Competitive Comments Submitted by Southpoint Surgery Center, LLC Regarding the Certificate of Need Applications for the 2018 Operating Room Need Determination for Durham County

Two applications were submitted in response to the need determination in the 2018 State Medical Facilities Plan for four operating rooms:

J-11631-18 Duke University Hospital Develop Four Additional Operating Rooms

J-11626-18 Southpoint Surgery Center Develop a New ASC with Two Procedure Rooms and

Four Operating Rooms

The following comments are submitted in accordance with N.C. Gen. Stat. § 131E-185(a1) (1) and address the representations in the project applications, including a comparative analysis and discussion as to whether the applications comply with the Certificate of Need ("CON") review criteria. These comments submitted by Southpoint Surgery Center, LLC are not intended to include any additional information that would represent an amendment to its application.

Comparative Analysis

Demonstration of Need and Unnecessary Duplication

Southpoint Surgery Center, LLC (Southpoint) adequately demonstrates the need for the proposed freestanding ambulatory surgical facility with four operating rooms and two procedure rooms. Furthermore, Southpoint effectively demonstrates that its proposed ambulatory surgery center will not result in unnecessary duplication of existing or approved operating rooms in the service area. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference. The Southpoint application is the most effective proposal to fulfill the need determination for four operating rooms.

Duke University Hospital (DUH) proposes to add four operating rooms to the hospital's outpatient surgery department located at North Pavilion. However, DUH does not adequately demonstrate that the utilization projections for the operating rooms are based on reasonable assumptions. Total outpatient surgery case volumes at DUH have declined for each of the three previous years. Operating rooms at North Pavilion do not improve patient access to cost effective ambulatory surgery services as compared to the CON-approved Arrington Ambulatory Surgery Center. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

Conformity with All Applicable Criteria

Southpoint is conforming to all CON review criteria. In contrast, the DUH application fails to conform to multiple CON review criteria. Please see the criterion-specific comments regarding the DUH application for additional discussion.

Geographic Access

Southpoint proposes a new freestanding ASC in southern Durham in the Triangle Township that holds 35 percent of the Durham County population. Geographic access to the proposed facility in south Durham is supported by Highways 751 and Interstate 40, providing outstanding access. The proposed Southpoint location is supported by the participating physicians as demonstrated by the letters of support in Exhibit C.4(b). Therefore the Southpoint is an effective proposal to improve geographic access.

DUH proposes to add four hospital-licensed operating rooms to the existing nine operating rooms at North Pavilion, three blocks north of the main hospital operating rooms. All of the existing operating rooms in the service area are located in Durham Township. Consequently, the proposed location does not improve geographic access. The DUH application is not an effective proposal to improve geographic access.

New Alternative Provider

Southpoint provides a new alternative surgery provider that would enhance patient choice and support physician recruitment. Numerous physicians documented their intent to perform surgery at the proposed Southpoint facility. In contrast, the DUH application adds operating room capacity to an existing location. Physician support letters did not adequately demonstrate which surgeons would be willing to perform cases at North Pavilion. Consequently, the Southpoint application is the most effective proposal.

Increasing Patient Access to Cost Effective Ambulatory Surgical Services

The Southpoint proposal provides a freestanding ambulatory surgical facility that will improve patient access to cost-effective ambulatory surgery. In contrast, the DUH application adds operating room capacity to an existing hospital-licensed facility with high average charges for outpatient cases. Consequently, the Southpoint application is the most financially effective proposal.

Scope of Surgical Services

The Southpoint application documents the scope of surgical services for the proposed operating rooms: this includes General Surgery, Gynecology, Orthopedic, Orthopedic Spine, Ophthalmology, Otolaryngology, Oral Surgery, Plastic Surgery, Urology, Vascular Surgery, Pain Management, and Podiatry. The DUH application fails to adequately describe the scope of services at the proposed ORs in the North Pavilion. Furthermore, the current scope of services at the existing North Pavilion ORs (as documented in the Criterion 3 comments) is limited as compared to hospital-based ORs at the main campus as well as the existing ORs at Duke Regional and Davis Ambulatory Surgical Center. Therefore, the Southpoint application is the most effective proposal.

