

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 12, 2013

PROJECT ANALYST: Michael J. McKillip

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: J-10077-13 / Duke University Health System d/b/a Duke University Hospital / Acquisition of two heart-lung bypass machines for a total of 9 upon project completion / Durham County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Duke University Health System d/b/a Duke University Hospital [**Duke University Hospital**] proposes to acquire two heart-lung bypass machines to support both open-heart and other surgical procedures. 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 2013 SMFP. There are no policies in the 2013 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- (2) Repealed effective July 1, 1987.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

The applicant, Duke University Hospital, proposes to acquire two heart-lung bypass machines. In Section II.1, page 7, the applicant describes the project as follows:

“This application proposes the acquisition of two heart-lung bypass machines to support both open-heart and other surgical procedures. The first machine will be purchased immediately upon award of the certificate of need. The second machine will be purchased the following year. The total capital cost of the project will be \$444,979.”

Population to be Served

In Section III.5, page 22, the applicant provides projected patient origin for Duke University Hospital’s heart-lung bypass services in the first two years of operation (FY2015 and FY2016), as shown in the table below.

County	Percent of Total
Wake	12.1%
Durham	10.6%
Alamance	5.3%
Orange	2.6%
Granville	2.3%
Lee	1.4%
Person	1.3%
Chatham	0.9%
Johnston	0.8%
Franklin	0.7%
Harnett	0.6%
Other NC Counties*	37.5%
Other States	25.1%
TOTAL	100.0%

*The applicant provides a complete list of the counties included in the “Other” category in Exhibit II.8.C of the application.

On page 23 of the application, the applicant states, “Duke projects that patient origin will remain consistent with current patient origin for patients requiring bypass services.” The applicant adequately identified the population proposed to be served.

Need for the Project

In Section III.1(a), pages 18-19, the applicant identifies eight categories of procedures that may involve the use of a heart-lung bypass machine at Duke University Hospital. The applicant states the seven existing machines are operating at 100% of practical capacity, which can create scheduling and operational difficulties. The applicant expects volumes to continue to increase.

In Section IV.1, page 25, the applicant provides a table showing the historical and projected utilization for the heart-lung bypass machines at Duke University Hospital (DUH) through the first three years of operation for the proposed project, which is summarized below:

Duke University Hospital Heart-Lung Bypass Machine Utilization

Year	Heart-Lung Bypass Units*	Total Heart-Lung Bypass Procedures	Percent Change
FY2011 – Actual	7	1,588	---
FY2012 – Actual	7	1,614	1.6%
FY2013 – Projected	7	1,640	1.6%
FY2014 – Projected	8	1,667	1.6%
FY2015 – Year 1	9	1,695	1.7%
FY2016 – Year 2	9	1,772	1.6%
FY2017 – Year 3	9	1,751	1.7%

*DUH currently operates seven heart-lung bypass units. In this application, the applicant proposes to acquire one additional unit in FY2014, for a total of 8 units, and one additional unit in FY2015, for a total of 9 units.

In Section III.1(b), page 19, the applicant describes its assumptions and the methodology used to project utilization of the heart-lung bypass machines at Duke University Hospital, as follows:

“Duke’s 7 existing bypass machines were utilized for a total of 891,468 minutes in fiscal year 2012 for 1614 patients, in addition to the time in which bypass machines were staffed on standby. This is equivalent to 2122 hours per year per machine. Exhibit II.8.B shows current utilization of Duke’s bypass equipment by ICD-9 code.

The volume of Duke’s procedures requiring bypass equipment grew 1.64% between FY 2011 and FY 2012. Duke conservatively projects continued growth at the same level through the development of the project and the first three project years, a rate that is also consistent with the service area population growth. According to Thomson Reuters, population growth in the Greater Triangle area is projected to be 9.9% between 2012 and 2017, and 7% statewide.

At that rate, Duke reasonably projects a volume of 1751 patients requiring bypass equipment during their procedures. Assuming the same average procedure time, Duke will need 967,116 minutes, or 16,119 hours, of bypass time. Duke would use 9 bypass machines an average of 1791 hours per year. We would note, furthermore, that even at existing volumes and no growth, Duke would still utilize 9 bypass machines an average of 1651 hours per year [per machine].”

