The Prostate Health Center

HAND DELIVERED

October 1, 2014

Ms. Martha Frisone, Acting Chief
Mike McKillip, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Comments on Competing Applications for a Certificate of Need for a Linear Accelerator in Wake County, Health Service Area IV; CON Project ID Numbers:

J-010318-14, UNC Hospitals Radiation Oncology, Holly Springs Campus
J-010322-14, Duke Raleigh Hospital Second Linear Accelerator

Dear Ms. Frisone and Mr. McKillip:

On behalf of Parkway Urology, LLC, Project ID J-010320-14, thank you for the opportunity to comment on the above referenced applications for a new linear accelerator in service area 20. During your review of the projects, I trust that you will consider the comments presented herein.

We recognize that the State's Certificate of Need (CON) award for the proposed linear accelerator will be based upon the State's CON health planning objectives, as outlined in the following statutes:

- G.S. 131E-176(14g)
- G.S. 131E-178
- GS-131E-183

Specifically, we request that the CON Section give careful consideration to the extent to which each applicant:

- Makes specific arrangements to coordinate care with patients' primary care providers.
- Provides evidence of community and physician support for the project
- Demonstrates that its available linear accelerators are operating at capacity

- Has demonstrated capacity to complete its approved Certificate of Need in a timely manner.
- Proposes the least costly Medicare payments
- Proposes access to Medically underserved groups including charity
- Proposes accessible linear accelerator support services on site
- Proposes the least costly capital investment
- Is located near a large minority population
- Demonstrates specific intent to refer patients from physicians.

COMPARATIVE RANK AMONG APPLICANTS (1 = BEST)

	Comparative Factor	Parkway Urology	Duke Raleigh Hospital	UNC Hospitals
1.	Program to Coordinate care with primary care provider	1	2	2
2.	Demonstrates Community Support	1	2	2
3.	Owned or approved linear accelerators operating at capacity	1	2	2
4.	Timely completion of projects	1	2	3
5.	Low Medicare Payment Rates	1	2	3
6.	Percentage of Underserved Care	1	2	3
7.	Support Services on Site	1	1	2
8.	Lowest capital investment	1	2	3
9.	Location near largest minority population	1	2	3
10.	Specific demonstration of support from referring physicians	1	2	3
	Total Score	**10**	**19**	**26**
	Average Rank	**1**	**1.9**	**2.6**

BASIS FOR RANK

	Comparative Factor	Parkway Urology	Duke Raleigh Hospital	UNC Hospitals
1.	Program to Coordinate care with primary care provider	Primary care physicians approve treatment plan	No program	No program
2.	Demonstrates Community Support	Letters from patients, churches, advocacy groups	Letter from American Cancer Society	Letter from American Cancer Society
3.	Owned or approved linear accelerators operating at capacity	yes	no	no
4.	Timely completion of projects	Linear accelerator CON completed ahead of schedule	Replacement linear accelerator project in progress	2010 CON for linear accelerator not yet operational
5.	Low Medicare Payment Rates	Global freestanding, lowest rates	Hospital OPPS	Hospital OPPS plus Medicare Academic
6.	Percentage of Underserved Care	**64.98**	**51.62**	**60.9**
7.	Support Services on Site	Simulator and Dosimetry	Simulator and Dosimetry	Neither
8.	Lowest capital investment	$3,794,262	$ 4,533,306	$ 4,384,019 incomplete
9.	Location near largest minority population – African American and Hispanic residents in zip code per 2010 Census	53,700 zip code 27610	10,219 zip code 27609	2,923 zip code 27540
10.	Specific demonstration of support from referring physicians	65 letters indicting intent to refer 2,580 patients	Letters intent to refer as appropriate	Letters duplicate referrals to Rex linear accelerators

DISCUSSION OF SUGGESTED COMPARISONS:

CONTINUITY OF CARE WITH PRIMARY CARE PHYSICIANS

Of the three applicants, only Parkway Urology includes the primary referring physician in the care plan for radiation treatment. This critical integration reduces handoff errors and assures full knowledge of the patient's health status when the short period of radiation therapy ends. This coordination is an essential component of the CMS Triple Aim of better care at lower cost with higher patient satisfaction.

ACCESS TO MEDICALLY UNDERSERVED PERSONS

Parkway Urology budgeted for generous Charity and Self Pay and proposes a larger proportion of its services to all underserved groups, including Medicare and Medicaid.

Comparison of Medically Underserved Payor Mix Percentages

Payor	Parkway Urology	UNC	Duke
Charity and Self Pay	5.22%	7.2	1.22
Medicare	58.2	41.5	45.7
Medicaid	1.56	12.2	4.7
Total Underserved	**64.98**	**60.9**	**51.62**

Comparison of Medicaid should also consider the fact that DUHS and UNC receive supplemental Medicaid payments from the State of NC for DSH (Duke received $39 million in 2013, see Exhibit 11 page 16). DSH payments apply to inpatient care, which would be provided on the Duke equipment.

CHARGE STRUCTURE

The least expensive to patients and payors is freestanding billing. See Exhibit 49 in CON Application J-10320-14.

- Parkway Urology – freestanding global includes physician fees
- UNC Hospitals – academic hospital outpatient prospective payment plus physician fees
- Duke Raleigh Hospital – hospital outpatient prospective payment plus physician fees

LOCATION

- Parkway Urology proposes to locate in an area that is accessible to all of its proposed service area, in zip code 27610, which has approximately 66,000 people 81.8 percent African American or Hispanic and a median income of $31,565[1].
- UNC Hospitals propose to locate in one of the most affluent parts of Wake County, zip code 27540, a location with a very low minority population (10.6 percent African American or Hispanic) and one third as many people, approximately 28,000.
- Duke proposes to locate at Duke Raleigh Hospital in zip code 27609, which has with twice the median income of the Parkway Urology zip code, ($66,448), half the population, 33,000, and only 31 percent African American or Hispanic[2].

SUPPORT SERVICES FOR PATIENTS –

- Only Parkway Urology and Duke propose to have simulation and treatment planning on site.
- Duke does not acknowledge importance of dietary/nutritional counseling for patients; Duke describes no coordination with local pharmacy; no indication that outpatient pharmacy not provided by DRAH will be coordinated for patients.
- UNC Hospitals propose to send patients to Chapel Hill and Rex for simulation and treatment planning, to Chapel Hill for social work and dietician services and to Rex for pharmacy services.

APPROPRIATE EQUIPMENT

- Parkway Urology proposes compatible Varian equipment that does not duplicate the infrequently needed capabilities of its Trilogy equipment.
- Duke proposes to acquire TrueBeam, which is among the most expensive of linear accelerators, to do largely complex treatments, and no SBR. Duke argues that a second TrueBeam will provide uniformity of equipment, but does not consider whether another less costly Varian would be more appropriate to the services proposed.
- UNC proposes an Elekta linear accelerator without a simulator at the site. UNC does not include costs of cabling or software to permit transfer of simulation and treatment planning to the proposed site.

COORDINATION WITH THE HEALTH CARE DELIVERY SYSTEM

- Parkway Urology provides letters from physicians in the referring specialties associated with the treatments it demonstrates are needed by the population to be served. Additional letters recently received are included in Attachment I to these comments.
- Duke failed to name facilities or individuals who have historically referred patients, page 117. All letters are from Duke, which suggests this is also a closed system.
- All UNC letters appear to be from UNC physicians. Suggests closed system.

---

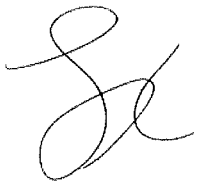
[1] http://www.city-data.com/zips/27610.html and http://www.zipdatamaps.com/27610
[2] http://www.city-data.com/zips/27609.html

APPLICANT ACCESS TO ALTERNATIVE SOLUTIONS

- Parkway Urology provides information to demonstrate that its one linear accelerator is operating at capacity and has sustained that use.
- UNC Hospitals has untapped capacity at Chapel Hill and at Rex Hospital. See Table 9G in the 2014 State Medical Facilities Plan, which does not include the linear accelerators obtained through the Academic Medical Center exemptions.
- Duke Raleigh has access to the undeveloped CCNC linear accelerator, which will bill at much lower freestanding charges and use the same equipment. Duke Raleigh also proposes to shift patients from the eight under capacity linear accelerators at Duke University Cancer Center in Durham to the proposed facility.
- Parkway Urology is operating at capacity and has demonstrated by history and letters of support that patients will use and that physicians will refer to its linear accelerator.

Given this information and the information in the attached comments, we believe that Parkway Urology proposed the most cost effective alternative with the highest quality and best access of the competing applications. We know yours is a difficult job and we appreciate your thoughtful attention to these comments.

Sincerely,



Kevin Khoudary, MD
President
Parkway Urology, LLC

Attachments

ATTACHMENTS

Attachment A

Individual Comments:
Duke Raleigh Hospital J-010322-14

COMPETITIVE REVIEW OF -
DUKE RALEIGH HOSPITAL, J-10322-14

OVERVIEW

Duke University Health System, Inc. d/b/a Duke Raleigh Hospital proposes to acquire a second linear accelerator for its Raleigh hospital campus. The proposed TrueBeam linear accelerator would be the fifth linear accelerator owned by the applicant in Linear Accelerator Service Area 20. The CON Section approved a request from DUHS to acquire Cancer Centers of North Carolina (CCNC) linear accelerators on August 22, 2014, including the as yet undeveloped linear accelerator at the Macon Pond Road facility (J-7931-07). That CON was awarded to CCNC almost four years ago, Feb 4, 2011.

The application is non-conforming to Criteria 1,3,4,5,6,7,8,12,13b, and 18a.

These comments are not intended to be exhaustive. They are only illustrations of issues with the referenced application.

CON REVIEW CRITERIA NCGS 131E-183(A)

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, ambulatory surgery operating rooms, or home health offices that may be approved.**

OVERVIEW

Though compliant with the need in the 2014 State Medical Facilities Plan, this application is not conforming to Policies GEN-3 and GEN-4.

POLICY GEN-3

The application does not address how the proposed volumes incorporate quality, cost effectiveness and access. The applicant, Duke University Health Systems ("DUHS") proposes to shift patients from its Comprehensive Cancer Center in Durham to facilities it proposes to acquire in Wake County. The Durham linear accelerators are operating far below the applicant's stated capacity. The 2014 License Renewal application for Duke University Medical Center indicates 4,738 ESTV per linear accelerator compared to its stated capacity of 9.320 ESTV's. The stated capacity was described in DUHS CON application Project No. J-8275-08 on, page 178, a copy of which is included in Attachment D to these comments. Data from the 2014 License Renewal Application are included in the discussion of Criterion 6 below and in Attachment E to these comments.

POLICY GEN-4

Project is not conforming to this policy. The project involves a capital expenditure in excess of $2 million and does not include an agreement to develop a water conservation plan as required by GEN-4. (See application pages 70-71).

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.**

Although the application identifies the counties to be served and the cancer incidence rates in the primary and secondary counties, documentation of need is tied to assumptions that: more physicians on the Duke Raleigh Hospital ("DRAH") staff will directly translate to more referrals to the proposed linear accelerator; that 67 percent of cancer patients will receive radiation treatment during the course of their illness; and, that 57 percent will receive external beam radiation treatment in a single year.

The application claims that a second linear accelerator is needed at DRAH notwithstanding the fact that DRAH has approval from the Agency to acquire three additional linear accelerators from Cancer Centers of North Carolina (CCNC). Please see Attachment C to these comments. All three CCNC linear accelerators are located or approved for location in Wake County. As noted below and elsewhere in these comments, linear accelerators owned by CCNC have substantial unused capacity at the time of this application and will have unused capacity by the third year of the proposed project.

The application frequently relies on hyperbole to justify need of the population to be served. It speaks of "pent up demand" for DRAH services in Wake County in both Section III (pages 62 and 72) and in Exhibit 19, pages 293, 303 through 304 However, the application contains no letters from patients or potential patients indicating they could not get services at DRAH. The application contains no count of patients referred out because they could not be treated at DRAH. The application notes on page 93 that "DUH patients from Wake County and elsewhere in the service area may elect to have their radiation oncology services at DRAH instead." The application argues for patient convenience, but provides no information from patients confirming this assumption.

The application erroneously notes that SBRT, a form of SRS treatments, would increase the number of ESTV's per patient (referred to as 'SBRT' on application page 97). This directly contradicts the statement in Duke Cancer Center CON Application J-8275-08, page 178 that SRS treatments will decrease ESTV's. For reference, see Attachment D to these comments.