Access by Medically Underserved

Southpoint projects that its operating rooms will serve 48 percent Medicare ambulatory surgery patients based on 370 patients per OR in Year 3. DUH projects to serve 43.7 percent Medicare inpatients and 35.6 percent outpatients with 131 inpatient cases per OR and 105 outpatients per OR in Year 3. However, the DUH projected surgery cases are not based on reasonable assumptions. The discussions regarding analysis of need found in Criterion (3) are incorporated herein by reference. Southpoint projects to serve the higher numbers of Medicare patients per OR based on reasonable assumptions and thus is the most effective provider regarding Medicare access.

Southpoint projects that its operating rooms will serve four percent Medicaid ambulatory surgery patients based on 31 ambulatory surgery patients per OR in Year 3. DUH projects to serve 17.8 percent Medicare inpatients and 9.7 percent outpatients with 53 inpatient cases per OR and 29 outpatients per OR in Year 3. However, the DUH projected surgery cases are not based on reasonable assumptions. The discussions regarding analysis of need in Criterion (3) are incorporated herein by reference. Southpoint projects to serve the higher numbers of Medicaid patients per OR based on reasonable assumptions and thus is the most effective provider regarding Medicare access.

Physician Support

The Southpoint application includes numerous physician support letters documenting the individual physician's intent to obtain privileges at the proposed facility; most of the letters include projections of the range of surgery cases to be performed at the facility. Many letters of support are included in the DUH application. However, these generic letters fail to document the individual physician's intent to utilize the operating rooms at North Pavilion. Furthermore the DUH physician support letters omit volume projections. Therefore, the Southpoint application is comparatively superior because the physician support letters are more compelling.

Comparative Data

Applicant Ducinet ID #	I 11/2/ 19	I 011/21 10	
Applicant Project ID #	J-11626-18	J-011631-18	
	Southpoint Surgery Center, LLC	Duke University Health System, Inc.	
Facility Location	7810 NC Highway	Duke North Pavilion	
	Durham, NC 27713	2400 Pratt Sr. Durham, NC, 27705	
	(Triangle Township – South Durham)	3 Blocks North of Duke University Hospital	
		(Durham Township – Central Durham)	
New Provider Option	Yes	No	
	New Legal Entity and New Facility Location	Exiting Legal Entity and Facility Location	
Total Capital Cost	\$12,066,630	\$17,200,000	
Total ORs at Facility Location		9 Existing ORs plus 4 proposed ORs in	
	4 ORs in New Freestanding ASC	Duke Ambulatory Surgery Center	
		Outpatient Department of DUH	
Year 1 Date	01/01/2021	07/01/2021	
Current Surgical Specialties	N/A	Existing Duke North Pavilion ORs currently	
	General surgery, gynecology, orthopedic,	provide <u>outpatient</u> gynecology, orthopaedic,	
Proposed Surgical Specialties	orthopedic spine, ophthalmology,	oral surgery, and plastic surgery.	
	otolaryngology, oral surgery, plastic	Specialties for the new ORs are not	
	surgery, urology, vascular surgery, pain	adequately documented.	
	management, podiatry		
Methodology Description	Projected shift of cases from NCSH plus	CAGR projections with shift of cases to	
	volume increases with new surgeons	Arringdon, Green Level ASC and North	
		Pavilion	
	L	I .	

