ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: October 29, 2013

PROJECT ANALYST: F. Gene DePorter
CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: Wake J-10164-13 Duke University Health System d/b/a Duke Raleigh Hospital/ Replace Linear Accelerator/ Wake 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 d/b/a Duke Raleigh Hospital [DUHS-DRH] proposes to replace the Varian 2/EX with a Varian TrueBeam linear accelerator with BrainLab ExacTrac. The Varian 2/EX is DUHS/DRH's only linear accelerator. The linear accelerator will be located in the lower level of MOB 7 at 3404 Wake Forest Road, Raleigh. 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 [2013 SMFP].

Consistency with Policies

The applicant indicates that none of the acute care policies in the 2013 State Medical Facilities Plan (2013 SMFP) is applicable.

The applicant states it is consistent with POLICY GEN-3: BASIC PRINCIPLES because;

> "*Its implementation will allow us to improve the quality of our radiation oncology services, expand access, and to support clinical research and education programs."*

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."*

DUHS-DRH provides a written statement regarding Policy GEN-4, in Section XI.7, page 59, describing the project's plan to assure improved energy efficiency and water conservation, as follows:

> *"The project will not effect energy operations or utility usage, but the architects and engineers employed by Duke University Health System to oversee the design, construction, and operation of DUHS facilities, work with the engineers employed on each project to maintain efficient energy operations to contain the cost of facilities."*

Exhibit III.2, page 124. contains a letter dated August 7, 2013 from the project architectural firm of Isley/Hawkins which addresses energy and water conservation as follows;

> *"The new LINAC vault and console areas will be conditioned with a split system heat pump that meets or exceeds the current SEER requirements of the North Carolina Energy Code. The new chiller for the LINAC will be an energy efficient model. Water usage change is anticipated to be net zero. Electrical lighting fixtures replaced will be energy efficient and in compliance with the special needs of the rooms. The site…will be treated for water quality by means of an underground sand filter. The project will include native or adapted plant species that are regionally sourced."*

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 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

DUHS-DRH proposes to replace an existing LINAC scanner at DRH and install the replacement LINAC in the same remodeled space. Square footage for the project includes 1,884 SF of new construction and 1,945 SF of renovated space.

Population to be Served

In Exhibit III.4 (a) and (b), pages 125-129, the applicant provides FY 2013 patient origin for DRH total hospital patient encounters, LinAcc encounters (not patients) and projected LinAcc encounters in the following table. The applicant maintains that the projected volume for 2014 through 2016 will remain constant.

FY 2013 Acute Care Services Patient Encounters		**FY 2013 LinAcc Patient Treatments**	**FY 2014 LinAcc Patient Treatments**	**FY 2015 LinAcc Patient Treatments**	**FY2016 LinAcc Patient Treatments**
County	**Total Encounters**	**Total Encounters**	**Total Encounters**	**Total Encounters**	**Total Encounters**
Wake	115,356	5,339	5,339	5,339	5,339
Johnston	6,481	518	518	518	518
Franklin	6,041	477	477	477	477
Nash	2,405	225	225	225	225
Durham	2,249	137	137	137	137
Harnett	2,188	73	73	73	73
Cumberland	1,335				
Wilson	1,078	101	101	101	101
Vance	822				
Wayne	787	46	46	46	46
Lee	763	113	113	113	113
Granville	753	48	48	48	48
Orange	617				
Sampson	676	85	85	85	85
Moore	520	28	28	28	28
New Hanover	504				
Robeson	475	2	2	2	2
Halifax	462	9	9	9	9
Warren	451	15	15	15	15
Carteret		45	45	45	45
Iredell		35	35	35	35
Cumberland		32	32	32	32
Edgecombe		32	32	32	32
Pender		30	30	30	30
Bladen		28	28	28	28
Burke		25	25	25	25
Dare		25	25	25	25
Duplin	449	23	23	23	23
Mecklenburg		23	23	23	23
Northampton		14	14	14	14
All Other N. C. Counties < 2%	6,128	5	5	5	5
Total North Carolina	150,540	7,533	7,533	7,533	7,533
Other States	2,849	75	75	75	75
Other Locations	949	28	28	28	28
Grand Total	154,338	7,636	7,636	7,636	7,636

Source: DRAH Finance

The applicant indicates that its assumptions regarding patient origin projections are based on historical patient origin and physician referrals to DRH's existing LinAcc services. The applicant adequately identified the population to be served.