The application fails to make a case that all three existing or approved CCNC linear accelerators and a second linear accelerator at DRAH will be fully utilized by Project Year 3, FY 2018. The methodology contains several logical flaws:

- It assumes that all historical CCNC physician cases will sustain at DRAH when ownership changes in 2014.
- It assumes that under DUHS ownership CCNC cases will decrease only 20 percent in 2015. The application provides no support for the assumption. As illustrated in alternative scenarios presented for illustration in Attachment J and in the data on application page 62, and Table 9G of the *2013, 2014 and Proposed 2015 State Medical Facilities Plan*, CCNC caseload and ESTV's have declined over the past three years. This trend is not addressed in the application. Furthermore, while CCNC currently has 15 physicians (ten medical oncologists, two gynecologic oncologists and three radiation oncologists) all of whom could refer patients to a linear accelerator, only six or 40 percent will transfer to DRAH (five medical oncologists and one gynecologic oncologist). The caseload is more likely to drop by 60 percent. Such a drop would give CCNC substantially more excess capacity than the DRAH application presents. Excess capacity is also more consistent with the case made by Duke in its 2013 petition to the State Health Coordinating Council (SHCC) that CCNC has substantial excess capacity.

  Page 3 of the DUHS 2013 petition shows the declining level of activity on the CCNC equipment, see Attachment F. However, the present Certificate of Need application masks the drop by using a 5-year CAGR. Use of the 5-year, rather than a 3-year CAGR is questionable in this case, because a CAGR calculation uses only the beginning and ending years and masks a situation in which demand rises and begins a sustained drop.

  $$CAGR = \left(\frac{Ending\ Value}{Beginning\ Value}\right)^{(1/\text{number of years})} - 1$$

  In fact, the declining demand for CCNC services is one of the factors that appear to have prompted the proposed sale to DUHS.

- On Exhibit 19 page 5, the present CON application notes that "local patients are familiar with the CCNC locations." This is not evidence of need for additional capacity. Moreover, the DUHS application makes no reference to the fact that when DUHS acquires CCNC; the charge structure for two of the linear accelerator locations will shift from freestanding to hospital-based. CCNC will have a new access barrier for patients who have deductible con-insurance burdens.

- The application's methodology for estimating both need and demand relies on data from a 2004 IMV study indicating that two thirds of cancer patients will get radiation therapy during their illness (ASTRO Fast Facts on Cancer[1]). A more recent report from the National Cancer Institute suggests that only 50 percent will get radiation therapy treatment. See Attachment G to these comments. The 2014 SMFP makes the same statement on page 123. Use of the lower estimate would reduce projected cancer patients in the DRAH service area by 996 in the year 2018. This would be reflected in a proportionate decrease in number of cases at DRAH under the methodology used in the application.

Projected Cancer Patients to Receive External Beam Radiation Therapy 2018

County	Total Cancer Patients	Projected LinAc Patients (65% of cancer patients receive radiation therapy, minus 12% that receive brachytherapy)	Projected LinAc Patients (50% of cancer patients receive radiation therapy, minus 12% that receive brachytherapy)	Difference
Franklin	335	192	147	44
Harnett	631	361	278	83
Johnston	954	546	420	126
Nash	430	246	189	57
Wake	5,195	2,972	2,286	686
Total	7,545	4,316	3,320	**996**

The application asserts that patients from service area are going to Duke University Medical Center Comprehensive Cancer Center because DRAH has reached capacity. It does not explore possibility that these patients may live closer to Duke University, or go to the Comprehensive Cancer Center for other specialist services like stem cell treatments that are not available at DRAH.

The application mentions addition of medical oncologists and GYN surgeons, to the DRAH medical staff, but does not tie these to an unserved need in the population to be served for their services. Indeed, these physicians have been practicing at CCNC.

In Section III, the application provides misleading information about the capacity of the CCNC linear accelerators by failing to acknowledge the approved and not yet operational linear accelerator at Macon Pond Road.

Page 69 indicates that DRAH provides "free healthcare services to members of Project Access" and "laboratory" services to the Open Door Clinic. That has nothing to do with the proposed linear accelerator. The application also refers to DRAH Community Benefit report, but that document makes no mention of the radiation therapy program.

The application falls short with regard to need of the population for a second linear accelerator at DRAH. As such, it is non-conforming to Criterion 3.

[1] .[1](https://www.astro.org/News-and-Media/Media-Resources/FAQs/Fast-Facts-About-Radiation-Therapy/Index.aspx)

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.**

The application proposes to relocate services provided at Duke Comprehensive Cancer Center in Durham to DRAH, which is not a Comprehensive Cancer Center. The application does not discuss the effect of the relocation of the service on ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care. It does not discuss the impact on the viability of the Duke Comprehensive Cancer Center.

The application is non-conforming to Criterion 3a.

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.**

On page 16, the application indicates that additional physicians added to the DRAH staff will bring new patients. The application recognizes that six out of seven of the new medical oncologists were formerly members of CCNC medical staff; and the application later uses these same physicians to justify utilization of the CCNC linear accelerators that the Agency has approved DUHS to acquire. The argument put forth that DUHS has no binding agreement to acquire these linear accelerators could as easily be made about the vendor contracts in this CON application. DUHS clearly has Agency approval to acquire three additional linear accelerators in Wake County.

The application justifies both DRAH and CCNC linear accelerators on caseload, not on ESTV's. It forecasts that CCNC patients will equal 250 per linear accelerator. This count is dependent on the assumption that 38 patients would elect to have radiation oncology services at CCNC, rather than Duke Comprehensive Cancer Center. The application provides no supporting documentation for the transfer; and, without the 38, even the flawed forecast is short of the 250 patients required in special Rule 10NCAC14C.1903(c).

Forecast Patients on CCNC Linear Accelerators

	FY 2016	FY2017	FY 2018
Palliative	234	255	280
Curative	398	434	476
Total	632	688	756
Number Linacs	3	3	3
Patients per Linac	211	227	252
Less DUHS transfers	37	88	38
CCNC caseload without DUHS transfers	174	189	214

Source: Exhibit 19 page 10 and Special Rule 10NCAC14C.1903(c).

The application fails to mention or provide a mechanism for transferring the planning and simulation information from Duke Comprehensive Cancer Center for the patients who would elect to shift from Duke Comprehensive Cancer Center to the CCNC facilities. Normally, this requires additional software and cabling that are not included in the application. Otherwise, the patients would require new planning and simulation at DRAH, a redundant expense.

Application page 38 notes CCNC "projects to serve served 689 patients in FFY 2014, or 345 per machine," but this calculation failed to count the approved, not operational machine. Including that equipment would reduce the ratio to 229 per machine.

The proposed linear accelerator will bill at Medicare Hospital OPPS rates, which are more expensive than the freestanding rates at the Macon Pond Road site.

The application presents alternatives to acquisition of the second linear accelerator, but does not choose the least costly or most effective. Hence, it is non-conforming to Criterion 4.

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.**

The financial proformas for Form D and Form E of the application are consistent with Revenue presented in Form C. The treatments listed on Forms D and E are consistent with the treatment counts presented on page 86 for two linear accelerators. Neither Section IV nor assumptions to the proforma Form B provide any information on how treatments are calculated. They include only a lump sum called "Dosimetry treatments."

However, the Expenses presented on Form B appear to reflect only one linear accelerator and do not reflect the increases in cases, treatments or staffing.

- The assumptions include no supporting table for staffing, so the reviewer must back into incremental staffing. Support staff personnel expenses increase by $236,410 between FY 2015 and FY 2016. That calculates to an average salary of $41,475 for the additional 5.7 FTE's listed between pages 125 and 126 (9.7 less 4.0 = 5.7). Of these additional positions, 6.2 have an annual a salary of approximately $100,000 (page 127). With wages understated, taxes and benefits are also understated.
- According to page 160 of the application, this project will be operational in July 2015. Hence, the proforma should show depreciation expense for the proposed linear accelerator in FY 2015, and maintenance costs in FY 2016. It does not. The replacement linear accelerator, CON Project No. J-10164-13 should be operational on September 30, 2015 (See Attachment H to these Comments). It should have maintenance costs in FY 2016. The proforma shows no maintenance cost for the replacement linear accelerator.
- Depreciation is supported by Note (7), which addresses only the proposed new linear accelerator. It does not cover the cost of the rest of the radiation oncology department, which is essential to operation of the radiation oncology program, for example, registration, preparation, consultation, simulation, physics and dosimetry planning,
- The replacement linear accelerator will have depreciation or maintenance expense, as will the replacement CT simulator, which is also mentioned in Project No. J-10164-13. These are missing in Form B.
- Other Indirect Expenses increase only with inflation. These expenses include billing which will also increase with the increase in treatments and cases. These expenses are understated.
- Expenses include no maintenance on the proposed replacement CT simulator, which is identified in Project No. J-10164-13
- The item: Other Direct Expenses, Note (5), is increased only by 3 percent inflation. They are not adjusted for increases in treatments, cases or increased simulations.

Notes to the Balance Sheet, Form A are limited. However, they do not mention the CCNC Acquisition or the proposed linear accelerator. Nor is it clear where Cash is used to make the proposed capital investment.

The application proposes 8.36 percent charity care, but does not indicate to whom it would apply. Note 2 to the financial statements shows significant contractual adjustments for all payors.

The replacement application, J-10164-13, proposes to be operational in July 2015. In this application for a proposed second linear accelerator, DUHS proposes to start construction in April 2015.The schedule provides no information that would change the schedule in J-10164-13. The two schedules combined indicate that DRAH would have no linear accelerator between April 1, 2015 and July 1, 2015, a full quarter of the operating year. With this unexplained, operational projections for sustained growth in caseload are not supported. See schedules in Attachment H.

The financial statements are clearly inconsistent with operational projections in both this application and the replacement CON Application. Hence financial statements are not reliable.

The application is non-conforming to Criterion 5.

6. **The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.**

Applicant fails to prove that CCNC could not accommodate the patients to be served by the proposed equipment. The CCNC equipment will be supported by only six of the 15 physicians associated with CCNC in 2014.

DRAH proposes to offer none of the services that are unique to the proposed TrueBeam equipment.

Moreover, in proposing to redirect patients from Duke University Medical Center Cancer Center, the application fails to acknowledge the fact that that Duke Comprehensive Cancer Center's eight linear accelerators are not yet operating at capacity according to the 2014 License Renewal Applications on file with DHSR at the time of the application.

Duke University Medical Center Linear Accelerator Statistics
Per 2014 License Renewal Application
Linear Accelerator Data for FY 2013 (Oct-Sept)

Type	CPT	Count	WT	ESTV
Simple	77403	344	1	344
	77404	237	1	237
Intermediate	77408	60	1	60
	77409	102	1	102
Complex	77412	277	1	277
	77413	7,507	1	7,507
	77414	10,837	1	10,837
	77416	48	1	48
Other				
IMRT	77418	12,944	1	12,944
SRS	GO339	382	3	1,146
SRD	GO340	557	3	1,671
Total Body		480	2.5	1,200
Field Checks	77147	3,063	0.5	1,531.5
Total		**36,838**		**37,904.50**
	Total Linear accelerators			8
	ESTV/ linear accelerator			4,738
	Patients			1,898
	Patients per linear accelerator			237.25

Source: DUHS 2014 License Renewal application page 15

Duke Comprehensive Cancer Center facility was approved to add three linear accelerators and two simulators in response to CON Application J-8275-08. The approved total capital cost for the Cancer Center project is $261,849,601. Funding was provided by the North Carolina Medical Care Commission, which reports $180 million outstanding principal in 2014[2]. Directing patients away from a facility owned by the applicant, a facility that is not operating at capacity, and on which substantial debt is still outstanding, would represent unnecessary duplication. Moreover, a review of patient origin by county at DUHS shows relatively small percentage of Wake County cancer patients in 2013 (229 /4,430 Wake County Cancer Cases[3]). The small percentage (5 percent) suggests that patients are going to Duke University Cancer Center for particular reasons associated with faculty, equipment, clinical trials or other programs.

The application provides no information to demonstrate that the asserted transfer of patients would occur. Moreover, partial treatment at Duke Comprehensive Cancer Center or CCNC would reduce the number of treatments provided at DRAH and add cost for new treatment planning for the DRAH equipment. The application does not indicate that all Duke University patients are treated on a True Beam.linear accelerator.

The application is non-conforming to Criterion 6.

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.**

The application:

- Projects volume for Macon Pond Road, but on page 128 says it has no basis for projecting the staffing for that location.
- Does not explain how shifts are covered by current staff (VII.5).
- Indicates in Section VII that 408 physicians will use the hospital facility – does not address how many will be associated with the linear accelerator.
- Makes no provision for the cost of commissioning in the capital cost.

The application is non-conforming to Criterion 7.

[2]Medical Care Commission 2014Annual Report page 28
http://www.ncdhhs.gov/dhsr/ncmcc/pdf/2014/annualreport2014.pdf
[3] NC State Center For Health Statistics Projected Cancer Cases by County 2013.

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.**

The application appears to contain no evidence of support from referring physicians other than Duke physicians. No letters from Open Door Clinic or Project Access indicate that DRAH provides linear accelerator services to their patients.

Presentation of information suggests that DRAH linear accelerator will serve a closed medical staff – limited to DRAH; it makes no provision for coordination of care with non-DRAH physicians or physicians who are not on the Duke medical staff.

