

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2018

Findings Date: September 27, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11508-18

Facility: Arrington Ambulatory Surgical Center

FID #: 180213

County: Durham

Applicants: Associated Health Services, Inc.

Duke University Health System, Inc.

Project: Relocate four surgical operating rooms from James E. Davis Ambulatory Surgery Center to develop a new ambulatory surgical center in southern Durham County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (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.

C

The applicants, Associated Health Services, Inc. (AHS) and Duke University Health System, Inc. (DUHS), propose to relocate four surgical operating rooms (ORs) from James E. Davis Ambulatory Surgery Center in northern Durham County to develop a new ambulatory surgical center (ASC) in southern Durham County to be known as Arrington Ambulatory Surgical Center. The new facility will also have four procedure rooms.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2018 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2018 SMFP applicable to this review. **Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities** on page 33 of the 2018 SMFP states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.

The capital expenditure for the proposed project is greater than \$5 million. In Section B.4, page 13, the applicants state, *“The new physical spaces in which the proposed new ASC will be located will be renovated to ensure energy efficiency and cost-effective utilities, including water conservation.”* In Section K.4(c), page 100 and Exhibit V, the applicants provide additional information about their plans for energy efficiency and water conservation. The applicants adequately demonstrate that the application includes a written statement to assure improved energy efficiency and water conservation for the proposed facility. On page 100 and in Exhibit V, the applicants state the energy efficiency and water conservation plan will include:

- low-flow toilets throughout the facility (page 100);
- closely monitored utility usage (page 100);

- boilers and air-cooled chillers will be energy efficient (Exhibit V);
- rooftop air handling units will economize capabilities and reduce cooling loads (Exhibit V); and
- light fixtures will have LED lights and will be controlled by occupancy sensors (Exhibit V).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion, subject to Condition (10) of Criterion (4), and for the following reasons:

- The applicants do not propose the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2018 SMFP.
- The applicants adequately demonstrate that the application is consistent with all applicable policies in the 2018 SMFP.

(2) Repealed effective July 1, 1987.

(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.

C

The applicants propose to relocate four surgical operating rooms from James E. Davis Ambulatory Surgery Center in northern Durham County to develop a new ASC in the southern Durham County. The proposed new ASC, Arrington Ambulatory Surgical Center, will also have four procedure rooms. The proposed new ASC will be located on the same site as Duke Health Arrington, a medical office complex located at 5601 Arrington Park Drive, in Morrisville.

In Section C.1, page 16, the applicants state the proposed ASC will be located in a new medical office building with Duke Primary Care (PDC) utilizing a “*sizable portion*” of the building to house physicians and other ambulatory services. Additional space will be leased to other

specialty practices to “*add incremental specialty services and improve continuity of care to patients*”.

Patient Origin

On page 57, the 2018 SMFP defines the service area for ORs as, “... *the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*” In Figure 6.1, page 62 of the 2018 SMFP, Durham County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

In Section C.2, pages 18-19, the applicants provide historical patient origin for Duke University Health System (DUHS) outpatient surgical cases and the percentage of total surgical cases for fiscal year (FY) 2017 for James E. Davis Ambulatory Surgical Center (DASC), Duke University Hospital (DUH), Duke Regional Hospital (DRH) and Duke Raleigh Hospital (DRAH). In Section C.2, pages 20-21, the applicants provide the projected patient origin for the first three operating years (OY) FY2021 through FY2023 for the proposed ASC, as shown in the tables below.

Historical Patient Origin Duke University Health System FY2017										
County	# of Cases	% of Cases	# of Cases	% of Cases						
	DASC		DUH		DRH		DRAH		DUHS Totals	
Durham	1,972	37.4%	5,438	24.1%	1,316	39.3%	449	4.1%	9,175	21.7%
Wake	675	12.8%	3,786	16.8%	427	12.7%	6,470	58.4%	11,358	26.9%
Orange	1,010	19.1%	1,426	6.3%	249	7.4%	131	1.2%	2,816	6.7%
Alamance	244	4.6%	813	3.6%	126	3.8%	69	0.6%	1,252	3.0%
Person	193	3.7%	754	3.3%	240	7.2%	28	0.3%	1,215	2.9%
Granville	206	3.9%	685	3.0%	183	5.5%	106	1.0%	1,180	2.8%
Cumberland	24	0.5%	544	2.4%	39	1.2%	230	2.1%	837	2.0%
Guilford	58	1.1%	425	1.9%	33	1.0%	45	0.4%	561	1.3%
Vance	56	1.1%	347	1.5%	68	2.0%	94	0.8%	565	1.3%
Johnston	36	0.7%	295	1.3%	27	0.8%	517	4.7%	875	2.1%
Franklin	35	0.7%	229	1.0%	40	1.2%	448	4.0%	752	1.8%
Chatham	175	3.3%	214	0.9%	24	0.7%	69	0.6%	482	1.1%
Harnett	6	0.1%	188	0.8%	19	0.6%	201	1.8%	414	1.0%
Nash	23	0.4%	249	1.1%	14	0.4%	200	1.8%	486	1.1%
Other States	211	4.0%	2,462	10.9%	197	5.9%	315	2.8%	3,185	7.5%
Other NC* Counties	353	6.7%	4,720	20.9%	350	10.4%	1,712	15.4%	7,135	16.9%
Total	5,277	100.0%	22,575	100.0%	3,352	100.0%	11,084	100.0%	42,288	100.0%

*Includes less than one percent of patients from each of the remaining counties in North Carolina

Arrington ASC - Surgical Cases Projected Patient Origin FY2021-FY2023						
	FY2021 OY1		FY2022 OY2		FY2023 OY3	
County	# of Cases	% of Cases	# of Cases	% of Cases	# of Cases	% of Cases
Durham	825	29.8%	1,092	28.9%	1,380	27.7%
Wake	454	16.6%	665	17.7%	972	19.5%
Orange	352	12.4%	454	11.7%	564	11.1%
Alamance	109	4.0%	145	3.9%	183	3.7%
Person	92	3.4%	124	3.3%	158	3.2%
Granville	93	3.4%	125	3.3%	159	3.2%
Cumberland	37	1.4%	53	1.5%	73	1.5%
Guilford	38	1.4%	52	1.4%	67	1.4%
Vance	34	1.3%	47	1.3%	62	1.3%
Johnston	31	1.1%	46	1.2%	69	1.4%
Franklin	27	1.0%	40	1.1%	60	1.2%
Chatham	60	2.1%	77	2.0%	97	1.9%
Harnett	14	0.5%	21	0.6%	31	0.6%
Nash	21	0.8%	31	0.8%	43	0.9%
Other States	188	7.1%	259	7.2%	337	7.1%
Other NC* Counties	359	13.7%	506	14.1%	680	13.4%
Total	2,733	100.0%	3,737	100.0%	4,936	100.0%

On page 21, the applicants state that projected patient origin for the proposed ASC is based on the weighted average historical ambulatory surgery patient origin for DUHS facilities that are projected to shift cases to the new facility. In Section Q, and Exhibit 12, the applicants provide their assumptions and methodology used to project patient origin. The applicants’ assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 22-47, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services. The applicants provide a list of the reasons they believe supports the need for the proposed project, as summarized below:

The growing number of ambulatory surgery cases in North Carolina - In Section C.4, page 24, the applicants report that ambulatory surgery accounts for 72% of all surgical utilization in North Carolina.

