ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: September 27, 2013

PROJECT ANALYST: Michael J. McKillip
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-10144-13 / Duke University Health System d/b/a Duke University Hospital / Renovations to the Duke North building, including infrastructure and technology upgrades to the bed tower, eleven operating rooms, and cardiac critical care unit / Durham

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

Duke University Health System d/b/a Duke University Hospital **[DUH]** proposes to renovate and modernize 29,000 square feet of space in the Duke North building, including infrastructure and technology upgrades to the bed tower, eleven operating rooms, and the cardiac critical care unit. There are no need determinations in the 2013 State Medical Facilities Plan (SMFP) that are applicable to this review. However, Policy GEN-4 of the 2013 SMFP is applicable to this review.

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

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

In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S.

131E-178, 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."

In Section III.2, pages 27-28, the applicant states:

> *"One of the major benefits of this project is modernizing the infrastructure and implementing upgrades that will improve energy and water efficiency. Duke is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability. The design team for this project will:*
>
> - *Implement environmental sustainability best practices to improve and reduce the facility's environmental impact.*
> - *Meet or exceed the requirements of the NC Building Code including ADA in effect when construction drawings are submitted.*
> - *Provide natural lighting where possible to augment electrical lighting and reduce electricity usage.*
> - *Design for maximum efficiency and life cycle benefits with new mechanical systems for heating, cooling and water.*
>
> *The proposed facility renovations will be completed using energy efficient material and methods, such as high efficiency lighting, new more efficient heating and air conditioning equipment and upgraded plumbing fixtures. The project will be designed to improve energy efficiency and water conservation."*

The applicant adequately demonstrates that it will assure improved energy efficiency and water conservation in the proposed project. Therefore, the application is consistent with Policy GEN-4.

In summary, the application is conforming to Policy GEN-4. Therefore, the application is conforming to 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

DUH proposes to renovate and modernize 29,000 square feet of space in the Duke North building, including infrastructure and technology upgrades to the bed tower, eleven operating rooms, and the cardiac critical care unit. In Section II.1(a), page 8, the applicant describes the components of the proposed project as follows:

"Duke University Hospital is proposing the renovation of existing space at its Duke North hospital building, including:

1) *The renovation of the Duke North bed tower and operating suite infrastructure, including electrical wiring to increase electrical capacity and connect second sources of power in the operating room and the 200 bed tower, replacement of air handling (AHUs) to improve temperate control and reduce maintenance in the inpatient setting, the installation of a new waste riser to replace fragile plumbing and support future plumbing renovations; and technology upgrades to provide consistent technology in the Duke North and DMP* [Duke Medical Pavilion] *platforms.*
2) *The renovation and modernization of nine operating rooms.*
3) *The upfit of two additional operating rooms with upgraded isolated power and cosmetic improvements; and*
4) *The renovation of a 16-bed cardiac critical care unit (7200).*

The total capital cost of the project is $48,400,000. No additional space is being constructed and there will be no addition to Duke's inventory of regulated assets, including beds, operating rooms, or major medical equipment."

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

"In 2007, Duke applied for and was awarded a certificate of need for the construction of a major hospital addition to accommodate the construction of 16 new operating rooms, the relocation of 160 beds, and the conversion of ____ [sic] *general acute care beds to intensive care beds.* [Note: The applicant was approved to convert 48 general acute care beds to intensive care beds]. *Please see Project #J-8030-07. The beds and operating rooms in the building now known as the Duke Medical Pavilion (DMP) are due to open for patient services in July 2013 (although other elements of the project are still under development). … The opening of the new operating rooms and the relocation of beds provides a unique opportunity to renovate existing space in Duke North with a minimum of interference with patient care. That*

is, while the volumes in the DMP are ramping up and before the full complement of new and old operating rooms are fully scheduled with block time, Duke can renovate the infrastructure, the older operating rooms and existing acute care bed space to bring the facility up to modern building codes and current hospital standards. These renovations of the existing facility are now able to take place in a unique window of opportunity afforded by the opening of the DMP without negatively affecting patient care, by minimizing the difficulties of construction noise, infection control, and maintenance of the supply and product chain."

