and

Orthopaedic Surgery Center of Garner, LLC

Comments on Competing Applications for Additional Operating Rooms in Wake County

November 2, 2020

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submitted by

Rex Hospital, Inc. and Orthopaedic Surgery Center of Garner, LLC

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Rex Hospital, Inc. d/b/a UNC REX Hospital and Orthopaedic Surgery Center of Garner, LLC (OSCG) (collectively, "UNC REX") hereby submit the following comments related to competing applications to develop additional operating rooms to meet the need identified in the *2020 State Medical Facilities Plan* (*2020 SMFP*) for three additional operating rooms in Wake County. UNC REX's comments on these competing applications include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*[1]." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, UNC REX has organized its discussion by issue, noting some of the general Certificate of Need (CON) statutory review criteria and specific regulatory criteria and standards creating the non-conformity on the following competitive applications:

- **WakeMed Cary Hospital (WakeMed Cary), Project ID # J-11960-20** (proposal to develop no more than one shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms upon project completion)

- **Valleygate Surgery Center (Valleygate), Project ID # J-11961-20** (proposal to develop a new ambulatory surgical facility with no more than one operating room and three procedure rooms)

- **Duke Health Garner Ambulatory Surgical Center (Duke Garner ASC), Project ID # J-11966-20** (proposal to develop a new ambulatory surgical facility with no more than one operating room and two procedure rooms)

- **Duke Health Green Level Ambulatory Surgical Center (Duke Green Level ASC), Project ID # J-11967-20** (proposal to add no more than two operating rooms for a total of no more than three operating rooms upon completion of this project and Project ID # J-11557-18 [develop an ambulatory surgical facility)]

[1] UNC REX is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to the applications filed on September 15, 2020 by UNC REX (Project ID # J-11963-20) or its affiliate (Project ID # J-11962-20).

UNC REX's detailed comments include not only general comments on the applications noted above, but also a comparative analysis which includes discussion of the UNC REX applications noted below:

- **Orthopaedic Surgery Center of Garner (OSCG)[2], Project ID # J-11962-20** (proposal to develop a new ambulatory surgical facility with no more than two operating rooms and two procedure rooms)

- **Rex Hospital (UNC REX Hospital), Project ID # J-11963-20** (proposal to add no more than one operating room for a total of no more than 32 operating rooms)

As detailed above, this review includes a mix of proposals for ambulatory surgical facilities (ASFs) and hospital-based operating rooms. Moreover, given the number of applications and proposed operating rooms, all the applications cannot be approved.

UNC REX has a long-standing, demonstrated commitment to developing projects that increase geographic and financial access to healthcare services, feature physician collaboration, and provide cost effective and efficient options for patient care. As detailed in its applications, UNC REX believes that the most appropriate way to meet the need for three additional operating rooms in Wake County identified in the *2020 SMFP* is to develop one additional operating room at UNC REX Hospital and a two operating room ASF in Garner. The UNC REX applications are the result of prudent healthcare planning to balance the need for hospital-based and freestanding ASF operating room capacity in Wake County, while increasing geographic access to surgery services.

The comments below include substantial issues that UNC REX believes render the competing applications listed above non-conforming with applicable statutory and regulatory criteria. However, as presented at the end of these comments, even if all these applications were conforming, the applications filed by UNC REX are comparatively superior to the others and represent the most effective alternative for expanding access to surgical services in Wake County.

[2] As noted in the application, as of the date of filing, Orthopaedic Surgery Center of Garner, LLC (OSCG), is wholly owned by Rex Orthopedic Ventures, LLC. Rex Orthopedic Ventures, LLC is wholly owned by Rex Healthcare, Inc., which is the parent of Rex Hospital, Inc. Upon completion of the project, the intent is that the limited liability company will be jointly owned by Rex Orthopedic Ventures, LLC (51 percent) and ASC3 JV, LLC (49 percent). ASC3 JV, LLC is wholly owned by individual physician members of Raleigh Orthopaedic Clinic, PA. OSCG will be included as part of the UNC Health system in Wake County as defined in the Operating Room Methodology in the *SMFP*.

COMMENTS ON WAKEMED CARY HOSPITAL

General Comments

At the outset, it is important to note that **the WakeMed Cary application fails to meet the bright line performance standard established in the criteria and standards for surgical services and operating rooms**. In particular, 10A NCAC 14C .2103(a) states that:

> "*An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*"

As documented in Table Q.16A on page 126 of the WakeMed Cary application, not only do WakeMed Cary and Capital City Surgery Center show a projected surplus of 3.66 and 1.89 operating rooms, respectively, in Fiscal Year (FY) 2025, which is the third full fiscal year of the WakeMed Cary project, **the WakeMed system shows an overall system surplus of 0.60 operating rooms in FY 2025**. As such, WakeMed fails to meet the requirement of the rule cited above, which requires an application proposing one additional operating room, like WakeMed, to project a deficit of at least 0.5 operating rooms. Despite this clear requirement, WakeMed chose to project a surplus at multiple facilities, including the one at which it proposes to add an operating room. The overall system does not conform with the rule. As explained in the issue-specific comments below, WakeMed Cary's application is also non-conforming with statutory and regulatory review criteria and should not be approved.

Moreover, according to the *2020 SMFP*, **the WakeMed system has the highest projected operating room surplus of any system in Wake County**. Further, WakeMed Cary, the location of the proposed operating room in this application, shows **the highest facility-specific surplus of operating rooms of any licensed facility in Wake County**. This surplus is projected to continue according to the *Proposed 2021 SMFP*, which shows that **WakeMed Cary is still projected to have the highest operating room surplus of any licensed facility in the county**. While the WakeMed Cary application argues that the *SMFP* methodology inappropriately limits its growth in case time (see the discussion beginning on page 30 of WakeMed Cary's application), the same is true for any other applicant experiencing case time growth, including UNC REX. Therefore, WakeMed is not being treated any differently than other applicants with existing facilities. In fact, throughout the WakeMed Cary application, WakeMed states that both average cases times and patient acuity have increased at WakeMed Cary but according to the American Hospital Directory, over the last three years, WakeMed Cary's Case Mix Index (CMI[3]) only increased from 1.48 to 1.49, which indicates that not only is WakeMed Cary's patient acuity level remaining fairly constant, but it also reveals that WakeMed Cary's surgical services are becoming less efficient as case times have increased but patient acuity level has remained relatively the same.

[3] CMI is a relative value assigned to Diagnosis Related Group (DRG) that reflects the clinical complexity and resource needs of patients with that DRG. A hospital's case mix index is an average of its patient population's case mix index. Higher CMI values reflect higher clinical complexity and resource needs for the hospital's patients overall.

Lastly, it should be noted that many of the same inaccuracies (and resulting issues of non-conformity) in WakeMed Cary's application discussed below were identified by UNC REX in its competitive comments submitted on WakeMed Cary's 2019 operating room application (Project ID # J-11759-19) submitted in response to the need for additional operating rooms in Wake County identified in the *2019 SMFP*. That application was denied. Of note, a comparison of the utilization methodology in WakeMed Cary's 2019 operating room application against the utilization methodology included in this application reveals that WakeMed completely disregarded inaccuracies (and resulting issues of nonconformity) identified by UNC REX in 2019 and as such, has included similar, if not identical, inaccuracies in its 2020 application.

Issue-Specific Comments

1. <u>The WakeMed Cary application fails to demonstrate the need for an additional operating room at WakeMed Cary.</u>

   While the specific issues with the application's utilization methodology will be addressed below, the WakeMed Cary application simply fails to demonstrate why another operating room is needed at WakeMed Cary. Although the application references some growth and historical and expected physician recruitment, WakeMed Cary has a sufficient number of operating rooms to meet its current and projected utilization, even if the latter is assumed to be accurate. As shown in the utilization table on page 127 of the WakeMed Cary application, WakeMed Cary will develop its 10th non-C-Section operating room in FY 2020. Further, as stated above, utilization projections on page 126 of the WakeMed Cary application show WakeMed Cary has a projected operating room surplus of 3.66 rooms in FY 2025, the proposed third full FY of the project, and the WakeMed system shows an overall system surplus of 0.60 operating rooms in FY 2025. As such, there is simply no need for WakeMed Cary to be approved for another operating room.

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

   Based on this issue, the WakeMed Cary application fails to demonstrate that the project is needed or that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183. As such, **the WakeMed Cary application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 8, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

2. <u>The WakeMed Cary application provides unreasonable utilization assumptions.</u>

   In Section Q, WakeMed provides its methodology for projecting utilization for the proposed project and for some of the other facilities in its system. WakeMed's utilization projections are based on erroneous data, as they improperly include non-surgical cases as a basis for projecting future operating room utilization. Of note, it is unclear whether these cases were historically performed in operating rooms or not; however, that is irrelevant, as the rules require applicants to base their projections on the methodology in the *2020 SMFP*. The *2020 SMFP* methodology uses data reported on LRAs and projects surgical volume forward to determine future need for

operating rooms. The methodology uses only those data which are reported as surgical cases performed in licensed operating rooms.[4] No other cases, including non-surgical cases performed in licensed operating rooms[5] or surgical cases performed outside of a licensed operating room[6], are included in the methodology. WakeMed's erroneous inclusion of non-surgical cases does not comport with the *SMFP* methodology, and it is therefore not in compliance with the operating room rules. Further, its methodology, based on this improper data, is therefore also flawed. Of note, if as part of its utilization methodology WakeMed Cary wanted to project to perform cases in an operating room that historically have been performed in a procedure room, it would need to identify the cases that are being proposed to shift as well as describe in detail the reasoning behind the shift.

As an example of this issue, the following figures compare the data on WakeMed Cary's LRA with data reported in the *SMFP* and finally with data reported in the application in Table Q.3 on page 119, which is included in Step 2 of WakeMed's utilization methodology.

[4] This data is reported in response to Table 9e) of the 2020 LRA form. Pursuant to N.C. GEN. STAT. § 131E-146(1c), a "Surgical Operating Room" is defined as a room "used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room."

[5] This data – all non-surgical cases, including cases receiving services in operating rooms or any other location – is reported in response to Table 9d) of the 2020 LRA form.

[6] Surgical procedures performed in unlicensed procedure rooms are reported in response to 9f) of the 2020 LRA form.

Table 8.d) from WakeMed Cary's 2016 LRA, page 12

2016 Renewal Application for Hospital:
WakeMed Cary Hospital

License No: **H0276**
Facility ID: **990332**

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

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

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

d) Surgical Cases by Specialty Area Table

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

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

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

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

Table Q.3 from the WakeMed Cary Application, page 119

Table Q.3
WakeMed Cary Hospital
Historic and Projected Surgery Case Volumes

Surgery Type	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	2015-2019 CAGR%	FY 2020 (5 Mos. Ann.)	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Inpatient	2,769	3,037	3,162	2,973	3,316	**4.61%**	3,104	3,469	3,629	3,796	3,971	4,154
Outpatient	4,815	4,820	5,242	4,956	4,919	**0.54%**	4,970	4,945	4,971	4,998	5,025	5,052
Total	7,584	7,857	8,404	7,929	8,235		8,074	8,414	8,600	8,794	8,996	9,206

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

	FY 2015		FY 2016		FY 2017		FY 2018		FY 2019	
	IP	OP	IP	OP	IP	OP	IP	OP	IP	OP
WakeMed Cary Application	2,769	4,815	3,037	4,820	3,162	5,242	2,973	4,956	3,316	4,919
LRA / *SMFP*	2,560	4,228	2,914	4,132	3,041	4,663	2,973	4,956	3,142	3,740
Difference	209	587	123	688	121	579	0	0	174	1,179
Total Difference (IP and OP)	**796**		**811**		**700**		**0**		**1,353**	

The source of the difference in the FY 2015 data reported in WakeMed Cary's application (excerpted below) is apparent when reviewing WakeMed Cary's 2016 LRA.

	FY 2015	
	IP	OP
WakeMed Cary Application	2,769	4,815
LRA / *SMFP*	~~2,560~~	~~4,228~~
Total Difference (IP and OP)	209	587

Table 8.e) from WakeMed Cary's 2016 LRA, page 12

c) Non-Surgical Cases by Category Table

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

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

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

> *"An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the*

2018 State Medical Facilities Plan. *The applicant is not required to use the population growth factor."* [Emphasis added]

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

The same error is repeated throughout this step, for FY 2016 and 2017. For brevity, the table below summarizes the difference between the correct data and the data included in WakeMed Cary's application, but the sources are the same (i.e. LRA, *SMFP*, application Table Q.3).

	FY 2016		***FY 2017***	
	IP	***OP***	***IP***	***OP***
WakeMed Cary Application	3,037	4,820	3,162	5,242
LRA / *SMFP*	2,914	4,132	3,041	4,663
Difference	123	688	121	579
Total Difference (IP and OP)	**811**		**700**	

Of note, the errors are consistently in WakeMed's favor, inflating its surgical utilization by thousands of hours each year.

Further, a review of WakeMed Cary's 2020 LRA suggests that the source of the difference in the FY 2019 data reported in WakeMed Cary's application (excerpted below) is likely inclusion of surgical procedures performed in unlicensed procedure rooms.

	FY 2019	
	IP	***OP***
WakeMed Cary Application	3,316	4,919
LRA / *SMFP*	3,142	3,740
Difference	174	1,179
Total Difference (IP and OP)	**1,353**	

Response 9.f) from WakeMed Cary's 2020 LRA, page 12

f) Number of surgical procedures performed in unlicensed Procedure Rooms. 1,343

While these surgical cases would be counted in the methodology if performed in licensed operating rooms, the application provides no evidence to suggest that it intends to do so in the future, much less the reason these cases were historically performed in procedure rooms and why they would be performed in operating rooms in the future. Without such assumptions and rationale, it is only reasonable to assume that WakeMed Cary intends to continue performing these cases in procedure rooms and that the volume cannot be counted in the operating room methodology. Since these errors are included in the foundational data for WakeMed's utilization methodology, the resulting projections are therefore also unreliable.