Growing ambulatory surgery volumes at DUHS facilities - In Section C.4, page 25, the applicants state that DUHS has four facilities which provide surgical services. Of those facilities, 88 operating rooms are located in Durham County and 15 are located in Wake County. On page 26, the applicants provide a table of outpatient (OP) and inpatient (IP) surgical cases by facility for FY2014 through FY2017 and the compound annual growth rate (CAGR) over that period of time, as illustrated below.

Facility	Surgical Cases	FY2014	FY2015	FY2016	FY2017	3 Year CAGR
DASC Total Cases	OP Cases	4,406	4,869	5,164	5,277	6.2%
	IP Cases	16,920	17,344	17,151	17,989	2.1%
	OP Cases	22,292	23,728	22,642	22,575	0.4%
DUH Total Cases		39,212	41,072	39,793	40,564	1.1%
	IP Cases	3,697	3,865	3,765	4,539	7.1%
	OP Cases	2,899	2,995	2,981	3,352	5.0%
DRH Total Cases		6,596	6,860	6,746	7,891	6.2%
	IP Cases	3,586	3,616	4,389	4,094	4.5%
	OP Cases	9,132	9,875	10,855	11,084	6.7%
DRAH Total Cases		12,718	13,491	15,244	15,178	6.1%
	IP Cases	24,203	24,825	25,305	26,622	3.2%
	OP Cases	38,729	41,467	41,642	42,288	3.0%
DUHS Total Cases		62,932	66,292	66,947	68,910	3.1%

Overall outpatient surgical cases at DUHS increased by a CAGR of 3 percent from FY2014-FY2017. According to Table B, page 73 of the 2018 SMFP, DASC is projected to have a surplus of 3.63 ORs in 2020. On page 27, the applicants state that DASC is, “*impacted by the size and the design*” of the facility. DASC opened in 1986 with the average size of its operating rooms being 300 square feet. However, in the three plus decades since DASC opened, there have been advances in surgical techniques and equipment which have influenced the need to increase the average size of ORs to between 500 and 600 square feet. The applicants further state on page 27, that DASC has experienced growth in its surgical volume attributed to cases being redirected from DUH in an effort to “*decompress*” capacity restraints at DUH. The applicants state this is not a long term solution given the physical restraints of DASC.

DUHS initiatives to improve regional ambulatory access - In Section C.4, page 27, the applicants state that all the existing ORs in Durham County are located in or near the acute care hospitals in central or northern Durham County. The proposed application would relocate four existing ORs to the southern part of Durham County. The applicants state on page 28 that the proposed relocation of the ORs is consistent with the shift to provide ambulatory care in centralized settings to expand access to regional and community care. On page 29, the applicants state that south Durham (city) and southern Durham County host more than half of the county’s total population. The applicants further state that the population in this area is growing at a comparatively faster rate than the overall county population. In Section C.4, page 30, the applicants provide a table which summarizes the projected population growth for Durham County, by ZIP Codes from 2017 - 2022, as illustrated below.

ZIP Code	Area	2017 Population	Projected 2022 Population	% Growth
27503	Bahama	3,651	3,846	5.3%
27701	Downtown Durham	25,925	27,315	5.4%
27704	Durham	39,670	42,834	8.0%
27705	Durham	46,613	50,397	8.1%
27708	Durham	3,667	3,782	3.1%
27712	North Durham	22,088	23,440	6.1%
Central & North Durham Subtotal		141,614	151,614	7.1%
27703	South Durham	52,397	57,197	9.2%
27709	South Durham	411	454	10.5%
27707	South Durham/Southpoint	49,509	52,802	6.7%
27713	South Durham/Southpoint	54,418	59,282	8.9%
South Durham Subtotal		156,735	169,735	8.3%
Durham County ZIP Code Total		298,349	321,349	7.7%

Source: Truven Health Analytics

As illustrated above, the six ZIP Codes that comprise Central and North Durham are projected to have a 7.1 percent population increase by 2022. The four ZIP Codes that comprise South Durham are projected to have an 8.3 percent population increase by 2022. On page 30, the applicants state that the proposed Arrington ASC is part of DUHS Ambulatory Growth Plan which aims to expand ambulatory care sites across the local community and ensure convenient access for patients throughout Durham County and surrounding counties. In Section C.4, pages 30-31, the applicants state that Arrington ASC will be designed to serve more than 30,000 patients per year in a lower cost setting. The applicants state they believe the proposed project will achieve the following:

- *enhance geographic access to ambulatory services;*
- *provide access to the communities DUHS serves;*
- *align primary and specialty care services;*
- *continue to ensure access and services to Durham County and increase lives touched across the local community;*
- *maximize existing DUHS capacity; and*
- *consolidate and co-locate complementary DUHS and non-DUHS services.*

On pages 31-32, the applicants state that DUHS will relocate the following facilities: Duke Primary Care (DPC) Morrisville Urgent Care located on Chapel Hill Road, Duke Department of Orthopaedics and Duke Eye Doctor, both of which are located on Page Road in Durham and Duke Fertility Center located on Fayetteville Street in Durham to the proposed new MOB.

Physician recruitment plans - In Section C.4, pages 31-32, the applicants state DPC currently has 45 physicians and advanced practice providers with a plan to recruit three incremental providers for a total of 48 physicians and advanced practice providers. With regard to the relocation of the Duke Eye Care Center, the applicants state that 15 physicians will relocate to the proposed facility with a plan to recruit seven additional incremental providers for a total of 22 physicians. Duke Fertility Center will relocate its clinic along with four physicians. The applicants further state on page 32 that, “*these physicians intend to shift a portion of their ambulatory surgery case volume to Arrington ASC.*” On page 32, the applicants state that in

addition to the existing specialty clinics. DPC will recruit, “12 incremental physicians in Women’s Health (2 MDs), Plastics (2 MDs), Urology (2 MDs, 1 APP), General Surgery (2 MDs, 1 APP), and Spine (2 MDs). The applicants provide 35 physician letters of support in Exhibit 14.

