

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 12, 2025

Findings Date: August 12, 2025

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: J-12644-25

Facility: Duke Raleigh Hospital

FID #: 923421

County: Wake

Applicant: Duke University Health System, Inc.

Project: Convert one existing operating room to a hybrid operating room

### 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.

C

Duke University Health System, Inc., (hereinafter referred to as “the applicant” or “DUHS”) proposes to develop a hybrid operating room at Duke Raleigh Hospital (DRAH) by relocating one existing operating room (OR) within the main hospital building and acquiring and installing angiography equipment.

#### **Need Determination**

The applicant does not propose to add any beds, services, or medical equipment for which there is a need determination in the 2025 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

#### **Policies**

There is one policy in the 2025 SMFP applicable to this application: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

#### **Policy GEN-4**

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 30 of the 2025 SMFP states:

*“Any person proposing a capital expenditure greater than \$4 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 are required to submit a plan of 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 proposed capital expenditure for this project is greater than \$5 million. In Section B, page 27, the applicant provides a written statement of its plan to assure improved energy efficiency and water conservation.

#### **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 following:

- The applicant does not propose to develop any beds or services or acquire any medical equipment for which there is a need determination in the 2025 SMFP.

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant states it will include water-conserving and energy-efficient fixtures to the extent consistent with clinical care needs.
- (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 convert one existing operating room to a hybrid operating room. In Section C, page 32, DRAH states that the proposal involves relocating an existing operating room within the main hospital building to create a hybrid operating room by acquiring and installing angiography equipment.

#### **Patient Origin**

On page 49, the 2025 SMFP defines the service area for ORs as “...*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1 on page 55 of the 2025 SMFP shows Wake County as its own OR service area. Thus, the service area for this facility is Wake County. Facilities may also serve residents of counties not included in their service area.

In Section C.3, the applicant provides historical and projected patient origin for vascular surgical procedures at DRAH, as summarized in the following table.

Duke Raleigh Hospital Vascular Surgery Procedures				
County	Historical Last Full FY 7/1/2023 to 6/30/2024		Third Full FY of Operation following Project Completion 7/1/2028 to 6/30/2029	
	Patients	% of Total	Patients	% of Total
Brunswick	3	0.52%	5	0.52%
Cabarrus	3	0.52%	5	0.52%
Caswell	3	0.52%	5	0.52%
Cumberland	6	1.04%	11	1.04%
Duplin	3	0.52%	5	0.52%
Durham	41	7.81%	80	7.81%
Edgecombe	3	0.52%	5	0.52%
Franklin	22	4.17%	43	4.17%
Granville	30	5.73%	58	5.73%
Halifax	3	0.52%	5	0.52%
Harnett	8	1.56%	16	1.56%
Hertford	3	0.52%	5	0.52%
Johnston	33	6.25%	5	0.52%
Moore	6	1.04%	11	1.04%
Nash	11	2.08%	21	2.08%
Onslow	3	0.52%	5	0.52%
Orange	6	1.04%	11	1.04%
Richmond	14	2.60%	27	2.60%
Robeson	6	1.04%	11	1.04%
Sampson	3	0.57%	5	0.52%
Scotland	3	0.52%	5	0.52%
Vance	17	3.13%	32	3.13%
Wake	254	47.92%	489	47.92%
Warren	19	3.65%	37	3.65%
Yancey	3	0.52%	5	0.52%
Virginia	22	4.17%	43	4.17%
Not Reported	6	1.04%	11	1.04%
<b>Total</b>	<b>530</b>	<b>100.0%</b>	<b>1,020</b>	<b>100.0%</b>

Source: Section C, pages 32 and 34-35

In Section C, page 34, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states that

*“DUHS projects that the patient origin for hybrid OR procedures will reflect the current patient origin for the vascular surgery procedures for FY 2024, with total procedures reflecting the methodology described in Section Q. DUHS facility patient origin is projected to be the same as FY 2024 patient origin for all encounters by percentage. DUHS projects a growth of 3% in all facility encounters reflecting historical trends and anticipated future population growth.”*

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

- The applicant states that the projected patient origin for hybrid OR procedures reflects the current patient origin for the vascular surgery procedures for FY 2024.
- The applicant states that the patient origin is projected to be the same as FY 2024 patient origin for all encounters by percentage.

