ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE:

January 20, 2012

PROJECT ANALYST

Les Brown

ASSISTANT CHIEF:

Craig R. Smith

PROJECT I.D. NUMBER:

J-8707-11 / Duke University Health System d/b/a Duke University

Hospital / Expansion of the Eye Center / 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

Duke University Health System (DUHS) d/b/a Duke University Hospital (DUH) proposes to construct an addition to the hospital's Wadsworth Eye Center (WEC) for the development of the Eye Clinic Building (ECB). The proposed project will be developed on the second and third floors of the new facility, with the four additional procedure rooms, prep, recovery and support services on the third floor adjoining the existing surgical services. The proposed ancillary services will be on the second floor. The first and fourth floors will include offices for DUH and the School of Medicine. There are no need determinations in the 2011 SMFP that are applicable to this project. However, Policy GEN-4 in the 2011 State Medical Facilities Plan (SMFP) is applicable to the review of the proposed project.

Policy GEN-4 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 efficient and water conservation standards incorporated in the latest editions of the North Carolina States 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 [sic] 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 Exhibit XI.7 the applicant states:

"[T]he Duke Eye Clinic Building (ECB) will develop and implement an energy efficiency and sustainability plan for the project that conforms to the energy efficiency and water conservation standards incoriporated in the latest editions of the North Carolina State Building Codes. The recently adopted North Carolina legislation (Bill 708), effective January 2012, the project will focus on improving energy efficiency in the following key areas:

- Efficient mechanical equipment systems
- Energy efficient lighting systems
- Energy efficient ventilation systems
- Higher efficiency service water heating
- Onsite supply of renewable energy
- Automatic day-lighting control systems"

The hospital provides a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and 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

Duke University Health System (DUHS) d/b/a Duke University Hospital (DUH) proposes to construct a 126,950 square foot addition to the hospital's Wadsworth Eye Center (WEC) for the development of the Eye Clinic Building (ECB). The proposed project will be developed on the second and third floors of the new facility, with the first and fourth floors to include offices for DUH and the School of Medicine. The five existing operating rooms and one procedure room will remain in the existing WEC.

On pages 8-10 the applicant states:

"Project Site

The Eye Clinic Building (ECB) will be constructed on a surface parking lot that separates the Wadsworth Eye Center (WEC) from Erwin Road, saving the cost of demolishing existing facilities. Parking for Eye Center patients and visitors has been relocated from the surface lot to two floors of the University's Parking Garage IX, next door to ECB.

Project Buildings

Eye Clinical Building

When the proposed project is complete, the second and third floors of the ECB will accommodate:

4 additional procedure rooms

- 15 additional prep and recovery bays ["Project Impact Facilities below shows 16 bays.]
- Subspecialty clinics and ancillary services relocating from WEC to ECB, including:
 - Cornea
 - Glaucoma
 - Low Vision
 - Vitreo-Retinal Diseases and Surgery
 - Intake / Work-up Rooms
 - Triage
 - Procedural Labs and Injection Rooms
 - Diagnostic and Imaging Equipment

Patient Support Services, including

- Patient Education and Resource Center
- Retail Space (optical shop; cafe)
- Expanded Registration and Waiting Areas

Wadsworth Eye Center

Renovations to the WEC will support sterile processing and the connection from the WEC to the ECB. Services remaining in their current locations include

- Comprehensive
- Contact Lens
- Neuro-Opthalmology
- Oculo-Plastic Ophthalmology
- Vision Rehabilitation Services

Project Impact

Implementation of the proposed project will expand the clinical facilities of the Eye Center in the following ways:

Facilities

Facilities	Now	Project Completion
Eye Exam Rooms	53	74
Operating Rooms	5	5
Procedures Rooms	1	5
Prep & Recovery Bays	25	41

Clinic Exam Room Allocations

Exam Room	Now	Project Completion
Vitreo-RetinalDisease		
& Surgery	15	16
Cornea	9	12
Glaucoma	7	8
Low Vision	1	4
Comprehensive &		
Contact Lens	14	15
Oculo-Plastic	5	5
Neuro-Ophthalmology	2	4
Intake / Work-up Room	0	10

Treatment Rooms and Diagnostic Equipment

Treatment Room/		
Diagnostic Equipment	Now	Project Completion
Laser Room	3	3
Injection Rooms	2	4
Ultrasound / A-Scan	1	1
Photography Stations	9	9
Visual Field Machines	4	4
Goldman Visual Field	2	2
Auto-refractor / OCT	0	1

Population to be Served

In Section III.5, page 25 of the application, the applicant provides projected patient origin for the patients to be served at the Eye Center in the first two years of the project (FY2017 and FY2018), which is summarized below.