Need to Replace the Existing Linear Accelerator

In Section III. 1 (a), page 14 the applicant states the following:

> *"Duke has operated its current linear accelerator since 2003. While it has been fully utilized for several years, beginning in FY 2012 DRH saw unprecedented growth in volume in the Radiation Oncology department, primary reflecting the addition of a Breast Surgical group and Urology group to the Private Diagnostic Center, Duke's faculty practice. Duke Raleigh's volumes for the past two year have often required running the existing equipment for 10 hours a day or more to accommodate patient's needs and maintenance issues.*
>
> *The current LinAcc was installed in 2003 and updated in 2011 with Image Guided Radiation Therapy (IGRT), Onboard Imaging (OBI), Respiratory Gating (RPG) and Rapid Arc. Even with the upgrades the age of the machine continues to be an issue, as reliability of the machine continues to decline as the machine continues to age. Over the past year Duke Raleigh has had 19 major failures related to the linear accelerator, 4 additional issues related to imaging, 3 other issues with the chiller that have resulted in 110 patient appointments being cancelled and countless more being delayed because of these issues."*

The applicant identified the following factors that support the need to replace the nine year old linear accelerator:

- Patient treatment times are to slow when compared with today's linear accelerator units,
- Improved auto-sequencing increases the speed of standard treatments,
- Current table weights do not accommodate the treatment of larger patients,
- Enhance therapists alerts on the treat console can reduce dangerous collisions,
- Higher resolution image detector panel will enhance patient portal image quality,
- New software modules that minimize time and increase accuracy are needed.

The proposed project is needed to enhance the patient experience and improve patient throughput. The proposed project will not result in a net increase in

LinAcc machines in Wake County. The applicant identifies the following benefits of the TrueBeam LinAcc:

- The unique design of the TrueBeam machine takes IGRT, IMRT, respiratory gated treatment, stereotactic body radiation therapy, volumetric intensity modulated arc therapy and 3-D conformal radiation therapy and combines them into one comprehensive and flexible treatment plan.
- A redesigned treatment console interface will seamlessly integrate all of the above technologies into one system, as compared to previous versions.
- Allows an increased dose-rate delivery, which could potentially make patient treatment times faster.
- Large-Field Intensity Modulated Radiation Therapy (IMRT) capability, which allows significantly fast delivery.
- Improved auto-sequencing.

Projected Utilization

In Section III. 1 (b), pages 16-17 the applicant states:

"*Duke's volume has exceeded the assumed capacity of a linear accelerator of 6,750 ESTVs per year for the past six years. For the past two years, utilization has been more than 140% of the standard*. [See the following table]:

Fiscal Year	External Beam / MRT Treatments	Average # of Treatments/Day	ESTVs
2008	6,225	24.6	7,566
2009	6,288	24.9	7,268
2010	6,594	26.2	7,572
2011	6,518	25.8	7,486
2012	8,505	33.8	9,810
2013	7,989	31.8	9,514

Source: Section III. 2 (b), page 16 of the application.
2008-2013 SMFP's, Linear Accelerators, Table 9, Service Area 20,

Duke reasonably anticipates that this high utilization will continue. The Wake County population continues to grow, and the Wake County incidence of cancer cases is projected to be the highest in the state. The five county Greater Wake Region, consisting of Wake, Johnston, Harnett, Nash and Franklin counties, included more than 1.45 million people in 2013 with a projected five-year growth rate of 8.45%. Approximately 10.5% of the population is age 65 and over. This portion of the population is expected to grow 27.5% by 2018."

Cancer incidence is also projected to grow. Truven (formerly Thomson Reuters) has projected an 11.8% increase in annual cancer cases for North Carolina between 2013-2018. Truven has projected that the Greater Raleigh Region will experience an 18.9% annual five year growth with Wake County having the highest increase in the state from 2013-2018. See the following table:

2013-2018 Cancer Case Volume for Duke Raleigh Hospital Service Area

County	2013 Incidence	2018 Incidence	Projected Growth
Franklin, NC	360	406	1.9%
Harnett, NC	721	840	16.6%
Johnston, NC	856	994	16.1%
Nash, NC	715	778	8.9%
Wake, NC	5,313	6,447	21.4%
Great Wake Total	7,963	9,466	18.9%

Source: Thomas Reuter's Incidence defined as number of new cases per year.