### **Analysis of Need**

In Section C, pages 37-43, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- **Growth in Vascular Procedures at Duke Raleigh Hospital** – The applicant states that the volume of procedures at DRAH that would benefit from being completed in hybrid operating room has grown significantly in recent years :

Duke Raleigh OR Vascular Procedures				
FY2021	FY2022	FY2023	FY2024	FY2025
330	427	417	535	596

Source: Section C, page 38

The applicant states that DRAH's three existing vascular surgeons are already exceeding their current OR block time and that the percentage of cases using hybrid capabilities will rise when the additional capabilities and efficiencies of a Hybrid OR are available.

- **Statewide Population Growth and Demographic Changes** – The applicant states that primary need for the project is to enhance benefits to clinical care and operational efficiency that will provide.

In Section C.4, page 39, the applicant provides the following population projections:

Population Growth 2020-2030				
County	April 2020 Base Population	July 2030 Population Estimate	Numeric Change	Percent Change
Alamance	171,426	195,390	23,964	14
Chatham	76,260	90,949	14,689	19.3
Durham	324,846	365,472	40,626	12.5
Franklin	68,621	94,444	25,823	37.6
Harnett	133,571	158,408	24,837	18.6
Johnston	215,994	290,489	74,495	34.5
Lee	63,280	75,142	11,862	18.7
Orange	148,717	161,200	12,483	8.4
Wake	1,129,352	1,358,482	229,130	20.3
State	10,439,539	11,743,841	1,304,302	12.5

Source: Section C, page 39

The applicant states the North Carolina Office of State Budget and Management (NCOSBM), projects Wake County will grow by a CAGR of 2.0 percent, or 125,304 additional residents, from 2024 to 2029.

<b>Wake County Projected Population Growth</b>	
<b>Year</b>	<b>Wake County Population</b>
2024	1,213,377
2025	1,238,170
2026	1,263,242
2027	1,288,376
2028	1,313,526
2029	1,338,681
CAGR	2.0%

Source: Section C, page 40

The following table summarizes Wake County's projected population growth by age cohort. In total, the service area population aged 65 and older is projected to increase by a CAGR of 4.9 percent during the next five years. The applicant states that the age cohort currently comprises approximately 14.0 percent of the total service area population and is projected to increase to approximately 16.1percent through 2029.

<b>Wake County Projected Population by Age Cohort</b>				
<b>Age Cohort</b>	<b>2024</b>	<b>2029</b>	<b>2024-2029 % Change</b>	<b>2024-2029 CAGR</b>
0-17	249,819	258,779	3.6%	0.7%
18-44	465,464	503,175	8.1%	1.6%
45-64	328,120	360,953	10.0%	1.9%
65+	169,974	215,774	26.9%	4.9%
<b>Total</b>	<b>1,213,377</b>	<b>1,338,681</b>	<b>10.3%</b>	<b>2.0%</b>

Source: Section C, page 40

<b>Wake County Projected Population by Age Cohort- % Make Up</b>		
<b>Age Cohort</b>	<b>2024</b>	<b>2029</b>
0-17	20.6%	19.3%
18-44	38.4%	37.6%
45-64	27.0%	27.0%
65+	14.0%	16.1%
<b>Total</b>	<b>100.0%</b>	<b>100/0%</b>

Source: Section C, page 40

The applicant states that in addition to the acute care services area of Wake County, many patients from adjacent counties and throughout North Carolina travel to DRAH for services including vascular surgery.

Projected Population, 2024- 2029				
Year	Durham	Franklin	Johnston	North Carolina
2024	340,727	80,236	249,714	10,984,106
2025	344,479	83,560	257,510	11,115,657
2026	348,463	85,740	264,489	11,241,251
2027	352,600	88,416	270,871	11,365,033
2028	356,845	91,277	276,822	11,489,769
2029	361,162	93,267	282,452	11,614,476
<b>CAGR</b>	<b>1.2%</b>	<b>3.1%</b>	<b>2.5%</b>	<b>1.1%</b>

Source: Section C, page 41

- The applicant states that the demographic data demonstrates there is a large and growing population in the counties from which DRAH patients reside.
- **High and Increasing Utilization of DUHS Provider Network, Patient Population, and Surgical Utilization** – The applicant states that the growth in vascular surgery cases at DRAH’s steady growth in surgery services more broadly, including procedures performed in operating rooms and in procedure rooms, as set forth in the following table:

Duke Raleigh Hospital Surgical Cases					
	FY2022	FY2023	Annualized FY2024	FY22-Annualized FY24 CAGR	FY2023 to Annualized FY2024
Total IP Cases	2,824	3,236	3,236	11.1%	7.7%
Total OP Cases	13,042	13,129	14,140	4.1%	7.7%
<b>Total Surgical Cases</b>	<b>15,866</b>	<b>16,365</b>	<b>17,626</b>	<b>5.4%</b>	<b>7.7%</b>

