North Carolina Specialty Hospital's Comments Regarding
Arringdon Ambulatory Surgery Center CON Project ID No. E-11508-18

Associated Health Services. Inc. and Duke University Health System, Inc. have filed a Certificate of Need (CON) application with the North Carolina Department of Health and Human Services to develop Arringdon Ambulatory Surgery Center (AASC) with the proposed relocation of four existing operating rooms from Davis Ambulatory Surgery Center (DASC). The application fails to conform to CON review criteria. Some of the major deficiencies include:

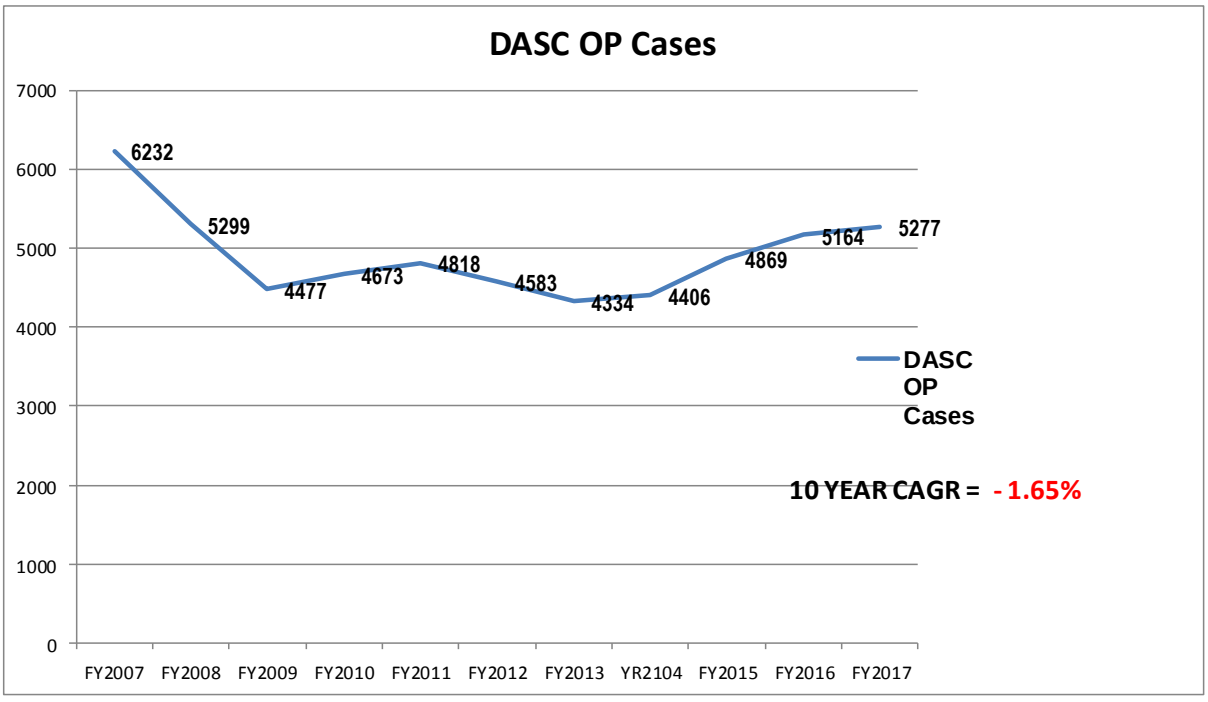
- The proposed relocation of four operating rooms reduces patient and physician access for six specialties that are currently provided at DASC including neurosurgery, otolaryngology, plastic surgery, urology, vascular surgery and oral surgery.
- Currently, 37.4% of the patients served at DASC are from Durham County. The proposed relocated ORs at AASC would decrease access for Durham residents to 27.7% by FY2023.
- The proposed relocation of operating rooms to Arringdon will substantially decrease Medicare patient access from 45.7% at DASC to 36.3% at AASC.
- The AASC utilization projections are overstated and unreliable because the applicants used inflated growth factors that far exceed the 5-Year Compound Annual Growth Rate (CAGR) and 10-Year CAGR for the DASC operating rooms.
- The DASC five year historical data shows that orthopedic and gynecology surgery have not achieved 5 percent CAGR which is what the applicant assumes will be the future growth.
- The DASC five year historical data shows that the only surgical specialty that has experienced significant numerical growth is ophthalmology, which does not require overly large operating rooms.
- The existing DASC has far more advanced surgical lasers used in ophthalmology and gynecology surgeries as compared to the equipment proposed for AASC; this makes it unlikely that the projected shift of these specialty cases will occur.
- The proposed project is not an effective alternative to address the OR capacity issues at Duke University Hospital because the hospital can submit a CON application to add AC-3 ORs to its facility at any time.
- The proposed project represents unnecessary duplication of healthcare services because it is based on overstated utilization projections and limited access to fewer surgical specialties.

