REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date:	July 21, 2022
Findings Date:	July 21, 2022
Project Analyst:	Kim Meymandi
Co-Signer:	Micheala Mitchell
Project ID #:	J-12212-22
Facility:	Duke Health Raleigh Ambulatory Surgical Center
FID #:	220335
County:	Wake
Applicant(s):	Duke University Health System, Inc. Associated Health Services, Inc.
Project:	Develop a new, separately licensed freestanding ASF on the Duke Raleigh Hospital campus by re-licensing one existing hospital-based OR from the Duke Raleigh Hospital license

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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.

NA

Duke University Health System, Inc. and Associated Health Services, Inc. (hereinafter referred to as "the applicant") propose to develop a new, separately licensed freestanding ambulatory surgical facility (ASF) on the Duke Raleigh Hospital (DRAH) campus by re-licensing one existing hospital-based operating room (OR) from the DRAH license.

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 2022 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There are no policies in the 2022 SMFP which are applicable to this review.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that this criterion is not applicable to this review.

(2) Repealed effective July 1, 1987.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, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop Duke Health Raleigh Ambulatory Surgical Center (DHR ASC), a new, separately licensed freestanding ASF, on the DRAH campus by re-licensing one existing hospital-based operating room OR from the DRAH license. The proposed new ASF will have three procedure rooms and will be located in Medical Office Building 9 (MOB 9) owned by Duke University Hospital System (DUHS) and on the same grounds as the main hospital building.

In Exhibit C.1, the applicant provides a copy of record #3607, issued by the Agency on July 13, 2021 exempting from CON review the relocation of OR 4 from DRAH to MOB 9. The applicant states in Section C.1, page 28 that that the hospital based OR that they propose to relicense (OR4) was relocated to MOB 9 and became operational in December 2021.

The following table identifies the DUHS licensed and approved facilities with ORs in Wake County.

Facility	# of Dedicated C-Section ORs	# of Inpatient ORs	# of Shared ORs	# of Dedicated Ambulatory ORs	# of Exclusions	Total # of ORs less Exclusions
Existing Facilities						
Duke Raleigh Hospital	0	0	15	0	0	15^^
Approved Facilities						
Duke Health Green Level ASC	0	0	0	1	0	1
Duke Health Garner ASC Project ID#J-11966-20	0	0	0	1	0	1
Duke Green Level Hospital Project ID# J-12029-21^	0	0	2	0	0	2

^DUHS was approved in Project ID# J-12029-21 to relocate 2 shared ORs from DRAH.
^^Upon completion of this proposed project and Project ID# J-12029-21 DRAH will be licensed for 13 ORs

In Section C.1, page 29, the applicant states that DHR ASC will provide outpatient surgical services including general surgery, ophthalmology, orthopaedics, and otolaryngology; as such, the ASC will be a multispecialty ambulatory surgical program as defined at §131E-176.15a, *"a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery."*

Patient Origin

On page 50, the 2022 SMFP states, *"Counties with at least one facility having a licensed OR that are not grouped with another county are single county service areas."* In Figure 6.1, page 55 of the 2022 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 30, the applicant states that DHR ASC is approved but not operational and therefore has no historical patient origin. The applicant provides the historical patient origin data for DRAH ambulatory surgery cases performed in licensed ORs at DRAH during the last full fiscal year (FY), FY2021, as reported on the 2022 License Renewal Application (LRA) and as summarized in the table below.

DRAH Ambulatory Surgery Historical Patient Origin
FY2021
7/1/2020-6/30/2021

County	Patients	% of Total
Cumberland	227	3.3%
Durham	275	3.9%
Franklin	253	3.6%
Johnston	328	4.7%
Moore	79	1.1%
Nash	104	1.5%
New Hanover	74	1.1%
Orange	84	1.2%
Pitt	109	1.6%
Wake	3,563	51.1%
Wayne	104	1.5%
Wilson	79	1.1%
Other NC Counties^	1,419	20.3%
Other States	277	3.9%
Total^^	**6,975**	**100.0%**

^Other includes less than 1% of patients from remaining NC counties
^^Numbers may not sum due to rounding

The applicant provides the projected patient origin for the first three full fiscal years at DHR ASC on page 32 of the application, as summarized below.

