

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 29, 2020

Findings Date: June 4, 2020

Project Analyst: Tanya M. Saporito

Assistant Chief: Lisa Pittman

Project ID #: J-11851-20

Facility: Duke University Hospital

FID #: 943138

County: Durham

Applicant(s): Duke University Health System, Inc.

Project: Acquire no more than one unit of angiography equipment to install in an existing OR and create a hybrid OR

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Duke University Health System, Inc. (DUHS or “the applicant”), operates Duke University Hospital (DUH), an acute care hospital located in Durham. DUHS also operates Duke Regional Hospital in Durham County and Duke Raleigh Hospital in Wake County. In this application, DUHS proposes to acquire one unit of angiography equipment to install in an existing operating room (OR) and create a hybrid OR at the DUH campus in Durham. DUHS currently operates two units of angiography equipment in two hybrid ORs. Upon project completion, the applicant would be licensed for three units of angiography equipment in three hybrid ORs. DUH is currently licensed for a total of 65 ORs (50 shared, 6 inpatient and 9 outpatient). This proposal will not change the licensed complement of ORs at DUH.

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 2020 State Medical Facilities Plan (2020 SMFP).

Policies

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities on page 31 of the 2020 SMFP is applicable to this review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

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

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

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

In Section B, page 15, the applicant explains why it believes its application is conforming to Policy GEN-4. The applicant states:

“DUHS will ensure the project will be pursued in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including 2020 SMFP Policy GEN-4... including water conservation ...”

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 based on the following:

- The applicant does not propose to develop any beds, services or equipment for which there is a need determination in the 2020 SMFP.
- The applicant does not propose to add any ORs to the inventory of ORs in Durham County.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 as stated above.

(2) Repealed effective July 1, 1987.

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

C

DUHS proposes to acquire one unit of angiography equipment and install it in what is currently internally designated as OR #54 at the DUH campus in Durham. By installing the proposed angiography equipment, DUH will convert OR #54 into a hybrid OR. The project involves renovating a portion of the adjacent sterile core and adjacent hybrid OR #53's control room to create a new control room to serve both hybrid ORs. The existing OR #54 will also be renovated to accommodate the proposed angiography equipment.

Patient Origin

The 2020 SMFP does not define a service area for angiography equipment.

In Sections C.2, pages 16-17, the applicant provides historical patient origin for procedures performed in DUH's existing hybrid ORs; and in C.3, pages 17-18, the applicant provides projected patient origin for the proposed project for the first three full fiscal years (FY) following project completion. The projected patient origin is the same in all three project years; therefore, the Project Analyst shows the future patient origin in just one column, as illustrated in the following table:

DUH Historical and Projected Patient Origin

COUNTY	% OF PATIENTS	
	HISTORICAL 7/1/18- 6/30/19	PROJECTED ALL THREE PROJECT YEARS
Alamance	3.35%	3.35%
Caswell	1.00%	1.00%
Chatham	0.81%	0.81%
Cumberland	3.44%	3.44%
Durham	18.64%	18.64%
Franklin	0.90%	0.90%
Granville	4.80%	4.80%
Guilford	2.08%	2.08%
Harnett	1.54%	1.54%
Johnston	0.72%	0.72%
Lee	0.90%	0.90%
Nash	1.00%	1.00%
Orange	3.53%	3.53%
Person	4.16%	4.16%
Robeson	2.90%	2.90%
Vance	4.07%	4.07%
Wake	9.41%	9.41%
Warren	1.18%	1.18%
Wilson	0.63%	0.63%
Other NC Counties	21.72%	21.72%
Virginia	8.14%	8.14%
Other States	5.07	5.07
Total	100.0%	100.0%

Source: application pages 16-18

Facilities may also serve residents of counties not included in their service area.

In Section C, page 19, the applicant provides the assumptions and methodology used to project its patient origin. The applicant assumes patient origin for the proposed hybrid OR will be the same as the two existing hybrid ORs at DUH. The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s experience providing the same service in the same service area.