In Step 3 of its methodology, WakeMed states that it projects to shift cases from various existing facilities to its approved ASFs in Cary and North Raleigh and provides the number of cases it projects to shift. The application fails completely to provide any methodology or rationale for the projected shifts, however; as such, they cannot be determined to be reasonable. Without any methodology or explanation, the case volume for these facilities cannot be relied upon to demonstrate conformity with the operating room rules.

In Step 5, WakeMed makes two incredible assumptions. First, it believes the *SMFP* methodology unfairly suppresses the need by limiting the actual case time growth. It should be noted that this function impacts all providers whose case time is growing more than 10 percent per year, including UNC REX, which has been negatively impacted by this function multiple times since its inception. Second, WakeMed believes it should exclude an operating room on the basis of its Level III Trauma status, even though it admits this is also not part of the *SMFP* methodology's assumptions[7]. When these erroneous assumptions are applied to WakeMed's projected utilization, only then is there a projected deficit of an operating room in Year 3. When the *SMFP* methodology is applied, as required by the operating room rules, **WakeMed Cary shows a surplus of four operating rooms in Year 3**, as shown in Table Q.11A on page 122 of its application.

In the same step, WakeMed projects a deficit of four operating rooms at WakeMed's Raleigh campus, but states that "WakeMed executive leadership believe that its current OR complement is sufficient." Somehow, WakeMed Cary, with a projected surplus of one operating room needs an operating room, but WakeMed Raleigh's purported four operating room deficit represents "sufficient" capacity. As shown in the table below, when using the case times from the 2020 SMFP, as required by the performance standards in the administrative rules, WakeMed has taken completely opposite positions regarding its need (or lack thereof) for operating rooms.

	FY 2025 Projected OR (Surplus)/Deficit Using Average Case Times Published in 2020 SMFP	***WakeMed Executive Leadership Belief***
WakeMed Raleigh	3.87 (deficit)	Deficit of 4 ORs is no problem!
WakeMed Cary	(3.66) (surplus)	Surplus of 4 ORs means we need...another OR!

Source: WakeMed Cary application page 126.

Clearly, this inconsistency is irreconcilable and WakeMed has not demonstrated its projections and proposal to be based on reasonable assumptions.

Based on these issues, the WakeMed Cary application fails to demonstrate that the project is needed or that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183. As such, **the WakeMed Cary application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 8, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

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

3. The WakeMed Cary application financials are not based on reasonable or supported assumptions.

   The WakeMed Cary application does not provide assumptions regarding how surgical services depreciation is calculated for the building or equipment, making the transition from existing depreciation to project year 1 depreciation ambiguous and unsupported. Also, the WakeMed application does not describe what comprises Indirect Expense (OH/Admin) within Surgical Services or how this expense is allocated to Surgical Services. This is especially important since this expense is the second largest line item expense for the service and comprises 20 percent ($12 million) of project year 3 expenses.

   Based on these issues, the WakeMed Cary application fails to demonstrate that the project is financially feasible based on reasonable and supported assumptions. As such, **the WakeMed Cary application should be found non-conforming with Criterion 5**.

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

   Specifically, the WakeMed Cary application fails to provide all requested information required in response to the Certificate of Need application form as it fails to identify all related entities in response to Form A Facilities. Section A.7(a) of the OR/GI Endo application form requires an applicant to "[i]dentify all existing and approved ASFs or acute care hospitals with ORs or GI Endo rooms located in North Carolina that are owned or operated by the applicant or a related entity by completing Form A Facilities, which is found in Section Q." [emphasis added].

   As defined in the definition portion of the Certificate of Need application form, when used in the application form, the term "related entities" means persons that:

   - Share the same parent corporation or holding company; or
   - Are a subsidiary of the same parent corporation or holding company; or
   - Are participants in a joint venture which provides surgical or GI endoscopy services.

   While WakeMed identifies WakeMed Raleigh, WakeMed Cary, and Capital City Surgery Center in response to Form A Facilities, it fails to identify Holly Springs Surgery Center, a joint venture between WakeMed, Novant Health, and Compass Surgical Partners. This is particularly important to this review as Holly Springs Surgery Center is located in an area that WakeMed Cary has historically considered its service area (Holly Springs) and has a projected surplus of operating rooms.

   Based on this issue, the WakeMed Cary application fails to provide information necessary to determine whether the proposed project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and with duly adopted standards, plans, and criteria. As such, **the WakeMed Cary application should be found non-conforming with Criteria 1 and 3**.

In summary, WakeMed has failed to demonstrate that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and that the project is needed, and the WakeMed Cary application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 8, and

18(a), as well as the performance standards at 10A NCAC 14C .2103. The WakeMed Cary application should not be approved.

COMMENTS ON VALLEYGATE SURGERY CENTER

General Comments

Valleygate Surgery Center's application is misleading in multiple ways and is also noticeably similar to the proposal Valleygate submitted in 2016 to develop a dental-only ASF in Wake County in response to a need identified in the *2016 SMFP* for a Dental Single Specialty ASF Demonstration Project in Region 1 (Project ID # J-11175-16), as oral/dental surgery represents more than half of the cases proposed to be performed at Valleygate Surgery Center in 2025, its third full operating year. Of the 11 providers that signed referral letters of support for the proposed project, 10 are pediatric dentists/oral surgeons and one is listed twice as an ophthalmologist and as a plastic surgeon. Simply put, Valleygate Surgery Center should be denied because it would result in an unnecessary duplication of services in Wake County. As the Agency is aware, and as reflected in the *2016 SMFP*, the SHCC determined that there was a need for a Dental Single Specialty ASF Demonstration Project, consisting of four facilities with up to two operating rooms each. In particular, a need was identified in the *2016 SMFP* for one facility to be located in each of the following regions: Region 1 (Health Service Area (HSA) IV), Region 2 (HSA III), Region 3 (HSA V and HSA VI), and Region 4 (HSA I and HSA II). Valleygate and Surgical Center for Dental Professionals of NC (SCDP) each applied for all four facilities and the Agency subsequently approved Valleygate to develop all four facilities. However, through a settlement agreement, Valleygate relinquished the right to develop the dental ASF in Region 1 (HSA IV) to SCDP. SCDP is now operational in Raleigh and is open to all oral/dental surgeons that meet specific criteria to ensure the safety and quality of surgical services provided to patients. As intended by the Dental Single Specialty ASF Demonstration Project, SCDP was developed to meet the need for dental-only ASF operating room capacity in the greater Triangle area and according to the *Proposed 2021 SMFP*, SCDP has excess ASF operating room capacity to accommodate oral/dental surgical procedures. Valleygate Surgery Center's application should be denied, based on the reasons noted above, as well as the issue-specific comments outlined below.

Issue-Specific Comments

1. <u>Valleygate Surgery Center, if approved, would result in an unnecessary duplication of services.</u>

   As noted above, the approval of Valleygate Surgery Center would result in an unnecessary duplication of services in Wake County. Wake County is home to SCDP, a freestanding ASF with two operating rooms and five procedure rooms that is solely dedicated to providing ASF capacity for the provision of low-cost oral/dental surgical procedures, which, notably, according to Google Maps, is only 7.6 miles from the proposed location of Valleygate Surgery Center. SCDP is only in its second year of operation and similar to the other dental-only ASFs that are a part of the Dental Single Specialty ASF Demonstration Project, volume at SCDP is still ramping up. As noted above, according to the *Proposed 2021 SMFP*, only 277 cases were performed in the two operating rooms at SCDP in Federal Fiscal Year (FFY) 2019. In addition, as noted previously, SCDP has <u>five</u> procedure rooms that, according to SCDP's 2020 LRA, were used to perform 517 procedures in FFY 2019. According to its 2016 application (Project ID # J-11170-16), each procedure room at SCDP was to be built to operating room FGI Guidelines; thus, SCDP appears to have <u>seven</u> operating room and procedure room spaces in its ASF that are capable of supporting the oral/dental surgery cases proposed to be performed at Valleygate Surgery Center. As demonstrated on page 144 of its utilization methodology, Valleygate assumes that in 2025, its third full year of operation, 75 percent of the total projected surgical hours will be in procedure rooms (75 percent = 4,034 procedure room surgical hours / 5,346 total projected surgical hours). Clearly, a significant

portion of the cases projected to be performed at Valleygate Surgery Center can be done safely and effectively in a procedure room, and there is plenty of excess procedure room capacity at SCDP. Even if an oral/dental case requires an operating room, SCDP has the capacity to accommodate such cases. In fact, on page 49 of the Valleygate Surgery Center application, Valleygate acknowledges that SCDP has available capacity by stating, "[I]n Wake County, SCDP also reported a very low utilization." Further, on page 87 of its application, Valleygate makes the erroneous claim that "only Valleygate Dental Surgery Holdings (VDSH) appears to have found an efficient operating model that can accommodate anesthesia supervised by anesthesiologists and pediatric dental surgery [emphasis added]." Today, SCDP is supporting dental and oral operating room cases that use anesthesia supervised by anesthesiologists. Valleygate's suggestion that SCDP has not "found an efficient operating model that can accommodate anesthesia supervised by anesthesiologists and pediatric dental surgery" is simply egregious and misleading. As evidence to the contrary, SCDP's Annual Evaluation Report Summary, published September 11, 2020, states, "the Agency determined that Surgical Center for Dental Professionals materially complies with the demonstration project criteria in Table 6D in the 2016 Plan and the conditions on the certificate of need[8]." Criterion 3 of Table 6D in the *2016 SMFP* states, "[T]he facility shall provide only dental and oral surgical procedures requiring sedation [emphasis added]." In consideration of the factors discussed above, it is clear that the approval of the Valleygate Surgery Center application would result in an unnecessary duplication of services in Wake County; thus, the Agency should deny this application.

Moreover, before adding potentially duplicative services, UNC REX believes that the State should have the opportunity to consider whether, in accordance with the demonstration project criteria, the approved dental-only ASFs that are a part of the Dental Single Specialty ASF Demonstration Project, are meeting or exceeding all program evaluation criteria. Then and only then, would it be appropriate to consider expanding the scope of the demonstration project to include additional sites. Notably, the Agency has previously – in the context of the 2010 Single Specialty ASF Demonstration Project – recognized the importance of project evaluation as a major component of demonstration projects. Of note, in 2010, the Agency recommended denial of a Petition submitted by Blue Ridge Bone and Joint Clinic requesting that the *2011 SMFP* include a demonstration project for a single specialty, two operating room, orthopedic ambulatory surgical facility in the Buncombe-Madison-Yancey operating room service area. In its report, the Agency noted its support of the demonstration project criteria and the importance of project evaluation and ultimately recommended denial of the Petition submitted by Blue Ridge Bone and Joint Clinic, despite the fact that the demonstration projects did not include a facility in the service area proposed in the petition. Here, given the fact that the Valleygate Surgery Center application is noticeably similar to the proposal Valleygate submitted in 2016 to develop a dental-only ASF in Wake County, the fact that volume at SCDP is still ramping up, and the proposed development of another primarily dental surgery center in the same service area as the demonstration project, UNC REX believes that approval of Valleygate's proposal would not only be duplicative, but also premature.

[8] Accessed at https://info.ncdhhs.gov/dhsr/mfp/pdf/2020/acsc/SurgicalCenterforDentalProf.pdf.

Based on these issues, the Valleygate Surgery Center application fails to demonstrate that the project is needed or that the project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. As such, **the Valleygate Surgery Center application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 8, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

2. The Valleygate Surgery Center application fails to demonstrate the need patients have for the proposed project.

Valleygate fails to mention any issues that would prevent the proposed patient population from being served at other ASFs in Wake County, including SCDP, or even hospitals in the county, many of which provide the specialties proposed and some of which have available capacity. In particular, Valleygate fails to discuss any issues with the facilities at which the surgeons supporting the project currently practice, nor does the application even mention which facilities they are. Further, on pages 23 through 27 of the Valleygate Surgery Center application, Valleygate describes that the initial focus of the proposed ASF will be on oral, dental, otolaryngology (ENT), ophthalmology, and plastic surgery procedures; however, Section C.4 of the Valleygate Surgery Center application describes *in detail* the need for freestanding ASF operating room capacity for dental and oral surgery. In fact, Section C.4 mentions very little about the need for ASF operating room capacity for the provision of ENT, ophthalmology, and/or plastic surgical procedures. Instead, the Valleygate Surgery Center application focuses heavily on the need for ASF operating room capacity for the provision of oral/dental surgical procedures and continually fails to acknowledge the available capacity at SCDP.

Additionally, as noted, while Valleygate projects to perform ENT cases at Valleygate Surgery Center, **there is no evidence of support from an ENT surgeon**. Moreover, even if the Valleygate Surgery Center application provided support from an ENT surgeon, it would be difficult to know, given the position taken recently by the owners of Valleygate, whether or not the dental/oral and ENT surgical cases proposed to be performed at Valleygate Surgery Center would be performed concurrently or if they would be performed as separate cases. As the Agency is aware, on March 4, 2020, Valleygate Dental Surgery Center filed a petition to "clarify and if appropriate to amend *2021 State Medical Facilities Plan* regarding Dental Single Specialty Ambulatory Surgical Facility Demonstration Project," in which Valleygate petitioned "for an interpretation that Dental Single Specialty Ambulatory Surgical Facility Demonstration Projects include dental/oral procedures that require participation of other appropriate specialists during the dental case," most notably ENT surgeons[9]. Valleygate's petition discusses, in detail, the need to complete ENT surgical procedures, including tympanostomy tube placement (ear tubes) and adenoidectomies (adenoid removal), during dental/oral cases and Valleygate even goes as far as to say on page three of its petition that, "[W]e rejected applying for conversion from a single to multi-specialty ambulatory surgical program because the cases are *still dental cases* [*Valleygate added emphasis]*." Given Valleygate Dental Surgery Center's recent petition, it is logical to assume that the ENT "cases" proposed to be performed at Valleygate Surgery Center are not actually separate surgical cases that should be counted separately, but are more likely ENT procedures that occur concurrently with dental/oral surgical cases. If they are, in fact, ENT procedures that occur concurrently with

[9] Accessed at https://info.ncdhhs.gov/dhsr/mfp/pets/2020/acs/Valleygate-Holdings-Spring-Petition-2020-CORRECTED.pdf.

dental/oral surgical cases, they are already accounted for in Valleygate Surgery Center's projected dental/oral case volume.

