ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: September 27, 2013
PROJECT ANALYST: Julie Halatek
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-10145-13 / Duke University Health System, Inc. d/b/a Duke University Hospital / Replace cardiac catheterization equipment / 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.

C

The Duke University Health System, Inc. (DUHS) d/b/a Duke University Hospital (Duke) proposes to replace Philips Integris cardiac catheterization equipment at Duke with a Philips Allura Xper FD20/10 system. The cardiac catheterization equipment to be replaced in this project is located in the Adult Cardiac Catheterization Lab (ACCL) at Duke. The ACCL is one of five adult cardiac catheterization units at Duke; it is specifically designed to treat adults with congenital heart defects. The applicant does not propose to acquire any medical equipment or develop any health service facility beds or services for which there is a need determination in the 2013 State Medical Facilities Plan (SMFP).

There is one policy in the 2013 SMFP applicable to the review of the application:

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES

"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, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN 4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan 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."

Duke provides a statement regarding its compliance with Policy GEN-4 in Section III.2, page 17:

"The construction to be undertaken for this project is relatively minimal, but Duke is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves.

This project will not affect hospital air handling units or water usage, but electrical lighting fixtures replaced will be energy efficient and in compliance with the special needs of the room. Duke will comply with state and local building codes and will avail itself of sustainable initiatives to the extent reasonable and appropriate."

The applicant adequately described the project's plan to assure improved energy efficiency and water conservation. Thus, the application is conforming to Policy GEN-4. Therefore, the application is conforming with this criterion.

(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 Duke University Health System, Inc. (DUHS) d/b/a Duke University Hospital (Duke) proposes to replace Philips Integris cardiac catheterization equipment at Duke with a Philips Allura Xper FD20/10 system. The cardiac catheterization equipment to be replaced in this project is located in the Adult Cardiac Catheterization Lab (ACCL) at Duke. The ACCL is one of five adult cardiac catheterization units at Duke; it is specifically designed to treat adults with congenital heart defects.

Population to be Served

In Section III.4(a)-(b), pages 18-19, the applicant provides FY 2012 patient origin for the entirety of Duke and for the Duke cardiac catheterization patient origin. In Section III.5(c), page 20, the applicant projects cardiac catheterization utilization for FYs 2015 and 2016, as illustrated in the following table:

Past and Projected Origin by County—Duke Patients and Duke Cardiac Catheterization Patients			
	FY 2012 Duke Patient Origin	**FY 2012 Duke Cardiac Catheterization Patient Origin**	**Projected FY 2015-2016 Duke Cardiac Catheterization Patient Origin**
County	**% of Total Patients**	**% of Total Patients**	**% of Total Patients**
Alamance	4.0%	5.2%	5.2%
Chatham	1.3%	0.7%	0.7%
Durham	28.0%	16.9%	16.9%
Franklin	1.3%	0.8%	0.8%
Granville	3.4%	3.2%	3.2%
Harnett	1.0%	0.8%	0.8%
Johnston	1.2%	1.3%	1.3%
Lee	0.7%	1.5%	1.5%
Nash	0.9%	0.7%	0.7%
Orange	3.6%	3.1%	3.1%
Person	3.7%	3.2%	3.2%
Wake	10.1%	9.9%	9.9%
Other NC	28.8%	36.0%	36.0%
Other states	12.0%	16.7%	16.7%
TOTAL	**100.0%**	**100.0%**	**100.0%**

The applicant states on page 20 that it does not project a significant change in patient origin patterns and that it therefore projects future patient origin that is consistent with past trends. The applicant adequately identifies the population to be served.

Need to Replace Existing Cardiac Catheterization Equipment

The applicant states on pages 12-13 of its application that the equipment was originally installed in 2001 and has surpassed its useful life. The applicant states that upgrading is not an option because Philips no longer manufactures the parts or the model used; therefore, the applicant decided to replace its cardiac catheterization equipment.

