

Location

Valleygate proposes to develop its ASF in newly constructed space in Garner. Currently, there are no existing/approved ASFs in the Garner area. According to Valleygate, this fact alone is sufficient to warrant its approval. Valleygate defines its "target area" in Section Q as a group of 29 census tracts in southern Wake County, northern Johnston County and northern Harnett County. The proposed Valleygate site is situated near the *northern* edge of this target area. The Johnston and Harnett County tracts comprise approximately 38 percent of the target area's total population, and are absolutely crucial to Valleygate's need methodology. However, Valleygate's claims of greater patient convenience fall flat. According to Google Maps, the town of Lillington, located near the southernmost point of the target area, is approximately 42 minutes' drive time from the Valleygate site. It is likely that Valleygate's selected its target area to include census tracts where there was no existing or approved ASF, and to include sufficient population to justify the projected volumes.

The reality is that the existing road network in Wake and surrounding counties makes nearly all areas of the county accessible. While the defined target area currently has no freestanding ASFs, several existing ASFs are located very close to the proposed Valleygate site. Capital City Surgery Center is located 7.8 miles from the center of Garner. SDSC, whose focus is Dental/Oral Surgery, is located approximately 8 miles from Garner. Holly Springs Surgery Center is located very close to the southern portion of Valleygate's target area.

Access to Dental/Oral Surgery

On pages 47-48, Valleygate provides information suggesting that Dental/Oral surgery is provided by only a few providers statewide. Valleygate cites 9 ASFs that reported Dental/Oral surgery volume in 2019. Valleygate omits the fact that Dental/Oral surgery is performed in acute care hospitals, as well as in dentists and oral surgeons' offices.

Referring Physicians, Dentists and Oral Surgeons

Valleygate received support from several physician and dental groups. However, most of these are located a significant distance from the target area identified in the application. While patient access is given as a chief reason for choice of location for an ASF, physician convenience, particularly in an urban county with a rapidly growing population and increasing vehicle traffic, cannot be understated. Please see Review Criterion 8.

For these reasons, the Valleygate proposal does not conform with Review Criterion 3.

Review 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.

In Section E, Valleygate lists a number of alternatives to the proposed project. On Page 71, the application states that Valleygate "determined that patients will benefit from development of a new freestanding ASF in southeast Wake County", citing the facility's non-HOPD charge structure and focus on Dental/Oral surgery. Valleygate notes that the Surgical Center for Dental Professionals (SCDP) ASF performed only 277 cases in during its first year of operation, despite projecting 1800 cases. SCDP opened in February 2019, so it is difficult to determine what its case volume might have been for a full year's operation. For these reasons, Valleygate rejected the status quo and opted to propose a facility that will compete directly with SCDP.

Valleygate also opted to locate its ASF in the Garner area, ostensibly because there are no existing/approved ASFs in southeast Wake County or Johnston County. Simply choosing a location because the surrounding area has no existing ASFs does not necessarily improve access to services. For the surgical specialties that Valleygate proposes, access is only marginally improved for patients, and arguably not at all for surgeons. Most of the physicians identified to practice at Valleygate base their practices well outside the target area. Please see discussion of Review Criterion 8. For these reasons, the project does not conform with Review Criterion 4.

Review Criterion 5

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

In Section Q, Valleygate provides detail on its projected surgical case volumes and corresponding financial projections. Although the project shows a positive return beginning in Project Year 2, the financial feasibility of the project is tenuous. In its pro formas, Valleygate proposes minimal Net Income per case in Project Years 1-3, as evidenced in the following table.

Year	Total	Gross	Net	Operating	Net
	Cases	Revenue	Revenue	Cost Per	Income
		Per Case	Per Case	Case	Per Case
Partial PY 1	293	\$5,933	\$1,570	\$2,110	(\$540)
Full PY 1	1,818	\$6,356	\$1,665	\$1,693	(\$29)
Full PY 2	2,324	\$6,239	\$1,647	\$1,597	\$50
Full PY 3	3,091	\$6,297	\$1,666	\$1,406	\$260

Source: Valleygate application, page 149

Valleygate's operating margins are so thin that falling short of its projected case volumes by as little as 10 percent could jeopardize the financial feasibility of the project. For this reason, Valleygate is nonconforming with Review Criterion 5.

Review Criterion 6

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

While Valleygate proposes to develop a multispecialty ASF, the primary focus of the new ASF will be Oral/Dental procedures requiring general anesthesia or sedation, for pediatric and adult patients. Valleygate makes numerous references to the need for Dental/Oral surgery in the area, and the dearth of providers who will perform such procedures. Surgical Center for Dental Professionals was approved as a Dental Surgery Demonstration Project in 2017 to develop an ASF dedicated to Dental/Oral surgery. The facility, which opened in February 2019, has not been operational long enough to know its full impact, particularly given the manner that COVID has affected negatively impacted healthcare providers in 2020.

Valleygate's projections in Sections C and Q are heavily weighted toward Oral/Dental procedures. On Page 87, Valleygate states that "only Surgical Center for Dental Professionals and the hospitals [can] accommodate all of the adult and pediatric oral surgery need in Wake County." Missing from the analysis is whether local dentists have sought privileges at other ASFs in Wake County.

Review Criterion 8

The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

A critical component to the success of a surgical provider is strong support from surgeons and referring physicians. On Page 94, the Valleygate application provides a list of physicians, dentists and oral surgeons expected to use its ASF. Only one of the practices listed is located within Valleygate's target area, and many are located a significant distance from the proposed ASF site. Please see the following table.

Valleygate Surgery Center Road Mileages and Drive Times to Proposed Site from Referring Practices Source: Google Maps, assuming shortest drive time						
Practice	Practice One-Way One- Located Shortest F Within Drive Mile Valleygate Time to Short Target Valleygate D					
Blue Water Pediatric Dentistry	345 Earnie Ln., Holly Springs, NC 27540	No	(min) 28	Time 22.3		
Capitol Oral & Facial Surgery	5804 Six Forks Rd., Raleigh, NC 27609	No	21	16.5		
Carolina Pediatric Dentistry	2800 Wakefield Pines Dr., Raleigh, NC 27614	No	34	29.8		
High House Pediatric Dentistry	1705 High House Rd., Cary, NC 27513	No	28	19.8		
New Century Ophthalmology Group	5720 Creedmoor Rd., Raleigh, NC 27612	No	23	18.6		
Raleigh Pediatric Dentistry	10931 Raven Ridge Rd., Raleigh, NC 27614	No	30	26.8		
Sandhills Pediatric & Family						
Dentistry	55 Amarillo Ln., Sanford, NC 27332	No	61	63.0		
Vaya Dental	4446 Fayetteville Rd., Raleigh, NC 27603	Yes	9	3.3		
Holly Springs Ear Nose Throat & Allergy	500 Holly Springs Rd., Holly Springs, NC 27540	No	28	15.1		

The average *one-way* drive time from the practices listed above to Valleygate's proposed site is 29.1 minutes, with a range of 9 to 61 minutes. It is questionable whether providers in these practices will find the Valleygate location to be convenient, particularly over the long-term. For these reasons, Valleygate does not conform with Review Criterion 8.

Review 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 would not have a favorable impact.

Valleygate seeks to be a new entrant in the Wake County surgery market, one focused on Dental/Oral, ENT, Plastic and General surgical procedures. Aside from Dental/Oral Surgery, Valleygate offers little in the way of differentiation. A dedicated provider of Dental/Oral Surgery, the Surgical Center for Dental Professionals (SCDP), is already located in Wake County and has been operational for less than two years. The full effect of SCDP has not yet been realized. Because less than one-half of Valleygate's projected case volume will be non-Dental/Oral Surgery, its impact on overall competition for surgical services in the county is likely to be minimal. Thus, the Valleygate proposal does not conform with Review Criterion 18a.

Orthopaedic Surgery Center of Garner – Develop ASF with Two Operating Rooms and Two Procedure Rooms

Project No. J-11962-20

Review 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.

Impact of Growth

The Orthopaedic Surgery Center of Garner (OSCG) application states on Page 30 that "inpatient surgical volume for facilities in Wake County increased 2.6 percent annually between FFY 2014 and 2019, while outpatient volume has increased at a lower rate, 1.3 percent annually". This voluntarily proves that the citizens of Wake County are not in need of two additional dedicated outpatient operating rooms, particularly single-specialty ORs dedicated to orthopaedic surgery.