Population to be Served

In Section III.5, pages 31-32, the applicant provides projected patient origin for DUH's surgical services and cardiac critical care unit (CCU) in the first two years of operation, as shown in the table below.

County	Surgical Services Percent of Total	Cardiac CCU Percent of Total
Alamance	3.5%	8.1%
Chatham	1.9%	1.2%
Durham	22.2%	21.6%
Franklin	1.0%	1.7%
Granville	2.9%	4.2%
Harnett	0.9%	9.5%
Johnston	1.3%	0.5%
Lee	0.5%	2.6%
Nash	1.2%	0.7%
Orange	4.5%	3.9%
Person	3.1%	6.1%
Wake	14.1%	6.9%
Other NC*	29.5%	28.2%
Out of State	13.5%	13.5%
TOTAL	**100.0%**	**100.0%**

*The applicant provides a complete listing of the counties included in *"Other NC"* in Exhibits III.4(b)1 and III.4(b)2.

On page 32 of the application, the applicant states *"projected patient origin is essentially the same as current* [FY2013] *patient origin."* The applicant adequately identified the population proposed to be served.

Need for the Project

In Section III.1(a) of the application, the applicant describes the factors supporting the need for the proposed project, including, the need to upgrade the infrastructure in the 34-year old Duke North building, (pages 13-15), the need to renovate and modernize the operating rooms to accommodate the changes in surgical equipment and technologies (pages 15-18), and the need to renovate and modernize the cardiac critical care unit to accommodate additional equipment, increase the space available for family, and increase and improve work spaces for nursing and

other clinical staff (pages 18-19). Also, the applicant states the need for the project is supported by projected service area population growth (pages 19-20), continued recruitment of faculty physicians and surgeons (pages 20-21), growth in surgical services utilization (pages 21-22), and increasing surgical case times (pages 22-26).

Operating Rooms

In Section IV.1, page 34, the applicant provides a table showing the historical and projected utilization for DUH's operating rooms through the first three years of operation (FY2017-FY2019) for the proposed project, which is summarized below:

Duke University Hospital Operating Room Utilization

Fiscal Year	Operating Rooms*	Inpatient Surgical Cases	Outpatient Surgical Cases	Total Surgical Cases	Percent Change
FY2011 Actual	49	15,220	21,144	36,364	---
FY2012 Actual	49	14,862	22,262	37,124	2.1%
FY2013 Projected**	65	15,318	22,119	37,437	0.8%
FY2014 Projected	65	15,776	22,445	38,221	2.1%
FY2015 Projected	65	16,247	22,800	39,047	2.2%
FY2016 Projected	65	16,732	23,156	39,888	2.2%
FY2017 Project Year 1	65	17,232	23,518	40,750	2.2%
FY2018 Project Year 2	65	17,747	23,891	41,638	2.2%
FY2019 Project Year 3	65	18,277	24,274	42,551	2.2%

*In Project I.D. # J-8030-07, pursuant to Policy AC-3, DUH was approved to develop 16 additional operating rooms. Therefore, upon completion of the project in July 2013, the number of operating rooms at DUH increased from 49 to 65 operating rooms [49 + 16 = 65].
**Applicant states FY2013 utilization is projected based on year-to-date data annualized.