OR Utilization	Inpatient Outpatient	Inpatient Outpatient
YR 1	YR 1 0 3,929	YR 1 19,947 21,076
YR 2	YR 2 0 4,189	YR 2 20,246 20,628
YR 3	YR 3 0 4,273	YR 3 20,654 20,434
Procedure Room Utilization	Inpatient Outpatient	
YR 1	YR 1 0 2,962	
YR 2	YR 2 0 3,021	N/A
YR 3	YR 3 0 3,081	
Average Net Revenue per OR	Inpatient Outpatient	Inpatient Outpatient
YR 1	YR 1 N/A \$2,924	YR 1 \$33,050 \$8,922
YR 2	YR 2 N/A \$3,012	YR 2 \$33,451 \$9,035
YR 3	YR 3 N/A \$3,102	YR 3 \$33,847 \$9,147
Average Net Revenue per PR		
YR 1	YR 1 N/A \$1,014	N/A
YR 2	YR 2 N/A \$1,045	
YR 3	YR 3 N/A \$1.076	
	Medicare Inpatient Outpatient	Medicare Inpatient Outpatient
YR 3 Medicare %	YR 3 N/A 48%	YR 3 43.7% 35.6%
Medicare Cases per OR	Cases/OR N/A 370/ OR	Cases/OR 131 / OR 105 / OR
	Medicare Inpatient Outpatient	Medicaid Inpatient Outpatient
YR 3 Medicaid %	YR 3 N/A 4 %	YR 3 17.8 % 9.7%
Medicaid Cases per OR	Cases/OR N/A 31 / OR	Cases/OR 53 / OR 29 / OR
Documentation of Support	Numerous physician support letters, many	Numerous physician support letters but
Physicians Other Providers	include surgery case projections	lacking in volume projections

Comments Specific to Duke University Hospital (DUH) CON Project ID # E-11631-18

The DUH application is not conforming to the CON Review Criteria due to multiple deficiencies as follows:

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

DUH does not adequately demonstrate the need for the proposed project based on reasonable utilization projections. Therefore, the applicant fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2018 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3. The DUH application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

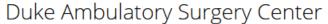
Criterion (3) "The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities,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

The DUH application fails to conform to Criterion 3 because the methodology and assumptions are unreasonable for multiple reasons:

- The North Pavilion location provides only outpatient surgery for a limited scope of surgical specialties, unlike the majority of ORs at the main DUH campus. Furthermore, the application fails to adequately describe what additional surgical specialties will be performed in the proposed additional operating rooms.
- Historical growth trends at DUH show that inpatient surgery is growing while outpatient surgery has decreased for the last three consecutive years. This decline in volume had already occurred prior to any new ambulatory surgery facilities being developed (such as Arringdon Surgery Center) to redirect outpatients. Therefore it is unreasonable to add operating room capacity at the North Pavilion which is an outpatient surgery location.
- Arringdon Surgery Center and the proposed Green Level ASC have the potential to shift more
 outpatient cases from DUH because these applications represent that the assumptions for these
 projects are conservative. Consequently DUH has less need for additional outpatient OR capacity.
- It is unreasonable for the applicant to state that there is genuine need for developing additional operating room capacity while simultaneously projecting that staffing levels are held constant; additional operating rooms and recovery areas require clinical staff in order to be safely utilized.
- Letters of support from Duke physicians lack volume estimates and have no commitments from the individual surgeons to perform cases at North Pavilion ORs.

DUH proposes to develop four additional operating rooms at the North Pavilion which is physically separate from the hospital's inpatient beds and emergency department. In fact, Duke North Pavilion is located three blocks north of Duke University Hospital and houses two Duke Health clinics that include

the Adult Blood and Marrow Transplant Center and the Duke Ambulatory Surgery Center. Operating rooms at this location served a limited scope of specialties as seen in the screenshot below of the Duke website.



Type: Duke University Hospital Outpatient Department, Surgery Center

*Hospital-based clinics are an extension of Duke Health hospitals and have additional facility charges. Some insurance companies process bills with a deductible and coinsurance rather than as a co-pay as for an office visit. This may impact the amount of the bill you are responsible for after payment from your insurance plan. Check with your insurance company before your visit to determine what your responsibility will be.