- Revenue and expense projections are not reliable due to the erroneous utilization projections, omission of building rent and incomplete and erroneous payor mix representations

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), North Carolina Specialty Hospital provides comments and documentation regarding how the AASC application does not conform to multiple CON criteria as follows:

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 AASC application erroneously projects 5 percent annual growth in future utilization for Davis Ambulatory Surgery Center when in fact the 10-Year CAGR is negative (– 1.65%) and the 5-Year CAGR is only 2.86 percent.



The following table provides the operating room utilization data and the resulting five year CAGR for the DUHS facilities.

		FY2012	FY2013	YR2104	FY2015	FY2016	FY2017	**5 YR CAGR**
DASC	OP Cases	4,583	4,334	4,406	4,869	5,164	5,277	**2.86%**
DUH	IP Cases	16,966	16,308	16,920	17,344	17,151	17,989	**1.18%**
	OP Cases	21,368	22,131	22,292	23,728	22,642	22,575	**1.11%**
	Total Cases	38,334	38,439	39,212	41,072	39,793	40,564	**1.14%**
DRH	IP Cases	3,647	3,346	3,697	3,865	3,765	4,539	**4.48%**
	OP Cases	3,229	3,173	2,899	2,995	2,981	3,352	**0.75%**
	Total Cases	6,876	6,519	6,596	6,860	6,746	7,891	**2.79%**
DRAH	IP Cases	3,830	3,844	3,586	3,616	4,389	4,094	**1.34%**
	OP Cases	12,159	10,394	9,132	9,875	10,855	11,084	**-1.83%**
	Total Cases	15,989	14,238	12,718	13,491	15,244	15,178	**-1.04%**
DUHS Total	IP Cases	24,443	23,498	24,203	24,825	25,305	26,622	**1.72%**
	OP Cases	41,339	40,032	38,729	41,467	41,642	42,288	**0.45%**
	Total Cases	65,782	63,530	62,932	66,292	66,947	68,910	**0.93%**

For the five year period through 2023, the AASC application uses 5 percent projected growth rates for outpatient cases at DASC, DRH and DRAH that far exceed the **actual 5-Year 0.45% CAGR that is demonstrated above for the DUHS OP Cases.**

Duke University Health System
Inpatient & Outpatient Surgery
Projected Annual Growth Rates, FY2018-FY2023

Projected Growth Rates, OR Cases		
DASC	OP	5.0%
DUH	IP	2.1%
	OP	0.4%
DRH	IP	3.5%
	OP	5.0%
DRAH	IP	2.3%
	OP	5.0%

Based on these overstated growth projections, the projected volumes of cases that are expected to shift are not reasonable. Additional reasons why the growth projections are unreasonable include:

- The application fails to acknowledge that increased competition from existing and approved ambulatory surgery centers and existing competing hospitals will likely stifle future growth for outpatient surgery at DASC, DRH and DRAH.
- The physician support letters included in Exhibit 14 do not include volume projections for OR cases and procedure room cases.
- The application unreasonably projects to perform approximately 20 percent more OR cases on a per physician basis for GYN, Ophthalmology and Orthopedics as compared to the actual utilization that has occurred at DASC.
- Historically, the percentages for GYN, Ophthalmology and Orthopedics at DASC and the other DUHS facilities have changed over time. On page 137 of the application, the methodology fails to demonstrate that it is reasonable to assume that the outpatient surgery cases percentages for GYN, Ophthalmology and Orthopedics (before the shift to Arringdon) will remain the same for FY2021, FY 2022 and FY 2023.
- The application wrongly assumes that it can reasonably predict the percentages and numbers of outpatient surgery cases that will shift to AASC because patients will continue to have the option to choose non-Duke facilities in Durham and Wake Counties.
- Erroneous and overstated utilization projections are also reflected in the patient origin percentages on pages 20 and 21 where the percentage of patients from Durham County declines from 29.5% in Year 1 to 27.7% in Year 3.