Enhanced access to lower cost surgical services - In Section C.4, page 42, the applicants state that, “ASCs offer valuable surgical and procedural services at a lower cost when compared to hospital charges for the same services.” On page 42, the applicants further state that the use of ASCs is a cost effective alternative because they are specialized and function on a much smaller scale thereby saving the patient, government and third party payors money.

Projected population growth in the service area - In Section C.4, pages 43-44, the applicants state that according to the North Carolina Office of State Budget & Management, Durham County is projected to grow by a CAGR of 1.5 percent during the next five years, 2018-2023. The applicants provide a table on page 44, which illustrates the projected population growth of Durham County by age cohort, as shown below.

Durham County Projected Population Growth by Age Cohort

Age Cohort	2018		2023		5-Year CAGR
	Population	CAGR	Population	CAGR	
<18	73,458	23.6%	79,657	23.8%	1.6%
18-24	35,116	11.3%	37,686	11.3%	1.4%
25-44	91,100	29.3%	92,699	27.7%	0.3%
45-64	72,302	23.3%	76,131	22.8%	1.0%
65+	38,871	12.5%	47,988	14.4%	4.3%
Total	310,847	100.0%	334,161	100.0%	1.5%

On pages 44-45, the applicants state that the young adult population ages 18-44 comprises over 40% of the total population of Durham County. The applicants state that this age group is more likely to suffer injuries related to sports. Additionally, the applicants note the aging of the Baby Boomer population, the prevalence of cataracts in adults 40+, as well as the 65+ age cohorts as further evidence of the need for the proposed ASC.

On page 46, the applicants state that in FY2017, 72% of the ambulatory surgery patient origin for DASC, DUH and DRH combined, came from outside Durham County. The applicants state that historically, those patients have come from Alamance, Granville, Orange, Person and Wake counties. On page 46, the applicants provide the projected population growth for those counties and North Carolina, as a whole, as illustrated below.

Projected Population Growth 2018-2023

County	2018	2019	2020	2021	2022	2023	5-Year CAGR
Alamance	163,041	165,294	167,588	169,883	172,176	174,469	1.4%
Granville	60,566	61,152	61,739	62,327	62,917	63,504	1.0%
Orange	143,873	145,383	146,889	148,394	149,896	151,396	1.0%
Person	39,997	40,125	40,248	40,365	40,476	40,585	0.3%
Wake	1,071,240	1,093,987	1,116,912	1,139,953	1,163,066	1,186,223	2.1%
North Carolina	10,388,837	10,504,294	10,619,432	10,734,343	10,849,092	10,963,754	1.1%

On page 46, the applicants state that the population growth in surrounding counties where DUHS patients reside is further evidence for the proposed ASC.

The information is reasonable and adequately supported for the following reasons:

- The applicants use publicly available data to document the projected increase in population in its service area.
- The applicants demonstrate the need for increased geographical access to surgical services in southern Durham County.
- The applicants use the methodology in the 2018 SMFP combined with their own historical data to project future utilization of their ORs.

Projected Utilization

In Section Q, page 127 and page 131, the applicants provide historical and projected utilization for its ORs in Durham and Wake counties, as illustrated in the following tables.

DUHS Historical OR Cases

Facility	Surgical Cases	FY2014	FY2015	FY2016	FY2017	3 Year CAGR
DASC Total Cases	OP Cases	4,406	4,869	5,164	5,277	6.2%
	IP Cases	16,920	17,344	17,151	17,989	2.1%
	OP Cases	22,292	23,728	22,642	22,575	0.4%
DUH Total Cases		39,212	41,072	39,793	40,564	1.1%
	IP Cases	3,697	3,865	3,765	4,539	7.1%
	OP Cases	2,899	2,995	2,981	3,352	5.0%
DRH Total Cases		6,596	6,860	6,746	7,891	6.2%
	IP Cases	3,586	3,616	4,389	4,094	4.5%
	OP Cases	9,132	9,875	10,855	11,084	6.7%
DRAH Total Cases		12,718	13,491	15,244	15,178	6.1%
	IP Cases	24,203	24,825	25,305	26,622	3.2%
	OP Cases	38,729	41,467	41,642	42,288	3.0%
DUHS Total Cases		62,932	66,292	66,947	68,910	3.1%

DUHS Projected OR Cases

Facility	Surgical Cases	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023	Projected 5 Year CAGR
DASC Total Cases	OP Cases	5,541	5,818	6,109	6,414	6,735	7,072	5.0%
	IP Cases	18,360	18,739	19,126	19,520	19,923	20,334	2.1%
	OP Cases	22,670	22,766	22,862	22,958	23,055	23,152	0.4%
DUH Total Cases		41,030	41,505	41,988	42,478	42,978	43,486	1.2%
	IP Cases	4,700	4,866	5,038	5,217	5,401	5,592	3.5%
	OP Cases	3,520	3,696	3,880	4,074	4,278	4,492	5.0%
DRH Total Cases		8,220	8,562	8,918	9,291	9,679	10,084	4.2%
	IP Cases	4,186	4,281	4,378	4,476	4,577	4,681	2.3%
	OP Cases	11,638	12,220	12,831	13,473	14,146	14,854	5.0%
DRAH Total Cases		15,824	16,501	17,209	17,949	18,724	19,534	6.1%
	IP Cases	27,246	27,886	28,541	29,213	29,901	30,607	3.2%
	OP Cases	43,369	44,500	45,682	46,919	48,214	49,569	3.0%
DUHS Total Cases		70,615	72,386	74,223	76,132	78,116	80,176	3.1%

In Section Q, pages 126-143, the applicants provide the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Review Historical DUHS OR Cases

The applicants identify the four facilities in Durham and Wake counties that have a combined total of 103 (88 ORs in Durham County and 15 ORs in Wake County) ORs by category, as illustrated below.

**Duke University Health System
 Licensed Facilities with Surgical Operating Rooms**

Facility	# Of Inpatient ORs (excludes dedicated C-Section ORs)	# Of Dedicated C-Section ORs	# Of Shared ORs	# Of Dedicated Ambulatory ORs	Total # Of ORs
Durham County					
DASC	0	0	0	8	8
DUH	7*	0	49	9	65
DRH	0	2	13	0	15
Wake County					
DRAH	0	0	15	0	15

*Including Dedicated Open Heart Surgery

Source: 2018 Licensure Renewal Applications for DUH and DRH, (Section 9.a) and DASC, (page 7).

