

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 24, 2020

Findings Date: January 24, 2020

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11799-19

Facility: Duke University Hospital

FID #: 943138

County: Durham

Applicant: Duke University Health System, Inc.

Project: Acquire two units of heart-lung bypass equipment for a total of eleven units upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Duke University Health System (DUHS) proposes to acquire two units of heart-lung bypass equipment to be located at Duke University Hospital (DUH) for a total of eleven units upon project completion.

Need Determination

The applicant does not propose to increase the number of licensed beds in any category, add any new health services, or acquire equipment for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2019 SMFP that are applicable to this review.

Policies

There are no policies in the 2019 SMFP which are applicable to this review.

Conclusion

In summary, 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 2019 State SMFP. There are no policies in the 2019 SMFP that are applicable to this review. Therefore, this criterion is not applicable.

- (2) Repealed effective July 1, 1987.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 two units of heart-lung bypass equipment to be located at DUH. DUH currently operates nine heart-lung bypass machines.

Patient Origin

On pages 99-102, the 2019 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in Gen. Stat. §131E-176(18b) “*means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.*”

Table 7A, page 100 of the 2019 SMFP, indicates there were 22 open-heart surgery programs in North Carolina in 2017, providing a statewide total of 10,005 procedures.

The 2019 SMFP does not discuss a need methodology or provide a definition of “service area” for open heart surgery services. However, Step 1, on page 55 of the 2019 SMFP defines the service area for operating rooms as the planning area in which the operating room is located. “*The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*” Figure 6.1 on page 60 of the 2019 SMFP shows Durham County as a single operating room service area. Thus, the service area for this project consists of Durham County. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 13 and C.3, page 14, the applicant provides the historical and the projected patient origin by county for the first three full fiscal years of the proposed project, as illustrated in the tables below.

Duke University Hospital Historical and Projected Bypass Patient Origin		
County	Historical FY2019	Projected FY2022-FY2024
Wake	14.2%	14.2%
Durham	9.5%	9.5%
Cumberland	3.3%	3.3%
Alamance	3.2%	3.2%
Guilford	2.9%	2.9%
Orange	2.6%	2.6%
Robeson	2.5%	2.5%
Person	2.1%	2.1%
Vance	2.1%	2.1%
Other NC Counties	38.7%	38.7%
Other States	18.9%	18.9%
Total*	100.0%	100.0%

Source: Tables on pages 13-14 of the application.
 *Totals may not foot due to rounding

In Section C.3, page 15, the applicant states projected patient origin is based on the historical (FY2018) patient origin for the proposed services, which is shown in a table on page 13 of the application. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 15-19, the applicant explains why it believes the population projected to utilize the proposed equipment need the proposed services, including:

- The utilization of DUH’s heart-lung bypass machines has increased for both open heart surgical procedures and other procedures that require heart-lung bypass machines or need the equipment on “standby” (pages 15-17).
- The projected growth in the primary and secondary service area populations (pages 17-19).

The information provided by the applicant in the pages referenced above is reasonable and adequately supported for the following reasons:

- The applicant provides information regarding the historical utilization of its existing heart-lung bypass machines.
- The applicant provides data supporting its utilization projections and projected population growth in the primary and secondary service areas.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the proposed heart-lung bypass equipment through the first three full fiscal years (FY2022-FY2024) as summarized in the following table:

	Actual FY2019	Interim FY2020	Interim FY2021	Project Year 1 FY2022	Project Year 2 FY2023	Project Year 3 FY2024
Heart-lung bypass units	9	9	9	11	11	11
Procedures	2,148	2,148	2,169	2,191	2,213	2,236
Percent Change	---	0.0%	1.0%	1.0%	1.0%	1.0%

Source: Section Q, Form C Utilization.