The AASC patient origin projections are unreasonable because the application predicts that the percentage of Durham patients that will utilize the new ASC after the four ORs are relocated will decrease. Page 19 of the application documents that 37.4% of DASC patients are currently from Durham County. Page 21 shows that Durham patients will have less access based on the patient origin projections:

Arringdon ASC

Projected Patient Origin, FY2021-2022

	% of Total by County		
	FY2021	FY2022	FY2023
Durham	29.80%	28.90%	27.70%

The application fails to adequately identify the population to be served. The Arrington CON application should be denied because the proposed relocation of operating rooms would reduce

the percentages of patients from Durham County and the proposed facility proposes fewer surgical specialties as compared to the DASC.

The Davis Ambulatory Surgery Center website (www.dukehealth.org/locations/davis-ambulatory-surgical-center) indicates that "the center provides high quality and convenient outpatient surgery for patients in Durham and surrounding communities." Some of the existing advanced equipment that is listed on the DASC website is outlined below:

- Femtosecond Lasers for cataract surgery and ORA – optiwave refractive analysis provides real time intraoperative measurements for refractive cataract surgery
- Laparoscopic video equipment
- Lasers for vascular, pain management, and gynecology procedures

The Arringdon application and equipment list in Exhibit 10 fail to adequately describe the types of advanced surgical equipment that would be provided at the proposed new facility. The absence of a femtosecond laser, laparoscopic video equipment and the laser for gynecology procedures would likely reduce the volumes and types of cases shifted from DASC in future years.

Criterion (3a) *In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.*

The application is nonconforming to Criterion 3a because it fails to demonstrate that the project to relocate four ORs will meet the needs of medically underserved patients at DASC. The proposed project includes a 50 percent reduction in the number of ORs that will be available at DASC for the physicians and patients to obtain neurosurgery, otolaryngology, plastic surgery, urology, vascular surgery and oral surgery. Currently, 37.4% of the patients served at DASC are from Durham County. The proposed relocated ORs at AASC will substantially decrease patient access for Durham residents to 27.7% by FY2023. The proposed relocation of operating rooms to Arringdon will substantially decrease access for Medicare patients from 45.7% at DASC to 36.3% at AASC. Utilization projections for the proposed project are based on

unreasonable assumptions regarding future growth in outpatient surgery as discussed in the Criterion 3 comments.

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

The proposed project is not an effective alternative and is nonconforming to Criterion 4 based on unreasonable utilization projections. The proposed AASC intends to offer fewer surgical specialties as compared to the ORs at DASC. It also appears that DASC offers greater access to advanced surgical equipment (femtosecond laser, laparoscopic video, laser for gynecology surgery) as compared to the AASC. The proposed location is very close to the county line in southeastern Durham County which decreases access for Durham residents, including low income persons who live in central Durham County..

Page 19 of the AASC application documents that **37.4 percent of the DASC patients are currently from Durham County**. Page 21 shows that Arrington will decrease the percentages of Durham patients:

Arringdon ASC

Projected Patient Origin, FY2021-2022

	% of Total by County		
	FY2021	FY2022	FY2023
Durham	29.80%	28.90%	27.70%

Instead of relocating the ORs, maintaining the status quo with these operating rooms will enable a higher percentage of patients from the Durham County service area to obtain access to more surgical specialties.

The application fails to adequately explain why the projected “shift” of up to 50% of the total outpatient orthopedic cases from DUH to the proposed AASC is reasonable. It is unrealistic for such high percentages of orthopedic subspecialty cases, such as Pediatrics, Oncology and Spine, to shift to the proposed AASC because DUH has more advanced surgical equipment and greater depth of resources. These include computer guided systems for surgery, intraoperative

MRI and CT. These advanced capabilities, combined with the clinical expertise of the surgeons, are likely why many outpatient surgery patients from distant counties and other states choose treatment at DUH. Absent these advanced surgical technologies at AASC, the utilization projections are not credible. While the application claims that Duke University Hospital has OR capacity constraints, the academic medical center has the option to submit a CON application to add ORs in accordance with Policy AC-3.