DHR ASC Operating Room Projected Patient Origin
FY2024-FY2026

County	1st Full FY 7/1/23-6/30/24		2nd Full FY 7/1/24-6/30/25		3rd Full FY 7/1/25-6/30/26	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wake	805	51.1%	975	51.1%	1,133	51.1%
Johnston	74	4.7%	90	4.7%	104	4.7%
Durham	62	3.9%	75	3.9%	87	3.9%
Franklin	57	3.6%	69	3.6%	80	3.6%
Cumberland	51	3.3%	62	3.3%	72	3.3%
Harnett	37	2.3%	45	2.3%	52	2.3%
Nash	23	1.5%	28	1.5%	33	1.5%
Pitt	25	1.6%	30	1.6%	35	1.6%
Orange	19	1.2%	23	1.2%	27	1.2%
Granville	18	1.1%	22	1.1%	25	1.1%
Other States	63	4.0%	76	4.0%	88	4.0%
Other NC Counties^	342	21.7%	414	21.7%	481	21.7%
Total^^	**1,575**	**100.0%**	**1,908**	**100.0%**	**2,218**	**100.0%**

^Other includes less than 1% of patients from remaining NC counties
^^Numbers may not sum due to rounding

DHR ASC Procedure Room Projected Patient Origin
FY2024-FY2026

County	1st Full FY 7/1/23-6/30/24		2nd Full FY 7/1/24-6/30/25		3rd Full FY 7/1/25-6/30/26	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wake	213	51.1%	213	51.1%	213	51.1%
Johnston	20	4.7%	20	4.7%	20	4.7%
Durham	16	3.9%	16	3.9%	16	3.9%
Franklin	15	3.6%	15	3.6%	15	3.6%
Cumberland	14	3.3%	14	3.3%	14	3.3%
Harnett	10	2.3%	10	2.3%	10	2.3%
Nash	6	1.5%	6	1.5%	6	1.5%
Pitt	7	1.6%	7	1.6%	7	1.6%
Orange	5	1.2%	5	1.2%	5	1.2%
Granville	5	1.1%	5	1.1%	5	1.1%
Other States	17	4.0%	17	4.0%	17	4.0%
Other NC Counties^	90	21.7%	90	21.7%	90	21.7%
Total^^	**416**	**100.0%**	**416**	**100.0%**	**416**	**100.0%**

^Other includes less than 1% of patients from remaining NC counties
^^Numbers may not sum due to rounding

In Section C, pages 30 and 34, the applicant provides the assumptions and methodology used to project patient origin for DHR ASC. The applicant states that projected patient origin for the operating room and procedure rooms at DHR ASC is based on the FY2021 patient origin of outpatient surgery performed in licensed ORs at DRAH. The applicant states that it does not expect the proposal to impact patient origin.

The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant has experience providing the same service in the same service area.
- The applicant bases projected patient origin on the existing ORs historical patient origin.

Analysis of Need

In Section C, pages 36-47, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 36, the applicant states the specific need for the project is based on the following factors:

- Growing ambulatory service volumes at Duke University Hospital System (DUHS) facilities (pages 36-40)
- Ambulatory surgery trends (pages 40-43)
- DUHS initiatives to enhance access to ambulatory services (pages 43-44)
- DUHS strategic growth involving primary and specialty physician recruitment (pages 43-44)
- Projected population growth in the service area (pages 44-47)

The information is reasonable and adequately supported based on the following:

- The applicant provides reasonable information regarding the historical growth rates of inpatient and ambulatory surgical cases at DRAH for the period FY2015 to FY2021.
- The applicant cites data from the SMFP regarding statewide ambulatory surgical utilization and growth.
- The applicant provides reasonable information regarding the technological advances in surgery that safely allow for the performance of an increasingly greater number of procedures in an outpatient setting at a reduced cost compared to the inpatient setting.
- The applicant uses clearly cited and reasonable historical and projected population growth statistics for the Wake County population to be served and the continued demand for the services proposed.
- The applicant provides reasonable information to support Wake County residents' need for access to high quality freestanding ASF services; and cites reasonable data demonstrating the cost-effectiveness of the proposal.

Projected Utilization

In Section Q Form C, Utilization, the applicant provides the projected utilization for DHR ASC, as illustrated in the following table.

Duke Health Raleigh ASC Projected OR Utilization

	1st Full FY 7/1/23-6/30/24	2nd Full FY 7/1/24-6/30/25	3rd Full FY 7/1/25-6/30/26
Operating Rooms			
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	1,575	1,908	2,218
Outpatient Surgical Case Time*	39.9	39.9	39.9
Outpatient Surgical Hours	1,048	1,269	1,475
Group Assignment*	5	5	5
Standard Hours per OR per Year*	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	0.8	1.0	1.1
Procedure Rooms			
Number of Procedure Rooms	3	3	3
Total Number of Procedures	416	416	416

*Applicant uses the surgical case time, group assignment and standard hours per OR per year as provided in the 2022 SMFP, pages 52-53.

In Section Q Form C, pages 108-119 the applicant provides the assumptions and methodology used to project operating room utilization, as summarized below:

Step 1: The applicant provides the FY2018-FY2021 surgical utilization rates for DRAH as shown in the table below.