On Page 35, the OSCG application provides a table showing 14 Ambulatory Surgery Facilities (ASFs) in Wake County with a total of 30 operating rooms. This list is incomplete. Settlement negotiations for the 2019 Wake County OR Need Determination resulted in the approval of one additional ASF, bringing the existing and approved total to 16 freestanding ASFs, which are approved for 38 ORs. Included in this list are 3 single-specialty ASFs with 5 ORs dedicated to orthopeadic surgery that are either open or under development. Additionally, no fewer than 9 multispecialty ASFs with 28 ORs either currently provide orthopaedic surgery or will do so after opening. The notion that there is a dearth of facilities that provide orthopaedic surgery is false.

Until these additional orthopaedic-focused centers are complete, it would be remiss to award any additional ORs to a single-specialty facility, as it would consequentially impact citizens of Wake County with non-orthopaedic surgical needs — especially when OSCG's own application cites that there is a greater need for inpatient OR availability in Wake County.

OSCG also states, on Page 48, that "older patients are more likely to have complication, co-morbidities, or other clinical indications that are less appropriate for care in freestanding ASF settings or may require a hospital-based setting for surgery". This further demonstrates that after both ORs in 2019 were awarded to ASFs, the state must balance the ORs allocated in Wake County to support these growing populations in the inpatient and hospital-based settings.

Comparison of Health Care Costs

On page 40, OSCG repeats UNC Rex's claim that they provide the lowest cost option in the market by providing carefully curated and incomplete data from the Blue Cross Blue Shield of North Carolina (BCBSNC) web site, "Estimated Health Care Costs of Select Top 20 Outpatient Surgical Procedures",

¹ Blue Ridge Surgery Center with 6 ORs, and Wake Spine and Specialty Surgery Center with 1 OR, were not included. In addition, Triangle Orthopaedics Surgery Center is now approved for 3 ORs.

comparing health care costs for two selected outpatient surgical procedures. The data is accompanied by the following statement:

"As demonstrated in the table above, Raleigh Orthopaedic Surgery Center provides lower costs per procedure for BCBS patients than any other ASF service provider in the county."

This is a misleading statement, since OSCG opted to use data that did not contain information for all Wake County ASFs, or even the ASFs they chose to include. Any analysis that does not include all Wake County ASC providers is automatically biased, inadequate, and illogical for consideration in such a decision to determine distribution of ORs. In the next sentence, OSCG states:

"The proposed Orthopaedic Surgery Center of Garner will expand access to these lower cost services."

While the table on Page 40 is offered as evidence of OSCG's supposed lower surgical costs, only 3 procedures are listed on the table, with no direct comparisons between all Wake County ASCs. OSCG has conveniently cherry-picked data from a single insurer, for only *three* surgical procedures, and for which complete data is available for only *two* surgical centers, as proof that it is the "low cost provider" for surgical services in Wake County. Without a more complete and transparent analysis of surgical costs across multiple payers, including Medicare, that includes all providers, this information is meaningless, intentionally misleading, and wholly inaccurate.

Comparison to Raleigh Orthopaedic Surgery Center

OSCG attempts, on Page 42, to use the success of Raleigh Orthopaedic Clinic's flagship Ambulatory Surgery Facility to prove the immediate success of an ASF that will be located over 20 miles away in a town with 378,147 fewer people according to the 2010 U.S. Census. The success of Raleigh Orthopaedic Surgery Center can, likely, in part be attributed to their long presence in the heart of Raleigh since 1919 – a presence and name recognition that is not proven to hold the same reputation over 30 minutes away.

For these reasons, utilizing this data artificially inflates the demand and does not prove similar enough to accurately predict such immediate success in a still growing part of the county.

Access to Care

On Page 54, OSCG provides the data table below as a demographic analysis of Wake County and Garner, provided by the U.S. Census Bureau (2018 data):

Statistic	Wake County	Garner
Median Household Income	\$76,956	\$61,873
Percent of Persons in Poverty	8.4%	10.5%
Percent of Persons with Disabilities	5.8%	7.5%
Percent of Residents 65+	12.0%	14.4%

Following this table, OSCG provides data for bordering Johnston County, which has a median household income that is significantly lower (\$56,842), as well as 13 percent of residents in poverty and 10.5 percent of residents with disabilities.

While OSCG proposes to meet the needs of Garner's and Johnston County's relatively underserved populations, its projected service to underserved groups, provided in Page 61, suggests that only certain patient groups would experience enhanced access to outpatient surgery. OSCG provides no estimate of the proportion of patients in the "Low Income Persons" category it would serve. However, OSCG projects that 1.3 percent of its patients will be Medicaid recipients, far below the Census Bureau estimates for "Percent of Persons in Poverty" for Wake County, Garner, and Johnston County shown on Page 54. OSCG projects that 22.8 percent of its patients will be Elderly and that 20.3 percent will be Medicare beneficiaries, well above the estimates for "Percent of Residents 65+" in its service area.

Additionally, OSCG concedes to only provide true Charity Care to a minimum of 3 patients per year for each ROC's 22 physicians, as outlined on Page 105. This amounts to a mere 66 patients. However, with this seemingly being an intricately tracked statistic, it warrants questioning why a baseline for this could not be provided if the remainder of their projections were based on other internally available data.

Furthermore, on page 96, OSCG states that:

"Patients will gain access to the proposed ASF via physician referral. Any patient contacting the ASF without a physician, or whose physician does not have privileges at the ASF, will be referred to a physician with privileges at the AS for consideration for surgery to be performed at the ASF."

This creates an undue burden on the patient both financially and medically. In order for physicians to gain privileges at OSCG, they must have an investment stake, which essentially closes it to independent surgeons. For a patient to have their procedure done at this new center, a patient must either abandon their preferred surgeon or reestablish as a new patient with an ROC surgeon, otherwise they must have their procedure done elsewhere. This creates an undue burden of duplicative billed services and wasted time for a patient to convince a new surgeon to "consider" performing a procedure deemed necessary by their original provider.

Please also see the discussion for Review Criterion 13.

Proposed Timetable

While touting greater access to surgical services to citizens of Wake County, OSCG delivers neither on breadth of offered services, nor speed to completion. These proposed single-specialty ORs will not be brought into service until at least July 2023, one of the last projects in the review to become operational. With consideration that this new ASF is owned by UNC Health, which has also seen significant years-long delays in opening up the Rex Holly Springs Hospital, it is reasonable to acknowledge that additional delays may prohibit patients from utilizing these valuable resources on a significantly shorter timetable as proposed by WakeMed.

Review Criterion 4

In Section E, OSCG outlined alternatives to its proposed project, including maintaining status quo, developing their ASF in a different location, and developing a different number of ORs. Like the Valleygate application, OSCG maintains that its proposed location will improve geographic access to surgery services to residents of southeastern Wake County, as well as Johnston County. Missing from

this discussion is analysis demonstrating that residents of Wake County lack access to orthopaedic surgery.

OSCG would be the fourth ASF in the county dedicated solely to orthopaedic surgery, and the third owned by UNC Health. Triangle Orthopaedics Surgery Center, originally approved as a single-specialty demonstration project, recently received approval to convert to a multi-specialty ASF. While this facility will no longer be dedicated to orthopaedic surgery, orthopaedics will likely continue to be its primary focus. The proposed OSCG ASF offers no service differentiation.

On Page 22, OSCG states that that Raleigh Orthopaedic Clinic's Garner office is the practice's busiest location. Absent from the discussion of alternatives was the option to relocate 1 of the 3 existing ORs at Raleigh Orthopaedic Surgery Center's Raleigh ASF to Garner. In Project No. J-11161-16, Raleigh Orthopaedic proposed to develop Raleigh Orthopaedic Surgery Center-West Cary ASF using the same process.

Therefore, the OSCG proposal does not conform with Review Criterion 4.