In Section Q, page 63, the applicant states,

“In the fiscal year 2019, Duke University Hospital provided 2148 bypass procedures in connection with 1913 discrete patient encounters (fiscal years run from July-June, so FY 2019 ran from July 2018-June 2019). Duke projects that beginning in FY 21, when the additional bypass equipment is operational, its bypass procedures will grow at a rate of 1% per year. This is conservative based on anticipated population growth and in light of historical utilization of DUH’s service that require bypass described in Section C. Duke assumes that the procedure/patient ratio will remain constant for these projections, so both encounters and procedures grow at 1% from FY 21 through FY 24. ... Duke would note that even without any growth in procedures, existing volumes justify the need for additional bypass equipment based on hours of use or staffing on standby. Duke is not projecting any increase in average time in use/standby per procedure.”

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

- The applicant’s utilization projections for the heart-lung bypass machines are supported by its historical utilization.
- The applicant’s utilization projections are supported by the projected population growth rates for the proposed primary and secondary service area.

Access

In Section C.11, page 23, the applicant states DUH will continue to provide services to all patients regardless of factors such as race, ethnicity, age, gender or disability. In Section L.3, page 53, the applicant projects the following payor mix for DUH bypass procedures during the second year of operation (FY2023) following completion of the project, as shown in the following table.

Payment Source	Percent of Total Bypass Procedures
Self-Pay	0.2%
Charity Care	0.6%
Medicare	46.4%
Medicaid	16.5%
Insurance	29.3%
TRICARE	1.5%
Other	5.3%
Total*	100.0%

Source: Table on page 53 of the application.

*Totals may not foot due to rounding.

The projected payor mix is reasonable and adequately supported.

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 identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services 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.

NA

The applicant does not propose to reduce, eliminate or relocate a facility or a 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

The applicant proposes to acquire two additional heart-lung bypass machines. In Section E.1, page 31, the applicant states the additional equipment is needed to accommodate existing demand for bypass services and that there are no other alternatives available to the hospital.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because there are no other alternatives available to meet the need for bypass services at DUH.

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 two additional heart-lung bypass machines for a total of no more than eleven heart-lung bypass machines at Duke University Hospital.**
- 3. 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.**
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, 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

5. 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 the 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 acquire two additional heart-lung bypass machines.

Capital and Working Capital Costs

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

Medical Equipment Cost	\$497,445
Contingency Costs	\$252,555
Total*	\$750,000

*Totals may not foot due to rounding

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 34-35, the applicant projects that no start-up or initial operating expenses will be associated with the proposed project because the proposed project does not involve a new service.

Availability of Funds

In Section F.2, page 33, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DUHS, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$750,000	\$750,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$750,000	\$750,000

* OE = Owner's Equity

Exhibit F.2(a) contains a letter dated October 7, 2019 from the Senior Vice President and Chief Financial Officer of DUHS documenting its intention to provide accumulated reserves

for the capital needs of the proposed project. Exhibit F.2(b) contains the audited financial statements of DUHS which show that as of June 30, 2019, the applicant had \$251 million in cash and cash equivalents, \$6.6 billion in total assets, and \$3.8 billion in net assets (total assets less total liabilities).

Financial Feasibility

In Section Q, the applicant provided pro forma financial statements for open heart surgery procedures which require the use of the heart-lung bypass machine for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that operating expenses will exceed revenues in each of the first three operating years of the project, as shown in the table below.

	1st Full Fiscal Year FFY2022	2nd Full Fiscal Year FFY2022	3rd Full Fiscal Year FFY2023
Total Procedures	2,191	2,213	2,236
Total Gross Revenues (Charges)	\$770,037,758	\$777,931,533	\$785,825,308
Total Net Revenue	\$249,174,902	\$253,390,133	\$257,651,785
Average Net Revenue per procedure	\$113,727	\$114,501	\$115,229
Total Operating Expenses (Costs)	\$275,406,942	\$285,221,934	\$295,414,782
Average Operating Expense per procedure	\$125,699	\$128,885	\$132,118
Net Income	(\$26,232,040)	(\$31,831,802)	(\$37,762,997)

However, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project for DUHS.