	FY2018	FY2019	FY2020*	FY18-FY20 CAGR	FY2021	FY18-FY21 CAGR
IP Cases	3,328	3,568	3,677	5.1%	3,273	-0.6%
OP Cases Performed in DRAH ORs	7,469	7,365	7,293		6,975	
OP Cases Performed in DRAH Procedure Rooms	3,880	4,125	4,308		5,669	
Total OP DRAH Surgical Cases	11,349	11,490	11,601	1.1%	12,644	3.7%
Total DRAH Surgical Cases	14,677	15,108	15,278	2.0%	15,917	2.7%

*Annualized based on pre-COVID data July-Feb
Source: DUHS Internal data

Step 2: The applicant projects surgical case growth rates based on ¼ of the FY18-FY20 CAGR for IP cases (1/4 x 5.1% = 1.3%) and the FY18-FY21 3-year CAGR for OP cases (3.7%).

Step 3: The applicant calculates IP and OP surgical cases based on the growth rates in Step 2 as summarized in the table below.

Surgical Cases	Growth Rate	FY2022	FY2023	FY2024	FY2025	FY2026
IP Cases	1.3%	3,315	3,357	3,400	3,444	3,488
OP Cases	3.7%	13,108	13,588	14,087	14,603	15,139
Total Cases		16,423	16,946	17,487	18,047	18,627

Source: Section Q, page 111

Step 4: The applicant reviews DRAH FY2021 OP surgical cases and uses the following factors to determine the cases appropriate for an ASC: OP surgical cases only, age > 18 years of age, Medicare reimbursement approved for ASC setting, grades I and II physical status assigned by American Society of Anesthesiologists with 50% graded as ASA III. Based on these factors, the applicant calculates that 72.6% of FY2021 OP surgical cases are appropriate for an ASC.

Step 5: The applicant applies the percentage calculated in Step 4 to OP cases calculated in Step 3 as shown in the following table.

Projected OP Cases Appropriate for ASC

	FY2022	FY2023	FY2024	FY2025	FY2026
Cases Appropriate for ASC	9,516	9,865	10,227	10,602	10,991

Source: Section Q, page 112

Step 6: The applicant provides the percentage of OP surgical cases performed by specialty at DRAH in FY2021 as illustrated in the following table.

DRAH
OP Surgery Cases by Specialty, FY2021

Service Line	FY2021	% of Total
Cardiothoracic	17	0.1%
General Surgery	2,154	17.0%
Gynecology	347	2.7%
Neurosurgery	727	5.7%
Ophthalmology	4,022	31.8%
Orthopedics	3,792	30.0%
Otolaryngology Head & Neck	838	6.6%
Plastic Surgery	175	1.4%
Podiatry	61	0.5%
Urology	511	4.0%
Total	12,644	100.0%

Source: DUHS Finance

Step 7: The applicant projects, based on the historical percentage of cases by specialty at DRAH (Step 6) applied to the projected ASC-appropriate cases by facility (Step 5), the potential number of ASC appropriate cases available to shift to DHR-ASC (Step 5 X Step 6) as summarized in the table below.

Specialty	% of Total Cases	FY2022	FY2023	FY2024	FY2025	FY2026
General	17.0%	1,621	1,681	1,742	1,806	1,872
Ophthalmology	31.8%	3,027	3,138	3,253	3,372	3,496
Orthopedics	30.0%	2,854	2,959	3,067	3,180	3,296
ENT	6.6%	631	654	678	703	728
Subtotal	85.5%	8,133	8,431	8,740	9,061	9,393
All Other Specialties	14.5%	1,383	1,434	1,487	1,541	1,598
Total	100.0%	9,516	9,865	10,227	10,602	10,991

Source: Section Q, page 114

Step 8: The applicant provides the number of OP surgical cases by specialty projected to shift to Arringdon ASC, Duke Health Green Level ASC, and Duke Health Garner ASC based on CON Project ID# J-12075-21, J-11966-20, and J-11557-18 respectively. The applicant notes that Duke Health Green Level ASC and Duke Green Level Hospital will become operational during FY2027 and therefore are not reflected during the first three operating years of the proposed project. The applicant calculates the number of appropriate ASC cases to shift to DHR ASC by subtracting the Arringdon ASC and Garner ASC cases from the numbers calculated in Step 7 and as illustrated in the tables below.