Duke uses the Epic Medical Record System which is incompatible with the North Carolina Health Information Exchange program and Duke has refused to exchange information with the NC HIE.

The Form B Expense allocation for support staff is insufficient to provide the incremental support staff required in Section VII. Because, as discussed in Criterion 5 above, other expenses are missing from Form B, it is impossible to tell if the project will generate sufficient revenue to cover the missing expenses.

The application is, at best, comparatively inferior in this area.

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.**

The proposed project will duplicate the capabilities of the linear accelerator DUHS proposes to acquire from CCNC at Macon Pond Road. And it will offer the services at a rate structure that is higher than the planned Medicare freestanding rate structure at Macon Pond Road. Thus the construction will increase the cost of providing the service.

Because the application overcounts projected volume at Macon Pond Road, the proposed construction/ renovation will unduly increase the costs of providing health services by DUH.

Construction schedules in the replacement linear accelerator CON application and this application suggest that DRAH will operate for one quarter in 2015 with no linear accelerator service. Construction of this application begins in the existing vault in April 2015, but the replacement linear accelerator does not become operational until July 2015. See schedule information in Attachment H to these comments.

The application is non-conforming to Criterion 12.

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:**

(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;

Duke is a non-profit tax exempt entity. Contrary to its statement in VI.11, it does have an obligation to provide charity care and to report it to the IRS. Duke failed to provide a copy of its 990 showing its required report of Charity care provided. Under Section 501(r) added to the IRS Code for Charitable 501(c) (3) hospitals, each hospital must:

- Establish written financial assistance and emergency medical care policies.
- Limit amounts charged for emergency or other medically necessary care to individuals eligible for assistance under the hospital's financial assistance policy.
- Make reasonable efforts to determine whether an individual is eligible for assistance under the hospital's financial assistance policy before engaging in extraordinary collection actions against the individual, and
- Conduct a community health needs assessment (CHNA) at least once every three years. (This CHNA requirement is effective for tax years beginning after March 23, 2012).

(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 physician.**

The proposed structure requires referral to a DRAH physician. The application makes no provision for involvement of non-DRAH or DUHS physicians in care plans for patients.

The application is non-conforming to Criterion 13(d)

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 the service for which competition will not have a favorable impact.**

COMPETITION

The project will not increase competition. It will add a fifth linear accelerator to DUHS in Service Area 20.

COST EFFECTIVENESS

Purchasing expensive Varian equipment, when DUHS has as yet undeveloped Agency approval to purchase an additional TrueBeam is not cost effective. The proposed solution will involve higher Medicare and Medicaid payments and contribute to long term high costs to patients and to Medicare.

All cost savings proposed for the project are those associated with placement in an existing vault of expensive equipment that will not be used for its design capabilities. Very few cancer patients have tumors of the type that justify SRS treatments. DUHS with more than 1800 patients provided only 939 such treatments (2.5 percent of total) in 2013.

The application is non-conforming to Criterion 18.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met:

(c) an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.

As discussed in Criterion 4 above, without the unjustified transfer of patients from Duke University Comprehensive Cancer, the applicant does not meet this performance standard.

Attachment B

Individual Comments: UNC Hospitals Radiation Oncology, Holly Springs Campus J-010318-14

COMPETITIVE REVIEW OF
UNC HOSPITALS RADIATION ONCOLOGY
HOLLY SPRINGS CAMPUS, J-010318-14

OVERVIEW

UNC Hospitals at Chapel Hill proposes to locate a hospital-based outpatient department in a new medical office building in Holly Springs that will house a linear accelerator. This project is non-conforming to Criteria: 1 (Policy Gen-3), 3,4,5,6,7,12 and 18a and 10A NCAC 14C.1903 (a) (1).

By naming UNC Hospitals as the applicant, instead of Rex Hospital (hereinafter "Rex"), the applicant is attempting to avoid the requirements of the special criteria. If Rex were the named applicant, as it should have been, Rex's application would be nonconforming with 10A NCAC14C.1903(a)(1). This criterion requires that an applicant's existing linear accelerators located in the proposed radiation therapy service area perform at least 6,750 ESTV treatments per machine or serve at least 250 patients per machine in the 12 months prior to the date the application was submitted. The inability to conform with required special criterion is the obvious reason the applicant has proposed that the linear accelerator should be part of UNC Hospitals' outpatient department, many miles away. This "strategy" becomes even more obvious when one considers that Rex is developing a hospital on the campus where the linear accelerator will be located and already operates Rex Healthcare of Holly Springs on that campus which provides urgent care, diagnostics, and physician practices. See Application, Exhibit 31, p. 781. Rex even owns the land on which the outpatient facility will be located. (Application, Exhibit 1)

UNC Hospitals' application cannot be approved because it is proposing an impermissible expansion of UNC Hospitals and because the application should have named Rex as an applicant. The applicant states that the proposed project will be provider-based to UNC Hospitals, operated as part of the existing UNC Hospitals' Department of Radiation Oncology under the Business Occupancy Exception, as permitted under NCGS § 131E-76(3). (Application, p. 31). The statute cited is part of the Hospital Licensure Act. Regulations promulgated pursuant to this statute state that a hospital license shall include only facilities and premises within a single county. 10A NCAC 13B .3101(f). Therefore, UNC Hospitals proposed outpatient facility in Wake County cannot be licensed as part of UNC Hospitals.

In citing NCGS 131E-76(3) as the justification for UNC Hospitals developing an outpatient department in another service area many miles from the UNC Hospitals campus, the applicant also is acting well beyond the permissible expansion of an existing facility recognized by the North Carolina Court of Appeals. In a case decided in 2000, *Christenbury Surgery Center v. N.C. Department of Health and Human Services*, the N.C. Court of Appeals allowed the expansion of an ambulatory surgery center to a second location within the same service area. The Court expressly cited and relied upon the fact that the expansion would be within the same service area. 138 N.C. App. 309.

The application must be denied for the additional reason that Rex should have been a named applicant. Rex will be involved in offering the services. Patients will have their initial treatment planning and simulation at either UNC Hospitals or Rex. (Application, p. 34) As set forth in a letter from Rex's Chief Operating Officer, Rex will make all ancillary and support services available as needed for patients of the proposed facility in Holly Springs. (Application, Exhibit 7). The proposed project will be located on the same campus as Rex's existing services allowing for enhanced coordination of care. (Application, p. 33)

Under the CON law, an entity that is involved in offering the proposed services must be named as an applicant. NCGS § 131E-176(18) and § 131E-178(a). As Administrative Law Judge Donald Overby concluded in a recent Final Decision at the Office of Administrative Hearings, the CON Section should analyze which entities are offering and developing the proposed service as required by the plain language of the CON statute. *United Home Care, Inc. v. CON Section*, 13 DHR 19690, p. 49. In the *United* case, the CON Section admitted that it looked only at the entity that will obtain licensure and certification and not which entities were offering and developing the proposed health service. For the reasons set forth above, even that analysis would not work in this case, because UNC Hospitals should not be able to obtain licensure and certification of its proposed outpatient department in another county.

In addition, the applicant proposes that it will have Provider-based reimbursement. However, Provider-based reimbursement requires a licensed provider in the county. For this additional reason, Rex Hospital should have been the applicant.

For these reasons, the UNC Hospitals' application should be found nonconforming with all applicable criteria. The discussion below addresses additional reasons that the application is nonconforming with several criteria.

Comments are intended to provide examples and are not exhaustive.

CON REVIEW CRITERIA

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, ambulatory surgery operating rooms, or home health offices that may be approved.

POLICY GEN-3

This policy requires an applicant to demonstrate that it will provide "equitable access while maximizing healthcare value for the resources expended."

- The application notes repeatedly that the location is for convenience of patients, yet notes that all simulation will be done at UNC Hospitals in Chapel Hill or Rex Hospital. Holly Springs has a population of approximately 27,000, a median household income of $86,430.[1] This is not the profile of a population at high risk for cancer. Resources expended in Holly Springs would mean that patients diagnosed and planned in Chapel Hill or Raleigh would go out of their way to get treatment in Holly Springs and would return to Chapel Hill or Rex for any adjustments to the simulation and treatment plan. The proposed location and linear accelerator would also require additional cabling and connections that are not detailed in the CON application equipment quotes. The application does not provide for sufficient investment to render the program operational.
- The applicant proposes a provider-based linear accelerator located in Holly Springs, North Carolina (page 31). Provider-based reimbursement requires a licensed provider in the county. Provider-based reimbursement under Medicare is higher across the board than freestanding reimbursement. (See Parkway Urology Application Exhibit 49). The applicant could have made this a freestanding facility, but chose instead, the highest possible reimbursement structure. The application does not maximize health care value for resources expended.

The application is non-conforming with Criterion 1.

[1] http://www.city-data.com/city/Holly-Springs-North-Carolina.html

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.**

The applicant identifies the population to be served as residents of Wake, Harnett, and Lee Counties, and identifies the "primary reasons" for a 22 percent increase in radiation therapy between 2010 and 2020 as "aging and growth of minority groups (page 71). Yet, the proposed location is in a part of Wake County that has a small population and few minorities. Holly Springs has a black population of 11.7 percent, one third that of the Wake County average.

Service Area 20, the service area for which the need was identified, includes Wake and Franklin Counties. The applicant excludes Franklin County from its intended service area, yet Franklin County has only one underutilized linear accelerator that has extremely limited capability.

The application provides no supporting documentation that physicians will refer patients to the proposed linear accelerator. Instead, letters repeat a mantra that the project will "reduce fatigue for patients travelling to Chapel Hill." One letter from Dr. Marks notes that six radiation oncologists in the Raleigh area refer 250 to 300 patients a year. However, the letter fails to detail whether these are the same patients referred to the four existing linear accelerators operated by Rex Hospital, which are underutilized or to the underutilized existing and approved linear accelerators at UNC Hospitals at Chapel Hill.

The application contains no letters from patients confirming this "fatigue."

Moreover, the high charge structure of an Academic Medical Center Outpatient Department, which will be associated with this proposed arrangement, will put the copayments for this outpatient service out of reach for low income Medicare patients.

The application is non-conforming to Criterion 3.

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.**

The application talks of 'repatriating Wake County patients who currently travel to Chapel Hill, but ignores the four linear accelerators operated by Rex Hospital that the Proposed *2015 State Medical Facilities Plan* and the *2014 State Medical Facilities Plan* Table 9G show are operating below state-defined capacity (4,530 and 4,850 ESTV per linear accelerator, respectively) . The application also overlooks the fact that UNC Hospitals at Chapel Hill are about to open one more linear accelerator whose efficient operation will require those patients. The application also fails to address whether these 'repatriated' patients are referred to UNC Hospitals at Chapel Hill to access clinical trials or other services uniquely available at UNC Hospitals at Chapel Hill.

The applicant claims that it does not own a linear accelerator in Service Area 20. However, in Exhibit 31, financial statements page 17 the application notes that UNC Hospitals is a part of UNC Health System, which includes Rex Hospital. And Rex Hospital owns four linear accelerators in Wake County, which do have excess capacity. The applicant is actually proposing an inconvenient location with a higher Medicare payment structure than Rex Hospital (academic medical center as compared to hospital outpatient prospective payment) for a less complex piece of equipment and an inconvenient treatment program.

On page 53, the application notes that patients will have to go to Rex Hospital to pick up prescriptions. On page 56, patients will be sent to UNC Hospitals for Dietician services, social work and pharmacy. This is hardly a program designed around patient convenience. Alternative methods of meeting the need are available to UNC Hospitals.

The application is non-conforming with Criterion 4.

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.**

- Proformas clearly indicate that the linear accelerator would be part of The Radiation Oncology Department of UNC Hospitals, which would suggest that the billing would be based on Medicare Academic Medical Center billing. The application provides no information to explain how that would be possible under NC Licensure and CMS Certification regulations. CMS defers to state regulations related to licensure.
- In fact, if the proposed Outpatient Department cannot be appropriately licensed, the proposed project would not meet Medicare and Medicaid Conditions of Participation and would not be eligible to bill Medicare or Medicaid.

The application is non-conforming with Criterion 5.

6. **The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.**

The application indicates on page 160 that UNC Hospitals holds a CON dated 2010 that is not yet operational. Yet, the application proposes to move patients from UNC Hospitals to the proposed location. This statement indicates that either the 2010 CON is unnecessary or the proposed project unnecessarily duplicates the first. Both will be billing at the same rate, according to the application. The application has no letters from patients indicating they wish to get care in Holly Springs, or from physicians indicating the number of patients they would refer to Holly Springs.

Moreover, as noted elsewhere in these comments, Criterion 4 and NCAC14C.1903, the applicant has significant unused capacity among its existing and approved linear accelerators.

The application is non-conforming with Criterion 6.

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.**

The application does not address the resources needed to provide simulation planning or the resources to transmit simulation plans from another location to the linear accelerator or the mechanism to make simulation planning compatible with both Rex and UNC programs. The application does not address whether simulators, physicists and dosimetrists at UNC Hospitals at Chapel Hill or Rex Hospital have capacity to absorb the proposed additional caseload.