Furthermore, as noted previously and discussed in detail below, Valleygate Surgery Center's application highlights a lack of support for the other two proposed non-dental surgical specialties, ophthalmology and plastic surgery, as only a single physician provided a referral letter of support for the proposed ASF and was listed for both ophthalmology and plastic surgery. Of note, while cases involving the area around the eye are called "oculoplastics," when performed by licensed ophthalmologists, they are clearly ophthalmologic cases, not plastic surgery cases, and there is no evidence that the supporting physician is board-certified in both specialties. Clearly, Valleygate fails to demonstrate why there is a patient-based need for the project it proposes.

Based on these issues, the Valleygate Surgery Center application fails to demonstrate that the project is needed or that the project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. As such, **the Valleygate Surgery Center application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 8, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

3. Valleygate Surgery Center's proposed service area is unreasonable and unsupported.

Valleygate Surgery Center's proposed service area is neither reasonable nor supported. On page 120 of the application, the applicant states that it simply "look[ed] at census tracts that had shared roadways and traffic patterns to Garner. The applicant also look[ed] at census tracts in which there are no freestanding ASFs." Valleygate also mentions that Harnett and Johnston counties do not have an ASF and alludes to the fact that this is reason enough to include portions of these counties in the proposed service area. This is the extent of the information provided by Valleygate to substantiate the reasonableness of the proposed service area, which, as mentioned, extends into Johnston and Harnett counties. Additionally, as noted above, the Valleygate Surgery Center application includes letters of support from 11 providers but does not include any detail as to the origin of the patients served by those 11 providers. The table below provides a list of all 11 providers and Google search results for their practice locations that are nearest to the proposed ASF location. Of note, nowhere in the Valleygate Surgery Center application does Valleygate provide a list, description, and/or map of the nearest practice of the providers proposed to perform cases at the proposed ASF.

Provider Name	*Nearest Practice Location**	*Distance to Garner Location (Drivetime in minutes / Distance)**
Vinod Jindal, MD	3400 Wake Forest Rd, Raleigh, NC 27609	18 min / 13.2 miles
Nazir Ahamad, DDS	5904 Six Forks Rd #101, Raleigh, NC 27609	22 min. / 18.2 miles
Raymond Tseng, DDS	1705 High House Rd, Cary, NC 27513	28 min. / 18.8 miles
Bryan Dunston, DDS	55 Amarillo Ln, Sanford, NC 27332	65 min. / 46.8 miles
Boo Lee, DDS	345 Earnie Ln, Holly Springs, NC 27540	28 min. / 22.3 miles
E. LaRee Johnson, DDS	2800 Wakefield Pines Dr # 110, Raleigh, NC 27614	35 min. / 31.1 miles
Mark Herring, DMD	1705 High House Rd, Cary, NC 27513	28 min. / 18.8 miles
David Olson, DDS	10931 Raven Ridge Rd # 105, Raleigh, NC 27614	30 min. / 20.9 miles
Burton Horwitz, DDS	400 Tew Ct #106, Clayton, NC 27520	12 min. / 8.8 miles
Shamik Vakil, DDS	4446 Fayetteville Rd, Raleigh, NC 27603	8 min. / 3.3 miles
Harpreet Wasson, DDS	3434 Kildaire Farm Rd #138, Cary, NC 27518	23 min. / 12.9 miles

*Source: Google and Google Maps.

As shown above, providers that signed a letter of support have practice locations ranging from three to over 45 miles away from the proposed Valleygate Surgery Center location. Interestingly, some of the providers listed above have practices in Sanford (Lee County). According to Google Maps, Garner – the proposed location of Valleygate Surgery Center – is a 45-mile drive from Sanford, and Fayetteville – the location of the existing Valleygate Dental Surgery Center – is also a 45-mile drive from Sanford. Thus, Valleygate's existing dental-only ASF in Fayetteville, Valleygate Dental Surgery Center, is equidistant to some of the physicians listed above and the location of Valleygate's proposed ASF in Garner. As mentioned above, the Valleygate Surgery Center application does not provide any patient origin information for the providers expected to perform cases at the ASF; thus, it is difficult to discern if an ASF in Garner would be convenient and/or accessible for patients of the providers proposed to practice at the ASF, much less if an ASF in Garner is convenient for the providers themselves, whose practice locations are up to 46 miles (and up to a 65-minute drivetime) away.

Further, as demonstrated in Exhibit C.3 of the Valleygate Surgery Center application, projected patient origin is in no way based on historical practice patterns. Instead, Valleygate Surgery Center's projected patient origin is based on its flawed proposed service area and the portion of cases that are expected to originate from Wake, Harnett, and Johnston counties. Furthermore, as demonstrated on page 29 of its application, Valleygate projects that less than 50 percent of its patients will originate from Wake County, while approximately 25 percent of its patients are projected to come from Harnett County. While it may be reasonable to assume that facilities located near the border of a county could serve a significant portion of their patients from other counties, the application fails to provide any evidence that the physicians supporting the application serve patients from the counties included in the patient origin. As mentioned above, Valleygate has a dental-only ASF in Fayetteville, which can easily serve the patients projected to travel from Harnett County, in many cases at a shorter distance.

Additionally, as stated on page 135 of its application, Valleygate Surgery Center assumes that, in addition to portions of Wake, Johnston, and Harnett counties (defined by census tracts) that it proposes to serve relative to ENT, ophthalmology, and plastic surgery, its proposed service area

for dental/oral surgery also includes all of Wake County because "there is a shortage of ASFs providing dental/oral surgery in the state even with the Dental Demonstration projects online. [T]here are 169 freestanding ASFs, only 13 of those offer dental/oral surgery. Of those 13 ASFs, only one is in Wake County." This assumption is unreasonable because, as discussed above, SCDP is close to the proposed location of Valleygate Surgery Center, SCDP has plenty of excess capacity to accommodate the cases proposed to be performed at Valleygate Surgery Center, and SCDP is still ramping up as it is only in its second year of operation. Moreover, it is quite plausible that Valleygate contrived a service area with a population that is large enough to derive its self-described "reasonable" utilization projections, as Valleygate Surgery Center's utilization methodology is in part based on the application of statewide use rates to project the need for dental/oral, ENT, ophthalmology, and plastic surgery in Valleygate Surgery Center's service area, as described in further detail below. In summary, Valleygate Surgery Center's proposed service area is unfounded and is in no way reasonable or supported.

Based on these issues, the Valleygate Surgery Center application fails to adequately identify the population to be served by the proposed project or to demonstrate that the project is needed. As such, **the Valleygate Surgery Center application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 8, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

4. The Valleygate Surgery Center application provides unreasonable utilization projections.

Valleygate Surgery Center's utilization methodology is completely contrived and unreasonable. As described in detail below, there are issues within each step of Valleygate Surgery Center's utilization methodology.

In order to project utilization for the proposed ASF, Valleygate first applied 2018 statewide ASF and hospital ambulatory surgery use rates for oral/dental, ENT, ophthalmology, and plastic surgery, that were calculated using the Department of Health and Human Services (DHHS) database, to the population of its proposed service area from 2020 to 2025, the projected third full FY of the proposed ASF. Page 122 of the Valleygate Surgery Center application states, "[T]he applicant assumes that the 2018 statewide use rates are reasonable and conservative because the target population is aging and growing faster than the state." While it might be true that the populations of Wake, Johnston, and Harnett counties are growing and aging, that is not enough evidence to support the use of statewide use rates in estimating the need for ambulatory surgical services within the proposed service area. For comparison, the table below provides the 2018 statewide ambulatory surgery use rates provided in the Valleygate Surgery Center application and Wake County's 2018 ambulatory surgery use rates that were calculated by UNC REX using the DHHS database and population data from the North Carolina Office of State Budget and Management (NC OSBM).

Specialty	*Valleygate 2018 Statewide Use Rate*	*2018 Wake County Use Rate*	*Difference Between Statewide and Wake County Use Rates*
ENT	6.1	9.3	-3.2
Ophthalmology	13.8	4.8	9.0
Plastics	1.5	1.0	0.5
Oral/Dental	1.8	2.2	-0.4

Source: DHHS database and NC OSBM.

As shown above, interestingly, Wake County's 2018 ambulatory surgery use rates for ophthalmology and plastic surgery are lower than statewide, while Wake County's ENT and oral/dental ambulatory surgery use rates are slightly higher than the statewide use rates. The application of statewide ambulatory surgery use rates, by surgical specialty, to the proposed service area population is a rudimentary way of projecting need and does not take into account local, patient-driven demand. The use of county-based use rates would have at least been somewhat more reasonable as it would have resulted in projected need estimates driven by historical utilization of the population that Valleygate Surgery Center is projecting to serve.

Next, Valleygate cites one non-peer reviewed article published by a consulting firm in 2017 that claims, "60 percent of all ambulatory surgery cases performed nationally will occur in an ASF by 2020." Valleygate uses this claim as its sole basis to assume that 60 percent of all the cases projected in the previous step would be appropriately served at an ASF. This assumption is flawed in that it does not take into account the experience of the providers proposed to perform cases at the ASF, it is the opinion of a single consulting firm with unknown biases, and is just simply not enough evidence to reasonably assume that 60 percent of all cases projected in the previous step, for all proposed specialties, would be appropriate for an ASF.

The next step in Valleygate's methodology projects total surgical hours for each proposed specialty based on the multiplication of the number of ASF-appropriate cases from the previous step to Valleygate's estimation of average case times for oral/dental, ENT, ophthalmology, and plastic surgery. Page 127 of the Valleygate Surgery Center application states, "[T]he applicant determined case times for each specialty based on experience and discussions with Valleygate Dental Surgery Holding, LLC ("VDSH") representatives, as well as, average times reported by physicians." There are several issues with this approach. First, Valleygate Dental Surgery Holdings, LLC is clearly an oral/dental surgery entity that would not have experience with average case times for ENT, ophthalmology, and plastic ambulatory surgery. Second, Valleygate states, "average times reported by physicians" but does not specify what type of physicians it is referring to or even the data source used. Third, and most importantly, Section C of the Valleygate Surgery Center application clearly states that new ASF facilities must "identify the average final case times from Step 5b of the OR Need Methodology in Chapter 6 of the *SMFP* in effect at the time the review begins for the group identified in response to Question 6(a)(ii) and use those times to project estimated surgical hours in Form C [emphasis added]." By using the average case times proposed in its utilization methodology, Valleygate Surgery Center is in clear violation of this requirement. While Valleygate claims that it uses the appropriate average case time in its Form C, it does not provide any assumptions or methodology specific to total surgical hours and operating room need shown in its Form C.

The subsequent step of Valleygate Surgery Center's utilization methodology involves estimating Valleygate Surgery Center's market share of its projected demand for dental/oral, ENT, ophthalmology, and plastic ambulatory surgery in the proposed service area. Valleygate projects fully ramped-up market shares ranging from 30 percent (ophthalmology) to 65 percent (ENT and plastic). As noted previously, the Valleygate Surgery Center application provides no evidence of support from an ENT surgeon; however, Valleygate assumes that it will reach 65 percent market share of all ENT cases in the service area by 2025 even though it does not provide any real evidence to support its ability to obtain such a large market share. Further, as discussed previously, given Valleygate Dental Surgery Center's recent petition, it appears as if the ENT cases proposed to be performed at Valleygate Surgery Center are actually ENT procedures that will be performed concurrently with dental/oral surgical cases and not, in fact, separate ENT cases that not already accounted for in Valleygate's projected dental/oral case volume. In addition, as noted previously, the Valleygate Surgery Center application includes support for both ophthalmology and plastic surgery cases from a single physician who was listed twice – once in support of each specialty, which is not enough evidence to assume that Valleygate Surgery Center can reach a market share of 30 and 65 percent for ophthalmology and plastic surgery, respectively, particularly given that the supporting physician is an ophthalmologist, with a single board certification[10], with no documentation that he can perform 65 percent of plastic surgery cases in the market (which would not include oculoplastic cases). Page 129 of the Valleygate Surgery Center application states, "[T]he applicant assumes market share will increase as the community and referring providers become more comfortable with Valleygate and aware of its lower charge schedule and provider friendly structure." While Valleygate has experience developing/operating three other dental-only ASFs in the state, the three ASFs are not in close proximity to Wake County and Valleygate has no real data to corroborate the assumed market shares, particularly for ENT, ophthalmology, and plastic surgery, which Valleygate has no experience providing and for which it has not provided evidence of physician support.

Next, Valleygate applies an in-migration factor of 10 percent for ENT, ophthalmology, and plastic surgery cases and a staggering 58.6 percent for oral/dental cases. Valleygate's assumed in-migration rate for ENT, ophthalmology, and plastic surgery is based on a portion of the in-migration associated with all patients who received ambulatory surgery at a Wake County hospital or ASF in 2018 that originated from outside of Wake County – regardless of specialty – even though portions of the proposed service area include Johnston and Harnett counties. Further, Valleygate's assumed in-migration for oral/dental cases of 58.6 percent is based on partial 2018 year-to-date data from its other dental-only ASFs. Nonetheless, under any assumption, an in-migration rate of 58.6 percent for oral/dental cases is just simply unreasonable, particularly in light of existing capacity at SCDP.

Lastly, the final step of Valleygate Surgery Center's utilization methodology involved splitting projected surgical hours into the operating room and three procedure rooms. Valleygate simply split hours based on available capacity among all four surgical/procedural spaces, which is further indication that a significant majority of the cases proposed to be performed at Valleygate Surgery Center can be performed in a procedure room as there is no discussion on the distinction of cases that require an operating room versus cases that can safely and efficiently be performed in its three proposed procedure rooms.