DRAH Case Shift to Arringdon ASC & Garner ASC

Specialty	FY2022	FY2023	FY2024	FY2025	FY2026
General	0	0	39	79	159
Ophthalmology	262	318	474	545	675
Orthopedic	139	280	452	517	584
ENT	0	0	47	67	102
Subtotal	401	598	1,012	1,208	1,520
All Other Specialties	21	27	68	91	138
Total	**422**	**625**	**1,080**	**1,299**	**1,658**

Source: Section Q, Page 116

DRAH ASC Appropriate Surgery Cases*

Specialty	FY2022	FY2023	FY2024	FY2025	FY2026
General	1,621	1,681	1,703	1,727	1,713
Ophthalmology	2,765	2,820	2,779	2,827	2,821
Orthopedic	2,715	2,679	2,615	2,663	2,712
ENT	631	654	631	636	626
Subtotal	7,732	7,833	7,728	7,853	7,873
All Other Specialties	1,362	1,407	1,419	1,450	1,460
Total	**9,094**	**9,240**	**9,147**	**9,303**	**9,333**

Source: Section Q, Page 116
*Formula: Step 7-DRAH Shift to Arringdon ASC and Garner ASC

Step 9: The applicant projects the percentage of DRAH that will shift to DRH ASC based on access to OP based (non-HOPD pricing) ambulatory surgery, physician preference, efforts to relocate ambulatory surgical utilization in existing DRAH ORs, reduced travel burden for patients seeking surgery in freestanding ASC, convenience and access. In Section Q, page 117 the applicant provides the projected percentage of ASC appropriate surgical cases that will shift to DRH ASC as shown in the following table.

% Shift to DRH ASC

Specialty	FY2024	FY2025	FY2026
General	3.0%	4.0%	5.0%
Ophthalmology	40.0%	50.0%	60.0%
Orthopedic	13.0%	14.0%	15.0%
ENT	15.0%	20.0%	25.0%

Step 10: The applicant calculates the projected OP surgical cases at the proposed DHR ASC by multiplying the numbers in Step 8 for DRAH ASC appropriate cases by the percentages in Step 9 and states that DHR ASC will be assigned to Group 5 based on the 2022 SMFP methodology. The following table shows the projected OP surgical cases for DHR ASC.

Specialty	FY2024	FY2025	FY2026
General	50	66	82
Ophthalmology	1,093	1,356	1,602
Orthopedic	342	365	386
ENT	91	121	149
Total	**1,575**	**1,908**	**2,218**

Source: Section Q, page117

Step 11: The applicant identifies the remaining surgical cases at DRAH following cases shifts to Arringdon ASC, Garner ASC and the proposed DHR ASC. The applicant begins with the projected number of surgical cases at DRAH calculated in Step 3 and projects that 55% of the cases will be performed in ORs and the remaining 45% will be appropriate for procedure rooms (PR). The applicant states that projections are based the FY2021 distribution of surgical cases by specialty performed in DRAH's ORs and procedure rooms as well as other respective locations. The following table summarizes the applicant's calculations found in Section Q pages 118 and 119.

DRAH Surgical Cases after Shifts to Arringdon and Garner ASCs

	FY2022	FY2023	FY2024	FY2025	FY2026
DRAH Case Shift to Arringdon & Garner	422	625	1,080	1,299	1,658
DRAH OP OR Cases	7,231	7,496	7,771	8,056	8,351
DRAH OP OR Case Shift to Approved ASCs	132	250	486	604	784
DRAH Remaining OP OR Cases	7,099	7,246	7,285	7,452	7,567
DRAH OP PR Cases	5,877	6,092	6,316	6,548	6,788
DRAH OP PR Case Shift to approved ASCs	291	375	594	696	875
DRAH Remaining OP PR Cases	5,586	5,718	5,722	5,851	5,913
DRAH Total Remaining OP Surgical Cases	**12,685**	**12,963**	**13,007**	**13,303**	**13,480**

Numbers may not foot due to rounding

DRAH Surgical Cases after Shift to DHR ASC

	FY2022	FY2023	FY2024	FY2025	FY2026
DRAH Case Shift to DHR ASC			1,575	1,908	2,218
DRAH OP OR Cases	7,099	7,246	7,285	7,452	7,567
DRAH OP OR Case Shift to DHR ASC			384	438	487
DRAH Remaining OP OR Cases	7,099	7,246	6,901	7,014	7,080
DRAH OP PR Cases	5,586	5,718	5,722	5,851	5,913
DRAH OP PR Case Shift to DHR ASC			1,191	1,470	1,731
DRAH Remaining OP PR Cases	5,586	5,718	4,530	4,381	4,182
DRAH Total Remaining OP Surgical Cases	**12,685**	**12,963**	**11,431**	**11,396**	**11,261**

Numbers may not foot due to rounding

In Section Q, page 120 the applicant provides the assumptions and methodology used to project procedure room volume. The applicant states that utilization for procedure room volume at DHR ASC is based on anticipated pain management procedures and cystoscopy procedures that can be performed in the three procedure rooms following conversion of the MOB platform to a freestanding ASC and calculates the number of projected procedures using 2022 DRAH license renewal application (LRA) information and the following methodologies:

Pain Management = 10% of FY2021 DRAH OP procedure volumes = 1,412 X 0.10 =141

Cystoscopy = ½ of FY2021 DRAH OP procedure volumes = 550 X 0.5 = 275

The applicant conservatively assumes volume will remain constant across the initial three project years and states that patients will find the proposed ASC more cost-effective and convenient.