Review Criterion 6

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

OSCG proposes a single-specialty ASF focused on orthopaedic surgery and is requesting more than half of the ORs in Wake County for 2020. Allocating any ORs would severely duplicate recently approved ORs which have the same single-specialty focus. OrthoNC has yet to open their approved ASF with 1 OR, and Raleigh Orthopaedic Surgery Center-West Cary was projected in the application to open September 21, 2020. Triangle Orthopaedics Surgery Center, which was approved to convert to a multi-specialty ASF but whose cases are majority orthopaedics, was awarded one OR in 2019 which has not yet been opened. Additional ORs have also recently been approved which will likely perform orthopaedic procedures, including three unopened ORs at Rex Holly Springs Hospital. Until all of these ORs are opened, there is insufficient data to support that any additional dedicated orthopaedic ORs are even needed, as these approved but unopened ORs may prove to adequately meet the orthopaedic demand of the market very shortly.

Review Criterion 13

The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medical 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 the purpose of determining the extend to which the propose service will be accessible, the applicant shall show:

 a. The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

- b. Its past performance in meeting its obligation, if under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving Federal assistance, including the existence of any civil rights equal access complaints against the applicant;
- c. That the elderly and medically underserved groups identified in the subdivision will be served by the applicant's proposed services and the extend which each of these groups is expected to utilize the proposed services; and
- d. That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by person physicians.

Despite its assertions in Section C that its project will improve access to surgical services by underserved groups, ² OSCG proposes to provide only a bare minimum of service to underserved payer groups such as Self Pay, Charity, and Medicaid. On Page 95, OSCG projects that 0.8 percent of its patients in Project Year 3 will be Self Pay, and 1.3 percent will be Medicaid. In contrast, approximately two-thirds of OSCG patients will be commercially insured. In its pro formas in Section Q, OSCG projects that only 0.6 percent of its annual gross revenues will be Charity Care. These proportions are well below other applicants in the review.

Information regarding OSCG contained in Forms C and F.2 illustrate OSCG's insignificant commitment to serving Medicaid and Charity patients.

Column:	Α	В	C=B÷A	D	E=D÷C	F	G=F÷C
Year	Total Annual Facility Cases	Total Gross Revenues- Facility	Gross Revenue Per Case	Total Gross Revenues- Medicaid	Medicaid Cases Per Year	Total Charity Care	Charity Care Cases Per Year
PY 1	1,843	\$45,034,773	\$24,436	\$592,492	24.2	\$285,523	11.6
PY 2	2,084	\$51,924,626	\$25,157	\$683,137	27.2	\$329,205	13.1
PY 3	2,291	\$59,373,774	\$25,916	\$781,140	30.1	\$376,433	14.5

The table above shows that in Project Year 3, OSCG will be performing, on average, only 2.5 Medicaid cases and 1.2 Charity Care cases per month, out of approximately 190 total projected monthly cases.

For a project that professes to enhance access to care by underserved groups, OSCG's projections fall short. The OSCG application does not conform with Review Criterion 13, specifically Item (c).

Review 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 would not have a favorable impact.

² See discussion of Review Criterion 3, "Access to Care."

OSCG proposes that an additional freestanding ASF will enhance competition and provide cost containment. However, OSCG fails to clearly detail how its ASF will do either. Most of the cost containment outline details how payers are proposing to contain costs, not how OSCG can do so with two additional ORs.

Further, OSCG stresses the quality ratings of Rex and ROC, yet acknowledges elsewhere in the application that the application for ORs is predicated on surgeon preference to perform in ORs instead of procedure rooms.

OSCG states this "proposed project will promote equitable access, particularly to the medically underserved groups", although, as stated in above section on Access to Care, they clearly state they would only be offering services to 1.3 percent of Medicaid patients a year and 66 Charity Care patients through their "Project Access" a year - this is not "equitable access". Please see discussion under Review Criteria 3 and 13.

UNC Rex Hospital – Develop One Additional Hospital-Based Operating Room Project No. J-11963-20

Review 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.

Impact of Rex-Holly Springs

The UNC Rex Hospital ("Rex") proposal, like its applications filed in 2018 (Project No. J-11555-18) and 2019 (J-11761-19), is based on premise of backfilling OR capacity slated to be relocated to Rex-Holly Springs Hospital (Project No. J-8669-11), which is projected to open in August 2021. Surgical utilization at area facilities has been increasing, particularly on the inpatient side – this has been a common theme among acute care facilities even where the number of freestanding ASFs has increased and more outpatient cases are being performed outside the hospitals.

Rex is projecting that some of its surgical volume at Rex-Main will shift to Rex-Holly Springs. However, until Rex-Holly Springs opens, it is impossible to gauge the impact of that facility, which is located more than 18 miles away, on Rex-Main's operations and volume. WakeMed believes that this relocation was thoroughly analyzed, vetted, and subsequently approved because it was not deemed to place an undue burden on the facility, physicians, or patients seeking services. As such, by way of UNC REX Hospital volunteering to relocate these operating rooms to another of their facilities, they have proven they are more than capable of continuing to serve their patients without disruption, despite the decrease in operating rooms and known future recruitment efforts.

While Rex's statement that it has the highest inpatient and outpatient surgery volume of any single provider in Wake County is true. However, it is also true that Rex-Main has the highest number of surgical operating rooms among Wake County providers.

Furthermore, UNC REX Hospital was approved, in a 2018 settlement, to develop two additional operating rooms (proposed in Project No. J-11555-18), which became operational on August 22, 2020. These two operating rooms offset the three they plan to relocate to Holly Springs Hospital, leaving their voluntary deficit at only one operating room — which, until the Rex-Holly Springs opening proves otherwise, may actually show that Rex-Main is not at a deficit due to the shift in volume.

Approving any additional ORs to Rex before the pieces of their puzzle are still shifting in motion would be a disservice to the citizens and patients seeking care in Wake County. This could potentially over resource a facility in a location that cannot yet accurately show a need, in spite of others that have.

Comparison of Health Care Costs

On Page 13, 32, 83, Rex provides data from the Blue Cross Blue Shield of North Carolina (BCBSNC) web site, "Estimated Health Care Costs of Select Top 20 Outpatient Surgical Procedures", comparing health care costs for two selected outpatient surgical procedures. The data is accompanied by the following sentence:

"As demonstrated in the table above, UNC REX Hospital provides lower costs per procedure for BCBS patients than Duke Raleigh (WakeMed Cary and WakeMed Raleigh's cost data was not available in the Blue Cross Blue Shield tool)."

This statement alone is disqualifying, since Rex opted to use data that did not contain information for all Wake County hospitals. Any analysis that does not include all Wake County hospital providers carries no weight. In the next sentence, Rex states:

"In fact, it is likely that UNC REX Hospital will continue to offer the <u>lowest cost of care</u> to patients for surgical services in Wake County when compared to other hospital providers as changes to the health insurance landscape unfold."

While the table on Pages 13, 32, 83 is offered as evidence of Rex's supposed lower surgical costs, only 2 procedures are listed on the table, with no direct comparisons between all Wake County hospitals. Rex has conveniently cherry-picked data from a single insurer, for only *two* surgical procedures, and for which data is available for only *two* hospitals, as proof that it is the "low cost provider" for surgical services in Wake County. Without a more complete analysis of surgical costs across multiple payers, including Medicare, that includes all providers, this information is meaningless.

Patient Origin

On Page 19, the Rex application provides projected patient origin for its operating rooms at Rex-Main in Project Years 1-3. Projected patient origin is identical to historic patient origin shown on Page 18, despite the fact that Rex-Holly Springs Hospital is projected to draw surgical volume away from Rex-Main. The projected shift in case volume to Rex-Holly Springs would be expected to result in a corresponding change in projected patient origin. It is not reasonable to assume that Rex-Main's surgical patient origin would remain identical after the opening of Rex-Holly Springs.

For these reasons, the Rex application does not conform with Review Criterion 3.

Review 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 Rex application describes several options that were considered, in addition to the chosen alternative. Given the trend toward greater proportions of surgery being performed on an outpatient basis, and the cost savings this represents to payers and patients, it is unusual that Rex would propose to create additional inpatient capacity at Rex-Main. In Section C, Rex did not describe any difficulties in accommodating surgery patients with Rex-Main's existing complement of ORs, which will be supplemented with the 2 additional ORs approved in Project No. J-11555-18.