DUH has 16 AC-3 licensed approved ORs (see Project I.D. # J-8030-07)

The applicants provide a table on page 127, which illustrates the historical FY2014-FY2017 OR utilization for inpatient and outpatient cases. The applicants state that DUHS outpatient cases from FY2014-FY2017 increased by a CAGR of 3.0%. The applicants also state that DUHS inpatient cases increased by a CAGR of 3.2% during the same timeframe.

Step 2: Determine Projected Surgical Case Growth Rates (IP/OP) by DUHS Facility

The applicants provide a table page 128, which illustrates the three year CAGR for inpatient and outpatient cases from FY2014-FY2017 for DASC, DUH, DRH, DRAH and the total for DUHS, as shown below.

**Duke University Health System
 Inpatient & Outpatient Surgery
 FY2014-FY2017 Compound Annual Growth Rate**

		3 Year CAGR
DASC	OP Cases	6.2%
	IP Cases	2.1%
	OP Cases	0.4%
DUH	Total Cases	1.1%
	IP Cases	7.1%
	OP Cases	5.0%
DRH	Total Cases	6.2%
	IP Cases	4.5%
	OP Cases	6.7%
DRAH	Total Cases	6.1%
	IP Cases	3.2%
	OP Cases	3.0%
DUHS	Total Cases	3.1%

The applicants state that to accommodate outpatient surgery demand at DUH in recent years, the facility shifted cases to DASC and DRH, therefore the three year CAGR of 0.4% for DUH is not a reflection of decreasing demand. The applicants further state with regard to DASC, the facility is, “*impacted by the size and design of the facility.*” On page 129, the applicants provide the growth rate for inpatient and outpatient surgery cases for each DUHS facility, as shown below.

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

DASC	OP Cases	5.0%
	IP Cases	2.1%
	OP Cases	0.4%
DUH	Total Cases	1.2%
	IP Cases	3.5%
	OP Cases	5.0%
DRH	Total Cases	4.2%
	IP Cases	2.3%
	OP Cases	5.0%
DRAH	Total Cases	4.3%
	IP Cases	2.4%
	OP Cases	2.7%
DUHS	Total Cases	2.6%

On page 129, the applicants state the basis for the growth rates above are based on the following: historical growth in DUHS surgical cases, supported by, a growing and aging population in the service area, planned physician recruitment and surgical statistical data.

The applicants further state on page 129, that where the historical CAGR for outpatient cases exceeds 5%, the applicants only applied a 5% growth rate. For inpatient cases where the historical CAGR exceeds 4%, the applicants only applied one-half of the three year CAGR. For all other inpatient and outpatient cases, the applicants applied the respective three year CAGR, as illustrated below.

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

Projected Growth Rates			DUHS Growth Rate Assumptions
DASC	OP Cases	5.0%	3 year CAGR capped at 5%
	IP Cases	2.1%	3 Year CAGR
DUH	OP Cases	0.4%	3 Year CAGR
	IP Cases	3.5%	½ 3 Year CAGR
DRH	OP Cases	5.0%	3 year CAGR capped at 5%
	IP Cases	2.3%	½ 3 Year CAGR
DRAH	OP Cases	5.0%	3 year CAGR capped at 5%

Step 3: Projected DUHS OR Cases (IP/OP) by Facility (BEFORE Shift of Arrington Cases)

The applicants provide a table on page 131 with the projected surgical cases for DUHS from FY2018-FY2023. The applicants use a CAGR of 2.4% for inpatient cases and 2.7% for outpatient cases.

Step 4: Identify Historical OR Cases Appropriate for ASC (all specialties)

On page 132, the applicants state the following criteria was used to identify cases that would be appropriate for the proposed ASC:

- Outpatient surgical cases only;
- Adult patients (18 and older);
- Approved by Medicare for reimbursement in ASC-setting;
- Patients who are graded as American Society of Anesthesiologists (ASA) physical status 1 and II; and
- 50% of patients graded as ASA III.

The applicants provide a table on page 132, which outlines that FY2017 OR cases that were appropriate for an ASC. The applicants state that over half the outpatient cases at DUH would have been appropriate candidates for an ASC. The applicants state that 80.65% of the cases performed at DRH and 63.1% of those performed at DRAH were appropriate for an ASC. DUHS states that 100% of those cases performed at DASC were appropriate for an ASC. The applicants provide a table on page 133, which outlines the number of outpatient cases in FY2017 that were appropriate for an ASC.

Step 5: Projected OR cases Appropriate for Freestanding ASC (all specialties)

On page 134, the applicants provide a table that illustrates the percent of outpatient cases, by facility, which would be appropriate for a freestanding ASC, as shown below for FY2018 through FY2023.

**Duke University Health System
 Projected OR Cases Appropriate for ASC**

	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023
DASC	5,541	5,818	6,109	6,414	6,735	7,072
DUH	13,063	13,118	13,174	13,229	13,285	13,341
DRH	2,832	2,973	3,122	3,278	3,442	3,614
DRAH	7,348	7,715	8,101	8,506	8,931	9,378
Total	28,784	29,624	30,506	31,427	32,393	33,405

Step 6: Identify Percentage of GYN + Eye + Ortho Cases by Facility

In Section C, pages 22-24, the applicants state the proposed ASC will provide services for orthopaedics, ophthalmology, and gynecology. On pages 33-42, the applicants state that historically orthopaedic surgery makes up 19%, ophthalmic surgery makes up 27%, and gynecology surgery makes up 9% of all DUHS outpatient surgical cases in Durham County. (See tables on pages 37, 40, and 42).

On page 134, the applicants state DUHS anticipates the inclusion of other surgical specialties consistent with their physicians recruitment efforts. However, for the purposes of the proposed application, the applicants will focus on orthopaedics, ophthalmology and gynecology.

On page 135, the applicants provide a table which illustrates FY2017 combined percentage of outpatient cases for orthopaedics, ophthalmology and gynecology at DUHS facilities, as shown below.

**Duke University Health System
 of Gynecology + Ophthalmology + Orthopaedics
 Cases by Facility FY2017**

	Ortho + Eye + Gyn OP Cases	% of total FY2017 OP cases
DASC	4,092	77.5%
DUH	11,387	50.4%
DRH	1,721	51.3%
DRAH	6,679	60.3%
DUHS Total Combined OP Cases	23,879	

Step 7: Potential OP Cases to Shift to New Arrington ASC Based on Specialty

On page 135, the applicants project the potential number of outpatient cases to shift to the proposed Arrington facility based on the historical percentage of cases by specialty for each DUHS facilities, as illustrated below.