Source: Section C, page 41

- The applicant states that the growth of Duke Health Network in Wake County is supported by the demand of historical and projected demand of DRAH’s services.
- The applicant states that DUHS has committed to recruiting additional providers to serve this growing population.
- The applicant states that the number of Wake County “lives touched” by DUHS primary care providers increased by 6.1% from FY2019 to FY 2023 and the primary care visits provided by a DUHS primary care physician at a location in Wake County have increased by 9.5% from FY 2019 to FY 2023 as shown below.

Duke Primary Care – Wake County						
	FY2019	FY2020	FY2021	FY2022	FY2023	CAGR
Wake County Residents Lives Touched	115,928	119,759	122,407	139,606	146,656	6.1%
Primary Visits in Wake County Locations	306,839	321,895	335,744	401,100	440,982	9.5%

Source: Section C, page 43

- The applicant states that DUHS anticipates that its growth in primary care and other specialty physician categories will continue to drive the need for DUHS’s highly specialized services, including vascular surgery, in Wake County.
- The applicant states that the need for this project is driven by the clinical benefits of providing vascular surgery in a hybrid operating room environment.

- The applicant states that DUHS anticipates a continue demand for these services based on demographic trends in the area, as well as growth in DUHS's referral network and patient population.

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

- The applicant provides data showing the growth in vascular procedures at DRAH that would benefit from being performed in a hybrid operating room.
- The applicant provides data showing the projected growth and aging in the service area population.
- In Exhibit C.4, the applicant provides letters from surgeons expressing support for the proposed project.

### Projected Utilization

In Section Q, pages 90-91, the applicant provides historical and projected utilization, as illustrated in the following tables:

Current Duke Vascular of Raleigh Surgeons					
	FY2021	FY2022	FY2023	FY2024	CAGR
<b>Total</b>	330	395	366	530	17.1%

Source: Section Q, page 90

	FY 2024 Actual	2025	2026	2027	2028	2029
DRAH Hybrid Potential Procedures (3 existing providers)	530	583	641	705	765	765
Projected DRAH Hybrid Procedures (Incremental provider)			128	191	255	255
	<b>530</b>	<b>583</b>	<b>769</b>	<b>897</b>	<b>1,020</b>	<b>1,020</b>

Source: Section Q, page 91

In Section Q, pages 90-91, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant states that the approach is consistent with the approved application for an additional hybrid operating room at Duke University Hospital in J-11851-20, where utilization was projected based on the rooms' total capacity.
- The applicant states that by the third project year, DRAH will have four vascular surgeons scheduled for procedures in the hybrid operating room.
- The applicant states that the total utilization of this room is projected to be consistent with the full ramped-up volume for all four providers. In FY 2024, the total encounters performed by Duke Raleigh's Vascular provider group was 530. This group consists of 3 providers.
- The applicant states that an assumed annual case load per provider of 255.
- The applicant states that DRAH assumes that the newly recruited provider joining DRAH in FY 2026 will ramp up to 255 procedures/year by FY 2029, with 50% of capacity reached



- in the first year of joining the medical staff (FY 2026), 75% in FY 2027, and 100% in FY 2028, consistent with utilization growth after joining the practice.
- The applicant states that by reaching this total volume by FY 2029 would reflect an annual growth in vascular surgery procedures of 14.0% (an annual growth rate of 17.7% if growth achieved by FY 2028).

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

- Projected utilization is based on historical utilization at DRAH from FY2021 to FY 2024.
- In Exhibit C.4, the applicant provides letters from surgeons expressing support for the proposed project.

### **Access to Medically Underserved Groups**

In Section C, page 48, 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 this service, as clinically appropriate. DUHS does not and will not discriminate based on race, ethnicity, age, gender, or disability.”*

In Section C, page 49, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	12.1%
Racial and ethnic minorities	37.5%
Women	63.4%
Persons with Disabilities	N/A
Persons 65 and older	45.5%
Medicare beneficiaries	47.9%
Medicaid recipients	8.1%

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:

- The applicant provides a statement that it provides services to people in need of medical care including the medically underserved and it will continue to do so following the proposed project.
- The applicant provides a copy of DUHS’s Non-Discrimination Policy which is used by DRAH.

## **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.

- (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 does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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.