In Section IV.2, pages 35-36, the applicant describes the assumptions and methodology used to project the number of surgical cases to be provided at DUH during the first three years of operation as follows:

> *"The methodology is based on the following assumptions:*
>
> - *Recent growth in Duke's inpatient volumes have been constrained by Duke's very high utilization of its existing operating rooms and critical care units, described in Section III. Despite these constraints, Duke North's inpatient surgery volumes grew by 3% in FY 2013 due to the recruitment of several new surgical faculty members and aggressive operating rooms and bed capacity management. In light of anticipated population growth and continued faculty recruitment, Duke conservatively anticipates that growth will continue at least at this annual rate as the existing capacity constraints ease with the opening both of additional operating rooms and dedicated intensive care and intermediate step-down beds in the DMP* [Duke Medical Pavilion].
> - *Duke's outpatient surgeries grew at an overall rate of 2.3% from FY 2011 to FY 2013. Duke North outpatient surgeries in particular grew at an annual rate of*

7.4% from FY 2011 to FY 2013. Duke conservatively projects a continued annual growth of 3% in ambulatory surgery cases accommodated in Duke North/DMP operating rooms, and a slower growth of 1% in ambulatory cases accommodated in the Ambulatory Surgery Center operating rooms. This averages to total ambulatory surgery growth less than 2% per year, which is less than Duke's recent historical growth.

- *As set forth in Project ID J-8707-11, Duke has previously projected that volumes at the Eye Center will remain substantially the same pending the development of the new Eye Center building which is subject to ongoing fundraising efforts. Duke continues its fundraising efforts, but for the purposes of this project assumes that the Eye Center will continue to operate in its current configuration and that volumes will remain constant with FY 13 volumes, or 6264 outpatient procedures and 65 inpatient procedures per year.*
- *Duke conducted extensive interviews with Duke surgeons regarding their anticipated surgical caseloads beginning in FY 14 after the opening of the DMP provides additional block time. These interviews support Duke's projections that surgical procedures will grow significantly after the easing of the existing capacity constraints.*

Note that these projections are more conservative that those set forth in the Duke DMP application in 2007. This reflects several factors. The filing of the application predated both the economic downturn beginning in 2008 and the enactment of the Patient Protection and Affordable Care Act. In addition, as this project necessarily entails taking existing operating rooms out of service during their renovation, the effective operating room capacity of the hospital will be less than 65 rooms during the interim years of the project. Finally, increasing case time will continue to affect the effective capacity of Duke's operating rooms. Accordingly, and to ensure the financial feasibility of this project, Duke has made more conservative and gradual projections about the rate at which Duke will reach full utilization of its operating rooms."

The following table shows the historical utilization for DUH's operating rooms from FY2007 through FY2012, as reported to DHSR in DUH's *Hospital License Renewal Application* forms for 2008-2013.

Fiscal Year	Total Surgical Cases	Percent Change
2007	33,718	---
2008	34,066	1.0%
2009	34,994	2.7%

2010	36,099	3.2%
2011	36,364	0.7%
2012	37,124	2.1%

Source: Hospital License Renewal Application forms, 2008-2013.

As indicated in the table above, DUH's total surgical case volumes increased from 33,718 cases in FY2007 to 37,124 cases in FY2012, or by 10.1 percent over the five-year period. The applicant projects DUH's surgical case volumes will continue to grow at its historical growth rate of approximately 2 percent per year through the first three years of operation following completion of the project. Exhibit V.3 of the application contains letters from physicians, including the Vice-Chair of the Department of Surgery for DUH, expressing support for the proposed project. The projected utilization of the operating rooms at DUH is based on reasonable, credible and supported assumptions. DUH adequately demonstrates the need for the proposed renovations to the operating rooms.

Cardiac Critical Care Unit

In Section IV.1, page 36, the applicant provides a table showing the historical and projected utilization for DUH's cardiac CCU through the first three years of operation (FY2017-FY2019) for the proposed project, which is summarized below:

Duke University Hospital Cardiac Critical Care Unit Utilization

Fiscal Year	# of Beds	Patient Discharges	Patient Days of Care	Average Occupancy Rate
FY2011 Actual	16	1,674	4,979	85.3%
FY2012 Actual	16	1,664	5,186	88.8%
FY2013 Projected*	16	1,683	5,186	88.8%
FY2014 Projected	16	1,683	5,186	88.8%
FY2015 Projected	16	1,683	5,186	88.8%
FY2016 Projected	16	1,683	5,186	88.8%
FY2017 Project Year 1	16	1,683	5,186	88.8%
FY2018 Project Year 2	16	1,683	5,186	88.8%
FY2019 Project Year 3	16	1,683	5,186	88.8%

*Applicant states FY2013 utilization is projected based on year-to-date data annualized.