County	Eye Center Patients
Durham	22.1%
Wake	14.2%
Orange	8.2%
Alamance	3.4%
Person	2.3%
Granville	2.4%
Other NC Counties	35.2%
Other States	
& Countries	12.2%
Total	100.0%

The applicant states that the projected patient origin is based on the current patient origin in FY2011.

The applicant adequately identifies the population to be served.

Need for the Proposed Service

On pages 19-22 the applicant states that the need for the project is based on the following factors:

- Growth of the population: The 2010 population of the greater triangle area (2,160,134) is projected to increase by 11.5% by 2015.
- Aging of the population: The 2010 65 and over population is projected to increase by 31.4%. The 65+ population accounted for 52% of the Eye Center patients during FY2011. Thomson Reuters projects that ophthalmology clinic visits in the greater triangle area will increase by 3.1% per year during 2009-2014 and that ambulatory surgery eye procedures will increase by 3.5% per year during this period.
- Conditions of Eye Center patients: Most of the patients' conditions are progressive, resulting in increases in the number of visits per patient per year.
- Advances in diagnosis and treatment: These advances result in more specialization, including the rapidly-growing areas of neuroophthalmology and oculo-plastics oncology.
- Status of existing facility: Since the WEC opened in 1973, the building designed for 20,000 outpatient clinic visits per year experienced 64,552 visits and 6,457 surgical procedures in

FY2011. It can no longer accommodate the growing demand.

<u>Utilization Projections</u>

Exhibit IV.1 includes the projected clinic visits, ancillary services, ophthalmology surgical cases and minor procedures to be performed in the interim years and the first three years of operation following completion of the project, as shown in the tables below.

Year	Eye Center	Ancillary
	Clinic Visits (1)	Services (2)
FY 2010	64,477	48,879
FY 2011	64,552	38,505
FY 2012	67,086	35,738
FY 2013	67,086	37,166
FY 2014	67,086	38,661
FY 2015	67,086	40,228
FY 2016	67,086	41,869
FY 2017	81,668 (3)	43,589
FY 2018	85,012	45,392
FY 2019	88,517	47,281

- (1) Subspecialty ophthalmologists
- (2) Includes lasers, injections, ultrasound, photography, visual field machines and other diagnostic tests.
- (3) Includes clinic visits shfted from satellite locations in Cary and at Page Road, Southpoint and North Duke Street in Durham.

Surgical Cases & Minor Procedures

Surgicus		nor Frocedure		T		
	Outpatient Eye Center Cases					
					Total OP	
		Minor		Ophthalmology	Ophthalmology	%
	Surgical	Procedures		Surgical Cases	Cases & Minor	Annual
Year	Cases	(1)	Total	@ Davis ASC (2)	Procedures	Change
FY 2010	4,092	2,300	6,392		6,392	
FY 2011	4,093	2,260	6,353		6,353	-0.6%
FY 2012	4,262	1,955	6,217	440	6,657	4.8%
FY 2013	4,544	1,705	6,249	913	7,162	7.6%
FY 2014	4,788	1,559	6,347	1,251	7,598	6.1%
FY 2015	5,053	1,290	6,343	1,723	8,066	6.2%
FY 2016	5,326	1,016	6,342	2,200	8,542	5.9%
FY 2017	5,656	2,747	8,403 (3)	658	9,061	6.1%
FY 2018	5,924	3,604	9,528 (3)		9,528	5.2%
FY 2019	6,210	3,815	10,025		10,025	5.2%

- (1) Cataracts < 60 minutes, to be performed in 4 new procedure rooms following projection completion.
- (2) Davis Ambulatory Surgery Center used for overflow Eye Center cases until project completion.

(3) Includes surgical cases shifted from Davis ASC after project completion.

The utilization projections in the tables above are based the following assumptions and methodology provided on pages 12-13, and Exhibit IV.1.