C

The applicant proposes to convert one existing operating room to a hybrid operating room.

In Section E, page 57, the applicant describes the alternatives it 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 would limit the scope of procedures that can be provided and entail longer case times than would be achieved with a hybrid operating room.
- **Upgrade its current platform**: The applicant states that by replacing the existing injector and acquiring additional portable angiography equipment.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant's proposal is the most effective alternative to meet the growing demand for providing vascular surgery procedures is to create a state-of-the art hybrid OR environment.

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory review criteria. Therefore, the application can be approved.

## **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. Therefore, the application is approved subject to the following conditions:

- 1. Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall convert one existing operating room to a hybrid operating room by acquiring and installing angiography equipment at Duke Raleigh Hospital.**
- 3. 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 January 1, 2026.**
- 4. 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.**
- 5. The certificate holder 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.**

**6. 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 convert one existing operating room to a hybrid operating room.

**Capital and Working Capital Costs**

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

<b>DRAH Hybrid OR Projected Capital Cost</b>	
Construction/Renovation Contract(s)	\$2,990,610
Architect/Engineering Fees	\$407,000
Medical Equipment	\$3,197,712
Non Medical Equipment	\$110,000
Furniture	\$10,000
Contingency	\$339,761
<b>Total</b>	<b>\$7,055,083</b>

In Section F, page 60, the applicant states there will be no start-up costs or initial operating expenses because the applicant proposes the relocation of an existing operating room.

In Section Q, page 92 and Exhibit F.1a and F.1b, the applicant provides the assumptions used to project the capital cost.

The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibits F.1a and F.1b and Section Q, the applicant provides construction costs for this project are based on the input from the project architect, included at Exhibit F.1(a). The equipment costs are based on project estimates from the project champions as documented in Exhibit F.1(b).
- The applicant states that the nonmedical costs and other project costs were provided by DUHS Facility Planning Design and Construction staff based on prior project experience.

**Availability of Funds**

In Section F, page 58, the applicant states that the capital cost will be funded through the accumulated reserves of Durham University Health System. Exhibit F.2a contains a letter dated April 14, 2025, from the Senior Vice-President, Chief Financial Officer, Treasurer for Duke University Health System stating that the capital cost for the proposed project will be funded with accumulated reserves. Exhibit F.2b contains a copy of DUHS audited financial statements for the year ending June 2024. As of June 2024, DUHS had sufficient reserves for the proposed project.

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

- The applicant provides documentation of Duke University Health System commitment to use the necessary funding toward development of the proposed project in Exhibit F.2 of the application.
- The applicant documents the availability of sufficient financial resources to fund the proposed capital cost in Exhibit F.2 of the application.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following project completion. The following table shows the projections for hybrid OR procedures services:

<b>DRAH - Hybrid OR Procedures</b>			
	<b>1<sup>st</sup> Full FY 7/1/26-6/30/27</b>	<b>2<sup>nd</sup> Full FY 7/1/27-6/30/28</b>	<b>3<sup>rd</sup> Full FY 7/1/28-6/30/29</b>
Total Hybrid OR Procedures	897	1,020	1,020
Total Gross Revenues (Charges)	\$58,205,326	\$66,210,279	\$66,210,279
Total Net Revenue	\$17,385,547	\$20,230,278	\$20,949,318
Average Net Revenue per OR	\$19,382	\$19,834	\$20,539
Total Operating Expenses (Costs)	\$10,561,997	\$12,271,586	\$12,668,992
Average Operating Expense per OR	\$11,775	\$12,031	\$12,421
Net Income	\$6,832,551	\$7,958,693	\$8,280,326

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant explains how it accounts for projected operating expenses and explains its revenue projections.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 costs are based on reasonable and adequately supported assumptions for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - 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 revenues and operating expenses for all the reasons described above.
- (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 convert one existing operating room to a hybrid operating room.

The 2025 SMFP defines the service area for OR as “*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1, on page 55, shows Wake County is a single county operating room service area. Therefore, the service area is Wake County. Facilities may also serve residents of counties not included in their service area.

The applicant states that there is not a comprehensive inventory of facilities that operate hybrid operating rooms. None of the existing Wake County hospitals currently report hybrid operating rooms on their most recent hospital license renewal applications. The applicant states that Duke University Hospital operates hybrid operating rooms in Durham County.