In Section IV.1, page 36, the applicant describes the assumptions and methodology used to project the utilization of the cardiac CCU at DUH during the first three years of operation as follows:

> *"FY 12 and annualized FY 13 year-to-date volumes remain constant at 5186 patient days per year. The unit is already currently operating at nearly 89% occupancy, which reflects an average daily census of more than 14.2 out of 16 beds. Because it is not increasing the number of beds, the project is not designed to increase capacity of this unit, but rather to ensure infrastructure adequacy and to increase patient satisfaction and operational efficiencies. Therefore, to be conservative for the purposes of this*

application, Duke simply projects that annual volumes will remain the same in this unit."

As indicated in the table above, DUH's cardiac CCU operated at 85% and 89% of capacity in FY2012 and FY2013, respectively. The applicant projects utilization of the cardiac CCU will remain at historical levels through the first three years of operation following completion of the project. Exhibit V.3 of the application contains letters from physicians, including the Chief of Division of Cardiology and Director of the Duke Heart Center, expressing support for the proposed project. The projected utilization of the cardiac CCU at DUH is based on reasonable, credible and supported assumptions. DUH adequately demonstrates the need for the proposed renovation of the cardiac CCU.

Access

The applicant projects 61.9% of its surgery patients will be covered by Medicare (47.3%) and Medicaid (14.6%), and projects 72.7% of its cardiac CCU patients will be covered by Medicare (64.7%) and Medicaid (8.0%).The applicant demonstrates adequate access for medically underserved groups to the proposed 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, pages 28-29, the applicant describes the alternatives considered, including maintaining the status quo and undertaking a more limited upgrade to the infrastructure of Duke North.

- The applicant states it rejected the status quo alternative due to the need to update the aging building and ensure safe and efficient patient care.

- The applicant considered the alternative of undertaking a more limited upgrade to the infrastructure, but rejected it because it would not address the problem of the too-small operating rooms and lack of modernized facilities. Also, it would be more expensive and more disruptive to operations to complete the infrastructure upgrades now, and then later undertake the needed renovations to the operating rooms and other areas included in this project.

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 $48,400,000. In Section VIII.3, the applicant states the capital cost will be financed with accumulated reserves of Duke University Health System (DUHS). In Section IX.1, the applicant projects no start-up or initial operating expenses. In Exhibit VIII.6, the applicant provides a letter signed by the Senior Vice President and Chief Financial Officer for DUHS, which states

> *"This will certify that Duke University Health System has as much as $50,000,000 in accumulated reserves to devote to the Duke North Transformation project at Duke*

University Hospital, including infrastructure upgrade and renovation and upgrade of the cardiac critical care unit and nine operating rooms."

Exhibit VIII.9 of the application contains audited consolidated financial statements for DUHS for the year ended June 30, 2012, which documents that DUHS had $243 million in cash and cash equivalents and $963 million in total current assets as of June 30, 2012. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the proposal.