Projected utilization is reasonable and adequately supported based on the following:

- Projected utilization is based upon the historical OP surgery utilization at DRAH, using its three-year CAGR of 3.7%, which the applicant calculates using 8 months of data (July-Feb) in FY2020 to represent pre-COVID surgical utilization.
- Historical growth rates for OP surgery utilization at DRAH occurred prior to the proposed conversion to a lower cost, freestanding setting, which will improve patient and physician access compared to the hospital-based facility, which supports continued volume growth.
- Population projections and demographics support continued growth.
- The applicants considered the specialty surgical procedures to be offered at the proposed DRH ASC and projected utilization based on those specialties.
- Projected procedures in the proposed procedure rooms are based on historical data from LRAs.

Access to Medically Underserved Groups

In Section C.6, page 52 the applicant states:

> *"All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will have access to Duke health Raleigh AS C, as clinically appropriate. DUHS does not and will not discriminate based on race, ethnicity, age, gender, or disability."*

On page 54, the applicant provides the estimated percentage for each medically underserved group during the third full fiscal year, as shown in the following table.

MEDICALLY UNDERSERVED GROUPS	% OF TOTAL PATIENTS
Low income persons	8.0%
Racial and ethnic minorities	32.1%
Women	51.4%
Persons with disabilities	*
The elderly	57.0%
Medicare beneficiaries	57.0%
Medicaid recipients	2.7%
Total	**100.0%**

*applicant does not track this data

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- DUHS related facilities have a history of providing services to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 all the reasons described above.

(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, … persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant proposes to develop a new, separately licensed freestanding ASF, on the DRAH campus by re-licensing one existing hospital-based operating room OR from the DRAH license. The proposed new ASF will also have three procedure rooms reallocated from DRAH and will be located in Medical Office Building 9 (MOB 9) owned by Duke University Hospital System and on the same grounds as the main hospital building. The proposed project does not reduce, relocate, or eliminate any ORs from the DRAH campus, therefore Criterion (3a) is not applicable.

(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 applicant proposes to develop a new, separately licensed freestanding ASF, on the DRAH campus by re-licensing one existing hospital-based operating room OR from the DRAH license.

In Section E.2, pages 62-63, the applicant describes the alternatives 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 applicant states that maintaining the status quo is not an effective alternative because this alternative fails to recognize the growing demand for outpatient surgery and the cost-effective benefits of the proposed project. Therefore, the applicant determined this is not the most effective alternative.
- *Construct a New ASC in Another Location*-The applicant states that this alternative would not be cost-effective because it would require new construction or significant renovations to accommodate the proposed ASC.

The applicant adequately demonstrates 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 review criteria.
- The applicant provides credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

1. **Duke University Health System, Inc. and Associated Health Services, Inc. (hereinafter certificate holder)shall materially comply with all representations made in the certificate of need application.**

2. **The certificate holder shall develop a freestanding multispecialty ambulatory surgical facility on the Duke Raleigh Hospital campus by relicensing no more than one existing hospital-based operating room from the Duke Raleigh Hospital license and reallocating three procedure rooms.**

3. **Upon project completion, Duke Health Raleigh Ambulatory Surgical Center shall be licensed for no more than one operating room and three procedure rooms.**

4. **The Duke University Health System shall take the necessary steps to delicense one operating room on the Duke Raleigh Hospital License #H0238. The Duke Raleigh Hospital License #H0238 shall have a total of 12 operating rooms upon completion of this project and Project ID #J-12029-21 (relocate two shared operating rooms from Duke Raleigh Hospital).**

5. **Progress Reports:**

    a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.**
    b. **The certificate holder shall complete all sections of the Progress Report form.**
    c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    d. **The first progress report shall be due on February 1, 2023.**

6. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**

7. **The certificate holder 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.**

8. **For the first three years of operation following completion of the project, the certificate holder 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.**

9. **The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**

10. **Procedures performed in the procedure rooms 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.**

11. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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. **The certificate holder 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 applicant proposes to develop a new, separately licensed freestanding ASF, on the DRAH campus by re-licensing one existing hospital-based operating room OR from the DRAH license.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicants project the total capital cost of the project as shown in the table below.

Site Costs	$0
Construction Costs	$0
Medical Equipment	$850,000
Miscellaneous Costs	$150,000
Total	**$1,000,000**

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

In Section F.3, page 66, the applicant projects that start-up costs will be $220,454 and although the applicant states in F.3a that there will be initial operating expenses, answers provided by the applicant for F.3.c, F.3.d and F.3.f are consistent with there not being any initial operating expenses and the Project Analyst concludes that the response for F.3.a is a typographical error for a total working capital of $220,454. In Section F.3, pages 66 and 67, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant identifies the costs included in the estimated start-up costs.
- The applicant bases its projections on its experience operating other ASCs.