In Section G, page 66, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved operating room services in Wake County. The applicant states:

*“...the need for hybrid operating room capacity is to treat more effectively and efficiently patients already seeking services at Duke Raleigh Hospital and in the Duke University Health System. This functionality is specifically needed to meet the demand for this existing and projected patient population, and does not duplicate the equipment that may be available for patients at other providers. To the extent that Duke University Hospital operates a hybrid operating room, the Duke Raleigh Hospital project provides a more convenient option for patients who would otherwise need to travel to a different county for these services.*”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in Wake County based on the following:

- The proposal would not result in an increase in the number of ORs in Wake County.
- The applicant adequately demonstrates that there is a need for the proposed hybrid OR to more effectively and efficiently treat patients seeking vascular surgery services at Duke Raleigh Hospital and in the Duke University Health System.

### **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.

- (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 convert one existing operating room to a hybrid operating room.

In Section Q, Form H Staffing, the applicant provides the current and projected full-time equivalent (FTE) positions for the proposed hybrid OR services at DRAH for the first three full fiscal years, summarized below:

<b>Duke Raleigh Hospital Staffing Hybrid OR Services</b>				
<b>Positions</b>	<b>Current Staff 12/31/2023</b>	<b>1<sup>st</sup> Full FY FFY2027</b>	<b>2<sup>nd</sup> Full FY FFY2028</b>	<b>3<sup>rd</sup> Full FY FFY2029</b>
Registered Nurses	5.9	7.0	9.0	9.0
Physician Assistant	0.5	1.0	1.0	1.0
Interventional Technician	2.5	4.5	4.5	4.5
Nurse Anesthetists	1.0	2.0	2.0	2.0
Surgical Technicians	5.6	5.7	6.0	6.4
<b>Total</b>	<b>15.4</b>	<b>14.5</b>	<b>16.5</b>	<b>16.5</b>

The assumptions and methodology used to project staffing are provided in Section H and Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3(b). In Section H, pages 68-69, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant states that DUHS uses the internet actively to recruit clinical and non-clinical staffing, utilizes social medical platforms, and newspaper advertisements.
- The applicant adequately demonstrates its methods to train and retrain staff , as well as provide continuing education.

### **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.

- (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 convert one existing operating room to a hybrid operating room.

### **Ancillary and Support Services**

In Section I, page 71, the applicant identifies the necessary ancillary and support services for the proposed OR and vascular surgery services. On page 71, 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.

### **Coordination**

In Section I, page 72, 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 states Duke Raleigh Hospital is operated under the CMS provider number of Duke University Hospital, an Academic Medical Center Teaching Hospital that serves



- as a primary teaching location for medical students, residents, fellows, nurses, and other health care professionals.
- The applicant states that Duke Graduate Medical Education includes more than 160 residency and fellowship programs, with over 1,000 trainees.
  - The applicant states that Duke Raleigh Hospital also provides training opportunities for students in the area, including students from UNC, Wake Tech, and other local training programs and community investments and collaborations.

### **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.

- (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

- (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

The applicant proposes to convert one existing operating room to a hybrid operating room.

In Section K, page 74, the applicant states that the project involves renovating 1,403 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 74, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the applicant's experience developing hybrid operating rooms at Duke University Hospital, the applicant has worked with an architect to develop a cost-effective plan to implement the equipment necessary to create hybrid functionality in existing space in the surgical platform at Duke Raleigh Hospital

On page 75, the applicant adequately explains 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 based on the following:

- The applicant states that the reimbursement for these services by patients and payors are set by government or contracted rates that will not change as the result of this project.
- The applicant states that the costs of the project are necessary to provide the additional functionality, which will improve efficiency and access to critical patient care services

On page 27, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit F.1(a).

### **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.

- (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

In Section L, page 77, the applicant provides the historical payor mix during FY2024 for DRAH , as shown in the table below.

Duke Raleigh Hospital Historical Payor Mix, FY2024	
Payor Source	Percentage of Total Patients Served
Self-Pay	0.8%
Charity Care	3.4%
Medicare	46.8%
Medicaid	7.9%
Insurance	38.7%
Workers Compensation	0.2%
TRICARE	1.4%
Other (all other)	0.9%
<b>Total</b>	<b>100.0%</b>

Source: Section L, page 77

In Section L, page 78, the applicant provides the following comparison.

Duke Raleigh Hospital	Percentage of Total Patients Served by the Facility during the Last Full FY	Percentage of the Population of the Service Area
Female	63.4%	451.0%
Male	36.6%	49.0%
Unknown		
64 and Younger	55.3%	86.6%
65 and Older	44.7%	13.4%
American Indian	0.5%	0.8%
Asian	3.2%	9.4%
Black or African-American	25.6%	20.6%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	62.5%	66.3%
Other Race	3.9%	0.0%
Declined / Unavailable	4.2%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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 78-79, the applicant states it has no such obligation.

