

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 13, 2015

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: J-10362-14

Facility: Duke Cancer Center Cary Radiation Oncology

FID #: 960894

County: Wake

Applicant: Duke University Health System d/b/a Duke Raleigh Hospital

Project: Replace existing linear accelerator located at Duke Cancer Center Cary Radiation Oncology

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.

CA

Duke University Health System d/b/a Duke Raleigh Hospital (the applicant) currently owns and operates a linear accelerator located at Duke Cancer Center Cary Radiation Oncology (Cary Radiation Oncology), 300 Ashville Avenue, Cary. The applicant proposes to replace the existing linear accelerator operated by Duke University Health System and located at Cary Radiation Oncology.

Need Determination

The applicant does not propose to develop beds, add new health services or acquire medical equipment for which there is a need determination in the 2014 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2014 SMFP that are applicable to this review.

Policies

As stated above, there are no need determinations in the 2014 SMFP that are applicable to this review; therefore Policy GEN-3: Basic Principles, on page 38 of the 2014 SMFP, does not apply. However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 38 of the 2014 SMFP, is applicable to the review of this proposal. 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 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, page 22, the applicant addresses Policy GEN-4 and its plan for energy efficiency and water conservation, stating that Duke will comply with the North Carolina and local building codes. The applicant also states that it will avail itself of reasonable and possible sustainable initiatives. The architect’s letter in Exhibit 14 also references the “*statement and plan regarding Energy and Water Conservation*” and notes energy and water efficiencies that are reasonably expected with the replacement project. The applicant adequately demonstrates the proposal includes a plan to assure improved energy efficiency and water conservation.

Therefore, the application is conforming to this criterion subject to Condition 5 in Criterion (4).

Conclusion

In summary, the applicant adequately demonstrates that its proposal to replace the existing linear accelerator (linac) is consistent with Policy GEN-4. Therefore, the application is conforming to this criterion, subject to Condition 5 in Criterion (4).

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to replace the existing linear accelerator owned and operated by Duke University Health System (DUHS) and located at Cary Radiation Oncology.

In Section I, pages 6-8, the applicant describes DUHS and its health services, as follows.

DUHS includes the following owned facilities:

- Duke University Hospital (DUH), Durham County,
- Duke Raleigh Hospital (DRH), Wake County,
- Duke Home Health,
- Duke Home Infusion,
- Duke Hospice (Durham office),
- Duke Hospice (Raleigh office),
- Hock Family Pavilion, and
- Duke Hospice at the Meadowlands.

DUHS leases and operates the following facilities:

- Duke Regional Hospital (formerly Durham Regional Hospital), and
- Davis Ambulatory Surgery Center.

DUHS owns and operates linear accelerators in the following locations:

- Duke Cancer Center Raleigh, DRH Campus, Raleigh,
- Duke Cancer Center Macon Pond, 4101 Macon Pond Rd, Raleigh,
- Duke Cancer Center Cary Radiation Oncology, 300 Ashville Ave., Cary,
- Duke University Hospital, Duke Cancer Center, Level 100, Rm BN55, Durham,
- Duke University Hospital, Duke Cancer Center, Level 100, Rm BN54, Durham,
- Duke University Hospital, Duke Cancer Center, Level 100, Rm BN47, Durham,
- Duke University Hospital, Morris Bldg, SubBsmnt, Rm 005131, Durham,
- Duke University Hospital, Morris Bldg, SubBsmnt, Rm 005133, Durham,
- Duke University Hospital, Morris Bldg, SubBsmnt, Rm 005139, Durham,
- Duke University Hospital, Morris Bldg, SubBsmnt, Rm 005121, Durham,
- Duke University Hospital, Morris Bldg, SubBsmnt, Rm 005123, Durham, and
- Duke Regional Hospital, Radiation Oncology Clinic, Durham.

The Duke Cancer Center Macon Pond (Macon Pond) and Cary Radiation Oncology linear accelerators were acquired by DUHS as part of the 2014 acquisition of the Cancer Centers of North Carolina (CCNC) radiation oncology business which included the Macon Pond and Cary locations. In this application, the applicant proposes to replace the existing Cary Radiation Oncology linear accelerator. In a separate application submitted during the same December 1, 2014 review cycle, the applicant proposes to replace the existing linear accelerator at Macon Pond. In addition to the replacement applications, the applicant also submitted an application in the September 1, 2014 review cycle in response to the 2014 need determination for one additional linear accelerator for Wake County. The three linear accelerator applications are not competing applications. Pursuant to 10A NCAC 14C .0202(f), “*Applications are competitive if they, in whole or in part, are for the same or similar services and the agency determines that the approval of one or more of the applications may result in the denial of another application reviewed in the same review period [emphasis added].*” The approval of either of the two replacement applications filed in the December review cycle would not result in the denial of any other application. The application filed in the September review cycle would not have been reviewed in the “*same review period.*” Therefore, the three applications are not competitive pursuant to 10A NCAC 14C .0202(f). The applicant has since withdrawn the application filed in response to the need determination for the September review cycle.