The applicant projects utilization will grow by 1.64 percent per year from FY2013 to FY2017, or by approximately 6.8 percent over the four-year period, based on the historical growth in utilization of DUH’s heart-lung bypass machines from FY2011 to FY2012. Exhibit V.3 of the application contains letters from physicians expressing support for the proposed project. Based on the projected population growth in the applicant’s service area and the historical utilization of the applicant’s heart-lung bypass equipment, the applicant’s utilization projections are reasonable, credible and supported. Therefore, the applicant adequately demonstrated the need to acquire two additional heart-lung bypass machines.

Access

The applicant projects 59.3% of its patients will be covered by Medicare (47.5%) and Medicaid (11.8%). The applicant demonstrates adequate access for the underserved to its services.

In summary, the applicant adequately identified the population to be served, adequately demonstrated the need the population projected to be served has for the proposed project, and demonstrated all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (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

- (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

In Section III.3, page 20, the applicant describes the alternatives considered, including maintaining the status quo and acquiring only one additional heart-lung bypass machine.

- The applicant states it rejected the status quo alternative due to high rates of equipment utilization for the existing DUH heart-lung bypass equipment, the difficulties encountered providing routine maintenance and ensuring capacity to support emergencies.
- The applicant considered the alternative of acquiring only one additional heart-lung bypass machine, but rejected it because this alternative would not address the anticipated increases in utilization, and would require duplication of effort and delays associated with undertaking the certificate of need process again in the near future.

The applicant adequately demonstrated that the proposal is its least costly or most effective alternative to meet the need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Duke University Health System d/b/a Duke University Hospital shall materially comply with all representations made in the certificate of need application.**
 - 2. Duke University Health System d/b/a Duke University Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**
 - 3. Duke University Health System d/b/a Duke University Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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

In Section VIII.1, the applicant projects its capital cost for the project to be \$444,979. In Section VIII.3, the applicant states the capital cost will be financed with accumulated reserves. In Section IX.1, the applicant projects no start-up expenses or initial operating expenses. In Exhibit VIII.6 of the application, the applicant provides a letter from the Senior Vice President and Chief Financial Officer for Duke University Health System, which states

"This will certify that Duke University Health System has as much as \$500,000 in accumulated reserves to devote to the acquisition of heart-lung bypass equipment at Duke University Hospital."

Exhibit VIII.9 of the application contains audited financial statements for Duke University Health System, Inc. and Affiliates (DUHS) for the year ended June 30, 2012, which documents that DUHS had \$243 million in cash and cash equivalents as of June 30, 2012. The applicant adequately demonstrated the availability of funds for the projected capital costs described in the application.

In pro forma financial statements for DUH's heart-lung bypass services (Form C), the applicant projects expenses will exceed revenues in each of the first three operating years, as shown below:

Duke University Hospital Heart-Lung Bypass Services

	FY2015	FY2016	FY2017
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	Year 1	Year 2	Year 3
Total Net Revenue	\$152,454,256	\$154,238,218	\$156,059,053
Total Expenses	\$157,648,388	\$165,097,384	\$170,547,437
Net Income (Loss)	(\$5,194,132)	(\$10,859,166)	(\$14,488,384)

However, in pro forma financial statements for DUHS (Form B), the applicant projects revenue will exceed operating costs (expenses) in each of the first three operating years, as shown below:

Duke University Health System

(All \$ are in 000's)	FY2015 Year 1	FY2016 Year 2	FY2017 Year 3
Total Net Revenue	\$2,805,065	\$2,881,395	\$2,968,149
Total Expenses	\$2,516,544	\$2,597,409	\$2,685,021
Net Income (Loss)	\$288,521	\$283,986	\$283,128

Operating costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application for the assumptions. See Criterion (3) for discussion regarding utilization assumptions which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues, and the application is conforming with this criterion.

- (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, Duke University Hospital (DUH), proposes to acquire two heart-lung bypass machines. The following table shows the heart-lung bypass equipment utilization for open-heart surgical patients for other providers in the applicant's service area, based on data reported to DHSR on the hospitals' 2013 *Renewal Application for Hospital* forms. It should be noted that the hospitals do not report heart-lung bypass equipment utilization for other types of surgical procedures.