In pro forma financial statements for DUH (Form B), the applicant projects revenues will exceed expenses in each of the first three operating years, as shown below:

Duke University Hospital

(All $ are in 000's)	FY2016 Year 1	FY2017 Year 2	FY2018 Year 3
Total Revenues	$2,968,582	$3,041,321	$3,168,469
Total Expenses	$2,658,339	$2,749,834	$2,869,669
Net Income (Loss)	$310,243	$291,487	$298,800

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

DUH proposes to renovate and modernize 29,000 square feet of space in the Duke North building, including infrastructure and technology upgrades to the bed tower, eleven operating rooms, and the cardiac critical care unit. The following table shows the acute care beds utilization for the existing hospital providers in the Durham County service area:

Utilization of Existing Hospitals in DUH's Primary Service Area

	Licensed Acute Care Beds	2012 Acute Care Patient Days	Average Daily Census	Average Occupancy Percent
Duke Regional Hospital	316	56,591	155	49.1%
Duke University Hospital	924	236,337	647	70.1%
North Carolina Specialty Hospital	18	4,068	11	61.9%

Source: *Proposed 2014 State Medical Facilities Plan,* Table 5A.

The following table shows the operating room utilization for the existing providers in the Durham County service area:

Utilization of Existing Operating Rooms in DUH's Primary Service Area

	Operating Rooms*	Inpatient Surgical Cases*	Ambulatory Surgical Cases
James E. Davis Ambulatory Surgical Center	8	NA	4,583
Duke Regional Hospital	13	3,647	3,229
Duke University Hospital	49	16,966	21,368
North Carolina Specialty Hospital	4	1,553	4,973

Source: *Proposed 2014 State Medical Facilities Plan,* Table 6A.
*Excludes dedicated C-section operating rooms and C-section surgical cases.

In Section III.6, page 32, the applicant states

> *"As an academic medical center, Duke is not required to demonstrate the utilization of other providers for the proposed new institutional health service. However, given that this project simply proposes the acquisition of replacement equipment necessary to support services already provided by Duke, other providers would not be in a position to meet the identified need in any event."*

In Section IV.1, page 34, the applicant provides a table showing the historical and projected utilization for DUH's operating rooms through the first three years of operation (FY2017-FY2019) for the proposed project, which is summarized below:

Duke University Hospital Operating Room Utilization

Fiscal Year	Operating Rooms*	Inpatient Surgical Cases	Outpatient Surgical Cases	Total Surgical Cases	Percent Change
FY2011 Actual	49	15,220	21,144	36,364	---
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FY2017 Project Year 1	65	17,232	23,518	40,750	2.2%
FY2018 Project Year 2	65	17,747	23,891	41,638	2.2%
FY2019 Project Year 3	65	18,277	24,274	42,551	2.2%

*In Project I.D. # J-8030-07, pursuant to Policy AC-3, DUH was approved to develop 16 additional operating rooms. Therefore, upon completion of the project in July 2013, the number of operating rooms at DUH increased from 49 to 65 operating rooms [49 + 16 = 65].
**Applicant states FY2013 utilization is projected based on year-to-date data annualized.

In Section IV.1, page 36, the applicant provides a table showing the historical and projected utilization for DUH's cardiac CCU through the first three years of operation (FY2017-FY2019) for the proposed project, which is summarized below:

Duke University Hospital Cardiac Critical Care Unit Utilization

Fiscal Year	# of Beds	Patient Discharges	Patient Days of Care	Average Occupancy Rate
FY2011 Actual	16	1,674	4,979	85.3%
FY2012 Actual	16	1,664	5,186	88.8%
FY2013 Projected*	16	1,683	5,186	88.8%
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FY2017 Project Year 1	16	1,683	5,186	88.8%
FY2018 Project Year 2	16	1,683	5,186	88.8%
FY2019 Project Year 3	16	1,683	5,186	88.8%

*Applicant states FY2013 utilization is projected based on year-to-date data annualized.

DUH projected utilization for the operating rooms, and demonstrated the need to renovate eleven existing operating rooms. The applicant proposes to renovate eleven existing operating rooms, and does not propose to add to the total number of operating rooms in the applicant's service area. Similarly, DUH projected utilization for the cardiac CCU, and demonstrated the need to renovate the existing cardiac CCU. The applicant proposes to renovate the existing 16-bed cardiac CCU, and does not propose to add to the total number of acute care beds in the applicant's service area. 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 Exhibit VII.1, the applicant provides the current and proposed staffing for Duke North services, as shown in the table below.