Duke University Health System
Potential OP Cases Available to Shift to New Arrington ASC Based on Specialty OR Cases
Appropriate for ASC

	FY2021	FY2022	FY2023
Shift from DASC	4,974	5,223	5,484
Shift from DUH	6,673	6,701	6,729
Shift from DRH	1,683	1,767	1,856
Shift from DRAH	5,126	5,382	5,651
Total	18,456	19,073	19,720

Step 8: Percentage Shift to New Arrington ASC ORs

On page 136, the applicants project that a portion of those patients who historically had ambulatory surgery at DASC, DUH, DRH and DRAH will opt to have future procedures performed at the proposed ASC. The applicants state that a shift in utilization is reasonable based on the following factors:

- surgical privileges for physicians whose clinic will be relocated to the proposed facility;
- privileges for other DUHS surgeons;
- efforts to decompress capacity constraints in existing DUH ORs;
- reduced travel for patients;
- access to outpatient based ambulatory surgery services;
- improved OR size and layout in proposed new facility;
- more timely access to ambulatory surgery scheduling; and
- convenient location for the growing county population.

On page 137, the applicants provide a table which summarizes the percentage of cases projected to shift to the proposed facility, by specialty, as illustrated below.

**Duke University Health System
 Projected OP Cases by Facility, Specialty & Projected Shifts**

Adult, Medicare Approved, ASA Appropriate for ASC Gynecology, Ophthalmology & Orthopaedics Cases					Step 8		
DASC OP Surgery Cases Before Shift					% Shift to Arrington		
Specialty	% of Total	FY2021	FY2022	FY2023	FY2021	FY2022	FY2023
GYN	6.4%	412	433	454	40.0%	50.0%	60.0%
Ophthalmology	54.2%	3,476	3,650	3,833	15.0%	20.0%	25.0%
Orthopedics	16.9%	1,085	1,140	1,197	70.0%	75.0%	80.0%
Subtotal	77.5%	4,973	5,223	5,484			
All Other	22.5%	1,440	1,512	1,588	0.0%	0.0%	0.0%
Total	100.0%	6,413	6,735	7,072			
DUH OP Surgery Cases Before Shift							
GYN	7.5%	992	996	1,000	10.0%	15.0%	20.0%
Ophthalmology	24.3%	3,221	3,235	3,248	10.0%	15.0%	20.0%
Orthopedics	18.6%	2,459	2,470	2,480	30.0%	40.0%	50.0%
Subtotal	50.6%	6,673	6,701	6,729			
All Other	49.6%	6,556	6,584	6,612	0.0%	0.0%	0.0%
Total	100.0%	13,229	13,285	13,341			
DRH OP Surgery Cases Before Shift							
GYN	25.3%	829	871	914	0.0%	2.5%	5.0%
Ophthalmology	2.3%	76	80	84	0.0%	2.5%	5.0%
Orthopedics	23.7%	778	816	857	0.0%	2.5%	5.0%
Subtotal	51.3%	1,683	1,767	1,855			
All Other	48.7%	1,595	1,675	1,759	0.0%	0.0%	0.0%
Total	100.0%	3,278	3,442	3,614			
DRAH OP Surgery Cases Before Shift							
GYN	3.9%	332	349	366	2.5%	5.0%	10.0%
Ophthalmology	27.1%	2,306	2,421	2,542	2.5%	5.0%	10.0%
Orthopedics	29.2%	2,487	2,612	2,742	2.5%	5.0%	10.0%
Subtotal	60.3%	5,125	5,382	5,650			
All Other	39.7%	3,380	3,550	3,727	0.0%	0.0%	0.0%
Total	100.0%	8,505	8,932	9,377			

The applicants state on page 138, that 100 percent of the cases at DASC are appropriate for an ASC as compared to 80.5 percent of the ambulatory cases performed at DRH. The applicants state that DASC and DRH are adjacent to one another in northern Durham city. Patients with higher acuity are directed to DRH and those patients with lower acuity are directed to DASC.

Step 9: Projected OP cases at New Arrington ASC (based on shift from source facility)

On page 139-141, the applicants provide tables which summarizes the projected shift of surgical cases from each DUHS facilities, by specialty, to Arrington ASC. The table shown below summarizes those tables.

**Arrington ASC
 Projected Surgical Cases FY2021-FY2023**

Cases Shifted from DASC			
Specialty	FY2021	FY2022	FY2023
GYN	165	216	273
Ophthalmology	521	730	958
Orthopedics	760	855	957
Total	1,446	1,801	2,188
Cases Shifted from DUH			
GYN	99	149	200
Ophthalmology	322	485	650
Orthopedics	738	988	1,240
Total	1,159	1,622	2,090
Cases Shifted from DRH			
GYN	0	22	46
Ophthalmology	0	2	4
Orthopedics	0	20	43
Total	0	44	93
Cases Shifted from DRAH			
GYN	8	17	37
Ophthalmology	58	121	254
Orthopedics	62	131	274
Total	128	269	565
Total Cases To be Shifted All Sites by Specialty			
GYN	272	405	555
Ophthalmology	901	1,338	1,866
Orthopedics	1,560	1,994	2,515
Total	2,733	3,737	4,936

Source: Application pages 139 and 141

Step 10: Identify Remaining Surgical Cases at Existing DUHS Facilities

On page 142, the applicants provide a table that illustrates the number of surgical cases projected to remain at each of the DUHS facilities following a shift of outpatient surgical cases to the proposed facility, as shown below.

**Duke University Health System
 Projected OR Cases
 After Shift of Cases to Arrington ASC**

Facility	Surgical Cases	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023
DASC Total Cases	OP Cases	5,541	5,818	6,109	4,968	4,934	4,884
	IP Cases	18,360	18,739	19,126	19,520	19,923	20,334
	OP Cases	22,670	22,766	22,862	21,799	21,432	21,062
DUH Total Cases		41,030	41,505	41,988	41,319	41,355	41,396
	IP Cases	4,700	4,866	5,038	5,217	5,401	5,592
	OP Cases	3,520	3,696	3,880	4,074	4,234	4,399
DRH Total Cases		8,220	8,562	8,918	9,291	9,635	9,991
	IP Cases	4,186	4,281	4,378	4,476	4,577	4,681
	OP Cases	11,638	12,220	12,831	13,473	13,877	14,289
DRAH Total Cases		15,824	16,501	17,209	17,949	18,454	18,970
	IP Cases	27,246	27,886	28,541	29,213	29,901	30,607
	OP Cases	43,369	44,500	45,682	44,186	44,477	44,634
DUHS Total Cases		70,615	72,386	74,223	73,399	74,378	75,241

Step 11: Project 2023 OR Need at DUHS Facilities

On page 143, the applicants provide a table, based on the 2018 SMFP methodology, which projects the ORs needed by 2023 for DUHS facilities. Using the 2018 SMFP methodology, the applicants illustrate the following ORs will be needed by 2023 at DUHS facilities, as shown below.