[10] https://www.dukehealth.org/find-doctors-physicians/vinod-k-jindal-md

In summary, Valleygate Surgery Center's utilization methodology is based on the application of statewide use rates to an unreasonable service area. Valleygate uses its own case times to project surgical hours instead of the prescribed average case time in the OR Need Methodology, it uses unfounded market shares to project utilization, and provides no clear distinction between cases that require an operating room versus those than can be performed safely in a procedure room. Valleygate also assumes unreasonable in-migration factors, particularly for dental/oral procedures. Overall, the utilization methodology presented in the Valleygate Surgery Center application is clearly contrived and unreasonable.

Based on these issues, the Valleygate Surgery Center application fails to adequately identify the population to be served by the proposed project or to demonstrate that the project is needed. As such, **the Valleygate Surgery Center application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 8, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

5. The Valleygate Surgery Center application fails to demonstrate that it meets the operating room performance standards.

The performance standards at 10A NCAC 14C .2103 state:

> "*An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*" [Emphasis added]

On page 65 of its application, Valleygate wrongfully assumes that the performance standard does not apply when it states, "[T]here are no existing or approved operating rooms in the VSC health system in Wake County. Hence, this rule does not apply [emphasis added]." The performance standard above clearly states that that an applicant proposing to increase the number of operating rooms in a service area must demonstrate that need for the proposed operating rooms and Valleygate erroneously asserted that the performance standard does not apply to its proposed project simply because it does not have any existing or approved operating rooms in Wake County.

Based on these issues, the Valleygate Surgery Center application fails to demonstrate that the project is needed. As such, **the Valleygate Surgery Center application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 8, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

6. The Valleygate Surgery Center application fails to show evidence of availability of resources for the provision of the "multispecialty" services which Valleygate proposes to provide or coordination with the existing healthcare system.

Page 20 of the Valleygate Surgery Center application states, "[t]he applicant Valleygate Surgery Center, LLC ("VSC") proposes to develop a new, licensed multispecialty ambulatory surgery facility

(ASF) with one OR in response to the need identified in Table 6C of the *2020 State Medical Facilities Plan* ("*SMFP*")." However, the Valleygate Surgery Center application fails to show evidence of availability of resources, including health manpower and management personnel, for the provision of the "multispecialty" services Valleygate proposes to provide. Specifically, N.C. GEN. STAT. § 131E-176(15a) defines a multispecialty ambulatory surgical program as "*a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery."* Notably, while Valleygate claims that Valleygate Surgery Center will be a multispecialty ASF, the only physician support provided in the application is from pediatric dentists, oral surgeons, and a single ophthalmologist. Exhibit I.3 of the Valleygate Surgery Center application contains a summary table of physicians that provided referral letters of support. There is no support provided by an otolaryngologist. Also of note, Dr. Vinod Jindal, M.D. is listed twice, once as an ophthalmologist and once as a plastic surgeon. First, this is misleading. Second, according to several websites, including a Duke Health website[11], Dr. Jindal is a board-certified ophthalmologist but there is no mention of Dr. Jindal offering plastic surgery services. In fact, there is no evidence in the Valleygate application to demonstrate who is qualified to perform which specialties. Even if Dr. Jindal performs oculoplastic surgical procedures, oculoplastics is not in the list of specialty areas above, and it is not the same as plastic surgery performed by plastic surgeons. Rather, oculoplastic surgery is surgery involving the skin around the eye. An oculoplastic surgeon is a specialized ophthalmologist who has completed one or two years of additional fellowship training in oculoplastics following ophthalmology residency training. Oculoplastic surgeons perform procedures such as the repair of droopy eyelids (blepharoplasty), repair of tear duct obstruction, orbital fracture repairs, removal of tumors in and around the eyes, as well as eyelid and facial reconstruction, among many other procedures. The types of plastic surgery procedures described on page 27 of the Valleygate Surgery Center application, such as rhinoplasty, cleft palate correction, and local flap reconstruction, are not the type of procedures that would be performed by an oculoplastic surgeon. At best, Dr. Jindal is performing oculoplastic procedures, which is not the same as plastic surgery. Further, as discussed previously, given Valleygate Dental Surgery Center's recent petition, it appears as if the ENT cases proposed to be performed at Valleygate Surgery Center are actually ENT procedures that will be performed concurrently with dental/oral surgical cases and not, in fact, separate ENT cases. Thus, they are already accounted for in Valleygate's projected dental/oral case volume. If dental/oral and ENT cases are going to be performed concurrently, it could be argued that ENT should not be counted as a separate specialty in regard to qualifying for the definition of a multispecialty ASF. Moreover, despite overarching claims by Valleygate that it will offer multispecialty services, its application lacks evidence demonstrating that it will actually have otolaryngology, ophthalmology, and plastic surgeons practicing at Valleygate Surgery Center, which calls into question its ability to provide the services it proposes. Given the foregoing, Valleygate's alleged "multispecialty" services appear to be contrived merely to meet the definition of a "multispecialty ambulatory surgical program" under N.C. GEN. STAT. § 131E-176(15a) as there is no credible basis to support such proposed "multispecialty" services.

Based on this issue, the Valleygate Surgery Center application fails to show the need for the project or evidence of availability of resources, including health manpower and management personnel, for the provision of the "multispecialty" services Valleygate proposes to provide and it

[11] Duke Health website accessed at https://www.dukehealth.org/find-doctors-physicians/vinod-k-jindal-md?utm_source=google&tum_medium=organic&utm_campaign=Directory+Management.

fails to show that the proposed service will be coordinated with the existing healthcare system. As such, **the Valleygate Surgery Center application should be found non-conforming with Criteria 3, 7, and 8**.

7. The Valleygate Surgery Center application fails to demonstrate how water, sewer and waste disposal, and power will be provided to the proposed site.

   On page 102 of the Valleygate Surgery Center application, in response Section K.4(d)-(f), Valleygate directs the reader to Exhibit K.4 in order to provide evidence as to how water, sewer and waste disposal, and power will be provided to the proposed site. However, Exhibit K.4 is a letter from Anuj James, DDS, a managing member of Valleygate Surgery Center, LLC, that simply claims that Wake Real Estate Properties, LLC has determined that the proposed property has adequate access to water, sewer, and power to support the proposed ASF. The letter does not provide any real evidence of the availability of the utilities required to operate the proposed ASF. In fact, according to the Village Family Dental website[12], Dr. James is a general dentist with Village Family Dental; thus, it is unlikely that Dr. James can officially attest to the adequacy of water, sewer and disposal, and power available at the proposed site to support the proposed Valleygate Surgery Center.

   Based on this issue, the Valleygate Surgery Center application fails to demonstrate how water, sewer and waste disposal, and power will be provided to the proposed site. As such, **the Valleygate Surgery Center application should be found non-conforming with Criterion 12**.

In summary, Valleygate has failed to adequately identify the population to be served by the proposed project, to demonstrate that the project is needed, to demonstrate that the project will not result in unnecessary duplication of existing or approved health service capabilities or facilities, or show evidence of availability of resources, including health manpower and management personnel, for the provision of the services proposed, and the Valleygate Surgery Center application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 7, 8, 12, 18(a), and the performance standards at 10A NCAC 14C .2103. The Valleygate Surgery Center application should not be approved.

[12] Accessed at https://www.vfdental.com/our-staff/general-dentists/dr-a-james/.

COMMENTS ON DUKE GARNER AMBULATORY SURGICAL CENTER

Duke's Failure to File Complete Garner ASC Application

For the reasons explained below, Duke Health's Duke Garner ASC application is unapprovable because Duke Health failed to file the required original and one copy of that full application. Pursuant to 10A NCAC 14C .0203(b), an applicant is required to file an original **and** a copy of the application being submitted to the Agency. In particular, 10A NCAC 14C .0203(b) states:

> "An original **and a copy** of the application **shall** be file-stamped as received by the agency no later than 5:30 p.m. on the 15th day of the month preceding the scheduled review period . . . . An application shall not be included in a scheduled review if it is not received by the agency by this deadline . . . . [Emphasis added]

The Agency's own rule says a copy **shall** be filed by the deadline. Thus, it is mandatory to file an original **and** a copy of the application by the deadline. Duke Health failed to file that necessary copy for the Duke Garner ASC project, making that application unapprovable.

In OAH filings earlier this year, where a competing applicant (Southpoint) slightly, inadvertently underpaid its filing fee, Duke asserted the sanctity of the CON filing requirements. The payment of the CON application fee and the requirement to file an application copy are both requirements of a CON applicant, and Duke's arguments regarding the importance of the filing fee are equally applicable to the importance of filing a copy of a CON application. Citing to the filing requirements and three separate Agency witnesses, Duke stated:

> [T]here is no dispute that the burden for computing and submitting a proper application fee with its CON application rested solely upon Southpoint pursuant to a statutory mandate governing the CON application process and the Agency's role therein. See N.C. Gen. Stat. § 131E-182(c); Southpoint Ex. 5, Dep. Inman, Vol. 2, pp. 55-57; Southpoint Ex. 6, Dep. Hale, pp. 143-46; Southpoint Ex. 8, Dep. Frisone, pp. 106-08.

Duke's Brief, p. 5.[13] Likewise, here, the burden of filing the requisite original and copy of each application is squarely on the applicant, Duke Health.

[13] The full title of this document is Duke's Response to Southpoint Surgery Center's Motion for Partial Summary Judgment and Duke's Cross Motion for Partial Summary Judgment, filed in 19 DHR 2537 on January 3, 2020.

In the very same case, the Agency instructed the tribunal on how to interpret the word "shall."

> "The word 'shall' is defined as 'must' or 'used in laws, regulations, or directives to express what is mandatory.'" Internet East, Inc. v. Duro Communications, Inc., 146 N.C. App. 401, 405-06, 553 S.E.2d 84, 87 (2001) (internal citations omitted). "When the language of a statute is clear and unambiguous, there is no room for judicial construction and the courts must give the statute its plain and definite meaning." State v. Lewis, 231 N.C. App. 438, 443-44, 752 S.E.2d 216, 220 (2013).

Agency's Brief, p. 5.[14]

Duke argued that Southpoint was seeking to avoid blame, to relieve itself of Southpoint's own filing error. Duke maintained that:

> . . . Southpoint seeks to abrogate its failure to submit the proper application fee and shift its burden onto the Agency, thereby freeing Southpoint from the consequences of its own error. This is a wholly improper attempt by Southpoint to twist the rule of law into a contorted knot of circular logic.

Duke's Brief, p. 5. To the extent that arguing such relief is a contorted knot of circular logic, that knot now lays on Duke's own doorstep. To the extent Duke argues the Agency has the burden of looking through other CON applications filed by Duke to "cobble together" a complete copy, Duke's criticisms of Southpoint are equally applicable to Duke itself in this case.

Duke then admonished Southpoint about its exclusive obligations, asserting the following:

> The fact that Southpoint incorrectly calculated the application fee required for the proper submission and review of its application rests upon Southpoint and no one else. Yet, Southpoint seeks to have this Court find that the Agency erred as a result of Southpoint's own mistake. Such a conclusion would be absurd.

Duke's Brief, p. 5-6.

[14] The full title of this document is Respondent's Memorandum of Law in Opposition to Southpoint Surgery Center's Motion for Partial Summary Judgment, filed in 19 DHR 2537 on January 3, 2020.

Duke then continued its advice on assigning blame for an applicant's own carelessness:

> Southpoint's attempt to blame the Agency for Southpoint's own carelessness is as transparent as it is duplicitous. It seeks to shift the statutory obligation imposed upon Southpoint onto the Agency, and thereby use the Agency's regulatory processes as a sword against the Agency itself. Yet, the simple fact remains: Southpoint is solely and completely responsible for the failure to submit the proper application fee. In short, the sequence of events which ultimately led to the disapproval of the Southpoint application by the CON Section was set in motion solely and entirely by Southpoint itself.

Duke's Brief, p. 6.

Likewise, Duke Health is the only party that failed to file its Garner ASC application in compliance with the CON Section's mandatory rules.

Details of Duke's Failure to File Complete Garner ASC Application

As referenced above, the mandatory rule at 10A NCAC 14C .0203(b), requires each applicant to file an original and a copy of the application being submitted to the Agency. In particular, 10A NCAC 14C .0203(b) states:

> "*An original and a copy of the application shall be file-stamped as received by the agency no later than 5:30 p.m. on the 15th day of the month preceding the scheduled review period. In instances when the 15th of the month falls on a weekend or holiday, the filing deadline is 5:30 p.m. on the next business day. An application shall not be included in a scheduled review if it is not received by the agency by this deadline. Each applicant shall transmit, with the application, a fee to be determined according to the formula as stated in G.S. 131E-182(c).*" [Emphasis added]

The Agency has provided "Instructions for Submitting Completed Certificate of Need Application Forms," which indicate that an applicant must submit one paper/hard copy of the application. However, the application copy may be submitted electronically (on a CD or DVD) in lieu of a second paper/hard copy.

Submitting the Application

1. Each volume of the application should be bound together by punching two holes in the left hand margin and fastening the pages together with a metal paper fastener (e.g., ACCO ® Paper Fasteners). Place a sturdy cover on the front and back to protect the first and last pages from damage. **Do not submit the application in a 3-ring binder or notebook.**
2. Pursuant to 10A NCAC 14C .0203(b), the applicant is required to submit *"An original and a copy of the application."* Beginning with the review cycle starting February 1, 2014, the applicant may submit the copy of the application on a CD or DVD in lieu of a paper copy. If the applicant chooses to submit the copy on a CD or DVD, the entire application must be included on the disk. The application itself should be in Microsoft Word or Excel while the exhibits may be in Word, Microsoft Excel or PDF. The original application, including exhibits, must be printed and submitted as a "hard copy." No more than one application, including exhibits, may be saved onto the same disk.