Duke North Staffing	**Current FTEs**	**Proposed FTEs**
Administration	27.12	27.92
Registered Nurse	572.89	695.89
Licensed Practical Nurse	0.47	0.47
Aides/Orderlies	18.80	19.61
Other*	118.18	144.66
Surgical Technicians	35.37	45.51
Technologists	2.42	2.56
Total	**775.25**	**936.62**

*The applicant states *"Other"* includes clinical trial assistants, data technicians, programmers, and sterile processing technicians.

The applicant states, *"Fixed FTEs for FY18 are assumed to remain constant from current staffing levels, and variable FTEs will increase with the increase in procedure volume in surgical services."* In Section VII.3, page 51, and Section VII.6, page 52, the applicant states that it does not anticipate any difficulties identifying, hiring, and retaining qualified staff for the proposed project. In Section VII.8, page 53, the applicant identifies Thomas A. Owens, M.D. as the Medical Director for DUH. Exhibit V.3 of the application contains copies of letters from physician and surgeons expressing support for the proposed project. 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, page 8, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at DUH. Exhibit V.2 contains a list of facilities with which DUH has transfer agreements, and a copy of a sample transfer agreement. Exhibit V.3 contains copies of letters from physician and surgeons expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will be available and that 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

The applicant proposes to renovate 29,000 square feet of space in the Duke North building. No new construction is proposed.

(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 48, the applicant provides the payer mix during FY2012 for the surgical and cardiac CCU services at DUH, as shown in the table below.

Payer Category	Surgical Services as % of Total	Cardiac CCU Discharges as % of Total
Self Pay/Indigent/Charity	1.7%	4.2%
Medicare/Medicare Managed Care	39.9%	64.1%
Medicaid	15.4%	7.6%
Commercial Insurance	0.8%	0.5%
Managed Care	34.6%	19.2%
Other	7.0%	4.3%
Total	**100.0%**	**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. 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 surgical services and cardiac CCU 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;

C

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."

In Section VI.10 (a), page 47, 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, pages 49-50, the applicant provides the projected payer mix for the second full fiscal year following completion of the proposed project (FY2018) for the surgical and cardiac CCU services at DUH, as shown in the table below.

Payer Category	**Surgical Services as % of Total**	**Cardiac CCU Discharges as % of Total**
Self Pay/Indigent/Charity	0.9%	4.9%
Medicare/Medicare Managed Care	47.3%	64.7%
Medicaid	14.6%	8.0%
Commercial Insurance	0.9%	0.7%
Managed Care	47.3%	18.6%
Other	6.6%	3.0%
Total	**100.0%**	**100.0%**

In Section VI.15(b), page 50, the applicant describes its assumptions as follows:

"For surgery services, projected payor mix is based on the annualized payor mix for FY13, with the following projections: 1% of patients will shift from managed care to Medicare each year to an aging of the population, and Self-pay patients will decline by 10% as a result of the Affordable Care Act, with those patients becoming covered by managed care. For Unit 7200 patients, who reflect different demographics, projected payor mix is based on the annualized payor mix for year-to-date FY 13 patients, with a conversion of 1% of managed care patients to Medicare per year between FY 2014 and FY 2019 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 46, the applicant describes the range of means by which a person will have access to its services. The information provided is reasonable and credible and supports a finding of conformity 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 V.1, page 37, 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 North Carolina Central University. 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

DUH proposes to renovate and modernize 29,000 square feet of space in the Duke North building, including infrastructure and technology upgrades to the bed tower, eleven operating rooms, and the cardiac critical care unit.

In Section V.7, page 42, 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 with the renovation of infrastructure and modernization of existing facilities."*

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 renovate and modernize the Duke North building 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

DUH 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 DUH 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