In Section III.1(a), page 12, the applicant states:

> *"This equipment is Duke's only biplane equipment in the ACCL program. The biplane lab is a specialized room and very different from the other adult catheterization labs in that it can serve adult congenital heart patients. … No other adult cardiac catheterization lab (which are all monoplane equipment) at Duke University Hospital is currently equipped for these procedures.*
>
> *As a result of its age, during FY12 this equipment had 19 service calls, which led to equipment downtime. When the equipment to be replaced fails during a procedure, the patient must be relocated. Congenital cases and other cases requiring biplane equipment must be cancelled unless they can be scheduled in one of DUH's two pediatric catheterization biplane rooms, which are staffed and equipped for the specialized treatment of pediatric patients and are therefore not optimal for the regular treatment of adult patients."*

In Section III.1(b), page 13, the applicant states that the average interventional procedure takes three times longer than the average diagnostic procedure. Because Duke is an academic medical center and teaching hospital, factors such as the participation of students and the heightened complexity of cases play a role in the length of interventional cases. On page 14, the applicant states that due to the length of procedures, the five existing adult cardiac catheterization labs are at approximately 80% of capacity. The applicant provides a table on page 14 documenting its procedure volume, case time with both five labs and four labs, and percent of capacity for the last four fiscal years, as shown below:

Duke Adult Cardiac Catheterization Lab Cases				
	FY09	**FY10**	**FY11**	**FY12**
Diagnostic cases	3,402	3,358	3,498	3,450

Interventional cases	1,042	960	917	974
Peripheral cases	259	682	378	381
Adult Congenital cases	60	74	75	56
Total cases	4,763	4,774	4,868	4,861
Case Time (hrs/yr)	10,691	10,868	10,669	10,618
Hours of Operation per Room per Day	10.5	10.5	10.5	10.5
Available Case Time (hrs/yr)	13,440	13,440	13,440	13,493
Percent of Capacity*—5 labs	79.5%	80.9%	79.4%	78.7%
Percent of Capacity*—4 labs	99.4%	101.1%	99.2%	98.4%

*Capacity based on hours of operation

In Chapter 9 of the 2013 SMFP, there is a methodology for determining the number of cardiac catheterization units needed in a given facility is listed. That methodology calculates the weighted total of diagnostic procedures (1 diagnostic procedure = 1 diagnostic-equivalent procedure) in addition to the weighted total of interventional procedures (1 interventional procedure = 1.75 diagnostic-equivalent procedures) and pediatric procedures (1 pediatric procedure = 2 diagnostic-equivalent procedures). The methodology then divides the total of the three types of catheterization by 80% of the capacity of a single unit of cardiac catheterization equipment (capacity of one unit = 1500 procedures; 1200 = 80% of capacity). The number that results is the number of units of cardiac catheterization equipment needed. Case time is not factored into the 2013 SMFP methodology.

Applying the 2013 SMFP methodology to Duke's adult cardiac catheterization lab historical utilization:

Duke Adult Cardiac Catheterization Lab Units Needed—Past Utilization				
	Diagnostic Cases	**Interventional Cases**	**Diagnostic-Equivalent Total**	**Total Units Needed**
FY09	3,402	1,042	5225.55	4.35
FY10	3,358	960	5038.00	4.20
FY11	3,897	1,596	5102.75	4.25
FY12	3,450	974	5154.50	4.30

Note: Capacity based on 1500 cases per unit per year

The above table does not include pediatric procedures, adult congenital procedures, or peripheral procedures. According to Duke, adult congenital procedures are not currently reported as either diagnostic or interventional procedures on the licensure renewal application because the medical procedure codes used to designate adult congenital cases are not requested on the licensure renewal application. Duke has included footnotes of cases it reported noting that it excluded adult congenital procedures from the numbers listed on the licensing renewal application. According to Duke, the adult congenital procedures are a mix of diagnostic and therapeutic procedures. Without breaking down each component of each individual procedure, Duke estimates that adult congenital procedures are approximately 40% therapeutic procedures and 60% diagnostic procedures.

The 2013 SMFP shows that Duke operates seven units of cardiac catheterization equipment. The 2013 SMFP shows a need for 6.74 cardiac catheterization units based on past utilization, which includes both adult and pediatric diagnostic and interventional types of procedures.

Applying the 2013 SMFP methodology to Duke's cardiac catheterization procedure projection for both adult and pediatric cardiac catheterization procedures, excluding adult congenital and peripheral cases:

Duke Cardiac Catheterization Lab Units Needed—Projected Utilization (Adult and Pediatric)				
	Diagnostic Cases	**Interventional Cases**	**Diagnostic-Equivalent Total**	**Total Units Needed**
FY15	3,927	2,141	7673.55	6.40
FY16	3,927	2,178	7738.50	6.45
FY17	3,927	2,217	7806.75	6.51

Note: Capacity based on 1500 cases per unit per year

In Section III.1(b), page 15, the applicant states that the population growth of its primary service area will grow at a faster rate than that of the state population growth. Additionally, the applicant states that its average patient age for cardiac catheterization services is 61 years old, and the population growth for age groups that are age 61 and higher will grow at a faster rate than other populations, as shown below.