The application is non-conforming with Criterion 7.

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.**

Without Rex Hospital as an applicant, and absent a contract for simulation and treatment planning with Rex Hospital, the application fails to demonstrate availability of essential support services in Wake County.

The application is non-conforming to criterion 8.

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.**

The letter from the architect in Exhibit 34 does not describe, nor does the application indicate how costs for "furnishings, signage, IT", identified in Section VIII were derived. There is no way to tell that the cost, design and means of construction are complete. The application does not demonstrate or provide evidence of the necessary cabling and software to provide seamless transfer of treatment plans to this equipment. Nor does it indicate that the simulator capability at Rex Hospital or UNC Hospitals at Chapel Hill can support the proposed equipment.

Moreover, the decision to use the Provider-based exemption in GS 131E-76(3) involves low cost construction and high charges to patients. The provider-based exemption permits the applicant to bill on the high charge rate structure identified in Exhibit 49 of the Parkway Urology CON application, J-10320-13

The application is non-conforming with Criterion 12

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:**

(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**

Responses in Section VI and in the financial proforma make it impossible to determine the extent to which these groups will have access to the proposed equipment. All data are summarized for UNC at Chapel Hill.

(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 physician.**

The application structure indicates that patients who wish access to this service must first be patients of UNC Hospitals at Chapel Hill or of Rex Hospital. These are the only places a patient can receive essential treatment planning. Maria Parham Medical Center tried this and ultimately found patients are better served with an on-site simulator (Project No. K-7839-07). The proposed UNC program indicates restricted access.

The application is non-conforming with Criterion 13.

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 the service for which competition will not have a favorable impact.**

Competition

The application notes on page 132 that the proposed project is not being developed to foster competition, then goes on the state that the project will foster competition. Data in the application suggest that most of the "competition" will be internal to UNC Hospitals, thus stretching the applicant's own resources.

Cost Effectiveness

As noted in response to Criterion 5, the project is not cost effective. Proposed charge structures based on academic medical center Medicare rates, will be among the highest in the region. Capital costs are understated, because essential elements are missing. The application proposed to duplicate existing under used resources.

Access

The application says the project will increase access with reduced out of pocket costs for patient gas and parking, but fails to calculate the extra patient costs associated with travelling across two or three counties to get essential ancillary support services and treatment planning. It also ignores the additional out-of-pocket costs associated with the academic medical center charge structure and the hidden costs associated with coordination of care across multiple locations and care teams.

The application is non-conforming with Criterion 18a.

. 10A NCAC 14C .1903 PERFORMANCE STANDARDS

(a) **An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met:**

(1) **an applicant's existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted;**

The response that this is not applicable that UNC Hospitals does not have any existing linear accelerators in the service area which includes Wake and Franklin Counties is incomplete and inaccurate. As noted in the introductory paragraphs to these comments. UNC Hospitals includes Rex Hospital. The following statistics for Rex Hospital were derived from Licensure Renewal Applications and State Medical Facility Plan Tables 9.G

Rex Hospital Linear Accelerators

	2010	2011	2012	2013
Linear accelerators SA 20	4	4	4	4
ESTV	19,636	18,898	19,401	18,118
ESTV Per LinAc	4,909	4,725	4,850	4,530
Cases	625	701	771	663
Cases per LinAc	156.	175.	193	166

Source: State Medical Facilities Plans 2012 through Proposed 2015 and Hospital License Renewal Applications

The applicant is non-conforming to this Criterion.

(3) **an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.**

Use of the Rex Hospital linear accelerators has been declining since 2010. If the number of patients and ESTV's were to hold constant through Year 03, the applicant would fail this standard as well.

All UNC Linear accelerators in SA 20

	Yr. 01	Yr. 02	Yr. 03
Total Patients	795	865	938
Total ESTV's	21,439	23,208	25,052
Total Linear accelerator	5	5	5
Pts/linear accelerator	159	173	188
ESTV/Linear accelerator	4287.8	4641.6	5010.4

Source: Rex Hospital data from (a)(1) above to the following table from the UNC application.

Holly Springs Linear Accelerator

	Yr. 01	Yr. 02	Yr. 03
Total Patients	132	202	275
Total ESTV's	3,321	5,090	6,934

Attachment C

CON Section Approval for CCNC Acquisitions

Comments: CON Project ID# J-010320-14

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

August 8, 2014

Kenneth L. Burgess, Esq.
William R. Shenton, Esq.
Poyner Spruill, LLP
P.O. Box 1801
Raleigh NC 27602-1801

Transfer for Good Cause

Project ID#:	J-7941-07
Facility:	Cancer Centers of North Carolina - Raleigh
Project Description:	Acquire a second linear accelerator with stereotactic radiosurgery capabilities to be located at the Macon Pond Road facility in Raleigh
County:	Wake
FID #:	050382

Dear Mr. Burgess and Mr. Shenton:

This letter responds to your correspondence of August 1, 2014, in which you requested approval of a transfer of ownership or control of the above referenced project for good cause. The Agency has determined that good cause exists based on finding the transfer will enable the new owner, Duke University Health System d/b/a Duke Raleigh Hospital, to develop the project in material compliance with the representations in the application and with the conditions of approval. Consequently, the Agency shall not withdraw the certificate of need as a result of this transfer.

Please be advised that pursuant to G.S. 131E-181(b), any person who subsequently acquires a certificate of need is required to materially comply with the representations made in the application that was submitted to the Agency for the project. Further, in accordance with G.S. 131E-190(i), the Agency may bring action in Superior Court for injunctive relief requiring the successor to operate the service in material compliance with those representations.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

If you have any questions concerning this matter, please do not hesitate to call me. Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

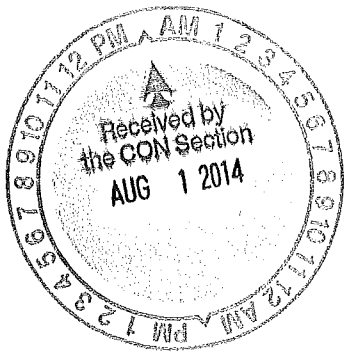
Sincerely,

Michael J. McKillip, Project Analyst

Martha J. Frisone, Interim Chief
Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR
Radiation Protection Section, DHSR

Poyner Spruill LLP



August 1, 2014

Via Hand Delivery

Kenneth L. Burgess
Partner
D: 919.783.2917
F: 919.783.1075
kburgess@poynerspruill.com

William R. Shenton
Partner
D: 919.783.2947
F: 919.783.1075
wshenton@poynerspruill.com

Martha Frisone
Acting Chief
Certificate of Need Section
N.C. Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Request for Transfer for Good Cause Determination Pursuant to N.C. Gen. Stat. § 131E-189(c): Cancer Centers of North Carolina, PC and AOR Management Company of Virginia, LLC, Project I.D. No. J-7941-07

Dear Ms. Frisone:

Our firm represents Duke University Health System, Inc. d/b/a Duke Raleigh Hospital ("DUHS"). By separate correspondence of this same date, we wrote to inform the Certificate of Need Section ("CON Section") that DUHS plans to proceed with one of two alternate transactions to either: (1) acquire 100 percent of the ownership interests in a corporate entity that will own the oncology centers and associated equipment currently owned and operated by Cancer Centers of North Carolina, PC ("CCNC") and AOR Management Company of Virginia, LLC ("AOR") located in Raleigh, Cary, and Clayton, North Carolina, or (2) acquire ownership and control of these oncology centers. *See* our August 1, 2014 Request for No Review Determination and Notice of Exempt Transaction – Transfer of Ownership Interests in Medical Oncology and Radiation Oncology Centers.

As you are probably aware, DUHS owns and operates Duke Raleigh Hospital, a licensed acute care hospital located in Raleigh, and provides a comprehensive array of medical and surgical services at Duke Raleigh Hospital. CCNC is a North Carolina professional corporation that employs physicians who provide oncology treatment services. CCNC and AOR, a subsidiary of US Oncology, Inc. ("USON"), own and operate offices in Raleigh, Cary and Clayton, where CCNC provides a variety of services including medical oncology, radiation oncology, ENT oncology, and/or gynecologic oncology. These offices include a center located at 4101 Macon Pond Road in Raleigh ("Macon Pond Center"), where CCNC provides medical oncology, radiation oncology, ENT oncology and gynecologic oncology services to patients.

The CON Section previously issued to CCNC and AOR, a certificate of need ("CON") effective February 4, 2011, to acquire a linear accelerator with stereotactic radiosurgery capabilities (the "Trilogy Linac") to be located at CCNC and AOR's Macon Pond Center (Project I.D. No. J-7941-07). A copy of the CON is attached as Appendix 1 to this correspondence. That CON project has not yet been fully developed. The alternate transactions referenced above and described in more detail in our Request for No Review Determination and Notice of Exempt Transaction, will include assuming the control and

operation of the Macon Pond Center. The acquisition of the Trilogy Linac authorized by the CON involves equipment proposed to be located and operated at the Macon Pond Center.

The Certificate of Need Law provides that "[a] certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c)." N.C. Gen. Stat. § 131E-181(a). However, the Certificate of Need Law further provides at N.C. Gen. Stat. § 131E-189(c) that "[t]ransfers resulting from death or personal illness or other good cause, as determined by the Department, shall not result in withdrawal if the Department receives prior written notice of the transfer and finds good cause."

By virtue of this correspondence, we are providing the CON Section the notice required by N.C. Gen. Stat. § 131E-189(c) and requesting a determination by the CON Section that good cause exists for the transfer of the Trilogy Linac CON. In support of this request, we note the following:

- Fundamentally, the transfer of this CON to DUHS will be part of a larger transaction which will result in DUHS becoming the operator of substantially all the assets used in the radiation oncology business of the current holders of the CON. Thus, rather than an isolated transfer of the CON for an individual project, this transfer is being proposed as part of a larger transaction in which DUHS will step into the shoes of the holders of the CON and assume responsibility for operation of all of the radiation oncology assets that they have used to treat patients. In essence, DUHS will be assuming control of the radiation oncology business to which the CON was issued. The Trilogy Linac was proposed to supplement and extend the range of radiation therapy services offered by CCNC, and DUHS will become the entity offering all of those services. The CON Section has previously approved similar good cause transfer requests. *See*, *e.g.*, Good Cause Transfer Determination dated July 11, 2014 regarding MedWest Harris Hospital CON for relocation and expansion of Emergency Department and x-ray unit (Appendix 2); Good Cause Transfer Determination dated September 26, 2007 regarding Mecklenburg Diagnostic Imaging CON for acquisition of a fixed MRI scanner (Appendix 3);

- A denial by the CON Section of this transfer for good cause request could preclude the planned expansion of radiation oncology services to include the Trilogy Linac authorized by the CON, thus denying the citizens of Wake County and surrounding areas the benefits outlined in CCNC and AOR's CON application, including the availability of a linear accelerator with stereotactic radiosurgery capabilities;

- The transfer of the Trilogy Project to DUHS will provide benefits to the citizens of Wake County and surrounding areas by bringing to the Project the expertise, experience and resources of DUHS;

- DUHS or a wholly owned subsidiary of DUHS is the entity which will be the direct post-closing owner of the Macon Pond Center currently owned and operated by CCNC and AOR, the entities to which the CON was issued. DUHS hereby commits to develop the project in material compliance with the representations made in CCNC and AOR's CON application and with the conditional approval of that CON application and as otherwise approved by the CON Section. DUHS would assume the responsibilities of both current CON holders and would not anticipate any continued management services agreement with AOR; and

- We understand the next progress report for the Trilogy Linac project will not be due until December 2014. DUHS is committed to developing the Trilogy Linac project as promptly as feasible following the transfer of the CON; and implementation of this project will not be further delayed or postponed as a result of the requested transfer. Once the transfer is approved by the CON Section and the transfer occurs, DUHS will contact the CON Section about future progress reports and details of the implementation of the project.

In summary, the planned alternate transactions and the related transfer of the Trilogy Linac CON are an important aspect of future oncology care in Wake County and the surrounding areas served by the Macon Pond Center. As such, we believe that good cause exists within the meaning of N.C. Gen. Stat. § 131E-189(c) for transfer of the CON. We hereby request that the CON Section find that good cause exists for the proposed CON transfer and the development of this project by DUHS or an affiliate, and also confirm that it will not withdraw the CON for Project I.D. No. J-7941-07 as a result of the transfer. We have enclosed a copy of the materials referenced in this letter (see attached Appendices).

Thank you in advance for your prompt consideration of this request. DUHS wishes to move forward with the planned alternate transactions as soon as feasible, and accordingly, requests a response from you on or before August 22, 2014, if possible.

Please contact us if you have questions or need any additional information.