In Section II.1, pages 9-10, the applicant discusses each component of the proposed project, including the replacement of the Cary Radiation Oncology linear accelerator acquired upon the applicant’s acquisition of CCNC, the renovation of the space to accommodate the replacement equipment, and the temporary use of the existing Macon Pond linear accelerator for which the applicant is seeking replacement in Project ID #J-10363-14. In Section II, page 9, the applicant states:

“In addition, Duke seeks approval to use on a temporary basis an existing scanner scheduled for replacement on the Duke Raleigh Hospital, during the replacement of the scanner at Cary in order to meet patient needs. As set forth in Section III, upon the installation and operation of the approved replacement linear accelerator on the Duke Raleigh Hospital campus, Duke would then commence the removal and replacement of an existing linear accelerator located at Macon Pond (proposed in a certificate of need application filed concurrently with this one). While the Macon Pond linear accelerator is unavailable, Duke proposes to use the existing Duke Raleigh hospital linear accelerator as a temporary replacement to help accommodate patient demand that would otherwise have been served at Macon Pond. Upon the installation and operation of the replacement linear accelerator at Macon Pond, Duke would commence with the proposed replacement project in this application, and would use the existing Raleigh linear accelerator as a temporary replacement to accommodate patient demand that would otherwise have been served at the Cary location. Upon completion of this project, the existing linear accelerator would then be removed permanently from service in North Carolina. At no time would Duke Raleigh Hospital operate more than 3 linear accelerators without the prior approval of the CON Section (except, where clinically necessary, for necessary completion of patient treatment on a machine on which their treatments commenced.)”

Subsequent to the submission of this application, the settlement of the appeal regarding the transfer of ownership of the certificate of need approved in Project ID #J-7941-07 confirmed the Agency's approval for DRH to develop a second linear accelerator on the DRH campus. Therefore DRH now has approval to own and operate a total of four linear accelerators: one at Macon Pond, one at Cary Radiation Oncology and two on the DRH campus.

In Section II.1(b), page 10, the applicant explains Duke's plan to transition from providing radiation oncology services as a freestanding facility operated by DUHS to providing the services at Cary Radiation Oncology through the DRH Department of Radiation Oncology in January 2015.

Population to be Served

In Section III.5, pages 25-27, the applicant states that the primary service area for the proposed service is Wake County, which represented approximately 70% of DRH's FY2013 and FY2014 radiation therapy patient origin and 84% of CCNC's radiation oncology patients in Cary, as reported on the January 2014 CCNC Linear Accelerator Equipment Registration and Inventory. The applicant further states:

“The secondary service area of Duke Raleigh Hospital and its radiation oncology service consists of Franklin, Johnston, Nash and Harnett counties. During FY2013, these four counties accounted for 15% of total patient encounters at Duke Raleigh. These counties accounted for 10% of CCNC's patients in Cary.”

In Section III.4, pages 23-24, the applicant provides the historical patient origin for linear accelerator services at DRH and CCNC Cary, as follows:

Duke Raleigh Hospital Historical Linac Patient Origin

County	FY 2014 Patients	Percent of Total
Wake	286	69.6%
Franklin	22	5.4%
Johnston	19	4.6%
Harnett	12	2.9%
Nash	10	2.4%
Durham	4	1.0%
Other*	58	14.1%
Total	411	100.0%

*Other is identified in the table on pages 23-24 as 24 other NC counties and 15 other states.

**CCNC Cary Radiation Oncology
 Historical Linac Patient Origin, CY2013**

County	FY 2013 Patients	Percent of Total
Wake	236	83.7%
Franklin	0	0.0%
Johnston	7	2.5%
Harnett	20	7.1%
Nash	0	0.0%
Durham	2	0.7%
Other*	17	6.0%
Total	282	100.0%

Source: January 2014 CCNC Linear Accelerator Equipment Registration and Inventory
 *Other is identified only as 15 patients from “Other Counties” and 2 from “Other States”.

The CCNC Cary patient origin table on page 24 of the application includes errors in the computation of percent of total patients. The table above reflects the number of patients as provided on page 24 with the correctly calculated percentages. The applicant provides a geographical map on page 26 showing the primary service area of Wake County, its surrounding counties and the locations of DRH’s radiation oncology services.

In Section III.5(c), page 26, the applicant provides Cary Radiation Oncology’s projected linear accelerator patient origin by percentage by county of residence, as shown below.

**Duke Cancer Center Cary Radiation Oncology
 Projected Linac Patient Origin**

County	FY 2018 % of Total	FY 2019 % of Total
Wake	79.92%	79.90%
Franklin	3.10%	3.10%
Johnston	4.58%	4.59%
Harnett	3.84%	3.85%
Nash	0.62%	0.62%
Other*	7.93%	7.94%
Total	100.00%	100.00%

*Other is not further identified in the application. Totals may not sum due to rounding.

As the table above illustrates, the applicant projects that the patient origin for linear accelerator services in the project’s first two operating years, FY 2018 and FY 2019 is expected to be relatively consistent with the historical percentages for DRH’s radiation oncology patient origin and that of CCNC.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to replace the existing Cary Radiation Oncology linear accelerator. In Section III.1, pages 16-21, the applicant discusses the unmet need served by the proposed project and states that it is primarily internal to DUHS and results from the following factors:

- The age of the existing equipment to be replaced and its inadequacies and technical deficiencies when there is high demand for advanced capabilities in radiation therapy technologies (pages 16-17);
- DUHS's desire to provide a consistent technology platform for all Duke cancer services in Wake County (page 16);
- Historical and projected population growth in the proposed service area, especially for the 65+ age group, the most likely group to utilize oncology services (page 19);
- Growth in newly diagnosed cancer cases and utilization of cancer-related services (page 19); and
- High utilization of all three of DRH's existing linear accelerators (pages 18-21).