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

DUH proposes to acquire two additional heart-lung bypass machines.

On pages 99-102, the 2019 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in Gen. Stat. §131E-176(18b) *“means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.”*

The 2019 SMFP does not discuss a need methodology or provide a definition of “service area” for open heart surgery services. However, Step 1, on page 55 of the 2019 SMFP defines the service area for operating rooms as the planning area in which the operating room is located. *“The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.”* Figure 6.1 on page 60 of the 2019 SMFP shows Durham County as a single county operating room service area. Thus, the service area for this project consists of Durham County. Facilities may also serve residents of counties not included in their service area.

According to the 2019 SMFP, Table 7A, there were 22 facilities in North Carolina that provided 10,005 open-heart surgery procedures in 2017, as shown in the table below.

STATEWIDE OPEN-HEART SURGERY PROCEDURES				
FACILITY	CITY	COUNTY	# OF PROCURES PERFORMED IN FY2017*	# OF PROCURES PERFORMED IN FY2018**
Cape Fear Valley Medical Center	Fayetteville	Cumberland	292	238
CarolinaEast Medical Center	New Bern	Craven	248	256
Carolinas HealthCare System - NorthEast	Concord	Cabarrus	235	273
Carolina HealthCare System - Pineville	Charlotte	Mecklenburg	252	225
Carolinas Medical Center	Charlotte	Mecklenburg	869	682
CaroMont Regional Medical Center	Gastonia	Gaston	230	278
Cone Health	Greensboro	Guilford	547	627
Duke Regional Hospital	Durham	Durham	98	148
Duke University Hospital	Durham	Durham	1,095	1,130
FirstHealth Moore Regional Hospital	Pinehurst	Moore	351	288
Frye Regional Hospital	Hickory	Catawba	232	222
High Point Regional Health System	High Point	Guilford	129	112
Mission Hospital	Asheville	Buncombe	962	939
New Hanover Regional Medical Center	Wilmington	New Hanover	482	480
North Carolina Baptist Hospital	Winston-Salem	Forsyth	689	758
Novant Health Forsyth Medical Center	Winston-Salem	Forsyth	580	635
Novant Health Presbyterian Medical Center	Charlotte	Mecklenburg	397	406
Rex Hospital	Raleigh	Wake	612	602
Southeastern Regional Medical Center	Lumberton	Robeson	39	44
University of North Carolina Hospitals	Chapel Hill	Orange	445	430
Vidant Medical Center	Greenville	Pitt	654	675
WakeMed	Raleigh	Wake	567	512
Total Procedures			10,005	9,960

Source: *Table 7A, 2019 SMFP

**Table 7B, Proposed 2020 SMFP

DUH proposes to acquire two additional heart-lung bypass machines for a total of eleven units upon project completion. The applicant does not propose any new services.

In Section G.3, page 39, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved open heart services with a heart-lung bypass machines. The applicant states:

“As described in Section C.4, Duke demonstrates the need the population has for the proposed additional bypass equipment based on its own existing utilization. This project will not duplicate any existing facilities nor significantly expand any services, but will simply make DUH’s open heart and other bypass procedures more efficient and accessible.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates the need for two additional heart-lung bypass machines.

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 in the third operating year (FY2024) for the proposed services, as illustrated in the following table.

POSITION	CURRENT FTE STAFF	PROJECTED FTE STAFF YEAR 3
Clerical Staff	0.19	1.00
Perfusionist	28.78	32.00
Perfusionist Chief	0.92	1.00
Totals*	30.00	34.00

*Totals may not foot due to rounding

The assumptions and methodology used to project staffing are provided in Section Q, Form H. Adequate costs for health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 40-41, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 44, the applicant identifies the medical director for the services. In Exhibit H.3, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I.1(b), page 42, the applicant states that the following ancillary and support services are necessary for the proposed services and explains how the necessary services will be made available:

- Administration
- Business office
- Medical records
- Professional services
- Nursing
- Pharmacy
- Medical supplies
- Imaging
- Laboratory/Pathology
- Social services
- Therapy
- Food & Nutrition services
- Housekeeping
- Linen service
- Material management
- Pastoral care
- Facility maintenance

In Section I.3, pages 43-44, the applicant discusses its relationships with the referring physician community. Exhibit C.4 of the application contains support letters from physicians expressing support for the proposed project. The applicant adequately demonstrates that the necessary ancillary and support services will be made available and 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.