With best regards, we are

Very truly yours,

Kenneth Burgess/RS

Kenneth L. Burgess

William R. Shenton

cc: Christy Gudaitis, Esq., Counsel for DUHS
Catharine Cummer, Esq., Counsel for DUHS
Larry Robbins, Esq., Counsel for CCNC
Scott Aitken, Esq., Counsel for USON

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

August 8, 2014

Kenneth L. Burgess, Esq.
William R. Shenton, Esq.
Poyner Spruill, LLP
P.O. Box 1801
Raleigh NC 27602-1801

Exempt from Review – Acquisition of Facilities

Facilities:	Cancer Centers of North Carolina – Raleigh and Wake Radiation Oncology Services
Acquisition by:	Duke University Health System d/b/a Duke Raleigh Hospital
County:	Wake and Johnston
FID #s:	050382 (Raleigh facility) and 960894 (Cary facility)

Dear Mr. Burgess and Mr. Shenton:

In response to your letter of August 1, 2014, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(8). Therefore, Duke University Health System d/b/a Duke Raleigh Hospital may proceed to acquire the above referenced health service facilities without first obtaining a certificate of need. Note that pursuant to G.S. 131E-181(b): "*A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.*"

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Michael J. McKillip
Project Analyst

Martha J. Frisone, Interim Chief
Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR
Radiation Protection Section, DHSR

Certificate of Need Section
www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-733-8139
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center •Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer

Poyner Spruill LLP

August 1, 2014

Kenneth L. Burgess
Partner
D: 919.783.2917
F: 919.783.1075
kburgess@poynerspruill.com

William R. Shenton
Partner
D: 919.783.2947
F: 919.783.1075
wshenton@poynerspruill.com

Via Hand Delivery

Martha Frisone
Acting Chief
Certificate of Need Section
N.C. Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Request for No Review Determination and Notice of Exempt Transaction – Transfer of Ownership Interests in Medical Oncology and Radiation Oncology Centers

Dear Ms. Frisone:

We are writing on behalf of our firm's client, Duke University Health System, Inc. d/b/a Duke Raleigh Hospital ("DUHS"), regarding alternate proposed transactions described below that DUHS plans to undertake which would involve DUHS or an affiliate of DUHS taking steps to continue the operation of existing oncology centers in Wake and Johnston Counties that currently are owned by Cancer Centers of North Carolina, P.C. ("CCNC") and AOR Management Company of Virginia, LLC ("AOR"), a subsidiary of US Oncology, Inc. ("USON"). Before proceeding with one of these proposed transactions, DUHS is requesting that the Certificate of Need Section issue written confirmation that the proposed transactions and related activities described below, and the subsequent provision of radiation therapy and other oncology services at these oncology centers with the existing linear accelerators and treatment simulator equipment described below, will not constitute a new institutional health service or require a certificate of need.

1. **Background on Oncology Centers and Equipment**

DUHS is a North Carolina nonprofit corporation, with its principal place of business in Durham County, North Carolina. Duke owns and operates Duke Raleigh Hospital, a licensed acute care hospital located in Raleigh, Wake County, North Carolina. Duke provides a comprehensive array of medical and surgical services at Duke Raleigh Hospital.

CCNC is a North Carolina professional corporation that employs physicians licensed to practice medicine in North Carolina, who provide oncology treatment services. CCNC has cared for patients residing in and around Wake and Johnston Counties for over 30 years. CCNC and AOR own and operate the following offices where CCNC provides a variety of services including medical oncology, radiation oncology, ENT oncology, and gynecologic oncology:

Wake County

Cary Offices:

- 216 Ashville Ave., Suite 20, Cary, NC 27518 (medical oncology)
- 300 Ashville Ave., Suite 110, Cary, NC 27518 (radiation oncology)

Raleigh Offices:

- 4101 Macon Pond Road, Raleigh, NC 27607 (ENT oncology, gynecologic oncology, medical oncology, and radiation oncology)
- 10010 Falls of Neuse Road, Suite 203, Raleigh, NC 27614 (medical and ENT oncology)

Johnston County

Clayton Office: 555 Medical Park Place, Suite 201-B, Clayton, NC 27520 (medical oncology)

CCNC's radiation oncology centers include the following equipment:

(1) Varian Clinac 2100C/D linear accelerator, operating at the Macon Pond center in Raleigh ("Macon Pond Linac");

(2) GE Lightspeed Qx/I CT Scanner, operating at the Macon Pond center in Raleigh ("Macon Pond CT Scanner")

(3) Siemens Primus linear accelerator, operating at the Cary radiation oncology center ("Cary Linac");

(4) Siemens SimView 3000 simulator, operating at the Cary radiation oncology center ("Cary Simulator").

The Macon Pond and Cary Linacs (collectively, the "Linacs") are used to provide radiation therapy treatments to patients, as they have been since they were initially acquired and installed at these locations. The Macon Pond CT Scanner and Cary Simulator each is used as a treatment simulator to help plan radiation therapy treatments delivered on the Linacs.

Macon Pond Oncology Center. In 2001, the CON Section issued a determination confirming that Raleigh Hematology Oncology Associates, P.C. ("RHOA"), now known as CCNC, operated a grandfathered oncology treatment center, within the meaning of the CON Law. *See* Grandfathered Oncology Treatment Center Determination and Request Correspondence (Appendix 1). RHOA was approved by the CON Section in 2004 to relocate its oncology treatment center and to expand the center with the acquisition of a reconditioned linear accelerator, computed tomography ("CT") simulator, and treatment planning equipment, without a certificate of need. *See* No Review Determination and Request Correspondence Regarding Macon Pond Linac and CT Scanner (Appendix 2). The Macon Pond Linac and CT Scanner were purchased in March 2005 consistent with the CON Section's no review determination. *See* CCNC January 2014 Registration and Inventory of Medical Equipment, pp. 2-3 (Appendix 3). At that time, linear accelerators and simulators were not specifically regulated, but instead, the CON Law regulated oncology treatment centers, which were included within the definition of "health service facility" in N.C. Gen. Stat. § 131E-176. *See* N.C. Gen. Stat. § 131E-176 (1997) (Appendix 4).

Cary Oncology Center. In April 2011, CCNC acquired the limited liability company that owns the radiation oncology center and associated equipment formerly operated by Wake Radiology Oncology Services, PLLC ("WROS"), located at 300 Ashville Avenue in Cary. CCNC acquired membership interests in this LLC pursuant to a Declaratory Ruling issued on September 27, 2010 (Appendix 5), which confirmed that this acquisition did not require a certificate of need. Since that acquisition, CCNC has been providing radiation therapy to patients on the Cary Linac and Simulator at the Cary radiation oncology center.

The original CON for this Cary center was issued to WROS in 1997, and this CON specifically authorized the development of "an oncology treatment center consisting of one medical linear accelerator, one therapeutic simulator and specialized computer systems . . . ." *See* Certificate of Need issued to WROS for Project I.D. No. J-5464-96 (Appendix 6). Thus, the CON for the Cary center now owned and operated by CCNC and AOR, specifically authorized the operation of an oncology treatment center -- a facility providing services for the diagnosis, evaluation or treatment of cancer, including a linear accelerator and simulator to furnish radiation oncology services.

Grandfathered Oncology Centers Developed Prior to 2005 Changes to CON Law. Based upon changes to the Certificate of Need Law which took effect August 26, 2005, the law now regulates the acquisition of linear accelerators and simulators regardless of cost. N.C. Gen. Stat. § 131E-176(16)(f1)5a and 9. Under the 2005 changes to the law, "oncology treatment centers" are no longer a regulated type of new health service facility. *See* 2005 N.C. Sess. Laws 325, §§ 1 and 7. However, because the Linacs, Macon Pond CT Scanner and Cary Simulator were acquired prior to the current CON Law provisions which specifically regulate acquisitions of these types of new equipment, they are "grandfathered" as part of the oncology treatment centers for which they were acquired, and should not be subject to regulation under the current provisions of the law. Even if they were not grandfathered, however, it is our understanding that their acquisition as set forth below is not subject to certificate of need review.

Trilogy Linac CON. In addition to the two existing Linacs described above, in February of 2011, CCNC and AOR obtained a certificate of need to acquire a Trilogy linear accelerator with stereotactic radiosurgery capabilities ("Trilogy Linac"). Contemporaneously with this letter, DUHS is submitting a transfer for good cause request to the CON Section regarding this Trilogy Linac certificate of need.

DUHS, CCNC and USON (collectively, the "Parties") have discussed and reached agreement in principle on the alternate proposed transactions described below, with the ultimate goal being to ensure that the Oncology Centers currently owned by CCNC and USON continue operating uninterrupted to provide needed diagnostic and therapeutic services to cancer patients residing in and around Wake and Johnston Counties, and to continue improving cancer care and access for patients and their families in this area. *See* Support Letter from CCNC and USON (Appendix 7). Continuity of patient care is a fundamental objective of the Parties' agreement.

2. Proposed Acquisition of Corporate Ownership Interests.

DUHS is providing this letter to request a no review determination regarding a transaction being considered by the Parties, in which DUHS or an affiliated entity of DUHS ("Duke") would acquire 100 percent of the ownership interests in a corporate entity that will own the CCNC Oncology Centers and associated equipment. This proposed acquisition of corporate ownership interests will proceed in two steps. First, CCNC and/or USON will transfer all of their interests in the Oncology Centers and their associated equipment to a wholly-owned subsidiary (the "LLC"). The transaction will be completed with Duke purchasing 100% of the membership interests in the LLC as a second step.

The Oncology Centers owned by the LLC and their equipment will continue to serve patients at the same locations. There will be no purchase of additional equipment, nor will any new services be offered, as a result of this proposed transaction. The only change will be the membership composition of the corporate entities that own the Oncology Centers and equipment, with CCNC and/or USON initially transferring their ownership interests to the wholly-owned subsidiary LLC, followed by a separate transaction in which Duke will acquire all of the membership interests in the LLC. The entity that owns the Linacs and Simulator will not change as a result of Step 2 of the proposed transaction.

At some point subsequent to the proposed transaction, and probably quite soon thereafter, the LLC would likely be merged into DUHS or otherwise consolidated with DUHS pursuant to an internal corporate reorganization, in the interests of operational efficiencies and streamlining the corporate organization. Where DUHS or an entity affiliated with DUHS would be the sole member of the LLC and essentially will be stepping into the shoes of the operators of these existing oncology centers and their equipment, all of which have been previously reviewed by the CON Section, in order to allow the centers to continue serving patients, such an internal corporate reorganization will be nothing more than an administrative activity which should not be subject to CON review.

Based upon the clear terms of the CON Law and the long-standing approach that the Division of Health Service Regulation ("DHSR") and the CON Section have taken to the purchase of equity interests in existing North Carolina health care facilities when there is no change in the services offered or the equipment employed to offer the services, DUHS respectfully submits that none of these steps relating to the acquisition of corporate ownership interests constitutes a new institutional health service that requires a certificate of need. The CON Law focuses on the development and offering of those "new institutional health services" that would create additional capacity, and which are catalogued in N.C. Gen. Stat. § 131E-176(16). Each of these new institutional health services entails in some way the acquisition or establishment of a *new* health service, *new* equipment, *new* facilities, or expansions and relocations of existing facilities or services (which also would have an impact on how health services are deployed and utilized). In keeping with its fundamental goals, the CON Law expressly recognizes that certain activities are not subject to review.

The CON Law provides that no person shall offer or develop a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178. However, none of the components of the "new institutional health service" definition address, directly or indirectly, the acquisition of membership interests in an organization that already is operating a health service. This type of transaction is among the activities that are "administrative and other activities that are not integral to clinical management," and which are specifically excluded from the definition of "health service" in the CON Law. N.C. Gen. Stat. § 131E-176(9a). Therefore, an acquisition of corporate ownership interests, such as the proposed transaction at issue in this request, does not involve a new institutional health service and should not be subject to CON review.

In prior declaratory rulings and no review determinations, DHSR and the CON Section have recognized that transactions which are limited to an acquisition of underlying corporate membership interests in an existing legal entity which owns and operates an existing oncology center and its associated equipment, such as this proposed transaction, fall within the above-referenced exclusion recognized in the definition of "health service" in the CON Law. Accordingly, DHSR and the CON Section have consistently determined that events such as this proposed acquisition of the ownership interests in the CCNC oncology centers do not trigger certificate of need review under either the linear accelerator or simulator provisions in N.C. Gen. Stat. § 131E-176)(17)(f1)5a and 9, or the $2,000,000 capital expenditure provision in N.C. Gen. Stat § 131E-176(16)(b).