Population Growth by Service Area and Age Group							
		Population Change 2012-2017		**Population % Change by Age Cohort 2012-2017**			
Regions	**2012 Population**	**% Change**	**5 Year Growth**	**0-17**	**18-44**	**45-64**	**65+**
Greater Triangle	2,220,140	9.9%	219,794	10.8%	2.0%	14.8%	27.2%
Secondary	2,095,469	4.1%	85,599	3.5%	0.3%	3.2%	16.9%
Total GT and S	4,315,609	7.1%	305,912	7.3%	1.2%	9.0%	21.5%
North Carolina	9,783,974	7.0%	684,878	7.0%	1.4%	8.3%	20.9%

Source: Thomson Reuters

The applicant states on page 16 that it contracts with a company that has a market prediction tool, and that the proprietary data suggests increases in inpatient peripheral procedures and adult congenital procedures (11.1%); outpatient peripheral procedures (37%); and outpatient interventional procedures (73.4%).

The applicant adequately demonstrates the need to replace the biplane cardiac catheterization equipment because of past utilization and the unique capabilities of the biplane equipment.

Projected Utilization

In Section IV.1, pages 23-24, the applicant provides annual utilization of its cardiac catheterization equipment for the last four fiscal years (with two of the years having interim data) and projected utilization for the first three fiscal years following completion:

Past and Projected Utilization of Duke Cardiac Catheterization Units							
	FY 2011 (7/1/10-6/30/11)	**FY 2012 (7/1/11-6/30/12)**	**Interim FY 2013 (7/1/12-6/30/13)**	**Interim FY 2014 (7/1/13-6/30/14)**	**FY 2015 (7/1/14-6/30/15)**	**FY 2016 (7/1/15-6/30/16)**	**FY 2017 (7/1/16-6/30/17)**
Units	7	7	7	7	7	7	7
Diagnostic Procedures	4,125	3,927	3,927	3,927	3,927	3,927	3,927
Therapeutic Procedures	1,838	2,032	2,067	2,104	2,141	2,178	2,217

The applicant states on page 23 that because the application is for replacement equipment, as opposed to increasing capacity, Duke is relying on conservative growth projections. The applicant used a projected annual growth rate of 2%, which it believes is consistent with population growth.

In summary, the applicant adequately identified the population to be served and demonstrated the need to replace the biplane cardiac catheterization equipment in the ACCL at Duke. Therefore, the application is conforming with 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, pages 17-18, the applicant described several alternatives considered prior to the submission of this application, which include:

1. Maintain the Status Quo: The applicant rejected this alternative because it did not provide appropriate technology for high quality care; impeded the growth and renovation plan for the Heart Center; limited the number of cases performed; prevented congenital cases from being performed; and negatively impacted the work culture, satisfaction, and recruiting ability.

2. Upgrade Equipment: The applicant rejected this alternative because the manufacturer no longer makes the model or parts needed to upgrade.

3. Do Not Replace ACCL Lab: The applicant rejected this alternative because it would be unable to accommodate adult congenital cases. The applicant states that it is one of the few hospitals in the nation that provides support for this type of procedure and the applicant is part of advancements in the area of adult congenital cases.

4. Replace with Different Equipment: The applicant rejected this alternative because the applicant already uses Philips equipment as its preferred vendor for cardiac services. The applicant states that an alternative company would require heavy investments in IT infrastructure to keep current systems and new systems in sync.

Based in part on the actual utilization and projected utilization of the equipment; the difficulties with service and repair of the existing equipment; the difficulties that would occur if a new system were implemented; and the applicant's stated need to maintain a program which is available at limited facilities around the country, the applicant adequately demonstrated that the proposed alternative is the most effective or least costly alternative.

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

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

1. Duke University Health System, Inc. d/b/a Duke University Hospital shall materially comply with all representations made in the certificate of need application.

2. Duke University Health System, Inc. 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, Inc. 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.