Availability of Funds

In Section Q, Form F.1a, the applicants state that the capital cost will be funded by the applicant as shown in the table below.

Sources of Capital Cost Financing

TYPE	DUHS	TOTAL
Loans	$0	$0
Accumulated reserves or OE*	$1,000,000	$1,000,000
Bonds	$0	$0
Other (funding from parent company)	$0	$0
Total Financing	**$1,000,000**	**$1,000,000**

In Section F, pages 65 and 68, the applicant states that the capital costs and working capital costs of the project will be funded with cash reserves of DUHS. In Exhibit F.2, the applicant provides a letter dated April 7, 2022, from the Senior Vice President, Chief Financial Officer & Treasurer for DUHS documenting its intention to provide as much as $2,000,000 to cover all capital and working capital costs of the proposed project. Exhibit F.2 contains the Consolidated Financial Statements for DUHS, Inc. and Affiliates for the years ending June 30, 2021 and 2020.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F.2 contains a letter from the Senior Vice President, Chief Financial Officer & Treasurer for DUHS, documenting that DUHS, Inc. intends to fund the total projected cost of the project through accumulated reserves.
- Exhibit F.2 contains a copy of DUHS, Inc. and Affiliates consolidated balance sheet as of June 30, 2021, showing cash and cash equivalents in excess of $98 million and over $5.0 billion in assets to fund the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1ST FULL FISCAL YEAR 7/1/23-6/30/24	2ND FULL FISCAL YEAR 7/1/24-6/30/25	3RD FULL FISCAL YEAR 7/1/25-6/30/26
Total OR Cases	1,575	1,908	2,218
Total Gross Revenues (Charges)	$14,093,719	$17,065,025	$19,947,026
Total Net Revenue	$6,054,535	$7,221,449	$8,338,699
Average Net Revenue per Case	$3,844	$3,784	$33,760
Total Operating Expenses (Costs)	$4,612,507	$5,700,918	$6,460,067
Average Operating Expense per Case	$2,928	$2,988	$2,913
Net Income	$1,442,028	$1,520,532	$1,878,632

The assumptions used by the applicant 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

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.

- The applicant adequately demonstrates 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 applicant proposes to develop a new, separately licensed freestanding ASF, on the DRAH campus by re-licensing one existing hospital-based operating room OR from the DRAH license.

On page 50, the 2022 SMFP states, *"Counties with at least one facility having a licensed OR that are not grouped with another county are single county service areas."* In Figure 6.1, page 55 of the 2022 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in Wake County, and the inpatient and outpatient case volumes for each provider, from pages 66, 67, 79 and 80 of the 2022 SMFP.

Wake County Operating Room Inventory and Cases

	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjust-ments	AdjustedPlanning Inventory	IP Surgery Cases	OP Surgery Cases
Duke Health Green Level ASC	0	0	0	0	1	1	0	0
Duke Health Garner ASC	0	0	0	0	1	1	0	0
Duke Raleigh Hospital	0	0	15	0	0	15	3,369	6,575
Duke University Health System Total	**0**	**0**	**15**	**0**	**2**	**17**		
Rex Surgery Center of Cary	0	4	0	0	0	4	0	3,810
Raleigh Orthopedic Surgery Center	0	3	0	0	0	3	0	4,126
Rex Surgery Center of Wakefield	0	2	0	0	0	2	0	2,325
Raleigh Orthopedic Surgery-West Cary	0	1	0	0	0	1	0	0
Rex Hospital (incl. Rex Holly Springs)	3	0	25	-3	-1	27	7,631	10,839
Orthopaedic Surgery Center of Garner	0	0	0	0	1	1	0	0
UNC Health Care System Total	**3**	**10**	**25**	**-3**	**0**	**38**		
WakeMed Surgery Center-Cary	0	0	0	0	1	1	0	0
WakeMed Surgery Center-North Raleigh	0	0	0	0	1	1	0	0
Capital City Surgery Center	0	8	0	0	-1	7	0	6,055
WakeMed (incl. WakeMed North)	8	0	20	-5	-1	22	7,952	11,194
WakeMed Cary Hospital	2	0	9	-2	1	10	2,867	3,681
WakeMed System Total	**10**	**8**	**29**	**-7**	**1**	**41**		
OrthoNC ASC	0	0	0	0	1	1	0	0
RAC Surgery Center	0	0	0	0	1	1	0	0
Surgical Center for Dental Professionals*	0	2	0	0	0	0	0	360
Blue Ridge Surgery Center	0	6	0	0	0	6	0	4,938
Raleigh Plastic Surgery Center^	0	1	0	0	0	1	0	303
Triangle Orthopedic Surgery Center	0	2	0	0	1	3	0	2,497
Wake Spine and Specialty Surgery Center	0	0	0	0	1	1	0	0
Holly Springs Surgery Center	0	3	0	0	0	3	0	2,266
Valleygate Surgery Center	0	0	0	0	1	1	0	0
Total Wake County ORs	**13**	**32**	**69**	**-10**	**11**	**113**		

Source: 2022 SMFP, Table 6A and Table 6B. The table also includes three projects approved pursuant to the 2020 need determination.
^Underutilized facility, excluded from need determination calculations.
*Ambulatory surgery demonstration project included in the inventory, but not included in the need determination calculations.