More specifically, this no review request is consistent with the following prior declaratory rulings which have interpreted the applicability of the CON Law to the purchase of ownership interests in corporate entities that own linear accelerators:

- *In re: Request for Declaratory Ruling by JRH Ventures, LLC et al.* dated January 2012 (transfer of membership interests and change in membership composition of existing owners of linear accelerators did not require a CON) (Appendix 8)

- *In Re: Request for Declaratory Ruling by Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System et al.* dated January 2012 (acquisition of membership interests in existing radiation oncology center did not require a CON) (Appendix 9)

- *In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc.* dated August 18, 2011 (transfer of two CON-approved radiation oncology facilities to two wholly-owned subsidiaries did not constitute a new institutional health service or require a certificate of need) (Appendix 10)

- *In re: Request for Declaratory Ruling by Rex Healthcare, Inc. and Smithfield Radiation Oncology, LLC* dated December 21, 2007 (acquisition of 100% of the membership interest of Smithfield Radiation Oncology, LLC, which owned and operated a linear accelerator, was not subject to CON review) (Appendix 11)

While DHSR has in the past responded to these types of proposed transactions through declaratory rulings, most recently the CON Section has acknowledged it is appropriate to address this type of transaction through a no review determination:

- *In re: Request for No Review Determination by East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital* dated September 20, 2012 (acquisition of 100% of the membership interests in existing owner of linear accelerator did not require a CON) (Appendix 12)

- *In re: Request for No Review Determination by Radiation Therapy Services, Inc. et al.* dated January 6, 2012 (acquisition of membership interests in corporate entities that owned Cancer Centers of North Carolina-Asheville, P.C.'s oncology center including linear accelerator and CT scanner did not require a CON) (Appendix 13)

The CON Law is intended to regulate new institutional health services and is not intended to impede routine business transactions such as an acquisition of a limited liability company's ownership interests. This proposed transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of linear accelerators will not change. The Oncology Centers and their equipment have been established and operating for years. As a result, the proposed transaction does not implicate the fundamental objective of the CON Law -- to control the new development or expansion of health service facilities.

3. <u>Proposed Exempt Acquisition of Existing Health Service Facilities</u>.

In the alternative, DUHS is providing this letter pursuant to N.C. Gen. Stat. § 131E-184(a)(8) to inform the CON Section that Duke will acquire ownership and control of the CCNC Oncology Centers, located in Raleigh, Cary, and Clayton, North Carolina. The CON Law provides that, upon receiving prior written notice, the CON Section "***shall exempt*** from certificate of need review" the acquisition of "an

existing health service facility, including equipment owned by the health service facility at the time of acquisition." N.C. Gen. Stat. § 131E-184(a)(8) (emphasis added).

Duke, CCNC and USON will enter into a purchase agreement pursuant to which Duke will acquire the Oncology Centers, including substantially all of the radiation oncology assets associated with the Centers. Thus, in the proposed exempt transaction, Duke will acquire ownership and control of the existing CCNC oncology treatment centers which are existing health service facilities under the CON Law. As discussed in Part 1 above, prior to the 2005 changes to the CON Law, facilities providing diagnostic and therapeutic services to cancer patients were regulated as oncology treatment centers, which were included within the definition of "health service facility" in N.C. Gen. Stat. § 131E-176. Both CCNC's Macon Pond and Cary radiation oncology centers were established and have continued to operate as oncology treatment centers, under applicable CON Law. As set forth above, the Macon Pond radiation oncology center is part of a grandfathered oncology treatment center, and the Cary radiation oncology center was established pursuant to a CON which specifically authorized development of an oncology treatment center with a linear accelerator and simulator. Accordingly, both of these oncology centers and their equipment were developed as health service facilities and should continue to be treated as such under the CON Law. Because the Linacs and treatment simulators at these centers were acquired in conjunction with these oncology treatment centers before the 2005 change in the CON Law, this equipment is clearly grandfathered and should not be subject to regulation under the current provisions of N.C. Gen. Stat. § 131E-176(16)(f1)5a and 9 for purposes of either this proposed exempt acquisition of existing health service facilities or the proposed acquisition of corporate ownership interests described above in Part 2.

The medical oncology, ENT oncology and gynecologic oncology offices and associated equipment owned by CCNC and USON are part of and operated in connection with the existing oncology treatment facilities to be acquired in this transaction. These medical offices do not constitute a separate "new institutional health service" or "new institutional health facility," as defined in N.C.G.S. § 131E-176, and therefore, did not require a certificate of need. Moreover, for purposes of certificate of need, these components of the Oncology Centers essentially are akin to physician offices which are specifically exempted from certificate of need review and approval by the CON Section.

4. Conclusion

For all of the foregoing reasons, the regulation of events like the proposed transactions described above, involving existing and previously reviewed and approved facilities and their associated equipment which do not otherwise implicate the fundamental purposes of the CON Law stated in N.C. Gen. Stat. § 131E-175, is beyond the scope of the CON Law, and should not require a CON. North Carolina courts have recognized that because the CON Law interferes with the normal right to do business, it must be narrowly construed. *See HCA Crossroads Residential Centers, Inc. v. N.C. Dep't of Human Resources*, 327 N.C. 573, 579, 398 S.E.2d 466, 470 (1990) ("When viewed in its entirety, Article 9 of Chapter 131E of the General Statutes, the Certificate of Need Law, reveals the legislature's intent that an applicant's fundamental right to engage in its otherwise lawful business be regulated but not be encumbered with unnecessary bureaucratic delay.") Failure to issue the requested exemption and no review determinations would delay and impede DUHS in proceeding with a lawful business transaction.

We have enclosed a copy of the materials referenced in this letter (see attached Appendices). Based upon the information provided in this letter, DUHS respectfully requests your earliest possible attention to this request and looks forward to your written confirmation that the proposal described herein does not require a certificate of need. In order to ensure continued and uninterrupted care for cancer patients residing in and around Wake and Johnston Counties, DUHS and the other Parties wish to move

forward with the pending transaction as soon as feasible, and accordingly, request a response from you on or before August 22, 2014, if possible.

Thank you for your attention to this matter, and please let us know if there is any additional information you may require.

With best regards, we are

Very truly yours,

Kenneth L. Burgess

Kenneth L. Burgess

William R. Shenton

William R. Shenton

cc: Christy Gudaitis, Esq., Counsel for DUHS
Catharine Cummer, Esq., Counsel for DUHS
Larry Robbins, Esq., Counsel for CCNC
Scott Aitken, Esq., Counsel for USON

Attachment D

Excerpts from Duke Cancer Center CON ApplicationJ-8275-08, pages 178-181

COPY
J-8275-08

CANCER CENTER EXPANSION
NOVEMBER 17, 2008
VOLUME I

Exhibit II.8 C

The table on the following page documents our projection that each of the 3 proposed LINACs and 5 existing LINACs will provide more than 6750 ESTV treatments and serve more than 250 patients in third of operation of the new equipment.

Our projections rest on two assumptions:

1) That the ratio of ESTV treatments to patients serviced will remain constant from FY2008 through FY2015. Actually, the substitution of SRS and SRT procedure for standard external beam treatments is likely to reduce the ratio, making our assumption very conservative
2) That our LINACs will be able to provide as many as 9320 ESTV treatments in FY2012 because they will by then be equipped with Rapid Arc or an equivalent technology that reduces the machine time required for treatments.

LINEAR ACCELERATOR ESTVs PER MACHINE	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015
# of Units	5	5	5	5	5	5	8	8	8
# of Linac Treatments	31,623	33,089	34,873	36,646	38,669	40,914	43,733	46,317	49,030
# of ESTV Treatments	37,438	37,245	39,566	41,638	43,999	46,598	49,810	52,753	55,797
# of ESTVs per Machine	7,488	7,449	7,913	8,328	8,800	9,320	6,226	6,594	6,975
# of Patients	1,445	1,530	1,612	1,694	1,788	1,892	2,022	2,142	2,267
# of Patients per Machine	289	306	322	339	358	378	253	268	283

Exhibit II.8 C2

The number of patients projected to receive simulations from the 4 CT simulators to be operated by the Duke Hospital Department of Radiation Oncology during the first 3 years of the project and the number of procedures they are projected to receive are listed on the following page. The patients receiving simulations from the Department's 3 existing machines are distributed by county and state of origin on the following page. We do not anticipate or project any change in geographic origin between now and the third year of the project.

Duke University Hospital
Radiation Therapy Simulations by CPT

CPT CODE	DESCRIPTION	ACTUAL FY2008	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015
77280	THER RAD SIMULATION,SMPL	575	606	637	672	711	760	805	852
77285	THER RAD SIMULATION,INT	6	6	7	7	7	8	8	9
77290	THER RAD SIMULATION,CMPL	1,585	1,670	1,755	1,852	1,960	2,095	2,219	2,349
77295	THER RAD SIMULATION,3D	851	897	942	995	1,052	1,125	1,191	1,261
	Total Procedures	3,017	3,180	3,341	3,526	3,730	3,988	4,223	4,470
	Total Patients	1,789	1,885	1,981	2,091	2,212	2,364	2,504	2,651

Attachment E

Duke University Medical Center
2014 License Renewal Application

Comments: CON Project ID# J-010320-14

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
1205 Umstead Drive, 2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only
License # H0015 Medicare # **340030**
Computer: 943138
PC _____ Date _____

License Fee: **$17,697.50**

2014
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant: **Duke University Health System, Inc.**
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: **Duke University Hospital**
Other: _____
Other: _____

Facility Mailing Address: P O Box 3814 DUMC
Durham, NC 27710

Facility Site Address: 2301 Erwin Road
Durham, NC 27710
County: Durham
Telephone: (919)684-8111
Fax: (919)681-8921

Administrator/Director: Kevin Sowers
Title: CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: _____ **Title:** President
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: CATHARINE W. CUMMER **Telephone:** (919)668-0857

E-Mail: CATHARINE.CUMMER@DUKE.EDU

Primary National Provider Identifier (NPI) registered at NPPES 1992703540

If facility has more than one "Primary" NPI, please provide SEE FOOTNOTE

For questions regarding NPI contact Azzie Conley at (919) 855-4646.

11. Linear Accelerator Treatment Data (including Cyberknife® & Similar Equipment)

CPT Code	Description	# of Procedures
Simple Treatment Delivery		
77401	Radiation treatment delivery	–
77402	Radiation treatment delivery (<=5 MeV)	–
77403	Radiation treatment delivery (6-10 MeV)	344
77404	Radiation treatment delivery (11-19 MeV)	237
77406	Radiation treatment delivery (>=20 MeV)	–
Intermediate Treatment Delivery		
77407	Radiation treatment delivery (<=5 MeV)	–
77408	Radiation treatment delivery (6-10 MeV)	60
77409	Radiation treatment delivery (11-19 MeV)	102
77411	Radiation treatment delivery (>=20 MeV)	–
Complex Treatment Delivery		
77412	Radiation treatment delivery (<=5 MeV)	277
77413	Radiation treatment delivery (6-10 MeV)	7,507
77414	Radiation treatment delivery (11-19 MeV)	10,837
77416	Radiation treatment delivery (>= 20 MeV)	48
Other Treatment Delivery Not Included Above		
77418	Intensity modulated radiation treatment (IMRT) delivery	12,944
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator	–
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions	–
G0339	(Image-guided) robotic linear accelerator-based stereotactic radiosurgery in one session or first fraction	382
G0340	(Image-guided) robotic linear accelerator-based stereotactic radiosurgery, fractionated treatment, 2nd-5th fraction	557
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linac)	–
	Pediatric Patient under anesthesia	–
	Neutron and proton radiation therapy	–
	Limb salvage irradiation	–
	Hemibody irradiation	–
	Total body irradiation	480
Imaging Procedures Not Included Above		–
77417	Additional field check radiographs	3,063
	Total Procedures – Linear Accelerators	36,838
Gamma Knife® Procedures		
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of one session; multisource Cobalt 60 based (Gamma Knife®)	–
	Total Procedures – Gamma Knife®	–

11. Linear Accelerator Treatment Data *continued*

a. Number of patients who received a course of radiation oncology treatments on linear accelerators (not the Gamma Knife®). Patients shall be counted once if they receive one course of treatment and more if they receive additional courses of treatment. For example, one patient who receives one course of treatment counts as one, and one patient who receives three courses of treatment counts as three. .
Patients 1,898 **(This number should match the number of patients reported in the Linear Accelerator Patient Origin Table on page 26.)**

b. Linear Accelerators
1. TOTAL number of Linear Accelerator(s) 8
2. Of the TOTAL number above, number of Linear Accelerators configured for stereotactic radiosurgery 2
3. Of the TOTAL number above, Number of CyberKnife® Systems: –
Other specialized linear accelerators (1) 1 Identify Manufacturer of Equipment VARIAN

c. Number of Gamma Knife® units –

d. Number of treatment simulators ("machine that produces high quality diagnostic radiographs and precisely reproduces the geometric relationships of megavoltage radiation therapy equipment to the patient."(GS 131E-176(24b))) 2

12. Telemedicine

a. Does your facility utilize telemedicine to have images read at another facility? NO

b. Does your facility read telemedicine images? YES

13. Additional Services:

a) **Check if Service(s) is provided: (for dialysis stations, show number of stations)**

	Check		Check
1. Cardiac Rehab Program (Outpatient)	X	5. Rehabilitation Outpatient Unit	X
2. Chemotherapy	X	6. Podiatric Services	X
3. Clinical Psychology Services	X	7. Genetic Counseling Service	X
4. Dental Services	X	8. **Number** of Acute Dialysis Stations	12

b) **Hospice Inpatient Unit Data:**
Hospital-based hospice units with licensed hospice beds. List each county served and report **all patients by county of residence**. Use each patient's age on the admission day to the Licensed Hospice Inpatient Facility. **For age categories count each inpatient client only once.**

Duke University Hospital License Renewal Application 2014
Footnote for Page 16

---

(1) One noted as specialized is also being counted as stereotactic radiosurgery.