In Section VIII.1, page 47, the applicant states that DUHS will bear the entire capital cost and is responsible for all capital costs. The applicant projects the capital cost for the proposed project will be $2,686,090, as shown in the following table:

Cardiac Catheterization Replacement Capital Cost	
Construction Contract	$769,758
Miscellaneous Project Costs	
Fixed Equipment	$1,385,592
Architect/Engineering Fees	$154,810
Permits/Inspection	$25,530
Contingency	$350,400
Total Capital Cost of Project	**$2,686,090**

In Section IX.1, page 53, the applicant indicates that the project is not a new facility or service and therefore will not have start-up and initial operating expenses. The applicant states on page 49 that the project will be financed using accumulated reserves of DUHS. In Exhibit VIII.6, the applicant provides a letter dated June 6, 2013 from the Senior Vice President, Chief Financial Officer and Treasurer, which verifies the availability of DUHS accumulated reserves for the proposed project.

Exhibit VIII.9 contains the most recent audited financial statements available (FY 2012) for DUHS. The line item "*Cash and cash equivalents*" shows a value of $243,215,000 as of June 30, 2012. The line item "*Total assets"* shows a value of $4,165,672,000, and the line item "*Total net assets"* shows a value of $2,069,383,000 as of June 30, 2012. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements and assumptions (immediately following Section XII) for the first three operating years of the project following completion. The following table illustrates projected procedures, average charge, gross revenue, net revenue, expenses and net income for cardiac catheterization services (on all equipment) at Duke. The applicant projects that revenues will exceed operating costs in each of the first three years of operation for cardiac catheterization services. The revenue projections from information provided on Forms D and E are as follows:

Revenue Projections for Duke Cardiac Catheterization Procedures			
	First Full FY 2015	**Second Full FY 2016**	**Third Full FY 2017**
# of Procedures	6,068	6,105	6,144
Projected Average Gross Charge per Procedure	$78,763	$83,561	$88,655
Gross Revenue	$477,933,884	$510,139,905	$544,696,320

Projected Average Net Revenue (Reimbursement) per Procedure	$21,144	$21,118	$21,095
Net Revenue	$128,301,792	$128,925,390	$129,607,680

The applicant also provided pro forma financial statements for the first three project years for DUHS. The applicant projects that revenues will exceed expenses in each of the first three project years, as shown below:

Revenue Projections for DUHS			
	First Full FY 2015	**Second Full FY 2016**	**Third Full FY 2017**
Total Operating Revenue*	$2,805,065,000	$2,881,395,000	$2,968,149,000
Total Expenses	$2,689,555,000	$2,791,160,000	$2,896,534,000
Net Revenue	$115,510,000	$90,235,000	$71,615,000
Non-Operating Revenue	$173,011,000	$193,751,000	$211,513,000
Excess Revenue Over Expenses	$288,521,000	$283,986,000	$283,128,000

*Operating Revenue = Net Patient Revenue + Non-Patient Revenue

Projected costs and revenues are based on reasonable assumptions, including projected utilization. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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.

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The Duke University Health System, Inc. (DUHS) d/b/a Duke University Hospital (Duke) proposes to replace Philips Integris cardiac catheterization equipment at Duke with a Philips Allura Xper FD20/10 system. The cardiac catheterization equipment to be replaced in this project is located in the Adult Cardiac Catheterization Lab (ACCL) at Duke. The ACCL is one of five adult cardiac catheterization units at Duke; it is specifically designed to treat adults with congenital heart defects. Duke states that it is one of a few providers nationally with the technology available to perform procedures involving adult congenital cases, and that the equipment being replaced is specific to those procedures.

The 2013 SMFP shows that Duke operates seven units of cardiac catheterization equipment. The 2013 SMFP shows a need for 6.74 cardiac catheterization units based on past utilization, which includes both adult and pediatric diagnostic and interventional types of procedures. The past utilization numbers do not include adult congenital cases due to the mixed nature of the procedures. The applicant projects growth in the number of interventional procedures while diagnostic procedures will remain constant.

Duke demonstrates the need to replace the current equipment due to its age and that it has evaluated alternatives before selecting the replacement equipment alternative. The replacement equipment alternative does not add cardiac catheterization equipment to the number of cardiac catheterization units at Duke or in Duke's proposed service area and, therefore, does not duplicate any existing or approved cardiac catheterization equipment in its service area.