Age and Inadequacy of Existing Equipment

In Section III.1, pages 16-17, the applicant states that due to the age of the machine, it has reached the end of its life, requires frequent downtime for maintenance resulting in missed treatments, has difficulty with parts replacement and is not well suited to intensity-modulated radiation therapy (IMRT) or image-guided radiation therapy (IGRT) capabilities. The applicant is proposing to replace the equipment with technology that it has already acquired for the hospital campus and which will provide a consistent technology platform for its radiation oncology services. The applicant provides a list of benefits associated with the proposed equipment on pages 17-18, which include increased dose-rate delivery, on-board imaging enhancements and streamlined physics quality assurance.

Historic and Projected Population Growth

On page 19 of the application, the applicant provides 2014-2019 population growth on a four-zip code Cary area, consisting of 27519, 27513, 27511, and 27518. The total projected growth for the Cary area during that period is 8.3%, with a compound annual growth rate of 1.6%. The applicant states:

“It is notable that the town of Cary exceeds the population threshold of 120,000 used in the annual State Medical Facilities Plan as a “geographical accessibility criterion” for linear accelerator planning.”

Growth in Cancer Cases and Incidence Rates

In Section III.1, pages 19-20, the applicant provides the following projected cancer incidence rates for the Greater Wake Region, showing the region is expected to experience an 18.9% increase in cancer incidence by 2018.

Cancer Incidence Projections for Greater Wake

County	2013 Incidence	2018 Incidence	Projected Growth
Franklin	360	406	12.9%
Harnett	721	840	16.6%
Johnston	856	994	16.1%
Nash	715	778	8.9%
Wake	5,313	6,447	21.4%
Greater Wake	7,963	9,466	18.9%

Source: Thomson Reuters, Incidence as defined as number of new cases per year.

The applicant states that the growth and aging of the population will drive continued demand for services in Cary. The applicant further states that the combination of the CCNC and Duke Cancer Institute medical and radiation oncologists will drive continued growth in referrals in addition to the historical 30% of CCNC's linear accelerator patients who were referred for treatment by physicians not affiliated with CCNC.

High Utilization of Duke Raleigh Hospital and CCNC Linear Accelerators

In Section III, pages 20-21, the applicant states that the growing need for radiation oncology services in Wake County is reflected in DUH's historically increasing radiation oncology utilization by patients in the DRH service area as shown below.

Linear Accelerator Patients from Duke Raleigh Hospital Service Area

County	FY2012	FY2013	FY2014	2 Yr CAGR
Franklin	14	12	17	11.7%
Harnett	9	23	19	43.5%
Johnston	21	34	34	26.9%
Nash	13	19	23	32.7%
Wake	176	229	265	22.7%
Total	233	317	358	24.0%

Note: Calculations may not be precise due to rounding.

The table above shows a 24% 2-year compound annual growth rate in the number of linear accelerator patients from DRH's service area seeking radiation services at DUH in Durham. The applicant suggests this reflects a demand for Duke-provided cancer services in DRH's service area.

The applicant states, on page 18 of the application, that CCNC served 282 patients at its Cary facility during FY2013. CCNC’s 2013 total treatments at Cary Radiation Oncology and Macon Pond decreased seven percent from 2011 after a four percent increase in 2011 over 2010. However, as noted by the applicant, the linear accelerator at Cary exceeded the SMFP prescribed capacity threshold of 250 patients in 2013. On page 18, the applicant further states:

“During FFY2013 (Oct 12-Sept 13) CCNC served 667 total patients on its two existing linear accelerators, including 282 patients in Cary. During June [sic] 2013-June 2014 (the most recent 12 months), the Macon Pond and Cary linear accelerators together served 689 total patients, or an average of 345 patients per machine. ... Combined, the existing Duke Raleigh and CCNC linear accelerators served a total of 1100 patients from July 2013-June 2014, or an average of 367 patients per machine. Without any further growth, that volume reflects appropriate utilization of 4.4 machines.”[emphasis in original]

On page 21, the applicant states:

“...the single existing linear accelerator on the hospital campus treated 411 radiation therapy patients during FY2014 (July 2013 – June 2014), and is therefore already at 82% of utilization appropriate for 2 machines, even before an additional machine is implemented there.”

Based on the statistics presented above, the applicant states that the linear accelerator services at both Duke Raleigh Hospital and CCNC have historically been highly utilized. In Section III.1, pages 16-22, the applicant adequately demonstrates, based on current utilization, the demand for state-of-the-art enhanced radiation therapy services.

Projected Utilization

In Section IV.1, pages 30-38, the applicant projects linear accelerator utilization at Cary Radiation Oncology for the interim years and the first three fiscal years following completion of the project, as illustrated in the table below.

Historical and Projected Utilization

	Last Year	Interim Years			Project Years		
	FY2014*	FY 2015*	FY2016	FY2017	FY2018	FY2019	FY2020
Linear Accelerators	1	1	1	1	1	1	1
ESTV Treatments	7,141	5,713	4,868	3,998	7,237	7,341	7,445
Projected Increase		-20.00%	-14.79%	-17.87%	81.02%	1.44%	1.42%
Capacity	105.79%	84.64%	72.12%	59.23%	107.21%	108.76%	110.30%

*Equipment operated by CCNC through November 7, 2014.