In Section L, page 79, the applicant states that no patient civil rights access complaints have been filed against Duke Raleigh Hospital in the 18 months immediately preceding the application deadline.

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 80, 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.

Duke Raleigh Hospital Hybrid OR Procedures Projected Payor Mix, FY 2029	
Payor Source	Percentage of Total Patients Served
Self-Pay	1.0%
Charity Care	1.5%
Medicare	73.8%
Medicaid	6.8%
Insurance	16.9%
Other govt payors including Tricare	100.0%
<b>Total</b>	<b>1.0%</b>

Source: Section L, page 80

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.0% of total services will be provided to self-pay patients, 1.5% to charity care patients, 73.8% to Medicare patients and 6.8% to Medicaid patients.

On page 80, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the applicant's historical payor mix for the hybrid OR procedures for FY2024.

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.

- (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 82, 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 convert one existing operating room to a hybrid operating room.

In Section M, page 83, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility.

**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.

- (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 convert one existing operating room to a hybrid operating room.

On page 49, the 2025 SMFP defines the service area for OR as “*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1, on page 55, shows Wake County is 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 applicant states that there is not a comprehensive inventory of facilities that operate hybrid operating rooms. None of the existing Wake County hospitals currently report hybrid operating

rooms on their most recent hospital license renewal applications. The applicant states that Duke University Hospital operates hybrid operating rooms in Durham County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, the applicant states:

*“The project will have a positive effect on competition by creating hybrid OR functionality at a new provider in Wake County and will allow patients who seek Duke services to access them within the service area.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 84, the applicant states:

*“This project will not directly affect the charges or reimbursement for services for patients or payors for the proposed services because reimbursement rates are set by the federal government and commercial insurers. However, reducing procedure time and increasing access to services in Wake County, this project may reduce costs for both the hospital and for patients who would otherwise need to travel for services.*

*DUHS will continue to participate in initiatives aimed at promoting cost-effectiveness and optimizing quality healthcare. For example, Duke Connected Care, the physician-led accountable care organization (ACO) formed by Duke Health to improve health outcomes and address the national challenge of rising healthcare costs, saved Medicare \$19 million in 2022, the most recent year for which results have been reported. Duke’s ACO, which also exceeded evidence-based quality standards, generated the most cost savings among North Carolina ACOs participating in the Medicare Shared Savings Program, an initiative of the Centers for Medicare & Medicaid Services (CMS). The Duke ACO’s participants include the health system and its three existing hospitals, Duke Primary Care, Duke Health Integrated Practice, Inc., and independent community providers in a seven-county region around the greater Triangle. Providing this service at the hospital also ensures that patients who may have insurance network limitations continue to have access to the services within the county.”*

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

Regarding the impact of the proposal on quality, in Section N, pages 84-85, 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 long history of providing patient care. DUHS has robust quality-related policies and procedures, and its quality management programs emphasize a customer-oriented perspective that is used to determine the needs of patients, physicians, and others who utilize hospital services.”*

See also Sections O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 85, the applicant states:

*“This project will improve access to these procedures in Wake County, providing more convenient care and better access for patients, especially those with transportation challenges, who would otherwise have to travel to Durham County for access to Duke-provided services if that is their choice. Section L.3 includes payor mix projections that demonstrate DUHS’s commitment to ensuring access for medically underserved patients. The initiatives described in response to Policy GEN-5 questions are designed to promote equitable access to care, but this demands necessary capacity to provide the care that patients need. Therefore, this project will promote access.”*

See also Section L and C 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 all the reasons described 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.



The applicant proposes to convert one existing operating room to a hybrid operating room.

In Section Q, Form O, page 9, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 14 of these types of facilities located in North Carolina.

In Section O, page 86, the applicant states that, during the 18 months immediately preceding the submittal of the application, two incidents related to quality of care occurred in Maria Parham Hospital and Wilson Medical Center of these facilities. The applicant states that all the problems have been corrected. 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, incidents related to quality of care occurred in Maria Parham Hospital and Wilson Medical Center of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 14 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 proposes to convert one existing operating room to a hybrid operating room. The applicant does not propose to increase the number of operating rooms in the service area. Therefore, there are no rules that apply to the proposed project.