The data in the above table was provided by Truven. The applicant has not provided information related to Truven's sources or methodologies for calculating projections. However, the SMFP's going back to 2008 are a historic source for ESTV volumes by year , service area and provider. This data provides a basis for making reasonable estimates on the future ESTV volume at Duke Raleigh Hospital.

The current site of the Linear Accelerator remains the best location due to the proximity of Radiation Oncology to Surgery, Medicine and Radiology.

In summary, the applicant adequately identified the population to be served and demonstrated the need to replace the linear accelerator at Duke Raleigh Hospital. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section III.3, page 18, the applicant described alternatives considered prior to submitting this application:

1) Maintenance of the Status Quo-In Section III, page 5 of these findings, the applicant stated the following; *"Duke Raleigh has had 19 major failures related to the linear accelerator, 4 additional issues related to imaging, 3 other issues with the chiller that have resulted in 110 patient appointments being cancelled and countless more being delayed because of these issues."* The problems with the current linear accelerator are beyond repair and reflect a unit that is old and missing the contemporary state-of-the-art capabilities that increase treatment time, improve treatment capabilities and are sensitive to patients needs.

2) Installation of replacement equipment in the space housing the existing equipment with remodeling of the current space and placement of the new linear accelerator in the renovated volt.

Alternative 2 is the applicant's choice to ensure continuity of services to patients.

The applicant has adequately demonstrated that the least costly, cost effective and patient sensitive is proposed. The application is conforming to all applicable statutory review criteria, and thus is approvable. A project that can not be approved cannot be an effective alternative. Therefore, the application is conforming with this criterion and approved subject to the following conditions:

1. **Duke University Health System d/b/a Duke Raleigh Hospital shall materially comply with all representations made in this certificate of need application.**

2. **Duke University Health System d/b/a Duke Raleigh Hospital shall acquire no more than one linear accelerator to replace the existing Varian 2/EX linear accelerator for a total of no more than one linear accelerator upon project completion.**

3. **Duke University Health System d/b/a Duke Raleigh Hospital shall dispose of the Varian 2/EX linear accelerator by removing it from North Carolina.**

4. **Duke University Health System d/b/a Duke Raleigh 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.**

5. **Duke University Health System d/b/a Duke Raleigh 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 State Building Codes. The plan must be consistent with the applicant's representations in the written statement as described in paragraph one of Policy GEN-4.**

6. **Duke University Health System d/b/a Duke Raleigh 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., pages 45-47, the applicant projects the total capital cost for the project to be $8,292,201 as shown in the following table:

Site Costs	
Site Inspection and Survey	$28,000
Legal Fees and Subsoil Investigation	$5,000
Site Preparation Costs	$770,000
Sub-Total Site Costs	**$803,000**
Construction Contract	
Sub-Total Construction Contract	**$2,106,000**
Miscellaneous Project Costs	
Fixed Equipment	$4,035,000
Furniture	$50,000
Architectural and Engineering Fees	$497,000
Permits and Inspections	$47,365
Contingency Fund	$753,836
Sub-Total Miscellaneous	**$5,383,201**
Total Capital Costs of Project	**$8,292,201**

The applicant does not propose a new facility or service. Therefore, there are no start-up expenses or initial operating expenses. This project will be funded through the accumulated reserves of Duke University Health System. Exhibit VIII.6 contains a letter from the Senior Vice President, Chief Financial Officer and Treasurer of Duke University Health System dated August 8, 2013 addressed to the President of Duke Raleigh stating the following:

> "*This will certify that Duke University Health System has as much as $8,500,000 in accumulated reserves to devote to the linear accelerator replacement project at Duke Raleigh Hospital."*

Exhibit VIII.9-Duke University Health Systems, Inc. and Affiliates consolidated financial statements for June 30, 2012 and 2011, page 187, Net Assets Unrestricted, identifies the amounts available for capital projects such as this proposal. The Unrestricted Net Assets indicates that available funds in 2011 were $2,101,796,000 and in 2012 were $2,019,346,000. 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 in the Pro Forma section (immediately following Section XII) for the first three operating years of the project following completion. The following table illustrates projected procedures, average charges, gross revenue, net revenue, expenses and net income for Linear Accelerator services for the replacement linear accelerator at Duke Raleigh Hospital. The applicant projects than revenue will exceed operating cost in each of the first three operating years for linear accelerator services. The revenue projections provided on Forms D and E are as follows:

	1st Full FY* 2017	**2nd Full FY 2018**	**3rd Full FY 2019**
# of Procedures	11,241	11,354	11,467
Projected Average Gross Charge per Procedure	$1,976	$2,074	$2,177
Gross Revenue	$22,213,608	$23,546,425	$24,959,210
Projected Average Net Revenue per Procedure	$502	$491	$481
Net Revenue	$5,638,066	$5,577,712	$5,517,676

* FY is July 1 to June 30.

The applicant also provided pro forma financial statements in the Pro Forma Section for the first three project years for Duke University Health System. The applicant projects that revenues will exceed expenses in each of the first three project years. The revenue projections provided in Form B, are as follows:

	1st Full FY 2017	2nd Full FY 2018	3rd Full FY 2019
Total Net Revenue	$5,638,066	$5,577,712	$5,517,676
Total Expenses	$4,061,402	$4,191,558	$4,281,902
Net Revenue	$1,576,664	$1,386,153	$1,235,774

($ are in 000)

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 criteria.

The applicant demonstrated that the immediate and long term financial feasibility of the proposal is based upon reasonable projections of the costs of, and charges for providing replacement linear accelerator service at Duke Raleigh Hospital.

(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 d/b/a Duke Raleigh Hospital [DUHS-DRH] proposes to replace a Varian 2/EX with a Varian TrueBeam linear accelerator with BrainLab ExacTrac at a total capital cost of $ 8,292,201 for equipment and renovation of existing space to accommodate the replacement equipment. This project will not result in the addition of a linear accelerator either in Linear Accelerator Service Area 20 or in Wake County.

The SMFP need methodology for linear accelerators uses 6,750 ESTVs (equivalent simple treatment visits), as a benchmark utilization standard. The Duke Raleigh Hospital linear accelerator volume is the second highest number of ESTVs per linear accelerator in Service area 20, at 7,486 procedures per operational machine and exceeding the standard by 34.5%. Duke Raleigh is one of two providers in the linear accelerator service area that exceeds the planning standard.

2013 State Medical Facilities Plan
Linear Accelerators and Radiation Oncology Procedures
Service Area 20

Facility	County	# Linear Accelerators	Total Procedures	Procedures per Operational Linac
Franklin County Cancer Center	Franklin	1	1,407	1,407
Cancer Centers of North Carolina	Wake	2*	16,703	8,352
Duke Raleigh Hospital	Wake	1	7,486	7,486
Rex Hospital	Wake	4	18,898	4,725

Source: 2013 SMFP, Service Area 20, page 146.
2012 License Renewal Applications
*CCNC has a certificate of need to acquire a third Linear Accelerator.

Table 9J; page 153 of the 2013 SMFP indicates that a certificate of need was issued to Parkway Urology, PA d/b/a/ Cary Urology, PA on 2/23/2011 to acquire one dedicated linear accelerator as part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men. The prostate cancer linear accelerator is not counted in the regular inventory of linear accelerators.

In Section III.6 (a), page 19, the applicant provides an inventory of operational linear accelerators for Service Area 20 for 2011-2012 as published in the proposed 2014 State Medical Facilities Plan from the most recent hospital License Renewal Application or the Linear Accelerator Registration and Inventory Forms.

2012 Linear Accelerators and Radiation Oncology Procedures
Service Area 20

Facility	County	# Linear Accelerators	Total Volume	Volume per Machine
Franklin County Cancer Center	Franklin	1	141	141
Cancer Centers of North Carolina	Wake	2*	15,771	7,886
Duke Raleigh Hospital	Wake	1	9,807	9,807
Rex Hospital	Wake	4	19,401	4,850
Cary Urology	Wake	1	--	--

Source: 2013 SMFP, Service Area 20, page 146.
2012 License Renewal Applications
*CCNC has a certificate of need to acquire a third Linear Accelerator.