The assumptions and methodology used for determining Cary Radiation Oncology’s projected utilization begin on page 30 and are summarized as follows:

- Fiscal Years run from July 1 through June 30.
- The first full year of operation following completion of the project is FY 2018.
- The assumptions are based on combined projections for both radiation oncology sites acquired by Duke Raleigh Hospital from CCNC (Macon Pond and Cary).
- FY 2014 volumes are based on the historical volumes provided by CCNC.
- In FY 2015, the applicant projects (pages 30-31) total patients equal to 80% of the patients treated on the CCNC equipment in FY 2014. The applicant states that the decrease is conservative and reflects the potential effects of the transition of ownership from CCNC to the applicant. The projection does not assume any redirection of DRH service area patients from DUH during this transition year.

	FY2014	FY2015
Patients	689	551

- From FY 2016 through FY 2018, the applicant projects patient volumes at the Macon Pond and Cary Radiation Oncology sites will grow by 6% per year, reflecting two concurrent trends: service area population growth (1.5-2% annually) and increase in market share (3.5-4% annually) as discussed by the applicant on pages 31-33. The applicant states that based on the uncertainty of the resolution of Project ID #J-7941-07, its projections are conservative and project a lower total growth at the Macon Pond and Cary sites to reflect both constraints on capturing additional market share imposed by limited capacity and the lack of Stereotactic Radiosurgery (SRS) capability.
- In FY 2019, the applicant projects volume growth of 1.5%, reflecting population growth, but no additional increase in market share.

Patient Volume at Macon Pond and Cary

	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019
Increase		-20.0%	6.0%	6.0%	6.0%	1.5%
Patients	689	551	584	619	656	666

- The applicant projects the total volume will be allocated between Macon Pond and Cary consistent with the current patient volumes at that site, resulting in the following patient volume for the Cary linear accelerator, as shown on page 34 of the application.

Patient Volume at Cary Radiation Oncology

	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
Patients	314	251	266	282	299	304	308

- In FY 2016-2019, the applicant projects that 10% of historic DUH linac patients from DRH's service area of Wake, Johnston, Franklin, Harnett, and Nash counties will seek treatment at the outpatient sites in Wake County, with slightly more than 50% (20) going to Cary, which is closer to DUH, and slightly less than 50% going to Macon Pond (pages 34-35).

DUH Linac Patients from Greater Wake Region (DRH's Service Area)

Counties	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019
Franklin	17	18	18	18	18	18
Harnett	19	19	19	20	20	20
Johnston	34	34	35	35	36	36
Nash	23	23	23	23	23	23
Wake	265	270	276	281	287	292
Greater Wake SA Patients	358	364	371	377	384	389
Approximate 10% Shift	0	0	38	39	39	39

Calculations may not be precise due to rounding.

**Shift of DRH Service Area Linac Patients from DUH
 to the Cary Radiation Oncology and Macon Pond Locations**

Counties	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
Shift of Patients (10%)	0	0	38	39	39	39	39
Shift to Cary Radiation Oncology (20 patients)	0	0	20	20	20	20	20
Shift to Macon Pond	0	0	18	19	19	19	19

The following table reflects the projected number of patients at Cary Radiation Oncology after the shift of DRH service area patients from DUH to Cary Radiation Oncology.

**Patient Volume at Cary Radiation Oncology
 after DUH Shift of SA Patients**

	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
Patients at Cary Radiation Oncology prior to Shift (p.34)	314	251	266	282	299	304	308
SA Shift from DUH			20	20	20	20	20
Patients at Cary Radiation Oncology after DUH Shift			287	303	320	324	329

Totals may not sum due to rounding.

- The applicant states that the pro forma financial statements in the application reflect a conservative projection for FY 2016 and FY 2017 because the installation of the replacement equipment will take up to three months of FY 2016 and up to five months in FY 2017 (page 35) to complete, as shown below.

Projected Patient Volume at Cary Radiation Oncology

	FY2014	FY2015	FY2016*	FY2017*	FY2018	FY2019	FY2020
Patients	314	251	215	177	320	324	329

*Reflects services for nine months in FY 2016 and seven months in FY 2017.

- The applicant projects treatment volumes based on CCNC’s FY2014 radiation therapy utilization: 16,720 total treatments (13,956 external beam and IMRT + 2,764 dosimetry treatments) on 689 patients or a ratio of 24.3 total treatments per patient. The applicant provides a table on page 36 detailing the number of treatments by type and the number of ESTVs each year. The applicant does not discuss its calculations in detail or provide the basis for the breakdown of treatment by type, however, a calculation by the analyst reveals that simple and intermediate treatments account for less than 1%, complex treatments - 70%, IMRT treatments - 16% and dosimetry treatments – 13 to 14% of the total number of treatments each year. Based on the definitions in the SMFP, the following table shows the analyst’s calculated projected ESTVs.