For both Duke Health applications – Duke Garner ASC and Duke Green Level ASC – Duke Health opted to submit the application copy (in both instances) electronically in lieu of a second paper/hard copy.

Upon requesting copies of the Duke Health applications, UNC REX received electronic copies of the applications (as submitted by Duke Health to the Agency as its application copies). UNC REX received a total of six PDF documents [three separate PDF files per application (the application narrative, the proformas and assumptions, and the exhibits)]. In particular, UNC REX received the following six PDF files:

- "Duke Health Garner ASC Application Narrative"[15],
- "Duke Health Garner ASC Application Proformas and Assumptions",
- "Duke Health Garner ASC Exhibits"
- "Duke Health Green Level ASC CON Application Narrative"[16],
- "Duke Health Green Level ASC CON Application Proformas and Assumptions", and
- "J-11967-20 Exhibits"

The PDF file labeled "Duke Health Garner ASC Application Narrative" appears to contain the application narrative for the Duke Green Level ASC application, while the PDF file labeled "Duke Health Green Level ASC CON Application Narrative" appears to contain the application narrative for the Duke Garner ASC application.

As discussed in detail below in the issue-specific comments, the required copy of the Duke Garner ASC application (submitted by Duke Health electronically) fails to include the following exhibits:

- Exhibit A-1 – Articles of Incorporation
- Exhibit F.1(c)-1 – Letter from Project Architect
- Exhibit F.1(c)-2 – Equipment List
- Exhibit I.3 – Medical Director Letters

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[15] UNC REX initially requested copies of the Duke Health applications on September 16, 2020. In response to this request, UNC REX received electronic copies of the application narratives and proformas and assumptions on September 25, 2020 and electronic copies of the exhibits on October 12, 2020. UNC REX reviewed the PDF labeled "Duke Health Garner ASC Application Narrative" and upon realizing that this PDF actually contained the application narrative for Duke Green Level ASC, contacted the Agency on October 21, 2020 to inquire regarding the source of the mislabeling. At that time, the Agency apprised UNC REX that Duke Health submitted its required application copies electronically and that, as such, the PDF files were labeled by Duke Health (not the Agency as might occur if the applicant were to have submitted the application copy as a second paper/hard copy which the Agency would then scan, name, and send to interested parties requesting copies). After bringing the mislabeling to the attention of the Agency and requesting that the Agency re-send the electronic copies (for UNC REX to double check/confirm the mislabeling), the Agency re-named the PDFs that referenced Garner to Green Level and vice versa (believing Duke's error to be a case of mislabeling that impacted all of six of the PDF files, not just the application narratives) and re-sent the electronic copies to UNC REX on October 22, 2020. As such, and in order to preserve the electronic application copies as submitted (and labeled) by Duke Health, in referring to the PDF file labeled "Duke Health Garner ASC Application Narrative," UNC REX is referring to the file as submitted by Duke Health and as received by UNC REX on September 25, 2020, which, while labeled "Duke Health Garner ASC Application Narrative," actually includes the application narrative for Duke Green Level ASC.

[16] In order to preserve the electronic application copies as submitted (and labeled) by Duke Health, in referring to the PDF file labeled "Duke Health Green Level ASC CON Application Narrative," UNC REX is referring to the file as submitted by Duke Health and as received by UNC REX on September 25, 2020, which, while labeled "Duke Health Green Level ASC CON Application Narrative," actually includes the application narrative for Duke Garner ASC.

- Exhibit K.1 – MOB Exemption Documentation
- Exhibit K.2 – Floor Plans
- Exhibit K.4 – Site Documentation

Given the confusion associated with Duke Health's labeling of its electronic copies, **UNC REX reviewed both exhibit books and confirmed that neither exhibit book (as submitted electronically by Duke Health as part of its application copy), contains the exhibits listed above for the Duke Garner ASC application**.

UNC REX contacted the Agency to request a time to conduct an in-person inspection of the original paper/hard copy of each of the Duke Health applications. The Agency granted UNC REX's request and an in-person inspection of the Duke Health applications occurred on-site at the office of the Agency on October 27, 2020.

After requesting and being granted approval to conduct a time-limited in-person inspection of the original paper/hard copy of the Duke Garner ASC application, UNC REX learned that the original paper/hard copy does include each of the exhibits listed below – all of which were omitted from the required copy of the Duke Garner ASC application (please see the issue-specific comments below for a detailed discussion of the documentation/information omitted from the required copy of the Duke Garner ASC application).

- Exhibit A-1 – Articles of Incorporation
- Exhibit F.1(c)-1 – Letter from Project Architect
- Exhibit F.1(c)-2 – Equipment List
- Exhibit I.3 – Medical Director Letters
- Exhibit K.1 – MOB Exemption Documentation
- Exhibit K.2 – Floor Plans
- Exhibit K.4 – Site Documentation

The Agency should not accept for review or accept the application as complete given the documentation that appears in its original paper/hard copy, but not in its required second application copy.

Moreover, had UNC REX not gone to the effort of requesting approval to conduct an in-person inspection of the original paper/hard copies of the Duke Health applications and had the Agency not granted UNC REX's request, UNC REX would have missed the opportunity to comment on information which appears only in the original paper/hard copy of the Duke Garner ASC application (documentation which was omitted from the required copy of the Duke Garner ASC application).

All applicants submitting comments on the Duke Health Garner ASC application who did not request an in-person inspection of the original paper/hard copy of the Duke Garner ASC application, have missed the opportunity to comment on information which appears only in the original paper/hard copy of the Duke Garner ASC application. Moreover, because both the original paper/hard copy application and the electronic copy of the Duke Garner ASC application have been deemed "complete" by the Agency, Duke Health may not amend its application. See 10A NCAC 14C .0204.

Issue-Specific Comments

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

   As noted above, Duke Health opted to submit the application copy for the Duke Garner ASC application electronically in lieu of a second paper/hard copy. The copy of the Duke Garner ASC application (as submitted electronically by Duke Health) fails to include the following:

   - Exhibit A-1 – Articles of Incorporation
   - Exhibit F.1(c)-1 – Letter from Project Architect
   - Exhibit F.1(c)-2 – Equipment List
   - Exhibit I.3 – Medical Director Letters
   - Exhibit K.1 – MOB Exemption Documentation
   - Exhibit K.2 – Floor Plans
   - Exhibit K.4 – Site Documentation

   The required copy of the Duke Garner ASC application completely omits Exhibit A.1. As to the other exhibits noted above, while the Duke Garner ASC application purports to contain this information, the information provided in each of these exhibits relates to the Duke Green Level ASC application and not the Duke Garner ASC application.

   - Exhibit F.1(c)-1 – Letter from Project Architect[17]

     - The "Re:" subject line of this letter from Leslie L. Hanson, AIA (Principle with HKS, Inc.) reads "**Architect's Certification Letter FPDC 4033 HSOC Green Level ASC Build-out of 2 Operating Rooms**" [emphasis added].

     - The body of this letter from Leslie L. Hanson, AIA (Principle with HKS, Inc.) speaks to the capital cost of the Duke Green Level ASC application, not the Duke Garner ASC application. In particular, this letter notes that "the estimated construction cost for the proposed for the build-out [sic] of two Operating Rooms at the Green Level Ambulatory Surgery Center of $3,675,000 represents the cost that may be expected for the building scope, quality, and location reflected in the program." [emphasis added].

     Notwithstanding the references to the Duke Green Level ASC, the total construction / renovation contract amount identified in this exhibit ($3,675,000) does not match the construction / renovation contract amount identified in Form F.1a for the Duke Garner

[17] Please see PDF page 131 of 288 of the "Duke Health Garner ASC Exhibits" electronic file. Given Duke's mislabeling of the application narratives, and in an abundance of caution, UNC REX reviewed Exhibit F.1(c)-1 in the electronic Duke Health Green Level ASC exhibit book submitted by Duke Health labeled "J-11967-20 Exhibits" (PDF page 140 of 297) and confirmed that it too contains a capital cost letter for the Duke Green Level ASC application. In other words, neither electronic exhibit book submitted by Duke Health contains a certified capital cost letter for the Duke Garner ASC application.

ASC application ($6,750,000); rather, it matches the construction / renovation contract amount identified in Form F.1a for the Duke Green Level ASC application ($3,675,000).

As such, the copy of the Duke Garner ASC application fails to demonstrate that that the project is the most effective or least costly alternative. Further, neither electronic exhibit book submitted by Duke Health contains a certified capital cost letter for the Duke Garner ASC application, and as such Duke Health has not demonstrated that the project proposed in the Duke Garner ASC application is the most effective or least costly alternative.

- Exhibit F.1(c)-2 – Equipment List[18]

    - The equipment list provided is titled "Duke University Health System Green Level ASC Operating Room Budget" [emphasis added].

    - The total budget identified is $825,000.

    Notwithstanding the reference to the Duke Green Level ASC, the total equipment budget identified in this exhibit ($825,000) does not match the medical equipment budget identified in Form F.1a ($3,650,000).

    As such, the copy of the Duke Garner ASC application fails to demonstrate that that the project is the most effective or least costly alternative. Further, neither electronic exhibit book submitted by Duke Health contains an equipment list for the Duke Garner ASC application, and as such Duke Health has not demonstrated that the project proposed in the Duke Garner ASC application is the most effective or least costly alternative.

- Exhibit I.3 – Medical Director Letters[19]

    - This exhibit includes two medical director letters – one from David E. Attarian, M.D. and one from Peter Grossi, M.D.

    - The body of the letter from David E. Attarian, M.D. speaks to his support for the Duke Green Level ASC proposal and his intention to serve as co-Medical Director of the Duke Green Level ASC.

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[18] Please see PDF pages 133-134 of 288 of the "Duke Health Garner ASC Exhibits" electronic file. Given Duke's mislabeling of the application narratives, and in an abundance of caution, UNC REX reviewed Exhibit F.1(c)-2 in the electronic Duke Health Green Level ASC exhibit book submitted by Duke Health labeled "J-11967-20 Exhibits" (PDF pages 142-143 of 297) and confirmed that it too contains an equipment list for the Duke Green Level ASC application. In other words, neither electronic exhibit book submitted by Duke Health contains an equipment list for the Duke Garner ASC application.

[19] Please see PDF pages 202-230 of 288 of the "Duke Health Garner ASC Exhibits" electronic file. Please note that given Duke's mislabeling of the application narratives, and in an abundance of caution, UNC REX reviewed Exhibit I.3 the electronic Duke Health Green Level ASC exhibit book submitted by Duke Health labeled "J-11967-20 Exhibits" (PDF pages 211-239 of 297) and confirmed that it too contains medical director letters for the Duke Green Level ASC application. In other words, neither electronic exhibit book submitted by Duke Health contains medical director letters for the Duke Garner ASC application.

- The body of the letter from Peter Grossi, M.D. speaks to his support for the Duke Green Level ASC proposal and his intention to serve as co-Medical Director of the Duke Green Level ASC.

Notwithstanding the references to the Duke Green Level ASC, the co-Medical Directors identified in this exhibit (David E. Attarian, M.D. and Peter Grossi, M.D.) do not match the co-Medical Directors identified in Section I.3(b) of the Duke Garner ASC application (Gary Faerber, M.D. and Stephen Klein, M.D.)[20]; rather, they match the co-Medical Directors identified in Section I.3(b) of the Duke Green Level ASC application (David E. Attarian, M.D. and Peter Grossi, M.D.).[21]

As such, the copy of the Duke Garner ASC application fails to demonstrate the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided. Further, neither electronic exhibit book submitted by Duke Health contains appropriate medical director documentation for the Duke Garner ASC application, and as such Duke Health has not demonstrated that the project proposed in the Duke Garner ASC application will have available resources, including health manpower and management personnel, for the provision of the services proposed.

- Exhibit K.1 – MOB Exemption Documentation[22]

  - This exhibit includes documentation regarding two exemption requests to develop a physician office building on Green Level West Road in Cary.

  - Documentation regarding the first exemption request includes the following project description: "Develop a physician office building to be located on Green Level West Road in Cary" [emphasis added].

  - Documentation regarding the second exemption request includes the following project description: "Develop a physician office building at 3208 Green Level W Road in Cary" [emphasis added].

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[20] Please see page 89 of the Duke Garner ASC application [note: while this PDF file (as received by UNC REX on September 25, 2020 from the CON Section) was labeled "Duke Health Green Level ASC CON Application Narrative," the response to Section A.4(a) in this document clearly identifies the document as the application narrative to the Duke Garner ASC application].

[21] Please see page 89 of the Duke Green Level ASC application [note: while this PDF file (as received by UNC REX on September 25, 2020 from the CON Section) was labeled "Duke Health Garner ASC Application Narrative," the response to Section A.4(a) in this document clearly identifies the document as the application narrative to the Duke Green Level ASC application].

[22] Please see PDF pages 232-236 of 288 of the "Duke Health Garner ASC Exhibits" electronic file. Given Duke's mislabeling of the application narratives, and in an abundance of caution, UNC REX reviewed Exhibit K.1 in the electronic Duke Health Green Level ASC exhibit book submitted by Duke Health labeled "J-11967-20 Exhibits" (PDF pages 241-245 of 297) and confirmed that it too contains MOB exemption documentation for the Duke Green Level ASC application. In other words, neither electronic exhibit book submitted by Duke Health contains MOB exemption documentation for the Duke Garner ASC application.

The documentation provided in this exhibit clearly relates to the Duke Green Level ASC application and not the Duke Garner ASC application, which according to Duke Health will be located at 1011 New Rand Road in Garner,[23] not 3208 Green Level West Road in Cary.

As such, the copy of the Duke Garner ASC application fails to demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative. Further, neither electronic exhibit book submitted by Duke Health contains exemption request documentation for the Duke Garner ASC application, and as such Duke Health has not demonstrated that the cost, design, and means of construction in the project proposed in the Duke Garner ASC application is the most reasonable alternative.