One alternative apparently not considered was to seek additional OR capacity at Rex Holly Springs, which has yet to be developed, thereby leaving Rex's main campus OR inventory intact.

When compared with other proposals in this review, the Rex application is neither the least costly nor most effective alternative, and thus does not conform with Review Criterion 4.

Review Criterion 6

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

In Settlement negotiations, Rex Hospital was approved for 2 of the 6 operating rooms allocated to Wake County in the 2018 SMFP. UNC Health, Rex's parent company, currently operates or is approved for six locations in Wake County where surgical services are performed, including 4 freestanding ASFs:

- Rex Hospital Main Campus
- Rex Surgery Center of Cary
- Rex Surgery Center of Wakefield
- Raleigh Orthopaedic Surgery Center-Raleigh
- Raleigh Orthopeadic Surgery Center-West Cary
- Rex Holly Springs Hospital under development

While Rex maintains that it is seeking additional OR capacity at its main campus to offset ORs earmarked for relocation to Rex Holly Springs Hospital, this is same justification provided in its 2018 application. Thus, Project No. J-11963-20 is duplicative of the approved Project No. J-11555-18.

For these reasons, the Rex application does not conform with Review Criterion 6.

Review Criterion 12

Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

Rex proposes to renovate 425 square feet at its main campus to accommodate one additional operating room. The room is designated on the line drawing in Exhibit C.1 as "OR 52". WakeMed could only identify 6 ORs in the line drawing in Exhibit C.1. The line drawing does not identify all the existing surgical ORs at Rex, thus is not possible for the Agency to verify that Rex will have 25 surgical ORs upon project completion.

For this reason, the Rex application does not conform with Review Criterion 12.

Review 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 would not have a favorable impact.

Rex, through its parent company UNC Health Care, has again proposed to monopolize development of all available operating rooms allocated in the 2020 Wake County review, by proposing to add one OR at Rex-Main Campus and two ORs at Orthopaedic Surgery Center of Garner, a partnership between UNC Health Care and Raleigh Orthopaedic Clinic, which is currently solely owned by UNC Health. UNC Health sought approval for all 6 ORs available in the 2018 Wake County review, both available ORs in the 2019 review, and again all three available ORs in 2020.

On Page 33, Rex describes the cost containment program being enacted by Blue Cross Blue Shield of North Carolina (BCBSNC), and how the proposed project "will assist UNC Rex Hospital to better meet the goals of these payors, which will ultimately lower costs, expand access, and improve the quality of care for its patients." The program Rex described will affect all North Carolina health care facilities that treat BCBSNC enrollees. Though Rex thoroughly describes BCBSNC's plan, they fall significantly short in even beginning to detail a plan on how an additional OR would support expanded access to all patients and decrease costs. In fact, on Page 74 quoted below, Rex states quite the opposite, and how it has no obligation to provide these very same services, contradicting their statement on Page 33.

"UNC REX Hospital has had no obligation to provide uncompensated care, community service, or access to care by medically underserved, minorities, or handicapped persons during the last three years. However, in order to maintain UNC REX Hospitals' 501(c)(3) tax-exempt status, it is necessary to fulfill a general obligation to provide access to healthcare services for all patients needing care, regardless of their ability to pay. UNC REX Hospital does this on a routine basis for all patients regardless of referral source."

Rex further states that their portion of self-pay patients for OR utilization is 2.7 percent. In contrast, WakeMed proposes providing 7.4 percent total surgical cases to self-pay patients, more than 2.5 times the access that Rex will provide with their proposed project.

Approving three operating rooms to UNC Health (two to OSCG and one to Rex-Main), would effectively eliminate the ability of competitors in the market from offering Wake County residents different services at potentially lower rates, by monopolizing competitive growth in the market through prioritizing a single-specialty ASC and/or awarding duplicative resources.

For these reasons, the Rex application does not conform with Review Criterion 18a.

Section Q: Projections/Pro Formas

Projected Utilization at UNC Rex Hospital

In Section Q, the Rex application describes projected surgical utilization at all facilities owned by UNC Health in Wake County. For Rex-Main, the utilization methodology projects inpatient surgery to increase by a modest 1.3 percent per year through 2025, although inpatient CAGR for 2018-2020 was

2.6 percent. For outpatient surgery, Rex again projects a conservative annual growth rate of 2.2 percent through 2025, matching its historic CAGR for 2018-2020.

Closer examination of Rex's surgery volume suggests that its outpatient case volumes may be growing more slowly than disclosed in the application. When data from 2015-2017 were added to the timeline to match the corresponding time period for inpatient surgery, Rex's actual historic outpatient surgery CAGR was much lower, as shown below.

Rex Hospital Outpatient Surgery Volume Excluding Rex Surgery Center of Wakefield FYs 2015-2020					
Rex FY	OP Cases	Source			
2015	11,577	Rex LRA			
2016	11,062	Rex LRA			
2017	10,720	Rex internal data			
2018	10,898	Rex internal data			
2019	11,705	Rex internal data			
2020**	11,890	Rex internal data			
CAGR	0.53%				

It is not clear why Rex chose to omit its FYs 2015-2017 outpatient case volumes, but its outpatient surgery CAGR for 2015-2020 indicates relatively flat growth. The data indicates that development of additional surgery centers in Wake County in recent years, including Raleigh Orthopaedic Surgery Center-Main, Raleigh Orthopaedic Surgery Center-West Cary, Triangle Orthopaedics Surgery Center, and Holly Spring Surgery Center may have impacted Rex's outpatient surgery volumes, at least in the short-term. Applying a lower growth rate through 2025 would negatively impact Rex's projected outpatient volumes, as well as its financial projections.

Furthermore, Rex states that "surgical cases that surgeons performed in Raleigh Orthopaedic Surgery Center's procedure rooms due to operating room capacity constraints would have been performed in operating rooms if there had been sufficient capacity" confirms that the cases mentioned were appropriate for the procedure room and should continue to be performed in the procedure room setting. Any argument in opposition would indicate potential safety or ethical questions of performing procedures in inappropriate settings of care for patients at high risk of complications, or in unnecessarily financially burdensome settings of care that are contraindicated, simply because a surgeon preferred to perform in a hospital.

Rex projects their surgical utilization after the shift of three operating rooms to their Holly Springs location. In their table on page 8 of Assumptions and Methodology, they show that their total outpatient utilization will return to within 49 cases, and inpatient utilization will return to within 178 cases by SFY26. Rex also frequently projects a need of 3.5 operating rooms, which seemingly fails to include the two operating rooms they were awarded in the 2018 settlement.

Shift of Cases to Rex Holly Springs

Rex Holly Springs Hospital (Project No. J-8669-11) was proposed in 2011 and originally slated for completion in 2014. According to the Rex application in this review, the new hospital is currently scheduled to open in August 2021. Projections for Holly Springs Hospital have not been modified since

originally proposed in 2011. However, the demographics of Wake County have changed dramatically since then, and the number of existing and approved surgical providers and ORs throughout the county is much larger. Although the Agency found the projected shift of cases from Rex-Main to Rex-Holly Springs to be reasonable in the 2018 and 2019 Wake County OR reviews, there have been sufficient changes in the Wake County healthcare landscape in recent years to warrant re-examining these projections. Several issues can be raised, including:

- Is it still reasonable to assume that 90 percent of Rex-Holly Springs' surgical volumes will be the result of cases shifted from Rex-Main?
- Should projections for Rex-Holly Springs have been modified to reflect demographic changes in Wake County and the Holly Springs area during the interim years since originally proposed?
- Will the development of new ASFs in Wake County in recent years affect projected surgery utilization at Rex-Holly Springs?
- Will the opening of Rex Holly Springs Hospital impact utilization at Rex Surgery Center of Cary and/or Raleigh Orthopaedic Surgery Center-West Cary?

Such questions are not unreasonable, given the amount of time that has passed since Rex Holly Springs was first proposed.

Duke University Health System – Development New Freestanding ASF with One Operating Room and Two Procedure Rooms Project No. J-11966-20

Duke proposes to develop a new ambulatory surgery center with one surgical operating room and two procedure rooms in Garner in Wake County ("Duke-Garner") (Project No. J-11966-20), This application is nonconforming with several CON Review Criteria, as evidenced below.