Txt by Type	ESTVs /Txt	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
Total Treatments		7,636	6,109	5,224	4,290	7,765	7,875	7,985
IMRT	1.0	1,223	979	822	676	1,224	1,242	1,260
Simple	1.0	38	30	24	20	36	37	37
Intermediate	1.0	31	24	19	16	29	30	30
Complex	1.0	5,356	4,285	3,645	2,994	5,421	5,498	5,576
Dosimetry	0.5	494	396	357	292	527	535	542
Total ESTVs		7,142	5,714	4,867	3,998	7,237	7,342	7,445

A comparison of the analyst’s table above with the applicant’s table on page 36 reveals only an occasional insignificant rounding difference.

As shown in the table above and in Section IV, page 36, the applicant projects that the Cary Radiation Oncology linear accelerator will average 7,445 ESTVs in the third project year, FY 2020.

The applicant adequately demonstrates projected utilization is based on reasonable, credible, and supported assumptions.

Access

In Section VI, page 45, the applicant states that the services of DUHS hospitals and clinics are open to all area and non-area residents for inpatient, outpatient, and other healthcare services on a walk-in, emergency, appointment or referral basis. The applicant further states:

“As part of DUHS, Duke Raleigh Hospital will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

The applicant further addresses access to its services in Section VI.14-15, pages 53-54 and provides the following payor mix for the second full fiscal year of the proposed project.

**Duke Raleigh Hospital
July 1, 2018- June 30, 2019
All Services**

Payor Category	Percent of Total Utilization
Self Pay/ Indigent/ Charity	4.2%
Medicare/ Medicare Managed Care	62.6%
Medicaid	8.7%
Commercial Insurance	0.3%
Managed Care	21.3%
Other *	2.9%
Total	100.0%

* Not specified.

**Duke Cancer Center Cary Radiation Oncology
July 1, 2018- June 30, 2019
Linear Accelerator Services**

Payor Category	Percent of Total Utilization
Self Pay/ Indigent/ Charity	1.2%
Medicare/ Medicare Managed Care	50.4%
Medicaid	1.4%
Commercial Insurance	0.0%
Managed Care	47.0%
Total	100.0%

The discussion regarding access found in Criterion (13) is incorporated herein by reference. The applicant adequately demonstrates 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.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project based on reasonable and supported utilization projections and assumptions and demonstrates the extent to which all residents of the area, and in particular, underserved groups, are likely to have access to the services. 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 22, the applicant discusses the only alternatives to replacing the existing linear accelerator that were considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant states that replacement of the existing machine cannot be postponed long-term because of the factors discussed in Section III.1, pages 16-21, specifically, the age of the machine, the maintenance downtime, lack of availability of support parts, and lack of image-guided radiation therapy (IGRT) capability or the ability to upgrade to IGRT. Therefore, this option was rejected.
- 2) Relocation to a different location – The applicant states that construction of a new vault in a different location would add unnecessary expense to this project at this time. The applicant further states that significant medical and other cancer services are already provided at this location and enable patients to get coordinated cancer care in one location. Thus relocating to a different location was not considered a reasonable alternative.

The applicant demonstrates that acquiring a replacement linear accelerator is the most effective alternative to meet the identified need.

Furthermore, the application is conforming or conditionally conforming to all other statutory review criteria. Therefore, the application is approvable. An application that cannot be approved is not 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 Raleigh Hospital shall materially comply with all representations made in the 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 linear accelerator located at Duke Cancer Center Cary Radiation Oncology for a total of no more than one linear accelerator at Duke Cancer Center Cary Radiation Oncology. Upon project completion, Duke Raleigh Hospital shall own and operate no more than a total of four linear accelerators, including Project ID #J-7941-07.**
 3. **Duke University Health System d/b/a Duke Raleigh Hospital shall dispose of the existing Cary Radiation Oncology 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 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 Agency 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, pages 65-66, the applicant projects the total capital cost as shown in the table below.

Project Capital Costs

Construction Contract	\$1,015,253
Equipment/Furniture	\$3,596,057
Architect & Engineering Fees	\$141,000
Consultant Fees	\$34,800
Contingency Fund	\$612,890
Total Capital Cost	\$5,400,000

In Section IX, page 71, the applicant states there will be no start-up or initial operating expenses for this project.

In Section VIII.3, page 67, the applicant states that the total capital cost will be funded with the accumulated reserves of Duke University Health System. Exhibit 16 contains a letter from the Chief Financial Officer of DUHS which documents the availability of adequate funds for the capital and operating costs of the proposed project.

Exhibit 7 contains the audited financial statements for Duke University Health System, Inc. and Affiliates for years ending June 30, 2014 and 2013. According to the financial statements, as of June 30, 2014, DUHS had \$167,190,000 in cash and cash equivalents, \$884,683,000 in total current assets, \$4,873,711,000 in total assets and \$3,012,756,000 in total net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

The applicant projects a positive net income for Cary Radiation Oncology in each of the first three operating years of the project as shown in the table below.

**Duke Cancer Center Cary Radiation Oncology
 Linear Accelerator Services**

	Project Year 1 FY2018	Project Year 2 FY2019	Project Year 3 FY2020
Projected Radiation Oncology Treatments	7,765	7,875	7,985
Projected Average Charge per Treatment	\$2,515	\$2,666	\$2,826
Gross Patient Revenue	\$19,531,858	\$20,994,019	\$22,567,980
Deductions from Gross Patient Revenue	\$14,947,538	\$16,338,152	\$17,838,842
Net Patient Revenue	\$4,584,320	\$4,655,867	\$4,729,138
Total Expenses	\$2,916,546	\$3,210,873	\$2,972,170
Net Income	\$1,667,778	\$1,444,994	\$1,756,968

*Source: Form C. Totals may not sum due to rounding.