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The applicant adequately demonstrated the need to replace the existing equipment. See Criteria (3) for discussion regarding the need to replace the existing linear accelerator and historic and projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrated that the proposal would not result in unnecessary duplication of existing or approved linear accelerator capacity in Wake and Franklin Counties and is conforming to 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) and (b), pages 36-42, the applicant provides current and projected staffing for linear accelerator services. The applicant anticipates adding 0.1 FTE radiation technician. The following table shows the current (FY2014) and projected (FY2017) staffing by position and salary:

Position Title	2014 FTEs	2017 FTEs	2014 Salary	2017 Salary
Administrator	1.0	1.0	$85,156	$ 94,055
Chief Therapist	1.0	1.0	$96,330	$106,397
Radiation Techs.	5.0	5.1	$78,240	$86,417
Registered Nurses	2.5	2.5	$73,332	$80,996
Nurse Practitioner	1.0	1.0	$104,604	$115,536
Pt. Serv. Associate	2.0	2.0	$29,589	$32,681
Dosimetrist	2.0	2.0	$90,895	$100,394
Total	**14.5**	**14.6**	**$1,099,389**	**$1,222,237**

In Section VII.8 (a), the applicant identified its Chief of Staff and Medical Director who is a Medical Oncologist.

The applicant adequately demonstrated the availability of resources, including health manpower and administrative personnel for he proposed service. Therefore, the applicant 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.

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Duke Raleigh Hospital is an existing acute care hospital and provides ancillary and support services for its inpatient and outpatient services. In Section II. 2, (a), (b) and (c), pages 8-9, the applicant lists support services provided by Duke Raleigh Hospital for Oncology patients utilizing linear accelerator services as the following:

Laboratory	Social Work
Radiology	Patient Education
Pharmacy	Patient Transportation
Nutrition	Recreational Therapy
Counseling	
The applicant further states the following: *"Duke Raleigh Hospital provides all these services, and none will have to be expanded to implement the project proposed in this application.* *Documentation of the availability of the necessary ancillary support services is afforded by the fact they all exist now and serve to facilitate radiation oncology services to more than 400 patients each year."*	

In Section V, pages 24-26, Duke Raleigh Hospital provides multiple listings of links that relate to the clinical needs of health care professionals training programs in the area as well as transfer agreements with other acute care hospitals in the area and beyond (See Exhibit V.2. for a Sample Transfer Agreement). Duke Raleigh Hospital continues to build physician relationship through the patient transfer mechanism and physicians practicing in the Hospital's primary and secondary service area. Further, support of Duke Raleigh Oncology services is demonstrated by support letters (See Exhibit V.3) for the proposed linear accelerator replacement by leadership of the Medical Staff, Board and Management of Duke Raleigh Hospital.

The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services will continue to be coordinator with the existing healthcare system. Therefore, the applicant is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(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.

Duke's Facility Planning Design and Construction Office project total construction cost of $2,876,000. This estimate is based on Exhibit 15a which contains the architect's construction cost certification letter dated August 12, 2013 in which the architect provides the following breakdown of costs:

Total Construction Cost Estimate	$2,876,000
Labor and Material Costs	
Material Costs (40%)	$1,150,400
Labor Costs (60%)	$1,725,600
SUB-TOTAL =	$ 2,876,000
Total Construction	$2,876,000

In Section XI. 7, page 59, the applicant indicates that this project will not effect energy operations or utility usage. Architects and engineers employed by Duke University health system over see each project to maintain efficient energy operations and contain cost of utilities.

This project involves a total of 3,829 square feet of which 1,884 square feet is new construction and 1,945 square feet is renovation. The project construction cost per square foot is $550.

The applicant adequately addresses emergency efficiencies and notes that Duke University Health System engineers and architects will work with outside engineers and architects to maintain efficient energy operations to contain the costs of utilities. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. Therefore, the applicant is conforming to 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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The following table illustrates the current payor mix for Duke Raleigh Hospital as reported by the applicant in Sections VI. 12-13, pages 33-35.

Payor Category	**Entire Facility FY 13 Patient Days as % of Total Utilization**	**Linear Accelerator FY 13 Projected Treatment Procedures as % of Total Utilization**
	Percent of Total	**Percent of Total**
Self Pay/Indigent/Charity	3.9%	1.2%
Medicare/Medicare Managed Care	60.3%	41.7%
Medicaid	8.8%	4.7%
Commercial	1.0%	0.5%
Managed Care	24.1%	49.7%
Other (Specify)	1.8%	2.2%
Total	**100.0%**	**100.0%**

In Section VI.4 (a) and (b) page 29, the applicant states "*All persons will have access to the proposed service.*" See Exhibit VI.4 for a copy of the

Duke Raleigh Admissions Policies. Exhibit VI.4 includes copies of the Duke Raleigh Hospital's written policies on Admissions, Patient Rights, Credit and Collection, Non-Discrimination policy, Discounts, and Charity Care Policy.