See Criterion (3) for discussion regarding the need to replace the existing cardiac catheterization equipment and historic and projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrates that the proposal would not result in unnecessary duplication of existing or approved cardiac catheterization equipment in Durham County and 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.

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In Section VII.1 (a) & (b), pages 38-43, the applicant provides current and projected staffing for cardiac catheterization services. The applicant does not anticipate adding staff. The following table shows the current (2013) and projected (2017) staffing by position and salary.

Current and Proposed Staffing for Duke Cardiac Catheterization				
Position	**2013 FTEs**	**2017 FTEs**	**2013 Average Hourly Contract Rate**	**2017 Average Hourly Contract Rate**
Physicians Assistants	.37	.38	$53.21	$56.26
RNs	19.74	19.97	$42.51	$45.24
Aides/Orderlies	1.26	1.28	$14.61	$15.49
Cardiac Catheterization / EP Technicians	15.82	15.84	$40.25	$43.30
Total	37.19	37.47		

In Section VII.8, the applicant identifies its Chief of Staff and Medical Director for Duke.

The applicant adequately demonstrates the availability of adequate resources, including health manpower and management personnel, for the provision of the proposed services. Therefore, the application is conforming with 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.

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Duke is an existing acute care hospital and provides ancillary and support services for its inpatient and outpatient services. In Section II.2(a)-(c), page 8, the applicant identifies the following services it provides to support cardiac catheterization services:

- Clinical Engineering
- Patient Transport Services
- Radiation Safety
- Surgical Services
- Anesthesiology
- Respiratory Therapy

The applicant also states that the ancillary services will be provided as they are now, and documents their availability by noting that it performed 5,959 cardiac catheterization procedures in the previous year.

In Section V, pages 25-28, and Exhibit V.2, the applicant documents that cardiac catheterization services are coordinated with the existing healthcare system.
The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would continue to be coordinated with the existing healthcare 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

NA

(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;

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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 for Durham County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	**2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population ***	**2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)***
Durham County	16.0%	5.7%	20.1%

Statewide	17.0%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21.

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 45.9% for those age 20 and younger and 30.6% 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 payor 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 following table illustrates the current payor mix for Duke as reported by the applicant in Sections VI.12-VI.13, pages 35-36.

Current Payor Mix for Duke		
Payor Category	**FY 2012 Entire Facility**	**FY 2012 Cardiac Catheterization**
Self Pay/Indigent/Charity	3.9%	2.2%
Medicare/Medicare Managed Care	39.1%	48.7%
Medicaid	18.5%	9.6%
Commercial Insurance	0.8%	0.8%
Managed Care	31.3%	33.0%
Other*	6.3%	5.6%
TOTAL	100.0%	100.0%

*"Other" includes Duke Select; Champus Tricare; Durham VA; Tricare Standard; other Non-NC Medicaid; or other government agencies and programs

In Section VI.4(a), pages 30-31, the applicant states:

> "*Uninsured patients who are scheduled for a visit with one of our physicians are referred to our financial counseling staff. They would first determine whether the patient is a resident of Durham County or is to be seen in a follow-up to a visit to Duke University Hospital Emergency Department. If the answer to either is yes, the visit is scheduled, and the patient is contacted to determine the patient's possible eligibility for Medicaid or other insurance. If the answer to both is no, the physician is informed that the patient is not financially cleared. At that point the physician may choose to accept the patient anyway. The visit is scheduled and the patient is contacted to determine insurance eligibility. The patient will be seen and treated as ordered by the physician. An exhaustive effort to qualify the patient for Medicaid or other insurance will be made.*
> *If it fails, the uninsured patient would automatically receive a 65% discount from charges. The financial counseling staff will then review the patient's assets, other obligations, and ability to pay the amount outstanding over time. If it turns out that the patient is without assets and unable to pay, the patient will be invited to apply for charity care, and if appropriate documentation is provided, the application will be approved.*"

See also Exhibit VI.4 for a copy of Duke's policies on patient rights, patient admissions, and discounts, as well as a statement of DUHS' charity care policy.

The applicant demonstrates that medically underserved populations have adequate access to services available at Duke. 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

In Section VI.11, pages 34-35, the applicant states:

> "*Duke University Health System hospitals have now 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.*

They have no special obligation under applicable Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons other than those obligations which apply to private, not-for-profit, acute care hospitals which participate in the Medicare, Medicaid, and Title V programs."