This innovative, state-of-the-art facility offers the latest surgical technology and anesthetic techniques, combined with warm, personalized care in an attractive, comfortable atmosphere designed to put patients at ease.

- Puke North Pavilion 2400 Pratt Street Durham, NC 27710
 - Get Directions
- Appointments 919-421-3981
 - Office **919-668-2000**
- Fax 919-613-5229

Services

Surgery services at this location include:

- > Ankle and foot treatments
- > Breast cancer surgery, including breast reconstruction
- > Hip replacement surgery
- > Endometriosis treatment
- Oral surgery
- > Wound management

Duke's methodology and assumptions for the proposed project are unreasonably based on projected future growth for outpatient surgery cases directed to North Pavilion and the expected shift of outpatient surgery cases to the Arringdon Surgery Center plus the proposed Green Level ASC. But North Pavilion does not offer patients lower charges and cost savings. Nor is the facility convenient because parking is only available in the parking garage adjacent to North Pavilion with a fee of \$2 per hour or a maximum \$8 per day. Given these choices, future surgery patients are least likely to select North Pavilion for outpatient surgery.

The pending addition of 90 acute care beds and the expected increase in days of care at DUH will have no direct impact on surgery utilization at North Pavilion because inpatient surgery cannot be performed in the outpatient facility. Physician recruitment plans for other Duke locations in Wake, Durham and Alamance Counties will not boost outpatient surgery referrals to North Pavilion because Duke proposes other less costly freestanding ambulatory surgery centers to shift outpatient surgery away from DUH.

According to the 2018 State Medical Faculties Plan, DUH is licensed for a total of 65 operating rooms including 6 inpatient ORs, 9 ambulatory operating rooms and 50 shared ORs. In contrast to what is reported in the DUH license renewal application, DUH advertises that it has 68 operating rooms as stated on the Duke Nursing website:



The above website represents the following OR inventory at DUH:

Duke Hospital	35 ORs
Duke Medicine Pavilion	18 ORs
Ambulatory Surgery Center	9 ORs
Eye Center	6 ORs
Total	68 ORs

Thus, DUH actually has more surgical capacity than what is reported in its CON application.

As seen in the following table from page 106 of the DUH application, inpatient surgery at Duke University Hospital (DUH includes North Pavilion ORs) has a 4-Year CAGR of 2.0% while outpatient has a meager 0.2% CAGR. However, DUH outpatient surgery only increased one year (FY2015).

Duke University Health System Historical OR Cases, FY2014-FY2018

		FY2014	FY2015	FY2016	FY2017	FY2018	4-YR CAGE
DASC	OP Cases	4,406	4,869	5,164	5,277	7,645	14.8%
	IP Cases	16,920	17,344	17,151	17,989	18,325	2.0%
	OP Cases	22,292	23,728	22,642	22,575	22,509	0.2%
DUH	Total Cases	39,212	41,072	39,793	40,564	40,834	1.0%
	IP Cases	3,697	3,865	3,765	4,539	4,153	3.0%
	OP Cases	2,899	2,995	2,981	3,352	3,992	8.3%
DRH	Total Cases	6,596	6,860	6,746	7,891	8,145	5.4%

Source: DUH, DRH, and DASC Annual License Renewal Applications, FY2018 based on DUHS Internal Data

Outpatient surgery cases at DUH are trending down from 23,728 cases in FY2015 to 22,509 cases in FY 2018 for a 3-YR CAGR of -1.74% percent. FY2015 is the only year where outpatient surgery increased over the previous year. One year of positive utilization in FY2015 does not adequately support a long term growth trend for the purposes of making future projections. The application fails to adequately explain the decline in outpatient surgery utilization even though DUH continues to recruit physicians and provide surgical care to a growing and aging population.