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 and charges for providing health services by the person proposing the service.*

Critical problems with the financial projections cause the AASC application to be nonconforming to Criterion 5 as follows:

- Contrary to the historical five year 0.45% CAGR for the DUHS combined OP cases, the application unreasonably predicts 5% growth for the future five years.
- The application makes inconsistent statements regarding the lease of space for the ASC. The financing letter in Exhibit 13 discusses the building lease but no rent is included in the financial proforma statement.
- The AASC Financial Forms F.4 and F.5 omit the payor categories of Charity Care, Workers Compensation and TRICARE, which is inconsistent with the CON Form that has been issued by the Agency.
- The AASC financial assumptions are unreliable because the revenue assumptions omit Charity Care, Workers Compensation and TRICARE and the deduction assumptions include no Charity Care assumption that shows the mathematical calculation and assumptions for the Charity line item amounts in Form F.3.

The Davis Ambulatory Surgery Center website (www.dukehealth.org/locations/davis-ambulatory-surgical-center) documents that the existing facility accepts TRICARE. However the AASC project application omits TRICARE.

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.*

The proposed project will result in unnecessary duplication of existing health services and the application is nonconforming to Criterion 6 due to the unreasonable utilization projections as discussed in the Criterion 3 comments. The application is flawed due to overstated growth projections and the unsupported shift of cases from existing DUHS facilities. According to the 2018 SMFP, Duke Regional Hospital (DRH) currently has a surplus of operating room capacity. It is unreasonable for the applicants to predict a shift cases from DRH because it has surplus OR capacity combined with minimal outpatient growth growth (0.75% 5 Yr CAGR).

Criterion (13) *The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:*

> ***(c)*** *That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services.*

The application does not conform to Criterion 13c because the proposed relocation of operating rooms to Arringdon will substantially decrease access for Medicare patients from 45.7% at DASC to 36.3% at AASC.

Davis Ambulatory Surgical Center
Last Full FY before Submission of Application
(07 / 01 / 2016 to 06 / 30 / 2017)

Payor Source	Entire Facility or Campus	Operating Rooms	Procedure Rooms	GI Endo Rooms
Self-Pay	%	0.8%	0.2%	%
Charity Care	%	%	%	%
Medicare *	%	45.7%	51.7%	%
Medicaid *	%	3.5%	4.2%	%
Insurance *	%	47.5%	39.6%	%
Workers Compensation	%	%	%	%
TRICARE	%	%	%	%
Other (workers comp, other government)	%	2.5%	4.2%	%
Total	100.0%	100.0%	100.0%	100.0%

* Including any managed care plans.