The applicant also projects a positive income for the DUHS in each of the first three operating years of the project as illustrated in the table below.

Duke University Health Systems

	Project Year 1 FY2018 (in 000's)	Project Year 2 FY2019 (in 000's)	Project Year 3 FY2020 (in 000's)
Gross Patient Revenue	\$10,949,590	\$11,824,462	\$12,769,237
Deductions from Gross Patient Revenue	\$8,323,684	\$9,169,041	\$10,100,513
Net Patient Revenue	\$2,625,906	\$2,655,421	\$2,668,724
Non-Patient Revenue	\$181,436	\$186,207	\$191,131
Total Operating Revenue	\$2,807,342	\$2,841,628	\$2,859,855
Total Expenses	\$2,662,116	\$2,694,688	\$2,712,003
Operating Income	\$145,226	\$146,940	\$147,851
Non-Operating Revenue & Expense	\$176,879	\$182,997	\$189,309
Excess Revenue over Expenses	\$322,105	\$329,937	\$337,161

* Source: Form B. Totals may not sum due to rounding.

The assumptions used by the applicant in the preparation of the pro forma financial statements, including projected utilization, are reasonable. See the Pro Forma Section of the application for the pro forma financial statements and the applicant's financial assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to 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

As discussed in Criterion (1), DUHS owns and operates three existing linear accelerators in Wake County: one at Duke Raleigh Hospital and the two recently acquired when DRH acquired CCNC's radiation oncology services at Macon Pond and Cary Radiation Oncology. In addition, the ownership transfer of an undeveloped linear accelerator awarded to CCNC for the Macon Pond location, Project ID #J-7941-07, was under appeal at the time this application was submitted. The case has since been settled and DUHS received approval to relocate the undeveloped linear accelerator from Macon Pond to the Duke Raleigh Hospital campus. Duke Raleigh Hospital therefore now owns three operational linear accelerators (one at DRH, one at Macon Pond and one at Cary Radiation Oncology) and one additional linear accelerator approved for development on the hospital campus, for a total of four DRH linear accelerators.

In this application, the applicant proposes to replace the existing Cary Radiation Oncology linear accelerator. The applicant is not proposing to add beds, other medical equipment or new services in Wake County.

In Section III.6, pages 27-28, the applicant states that based on the Draft 2015 SMFP, the most recent data available, the providers of radiation therapy services in the applicant’s proposed service area and their utilization are as shown in the table below.

Service Provider	County	# of Linear Accelerators	# of ESTVs	ESTVs / Linac	% of Capacity
Franklin County Cancer Center	Franklin	1	115	115	1.7%
CCNC/DUHS	Wake	2	15,429	7,715	114.3%
Duke Raleigh Hospital	Wake	1	9,526	9,526	141.1%
Rex Hospital	Wake	4	18,118	4,530	67.1%
Clayton Radiology	Johnston	1	3,605	3,605	53.4%
Smithfield Radiation Oncology	Johnston	1	4,394	4,394	65.1%
Nash General Hospital	Nash	2	8,138	4,069	60.3%

Note: The two CCNC/DUHS linacs shown above include only the operational linacs at Duke Cancer Center Macon Pond and Cary Radiation Oncology and do not include Project ID #J-7941-07, the transfer of which was under appeal at application submission and not yet developed. The list above excludes The Prostate Health Center specialty linac, which became operational in 2013 and reported 7,241 ESTVs in its first year. The list also excludes the 2014 need determination for an additional linear accelerator in Wake County.

As shown in the table above, the DUHS linear accelerators located at Duke Raleigh Hospital, Macon Pond and Cary Radiation operated above 100% of capacity. In Section III.6(b), page 28, the applicant states:

“As this project proposes the replacement of already highly utilized equipment at Cary, other providers would not be able to meet the need to replace the equipment that serves Duke’s patients. Moreover, Duke Raleigh and CCNC’s historic volumes show that other providers’ capacity is not affecting the demand or need for these services.”

On page 18, the applicant states:

“During FFY2013 (Oct 12-Sept 13) CCNC served 667 total patients on its two existing linear accelerators, including 282 patients in Cary. During June [sic] 2013-June 2014 (the most recent 12 months), the Macon Pond and Cary linear accelerators together served 689 total patients, or an average of 345 patients per machine. ... Combined, the existing Duke Raleigh and CCNC linear accelerators served a total of 1100 patients from July 2013-June 2014, ...”

As of the end of June 2014, with no further growth, the three DRH linear accelerators average treating 367 patients per machine and the volume reflects utilization of 4.4 machines at the 250 patients per machine SMFP linear accelerator utilization threshold. (1,100 patients/250 patients per machine = 4.4 linear accelerators)

The applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved linear accelerators in the Service Area. Therefore, the application 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.

C

In Section VII.1, pages 56-57, the applicant provides Cary Radiation Oncology’s current and projected total number of full-time equivalent (FTE) positions, as shown in the following table.