In Section G.2, page 74, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the proposed service area. The applicant states:

> *"The proposed project will not result in unnecessary duplication of existing facilities because it does not increase the number of OR's in Wake County. The proposed project is needed to more effectively allocate the existing DUHS operating rooms between hospital and freestanding within Wake County, and thus expand access to free standing ambulatory surgical services."*

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

- the applicant adequately demonstrates that the proposed project will not increase the number of ORs in Wake County, and
- the applicant adequately demonstrates that the existing operating room is needed in addition to the other existing ORs in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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

The applicant proposes to develop a new, separately licensed freestanding ASF, on the DRAH campus by re-licensing one existing hospital-based operating room OR from the DRAH license.

In Section Q Form H Staffing, the applicant provides projected full-time equivalent (FTE) positions for the proposed services, as summarized in the following table.

Projected FTE Positions

Position	FY2024	FY2025	FY2026
Registered Nurses	6.85	8.95	8.95
Certified Nurse Aides/Nursing Assistants	0.40	0.60	0.60
Clinical Operations Director	0.50	0.75	0.75
Surgical Technicians	2.40	2.60	2.60
Surgical Attendant	0.40	0.60	0.60
Radiology Technologists	0.40	0.50	0.60
Pharmacy Technicians II	0.40	0.60	0.60
Sterile Processing Tech III	0.40	0.50	0.60
Supply Chain Associate	0.60	0.80	0.80
Financial Care Counselor	0.50	0.70	0.70
TOTAL	**12.85**	**16.60**	**16.80**

In Section Q Form H Assumptions, the applicant provides the assumptions and methodology used to determine staffing needs. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3 Operating Costs. In Section H.2,

pages 77-78, the applicant describes DUHS's experience and process for recruiting and retaining staff and its proposed training and continuing education programs.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to develop a new, separately licensed freestanding ASF, on the DRAH campus by re-licensing one existing hospital-based operating room OR from the DRAH license.

Ancillary and Support Services

In Section I.1, page 79, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 79-80, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant identifies the necessary ancillary and support services for OR patients located in or near Wake County and how these will be made available.
- The applicant describes how the necessary ancillary and support services will be coordinated with the existing healthcare system.

Coordination

In Section I.2, page 80, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has numerous years of experience serving the needs of OR patients.
- The applicant has established relationships with community health care and ancillary service providers where OR patients can receive appropriate referrals for necessary services related to their condition.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all 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 applicant does 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 applicant does 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.

(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 applicant is 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.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

(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 … persons [with disabilities], 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

DHR ASC is currently not an existing facility. The hospital based OR for the proposed facility is to be relicensed from DRAH. In Exhibit Q, the applicant provides the historical payor mix during the last full fiscal year (7/1/20 to 6/30/21) for surgical services at DRAH, as shown in the following table:

PAYOR CATEGORY	# OF PATIENTS	% OF TOTAL
Self-Pay	35	0.3%
Charity Care	177	1.4%
Medicare*	5,767	45.6%
Medicaid*	510	4.0%
Insurance*	5,610	44.4%
Workers Compensation	88	0.7%
TriCare	269	2.1%
Other	188	1.5%
Total	**100.0%**	**100.0%**

*Including any managed care plans.

In supplemental information requested by the Agency, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	60.26%	51.40%
Male	39.66%	48.60%
Unknown	0.08%	NA
64 and Younger	56.49%	88.00%
65 and Older	43.51%	12.00%
American Indian	0.43%	0.80%
Asian	3.25%	7.70%
Black or African-American	26.58%	21.00%
Native Hawaiian or Pacific Islander	0.13%	0.10%
White or Caucasian	62.27%	67.90%
Other Race	3.80%	NA
Declined / Unavailable	3.56%	NA

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documented 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. Therefore, the application is conforming to this criterion.

(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 persons with disabilities 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, pages 89-90, the applicant states the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 90, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any related entities located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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 91, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below:

PAYOR CATEGORY	% OF TOTAL
Self-Pay	0.2%
Charity Care	1.1%
Medicare*	56.7%
Medicaid*	2.7%
Insurance*	35.4%
Workers Compensation	0.4%
TRICARE	2.2%
Other	1.3%
Total	**100.0%**

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.2% of total surgical services in the OR will be provided to self-pay patients, 56.7% to Medicare patients and 2.7% to Medicaid patients.