There are numerous erroneous references in Duke-Garner application to the Duke-Green Level project (Project No. J-11967-20), particularly in Section Q. Specifically, Form C, Form F.1a, Form F.2, Form F.3 and Form H all reference Duke-Green Level, rather than Duke-Garner. The Need Methodology in Section Q, however, describes Duke-Garner. While Duke considers Project Nos. J-11966-20 and J-11967-20 to be "complementary" applications, each application must contain accurate references and be capable of being evaluated independently.

Review 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.

Overview

The proposed Duke Garner facility will be a new freestanding ASF located in Garner within a new DUHS medical office building to be developed at 1011 New Rand Road,

Garner, NC 27529, with a total of 1 ORs and 2 procedure rooms upon completion. The Duke-Garner project will be developed to allow Duke Medicine physicians based in Durham and Raleigh access to a second freestanding ASF located in Wake County.

<u>Surgical Utilization at Duke Raleigh Hospital</u>

Throughout Section C, the Duke-Garner proposal describes growth in surgical utilization at Duke Raleigh Hospital, and capacity constraints on its existing operating rooms and procedure rooms. On pages 23-24, Duke indicates that its 2015-2020 inpatient surgery CAGR was 1.9 percent, while outpatient surgery CAGR over the same period was 4.2 percent. However, , on page 120 in Section Q, Duke opts to utilize the 2018-2020 inpatient CAGR of 5.5 percent (capped at 5.0 percent), and outpatient CAGR of 1.1 percent. Duke provides no explanation of why it uses the CAGRs for the shorter timeframe, although a higher CAGR for inpatient cases results in higher projected inpatient surgical hours.

Claims Regarding Improved Geographic Access Are Exaggerated

Throughout the application, Duke insists that development of the Garner ASF will increase access to outpatient surgical services. Despite these assertions, the Duke-Garner project will be located far from Duke's major acute care facilities, and presumably, many of the surgeons who currently practice there. The proposed site is approximately 36 road miles from Duke University Hospital and 14 road miles on the fastest route from Duke Raleigh Hospital. In fact, travel time to the Duke-Arringdon site from Duke-Raleigh is generally less than the travel time to reach Duke-Garner. Please see the following table.

From Duke Raleigh Hospital	Shortest Route		Fastest Route	
(3400 Wake Forest Rd, Raleigh, NC 27609) to:	Distance (miles)	Drive Time (minutes)	Distance (miles)	Drive Time (minutes)
Duke-Garner 1011 New Rand Road, Garner, NC 27529	11.9	~31	13.8	~21
Duke-Arringdon 5601 Arringdon Park Dr., Morrisville, NC 27560	16.5	~30	16.8	~19

Source: Google Maps, www.google.com/maps

The Duke-Garner project's success is dependent upon a number of factors, including:

- Large shifts of current patient case volumes from existing facilities and to several proposed facilities;
- Support from surgeons from Duke Medicine's Private Diagnostic Clinic (PDC) many of whom practice at two or more Duke practice locations, including Duke University Hospital in Durham, Duke Raleigh Hospital, and other community locations throughout the Triangle area; and,
- The assumption that patients from a wide geographic area will be attracted to the Duke-Garner facility, despite being located more closely to other Duke and non-Duke surgery centers in the region.

On Pages 31, the Duke-Garner application describes projected population growth in Wake County at the ZIP Code level, showing that many of the zip codes in Wake County have projected population growth rates that exceed the overall county growth rate – however it should be noted that Garner is not one of the highest growth areas listed so their argument here falls short. Also, on Page 18, the application states the Duke-Garner projected patient origin: "is based on the FY2020 ambulatory surgery patient origin for Duke Raleigh Hospital (DRAH)" and "the vast majority (approximately 74 percent in project year 3) of Duke Health GarnerASC's surgical cases are based on the projected shift of ASC-appropriate cases from DRAH to the proposed facility. The remainder is expected to shift from Duke University Hospital, which serves the same primary service area." This is problematic in the sense that Duke projects no difference in patient origin between Duke-Raleigh and Duke-Garner, despite the fact that the new ASF will be located 23 road miles from Duke-Raleigh, geographically closer to the high-growth area of southern Wake County. Muddying the waters even further, the application does not account for the origin of patients they claim will shift from Duke University Hospital, 36 miles away. These inconsistencies make the projections suspect, not to mention common sense would suggest that one would expect Duke-Garner's patient origin to have higher proportions of patients from Wake County (projected in the application to be 51.1 percent), and smaller proportions from areas such as Franklin, Cumberland, and Nash Counties.

In Section Q, Duke projects that approximately 75 percent of Duke-Garner's volume will result from a shift of cases from Duke-Raleigh, which received 25 percent of its FY 2019 outpatient surgery patients from "Other States" and "Other NC Counties" – given this large patient origin area it is improbable that shifting cases from DRAH to Duke-Garner will positively impact access. Furthermore, the new ASF will be less proximate for many residents of Wake County and the region.

WakeMed believes that failure to account for a shift in patient origin proves that the Duke-Garner application does not improve geographic access to outpatient surgical services.

Discrepancies in Surgery Volumes Reported at Duke Raleigh Hospital

Duke submitted two CON applications for operating rooms in the Wake County Operating Room Service Area in 2018, based on the need determination in the 2018 SMFP:

- Project No. J-11557-18: Develop a freestanding ASF (Duke-Green Level) with four ORs;
- Project No. J-11558-18: Develop two additional shared ORs at Duke Raleigh Hospital.

The 2018 Wake County Operating Room Service Area need determination for six ORs was driven largely by the surgical volumes reported for Duke Raleigh Hospital. Just prior to the Agency's decision date, Duke withdrew Project No. J-11558-18 - Duke-Raleigh had been erroneously combining the volumes performed in its licensed operating rooms and unlicensed procedure rooms, which had overstated Duke-Raleigh's surgical volumes for an undetermined number of years. Because the 2018 Duke-Green Level application's utilization projections were integrally tied to volume shifts from Duke-Raleigh, the Agency denied this application, due to the unreliability of the Duke-Raleigh volumes.

In the 2020 Duke-Garner application, there is only a mere footnote mention of these significant reporting errors from the previous application, and no mention of how they have been reconciled in a trustworthy manner. Rather, Duke describes its outpatient surgical volumes at Duke-Raleigh as having been performed in ORs or in procedure rooms. Duke cites no difference in reimbursement based on location where the case is performed. Because Duke-Garner's projections are still largely dependent on cases to be shifted from Duke-Raleigh, Duke's failure to note how it has accounted for its prior reporting errors at Duke-Raleigh make the projections in this application unreliable.

For these reasons, the Duke-Garner application does not conform with Review Criterion 3.

Review 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 Duke-Garner application describes several alternatives to the proposed project, including maintaining the status quo, developing additional ORs at Duke Raleigh Hospital, developing 3 ORs in a single location, and developing a new ASF in another location. The application does not provide an adequate discussion as to why developing 2 additional ORs at Duke-Garner is the most optimal alternative.

Throughout the application, Duke describes the continued growth in surgical volume and related OR capacity issues at Duke Raleigh Hospital, and posits that the most effective alternative to deal with this growth is to develop additional ORs, not at Duke-Raleigh, but at Duke-Garner. Given the continued growth in surgery volumes at Duke-Raleigh, another more effective alternative would be to develop a new ASF adjacent to Duke Raleigh Hospital, where surgeons could easily access both ASF and hospital ORs and where patients would not be unduly indisposed by additional travel time. This alternative was not discussed.

On Page 62, the Duke-Garner application contains the following statement: "...the proposed additional ORs to be developed in connection with both DUHS ASC projects will increase access to cost effective, dedicated-ambulatory surgical services for many of the

patients whose surgical cases have historically been performed in DRAH's ORs and procedure rooms." However, there is little evidence provided that shifting cases from Duke-Raleigh to a proposed site located 12 miles south would increase access.

A more effective alternative would be to shift some cases, where reasonable, to the Duke-Arringdon facility and develop either additional licensed OR capacity at, or a freestanding ASF adjacent to, Duke Raleigh Hospital.

For these reasons, the Duke-Green Level application does not conform with Review Criterion 4.