Analysis of Need

In Section C, pages 19-21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- The applicant describes what a hybrid OR is and its benefits to patients and clinicians, because it allows a multidisciplinary team to perform complex interventional procedures on emergency and non-emergency patients in one single surgery site (page 19).

- DUH currently operates two hybrid ORs (OR #33 and OR #53). In FY 2019, the applicant performed 1,176 cases in the two, existing hybrid ORs, but states that those numbers may be artificially lower than the actual number of cases, because OR team members click a button to document the use of angiography equipment in the hybrid ORs. Since it is a manual method of recording, the actual numbers may be higher. See the following table that illustrates the percentages of cases performed in FY 2019 in DUH’s two hybrid ORs:

DUH FY 2019 Hybrid OR Cases Using Angiography Equipment

CASE TYPE	OR #33		OR #53	
	# CASES	% OF CASES USING ANGIOGRAPHY EQUIPMENT	# CASES	% OF CASES USING ANGIOGRAPHY EQUIPMENT
Vascular	631	77.0%	0	88.0%
Cardiothoracic	0		486	
Other	11		48	
Total # Cases	642		534	

*Source: Application pages 19-20

- The applicant states the hybrid OR will provide the surgical team with additional flexibility for a number of reasons, even if the proposed angiography equipment is not needed for a particular surgical procedure. Ultimately, patient throughput and efficiency will benefit from this proposal (page 20).
- DUH’s existing hybrid ORs are highly utilized. In calendar year (CY) 2019, the combined utilization of the two hybrid ORs during scheduled block time was more than 70%. The applicant states the complexity of the cases typically performed in a hybrid OR combined with the high percentage of emergent cases at DUH result in some cases that would benefit from a procedure in a hybrid OR being delayed, which means patients are not effectively served. The addition of a third hybrid OR would decrease the patient delays and still accommodate emergency procedures that may arise (page 20).
- The proposed development of the hybrid OR with angiography equipment will provide an environment for minimally invasive procedures in the future, which the applicant states is needed at DUH. The applicant states the U.S. Food and Drug Administration (FDA) in 2019 approved transcatheter aortic valve replacement (TAVR) procedures for all patients with a low risk of death or major complications associated with open heart surgery. The applicant states DUH cardiothoracic surgeons currently have a wait list for patients who need the TAVR procedure, and without an additional hybrid OR, the wait list will grow (pages 20-21).
- Additional minimally invasive surgical procedures that use a hybrid OR environment continue to be performed at DUH, as the hospital participates in

clinical trials for mitral valve repair and Delcath chemotherapy (a targeted chemotherapy treatment). The applicant states it anticipates it will participate in additional clinical trials in the future (page 21).

- Population growth in DUH’s service area is projected to increase by 9.5%, which the applicant states is two times the national average population growth. The applicant states the increased population will also drive the need for additional hybrid OR capacity at the hospital (page 21).

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

- The applicant bases its need for the proposed angiography equipment and hybrid OR on cases performed in the existing hybrid ORs and the continued issue of delaying surgical procedures that could be performed in a hybrid OR.
- The applicant anticipates performing additional TAVR procedures and continuing to participate in clinical trials, which drive the need for additional hybrid OR capacity at DUH.
- Population growth in DUH’s service area is projected to increase.

Projected Utilization

In Section Q, the applicant provides historical and projected utilization, as illustrated in the following table:

HYBRID OR EQUIPMENT	PRIOR FULL FY (7/1/18-6/30/19)	INTERIM FULL FY (7/1/19-6/30/20)	INTERIM FULL FY (7/1/20-6/30/21)	1 ST FULL FY (7/1/21-6/30/22)	2 ND FULL FY (7/1/22-6/30/23)	3 RD FULL FY (7/1/23-6/30/24)
# Units	2	2	3	3	3	3
# Procedures	1,105	1,127	1,197	1,658	1,681	1,705

In Section Q, page 69 the applicant provides the assumptions and methodology used to project utilization, as summarized below:

- The applicant states that it does not anticipate overall surgical volume to increase as a result of this project. The proposed hybrid OR will instead provide surgeons with flexibility they need to accommodate patient needs and hybrid OR equipment availability. The project will create more efficient block time scheduling for surgeons, which the applicant states will provide innovative, best-practice treatment options rather than volume growth.
- The applicant states that in FY 2019, the total encounters in the existing hybrid ORs were 1,105. The applicant projects the third (proposed) hybrid OR would begin each

project year with a baseline number equal to 50% of the total number of procedures performed in FY 2019, or 553 [1,105 / 2 = 553].