In Section L, page 91 the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years 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 of surgical cases at DRAH and a one-time shift of 2.7% from insurance volume to Medicare due to the anticipated aging population.

The Agency reviewed the:

- Application
- Exhibits to the application

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 93, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to develop a new, separately licensed freestanding ASF, on the DRAH campus by re-licensing one existing hospital-based operating room OR from the DRAH license.

In Section M, page 94, the applicant describes 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 M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant serves as a facility for graduate medical training.
- The applicant provides a copy of the Graduate Medical Training Letter of Agreement for Clinical Rotations in Exhibit M.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 applicant proposes to develop a new, separately licensed freestanding ASF, on the DRAH campus by re-licensing one existing hospital-based operating room OR from the DRAH license.

On page 50, the 2022 SMFP states, *"Counties with at least one facility having a licensed OR that are not grouped with another county are single county service areas."* In Figure 6.1, page 55 of the 2022 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in Wake County, and the inpatient and outpatient case volumes for each provider, from pages 66, 67, 79 and 80 of the 2022 SMFP.

Wake County Operating Room Inventory and Cases

	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjust-ments	Adjusted Planning Inventory	IP Surgery Cases	OP Surgery Cases
Duke Health Green Level ASC	0	0	0	0	1	1	0	0
Duke Health Garner ASC	0	0	0	0	1	1	0	0
Duke Raleigh Hospital	0	0	15	0	0	15	3,369	6,575
Duke University Health System Total	**0**	**0**	**15**	**0**	**2**	**17**		
Rex Surgery Center of Cary	0	4	0	0	0	4	0	3,810
Raleigh Orthopedic Surgery Center	0	3	0	0	0	3	0	4,126
Rex Surgery Center of Wakefield	0	2	0	0	0	2	0	2,325
Raleigh Orthopedic Surgery-West Cary	0	1	0	0	0	1	0	0
Rex Hospital (incl. Rex Holly Springs)	3	0	25	-3	-1	27	7,631	10,839
Orthopaedic Surgery Center of Garner	0	0	0	0	1	1	0	0
UNC Health Care System Total	**3**	**10**	**25**	**-3**	**0**	**38**		
WakeMed Surgery Center-Cary	0	0	0	0	1	1	0	0
WakeMed Surgery Center-North Raleigh	0	0	0	0	1	1	0	0
Capital City Surgery Center	0	8	0	0	-1	7	0	6,055
WakeMed (incl. WakeMed North)	8	0	20	-5	-1	22	7,952	11,194
WakeMed Cary Hospital	2	0	9	-2	1	10	2,867	3,681
WakeMed System Total	**10**	**8**	**29**	**-7**	**1**	**41**		
OrthoNC ASC	0	0	0	0	1	1	0	0
RAC Surgery Center	0	0	0	0	1	1	0	0
Surgical Center for Dental Professionals*	0	2	0	0	0	0	0	360
Blue Ridge Surgery Center	0	6	0	0	0	6	0	4,938
Raleigh Plastic Surgery Center^	0	1	0	0	0	1	0	303
Triangle Orthopedic Surgery Center	0	2	0	0	1	3	0	2,497
Wake Spine and Specialty Surgery Center	0	0	0	0	1	1	0	0
Holly Springs Surgery Center	0	3	0	0	0	3	0	2,266
Valleygate Surgery Center	0	0	0	0	1	1	0	0
Total Wake County ORs	**13**	**32**	**69**	**-10**	**11**	**113**		

Source: 2022 SMFP, Table 6A and Table 6B. The table also includes three projects approved pursuant to the 2020 need determination.
^Underutilized facility, excluded from need determination calculations.
*Ambulatory surgery demonstration project included in the inventory, but not included in the need determination calculations.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 95, the applicant states:

> *"The project will promote cost-effectiveness, quality, and access to services and therefore will promote competition in Wake County because it will allow DUHS to create a new point of access for freestanding ASC services and to better meet the needs of its existing patient population and to ensure the timely of services in a new convenient location."*

Regarding the impact of the proposal on cost-effectiveness, in Section N, page 95, the applicant states:

> *"This project will not affect the cost to patients or payors for the services provided by Duke Health Raleigh ASC because reimbursement rates are set by the federal government and commercial insurers. The nominal capital expenditure for this project is necessary to ensure that DUHS will continue to provide high-quality services that are accessible to patients"*

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 95-96, the applicant states:

> *"DUHS Is committed to delivering high quality care at all of its facilities and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its illustrious history of providing patient care."*

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 96, the applicant states:

> *"As previously stated, DUHS will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved."*

See also Sections C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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 Q, Form O, page 127, the applicant identifies four hospitals and six ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.5, page 99, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all three facilities, the applicant 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.

G.S. 131E-183 (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.

NA

The applicant does not propose to increase the number of operating rooms in the service area, therefore, the criteria and standards for surgical services and operating rooms do not apply.