The physicians who intend to perform cases at North Pavilion are not clearly identified in the DUH application. DUH fails to identify the types of surgical specialties to be shifted to the North Pavilion ORs. Moreover, this application lacks the detailed OR case projections by surgical specialty that gave credibility to the projections in the Arringdon CON application Project ID # J-11508-18. The Arringdon Ambulatory Surgery Center is already projected to shift large percentages of outpatient cases for orthopedics, ophthalmology and gynecology specialties away from DUH. Since these three specialties represent more than 50 percent of the total outpatient cases at DUH, it is unclear what outpatient cases by specialty would be appropriate to be redirected to North Pavilion.

For these reasons, the DUH North Pavilion surgery case projections are not adequately supported.

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

DUH does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Hospitalicensed operating rooms are not the most cost-effective alternative as compared to operating rooms in a freestanding ambulatory surgical facility. The DUH application is not conforming to Criterion (4).

Criterion (5) "Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the

proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."

The DUH financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments.

Erroneous staffing projections in Form H cause the financial statement Form F.3 to be inaccurate and unreasonable. Projected salaries in Form H are inconsistent with Form F.3. These discrepancies are too large to be explained away as typographical errors as seen in the following table..

Section Q, DUH Application

DUH Operating Rooms	Form H	Form F.3
Total Salaries YR 1	\$275,553,455	\$290,498,648
Total Salaries YR 2	\$285,171,707	\$304,882,944
Total Salaries YR 3	\$198,484,862	\$320,578,706

The DUH staffing projections for the project are unreasonable because the Form C utilization projections show increases of thousands of annual surgical hours to justify the four proposed additional operating rooms. Yet the Total Full Time Equivalent (FTEs) that are assigned to the existing and proposed additional ORs shows no increases through the first three years following the completion of the project.

The following table shows the DUH projected annual surgical hours and calculates the numbers of FTEs that should be added assuming the FTEs increase in the same proportion as the annual hours:

DUH Operating Rooms	7/1/2017	Intervening Years	7/1/2021	7/1/2022	7/1/2023
	6/30/2018		6/30/2022	6/30/2023	6/30/2024
Form C Total Surgical Hours	132,405		135,969	136,746	138,128
Increase Over 6/30/2018 Annual Hours			3,564	4,341	5,723
% Increase Over 6/30/2018 Annual Hours			2.69%	3.28%	4.32%
Form H DUH OR FTEs	3406.72		3406.72	3406.72	3406.72
Calculation of FTEs Added Based on Surgical Hour	s % Increase				
Form H DUH Total ORs FTEs			3406.72	3406.72	3406.72
% Increase Over 6/30/1018 Annual Hours			2.69%	3.28%	4.32%
Additional FTEs Based on % Increases of Total Ann	nual Surgical H	Hours	91.70	111.69	147.25

The above table shows the incremental staff that would be needed for the higher annual surgical hours with 91.7 FTEs added in Year 1, 111.69 FTEs added in Year 2 and 147.25 FTEs added in Year 3. Without additional staff for the proposed operating rooms, DUH fails to demonstrate that an adequate staffing expense is budgeted.

DUH implausibly proposes to increase its operating room capacity by 6.15 percent (4 ORs / 65 ORs) with no increases in direct care staff, ancillary or support staff. The applicant unreasonably projects no additional RN staffing for the proposed four additional operating rooms at North Pavilion. In contrast, the Arringdon Ambulatory Surgery Center project ID # J-11508-18, shows that the four outpatient operating rooms would require 20.8 RN FTE positions in Year 1, 26.0 RN FTE positions in Year 2 and 30.0 RN FTEs in Year 3. The Arringdon RN staffing projections make sense because operating rooms at

a new location will require additional staffing resources. Furthermore, in a previous CON application Project ID # J-10144-13 to renovate and modernize the bed tower and eleven operating rooms (with no increase in licensed capacity), DUH projected substantial increases in FTEs including the essential RN staff.