- Exhibit K.2 – Floor Plans[24]

    - The floor plans provided in Exhibit K.2 are labeled "FPDC 4033 ASC SCHEMATIC FLOOR PLAN DUKE GREEN LEVEL ASC" [emphasis added]

    - The floor plans identify three operating rooms (two additional operating rooms) and five procedure rooms

Notwithstanding the reference to the Duke Green Level ASC, the number of operating rooms and procedure rooms identified (three operating rooms (two additional operating rooms) and five procedure rooms) does not match the Project Description provided in Section 4(a) of the Duke Garner ASC application (one operating room and two procedure rooms).[25] Rather, it matches the number of operating rooms and procedure rooms identified in Section 4(a) of the Duke Green Level ASC application (three operating rooms (two additional operating rooms) and five procedure rooms).[26]

As such, the copy of the Duke Garner ASC application fails to demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative. Further, neither electronic exhibit book submitted by Duke Health contains floor plans for

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[23] Please see page 10 of the Duke Garner ASC application [note: while this PDF file (as received by UNC REX on September 25, 2020 by the CON Section) was labeled "Duke Health Green Level ASC CON Application Narrative," the response to Section A.4(a) in this document clearly identifies the document as the application narrative to the Duke Garner ASC application].

[24] Please see PDF page 238 of 288 of the "Duke Health Garner ASC Exhibits" electronic file. Please note that given Duke's mislabeling of the application narratives, and in an abundance of caution, UNC REX reviewed Exhibit K.2 in the electronic Duke Health Green Level ASC exhibit book submitted by Duke Health labeled "J-11967-20 Exhibits" (PDF page 247 of 297) and confirmed that it too contains a floor plan for the Duke Green Level ASC application. In other words, neither electronic exhibit book submitted by Duke Health contains a floor plan for the Duke Garner ASC application.

[25] Please see page 8 of the Duke Garner ASC application [note: while this PDF file (as received by UNC REX on September 25, 2020 from the CON Section) was labeled "Duke Health Green Level ASC CON Application Narrative", the response to Section A.4(a) in this document clearly identifies the document as the application narrative to the Duke Garner ASC application].

[26] Please see page 8 of the Duke Green Level ASC application [note: while this PDF file (as received by UNC REX on September 25, 2020 from the CON Section) was labeled "Duke Health Garner ASC Application Narrative", the response to Section A.4(a) in this document clearly identifies the document as the application narrative to the Duke Green Level ASC application].

the Duke Garner ASC application, and as such Duke Health has not demonstrated that the cost, design, and means of construction in the project proposed in the Duke Garner ASC application is the most reasonable alternative.

- Exhibit K.4 – Site Documentation[27]

    - The "Re:" subject line of this letter from Brandon R. Finch, PE (Director, Institutional with McAdams) reads "**Zoning, Utilities, & Efficiency FPDC 4033 HSOC Green Level West Road New Building DKH-16050**" [emphasis added].

    - The body of this letter from Brandon R. Finch, PE (Director, Institutional with McAdams) speaks to energy and water conservation relative to the Duke Green Level ASC application, not the Duke Garner ASC application. In particular, this letter contains numerous references to Cary and to Green Level West Road.

    As such, the copy of the Duke Garner ASC application fails to demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative. Further, neither electronic exhibit book submitted by Duke Health contains site documentation for the Duke Garner ASC application, and as such Duke Health has not demonstrated that the cost, design, and means of construction in the project proposed in the Duke Garner ASC application is the most reasonable alternative.

Based on these issues, the copy of the Duke Garner ASC application fails to provide information necessary to determine whether the proposed new institutional health service is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and with duly adopted standards, plans, and criteria. The Duke Garner ASC application fails to demonstrate that the project is needed, that it is the most effective or least costly alternative, or that the cost, design, and means of construction proposed represent the most reasonable alternative. As such, **the Duke Garner ASC application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 7, 12, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

2. The Duke Garner ASC application cannot be approved as submitted, as it is incomplete and fails to document surgeon support necessary to develop the project as proposed.

    As noted above, Duke Health opted to submit the application copy for the Duke Garner ASC application electronically in lieu of a second paper/hard copy. Following a review of the copy, UNC REX determined that the copy of the Duke Garner ASC application (as submitted

[27] Please see PDF pages 240-244 of 288 of the "Duke Health Garner ASC Exhibits" electronic file. Please note that given Duke's mislabeling of the application narratives, and in an abundance of caution, UNC REX reviewed Exhibit K.4 in the electronic Duke Health Green Level ASC exhibit book submitted by Duke Health labeled "J-11967-20 Exhibits" (PDF pages 249-253 of 297) and confirmed that it too contains site documentation for the Duke Green Level ASC application. In other words, neither electronic exhibit book submitted by Duke Health contains site documentation for the Duke Garner ASC application.

electronically by Duke Health and provided to UNC REX by the CON Section) includes the same Exhibit C.4 Letters of Support as the copy of the Duke Green Level ASC application.[28]

The identical Exhibits C.4 include a total of 71 letters of support. While 14 of the 71 letters of support generally indicate support for both of Duke Health's applications, the remaining **57 letters of support are specific to Duke Green Level ASC and include no mention of Duke Garner ASC**. Further, please note that none of the 14 letters of support that generally indicate support for both of Duke Health's applications explicitly document the intent of a surgeon (or surgeons) to perform procedures at the proposed ASF, nor do they identify a type of surgical specialty to be performed at the proposed ASF.

After requesting and being granted approval to inspect the original paper/hard copy of the Duke Garner ASC application, UNC REX learned that the original paper/hard copy does include an Exhibit C.4 that is not identical to that provided in the Duke Green Level ASC application and instead appears to be specific to the Duke Garner ASC. Given the discrepancies between Duke Health's original paper/hard copy application and its required second application copy, UNC REX does not believe that the Agency should consider or evaluate the letters of support that appear in Duke Garner ASC's original paper/hard copy, but not in its required second application copy. As noted previously, had UNC REX not gone to the effort of requesting and receiving approval to conduct an in-person inspection of the original paper/hard copies of the Duke Health applications, it would have missed the opportunity to comment on information which appears only in the original paper/hard copy of the Duke Garner ASC application.

Based on these issues, the Duke Garner ASC application fails to demonstrate that the project is needed and fails to demonstrate coordination with the existing healthcare system. As such, **the Duke Garner ASC application should be found non-conforming with Criteria 1, 3, and 8**.

3. The Duke Garner ASC application proposes too many surgical specialties for a one operating room ASF and also fails to include enough equipment to support the proposed surgical specialties.

On page 17 of its application, Duke Health indicates that the proposed new ASF in Garner – with one operating room – will be a multispecialty facility that offers general surgery, ophthalmology, orthopaedics, urology, otolaryngology, gynecology, and plastic surgery. It is irrational to assume that an ASF with one operating room can reasonably accommodate seven different specialties in an efficient and cost effective manner. An ASF with one operating room would have a limited amount of block time for the considerable number of surgeons proposed to perform cases at Duke Garner ASC. As such, it would be difficult to manage the logistics involved with scheduling seven different surgical specialties for one operating room. To accommodate this many specialties with one room, surgeons of any given specialty may only be offered a single, or even partial, day of operating room availability per week, calling into question the likelihood of surgeons committing to practice at the ASF. The logistics involved with scheduling seven different surgical specialties for one operating room would be particularly difficult in consideration of the amount of equipment movement that would need to take to place in order to outfit the operating room with everything necessary to support each different surgical specialty.

[28] The identical Exhibit C.4 Letters of Support can be found on PDF pages 3-120 of 288 of the "Duke Health Garner ASC Exhibits" electronic file and on PDF pages 12-129 of 297 in the electronic Duke Health Green Level ASC exhibit book submitted by Duke Health labeled "J-11967-20 Exhibits."

In addition, the amount of equipment that would need to be purchased to support all seven surgical specialties proposed is neither realistic nor feasible considering the medical equipment capital cost allowance identified in Form F.1a ($3,650,000) as well as the limited number of cases to be performed at Duke Garner ASC, by specialty, as provided below.

Duke Garner ASC Projected OR Cases by Specialty

Specialty	*FY 2024*	*FY 2025*	*FY 2026*
General	56	113	211
GYN	16	32	57
Ophthalmology	207	318	483
Orthopedics	147	234	323
ENT	59	93	141
Plastic	16	33	55
Urology	40	65	99
Total	**541**	**888**	**1,369**

Source: Duke Garner ASC application page 133.

As shown above, Duke Garner ASC projects to provide a nominal number of cases by specialty, especially for gynecology, plastic, and urology.

Moreover, and as noted previously, following a review of the copy of the Duke Garner ASC application (as submitted electronically by Duke Raleigh), UNC REX was initially unable to analyze and/or discuss whether the types of equipment proposed are appropriate and/or sufficient to support the types and number of surgical specialties proposed, as the equipment list provided in Exhibit F.1(c)-2 of the copy of the Duke Garner ASC application is for Duke Green Level ASC; thus, there is no equipment list provided for Duke Garner ASC in Duke Health's required copy of the Duke Garner ASC application. However, after requesting and being granted approval to inspect the original paper/hard copy of the Duke Garner ASC application, UNC REX learned that while the original paper/hard copy does include an equipment list in Exhibit F.1(c)-2 that does not include a reference to the Duke Green Level ASC in the heading, the equipment list is otherwise identical to that provided in the Duke Green Level ASC application (and Exhibit F.1(c)-2). Given the discrepancies between Duke Health's original paper/hard copy application and its required second application copy, UNC REX does not believe that the Agency should give credit to Duke Health for an equipment list that appears in its original paper/hard copy, but not in its required second application copy. As noted previously, had UNC REX not gone to the effort of requesting and receiving approval to conduct an in-person inspection of the original paper/hard copies of the Duke Health applications, it would have missed the opportunity to comment on information which appears only in the original paper/hard copy of the Duke Garner ASC application.

Nonetheless, upon review of Exhibit F.1(c)-2 included with the original paper/hard copy of the Duke Garner ASC, UNC REX determined that the equipment list for Duke Garner ASC appears to be very generalized and not specific to, or inclusive of any one surgical specialty, and also there does not appear to be enough equipment accounted for to support all seven of the proposed specialties. Specifically, there is no indication that Duke Health included an allowance for different surgical trays or any other specialized equipment needed to support all of the proposed

specialties. Furthermore, Exhibit F.1(c)-2 provides a total operating room equipment expense total of $825,000; however, while Duke Health's Form F.1(a) for the Duke Garner ASC includes a medical equipment expense of $3,650,000, the application provides no detailed list of equipment above and beyond what is provided in the original paper/hard copy of Exhibit F.1(c)-2 for the one operating room. Thus, UNC REX is unable to discern whether or not Duke Health appropriately included the equipment necessary to perform all of the proposed cases, including the cystoscopy and YAG laser cases that are proposed to be performed in procedure rooms at Duke Garner ASC. Nonetheless, it is unreasonable to assume all seven specialties can be reasonably accommodated at the proposed one operating room ASF.

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

4. <u>The Duke Garner ASC application projects an unreasonable shift of patients from Duke Raleigh Hospital and Duke University Hospital.</u>

Duke Garner ASC's utilization methodology involves an unreasonable shift of patients that historically accessed Duke Raleigh Hospital and Duke University Hospital for outpatient surgical services. Notably, Step 9 of Duke Garner ASC's utilization methodology projects a shift of patients to Duke Garner ASC from Duke Raleigh Hospital and Duke University Hospital. On page 128 of the Duke Garner ASC application, Duke Health lists a number of reasons as to why it believes the shifts are reasonable, including efforts to decompress existing capacity constraints at Duke Raleigh Hospital and Duke University Hospital, efforts to reduce the travel burden for patients seeking ambulatory surgery, and efforts to provide a convenient location for the growing county population. However, these reasons are not sufficient enough to assume that the projected number of cases by specialty will shift from Duke Raleigh Hospital and Duke University Hospital to the proposed ASF, as the proposed shifts are not based on patients from the Garner area that have historically accessed Duke Health's facilities in Wake and Durham counties. In Section C of the Duke Garner ASC application, Duke Health claims that patients from all over Wake County travel to Durham County for surgery, but Duke Health fails to quantify the number of patients from the Garner area with the types of surgery proposed to be performed at the ASF in Garner to or quantify patients for whom travel to Garner would be more convenient than travel to Raleigh or Durham. As such, the proposed shift of patients is unfounded and purely speculative.

Further, page 35 of the Duke Garner ASC application states, "[R]esidents of Garner and surrounding communities already utilize Duke Health for healthcare services. Duke analyzed FY 2020 internal data (Epic) to identify the number of lives touched by any Duke Health (DUHS and PDC) specialty/service…During FY 2020, over 140,000 residents of Garner and surrounding areas sought some form of healthcare from Duke Health." There are several issues with this statement, including the fact that Duke Health does not define "Garner and surrounding areas," so it is difficult – if not impossible – to determine to which areas Duke Health is referring. In addition, according to the United States Census Bureau, Garner had an estimated population of only 30,508 in 2018, which is significantly lower than the 140,000 lives that Duke Health mentions, which calls into question what exactly Duke Health defines as "lives touched" and how, if at all, this number has any correlation to the demand for outpatient surgical services. Lastly, it is unreasonable to assume that the proposed one operating room ASF will have the same regional draw as Duke

Raleigh Hospital and Duke University Hospital. Duke Raleigh Hospital is 186-bed hospital that offers a comprehensive list of services, including cancer, orthopedic, cardiovascular, and neuroscience, and Duke University Hospital is a 924-bed, full-service tertiary and quaternary care hospital; thus, it is unlikely that Duke Garner ASC will experience the same level of regional draw experienced by Duke Health's larger hospitals that offer a much wider and multifaceted array of healthcare services. Further, the Duke Garner ASC application does not precisely describe the area from where it expects from which its patients to originate. In consideration of these factors, UNC REX believes that the proposed shifts to the Duke Garner ASC are purely speculative and have no reasonable basis.