- In the first two interim years, the applicant projects a ramp-up period in which utilization will increase by 2% annually, consistent with the applicant’s historical experience and population growth projections.
- In the second interim year, (FY 2021), the applicant projects 47 procedures during the first 2 months of the project.
- Beginning in the first full FY of the project, with the third hybrid OR completely functioning, the applicant projects hybrid OR volume in all three ORs will equal 1.5 times the current hybrid OR volume [baseline of 1,105 + 553, or 1.5 times 1,105].
- In each of the remaining two project years, the applicant projects volume will increase by 1.4%, which the applicant states is consistent with historical patterns. See the following table, prepared by the project analyst from information in Section Q that illustrates the projections:

DUH Historical and Projected Utilization, Hybrid ORs

	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Baseline Procedures (2 hybrid ORs)	1,105	1,105	1,105	1,105	1,105	1,105
First 2 months project ramp-up			47			
Additional OR, begin at ½ the volume of existing ORs	-	-		553	553	553
Growth of 2%		22	45			
Growth of 1.4% annually in three hybrid ORs					23	47
Total Procedures in Hybrid ORs	1,105	1,127	1,197	1,658	1,681	1,705

Numbers may not sum due to rounding

The applicant’s fiscal years are from July 1 to June 30.

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

- Projected utilization is based on the applicant’s historical experience in the existing hybrid ORs at DUH projected population growth in the area.
- The applicant’s projections are based on the internal needs of the DUH surgeons and the need of the population served by DUH in the hybrid ORs.

Access

In Section C, page 26, the applicant states services at DUH are available to all service area and non-service area residents and it will not discriminate based on race, ethnicity, age, gender or disability. The applicant provides a copy of DUHS’s non-discrimination policy in Exhibit C.11. In Section L, page 58, the applicant projects payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table:

DUH Projected Payor Mix, Second FY

PAYOR SOURCE	ENTIRE DUH	HYBRID OR
Self-Pay	0.39%	0.54%
Charity Care	2.19%	0.72%
Medicare*	45.22%	57.94%
Medicaid*	12.51%	11.98%
Insurance*	34.71%	21.67%
Workers Compensation	0.28%	0.10%
TRICARE	1.96%	0.14%
Other	2.74%	6.92%
Total	100.00%	100.00%

Source: Application page 58

Numbers may not sum due to rounding by Project Analyst

The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix for the same services.

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 following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the replacement linear accelerator proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

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.

CA

DUHS proposes to acquire one unit of angiography equipment and install it in what is currently internally designated as OR #54 at the DUH campus in Durham. By installing the proposed angiography equipment, DUH will convert OR #54 into a hybrid OR.

In Section E, page 35, the applicant states the project proposes to accommodate the existing demand for surgical services at DUH more efficiently and with optimal resources, and there was no other option available to the applicant than the proposal to acquire angiography equipment and convert and exiting OR to a hybrid OR. Therefore, there were no alternatives considered for this application.

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. shall materially comply with all representations made in the certificate of need application.**
- 2. Duke University Health System, Inc. shall acquire no more than one unit of angiography equipment to be installed in OR #54 and develop a hybrid operating room.**
- 3. Upon completion of the project, Duke University Hospital shall be licensed for no more than 65 ORs.**
- 4. Duke University Health System, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**

5. **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, Duke University Health System, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. **Payor mix for the services authorized in this certificate of need.**
 - b. **Utilization of the services authorized in this certificate of need.**
 - c. **Revenues and operating costs for the services authorized in this certificate of need.**
 - d. **Average gross revenue per unit of service.**
 - e. **Average net revenue per unit of service.**
 - f. **Average operating cost per unit of service.**
6. **Duke University Health System, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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

DUHS proposes to acquire one unit of angiography equipment and install it in what is currently internally designated as OR #54 at the DUH campus in Durham. By installing the proposed angiography equipment, DUH will convert OR #54 into a hybrid OR.