Assuming that the FTEs staffing levels for CON-approved Arringdon Ambulatory Surgery Center Project ID # J-11508-18 are based on reasonable assumptions for four ORs, the following table shows the amount of just the RN salaries that have been omitted from the DUH North Pavilion proposal to also develop four additional operating rooms:

	FTEs for 4 ORs	Projected Salaries	Omitted Salaries for RNs
	Arringdon #J-11508-18	DUH #J-1163118	DUH #J-1163118
YR 1 RN Salaries	20.0	\$98,842	\$1,976,840
YR 2 RN Salaries	26.0	\$102,301	\$2,659,826
YR 3 RN Salaries	30.0	\$103,881	\$3,116,430

As seen in the above table, the RN salary expense that has been omitted for the four proposed operating rooms at North Pavilion exceeds \$3,000,000 in Year 3. Taxes and benefits for these positions are also omitted from Form F.3. Consequently the projected expenses for the application are unreasonable. In summary, the DUH operational and financial projections are unreliable causing the application to not conform the Criterion 5.

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

DUH fails to demonstrate that its proposal will not result in unnecessary duplication of operating rooms because the utilization projections are unreliable. Additional ORs at North Pavilion are unnecessary because no staff will be added to support their utilization.

The following table shows the current OR planning inventory including Arringdon Surgery Center, CON Project ID No. E-11508-18 for the relocation of four operating rooms from Davis Ambulatory Surgery Center.

	Adjusted Planning Inventory
James E. Davis Ambulatory Surgical	8
Center	(-4 Pending)
Arringdon Ambulatory Surgery Center	+4 Pending
Duke University Hospital	64
Duke Regional Hospital	13
Combined Duke Health System	77
North Carolina Specialty Hospital	4

Duke Health System currently owns and controls 95.5 percent of the operating room inventory in Durham County. The proposal to add ORs at North Pavilion would increase the Health System's dominance and result in higher patient charges. This facility location that is less accessible as compared to both Davis Ambulatory Surgical Center and the CON-approved Arringdon Surgery Center. Furthermore the application is based on unreasonable utilization projections and is not conforming to Criterion (6).

Criterion (7) "The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided."

DUH's projected staffing and salaries that are unreasonable because the amounts included in Form H are inconsistent with Form F.3 as seen in the following table.

Section Q, DUH Application

DUH Operating Rooms	Form H	Form F.3
Total Salaries YR 1	\$275,553,455	\$290,498,648
Total Salaries YR 2	\$285,171,707	\$304,882,944
Total Salaries YR 3	\$198,484,862	\$320,578,706

The DUH application is not conforming to Criterion (7) because the Form H staffing projections unreasonably include the 3,406.72 total FTEs for the operating rooms in the current year 7/01/2018 with no increases for the total FTEs for Years 1, 2 and 3 even with the proposed four additional operating rooms.

The staffing projections for the project are unreasonable because the Form C utilization predicts increases of thousands of annual surgical hours to justify the four proposed additional operating rooms. Yet the Total Full Time Equivalent (FTEs) that are assigned to the existing and proposed additional ORs shows no increases through the first three years following the completion of the project. The following table shows the DUH projected annual surgical hours and calculates the numbers of FTEs that should be added assuming the FTEs are increased at the same percentages as the annual surgical hours:

DUH Operating Rooms	7/1/2017	Intervening Years	7/1/2021	7/1/2022	7/1/2023
	6/30/2018		6/30/2022	6/30/2023	6/30/2024
Form C Total Surgical Hours	132,405		135,969	136,746	138,128
Increase Over 6/30/2018 Annual Hours			3,564	4,341	5,723
% Increase Over 6/30/2018 Annual Hours			2.69%	3.28%	4.32%
Form H DUH OR FTEs	3406.72		3406.72	3406.72	3406.72
Calculation of FTEs Added Based on Surgical Ho	ours % Increa	ase			
Form H DUH Total ORs FTEs			3406.72	3406.72	3406.72
% Increase Over 6/30/1018 Annual Hours			2.69%	3.28%	4.32%
Additional FTEs Based on % Increases of Total	Annual Surgi	cal Hours	91.70	111.69	147.25