NA

The applicant does not propose any new construction or renovation of existing space as part of this project. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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.1(b), page 51, the applicant provides the historical payor mix during FY2019 for the entire hospital and the proposed service component, as shown below.

DUH Percent of Total Revenue Current Payor FY2019		
Payment Category	Entire Hospital	Bypass Procedures
Self-Pay	0.4%	0.2%
Charity Care	2.1%	0.6%
Medicare*	42.7%	43.7%
Medicaid*	12.7%	16.5%
Insurance*	37.0%	32.1%
Workers Compensation	0.3%	0.0%
TRICARE	2.0%	1.5%
Other (Other governmental)	2.7%	5.3%
Total*	100.0%	100.0%

*Includes all managed care plans

In Section L.1, page 50, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility in Last Fiscal Year	Percentage of the Population of the Durham County Service Area
Female	34.7%	52.3%
Male	65.3%	47.7%
Unknown	0.0%	0.0%
64 and Younger	59.3%	86.9%
65 and Older	40.7%	13.1%
American Indian	22.3%	0.9%
Asian	0.8%	5.5%
Black or African-American	1.2%	37.3%
Native Hawaiian or Pacific Islander	0.2%	0.1%
White or Caucasian	70.3%	53.7%
Other Race	3.2%	2.5%
Declined / Unavailable	2.2%	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 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.2, page 51, the applicant states it has no obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, but that DUHS provides services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor.

In Section L.2, page 52, the applicant states that during the last five years, four patient civil rights access complaints have been filed against DUHS. The applicant reports that three of the complaints have been closed without further investigation and one complaint is pending.

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.3, page 53, the applicant provides the projected payor mix in the second operating year (FY2023) for the entire hospital and the proposed service component, as shown below.

DUH Percent of Total Revenue Projected FY2023		
Payment Category	Entire Hospital	Bypass Procedures
Self-Pay	0.4%	0.2%
Charity Care	2.1%	0.6%
Medicare*	44.8%	46.4%
Medicaid*	12.7%	16.5%
Insurance*	34.9%	29.3%
Workers Compensation	0.3%	0.0%
TRICARE	2.0%	1.5%
Other (Other governmental)	2.7%	5.3%
Total*	100.0%	100.0%

*Includes all managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.2% of bypass procedures will be provided to self-pay patients, 0.6% to charity care patients, 46.4% to Medicare patients, and 16.5% to Medicaid patients.

In Section L.3, page 53, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, page 54, 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

In Section M.1, page 55, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes.

Conclusion

The Agency reviewed the:

- Application
- 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

DUH proposes to acquire two additional heart-lung bypass machines.

On pages 99-102, the 2019 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in Gen. Stat. §131E-176(18b) *“means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.”*

The 2019 SMFP does not discuss a need methodology or provide a definition of “service area” for open heart surgery services. However, Step 1, on page 55 of the 2019 SMFP defines the service area for operating rooms as the planning area in which the operating room is located. *“The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.”* Figure 6.1 on page 60 of the 2019 SMFP shows Durham County as a single county operating room service area. Thus, the service area for this project consists of Durham County. Facilities may also serve residents of counties not included in their service area.

According to the 2019 SMFP, Table 7A, there were 22 facilities in North Carolina that provided 10,005 open-heart surgery procedures in 2017, as shown in the table below.