Based on these issues, the Duke Garner ASC application fails to demonstrate that the project is needed. As such, **the Duke Garner ASC application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

5. The Duke Garner ASC application does not provide a Form C Utilization for Duke Green Level ASC.

The Duke Garner ASC application does not include a Form C Utilization for Duke Green Level ASC even though Duke Health is applying to develop an additional operating room at Duke Green Level ASC in a complementary application. Section C.7 requires that a proposal resulting in an increase in the number of operating rooms in a service area must complete a separate Form C Utilization for each facility in the applicant's health system, as that term is defined in Chapter 6 of the *SMFP* in effect at the time the review begins. Given that the Duke Garner ASC application does not include a Form C Utilization for Duke Green Level ASC, Duke Health Garner ASC is in violation of this requirement.

Based on this issue, the Duke Garner ASC application fails to demonstrate that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183. As such, **the Duke Garner ASC application should be found non-conforming with Criteria 1, 3, 4, and 6**.

6. The Duke Garner ASC application includes unreasonable procedure room assumptions.

The Duke Garner ASC application proposes to develop three procedure rooms as part of the proposed ASF. As mentioned previously, there is no floor plan for the Duke Garner ASC included in the copy of the Duke Garner ASC exhibit book; thus, UNC REX was initially unable to review the proposed facility layout. However, after requesting and being granted approval to inspect the original paper/hard copy of the Duke Garner ASC application, UNC REX learned that the original paper/hard copy does include a floor plan of the proposed ASF. Given the discrepancies between Duke Health's original paper/hard copy application and its required second application copy, UNC REX does not believe that the Agency should give credit to Duke Health for a line drawing that appears in its original paper/hard copy, but not in its required second application copy. As noted previously, had UNC REX not gone to the effort of requesting and receiving approval to conduct an in-person inspection of the original paper/hard copies of the Duke Health applications, it would have missed the opportunity to comment on information which appears only in the original paper/hard copy of the Duke Garner ASC application.

Nonetheless, while the original paper/hard copy does include a floor plan of the proposed ASF in Exhibit K.2 labeled "CONCEPT FLOOR PLAN DUKE Garner ASC," the floor plan is illegible. That is, the line drawing included in Exhibit K.2 of the original paper/hard copy appears grainy and

illegible, so much so that it is difficult to clearly identify the location of the proposed operating room, let alone other necessary support space. UNC REX believes it was able to identify the location of the proposed two procedure rooms (in the top left corner of the line drawing). Given the sizing of the room located directly below what UNC REX believes to be the two procedure rooms, UNC REX believes that this space may be the proposed operating room; however, UNC REX's belief is an educated guess and cannot be confirmed given the poor quality of the line drawing. Similarly, it is impossible to determine whether or not Duke Health has included sufficient prep and recovery space. The instructions in Section K of the CON application require that an applicant "[p]rovide legible line drawings (no larger than 11" x 17") that identify all new construction in an Exhibit. The use of each room or space should be labeled." The Duke Garner ASC application fails to meet this requirement.

Moreover, given the poor quality of the line drawing, it is difficult to assess whether or not the proposed facility layout includes adequate space necessary to accommodate the storage of all of the equipment needed to support all of the surgical specialties proposed by Duke Health. As noted previously, the logistics involved with scheduling seven different surgical specialties for one operating room would be particularly difficult in consideration of the amount of equipment movement that would need to take to place in order to outfit the operating room with everything necessary to support each different surgical specialty. As such, the Duke Garner ASC application (the original paper/hard copy as well as the electronic copy) fails to demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative.

Notwithstanding the discussion above, as stated on page 137 of its application, Duke Garner ASC proposes to perform cystoscopy and YAG laser cases in its procedure rooms. Cystoscopy procedures require a unique type of table in order to perform the procedures safely and effectively. A YAG laser is a relatively expensive, larger piece of equipment that is difficult to move around, making it easier to dedicate one procedure room to these types of procedures. As mentioned previously, the equipment list provided in the Duke Garner ASC application appears to be for Duke Green Level ASC, but regardless, it does not contain the equipment needed to support the types of cases proposed to be performed in the procedure rooms. Further, Duke Garner ASC does not provide enough information to explain the rationale behind determining which cases are appropriate for an operating room and those that are appropriate for a procedure room.

Based on these issues, the Duke Garner ASC application fails to demonstrate that the project is needed, that the proposed project is the least costly or most effective alternative, or that that the cost, design, and means of construction proposed represent the most reasonable alternative. As such, **the Duke Garner ASC application should be found non-conforming with Criteria 1, 3, 4, 6, 12, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

In summary, Duke Health has failed to demonstrate that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183, that the project is needed, that the project is the most effective or least costly alternative, the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided, or that the cost, design, and means of construction proposed represent the most reasonable alternative, and the Duke Garner ASC application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 7, 8, 12, 18(a), as well as the performance standards at 10A NCAC 14C .2103. The Duke Garner ASC application should not be approved.

COMMENTS ON DUKE GREEN LEVEL AMBULATORY SURGICAL CENTER

General Comments

It must be noted at the outset that the utilization methodology included with the Duke Green Level ASC application is contrived and not based on the patients from the areas surrounding Duke Green Level ASC that have historically accessed Duke Health surgical services. Instead, as detailed below, Duke Green Level ASC projects its utilization based on unreasonable shifts of patients – patients that have historically accessed Duke Raleigh Hospital and Duke University Hospital – to the proposed ASF. Similar to Duke Garner ASC, a significant oversight in the utilization projections for Duke Green Level ASC is that Duke Health assumes ASF-appropriate patients will shift to Duke Green Level ASC in the future but the application fails to mention the origin of the patients proposed to utilize the proposed two operating rooms. Although Duke Health provides reasoning as to how it estimated the number of ASF-appropriate patients, by specialty, that would be appropriate to shift from Duke Raleigh Hospital and Duke University Hospital to Duke Green Level ASC, it provides no information as to whether or not the patients proposed to use the ASF will be able to conveniently access Duke Green Level ASC. In other words, Duke Green Level ASC does not take into account local demand in the community that it proposes to serve, and ignores the fact that patients of Duke Health's hospitals in Wake and Durham County originate from a broad geographic area that is not likely to be true for an ASC. Given these reasons and those detailed below, UNC REX believes that the Agency should deny the Duke Green Level ASC application.

Issue-Specific Comments

1. <u>The Duke Green Level ASC application fails to demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative.</u>

   The floor plan of the proposed ASF provided in Exhibit K.2, labeled "FPDC 4033 ASC SCHEMATIC FLOOR PLAN DUKE GREEN LEVEL ASC," is illegible. While the text on the line drawing identifies three operating rooms (two additional operating rooms) and five procedure rooms, the remainder of the space shown on the line drawing is unclear as the line drawing appears grainy and illegible.

   Based on this issue, the Duke Green Level ASC application fails to demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative. As such, **the Duke Green Level ASC application should be found non-conforming with Criterion 12**.

2. <u>The Duke Green Level ASC application projects an unreasonable shift of patients from Duke Raleigh Hospital and Duke University Hospital.</u>

   Page 133 of the Duke Green Level ASC application provides the projected shift of patients from Duke Raleigh Hospital and Duke University Hospital to Duke Health Green Level ASC, as shown below.

Duke Green Level ASC Projected OR Cases

Specialty	*FY 2025*	*FY 2026*	*FY 2027*
Case Shift from DUH	137	233	473
Case Shift from DRAH	1,596	2,069	2,944
Total	**1,733**	**2,301**	**3,417**

Source: Duke Green Level ASC application page 133.

As shown above, the Duke Green Level ASC application projects 473, or 14 percent, of its total cases to shift from Duke University Hospital. This is unreasonable considering the fact that Duke Green Level ASC is closer to Duke University Hospital than it is to Duke Raleigh Hospital. According to Google Maps, the Duke Green Level ASC site is 19.6 miles from Duke University Hospital and approximately 24 miles from Duke Raleigh Hospital. Similar to the Duke Garner ASC application, the Duke Green Level ASC application assumes that the proposed shifts will occur based purely on speculative, qualitative reasons including access to outpatient-based (non-HOPD pricing) ambulatory surgery, modern operating room size and layout in a new facility, and more timely access to ambulatory surgery. These reasons are not sufficient enough to assume that the projected number of cases by specialty will shift from Duke Raleigh Hospital and Duke University Hospital to Duke Green Level ASC, as the proposed shifts are not based on patients from the area that surrounds Duke Green Level ASC that have historically accessed Duke Health's facilities in Wake and Durham counties. In Section C of its application, Duke Health claims that patients from all over Wake County will travel to Durham County for surgery, but Duke Health fails to quantify the number of patients from the proposed service area with the types of surgery proposed to be performed at Duke Green Level ASC to or quantify patients for whom travel to the Green Level site would be more convenient than travel to Raleigh or Durham. Lastly, similar to Duke Garner ASC, it is unreasonable to assume that Duke Green Level ASC, a three-room freestanding ASF, will have the same regional draw as Duke Raleigh Hospital and Duke University Hospital. Duke Raleigh Hospital is 186-bed hospital that offers a comprehensive list of services, including cancer, orthopedic, cardiovascular, and neuroscience, and Duke University Hospital is a 924-bed, full-service tertiary and quaternary care hospital; thus, it is unlikely that Duke Green Level ASC will experience the same level of regional draw experienced by Duke Health's larger hospitals that offer a much wider and multifaceted array of healthcare services. Further, the Duke Green Level ASC application does not describe exactly from where it expects its patients to originate. As such, UNC REX believes that the proposed shifts to Duke Green Level ASC are unfounded and purely speculative.

Based on these issues, the Duke Green Level ASC application fails to demonstrate that the project is needed. As such, **the Duke Green Level ASC application should be found non-conforming with Criteria 1, 3, 4, 6, and 18(a), as well as the performance standards at 10A NCAC 14C .2103**.

In summary, Duke Health has failed to demonstrate that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183, that the project is needed, or that the project is the most effective or least costly alternative, and the Duke Green Level ASC application should be found non-conforming with Criteria 1, 3, 4, 6, 12, and 18(a), as well as the performance standards at 10A NCAC 14C .2103. The Duke Green Level ASC application should not be approved.

COMPARATIVE ANALYSIS

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

- Conformity with Review Criteria
- Geographic Accessibility
- Documentation of Physician Support
- Patient Access to Lower Cost Surgical Services
- Scope of Services/Patient Access to Surgical Specialties
- Access by Underserved Groups
- Projected Average Revenue per Case
- Projected Average Operating Expense per Case

Conformity with Applicable Statutory and Regulatory Review Criteria

As discussed in the application-specific comments above, the WakeMed Cary application, the Valleygate application, the Duke Garner ASC application, and the Duke Green Level ASC application are non-conforming with multiple statutory and regulatory review criteria. In contrast, the UNC REX applications are conforming with all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with statutory and regulatory review criteria, the UNC REX applications are the most effective alternatives.

Geographic Accessibility

Three of the six applications – UNC REX Hospital, WakeMed Cary, and Duke Green Level ASC – propose adding the operating rooms to an existing (or approved) facility. The other three applications – OSCG, Duke Garner ASC, and Valleygate – propose to develop the operating rooms at a new ASF. The location proposed in the Valleygate application is close to locations where surgical services are already available and/or approved. Notably, the proposed Valleygate Surgery Center site is less than eight miles from SCDP's existing dental-only ASF, which is also in close proximity to WakeMed Children's Hospital. Only the OSCG and Duke Garner ASC applications propose to develop operating rooms in areas of high growth without existing access to surgical facilities; specifically, both propose to expand geographic accessibility to the Garner area. The OSCG application presents data and analysis regarding the need for additional operating room capacity in the Garner area and its ability to meet that need. The Duke Garner ASC application, however, bases its utilization projections on unreasonable shift assumptions as previously discussed. Further, the Duke Garner ASC application is not conforming with statutory and regulatory review criteria. Therefore, with regard to geographic accessibility, the OSCG application is the most effective alternative.

Documentation of Physician Support

Documentation of support from surgeons for a proposed project to develop a new ASF should be considered an important factor in this review. As noted previously, three applications – OSCG, Duke Garner ASC, and

Valleygate – propose to develop operating rooms at a new ASF. While all three of these applications include surgeon support, as noted previously, neither Duke Garner ASC nor Valleygate contain adequate documentation of surgeon support necessary to develop their projects as proposed.

The Duke Garner ASC application proposes to develop a multispecialty ASF offering the following specialties: general surgery, ophthalmology, orthopaedics, urology, otolaryngology, gynecology, and plastic surgery. Notably, while the Duke Garner ASC application purports to develop a multispecialty ASF, only 14 of the 71 letters of support provided in the electronic copy submitted by Duke Health indicate support for the Duke Garner ASC application. Moreover, none of these 14 letters of support, which generally indicate support for both of Duke Health's applications, explicitly document the intent of a surgeon (or surgeons) to perform procedures at the proposed ASF, nor do they identify a type of surgical specialty to be performed at the proposed ASF. While Duke Health's original paper/hard copy of the Duke Garner ASC application does include letters of support specific to the Duke Garner ASC application, given the discrepancies between the original paper/hard copy and the required second application copy, UNC REX does not believe that the Agency should give credit to Duke Health for letters of support that appear in its original paper/hard copy, but not in its required second application copy.

The Valleygate Surgery Center application proposes to develop a multispecialty ASF offering the following specialties: oral, dental, otolaryngology, ophthalmology, and plastic surgery. Notably, while the Valleygate Surgery Center application purports to develop a multispecialty ASF, the application does not even include one single letter of support from an otolaryngologist and includes a letter from literally one single physician attempting to document support for both ophthalmology and plastic surgery.

The OSCG application proposes to develop an ASF with an orthopaedic focus. Notably, and as documented in Exhibit I.2 of the OSCG application, UNC REX provides ample support from orthopaedic surgeons.