Utilization of Heart-Lung Bypass Equipment for Open-Heart Surgery in DUH's Service Area

	Total # of Heart-Lung Bypass Machines	Total Open-Heart Surgery Procedures Utilizing Heart-Lung Bypass Machines
Durham Regional Hospital	2	60
Rex Hospital	3	346
UNC Hospitals-Chapel Hill	4	391
WakeMed	5	553

Source: 2013 Renewal Application for Hospital (FY2012 data).

In Section IV.1, page 25, the applicant provides a table showing the historical and projected utilization for the heart-lung bypass machines at Duke University Hospital (DUH) through the first three years of operation for the proposed project, which is summarized below:

Duke University Hospital Heart-Lung Bypass Machine Utilization

Year	Heart-Lung Bypass Units*	Total Heart-Lung Bypass Procedures	Percent Change
FY2011 – Actual	7	1,588	---
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FY2017 – Year 3	9	1,751	1.7%

*DUH currently operates seven heart-lung bypass units. In this application, the applicant proposes to acquire one additional unit in FY2014, for a total of 8 units, and one additional unit in FY2015, for a total of 9 units.

In Section III.1(a), page 18, the applicant states

“Duke currently operates 7 heart-lung bypass machines, including one dedicated to pediatric patients. Surgeons at Duke rely on bypass machines to support not only open-heart surgery but also a wide variety of other kinds of procedures, including:

- *Heart and lung transplants*
- *Trauma resuscitations*
- *Nephrectomies and other tumor cases*
- *Closed heart valve replacements*
- *Stent repairs*
- *Pacemaker implants*
- *Convergence procedures to treat atrial fibrillation*
- *High risk obstetrics procedures*

In FY 2012, Duke’s 7 existing bypass machines were utilized for a total of 891,448 minutes, in addition to the time in which bypass machines were staffed on standby. This is equivalent to an average utilization of 2122 hours per year per machine. In addition, machines were provided and staffed on ‘standby’ basis for more than 220 other procedures. With all its machines used or staffed on standby at this level, utilization of the Hospital’s machines was at 100% of practical capacity in FY2012.

Duke’s volumes for procedures needing bypass equipment are anticipated to increase further. With the opening of additional operating rooms (including dedicated cardio-

thoracic operating rooms) in the Duke Medical Pavilion (developed pursuant to Project ID J-8030-08) in 2013 and the ongoing development of new surgical techniques, Duke anticipates continued growth in volume in procedures requiring the use of bypass equipment at least consistent with its recent historical growth.”

DUH projected utilization for the proposed heart-lung bypass machines, and demonstrated the need to acquire two additional heart-lung bypass machines. Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the applicant’s service area. Therefore, the application is conforming with this criterion.

- (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 VII.1, page 38, the applicant provides the current staffing for DUH’s heart-lung bypass (perfusion) department, as shown in the table below.

DUH Heart-Lung Bypass Staffing	FTEs
Perfusionist	18.0
Chief Perfusionist	2.0
Total	20.0

The applicant states the proposed project will not result in the addition of any staff to the hospital. In Section VII.8, page 41, the applicant identifies Thomas A. Owens, M.D. as the Medical Director for Duke University Hospital. Exhibit V.3 contains copies of letters of support from the Chairperson of the Department of Surgery and other surgeons at Duke University Hospital. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (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 II.2 of the application, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at Duke University Hospital. In Exhibit V.2 of the application, the applicant provides a copy of a sample transfer agreement and a list of facilities with which DUH has transfer agreements. In Exhibit V.3 of the application, the applicant provides letters from physicians supporting the proposed project. The applicant adequately demonstrates that the necessary ancillary and support services will be available and

the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with 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

- (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.

NA

- (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 VI.13, page 35, the applicant provides the payer mix during FY2012 for the heart-lung bypass services at Duke University Hospital, as shown in the table below.