Arringdon ASC

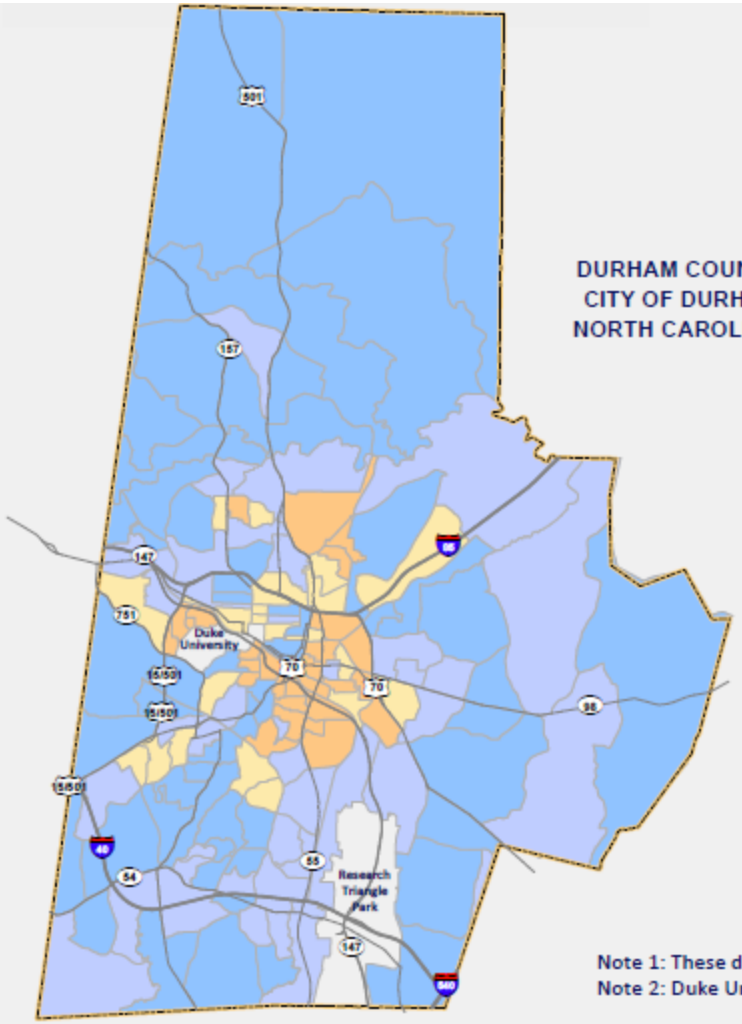
Payor Source	Entire Facility or Campus	Operating Rooms	Procedure Rooms	GI Endo Rooms
Self-Pay	%	1.3%	0.2%	%
Charity Care	%	%	%	%
Medicare *	%	36.3%	51.7%	%
Medicaid *	%	5.1%	4.2%	%
Insurance *	%	52.3%	39.6%	%
Workers Compensation	%	%	%	%
TRICARE	%	%	%	%
Other (workers comp & other government)	%	5.0%	4.2%	%
Total	100.0%	100.0%	100.0%	100.0%

* Including any managed care plans

Another concern is that the proposed project includes no commitment to provide access for Charity Care and TRICARE patients. In contrast, the DASC website states that the existing facility accepts TRICARE patients.

The proposed AASC location on the southeast border of Durham and Wake County decreases access for low income persons because the ORs will be more distant from the low income census tracts that are in central Durham County. The Arringdon location is in close proximity to the high income census tracts in Durham County as well as adjoining Wake County. The proposed site is just north of the town of Morrisville. According to the US Census Bureau, Morrisville has a median household income of more than $92,769 as compared to the overall Durham County median household income of $54,093. It is also reasonable to expect that the higher income population in southeastern Durham County includes more persons with commercial insurance and managed care.

The map on the following page was obtained from the City of Durham (https://durhamnc.gov/386/Demographics) and shows the low income areas of Durham County.. The maps on the page after are copied from the AASC project application, page 49.



Median Household Income

	2010	2011	2012	2013	2014	2015
DURHAM COUNTY	$47,401	$46,231	$51,094	$52,488	$50,504	$53,495
CITY OF DURHAM	$45,525	$43,654	$49,332	$50,522	$48,731	$52,106
NORTH CAROLINA	$43,326	$43,916	$45,150	$45,906	$46,556	$47,830