STATEWIDE OPEN-HEART SURGERY PROCEDURES				
FACILITY	CITY	COUNTY	# OF PROCURES PERFORMED IN FY2017*	# OF PROCURES PERFORMED IN FY2018**
Cape Fear Valley Medical Center	Fayetteville	Cumberland	292	238
CarolinaEast Medical Center	New Bern	Craven	248	256
Carolinas HealthCare System - NorthEast	Concord	Cabarrus	235	273
Carolina HealthCare System - Pineville	Charlotte	Mecklenburg	252	225
Carolinas Medical Center	Charlotte	Mecklenburg	869	682
CaroMont Regional Medical Center	Gastonia	Gaston	230	278
Cone Health	Greensboro	Guilford	547	627
Duke Regional Hospital	Durham	Durham	98	148
Duke University Hospital	Durham	Durham	1,095	1,130
FirstHealth Moore Regional Hospital	Pinehurst	Moore	351	288
Frye Regional Hospital	Hickory	Catawba	232	222
High Point Regional Health System	High Point	Guilford	129	112
Mission Hospital	Asheville	Buncombe	962	939
New Hanover Regional Medical Center	Wilmington	New Hanover	482	480
North Carolina Baptist Hospital	Winston-Salem	Forsyth	689	758
Novant Health Forsyth Medical Center	Winston-Salem	Forsyth	580	635
Novant Health Presbyterian Medical Center	Charlotte	Mecklenburg	397	406
Rex Hospital	Raleigh	Wake	612	602
Southeastern Regional Medical Center	Lumberton	Robeson	39	44
University of North Carolina Hospitals	Chapel Hill	Orange	445	430
Vidant Medical Center	Greenville	Pitt	654	675
WakeMed	Raleigh	Wake	567	512
Total Procedures			10,005	9,960

Source: *Table 7A, 2019 SMFP

**Table 7B, Proposed 2020 SMFP

DUH proposes to acquire two additional heart-lung bypass machines for a total of eleven units upon project completion. The applicant does not propose any new services.

In Section N.1, pages 93-94, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

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

- (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

Duke University Hospital is part of the Duke University Health System (DUHS). In Section Q, Form A, the applicant identifies three hospitals, Duke University Hospital, Duke Regional Hospital, and Duke Raleigh Hospital, that are owned or managed by DUHS.

In Section O.3, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred at the facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at the 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.

C

The Criteria and Standards for Open-Heart Surgery Services and Heart-Lung ByPass Machines as promulgated in 10A NCAC 14C .1700 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

SECTION .1700 – CRITERIA AND STANDARDS FOR OPEN-HEART SURGERY SERVICES AND HEART-LUNG BYPASS MACHINES

10A NCAC 14C .1703 PERFORMANCE STANDARDS

(a) An applicant that proposes to develop open-heart surgery services shall:

- (1) demonstrate that the projected utilization and proposed staffing patterns are such that each open heart surgical team shall perform at least 150 open heart surgical procedures in the third year following completion of the project; and
- (2) document the assumptions and provide data supporting the methodology used to make these projections.

-NA- The applicant does not propose to develop open-heart surgery services.

(b) An applicant that proposes to acquire a heart-lung bypass machine shall demonstrate either:

- (1) that the applicant's projected annual utilization of its existing, approved, and proposed heart-lung bypass machines (other than a machine acquired pursuant to 10A NCAC 14C .1703(b)(3)) will be at least 200 open heart surgical procedures per machine during the third year following completion of the project;
- (2) that the projected annual utilization of its existing, approved, and proposed heart-lung bypass machines (other than a machine acquired pursuant to 10A NCAC 14C .1703(b)(3)), will be at least 900 hours per year during the third year following completion of the project, as measured in minutes used or staffed on standby for all procedures; or
- (3) that the proposed machine is needed to provide coverage for open-heart surgery emergencies and will not be scheduled for use at the same time as the applicant's equipment used to support scheduled open heart surgical procedures.

-C- In Section C.4, page 12, the applicant demonstrates that the projected annual utilization of the existing, approved and proposed heart-lung bypass machines at DUH will be at least 900 hours per year during the third year following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.