Review Criterion 8

The applicant shall demonstrate that the provider of the proposed services will make available or otherwise make arrangement for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed services will be coordinated with the existing health care system.

The Duke-Garner application provides support letters from local physicians, however most are for their Green Level site with no mention of the Garner site. There is no standard regarding a minimum of number of letters expected or required. However, it is worth noting that all surgeon letters of support were provided by surgeons employed or otherwise affiliated with Duke Health System, despite the application stating "Exhibit C.4 includes letters from Duke Health and other surgeons in the community."

The disparity in the applications claims and actual letters of support provided indicate poor coordination at best and more likely intent for the facility to grant little, if any, real access to non-Duke physicians in the community. For this reason, the application does not conform to Review Criterion 8.

Review 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 would not have a favorable impact.

The Duke-Garner application provides rationale for how the proposed project will increase competition for surgical services in Wake County. On Page 107, Duke states:

"DUHS is the only integrated health system currently without an operational freestanding ASC in Wake County."

The following paragraph states:

"The planned ASC project represents a new opportunity for Wake County residents and DUHS patients to access Duke outpatient surgical services separate from the hospital charge structure."

It is not clear how either of these statements demonstrate a positive effect on competition. Although Duke Health System does not *currently* operate a freestanding ASF in Wake County, it has several facilities under development either in or adjacent to Wake County:

- Duke-Green Level facility has been approved for 1 OR and 5 procedure rooms in western Wake County via Project No. J-11557-18.
- The Duke-Arringdon facility (Project No. J-11508-18), approved to develop an ASF with 4 ORs and 4 procedure rooms, less than one-half mile from the Wake/Durham county line.
- Duke also owns Same Day Surgery Center-Franklin ("SDSC-Franklin") (Project Nos. K-8357-09 & K-10229-13), which is approved to develop a freestanding ASF with 2 ORs in Youngsville in southern Franklin County, approximately 4 miles from the Wake/Franklin county line. SDSC-Franklin will give Duke physicians yet another venue for outpatient surgery that is very close to, although not physically within, Wake County.

Given that Duke has two ASF projects already approved for development just outside the physical boundary of Wake County that will ultimately offer a total of 6 ORs, the claim that Duke does not have an operational freestanding ASC in wake county and Duke-Garner enhances competition is superfluous. For these reasons, the Duke-Green Level application does not conform with Review Criterion 18.

Section P: Timetable

Duke states that the Garner ASF project will not become operational until early 2023, one of the last projects in the review to open.

Section Q: Projections/Pro Formas

Duke ASFs Located Outside Wake County

In Section Q, the Duke-Garner application provides a lengthy discussion regarding OR capacity and utilization in the Duke system, both in Wake and Durham Counties. The methodology describes the historic surgical volumes at all Duke locations, regardless of location, as well as the projected shift of cases between Duke facilities. The discussion is confusing at times, because so many Duke facilities are impacted by so many proposed volume shifts between counties.

On Page 82, the application states that Duke-Garner:

"...will not result in any unnecessary duplication of services in the applicable service area (i.e., Wake County). The need for the proposed ASC is complementary to but independent of the need to develop Arringdon ASC."

This passage is important because Duke is using a technicality in the SMFP Operating Room Need Methodology to declare that because Duke-Green Level and Duke-Arringdon are located in separate counties, and therefore separate in OR Service Areas, the two facilities cannot be duplicative. This position would be more credible if the Duke-Garner utilization methodology did not specifically mention proposed shifts in case volumes from Duke-Raleigh to Duke-Arringdon.

The utilization methodology in Section Q contains no discussion of projected shifts in outpatient surgical volumes between Duke Raleigh Hospital and its SDSC-Franklin facility. Per Google Maps, this ASF will be located approximately 17 road miles from Duke-Raleigh and only 8.4 miles from Duke Health-Heritage.

Projected Utilization of Procedure Rooms

The utilization projections provided in Section Q show that Duke-Garner's projected procedure room volumes will be very low, calculated to be less than 1 case per room per day until Project Year 3. Please see the following table.

Duke-Garner ASC						
Projected Procedure Room Utilization Following Project Completion						
	Year 1	Year 2	Year 3			
Number of Procedure Rooms	2	2	2			
Annual Days of Operation	260	260	260			
Procedure Room Cases 108 178 274						
Cases/Room/Day	0.21	0.34	0.53			

Although there is no State standard regarding procedure room utilization and capacity, the Duke-Garner volumes are exceedingly low, with Year 3 utilization barely exceeding 0.5 cases per room per day.

Duke University Health System – Two Additional Operating Rooms at Approved Facility Project No. J-11967-20

Duke proposes to develop 2 additional ORs at its recently-approved Green Level Ambulatory Surgical Facility (Project No. J-11967-20), for a total of 3 ORs and 5 procedure rooms upon project completion. This application is nonconforming with several CON Review Criteria, as evidenced below.

There are numerous erroneous references in Duke-Green Level application to the Duke-Garner project (Project No. J-11966-20), particularly in Section Q. Specifically, Form C, Form F.1a, Form F.2, Form F.3 and Form H all reference Duke-Garner, rather than Duke-Green Level. The Need Methodology in Section Q, however, describes Duke-Green Level. While Duke considers Project Nos. J-11966-20 and J-11967-20 to be "complementary" applications, each application must contain accurate references and be capable of being evaluated independently.

Review 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.

Overview

The Duke Green Level facility will be a new freestanding ASF located in 40,000 square feet in a medical office building to be developed in west Cary, with a total of 3 ORs and 5 procedure rooms upon completion. The Duke-Green Level project will be developed to allow Duke Medicine physicians based in Durham and Raleigh access to a freestanding ASF located in Wake County.

Despite claims that the ASF will improve geographic access for patients, the Duke-Green Level project will be located far from Duke's major acute care facilities. The proposed site is approximately 20 road miles from Duke University Hospital and 23 road miles from Duke Raleigh Hospital. The project's success is dependent upon a number of factors, including:

- Large shifts of current patient case volumes from existing facilities to several proposed facilities;
- Surgeons from Duke Medicine's Private Diagnostic Clinic (PDC) many of whom practice at two or more Duke practice locations, including Duke University Hospital in Durham, Duke Raleigh Hospital, and other community locations throughout the Triangle area; and,
- That patients from a wide geographic area will be attracted to the Duke-Green Level facility, despite being located more closely to other Duke and non-Duke surgery centers in the region.

According to Google Maps, the Duke-Green Level location is 9.9 road miles from Duke's Arringdon Ambulatory Surgery Center (Project No. 11508-18) currently under development, a site which is physically located in Durham County but which is less than one-half mile from the Wake/Durham county line. Approval of the proposed Duke-Green Level project will give Duke Health System 7 freestanding outpatient ORs and 9 procedure rooms essentially in Wake County. Additionally, their proposed Duke-Garner Ambulatory Surgical Center would bring that total to 8 freestanding outpatient ORs and 11 procedure rooms. Although Duke-Arringdon and Duke-Green Level will be developed in separate SMFP

Operating Room Service Areas, their relative closeness suggests that the two facilities are duplicative. Please also see the discussion for Review Criterion 6.

Surgical Utilization at Duke Raleigh Hospital

Throughout Section C, the Duke-Garner proposal describes growth in surgical utilization at Duke Raleigh Hospital, and capacity constraints on its existing operating rooms and procedure rooms. On pages 23-24, Duke indicates that its 2015-2020 inpatient surgery CAGR was 1.9 percent, while outpatient surgery CAGR over the same period was 4.2 percent. However, , on page 120 in Section Q, Duke opts to utilize the 2018-2020 inpatient CAGR of 5.5 percent (capped at 5.0 percent), and outpatient CAGR of 1.1 percent. Duke provides no explanation of why it uses the CAGRs for the shorter timeframe, although a higher CAGR for inpatient cases results in higher projected inpatient surgical hours.

Claims Regarding Improved Geographic Access Are Exaggerated

Throughout the application, Duke insists that development of the Green Level ASF will increase access to outpatient surgical services. Despite these assertions, the Duke-Green Level project will be located far from Duke's major acute care facilities, and presumably, many of the surgeons who currently practice there. The proposed site is approximately 20 road miles from Duke University Hospital and 23 miles from Duke Raleigh Hospital. In fact, the Duke-Arringdon site is closer to Duke-Raleigh than will be Duke-Green Level. Please see the following table.