**Cary Radiation Oncology
 Current and Projected Staffing**

Position	Current FY 2015	Projected Year 2 FY 2018
Administrative		
Practice Manager	0.25	0.25
Chief Therapist	0.25	0.25
Subtotal*	0.50	0.50
Clinical		
Radiation Therapist	4.00	5.30
Registered Nurse	2.00	2.00
Subtotal	6.00	7.30
Support		
Patient Service Associate	1.00	2.00
Dosimetrist	1.00	2.00
Physicist	1.00	1.60
Subtotal	3.00	5.60
Total Staffing	9.50	13.40

*The applicant’s tables on pages 56-57 erroneously sum the subtotal for Administration; however, the calculation results in the correct total.

In Section VII.3, page 58, the applicant states:

“Duke Raleigh projects the need for approximately 4 additional FTEs over the life of the project. However, the need for these FTEs is not created by the project itself, which is simply a replacement of existing capacity and services.”

The applicant states, *“Duke is a significant healthcare employer in Wake County.”* The applicant further states that Duke offers competitive pay and attractive benefits to recruit qualified staff and its Human Resources Department adjusts to market demands as necessary to facilitate recruitment and retention of high quality staff.

In Section VII.8, pages 60-62, the applicant identifies DRH’s Chief of Staff / Medical Director as Michael Spiritos, M.D. and provides a list of Duke Raleigh Hospital’s active medical staff. In Section V.3(c), page 42, the applicant identifies Carol Hahn, M.D. as the Medical Director of Duke Radiation Oncology at DRH and states that she will continue in that role and will therefore serve as Medical Director for the services provided at Cary Radiation Oncology.

The applicant adequately demonstrates the availability of sufficient health manpower to continue providing radiation therapy services at Cary Radiation Oncology. 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.1(b), page 10, the applicant explains its plan to transition from providing radiation oncology services as a freestanding facility operated by the DUHS to providing the services through the DRH Department of Radiation Oncology in January 2015. The applicant further states that the services of the health system hospital and the physicians will be billed separately to patients and payors.

As the replacement equipment will be operated as part of the DRH Department of Radiation Oncology, the procedures performed on the proposed machine will be provided by DRH personnel and by physicians who are members of the faculty of the Duke University School of Medicine and the Private Diagnostic Clinic (the faculty practice plan) or other members of the DRH medical staff. The applicant states that DRH is not a separate corporation or entity from DUHS.

In Section II.2, pages 10-11, the applicant identifies the ancillary and support services that are currently available to Cary Radiation Oncology patients through Duke Raleigh Hospital. The applicant states:

“DUHS also currently provides many of these services at these locations, which will soon be operated as provider-based as outpatient hospital clinics, and has already expanded services as necessary to patients at these locations.”

The applicant discusses coordination with the existing health care system in Section V, pages 39-44. The applicant provides supporting documentation in Exhibits 9 and 18. The information provided in these sections and related exhibits is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.

- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

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

C

The following table illustrates DRH's and CCNC Cary's payor mix for FY 2014 as reported by the applicant and CCNC, respectively, and shown in Section VI, pages 51-52.

**Patient Days/Procedures as a Percent of Total Utilization
 July 1, 2013- June 30, 2014**

Payor Category	Duke Raleigh Hospital Facility	CCNC Cary Linear Accelerator Services
Self Pay/ Indigent/ Charity	4.2%	1.2%
Medicare/ Medicare Managed Care	60.8%	48.0%
Medicaid	8.8%	1.4%
Commercial Insurance	0.3%	0.0%
Managed Care	22.9%	49.4%
Other	2.9%	0.0%
Total	100.0%	100.0%

Note: Totals may not sum due to rounding.

In Section VI.4, page 46, the applicant states “*All persons will have access to the proposed service.*” In Section VI.1, page 45, the applicant also states,

“The services of Duke University Health System hospitals and clinics are open to all area and non-area residents for inpatient, outpatient, and other healthcare services on a walk-in, emergency, appointment, or referral basis. There is no discrimination on the basis of race or ethnicity, sex, age, income, religion, or handicapping condition.”

The applicant provides supporting documentation in Exhibits 3 and 8, which contain copies of DRH’s admissions policies and DUHS’s financial policies, respectively.

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, Franklin, Johnston, Harnett and Nash counties and statewide.

County	2010 Total # of Medicaid Eligibles as % of Total Population	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center) *
Wake	9.8%	3.3%	18.4%
Franklin	17.5%	7.4%	19.7%
Johnston	17.5%	6.7%	20.0%
Harnett	16.9%	6.2%	20.3%
Nash	19.6%	8.7%	19.7%
Statewide	16.5%	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 would not typically utilize the health 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 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 currently have adequate access to linear accelerator services provided at Cary Radiation Oncology. 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 51, the applicant states:

“Duke Raleigh is not obligated under federal regulations to provide uncompensated care, community service, or access by minorities or handicapped persons. For example, Duke Raleigh Hospital does not have any Hill-Burton uncompensated care requirements. However, as previously stated, Duke Raleigh Hospital does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. Duke Raleigh Hospital will continue to provide healthcare service and access for all persons, without federal obligation.”