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:

ITEM	COST
Site Costs	\$0
Construction Costs	\$1,922,999
Medical Equipment	\$2,430,407
Miscellaneous Costs	\$324,593
Total	\$4,677,999

In Section F.3, page 38, the applicant states that there are no start-up or initial operating expenses, as this is not a new service.

In Section Q, the applicant provides the assumptions used to project the capital cost. Exhibits F.1(a) and F.1(b) contain supporting documentation.

Availability of Funds

In Section F.2, page 36, the applicant states that the capital cost will be funded as shown in the table below.

SOURCES OF CAPITAL COST FINANCING	
TYPE	TOTAL
Loans	
Accumulated Reserves/ Investments or OE *	\$4,677,999
Bonds	
Other (Specify)	
Total Financing	\$4,677,999

*OE = Owner’s Equity

In Section F, page 37, the applicant states it will use accumulated reserves to fund the capital cost of the project. In Exhibit F.2(a), the applicant provides a January 31, 2020 letter from DUHS’s Senior Vice President and Chief Financial Officer & Treasurer that confirms the availability of the funds and the commitment of the funds to the project. The applicant also provides DUHS’s audited financial statements for fiscal years ending 2018 and 2019 in Exhibit F.2(a).

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:

	1 ST FULL FY FY 2022	2 ND FULL FY FY 2023	3 RD FULL FY FY 2024
Total Procedures (From Form C)	1,658	1,681	1,705
Total Gross Revenues (Charges)	\$13,222,531	\$13,765,018	\$17,182,887
Total Net Revenue	\$4,173,699	\$4,348,141	\$4,506,683
Average Net Revenue per patient encounter	\$2,517.31	\$2,586.64	\$2,643.22
Total Operating Expenses (Costs)	\$3,961,399	\$4,127,119	\$4,277,734
Average Operating Expense patient encounter	\$2,389.26	\$2,455.16	\$2,508.93
Net Income	\$212,300	\$221,022	\$228,949

Totals may not sum due to rounding

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

DUHS proposes to acquire one unit of angiography equipment and install it in what is currently internally designated as OR #54 at the DUH campus in Durham. By installing the proposed angiography equipment, DUH will convert OR #54 into a hybrid OR.

The 2020 SMFP does not define a service area for angiography equipment or hybrid ORs. In Section C, pages 16-18, the applicant defines its service area for its existing hybrid ORs, as shown in the following table:

COUNTY	DUH HYBRID OR PATIENT ORIGIN	
	# PTS.	% OF TOTAL
Alamance	37	3.35%
Caswell	11	1.00%
Chatham	9	0.81%
Cumberland	38	3.44%
Durham	206	18.64%
Franklin	10	0.90%
Granville	53	4.80%
Guilford	23	2.08%
Harnett	17	1.54%
Johnston	8	0.72%
Lee	10	0.90%
Nash	11	1.00%
Orange	39	3.53%
Person	46	4.16%
Robeson	32	2.90%
Vance	45	4.07%
Wake	104	9.41%
Warren	13	1.18%
Wilson	7	0.63%
Other NC Counties	240	21.72%
Virginia	90	8.14%
Other States	56	5.07%
Total	1,105	100.00%

Facilities may also serve residents of counties not included in their service area.

In Section G, page 42, the applicant states hybrid OR utilization is not separately reported from other OR utilization. Additionally, the applicant states:

“The project is not creating any new facility or operating rooms. Rather, it simply provides Duke with greater flexibility to accommodate its existing surgical services in the optimal environment for patient care, by enhancing the capabilities within Duke’s existing surgical platform.”

DUH is currently licensed for a total of 65 operating rooms and upon project completion, will be licensed for 65 total operating rooms.

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

- The applicant proposes to acquire angiography equipment and create a hybrid OR adjacent to an existing hybrid OR to better serve its patients and accommodate surgeons and schedules.