From Duke Raleigh Hospital	Shortest Route		Fastest Route	
(3400 Wake Forest Rd, Raleigh, NC 27609) to:	Distance (miles)	Drive Time (minutes)	Distance (miles)	Drive Time (minutes)
Duke-Green Level 3208 Green Level West Rd., Cary, NC 27519	22.5	30	23.9	27
Duke-Arringdon 5601 Arringdon Park Dr., Morrisville, NC 27560	16.8	28	17.1	22

Source: Google Maps, www.google.com/maps,

The Duke-Green Level project's success is dependent upon a number of factors, including:

- Large shifts of current patient case volumes from existing facilities and to several proposed facilities;
- Support from surgeons from Duke Medicine's Private Diagnostic Clinic (PDC) many of whom
 practice at two or more Duke practice locations, including Duke University Hospital in Durham,
 Duke Raleigh Hospital, and other community locations throughout the Triangle area; and,
- The assumption that patients from a wide geographic area will be attracted to the Duke-Green Level facility, despite being located more closely to other Duke and non-Duke surgery centers in the region.

On Pages 32-33, the Duke-Green Level application describes projected population growth in Wake County at the ZIP Code level, showing that many of the zip codes in the western half of Wake County have projected population growth rates that exceed the overall county growth rate. WakeMed does not dispute this, as its own application for WakeMed Cary Hospital (Project No. J-11960-20) contains a similar discussion. However, on Pages 18-20, the application states the Duke-Green Level projected patient origin: "is based on the FY2020 ambulatory surgery patient origin for Duke Raleigh Hospital

(DRAH)" and "the vast majority (approximately 86 percent in project year 3) of Duke Health Green Level ASC's surgical cases are based on the projected shift of ASC-appropriate cases from DRAH to the proposed expanded Duke Health Green Level ASC facility." This is problematic in the sense that Duke projects no difference in patient origin between Duke-Raleigh and Duke-Green Level, despite the fact that the new ASF will be located 23 road miles from Duke-Raleigh, geographically closer to the high-growth areas of western Wake County as well as Durham County. One would expect Duke-Green Level's patient origin to have higher proportions of patients from Wake and Durham Counties (projected in the application to be 51.1 percent and 4.3 percent, respectively), and smaller proportions from areas such as Johnston, Franklin, Cumberland, and Nash Counties, which are located further away from Duke-Green Level. Duke-Green Level will also be closer to Chatham County, a contiguous county which is projected to experience significant population growth, yet Duke-Green Level projects Chatham will comprise only 0.4 percent of volume throughout Project Years 1-3.

In Section Q, Duke projects that 86 percent of Duke-Green Level's volume will result from a shift of cases from Duke-Raleigh, which received 25 percent of its FY 2019 outpatient surgery patients from "Other States" and "Other NC Counties" – how many patients from these unspecified areas originated from counties south and east of Wake County and will be further away from Duke-Green Level? The new ASF will be less proximate for many residents of Wake County and the region. With slightly more than one-half of its patients projected to originate in Wake County, as well as the relative proximity of Duke-Arringdon, Duke-Green Level does little to enhance geographic access.

WakeMed believes that failure to account for a shift in patient origin proves that the Duke-Green Level application does not improve geographic access to outpatient surgical services.

<u>Discrepancies in Surgery Volumes Reported at Duke Raleigh Hospital</u>

Duke submitted two CON applications for operating rooms in the Wake County Operating Room Service Area in 2018, based on the need determination in the 2018 SMFP:

- Project No. J-11557-18: Develop a freestanding ASF (Duke-Green Level) with four ORs;
- Project No. J-11558-18: Develop two additional shared ORs at Duke Raleigh Hospital.

The 2018 Wake County Operating Room Service Area need determination for six ORs was driven largely by the surgical volumes reported for Duke Raleigh Hospital. Just prior to the Agency's decision date, Duke withdrew Project No. J-11558-18 - Duke-Raleigh had been erroneously combining the volumes performed in its licensed operating rooms and unlicensed procedure rooms, which had overstated Duke-Raleigh's surgical volumes for an undetermined number of years. Because the 2018 Duke-Green Level application's utilization projections were integrally tied to volume shifts from Duke-Raleigh, the Agency denied this application, due to the unreliability of the Duke-Raleigh volumes.

In the 2020 Duke-Green Level application, there is only a mere footnote mention of these significant reporting errors from the previous application, and no mention of how they have been reconciled in a trustworthy manner. Rather, Duke describes its outpatient surgical volumes at Duke-Raleigh as having been performed in ORs or in procedure rooms. Duke cites no difference in reimbursement based on location where the case is performed. Because Duke-Green Level's projections are still largely dependent on cases to be shifted from Duke-Raleigh, Duke's failure to note how it has accounted for its prior reporting errors at Duke-Raleigh make the projections in this application unreliable.

Review 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 Duke-Green Level application describes several alternatives to the proposed project, including maintaining the status quo, developing additional ORs at Duke Raleigh Hospital, developing 3 ORs in a single location, and developing a new ASF in another location. The application does not provide an adequate discussion as to why developing 2 additional ORs at Duke-Green Level is the most optimal alternative.

Throughout the application, Duke describes the continued growth in surgical volume and related OR capacity issues at Duke Raleigh Hospital, and posits that the most effective alternative to deal with this growth is to develop additional ORs, not at Duke-Raleigh, but at Duke-Green Level. Given the continued growth in surgery volumes at Duke-Raleigh, another more effective alternative would be to develop a new ASF adjacent to Duke Raleigh Hospital, where surgeons could easily access both ASF and hospital ORs and where patients would not be unduly indisposed by additional travel time. This alternative was not discussed.

On Page 60, the Duke-Green Level application contains the following statement: "...the proposed additional ORs to be developed in connection with both DUHS ASC projects will increase access to cost effective, dedicated-ambulatory surgical services for many of the patients whose surgical cases have historically been performed in DRAH's ORs and procedure rooms." However, there is little evidence provided that shifting cases from Duke-Raleigh to a proposed site located 23 miles west would increase access for residents located in areas south and east of Wake County.

The most recent publicly available outpatient surgery patient origin for Duke Raleigh Hospital was provided in the 2020 Hospital License Renewal Application, which contains FY 2019 data. On Page 20, the application provides the FY 2020 Duke Raleigh Hospital outpatient surgery patient origin, which is used to develop projected patient origin for both the Duke-Green Level and Duke-Garner projects. Of these, 1,926 cases, or 29.3 percent of total, came from 42 counties located either due south or east of Wake County, and thus further away from Duke-Green Level than Duke-Raleigh. Therefore, it could be assumed that the Duke-Green Level project will be *less accessible* for up to 29.3 percent of its potential patients, not including patients with potentially reduced access from parts of Wake County. Please see the following table.

Duke Raleigh Hospital						
FY 2020 Outpatient Su	irgery Cases	for Counties				
Located South and	East of Wal	ce County				
Listed in descending o	rder by nun	nber of cases				
	FY 2020 Percent of					
	OP Total Duke					
Surgery Raleigh						
County Cases Cases						
Johnston	319	4.85%				

Duke Raleigh Hospital FY 2020 Outpatient Surgery Cases for Counties Located South and East of Wake County Listed in descending order by number of cases

Listed in descending o	FY 2020	Percent of
	OP	Total Duke
	Surgery	Raleigh
County	Cases	Cases
Franklin	233	3.54%
Cumberland	201	3.06%
Nash	122	1.86%
Pitt	112	1.70%
Wayne	95	1.44%
Carteret	64	0.97%
Wilson	63	0.96%
New Hanover	60	0.91%
Onslow	50	0.76%
Robeson	49	0.75%
Halifax	49	0.75%
Craven	49	0.75%
Brunswick	44	0.67%
Beaufort	40	0.61%
Sampson	40	0.61%
Bertie	32	0.49%
Edgecombe	32	0.49%
Lenoir	25	0.38%
Warren	21	0.32%
Chowan	21	0.32%
Northampton	21	0.32%
Hoke	19	0.29%
Hertford	18	0.27%
Washington	17	0.26%
Bladen	14	0.21%
Duplin	13	0.20%
Martin	12	0.18%
Greene	12	0.18%
Pender	11	0.17%
Dare	11	0.17%
Richmond	11	0.17%
Columbus	8	0.12%
Perquimans	8	0.12%
Pasquotank	6	0.09%
Gates	5	0.08%
Scotland	4	0.06%
Pamlico	4	0.06%
Currituck	4	0.06%
Tyrrell	3	0.05%
Jones	2	0.03%
Hyde	2	0.03%
Subtotal South/East	1,926	29.29%
Total for Duke Raleigh	6,575	

A more effective alternative would be to shift some cases, where reasonable, to the Duke-Arringdon facility and develop either additional licensed OR capacity at, or a freestanding ASF adjacent to, Duke Raleigh Hospital.