In Section VI.10, page 50, the applicant states that it is not aware of any court actions filed alleging civil rights equal access violations against Duke University Health System facilities in the last five years. The applicant further states:

“Duke is aware of the following agency complaints that have been filed against DUHS facilities during that period:

- *A complaint of discrimination based upon disability against Duke University Hospital filed with OCR in 2010. OCR accepted the DUHS response without further action.*
- *A complaint of denial of access to service animal filed against Durham Regional Hospital with OCR in 2010. Corrective action (consisting of education regarding newly revised service animal regulations) was accepted on May 4, 2012 and has been implemented.”*

See Exhibit 3 for Duke Raleigh Hospital’s admission policies. 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 Sections VI.14 – VI.15, pages 53-55, the applicant projects the payor mix for the second operating year following completion of the proposed project, FY 2019, as shown in the following table.

**Patient Days/Procedures as a Percent of Total Utilization
 July 1, 2018- June 30, 2019**

Payor Category	Duke Raleigh Hospital	Cary Radiation Oncology Linac Services
Self Pay/ Indigent/ Charity	4.2%	1.2%
Medicare/ Medicare Managed Care	62.6%	50.4%
Medicaid	8.7%	1.4%
Commercial Insurance	0.3%	0.0%
Managed Care	21.3%	47.0%
Other	2.9%	0.0%
Total	100.0%	100.0%

Totals may not sum due to rounding.

The applicant states:

“There is a projected 1% shift each year of managed care patients to Medicare to reflect the aging of the patient population receiving these treatments.”

In Section VI, page 45, the applicant states that the services of DUHS hospitals and clinics are open to all area and non-area residents for inpatient, outpatient, and other healthcare services on a walk-in, emergency, appointment or referral basis. The applicant further stated:

“As part of DUHS, Duke Raleigh Hospital will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

On pages 47-48, the applicant further states:

“As documented in this application, Duke Raleigh Hospital serves the medically indigent through charitable care.

Duke Raleigh Hospital has a long history of being a community partner to many organizations and programs. Consistent with Duke Raleigh Hospital values, the hospital supports many community-based organizations whose goals and activities are compatible with Duke Raleigh Hospital. As examples, Duke Raleigh Hospital provides free healthcare services to members of Project Access, furnishes laboratory services at no cost to the Open Door Clinic, and sponsors a community program called Wholesome Routines designed to combat childhood obesity.”

The applicant demonstrates that medically underserved populations will continue to have adequate access to linear accelerator services at Cary Radiation Oncology. 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.9-10, pages 49-50, the applicant describes the means by which persons will have access to the facility, as follows:

“Access to the radiation therapy services to be provided by the proposed machine will typically be through referral to one of the radiation oncologists with privileges at Duke Raleigh Hospital.

...

Facilities that have historically referred patients to Duke Raleigh Hospital or its services include all those with which the Hospital now has transfer agreements (see Exhibit 9) and others as well. But most patients coming to the Hospital for treatment are referred by their physicians, and not by facilities or agencies.”

The information provided is reasonable and 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, pages 39-40, the applicant documents that it accommodates the clinical needs of health professional training programs in the service area and that it will continue to do so. Exhibit 10 contains a list of the health professional training programs that currently utilize DRH services as training sites. 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.

C

The applicant proposes to replace the existing linear accelerator located at Cary Radiation Oncology and operated by DUHS and do minor renovations to accommodate the new machine.

In Section III.6, pages 27-28, the applicant lists the providers of radiation therapy services in the applicant's proposed service area and shows their utilization, as shown in the table below.

Service Provider	County	# of Linear Accelerators	# of ESTVs	ESTVs / Linac	% of Capacity
Franklin County Cancer Center	Franklin	1	115	115	1.7%
CCNC / DUHS	Wake	2	15,429	7,715	114.3%
Duke Raleigh Hospital	Wake	1	9,526	9,526	141.1%
Rex Hospital	Wake	4	18,118	4,530	67.1%
Clayton Radiology	Johnston	1	3,605	3,605	53.4%
Smithfield Radiation Oncology	Johnston	1	4,394	4,394	65.1%
Nash General Hospital	Nash	2	8,138	4,069	60.3%

Note: The two CCNC/DUHS linacs shown above include only the operational linacs at Duke Cancer Center Macon Pond and Cary Radiation Oncology and do not include Project ID #J-7941-07, the ownership transfer of which was under appeal at the time of application submission and not yet developed. The list above excludes The Prostate Health Center specialty linac, which became operational in 2013 and reported 7,241 ESTVs in its first year. The list also excludes the 2014 need determination for an additional linear accelerator in Wake County.

As shown in the table above, the three existing DUHS linear accelerators located at Duke Raleigh Hospital, Macon Pond and Cary Radiation Oncology operated above 100% of capacity. In Section III.6(b), page 28, the applicant states:

“As this project proposes the replacement of already highly utilized equipment at Cary, other providers would not be able to meet the need to replace the equipment that serves Duke’s patients. Moreover, Duke Raleigh and CCNC’s historic volumes show that other providers’ capacity is not affecting the demand or need for these services.”

In Section V.7, page 43, 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 proposed project will improve the quality of oncology services, access to services and the cost effectiveness of radiation therapy services at Duke Raleigh. Duke Raleigh 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.”

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 for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criterion (13) is incorporated herein by reference.

The application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

Duke University Health System d/b/a Duke Raleigh Hospital is a licensed, acute care hospital and is accredited by the Joint Commission. According to the records in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents have occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to replace an existing linear accelerator; the licensed inventory of linear accelerators will remain the same. Therefore the Criteria and Standards for Radiation Therapy Equipment, promulgated in 10A NCAC 14C .1900, are not applicable to this review.