- Thomson Reuters' projections are used to project clinic visits, ancillary services, surgical cases and minor procedures. Thomson Reuters is a market intelligence company providing health care data and research on health care services, including "Outpatient Solutions," a specialized component which may be used for projecting outpatient volumes.
- The current Eye Center capacity for outpatient surgical cases and minor procedures is 6,452 cases a year
- Excess Eye Center cases (cataracts and lens procedures) will be performed at the Davis Ambulatory Surgery Center on Page Road in Durham during the interim years prior to project completion. These minor procedures "do not require extended prep and recovery time or the vibration-free ORs and ancillary services essential to the provision of the other, more complex procedures provided in the Eye Center."
- Upon project completion in FY 2017, the ophthalmology surgical cases performed at the Davis ASC will be shifted to the Eye Center.

The following table summarizes the utilization projections of the Duke Eye Center for the first three years of operation.

	Year 1 FY 2017 7/2017 – 6/2018	Year 2 FY 2018 7/2018 – 6/2019	Year 3 FY 2019 7/2019 – 6/2020
Clinic Visits	81,668	85,012	88,517
Ancillary Services	43,589	45,392	47,281
Surgical Cases	5,656	5,924	6,210
Minor Procedures	2,747	3,604	3,815

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for the proposed project. 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 the applicant describes the alternatives it considered, including renovating the Wadsworth Building, moving the adult subspecialty clinical services to a new freestanding facility off the DUH campus, relocating several subspecialty services to satellite clinics and maintaining the status quo. The application is conforming or conditionally conforming with all other applicable statutory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (12), (13), (14), (18a) and (20). Therefore, the applicant adequately demonstrates that its proposal is an effective alternative and is conforming with this criterion 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 add no more than four minor procedure rooms in the Eye Center for a total of five minor procedures rooms at the Eye Center following completion of the project.
- 3. Duke University Health System d/b/a Duke University Hospital shall 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 States Building Codes. The plan must be consistent with the applicant' representations in the written statesment as described in paragraph one of Policy GEN-4.

- 4. 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 or that would otherwise require a certificate of need.
- 5. 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.

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In Section VIII.1 the applicant projects the total capital cost for the project to be \$71,103,000, which includes \$2,772,000 for site preparation costs, \$44,274,000 for construction costs, \$7,203,000 for fixed equipment, \$903,000 for movable equipment, \$387,000 for furniture, \$489,000 for landscaping, \$5,802,000 for architectural and engineering fees and \$9,273,000 for contingency costs. In Section VIII.3 of the application, the applicant states that the project will be financed with a public campaign (\$53,603,000) and accumulated reserves (\$17,500,000). The application states that the Eye Center already has firm commitments for donations of \$13.7 million. In Section IX the applicant states there will be no start-up expenses or initial operating expenses.

Exhibit VIII.6 of the application contains an August 3, 2011 letter from the Senior Vice President and Chief Financial Office for Duke University Health System that states: "This letter will certify that Duke University Health System has as much as \$75 million in accumulated reserves to fund the renovation of the Wadsworth Building [existing Eye Center facility] and the construction of the Eye Clinical Building in the Duke University Eye Center."

Exhibit VIII.9 contains the audited financial statements for Duke University Health System which indicates that as of June 30, 2010, the applicant had cash and cash equivalents of \$86,350,000 and unrestricted net assets of \$1,582,863,000. The applicant adequately demonstrates the availability of funds for the capital needs of the project.

In Form C, Statement of Revenues and Expenses for the Duke Eye Center expansion, the applicant indicates the project will realize positive net income from operations in each of the first three years of operation. The projected costs and revenues are based on reasonable assumptions. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, 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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DUH proposes to construct an addition to the hospital's Wadsworth Eye Center for the development of the Eye Clinic Building. The applicant adequately demonstrates the need the population it proposes to serve has for each component of the proposed project. See Criterion (3) for discussion. Therefore, the applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing health service capabilities or facilities and 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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Exhibit VII.1 of the application contains a table showing the current and projected personnel that will be required to staff the proposed expansion of the hospital's Eye Center. The applicant projects the Eye Center's staffing will increase from 83.81 FTE employees in FY2011 to 116.34 FTE employees in the second year of project (FY2018). In Section VII.6, page 44 of the application, the applicant describes its experience in the recruitment and retention of staff. In Section VII.8, page 46 of the application, the applicant identifies David L. Epstein, M.D. as the medical director for the Eye Center. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed services and 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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On pages 14-15 the applicant states that all necessary ancillary and support services are already available at the Eye Center and Duke University Hospital. In Exhibit V.2 of the application, the applicant provides a copy of the standard transfer agreement and a list of facilities with which it has transfer agreements. In Exhibit V.3 are copies of letters from the Medical Director and Carl E. Ravin, MD, President of the Duke Private Diagnostic Clinic, on behalf of the physician faculty of the Duke University Medical Center, supporting the proposed expansion of the Eye Center. The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services would 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

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.