The above table shows the incremental staff that would be needed for the higher annual surgical hours with 91.7 added FTEs required in Year 1, 111.69 FTEs required in Year 2 and 147.25 FTEs required in Year 3. Without additional staff for the proposed operating rooms, DUH fails to demonstrate adequate evidence of available resources, including healthcare manpower.

The addition of four ORs to the existing nine ORs at North Pavilion represents a <u>44.4 percent increase</u> in capacity for this location. The application fails to demonstrate that the OR staff assigned to the North Pavilion will be adequate to staff the additional ORs. DUH's assumption that no additional staff will be needed at the proposed North Pavilion is incorrect because the applicant represents that more patients will be directed to this location, surgical hours will increase, and additional OR spaces and PACU expansion will be constructed.

Proposing to increase OR capacity with no additional staff is unsound. As stated in the application, surgery cases at DUH already take longer to perform than all surgical providers in North Carolina. Therefore, it is unreasonable for the applicant to add OR capacity at the outpatient surgery department to accommodate more long duration surgery cases without additional staffing resources. It is alarming that the applicant projects that <u>no additional RNs</u> will be needed to provide care in the pre-operative area, additional operating rooms, and the post-operative recovery for North Pavilion project. No documentation is provided that existing RN positions can be reassigned to the proposed North Pavilion operating rooms.

In the Arringdon Ambulatory Surgery Center Project ID # J-11508-18, the application shows that four outpatient operating rooms would require 20.8 RN FTE positions in Year 1, 26.0 RN FTE positions in Year 2 and 30.0 RN FTEs in Year 3. Assuming that the FTEs staffing level for CON-approved Arringdon Ambulatory Surgery Center Project ID # J-11508-18 are reasonable, the following table shows the amount of RN salaries that are omitted from the DUH North Pavilion proposed four additional operating rooms:

	FTEs for 4 ORs	Projected Salaries	Omitted Salaries for RNs
	Arringdon #J-11508-18	DUH #J-1163118	DUH #J-1163118
YR 1 RN Salaries	20.0	\$98,842	\$1,976,840
YR 2 RN Salaries	26.0	\$102,301	\$2,659,826
YR 3 RN Salaries	30.0	\$103,881	\$3,116,430

The table above only reflects the omitted RN positions and salaries from the proposed project. With no projected increases in FTEs, the staffing projections for the proposed ORs at DUH North Pavilion also omit the FTEs and salaries for Surgical Technicians, Central Sterile Supply Technicians, and Nursing Assistants. These necessary positions were included in the roster of additional surgical staff that would be essential to support Arringdon Ambulatory Surgery Center Project ID # J-11508-18. Furthermore DUH Project ID # J-10144-13 for hospital renovation and expansion included sizable FTE increases and salaries for surgery staff including RNs, Technicians, Central Sterile Supply Technicians, and Aides/Orderlies, based on the DUH assumption that "variable FTEs will increase with the increase in procedure volume in surgical services."

Unreasonable staffing projections and the omission of salary expenses cause the DUH application to be non-conforming to Criterion (7).

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

Developing additional ORs at North Pavilion fails to benefit patients because the facility location does not enhance access, the outpatient surgery charges are exceedingly high and this proposal lacks adequate staffing to ensure quality care. The DUH application also fails to conform to Criterion (18a) because the proposal does not adequately demonstrate that it will promote cost-effective services. The applicant's projected utilization is not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

10A NCAC 14C .2103 PERFORMANCE STANDARDS

The DUH application is not conforming to 10A NCAC 14C. 2103 Performance Standards (a), (b) and (e) because the applicant's projected utilization is not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.