Another alternative apparently not considered, one would be potentially far less expensive, would be to convert 2 of the 5 procedure rooms at Duke-Green Level, approved in Project No. J-11557-18, to licensed operating rooms. Such a proposal would only require equipment necessary to upfit the new ORs – the shell space for the ASF was approved in J-11557-18.

For these reasons, the Duke-Green Level application does not conform with Review Criterion 4.

Review Criterion 8

The applicant shall demonstrate that the provider of the proposed services will make available or otherwise make arrangement for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed services will be coordinated with the existing health care system.

The Duke-Green Level application provides a number of support letters from local physicians. There is no standard regarding a minimum of number of letters expected or required. However, it is worth noting that all surgeon letters of support were provided by surgeons employed or otherwise affiliated with Duke Health System.

On Page 89, the Duke-Green Level application states: "...any other community or North Carolina physicians will be able to continue to refer patients to DUHS for services, for treatment by DUHS physicians." The intent to make the ORs at Duke-Green Level available only to employed physicians demonstrates a lack of coordination with the existing health care system, and is a disservice to independent surgeons who do not wish to be employed by a larger system. For this reason, the application does not conform to Review Criterion 8.

Review Criterion 12

Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

With a capital cost of \$6,000,000, the Duke-Green Level proposal is the 3rd most expensive in the review; behind the Orthopaedic Surgery Center of Garner (J-11962-20) and the Duke-Garner (J-11966-20) proposals. It is an especially expensive proposal, considering that the project is an upfit of approved shelled space.

With a capital cost of \$666.67 per square foot $[6,000,000 \div 9,000 = 666.67]$, the Duke-Green Level project would *appear* to be, based information provided in the application, in line with most of the other proposals in the review. However, given that the proposed project proposes to upfit space for only 2 ORs, the cost per square foot is likely much higher. The line drawing provided in Exhibit K.2 was not of

sufficient quality to ascertain the square footage of each proposed OR. If one assumes each upfitted OR will be generously-sized at 650 square feet, the total project cost would be \$4,615.38 per square foot $[6,000,000 \div (650 \times 2) = 4615.38]$, making it one of the most expensive projects in the review, and the most expensive for an approved applicant.

For these reasons, the Duke-Green Level application does not conform with Review Criterion 12.

Review 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 would not have a favorable impact.

The Duke-Green level application provides rationale for how the proposed project will increase competition for surgical services in Wake County. On Page 107, Duke states:

"DUHS is the only integrated health system currently without an operational freestanding ASC in Wake County."

The following paragraph states:

"The planned ASC project represents a new opportunity for Wake County residents and DUHS patients to access Duke outpatient surgical services separate from the hospital charge structure."

It is not clear how either of these statements demonstrate a positive effect on competition. Although Duke Health System does not *currently* operate a freestanding ASF in Wake County, it has several facilities under development either in or adjacent to Wake County:

- Duke-Green Level facility has been approved for 1 OR and 5 procedure rooms in western Wake County via Project No. J-11557-18.
- The Duke-Arringdon facility (Project No. J-11508-18), approved to develop an ASF with 4 ORs and 4 procedure rooms, less than one-half mile from the Wake/Durham county line.
- Duke also owns Same Day Surgery Center-Franklin ("SDSC-Franklin") (Project Nos. K-8357-09 & K-10229-13), which is approved to develop a freestanding ASF with 2 ORs in Youngsville in southern Franklin County, approximately 4 miles from the Wake/Franklin county line. SDSC-Franklin will give Duke physicians yet another venue for outpatient surgery that is very close to, although not physically within, Wake County.

Given that Duke has two ASF projects already approved for development just outside the physical boundary of Wake County that will ultimately offer a total of 6 ORs, the effect on competition of additional ORs at Duke-Green Level is superfluous. For these reasons, the Duke-Green Level application does not conform with Review Criterion 18.

Section P: Timetable

Duke states that the Green Level ASF project will open in early 2024, which would be the last project in the review to become operational. Given that Duke-Green Level was originally approved in 2019, it is not clear why the project would open after Duke-Garner, which is being proposed for the first time.

Section Q: Projections/Pro Formas

Duke ASFs Located Outside Wake County

In Section Q, the Duke-Green Level application provides a lengthy discussion regarding OR capacity and utilization in the Duke system, both in Wake and Durham Counties. The methodology describes the historic surgical volumes at all Duke locations, regardless of location, as well as the projected shift of cases between Duke facilities. The discussion is confusing at times, because so many Duke facilities are impacted by so many proposed volume shifts between counties.

On Page 118, the application states that Duke-Green Level:

"...will not result in any unnecessary duplication of services in the applicable service area (i.e., Wake County). The need for Green Level ASC is complementary to but independent of the need to develop Arringdon ASC."

This passage is important because Duke is using a technicality in the SMFP Operating Room Need Methodology to declare that because Duke-Green Level and Duke-Arringdon are located in separate counties, and therefore separate in OR Service Areas, the two facilities cannot be duplicative. This position would be more credible if the Duke-Green Level utilization methodology did not specifically mention proposed shifts in case volumes from Duke-Raleigh to Duke-Arringdon.

The utilization methodology in Section Q contains no discussion of projected shifts in outpatient surgical volumes between Duke Raleigh Hospital and its SDSC-Franklin facility. Per Google Maps, this ASF will be located approximately 17 road miles from Duke-Raleigh and only 8.4 miles from Duke Health-Heritage. SDSC-Franklin will be located somewhat closer to Duke-Raleigh than will Duke-Green Level, yet the Duke-Green Level utilization methodology provides no description of the impact of SDSC-Franklin on surgical utilization at Duke facilities.

Projected Utilization of Procedure Rooms

In Project No. J-11-558-18, Duke-Green Level was approved in Settlement negotiations for 1 licensed OR and 5 unlicensed procedure rooms. In Project No. J-11967-20, Duke-Green Level seeks two additional licensed ORs, with no change in approved procedure room capacity. The utilization projections provided in Section Q show that Duke-Green Level's projected procedure room volumes will be very low, calculated to be less than 1 case per room per day until Project Year 3. Please see the following table.

Duke-Green Level ASC						
Projected Procedure Room U	Projected Procedure Room Utilization Following Project Completion					
Year 1 Year 2 Year 3						
Number of Procedure Rooms	5	5	5			
Annual Days of Operation 260 260 26						
Procedure Room Cases 687 1,007 1,517						
Cases/Room/Day	0.53	0.77	1.17			

The Year 3 utilization of only 1 procedure room at Duke Green Level would be 1.17 cases per room per day $[(1,517 \div 5) \div 260 = 1.1669]$.

Although there is no State standard regarding procedure room utilization and capacity, the Duke-Green Level volumes are exceedingly low. In the CON application for Project No. J-11558-18, procedure room volume projections at Duke-Green Level were the same, even though that application proposed *fewer* procedure rooms. Please see the following table.

Duke-Green Level ASC					
Comparison of Procedure	Room Volume I	Projections			
Between the 2018 a	nd 2019 Applica	tions			
	Duke-Green	Duke-Green			
	Level Level				
	Project No. Project No.				
	J-11558-18 J-11753-19				
Procedure Rooms Proposed	4	5			
Project Year 1 Volume	687	687			
Project Year 2 Volume 1,007 1,007					
Project Year 3 Volume	1,517	1,517			

It could be argued that the proposed capital outlay to develop 2 additional operating rooms at Duke-Green Level would be better spent converting 2 underutilized procedures rooms to licensed ORs.