- The proposal would not result in an increase in the number of operating rooms in the service area.
- The applicant adequately demonstrates that the proposed angiography equipment and hybrid OR is needed in addition to the existing or approved hybrid ORs.

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

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services for the first three project years (PY), as illustrated in the following table:

POSITION	CURRENT STAFF	PROJECTED STAFF		
	AS OF 12/31/2019	1 ST FULL FY (7/1/21-6/30/22)	2 ND FULL FY (7/1/22-6/30/23)	3 RD FY (7/1/23-6/30/24)
Nurse Practitioner	0.10	0.10	0.10	0.10
Registered Nurse	255.77	266.10	271.42	276.85
Surgical Technicians	78.48	81.65	83.28	84.95
Aides/Orderlies	1.71	1.78	1.82	1.85
Laboratory Technicians	0.03	0.03	0.03	0.03
Radiology Technologists	0.03	0.03	0.03	0.03
Respiratory Therapists	0.20	0.21	0.21	0.22
Materials Management	0.12	0.12	0.13	0.13
Administrator (Nurse Mgr)	4.00	4.00	4.00	4.00
Cardiology Technician	4.36	4.54	4.63	4.72
Total	344.79	358.56	365.65	372.88

The assumptions and methodology used to project staffing are provided in Section H. In Section H, page 43, the applicant states it does not anticipate hiring any new staff as a result

of this project, and the addition of angiography equipment to an existing OR will not impact staffing. The applicant states it will continue to fill any vacancies that may arise. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 43 and 44, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 47, the applicant identifies the current chief medical officer of the hospital and the current medical director of Periop Services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 for the reasons stated above

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

C

In Section I, page 45, the applicant states that the following ancillary and support services are necessary for the proposed services

- Administration
- Business office
- Medical records
- Professional services (physicians)
- Nursing
- Pharmacy
- Medical supplies
- Imaging
- Laboratory/pathology
- Social services
- Therapy
- Food & Nutrition services
- Housekeeping
- Linen service
- Materials management
- Pastoral care

- Facility maintenance

On page 45, the applicant adequately explains that each ancillary and support service is already available at DUH and will continue to be made available following project completion. provides supporting documentation in Exhibit I.1.

In Section I, page 46, the applicant describes its existing relationships with other local health care and social service providers and provides physician letters of support in Exhibit C.4.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care 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.

- (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. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;

- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The 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.

C

In Section K, page 51, the applicant states that the project involves renovating 1,543 square feet of existing space to accommodate the angiography equipment and convert the existing OR #54 into a hybrid OR. Line drawings are provided in Exhibit K.2.

On page 51 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal, and why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 52, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans, and references Policy GEN-4 and its requirements to ensure energy conservation and efficiency.

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.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as

medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section L, page 55, the applicant provides the historical payor mix during its FY 2019 (7/1/18-6/30/19) for the proposed services, as shown in the table below:

DUH Historical Payor Mix

PAYOR SOURCE	ENTIRE DUH	HYBRID OR
Self-Pay	0.39%	0.54%
Charity Care	2.19%	0.72%
Medicare*	42.96%	56.53%
Medicaid*	12.51%	11.98%
Insurance*	36.97%	23.07%
Workers Compensation	0.28%	0.10%
TRICARE	1.96%	0.14%
Other	2.74%	6.92%
Total	100.00%	100.00%

Source: Application page 55

In Section L, pages 54-55, 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	58.12%	52.3%
Male	41.13%	47.7%
Unknown	0.0%	0.0%
64 and Younger	66.10%	86.90%
65 and Older	33.90%	13.10%
American Indian	0.40%	0.90%
Asian	2.80%	5.50%
Black or African-American	26.50%	37.30%
Native Hawaiian or Pacific Islander	0.10%	0.10%
White or Caucasian	61.60%	53.70%
Other Race	5.50%	2.50%
Declined / Unavailable	3.10%	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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 56, the applicant states:

“Duke University Health System hospitals have satisfied the requirements of applicable federal regulations to provide, on an annual basis, a certain amount of uncompensated care in return for Hill Burton funds previously received. ... DUHS will continue to have a policy to provide all 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.”