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The applicant proposes 126,950 square feet of new construction and 10,375 square feet of renovations to the existing Eye Center facility. Exhibit XI.5(a) of the application contains a letter signed by James Kessler, AIA, which states the projected construction cost for the project is \$42,532,000, which is consistent with the applicant's projected construction costs in Section VIII.1, page 50 of the application. In Section XI.7 and Exhibit XI.7 of the application, the applicant describes the methods that will be used to maintain efficient energy operations. The applicant adequately demonstrates 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. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming with this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of

priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

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In Section VI.13 of the application, pages 38-39, the applicant provides a table showing the following payer mix for services provided by WEC and the entire DUH in FY2011.

Payer	Percent of Total Eye Center Patients	Percent of Total DUH Patients	
Self Pay/Indigent/Charity	1.7%	3.8%	
Medicare	53.7%	38.1%	
Medicaid	5.2%	20.9%	
Commercial Insurance	1.1%	0.9%	
Managed Care	34.6%	33.6%	
Other	3.7%	2.8%	
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. The following table illustrates those percentages as of June 2010 and CY 2008-2009, respectively. The data in the table were obtained on January 9, 2012. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	Total # of Total # of Medicaid Medicaid Eligibles Eligible as % of Age 21 and older Total Population as % of Total Population		% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
County			
Durham	16%	5.8%	20.1%
Wake	10%	3.4%	18.4%
Orange	9%	3.5%	18.9%
Statewide	17%	6.8%	10.7%

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 offered by the Duke Eye Center.

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. However, as of January 9, 2012, no population data were available by age, race or gender. Even if the data were available, 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 applicant demonstrates that medically underserved populations currently have adequate access to services available at the Duke Eye Center. Therefore, the application is conforming with 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;

In Section VI.10, the applicant states that, to the best of its knowledge, no civil rights or equal access complaints have been filed against any DUHS facility in the last five years. 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

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In Sections VI.14 and VI.15, pages 39-40, the applicant provides a table showing the following payer mix for services to be provided by the Duke Eye Center and DUH in the second full fiscal year of operation (7/1/2017 - 6/30/2018).

Payer Category	Duke Eye Center Percent of Total Utilization	Duke Hospital Percent of Total Utilization	
Self Pay/Indigent/Charity	0.0%	1.0%	
Medicare	56.5%	41.6%	
Medicaid	7.4%	22.9%	
Commercial Insurance	1.2%	0.9%	
Managed Care	31.6%	31.1%	
Other	3.6%	2.8%	
Total	100.0%	100.0%	

On page 39 the applicant describes its assumptions as follows:

- 1. "Managed Care patients are projected to convert to Medicare between FY2012 and FY2015 at the rate of 0.5% per year because of the projected growth in the population 65 and over.
- 2. The majority of self-pay patients are projected to convert to Medicaid and Managed Care by FY2015 due to health reform legislation."

The applicant demonstrates that medically underserved populations will have adequate access to the applicant's services and 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.

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The applicant describes the range of means by which a person will have access to the proposed services in Section VI.9 of the application. 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.

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See Section V.1 for documentation that the Eye Center will accommodate the clinical needs of area health professional training programs. DUH is an academic medical center teaching hospital. On page 29 the applicant states:

"The clinical facilities of the Duke University Eye Center serve as training sites for

- 21 Ophthalmology Fellows
- 17 Ophthalmology residents
- Medical School students
- Op Tech Program students School of Medicine
- Students enrolled in medical records training programs at Durham Technical Community College, Wake Technical Community College & Western Carolina
- Visiting Ophthalmologists
- Faculty and staff of the Eye Center"

The information provided is reasonable and credible and supports a finding of conformity 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.

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See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the proposal would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- O The applicant adequately demonstrates that the proposal is needed and that it is a cost-effective alternative to meet the demonstrated need [see Criteria (1), (3), (4) (5) and (12) for additional discussion];
- O The applicant has and will continue to provide quality services [see Criteria (7), (8) and (20) for additional discussion];
- The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

Therefore, 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.

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According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming with 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

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