Therefore, of the three applications that propose to develop a new ASF – OSCG, Duke Garner ASC, and Valleygate – the application submitted by OSCG is the most effective with respect to this comparative factor. The hospital applicants – UNC REX Hospital and WakeMed Cary – are equally effective with regard to physician support.

Patient Access to Lower Cost Surgical Services

As noted in the 2019 Wake County Operating Review (see Attachment 1), "*many, but not all outpatient surgical services can be appropriately performed either in a hospital licensed operating room (either shared inpatient/outpatient operating rooms or dedicated ambulatory surgery operating rooms) or in a non-hospital licensed operating room at an ambulatory surgery center; however, the cost for that same service will often be much higher in a hospital licensed operating room or, conversely, much less expensive if received in a non-hospital licensed operating room at an ASC.*" WakeMed Cary and UNC REX Hospital are existing hospitals that offer hospital licensed operating rooms. The remaining applicants would offer non-hospital licensed operating rooms. However, Valleygate, Duke Garner ASC, and Duke Green Level ASC are not conforming with statutory and regulatory review criteria. Therefore, they cannot be effective alternatives with regard to patient access to lower cost outpatient surgical services.

Scope of Services/Patient Access to Surgical Specialties

In general, ASFs, whether single specialty or multispecialty, provide access to a lower number of specialties than hospitals. This is especially true for hospitals like UNC REX Hospital, which provides

tertiary-level care to patients in Wake County. As noted in its application, "[a]s an existing acute care hospital, UNC REX Hospital currently provides inpatient surgical services in the following specialty areas: cardiothoracic, open heart surgery, general surgery, neurosurgery, obstetrics and Ob-Gyn, ophthalmology, oral surgery/dental, orthopaedics, otolaryngology, urology, and vascular. Like its existing operating rooms, the proposed operating room will also provide inpatient surgical services in the specialty areas noted above." As one of only two hospital applicants and the only tertiary surgical provider in this review, UNC REX believes that the UNC REX Hospital application is clearly the most effective alternative regarding access to surgical specialties.[29]

Relative to the proposed ASFs, the specialties proposed by each of the applicants are noted in the table below.

Proposed ASF	*Specialties Proposed in Application*
OSCG	Orthopaedics
Valleygate Surgery Center	Oral, dental*, otolaryngology, ophthalmology, and plastic surgery
Duke Garner ASC	General surgery, ophthalmology, orthopaedics, urology*, otolaryngology, gynecology, and plastic surgery
Duke Green Level ASC	General surgery, gynecology, ophthalmology, orthopaedics, otolaryngology, neurosurgery*, plastic surgery, podiatry*, urology*, and vascular*

*Not included in the list of specialties found in N.C. GEN. STAT. § 131E-176(15a).

Valleygate indicates that it proposes to develop a multispecialty ASF (see page 20 of the Valleygate Surgery Center application); however, as noted previously, Valleygate's project as proposed fails to show evidence of availability of resources, in this case, surgeon support, for the provision of the "multispecialty"[30] services Valleygate proposes to provide. Notably, while Valleygate claims that Valleygate Surgery Center will be a multispecialty ASF, the only physician support provided in the application is from pediatric dentists, oral surgeons, and one ophthalmologist (only two of the specialties noted in N.C. GEN. STAT. § 131E-176(15a)). There is no support provided by an otolaryngologist. Also of note, Dr. Vinod Jindal, M.D. is listed twice, once as an ophthalmologist and once as a plastic surgeon. As discussed in detail under the issue-specific comments, oculoplastics is not in the list of specialty areas found in N.C. GEN. STAT. § 131E-176(15a) and it is not the same as plastics. Despite overarching claims by Valleygate that it will offer multispecialty services, its application lacks evidence demonstrating that it will actually have otolaryngology, ophthalmology, and plastic surgeons practicing at Valleygate Surgery Center. Given the foregoing, Valleygate's alleged "multispecialty" services appear to be contrived merely to meet the definition of a "multispecialty ambulatory surgical program" under N.C. GEN. STAT. § 131E-176(15a) as there is no credible basis to support such proposed "multispecialty" services. As such, UNC REX does not believe the Agency should give credit to Valleygate for all the proposed specialties when comparing the number of surgical specialties offered among all competing applications. Valleygate's assertions are not credible.

[29] Of note, the other hospital applicant – WakeMed Cary – is not a tertiary surgical provider and it bears mention that not all of the specialties proposed by WakeMed are actually "specialties."

[30] A multispecialty ambulatory surgical program means "a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery." See N.C. GEN. STAT. § 131E-176(15a).

Duke Health indicates that it proposes to develop a multispecialty ASF in Garner (see page 17 of the Duke Garner ASC application); however, as noted previously, it is unreasonable to assume that all of the specialties proposed to be offered at Duke Garner ASC could reasonably be accommodated in the one operating room ASF. As such, UNC REX does not believe the Agency should give credit to Duke Garner ASC for all the proposed specialties when comparing the number of surgical specialties offered among all competing applications.

The two remaining ASF applications – OSCG and Duke Green Level ASC – propose to provide single specialty and multispecialty services, respectively. Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor. However, here, it is important to note that UNC REX demonstrated the need in its OSCG application to develop an orthopaedic focused ASF in Wake County in response to an unmet need in the county. Conversely, there are other ASFs in the county that can meet the specialty needs proposed by Duke Health in its Duke Green Level ASC. Further, each of the other ASF applications – Valleygate, Duke Garner ASC, and Duke Green Level ASC – are not conforming with statutory and regulatory review criteria. Moreover, among all the providers in the review, UNC REX Hospital provides the most diverse and comprehensive surgical specialties. Therefore, the UNC REX Hospital application is the most effective alternative with regard to providing Wake County patients with access to multiple surgical specialties.

Access by Underserved Groups

The following table shows each applicant's projected operating room cases to be provided to Self Pay/Indigent/Charity Care, Medicare, and Medicaid recipients in the third project year following completion of the project, based on the information provided in Section L.3(a) of each application. Consistent with previous Agency findings, the percentages below are based on operating room cases only.

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

Applicant	*Self Pay/ Indigent/Charity as % of Total*	*Medicare % of Total*	*Medicaid % of Total*
UNC REX Hospital	2.7%	44.7%	5.5%
WakeMed Cary	7.3%	47.9%	3.8%
OSCG	0.8%	20.3%	1.3%
Valleygate	4.1%	20.9%	55.0%
Duke Garner ASC	2.0%	44.0%	5.3%
Duke Green Level ASC	1.6%	47.2%	3.5%

Source: Each applicant's Section L.3(a)

As shown in the table above, comparing all applicants, WakeMed Cary projects the highest percentage of Self Pay/Indigent/Charity and the highest percentage of Medicare patients. Valleygate projects the highest percentage of Medicaid patients and UNC REX Hospital projects the highest percentage of Medicaid patients among the two hospital providers. However, as noted above, both the WakeMed Cary and Valleygate applications have errors that relate to utilization assumptions, and therefore are not appropriate for comparison.

Projected Average Revenue per Case

The following table shows the projected gross revenue per operating room case in the third year of operation based on the information provided in each applicant's pro forma financial statements (Form F.2). Consistent with previous Agency findings, the per case statistics below are based on operating room cases only.

Applicant	*Cases*	*Gross Revenue*	*Average Gross Revenue Per Case*
UNC REX Hospital	20,535	$667,675,625	$32,514
WakeMed Cary	8,802	$555,640,545	$63,127
OSCG	2,031	$59,373,774	$29,234
Valleygate	759	$19,464,119	$25,644
Duke Garner ASC	1,369	$11,496,759	$8,398
Duke Green Level ASC	3,417	$34,738,547	$10,166

Source: Each applicant's Forms C and F.2

As shown above, among all applicants, Duke Garner ASC, Duke Green Level ASC, and Valleygate project the three lowest average gross revenue per operating room case in the third project year. However, as noted in the application-specific comments above, Duke Garner ASC's, Duke Green Level ASC's, and Valleygate's projected utilization is unsupported and unreasonable, rendering their revenue per case unreasonable. Among the remaining applicants, OSCG and UNC REX Hospital project the next lowest gross revenue per case and are the most effective alternatives.

As noted above in the UNC REX Hospital application, adequate access to hospital-based operating rooms is an important consideration in this review. Between the two hospital-based applicants, UNC REX Hospital projects the lower gross revenue per case and is a more effective alternative.

The following table shows the projected net revenue per operating room case in the third year of operation based on the information provided in each applicant's pro forma financial statements (Form F.2). Consistent with previous Agency findings, the per case statistics below are based on operating room cases only.

Applicant	*Cases*	*Net Revenue*	*Average Net Revenue Per Case*
UNC REX Hospital	20,535	$228,089,338	$11,107
WakeMed Cary	8,802	$130,026,137	$14,772
OSCG	2,031	$11,638,953	$5,731
Valleygate	759	$5,149,933	$6,785
Duke Garner ASC	1,369	$5,479,201	$4,002
Duke Green Level ASC	3,417	$16,481,710	$4,823

Source: Each applicant's Forms C and F.2

As shown above, among all applicants, Duke Garner ASC and Duke Green Level ASC project the lowest average net revenue per operating room case. Among the remaining applicants, OSCG projects the lowest

average net revenue per operating room case, followed by Valleygate. Further, there are significant differences in the specialties proposed by each applicant, which also drives differences in revenue. As noted above, Duke Garner ASC's, Duke Green Level ASC's, and Valleygate's projected utilization is unsupported and unreasonable, rendering their revenue per case unreasonable.

Between the two hospital applicants, UNC REX Hospital projects lower net revenue per case and is therefore the most effective alternative with regard to net revenue per case.

Further, the WakeMed Cary, Valleygate, Duke Garner ASC, and Duke Green Level ASC applications are not conforming with all applicable statutory and regulatory review criteria. Therefore, the OSCG and UNC REX Hospital applications are the most effective alternatives with regard to patient revenue.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per case/procedure in the third year of operation for each of the applicants, based on the information provided in applicants' pro forma financial statements (Form F.3). Consistent with previous Agency findings, the per case expenses below include both operating room cases and procedure room procedures.

Operating Expenses per Case – Project Year 3

Applicant	*Cases*	*Operating Expenses*	*Average Operating Expense Per Case*
UNC REX Hospital	20,535	$192,639,806	$9,381
WakeMed Cary	8,802	$59,384,364	$6,747
OSCG	2,291	$8,673,441	$3,786
Valleygate	3,091	$4,346,151	$1,406
Duke Garner ASC	1,643	$4,797,803	$2,920
Duke Green Level ASC	4,934	$12,274,780	$2,488

Source: Form C Utilization and Form F.3.

As shown in the table above, Valleygate projects the lowest average operating expense per case in the third project year. However, not only does Valleygate's application contain unreasonable utilization projections, rendering its expenses per case unreliable, it also appears to have substantially understated its capital costs by not including sufficient costs for the equipment that would be required to offer all of the specialty services it proposes to provide. As such, by understating its capital costs, it has also understated its depreciation expense and therefore its operating expenses. While Duke Green Level ASC and Duke Garner ASC project the second and third lowest average operating expenses per case, both contain unreasonable utilization projections, rendering their expenses per case unreliable. Among the remaining applicants, OSCG projects the next lowest operating expenses per case and therefore is the most effective alternative with regard to operating expenses. Between the two hospital applicants, WakeMed Cary projects the lower operating expenses per case; however, its application contains unreasonable utilization projections and is not conforming with statutory and regulatory review criteria. Therefore, with regard to operating expenses, the UNC REX Hospital project is the most effective alternative among hospital applicants.

SUMMARY

In summary, among the six applications, none applied for all three operating rooms. As such, more than one applicant can be approved. UNC REX believes that some of the operating rooms should be approved for a hospital setting, where they can provide care to both inpatients and outpatients, as well as emergency patients, and provide access to more specialties and patients of all acuities. It is also important to expand access to lower cost surgical services in an ASF, which can (and should) also expand geographic access to residents of a large, growing and crowded county like Wake. To assess the most effective alternatives for these operating rooms, the following table summarizes the comparative analysis shown above.

Comparative Factor	*UNC REX Hospital*	*OSCG*	*WakeMed Cary*	*Valleygate Surgery Center*	*Duke Garner ASC*	*Duke Green Level ASC*
Conformity with Applicable Statutory and Regulatory Review Criteria	X	X				
Geographic Accessibility		X			X	
Patient Access to Lower Cost Surgical Services		X		X	X	X
Scope of Services	X		X			
Access by Underserved Groups			X	X		
Projected Average Revenue/Case	X	X				
Projected Average Operating Expense/Case	X	X				
Ability to Meet Complete Need Determination	X	X				

The bottom row indicates that because of the number of operating rooms proposed by the UNC REX applications (one at UNC REX Hospital and two at OSCG) and because both are conforming with all statutory and regulatory review criteria, both can be approved, and the entire need determination will be met. Please note that the table above does not imply that all of the applications are approvable; as noted above, the WakeMed Cary, Valleygate, Duke Garner ASC, and Duke Green Level ASC applications are non-conforming. However, even assuming that all the applications were conforming, the UNC REX applications are the most effective alternatives for the following reasons:

UNC Rex Hospital:

- Provides essential access to hospital-based surgery;
- Provides the greatest depth of services (tertiary facility);
- Between the hospital-based applications, projects the lowest gross and net revenue per case;
- With one proposed operating room, effectively complements other approvable applications.

OSCG:

- Expands geographic access to ASC services in Wake County;
- Has significant provider support for its proposed project;
- Provides access to low-cost surgical services;
- Projects the second highest percentage of care to self-pay/indigent/charity patients;
- Projects among the lowest revenue and expenses per case;

- With two proposed operating rooms, effectively complements other approvable applications.

In summary, UNC REX believes that its two complementary applications are clearly the most effective alternatives for three additional operating rooms needed in Wake County. They are also fully conforming to all applicable statutory and regulatory review criteria and comparatively superior on the relevant factors in this review. As such, the proposals by UNC REX Hospital and OSCG should be approved.