In Section L, pages 56-57, the applicant states that during the last five years five patient civil rights access complaints have been filed against several facilities owned by DUHS and located in North Carolina. The applicant states one complaint was voluntarily dismissed, three of the other four complaints were “*closed without further investigation*” and the fifth complaint, involving an allegation that the facility did not provide American Sign Language Interpreters on three patient encounters involved DUHS submitting documentation that interpreters had been provided. The resolution of that claim is pending.

The Agency reviewed the:

- application, and
- 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 58, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below:

DUH Projected Payor Mix FY 2023

PAYOR SOURCE	ENTIRE DUH CAMPUS	HYBRID OR
Self-Pay	0.39%	0.54%
Charity Care	2.19%	0.72%
Medicare*	45.22%	57.94%
Medicaid*	12.51%	11.98%
Insurance*	34.71%	21.67%
Workers Compensation	0.28%	0.10%
TRICARE	1.96%	0.14%
Other	2.74%	6.92%
Total	100.0%	100.0%

*Includes managed care plans

Totals may not sum due to rounding

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.39% of total services and 0.54% of services in the hybrid OR will be provided to self-pay patients, 45.22% and 57.94% respectively to Medicare patients and 12.51% and 11.98% respectively to Medicaid patients.

On page 58, 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, stating that the payor mix is not projected to change. The projected payor mix is reasonable and adequately supported because it is based on the applicant's experience providing radiation oncology services.

Conclusion

The Agency reviewed the:

- application, and
- 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 59, the applicant adequately describes the range of means by which patients will have access to the proposed services, which is by physician referral, emergency transfer or transfer from other hospitals.

The Agency reviewed the:

- application, and
- 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

In Section M, page 60, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates 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

DUHS proposes to acquire one unit of angiography equipment and install it in what is currently internally designated as OR #54 at the DUH campus in Durham. By installing the proposed angiography equipment, DUH will convert OR #54 into a hybrid OR.

The 2020 SMFP does not define a service area for angiography equipment or hybrid ORs. In Section C, pages 16-18, the applicant defines its service area for its existing hybrid ORs, as shown in the following table:

COUNTY	DUH HYBRID OR PATIENT ORIGIN	
	# PTS.	% OF TOTAL
Alamance	37	3.35%
Caswell	11	1.00%
Chatham	9	0.81%
Cumberland	38	3.44%
Durham	206	18.64%
Franklin	10	0.90%
Granville	53	4.80%
Guilford	23	2.08%
Harnett	17	1.54%
Johnston	8	0.72%
Lee	10	0.90%
Nash	11	1.00%
Orange	39	3.53%
Person	46	4.16%
Robeson	32	2.90%
Vance	45	4.07%
Wake	104	9.41%
Warren	13	1.18%
Wilson	7	0.63%
Other NC Counties	240	21.72%
Virginia	90	8.14%
Other States	56	5.07
Total	1,105	100.0%

Facilities may also serve residents of counties not included in their service area.

Regarding the expected effects of the proposal on competition in the service area and the impact of the proposal on cost effectiveness, in Section N, page 61, the applicant states:

“This project will not directly affect the cost-effectiveness of services, as the addition of angiography equipment to an existing operating room, does not involve any new services, but rather involves existing services for which charges and reimbursement will not change. ... This addition of hybrid OR capacity by

virtue of the conversion of an existing operating room will increase economies of scale and efficiency.”

Regarding the impact of the proposal on quality, in Section N, pages 61-62, the applicant states:

“DUH has quality-related policies and procedure, 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.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 62, the applicant states:

“...DUH 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.”

Considering all the information in the application, 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 (see Sections C, F, N and Q of the application and any referenced exhibits)
- Quality (see Sections C, N and O of the application and any referenced exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any referenced exhibits)

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 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 A, 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 three hospitals located in North Carolina.

In Section O, page 66, 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 and Certification 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 any 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 DUHS 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.

(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 acquire one unit of angiography equipment and install it in an existing OR to develop a hybrid OR. There are no administrative rules that are applicable to proposals to acquire angiography equipment and develop a hybrid OR.