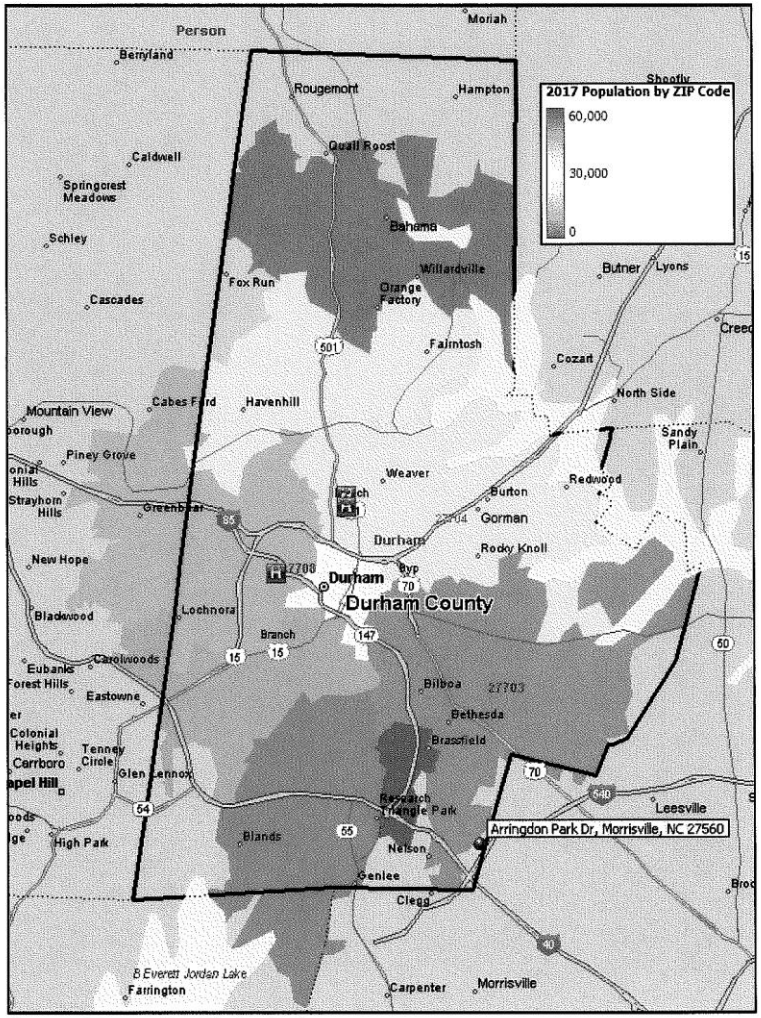
Greater than 120% of median household income for Durham County

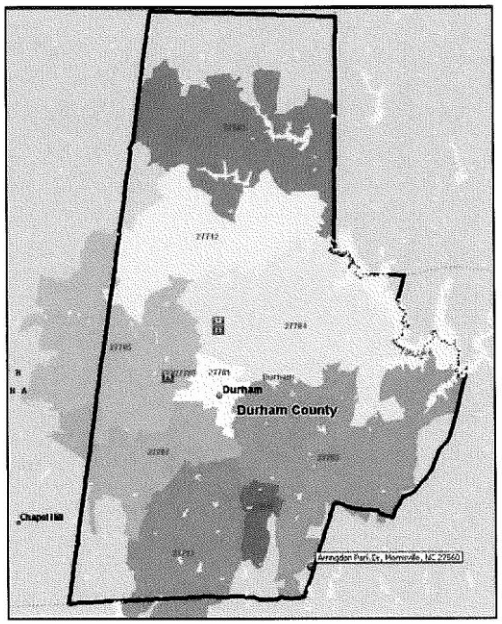
80% to 120% of median household income for Durham County

60% to 80% of median household income for Durham County

Less than 60% of median household income for Durham County

Note 1: These data are from the U.S. Census Bureau, American Community Survey (ACS).
Note 2: Duke University and Research Triangle Park excluded not included.





Roads removed from above map for ease of viewing zip code locations

Source: Truven Health Analytics

Note: The areas within Durham County that are not shaded include a zip code from an adjacent county that crosses the Durham County line but is assigned to the adjacent county.

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.*

The AASC applicants do not adequately demonstrate that any enhanced competition includes a positive impact on the cost effectiveness and access to the proposed services based on the information in the application and the following analysis:

- The applicants do not adequately demonstrate the need the population proposed to be served has for a separately licensed ASF located near the southeastern Durham County / Wake County line. See Criterion 3 for discussion.
- The applicants do not adequately demonstrate that the proposal is financially feasible. See Criterion 5 for discussion.
- The applicants do not adequately demonstrate that moving the ORs from near the center of the county, where more low-income and underserved groups reside, to the southeast Durham / Wake County border, where fewer low-income and underserved groups reside, will not negatively impact access by low-income and medically underserved groups. See Criterion 13c.

Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100

The .2103 PERFORMANCE STANDARDS are applicable to this review. The application is not conforming with all applicable criteria and standards.

- The applicants propose to establish a new freestanding ASF by relocating four operating rooms from DASC. However, the applicants do not adequately demonstrate the need for the four ORs in the proposed AASC because the projected utilization is not based on reasonable and adequately supported assumptions.
- On pages 22 to 62 and in Section Q, the applicants provide a description of the assumptions and methodology used in the development of the projections. However, projected utilization is not based on reasonable and adequately supported assumptions and data. See Criterion 3 for discussion.