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 Wake County and statewide.

County **Wake**	**June 2010 Total # of Medicaid Eligible's as % of Total Population ***	**June 2010 Total # of Medicaid Eligible's Age 21 and older as % of Total Population ***	**CY 2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) ***
Wake	10.0%	3.3%	18.4%
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. This age group is not as likely to use Duke Raleigh Hospital linear accelerator services as the population over the age of 21.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligible's 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 applicant's 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 have adequate access to services available at DRH. 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, page 33 the applicant states:

> "DRAH *is not obligated under public regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. …However, as previously stated, DRAH does not discriminate based on race ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. DRAH will continue to provide healthcare services and access for all persons, without federal obligation. And as previously stated, DRAH will continue to be accessible to persons with physical disabilities and handicaps, as required by the Americans with Disabilities Act."*

In Section VI. 10 (a), pages 32-33, the applicant states *"Duke Raleigh Hospital is not aware of any court cases filed alleging equal access violations in the past 5 years. Duke is aware of the agency complaints that have been filed against DUHS facilities during that time period, all of which have been resolved.*

The applicant demonstrates that 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 applicant projects payor mix for FY 2018, as follows:

Payor Category	Entire Facility Second Full Year (FY18) Patient Days as % of Total Utilization	Linear Accelerator Second Full Year (FY 18) Projected Treatment Procedures as % of Total Utilization
	Percent of Total	Percent of Total
Self Pay/Indigent/Charity	3.9%	1.2%
Medicare/Medicare Managed Care	66.9%	46.7%
Medicaid	8.5%	4.7%
Commercial	1.0%	0.5%
Managed Care	18.0%	44.7%
Other (Specify)	1.7%	2.2%
Total	**100.0%**	**100.0%**

In the table above the applicant illustrates the projected payor mix during the second full project year (FY 2018). The applicant indicates that the projected payor mix for hospital services and for linear accelerator services show some percentage difference for Medicare/Medicare Managed Care and the category of Managed Care. Otherwise, the 2018 payor mix remains the same. In Section VI.6, page 30 the applicant states:

> *"Consistent with the current DRH business practice all linear accelerator services offered will be available to all persons clinically eligible for services, regardless of their ability to pay DRAH will provide services without regard to race, color, religion, sex, age, national origin, handicap, or ability to pay."*

The applicant demonstrated that medically underserved populations will have adequate access to the proposed linear accelerator 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)-(d), page 32, the applicant documents the range of means by which patients have access to the services provided at DRH. The information provided is reasonable, credible, and supports a finding of conformity 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)-(c), pages 24-26, the applicant provides documentation that DRH will continue to accommodate the clinical needs of area health professional training programs.

The applicant adequately demonstrated that the DRH will continue to accommodate the clinical needs of health professional training programs, and therefore is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

The applicant proposes to replace an existing linear accelerator in the same location and renovate the space. This project will not increase the inventory of linear accelerators in Wake County.

In Section V.7, page 28, the applicant indicates how the replacement linear accelerator will foster quality, access, and cost-effectiveness as follows:

> *"Duke Raleigh Hospital is a valued and highly utilized provider in the service area, and ensuring continued capacity is necessary to provide patients a choice of providers. Replacing the equipment will enable Duke Raleigh to improve its quality and efficiency by decreasing maintenance issues."*

The information provided by the applicant is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition

in the service area and the 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 existing linear accelerator and that it is a cost-effective alternative;
- The applicant will continue to provide quality services; and
- The applicant will continue to provide adequate access to medically underserved populations.

The applicant is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

Duke Raleigh Hospital is accredited by the Joint Commission and certified for Medicare and Medicaid participation, according to the applicant no incidents have occurred at DRH 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 applicant 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 Linear Accelerator equipment, promulgated in 10A NCAC 14C .1900, are not applicable to this review since the applicant is not proposing an increase in the inventory of Linear Accelerator units.