DUH Heart-Lung Bypass Services Payer Category	Procedures as % of Total
Self Pay/Indigent/Charity	1.2%
Medicare/Medicare Managed Care	46.3%
Medicaid	11.8%
Commercial Insurance	0.7%
Managed Care	34.0%
Other	6.0%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
County			
Alamance	16%	6.2%	21.0%
Durham	16%	5.7%	20.1%
Granville	15%	6.3%	18.4%
Orange	9%	3.5%	18.9%
Person	18%	8.3%	18.0%
Wake	10%	3.3%	18.4%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and 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;

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. On page 33, the applicant states:

“Duke University Health System hospitals have now satisfied the requirements of Federal regulations to provide, on a annual basis, a certain amount of uncompensated care in return for Hill Burton funds previously received. ... They have no special obligation under applicable Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped person other than those obligations that apply to private, non-profit, acute care hospitals which participate in the Medicare, Medicaid and Title V programs. ... DRH will continue to provide charity care and other community services as previously described in Section VI.”

In Section VI.10 (a), page 34, the applicant describes three Office of Civil Rights complaints filed against DUHS facilities in last five years. The applicant states all three of the complaints have been fully resolved. Therefore, 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 VI.15, page 36, the applicant provides the projected payer mix for second full fiscal year following completion of the proposed project (FY2016) for the heart-lung bypass services at Duke University Hospital, as shown in the table below.

DUH Heart-Lung Bypass Services Payer Category	Procedures as % of Total
Self Pay/Indigent/Charity	1.2%
Medicare/Medicare Managed Care	47.5%
Medicaid	11.8%
Commercial Insurance	0.7%
Managed Care	32.8%
Other	5.9%
Total	100.0%

On page 36, the applicant states, *“Projected payor mix is based on current payor mix, with a decrease of 1% in managed care payors through 2018 due to an aging population in the service area.”* The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, 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 VI.9(a), page 33, the applicant describes the range of means by which a person will have access to its services. Therefore, the application is conforming with 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 V.1, page 26, the applicant states Duke University Hospital (DUH) has established relationships with area health professional training programs, including the Duke University School of Medicine, Duke School of Nursing, Durham Technical Community College, and the Medical University of South Carolina. The information provided in Section V.1 is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant, Duke University Hospital, proposes to acquire two heart-lung bypass machines.

The following table shows the heart-lung bypass equipment utilization for open-heart surgical patients for other providers in the applicant's service area, based on data reported to DHSR on the hospitals' *2013 Renewal Application for Hospital* forms. It should be noted that the hospitals do not report heart-lung bypass equipment utilization for other types of surgical procedures.

Utilization of Heart-Lung Bypass Equipment for Open-Heart Surgery in DUH's Service Area

	Total # of Heart-Lung Bypass Machines	Total Open-Heart Surgery Procedures Utilizing Heart-Lung Bypass Machines
Durham Regional Hospital	2	60
Rex Hospital	3	346
UNC Hospitals-Chapel Hill	4	391
WakeMed	5	553

Source: 2013 Renewal Application for Hospital (FY2012 data).

In Section V.7, page 29, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states, *“The project will promote cost-effectiveness, quality, and access to services and therefore will promote competition in the proposed service area because it will allow Duke to better meet the needs of its existing patient population, to respond to emergencies, and to ensure the safe provision of services by increasing its ability to perform routine and emergency equipment maintenance without disrupting patient care.”* See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need to acquire two heart-lung bypass machines and that it is a cost-effective alternative;
- ◆ The applicant adequately demonstrates that it will continue to provide quality services; and
- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

- (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 certified by CMS for Medicare and Medicaid participation, and licensed by the NC Department of Health and Human Services. According to files in the Acute and Home Care Licensure and Certification Section in the Division of Health Service Regulation, no incidents have occurred at Duke University Hospital within the eighteen months immediately preceding the date of the decision for which any sanctions or penalties

related to quality of care were imposed by the State. 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

Duke University Hospital proposes to acquire two heart-lung bypass machines. Therefore, the Criteria and Standards for Open-Heart Surgery Services and Heart-Lung Bypass Machines promulgated in 10A NCAC 14C .1700, are applicable to this review. The application is conforming to all applicable criteria and standards. The specific criteria are discussed below.