**Duke University Health System
 Projected OR Need**

Facility	OR Group	Standard Hr/OR/Yr	Surgical Cases Time		2023 Surgical Hrs	Surgical ORs Required	2023 Inventory	OR Need (Surplus)
DASC	5	1,312.5	OP	62.4	5,079	3.9	4	-0.1
			IP	267.7	90,723			
			OP	135.0	47,389			
DUH	3	1,950.0	Total		138,112	70.8	64	6.8
			IP	212.0	19,760			
			OP	131.2	9,620			
DRH	3	1,755.0	Total		29,379	16.7	13	3.7
			IP	206.0	16,071			
			OP	111.0	26,434			
DRAH	3	1,755.0	Total		42,505	24.2	15	9.2
Arrington	6	1,312.5	OP	68.6	5,643	4.3	4	0.3

Totals may not foot due to rounding

In Section Q, page 144, the applicants state that with regards to the four procedure rooms, those rooms will be used to perform orthopaedic (pain management) and ophthalmic procedures. The applicants provide historical and projected data for the nonregulated CON procedure rooms operated by DUHS on pages 144-146.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicants use historical data to project future OR utilization.
- The applicants use a reasonable CAGR to project future OR utilization.

Access

In Section C.8, page 56, the applicants state that all area residents will have access to the proposed services including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups. In Section L.3, page 111, the applicants project the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	Percent of Total Patients	
	Operating Rooms	Procedure Rooms
Self Pay	1.3%	0.2%
Medicare*	36.3%	51.7%
Medicaid*	5.1%	4.2%
Insurance*	52.3%	39.6%
Other(worker's Comp & other government sources)	5.0%	4.2%
Total	100.0%	100.0%

*Includes managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately identify the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support their assumptions.

- (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.

C

The applicants propose to relocate four surgical operating rooms from DASC to develop Arrington Ambulatory Surgical Center in the southern part of Durham County. The proposed new ASC will also have four procedure rooms and will be located at 5601 Arrington Park Drive, in Morrisville.

In Section D, page 63, the applicants explain why they believe the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project. On page 63, the applicants state:

“[T]he existing facility has limited surgical capacity based on the size and design of its existing operating rooms. AHS proposes to maximize ... licensed resources by relocating four ORs from DASC and develop a new ASC in southern Durham County.”

In Exhibit 4, the applicants provide a letter from the AHS Board as supporting documentation which states, *“DASC will remain able to accommodate providers and patients who prefer this location with the remaining four operating rooms”*.

In Section Q, page 142, the applicants provide projected utilization for DASC, as illustrated in the following table.

	FY2018	FY2019	FY2020	FY2021*	FY2022	FY2023
DASC	5,541	5,818	6,109	4,968	4,934	4,884

In Section Q, pages 132-138, the applicants provide their assumptions and methodology used to project utilization, which is summarized below.

- outpatient surgical cases;
- adult patients 18+;
- approved by Medicare reimbursement in ASC-setting;
- patients who are graded as ASA I and II;
- 50% of patients graded as ASA III; and
- patients with lower acuity needs

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicants use historical data to project future OR utilization.

- The applicants use a reasonable CAGR to project future OR utilization.

In Section D.5, page 68, the applicant states, “*AHS does not anticipate a significant change in DASC’s projected payor mix as a result of the proposed project. DASC will continue to provide substantive access to Medicare, Medicaid, and uninsured patients.*”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicants adequately demonstrate that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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.

CA

The applicants propose to relocate four surgical operating rooms from DASC to develop Arrington Ambulatory Surgical Center in the southern part of Durham County. The proposed new ASC will also have four procedure rooms.

In Section E.2(b), page 69, the applicants describe the alternatives they considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo - The applicants state that because of the growing surgical demands at DUHS facilities and the physical limitations at DASC this is not an effective alternative. Therefore, this alternative was rejected.
- Renovate DASC - The applicants state this would not improve geographic access to ambulatory services in Durham County. Neither would it enhance access to freestanding ASC services via the establishment of a second ASC in Durham County. Additionally, there is a lack of space in the existing facility to accommodate larger and

more modern operating rooms, and retrofitting older facilities creates construction issues. Therefore, this alternative was rejected.

- Relocate ORs to another geographic location - The applicants state that upon review of the projected population growth in Durham County and the location of existing ORs, that southern Durham County is the best geographic location to meet the needs of the population. No other location within Durham County would be more “*superior*” than the identified area in southern Durham County. Therefore, this alternative was rejected.
- Relocate a different complement of ORs - The applicants state that upon review of DUHS historical and projected utilization and considering DASC’s physical plant, relocating more or fewer ORs would not be an effective alternative. Therefore, this alternative was rejected.

The applicants adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory criteria.
- The applicants provide credible information to explain why they believe the proposed in the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Associated Health Services, Inc. and Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Associated Health Services, Inc. and Duke University Health System, Inc. shall develop a new multispecialty ambulatory surgical facility in Durham County by relocating four existing operating rooms from James E. Davis Ambulatory Surgery Center.**

- 3. Upon completion of this project, Arrington Ambulatory Surgical Center shall be licensed for no more than four operating rooms and four procedure rooms.**
- 4. Upon completion of this project, Associated Health Services, Inc. and Duke University Health System, Inc. shall take the necessary steps to delicense four operating rooms at James E. Davis Ambulatory Surgery Center. Upon project completion, James E. Davis Ambulatory Surgery Center will have four operating rooms and four procedure rooms.**
- 5. Associated Health Services, Inc. and Duke University Health System, Inc. as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F and Exhibit F.1 of the application or that would otherwise require a certificate of need.**
- 6. Associated Health Services, Inc. and Duke University Health System, Inc. shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
- 7. For the first three years of operation following completion of the project, Arrington Ambulatory Surgical Center shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 8. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
- 9. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**
- 10. Associated Health Services, Inc. and Duke University Health System, Inc. shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 11. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Associated Health Services, Inc. and Duke University Health System, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**

- a. **Payor mix for the services authorized in this certificate of need.**
- b. **Utilization of the services authorized in this certificate of need.**
- c. **Revenues and operating costs for the services authorized in this certificate of need.**
- d. **Average gross revenue per unit of service.**
- e. **Average net revenue per unit of service.**
- f. **Average operating cost per unit of service.**

12. Associated Health Services, Inc. and Duke University Health System, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (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.