Attachment F

Duke 2013 SHCC Petition, page 3

Comments: CON Project ID# J-010320-14

Excluding the Franklin County Cancer Center machine, the most recent utilization of the existing 7 machines in Service Area 20 as reported in the proposed 2013 SMFP is 44,493 ESTVs, an increase of 21.5% since the need for an additional machine was originally found in the 2007 SMFP. The population of the service area has also increased more than 25% since that time, from 900,876 (2007 SMFP) to 1,129,916 (proposed 2013 SMFP). Therefore, the need for an additional machine in the service area has only increased since 2007, yet the need is not met.

2. Relative utilization of linear accelerator providers in Service Area 20

Although the overall linear accelerator utilization has grown significantly since the need for an additional accelerator was found in the 2007 SMFP, two providers in particular have significantly higher utilization per machine than the others.

Service Area 20 linear accelerator utilization per existing machine

Facility	2007-08 (2010 SMFP)	2008-09 (2011 SMFP)	2009-10 (2012 SMFP)	2010-11 (2013 SMFP)	2011-12 (Exhibit C)
Duke Raleigh Hospital (1 machine)	7566	7268	7572	7486	9810.5
CCNC (1 machine until 2010-11, then 2 machines; does not include CON for additional machine not in service)	11,727	11,923	11,506	8351.5	
Wake Radiology Oncology Services (1 machine)	6216	4718	5633	--	
Rex Hospital (4 machines)	4242.5	4233	4909	4724.5	
Franklin County Cancer Center (1 machine)	not reported	not reported	not reported	1407	

As set forth above, the Duke Raleigh and CCNC linear accelerators are operating well above the assumed capacity of 6750 ESTVs per year, on a continued and regular basis. At the same time, Rex and Franklin County Cancer Center are operating well under that threshold.

In fact, while it has been operating in excess of assumed capacity for several years, Duke Raleigh's utilization has increased dramatically even further over the past year. As set forth in Exhibit C, Duke Raleigh provided 9810 ESTVs in 2011-12, 145% of the methodology's assumed linear accelerator capacity of 6750 ESTVs. Because patients must generally receive all of their treatments on a single machine, it is not always feasible for patients to seek out another

machine, it is not anticipated that this accelerator would alleviate the demand on the existing high-volume accelerators in the service area.

Attachment G

National Cancer Institute Fact Sheet, September 2014

Comments: CON Project ID# J-010320-14

Fact Sheet

In English
Reviewed: 06/30/2010

Radiation Therapy for Cancer

Key Points

- Radiation therapy uses high-energy radiation to kill cancer cells by damaging their DNA.
- Radiation therapy can damage normal cells as well as cancer cells. Therefore, treatment must be carefully planned to minimize side effects.
- The radiation used for cancer treatment may come from a machine outside the body, or it may come from radioactive material placed in the body near tumor cells or injected into the bloodstream.
- A patient may receive radiation therapy before, during, or after surgery, depending on the type of cancer being treated.
- Some patients receive radiation therapy alone, and some receive radiation therapy in combination with chemotherapy.

1. What is radiation therapy?

Radiation therapy uses high-energy radiation to shrink tumors and kill cancer cells (1). X-rays, gamma rays, and charged particles are types of radiation used for cancer treatment.

The radiation may be delivered by a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, also called brachytherapy).

Systemic radiation therapy uses radioactive substances, such as radioactive iodine, that travel in the blood to kill cancer cells.

About half of all cancer patients receive some type of radiation therapy sometime during the course of their treatment.

2. How does radiation therapy kill cancer cells?

Radiation therapy kills cancer cells by damaging their DNA (the molecules inside cells that carry genetic information and pass it from one generation to the next) (1). Radiation therapy can either

damage DNA directly or create charged particles (free radicals) within the cells that can in turn damage the DNA.

Cancer cells whose DNA is damaged beyond repair stop dividing or die. When the damaged cells die, they are broken down and eliminated by the body's natural processes.

3. Does radiation therapy kill only cancer cells?

No, radiation therapy can also damage normal cells, leading to side effects (see Question 10).

Doctors take potential damage to normal cells into account when planning a course of radiation therapy (see Question 5). The amount of radiation that normal tissue can safely receive is known for all parts of the body. Doctors use this information to help them decide where to aim radiation during treatment.

4. Why do patients receive radiation therapy?

Radiation therapy is sometimes given with curative intent (that is, with the hope that the treatment will cure a cancer, either by eliminating a tumor, preventing cancer recurrence, or both) (1). In such cases, radiation therapy may be used alone or in combination with surgery, chemotherapy, or both.

Radiation therapy may also be given with palliative intent. Palliative treatments are not intended to cure. Instead, they relieve symptoms and reduce the suffering caused by cancer.

Some examples of palliative radiation therapy are:

- Radiation given to the brain to shrink tumors formed from cancer cells that have spread to the brain from another part of the body (metastases).
- Radiation given to shrink a tumor that is pressing on the spine or growing within a bone, which can cause pain.
- Radiation given to shrink a tumor near the esophagus, which can interfere with a patient's ability to eat and drink.

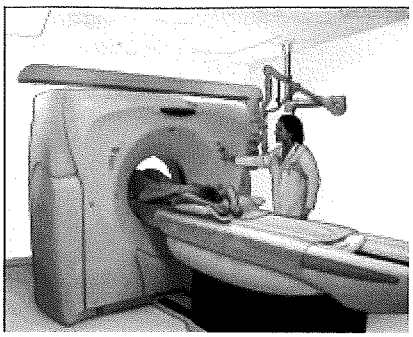
5. How is radiation therapy planned for an individual patient?

A radiation oncologist develops a patient's treatment plan through a process called treatment planning, which begins with simulation.

During simulation, detailed imaging scans show the location of a patient's tumor and the normal areas around it. These scans are usually computed tomography (CT) scans, but they can also include magnetic resonance imaging (MRI), positron emission tomography (PET), and ultrasound scans.

CT scans are often used in treatment planning for radiation therapy. During CT scanning, pictures of the inside of the body are created by a computer linked to an x-ray machine.

During simulation and daily treatments, it is necessary to ensure that the patient will be in exactly the same position every day relative to the machine delivering the treatment or doing the imaging.



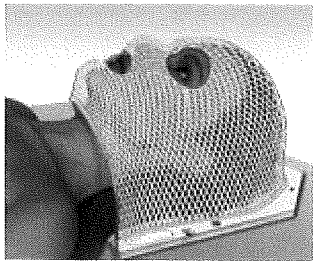
Computed Tomography Scanner. CT scans are often used in treatment planning for radiation therapy. During CT scanning, pictures of the inside of the body are created by a computer linked to an x-ray machine.

Body molds, head masks, or other devices may be constructed for an individual patient to make it easier for a patient to stay still. Temporary skin marks and even tattoos are used to help with precise patient positioning.

Patients getting radiation to the head may need a mask. The mask helps keep the head from moving so that the patient is in the exact same position for each treatment.

After simulation, the radiation oncologist then determines the exact area that will be treated, the total radiation dose that will be delivered to the tumor, how much dose will be allowed for the normal tissues around the tumor, and the safest angles (paths) for radiation delivery.

The staff working with the radiation oncologist (including physicists and dosimetrists) use sophisticated computers to design the details of the exact radiation plan that will be used. After approving the plan, the radiation oncologist authorizes the start of treatment. On the first day of treatment, and usually at least weekly after that, many checks are made to ensure that the treatments are being delivered exactly the way they were planned.



Radiation Therapy Head Mask. Patients getting radiation to the head may need a mask. The mask helps keep the head from moving so that the patient is in the exact same position for each treatment.

Radiation doses for cancer treatment are measured in a unit called a gray (Gy), which is a measure of the amount of radiation energy absorbed by 1 kilogram of human tissue. Different doses of radiation are needed to kill different types of cancer cells.

Radiation can damage some types of normal tissue more easily than others. For example, the reproductive organs (testicles and ovaries) are more sensitive to radiation than bones. The radiation oncologist takes all of this information into account during treatment planning.

If an area of the body has previously been treated with radiation therapy, a patient may not be able to have radiation therapy to that area a second time, depending on how much radiation was given during the initial treatment. If one area of the body has already received the maximum safe lifetime dose of radiation, another area might still be treated with radiation therapy if the distance between the two areas is large enough.

The area selected for treatment usually includes the whole tumor plus a small amount of normal tissue surrounding the tumor. The normal tissue is treated for two main reasons:

- To take into account body movement from breathing and normal movement of the organs within the body, which can change the location of a tumor between treatments.
- To reduce the likelihood of tumor recurrence from cancer cells that have spread to the normal tissue next to the tumor (called microscopic local spread).

6. How is radiation therapy given to patients?

Radiation can come from a machine outside the body (external-beam radiation therapy) or from radioactive material placed in the body near cancer cells (internal radiation therapy, more commonly called brachytherapy). Systemic radiation therapy uses a radioactive substance, given by mouth or into a vein, that travels in the blood to tissues throughout the body.

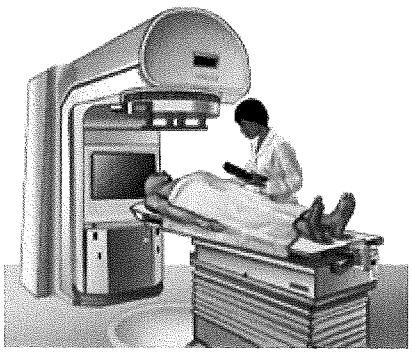
The type of radiation therapy prescribed by a radiation oncologist depends on many factors, including:

- The type of cancer.
- The size of the cancer.
- The cancer's location in the body.
- How close the cancer is to normal tissues that are sensitive to radiation.
- How far into the body the radiation needs to travel.
- The patient's general health and medical history.
- Whether the patient will have other types of cancer treatment.
- Other factors, such as the patient's age and other medical conditions.

External-beam radiation therapy

External-beam radiation therapy is most often delivered in the form of photon beams (either x-rays or gamma rays) (1). A photon is the basic unit of light and other forms of electromagnetic radiation. It can be thought of as a bundle of energy. The amount of energy in a photon can vary. For example, the photons in gamma rays have the highest energy, followed by the photons in x-rays.

Many types of external-beam radiation therapy are delivered using a machine called a linear accelerator (also called a LINAC). A LINAC uses electricity to form a stream of fast-moving subatomic particles. This creates high-energy radiation that may be used to treat cancer.



Linear Accelerator Used for External-beam Radiation Therapy. Many types of external-beam radiation therapy are delivered using a machine called a linear accelerator (also called a LINAC). A LINAC uses electricity to form a stream of fast-moving subatomic particles. This creates high-energy radiation that may be used to treat cancer.

Patients usually receive external-beam radiation therapy in daily treatment sessions over the course of several weeks (see Question 7). The number of treatment sessions depends on many factors, including the total radiation dose that will be given.

One of the most common types of external-beam radiation therapy is called **3-dimensional conformal radiation therapy (3D-CRT)**. 3D-CRT uses very sophisticated computer software and advanced treatment machines to deliver radiation to very precisely shaped target areas.

Many other methods of external-beam radiation therapy are currently being tested and used in cancer treatment. These methods include:

- **Intensity-modulated radiation therapy (IMRT)**: IMRT uses hundreds of tiny radiation beam-shaping devices, called collimators, to deliver a single dose of radiation (2). The collimators can be stationary or can move during treatment, allowing the intensity of the radiation beams to change during treatment sessions. This kind of dose modulation allows different areas of a tumor or nearby tissues to receive different doses of radiation.

  Unlike other types of radiation therapy, IMRT is planned in reverse (called inverse treatment planning). In inverse treatment planning, the radiation oncologist chooses the radiation doses to different areas of the tumor and surrounding tissue, and then a high-powered computer program calculates the required number of beams and angles of the radiation treatment (3). In contrast, during traditional (forward) treatment planning, the radiation oncologist chooses the number and angles of the radiation beams in advance and computers calculate how much dose will be delivered from each of the planned beams.

  The goal of IMRT is to increase the radiation dose to the areas that need it and reduce radiation exposure to specific sensitive areas of surrounding normal tissue. Compared with 3D-CRT, IMRT can reduce the risk of some side effects, such as damage to the salivary glands (which can cause dry mouth, or xerostomia), when the head and neck are treated with radiation therapy (4). However, with IMRT, a larger volume of normal tissue overall is exposed to radiation. Whether IMRT leads to improved control of tumor growth and better survival compared with 3D-CRT is not yet known (4).