10A NCAC 14C .1702 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to add an open heart surgery room or to acquire a heart-lung bypass machine shall use the acute care facility/medical equipment application form.

-C- The applicant used the Acute Care Facility/Medical Equipment application form.

(b) An applicant shall define the service area for the proposed project which shall be like the applicant's service area for other health services, unless the applicant documents that other providers are expected to refer patients to the applicant, including the methodology and assumptions used to define the service area.

-C- In Exhibit II.8.A, the applicant provides a map of the service area for the proposed project, which it states is the same as the service area for the hospital's other services. In Section III.5, pages 22-23, the applicant describes the assumptions it used to define the service area.

(c) An applicant shall provide the following information:

(1) the number of procedures performed on each heart-lung bypass machine owned by or operated in the facility during the 12-month period prior to the submission of the application, identified by ICD-9, ICD-10, or CPT code;

-C- In Section II.8, page 11, the applicant states it performed 1,614 procedures on its 7 existing heart-lung bypass machines during FY2012. Exhibit II.8.B contains a list of procedures by diagnosis code, and another list of procedures by procedure code.

- (2) *a projection of the number of procedures using the applicant's existing, approved and proposed heart-lung bypass machines in each of the first three years following completion of the proposed project identified by ICD-9, ICD-10, or CPT code, including the methodology and assumptions used to make the projections;*
- C- Exhibit II.8.B contains a table showing DUH's projected number of heart-lung bypass procedures by diagnosis code through the first three years following completion of the project. In Section II.8, page 11, and Section III.1(b), page 19, the applicant describes the methodology and assumptions used to make the projections.
- (3) *the number of patients from the proposed service area who are projected to receive procedures using the applicant's existing, approved, and proposed heart-lung bypass equipment by patient's county of residence in each of the first three years following completion of the proposed project, including the methodology and assumptions used to make these projections;*
- C- Section II.8, page 12, and Exhibit II.8.C contain tables showing DUH's projected number of heart-lung bypass procedures by the patient's county of residence in each of the first three years following completion of the project. In Section II.8, page 12, and Section III.1(b), page 19, the applicant describes the methodology and assumptions used to make the projections.
- (4) *the projected patient referral sources;*
- C- In Section II.8, page 12, the applicant describes the referral sources for DUH's heart-lung bypass services, including the Duke Heart Network, Duke's Maternal and Fetal Medicine Clinics, and the Pediatric Heart Network.
- (5) *evidence of the applicant's capability to communicate efficiently with emergency transportation agencies and with all hospitals serving the proposed service area;*
- C- In Section II.8, pages 12-13, the applicant describes DUH's capabilities to communicate with emergency transportation agencies and other hospitals serving the proposed service area.
- (6) *the number and composition of open heart surgical teams available to the applicant;
and*
- C- In Section II.8, page 13, the applicant states it can field as many as nine open heart surgical teams comprised of an attending surgeon, surgical fellow, physician assistant, attending anesthesiologist, anesthesiology fellow, circulating nurse, scrub nurse, perfusionist, and back-up perfusionist.
- (7) *evidence of the applicant's capability to perform both cardiac catheterization and open heart surgical procedures 24 hours per day, 7 days per week.*
- C- In Section II.8, page 13, the applicant states DUH currently has the capability to provide cardiac catheterization and open heart surgical services 24 hours per day, 7 days per week.

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 II.8, page 14, the applicant states DUH projects to meet the performance standard under subsection (2) of this Rule. The applicant states

“Duke’s 7 existing bypass machines were utilized for a total of 891,448 minutes in fiscal year 2012, in addition to the time in which bypass machines were staffed on standby. This is equivalent to 2122 hours per year per machine (plus standby time). Even without any growth in volume or procedure time, and without any additional time when the machines are required on standby for other procedures, 9 machines would be each currently by used an average of 1651 hours per year, well in excess of the required 900 hours per year.”

The application is conforming with this Rule.