C

The applicants propose to relocate four surgical operating rooms from DASC to develop Arrington Ambulatory Surgical Center in the southern part of Durham County. The proposed new ASC will also have four procedure rooms.

Capital and Working Capital Costs

In Section Q, Form F.1(a), the applicants state that the medical office building (MOB) will be constructed to house others services as well as the proposed ASC. The ASC represents 20 percent of the allocated square footage of the MOB, as such, the applicants allocated 20 percent of the MOB's total capital cost to the proposed project. Exhibit 13, contains a letter dated April 9, 2018 from the Vice President, Chief Financial Officer and Treasurer of DUHS which states,

“DUHS owns 100% of the equity of Associated Health Services, Inc. (“AHS”). ... AHS does not maintain a separate balance sheet or other financial statements from the system as a whole. ... The new ambulatory surgery center will be developed in a suite of a new medical office building under development that will be owned and operated by DUHS, on land that DUHS purchased. DUHS will document the provision of space in the new building via a lease or other appropriate arrangement between DUHS and AHS that will reflect AHS’s allocated share of building operating costs. Those allocated costs are included in the financial pro formas submitted with the CON application for this project.”

In Section Q, Form F.3, the applicants allocated building expenses in the amount of \$663,425 for the third full fiscal year. In Section Q, Form F.1(a), the applicants project the total capital cost of the project as shown in the table below.

Building Costs	\$540,000
Site Costs	\$1,320,000
Construction Costs	\$22,360,000
Miscellaneous Costs	\$10,066,000
Total	\$34,286,000

In Section Q, the applicants provide the assumptions used to project the capital cost.

In Section F, pages 79-80, the applicants project that start-up costs will be \$450,000 and initial operating expenses will be \$625,000 for a total working capital of \$1,075,000. In Section Q, the applicants provide the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 78, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Duke University Health System	Associated Health Services	Total
Loans	\$0	\$0	\$0
Accumulated reserves or OE *	\$34,286,000	\$0	\$34,286,000
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
Total Financing **	\$34,286,000	\$0	\$34,286,000

* OE = Owner's Equity

In Section F, page 80, the applicants state that the working capital needs of the project will be funded by DUHS owner's equity, as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$1,075,000
(c)	Lines of credit	\$0
(d)	Bonds	\$0
(e)	Total	\$1,075,000

See Exhibit 13 for projected funding letters and DUHS's audited financial statements.

Financial Feasibility

The applicants provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicants project that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

**Arrington Ambulatory Surgical Center
Projected Revenue**

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total of Cases	2,733	3,737	4,936
Total Gross Revenues (Charges)	\$27,139,210	\$36,728,189	\$48,110,827
Total Net Revenue	\$10,830,202	\$14,651,719	\$19,192,265
Average Net Revenue per case	\$3,962.75	\$3,920.72	\$3,888.22
Total Operating Expenses (Costs)	\$10,714,564	\$13,140,514	\$15,815,712
Average Operating Expense per case	\$3,920.44	\$3,516.33	\$3,204.16
Net Income	\$115,638	\$1,511,205	\$3,376,553

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately demonstrate that the capital and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicants adequately demonstrate availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicants adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicants propose to relocate four surgical operating rooms from DASC to develop Arrington Ambulatory Surgical Center in the southern part of Durham County. The proposed new ASC will also have four procedure rooms.

On page 57, the 2018 SMFP defines the service area for ORs as, "... the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1." In Figure 6.1, page 62 of the 2018 SMFP, Durham County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 65 of the 2018 SMFP, there are 92 ORs in Durham County, as illustrated below.

Facility	# of Inpatient ORs	# of Ambulatory ORs	# of Shared ORs	Total
James E. Davis Ambulatory Surgery Center		8		8
Duke University Hospital*	6	9	50	65
Duke Regional Hospital	2	13		15
NC Specialty Hospital			4	4
Total	8	30	54	92

*DUH has 16 licensed ORs approved under Policy AC-3 (Project I.D. # J-8030-07). Those 16 ORs are counted when determining a need for ORs.

Does not include CON adjustments for C-Section ORs

Source: 2018 SMFP and 2018 License Renewal Applications

In Section G, page 86, the applicants explain why they believe their proposal would not result in the unnecessary duplication of existing or approved OR services in Durham County. The applicants state:

"[I]t does not increase the number of ORs in Durham County. The proposed project is needed to more effectively geographically disperse the existing DUHS operating rooms within DUHS ... and expanded access to DUHS's well-utilized ambulatory surgical services."

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would not result in an increase of ORs in Durham County.
- The applicants adequately demonstrate that the proposed relocation of four ORs is needed to provide accessible and cost effective ambulatory surgical services to the southern portion of Durham County and surrounding counties.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing

- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

C

Arrington Ambulatory Surgical Center is a proposed new facility and therefore does not have existing staff. In Section Q, Form H, the applicants provide projected staffing for the proposed ASC services, as illustrated in the following table.

Position	Projected		
	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Med. Records Clerical	2.0	2.0	2.0
RNs	20.8	26.0	30.0
Technicians	5.7	7.9	10.5
CRNAs	5.8	6.4	6.4
NAs	1.5	1.7	1.9
Central Sterile Supply Techs	3.4	3.4	3.4
Administrator	1.5	1.5	1.5
Clerical	1.0	1.0	1.0
Business Office Manager	1.0	1.0	1.0
Business Office Clerical	6.0	8.0	10.0
TOTAL	48.7	58.9	67.7

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in Form F.2, which is found in Section Q. In Section H, pages 89-90, the applicants describe the methods to be used to recruit new positions and their proposed training and continuing education programs. In Section H, page 91, the applicants identify Dr. David Attarian as the proposed medical director. In Exhibit 3, the applicants provide a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section H, page 91, the applicants describes their physician recruitment plans. In Exhibit 7, the applicants provide supporting documentation.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section I, page 93, the applicants state that the following ancillary and support services are necessary for the proposed services:

- Reception, medical records and associated office requirements will be provided by DUHS;
- Administration will be provided by DUHS;
- Surgical services will be provided by physicians with privileges at Arrington ASC;
- Medical supplies by various vendors;
- Dietary / light snacks, post operatively by nursing staff, as needed;
- Laundry, maintenance, housekeeping, pharmacy and pathology provided through second party contracts; and
- Anesthesiology provided through contractual arrangement with separate billing for those professional services.