In Section VI.10, page 34, the applicant states:

"*Duke is not aware of any court actions filed alleging equal access violations in the past 5 years. Duke is aware of the following agency complaints that have been filed against DUH facilities during that time period:*

- *A complaint regarding access to a sign language interpreter and TTY devices at DUH and Duke clinics was filed with DOJ in 2008. The complaint was resolved in settlement in 2008.*
- *A complaint of discrimination against DUH based on disability filed with OCR in 2010. OCR accepted the DUHS response without further action.*
- *A complaint of denial access to service animal filed against Durham Regional Hospital with OCR in 2010. Corrective action (consisting of education regarding newly revised service animal regulations) was accepted on May 4, 2012 and has been implemented."*

…

"All complaints have been fully resolved. There are no outstanding complaints at this time."

The applicant demonstrates that medically underserved populations have adequate access to Duke's existing cardiac catheterization services. Therefore, the application is conforming with 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

The following table illustrates the projected payor mix for Duke as reported by the applicant in Sections VI.14-VI.15, pages 35-36.

Projected Payor Mix for Duke		
Payor Category	**FY 2016 Entire Facility**	**FY 2016 Cardiac**

		Catheterization
Self Pay/Indigent/Charity	2.8%	2.2%
Medicare/Medicare Managed Care	43.1%	49.1%
Medicaid	18.3%	9.6%
Commercial Insurance	0.9%	0.8%
Managed Care	28.6%	32.7%
Other*	6.3%	5.6%
TOTAL	100.0%	100.0%

*"Other" includes Duke Select; Champus Tricare; Durham VA; Tricare Standard; other Non-NC Medicaid; or other government agencies and programs

In Section VI.6, page 31, the applicant states:

> *"Duke University Hospital provides outpatient and inpatient services that regularly and routinely serve indigent and other medically underserved persons."*

The applicant demonstrates that medically underserved populations will have adequate access to cardiac catheterization services. Therefore, the application is conforming with 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, pages 33-34, the applicant documents the range of means by which patients have access to the services provided at Duke. The information provided is reasonable and credible. 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(a), page 25, the applicant states:

> *"The cardiac catheterization laboratories of Duke University Hospital are used primarily to train fellows in cardiac catheterization. Fellows complete a three-year residency training program in internal medicine and the first two years of a three-year cardiology fellowship before beginning two-year subspecialty fellowships in electrophysiology and cardiac catheterization. The laboratories*

are also used to provide pre-service and in-service training to nursing and allied health professionals working in the labs or being prepared for work in the labs."

In Section V.1(b), page 25, the applicant states:

"As indicated in the response to the preceding item and in many previous applications, schools in the area have wide access to Duke University Hospital for training for learners in health professional training programs. Many other learners come to Duke for training by special arrangements with members of the clinical faculty and the Hospital."

The information provided is reasonable and credible. Therefore, the application is conforming with 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 Duke University Health System, Inc. (DUHS) d/b/a Duke University Hospital (Duke) proposes to replace Philips Integris cardiac catheterization equipment at Duke with a Philips Allura Xper FD20/10 system. The cardiac catheterization equipment to be replaced in this project is located in the Adult Cardiac Catheterization Lab (ACCL) at Duke. The ACCL is one of five adult cardiac catheterization units at Duke; it is specifically designed to treat adults with congenital heart defects.

In Section V.7, page 28, 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 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 with the replacement of equipment at the end of life with state-of-the-art new equipment. Duke will be

hampered in its ability to offer congenital cardiac catheterization procedures without this equipment, and therefore would not be as able to offer options to patients in the area in need of these procedures."

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 replace the biplane cardiac catheterization equipment in the ACCL and that it is a cost-effective alternative;
- The applicant has and will continue to provide quality services; and
- The applicant has and will continue to provide adequate access to medically underserved populations.

The application is conforming with 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 is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Acute Care Licensure and Certification Section, Division of Health Service Regulation, no incidents have occurred at Duke 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.

NA

The Criteria and Standards for Cardiac Catheterization Equipment, promulgated in 10A NCAC 14C .1600, are not applicable to this review since the applicant is not proposing an increase in the inventory of cardiac catheterization equipment.