10A NCAC 14C .1704 SUPPORT SERVICES

(a) *An applicant that proposes to acquire a heart-lung bypass machine shall demonstrate that the following services will be available in the facility 24 hours per day, 7 days per week:*

- (1) *electrocardiography laboratory and testing services, including stress testing and continuous cardiogram monitoring;*
- (2) *echocardiography service;*
- (3) *blood gas laboratory;*
- (4) *nuclear medicine laboratory;*
- (5) *pulmonary function unit;*

- (6) *staffed blood bank;*
- (7) *hematology laboratory or coagulation laboratory;*
- (8) *microbiology laboratory; and*
- (9) *clinical pathology laboratory with facilities for blood chemistry.*

-C- In Section II.8, page 14, the applicant states DUH currently has the capability to provide all of these services 24 hours per day, 7 days per week.

(b) An applicant that proposes to develop open-heart surgery services shall demonstrate that the following services will be available in the facility 24 hours per day, 7 days per week:

- (1) a dedicated cardiac surgical intensive care unit;*
- (2) for facilities performing pediatric open heart surgery services, a pediatric intensive care unit that will be a distinct intensive care unit and will meet the requirements of 10A NCAC 14C .1300;*
- (3) an emergency department with full-time director, staffed for cardiac emergencies with acute coronary suspect surveillance area and voice communication linkage to the ambulance service and the coronary care unit; and*
- (4) cardiac catheterization services including both diagnostic and interventional cardiac catheterization capabilities.*

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

10A NCAC 14C .1705 STAFFING AND STAFF TRAINING

(a) An applicant that proposes to acquire a heart-lung bypass machine shall demonstrate that it can meet the following staffing requirements:

- (1) at least two cardiovascular surgeons on the medical staff, at least one of whom is certified by the American Board of Thoracic Surgery; and*

-C- In Section II.8, pages 15-16, the applicant provides a list of 21 cardiovascular surgeons, all of whom are certified by the American Board of Thoracic Surgery.

- (2) one perfusionist certified by the American Board of Cardiovascular Perfusion and licensed by the Perfusionist Advisory Committee of the North Carolina Medical Board per operational heart lung bypass machine and an additional licensed, certified perfusionist on standby.*

-C- In Section II.8, page 16, the applicant states, “*Duke University Hospital currently employs 20 certified and licensed perfusionists.*”

(b) An applicant that proposes to develop open-heart surgery services shall demonstrate that it can meet the following staffing requirements:

- (1) one cardiovascular surgeon who has been designated to serve as director of the open heart surgery program and who has the following special qualifications:*
 - (A) certification by the American Board of Thoracic Surgery; and*
 - (B) licensed by the North Carolina Medical Board to practice medicine; and*

- (2) *at least one open heart surgical team comprised of at least the following professional and technical personnel:*
- (A) *one cardiovascular surgeon board certified by the American Board of Thoracic Surgery;*
 - (B) *one assistant surgeon;*
 - (C) *one anesthesiologist certified by The American Board of Anesthesiology and trained in open heart surgical procedures;*
 - (D) *one certified registered nurse anesthetist;*
 - (E) *one circulating nurse or scrub nurse, with training in open heart surgical procedures;*
 - (F) *one operating room technician or nurse with training in open heart surgical procedures;*
 - (G) *one licensed, certified perfusionist;*
 - (H) *staff for the dedicated cardiac surgical intensive care unit to ensure the availability of 1 registered nurse for every 2 patients during the first 48 hours of post-operative care; and*
 - (I) *if pediatric open heart surgical procedures are performed, at least one cardiac surgeon trained to perform pediatric open heart surgical procedures.*

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

(c) *An applicant that proposes to acquire a heart-lung bypass machine or to develop open-heart surgery services shall demonstrate that it can provide the following:*

- (1) *staff training for certification in cardiopulmonary resuscitation and advanced cardiac life support; and*
- (2) *a program of staff education and training that ensures improvements in technique and the training of new personnel.*

-C- In Section II.8, page 17, the applicant states, “*Duke University Health System’s Department of Employee Educational Services and the clinical departments, including Surgery, Anesthesiology, Pediatrics, Medicine, and Radiology all provide pre-service and in-service education and training, including certification in cardiopulmonary resuscitation and advanced cardiac life support.*” The application is conforming with this Rule.