In Section I, page 94, the applicants describe their efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit 8.

The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing

- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicants do not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicants do not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicants are not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K, page 98, the applicants state that the project involves up fitting 39,080 square feet of space in a new medical office building. Exhibit 2 contains an Exempt from Review letter granting permission for the development of the MOB. Line drawings are provided in Exhibit 11.

On page 99, the applicants adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 5.

On pages 99-100, the applicants adequately explain why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 100-101, the applicants identify any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit 5.

On pages 102-104, the applicants identify the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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:

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

C

In Section L, page 108, the applicants provide the historical payor mix during the last full fiscal year for the services offered at DASC during FY2017 (7/1/2016-6/30/2017), as shown in the table below.

**James E. Davis Ambulatory
Surgical Center**

Payor Category	Percent of Total Patients	
	Operating Rooms	Procedure Rooms
Self Pay	0.8%	0.2%
Medicare*	45.7%	51.7%
Medicaid*	3.5%	4.2%
Insurance*	47.5%	39.6%
Other(worker's Comp & other government sources)	2.5%	4.2%
Total	100.0%	100.0%

*Includes managed care plans.

As shown in the table above, during the last full fiscal year of operation, DASC provided 0.8% of total ORs services to self-pay patients, 45.7% to Medicare patients and 3.5% to Medicaid patients. The applicants state that projected pay mix for the proposed ASC is based on the historical payor mix for DASC and other DUHS facilities.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicants adequately document the extent to which medically underserved populations served by a related entity, currently uses the applicants' services.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 108, the applicants state they have “no” obligation under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 110, the applicants state that during the last five years no patient civil rights access complaints have been filed against any facilities similar to the proposed ASC. However, there were four complaints filed against DUHS owned or by a related entity and located in North Carolina, as summarized below.

- Against Duke Raleigh Pain Clinic - filed on 12/11/15 and closed on 3/23/16 with no further investigation.
- Against Duke Raleigh Pain Clinic - filed on 2/15/16 and closed on 1/10/17 with no further investigation.
- Against DUHS - filed 3/20/17; three incidents. Pending as of 3/20/17 with response submitted to the DOJ.
- Complaint voluntarily dismissed.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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; and

C

In Section L, page 111, the applicants project the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Arrington Ambulatory Surgical Center

Payor Category	Percent of Total Patients	
	Operating Rooms	Procedure Rooms
Self Pay	1.3%	0.2%
Medicare*	36.3%	51.7%
Medicaid*	5.1%	4.2%
Insurance*	52.3%	39.6%
Other(worker's Comp & other government sources)	5.0%	4.2%
Total	100.0%	100.0%

*Includes managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicants project that 1.3% of total ORs services will be provided to self-pay patients, 36.3% to Medicare patients and 5.1% to Medicaid patients.

On pages 111-112, Exhibit 12, and page 6 of the response to written comments, the applicants provide the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for surgical and non-surgical procedures at DUHS facilities and the procedures that are projected for the Arrington ASC.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 112, the applicants adequately describe the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 113, the applicants describe the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit 3.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (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.

C

The applicants propose to relocate four surgical operating rooms from DASC to develop Arrington Ambulatory Surgical Center in the southern part of Durham County. The proposed new ASC will also have four procedure rooms.

On page 57, the 2018 SMFP defines the service area for ORs as, “... *the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*” In Figure 6.1, page 62 of the 2018 SMFP, Durham County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 65 of the 2018 SMFP, there are 92 ORs in Durham County, as illustrated below.

Facility	# of Inpatient ORs	# of Ambulatory ORs	# of Shared ORs	Total
James E. Davis Ambulatory Surgery Center		8		8
Duke University Hospital*	6	9	50	65
Duke Regional Hospital	2	13		15
NC Specialty Hospital			4	4
Total	8	30	54	92

*DUH has 16 licensed ORs approved under Policy AC-3 (Project I.D. # J-8030-07). Those 16 ORs are counted when determining a need for ORs.

Does not include CON adjustments for C-Section ORs

Source: 2018 SMFP and 2018 License Renewal Applications

In Section N, pages 115 and 117, the applicants describe the expected effects of the proposed services on competition in the service area and discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 115, the applicant states,

“ASCs provide cost-effective care that save the patient, government, and third-party payors money. Because ASCs are highly specialized and function on a much smaller scale, they are able to provide services at a lower price than a full-service hospital. On average, Medicare saves \$2.3 billion annually when surgical procedures are performed at ASCs instead of hospital outpatient departments ... this project will not increase the charges or projected reimbursement for these services

DUHS projects a combined Medicare / Medicaid payor mix of 41.4% at Arrington ASC.”

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section O, page 122, the applicants identify James E. Davis Ambulatory Surgery Facility, as the only other similar facility located in North Carolina owned, operated or managed by the applicants or a related entity.

In Section O, page 122, the applicants state that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care at any facility in North Carolina owned, operated or managed by the applicants or a related entity. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care in any of DUHS facilities. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all the facilities owned, operated or managed by the applicants or a related entity, the applicants provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in

order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2103 PERFORMANCE STANDARDS

- (a) *A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program shall demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the 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.*
- C- In Section Q, page 143, the applicants provide a table which illustrates the need for the four relocated operating rooms in the third year of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicants project that Arrington ASC, in OR group 6 would have an average final ambulatory case time of 68.6. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is conforming with this rule.
- (b) *A proposal 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 third operating year 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.*
- NA- The applicants do not propose to increase the number of existing ORs in Durham County, but rather the relocation of four existing ORs.
- (c) *An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved, and proposed dedicated C-section rooms during the third year of operation following completion of the project.*

-NA- The proposed project does not involve dedicated C-section ORs.

(d) *An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty area to a specialty ambulatory surgical program shall:*

(1) *provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,312.5 hours per operating room per year; and*

(2) *demonstrate the need in the third operating year of the 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.*

-NA- The applicants do not propose to convert a specialty ambulatory surgical program into a to a multispecialty ambulatory surgical program or to add a specialty area to a specialty ambulatory surgical program.

(e) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

-C- In Section Q, pages 126-143, the applicants provide the assumptions methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is conforming with this rule.