- **Image-guided radiation therapy (IGRT)**: In IGRT, repeated imaging scans (CT, MRI, or PET) are performed during treatment. These imaging scans are processed by computers to identify changes in a tumor's size and location due to treatment and to allow the position of the patient or the planned radiation dose to be adjusted during treatment as needed. Repeated imaging can increase the accuracy of radiation treatment and may allow reductions in the planned volume of tissue to be treated, thereby decreasing the total radiation dose to normal tissue (5).

- **Tomotherapy:** Tomotherapy is a type of image-guided IMRT. A tomotherapy machine is a hybrid between a CT imaging scanner and an external-beam radiation therapy machine (6). The part of the tomotherapy machine that delivers radiation for both imaging and treatment can rotate completely around the patient in the same manner as a normal CT scanner.

  Tomotherapy machines can capture CT images of the patient's tumor immediately before treatment sessions, to allow for very precise tumor targeting and sparing of normal tissue.

  Like standard IMRT, tomotherapy may be better than 3D-CRT at sparing normal tissue from high radiation doses (7). However, clinical trials comparing 3D-CRT with tomotherapy have not been conducted.

- **Stereotactic radiosurgery:** Stereotactic radiosurgery (SRS) can deliver one or more high doses of radiation to a small tumor (5, 8). SRS uses extremely accurate image-guided tumor

targeting and patient positioning. Therefore, a high dose of radiation can be given without excess damage to normal tissue.

SRS can be used to treat only small tumors with well-defined edges. It is most commonly used in the treatment of brain or spinal tumors and brain metastases from other cancer types. For the treatment of some brain metastases, patients may receive radiation therapy to the entire brain (called whole-brain radiation therapy) in addition to SRS.

SRS requires the use of a head frame or other device to immobilize the patient during treatment to ensure that the high dose of radiation is delivered accurately.

- **Stereotactic body radiation therapy:** Stereotactic body radiation therapy (SBRT) delivers radiation therapy in fewer sessions, using smaller radiation fields and higher doses than 3D-CRT in most cases. By definition, SBRT treats tumors that lie outside the brain and spinal cord. Because these tumors are more likely to move with the normal motion of the body, and therefore cannot be targeted as accurately as tumors within the brain or spine, SBRT is usually given in more than one dose (8). SBRT can be used to treat only small, isolated tumors, including cancers in the lung and liver (8).

  Many doctors refer to SBRT systems by their brand names, such as the CyberKnife®.

- **Proton therapy:** External-beam radiation therapy can be delivered by proton beams as well as the photon beams described above. Protons are a type of charged particle.

  Proton beams differ from photon beams mainly in the way they deposit energy in living tissue. Whereas photons deposit energy in small packets all along their path through tissue, protons deposit much of their energy at the end of their path (called the Bragg peak) and deposit less energy along the way.

  In theory, use of protons should reduce the exposure of normal tissue to radiation, possibly allowing the delivery of higher doses of radiation to a tumor (9). Proton therapy has not yet been compared with standard external-beam radiation therapy in clinical trials (10, 11).

- **Other charged particle beams:** Electron beams are used to irradiate superficial tumors, such as skin cancer or tumors near the surface of the body, but they cannot travel very far through tissue (1). Therefore, they cannot treat tumors deep within the body.

Patients can discuss these different methods of radiation therapy with their doctors to see if any is appropriate for their type of cancer and if it is available in their community or through a clinical trial (see Question 11).

Internal radiation therapy

Internal radiation therapy (brachytherapy) is radiation delivered from radiation sources (radioactive materials) placed inside or on the body (12). Several brachytherapy techniques are used in cancer treatment. Interstitial brachytherapy uses a radiation source placed within tumor tissue, such as within a prostate tumor. Intracavitary brachytherapy uses a source placed within a surgical cavity or a body cavity, such as the chest cavity, near a tumor. Episcleral brachytherapy,

which is used to treat melanoma inside the eye, uses a source that is attached to the eye.

In brachytherapy, radioactive isotopes are sealed in tiny pellets or "seeds." These seeds are placed in patients using delivery devices, such as needles, catheters, or some other type of carrier. As the isotopes decay naturally, they give off radiation that damages nearby cancer cells.

If left in place, after a few weeks or months, the isotopes decay completely and no longer give off radiation. The seeds will not cause harm if they are left in the body (see permanent brachytherapy, described below).

Brachytherapy may be able to deliver higher doses of radiation to some cancers than external-beam radiation therapy while causing less damage to normal tissue (1, 12).

Brachytherapy can be given as a low-dose-rate or a high-dose-rate treatment:

- In low-dose-rate treatment, cancer cells receive continuous low-dose radiation from the source over a period of several days (1, 12).
- In high-dose-rate treatment, a robotic machine attached to delivery tubes placed inside the body guides one or more radioactive sources into or near a tumor, and then removes the sources at the end of each treatment session. High-dose-rate treatment can be given in one or more treatment sessions.

  An example of a high-dose-rate treatment is the MammoSite® system, which is being studied to treat patients with breast cancer who have undergone breast-conserving surgery.

The placement of brachytherapy sources can be temporary or permanent (1, 12):

- For permament brachytherapy, the sources are surgically sealed within the body and left there, even after all of the radiation has been given off. The remaining material (in which the radioactive isotopes were sealed) does not cause any discomfort or harm to the patient. Permanent brachytherapy is a type of low-dose-rate brachytherapy.
- For temporary brachytherapy, tubes (catheters) or other carriers are used to deliver the radiation sources, and both the carriers and the radiation sources are removed after treatment. Temporary brachytherapy can be either low-dose-rate or high-dose-rate treatment.

Doctors can use brachytherapy alone or in addition to external-beam radiation therapy to provide a "boost" of radiation to a tumor while sparing surrounding normal tissue (12).

Systemic radiation therapy

In systemic radiation therapy, a patient swallows or receives an injection of a radioactive substance, such as radioactive iodine or a radioactive substance bound to a monoclonal antibody.

Radioactive iodine (^{131}I) is a type of systemic radiation therapy commonly used to help treat some types of thyroid cancer. Thyroid cells naturally take up radioactive iodine.

For systemic radiation therapy for some other types of cancer, a monoclonal antibody helps target the radioactive substance to the right place. The antibody joined to the radioactive substance

travels through the blood, locating and killing tumor cells. For example:

- The drug ibritumomab tiuxetan (Zevalin®) has been approved by the Food and Drug Administration (FDA) for the treatment of certain types of B-cell non-Hodgkin lymphoma (NHL). The antibody part of this drug recognizes and binds to a protein found on the surface of B lymphocytes.
- The combination drug regimen of tositumomab and iodine I 131 tositumomab (Bexxar®) has been approved for the treatment of certain types of NHL. In this regimen, nonradioactive tositumomab antibodies are given to patients first, followed by treatment with tositumomab antibodies that have ^{131}I attached. Tositumomab recognizes and binds to the same protein on B lymphocytes as ibritumomab. The nonradioactive form of the antibody helps protect normal B lymphocytes from being damaged by radiation from ^{131}I.

Many other systemic radiation therapy drugs are in clinical trials for different cancer types.

Some systemic radiation therapy drugs relieve pain from cancer that has spread to the bone (bone metastases). This is a type of palliative radiation therapy. The radioactive drugs samarium-153-lexidronam (Quadramet®) and strontium-89 chloride (Metastron®) are examples of radiopharmaceuticals used to treat pain from bone metastases (13).

7. Why are some types of radiation therapy given in many small doses?

Patients who receive most types of external-beam radiation therapy usually have to travel to the hospital or an outpatient facility up to 5 days a week for several weeks. One dose (a single fraction) of the total planned dose of radiation is given each day. Occasionally, two treatments a day are given.

Most types of external-beam radiation therapy are given in once-daily fractions. There are two main reasons for once-daily treatment:

- To minimize the damage to normal tissue.
- To increase the likelihood that cancer cells are exposed to radiation at the points in the cell cycle when they are most vulnerable to DNA damage (1, 14).

In recent decades, doctors have tested whether other fractionation schedules are helpful (1), including:

- Accelerated fractionation—treatment given in larger daily or weekly doses to reduce the number of weeks of treatment.
- Hyperfractionation—smaller doses of radiation given more than once a day.
- Hypofractionation—larger doses given once a day or less often to reduce the number of treatments.

Researchers hope that different types of treatment fractionation may either be more effective than traditional fractionation or be as effective but more convenient.

8. When will a patient get radiation therapy?

A patient may receive radiation therapy before, during, or after surgery. Some patients may receive radiation therapy alone, without surgery or other treatments. Some patients may receive radiation therapy and chemotherapy at the same time. The timing of radiation therapy depends on the type of cancer being treated and the goal of treatment (cure or palliation).

Radiation therapy given before surgery is called pre-operative or neoadjuvant radiation. Neoadjuvant radiation may be given to shrink a tumor so it can be removed by surgery and be less likely to return after surgery (1).

Radiation therapy given during surgery is called intraoperative radiation therapy (IORT). IORT can be external-beam radiation therapy (with photons or electrons) or brachytherapy. When radiation is given during surgery, nearby normal tissues can be physically shielded from radiation exposure (15). IORT is sometimes used when normal structures are too close to a tumor to allow the use of external-beam radiation therapy.

Radiation therapy given after surgery is called post-operative or adjuvant radiation therapy.

Radiation therapy given after some types of complicated surgery (especially in the abdomen or pelvis) may produce too many side effects; therefore, it may be safer if given before surgery in these cases (1).

The combination of chemotherapy and radiation therapy given at the same time is sometimes called chemoradiation or radiochemotherapy. For some types of cancer, the combination of chemotherapy and radiation therapy may kill more cancer cells (increasing the likelihood of a cure), but it can also cause more side effects (1, 14).

After cancer treatment, patients receive regular follow-up care from their oncologists to monitor their health and to check for possible cancer recurrence. Detailed information about follow-up care can be found in the National Cancer Institute fact sheet *Follow-up Care After Cancer Treatment*, which is available at http://www.cancer.gov/cancertopics/factsheet/therapy/followup on the Internet.

9. Does radiation therapy make a patient radioactive?

External-beam radiation does not make a patient radioactive.

During temporary brachytherapy treatments, while the radioactive material is inside the body, the patient is radioactive; however, as soon as the material is removed, the patient is no longer radioactive. For temporary brachytherapy, the patient will usually stay in the hospital in a special room that shields other people from the radiation.

During permanent brachytherapy, the implanted material will be radioactive for several days, weeks, or months after the radiation source is put in place. During this time, the patient is radioactive. However, the amount of radiation reaching the surface of the skin is usually very low. Nonetheless, this radiation can be detected by radiation monitors and contact with pregnant woman and young children may be restricted for a few days or weeks.

Some types of systemic radiation therapy may temporarily make a patient's bodily fluids (such as saliva, urine, sweat, or stool) emit a low level of radiation. Patients receiving systemic radiation therapy may need to limit their contact with other people during this time, and especially avoid contact with children younger than 18 and pregnant women.

A patient's doctor or nurse will provide more information to family members and caretakers if any of these special precautions are needed. Over time (usually days or weeks), the radioactive material retained within the body will break down so that no radiation can be measured outside the patient's body.

10. What are the potential side effects of radiation therapy?

Radiation therapy can cause both early (acute) and late (chronic) side effects. Acute side effects occur during treatment, and chronic side effects occur months or even years after treatment ends (1). The side effects that develop depend on the area of the body being treated, the dose given per day, the total dose given, the patient's general medical condition, and other treatments given at the same time.

Acute radiation side effects are caused by damage to rapidly dividing normal cells in the area being treated. These effects include skin irritation or damage at regions exposed to the radiation beams. Examples include damage to the salivary glands or hair loss when the head or neck area is treated, or urinary problems when the lower abdomen is treated.

Most acute effects disappear after treatment ends, though some (like salivary gland damage) can be permanent. The drug amifostine (Ethyol®) can help protect the salivary glands from radiation damage if it is given during treatment. Amifostine is the only drug approved by the FDA to protect normal tissues from radiation during treatment. This type of drug is called a radioprotector. Other potential radioprotectors are being tested in clinical trials (see Question 11).

Fatigue is a common side effect of radiation therapy regardless of which part of the body is treated. Nausea with or without vomiting is common when the abdomen is treated and occurs sometimes when the brain is treated. Medications are available to help prevent or treat nausea and vomiting during treatment.

Late side effects of radiation therapy may or may not occur. Depending on the area of the body treated, late side effects can include (1):

- Fibrosis (the replacement of normal tissue with scar tissue, leading to restricted movement of the affected area).
- Damage to the bowels, causing diarrhea and bleeding.
- Memory loss.
- Infertility (inability to have a child).
- Rarely, a second cancer caused by radiation exposure.

Second cancers that develop after radiation therapy depend on the part of the body that was treated (16). For example, girls treated with radiation to the chest for Hodgkin lymphoma have an

increased risk of developing breast cancer later in life. In general, the lifetime risk of a second cancer is highest in people treated for cancer as children or adolescents (16).

Whether or not a patient experiences late side effects depends on other aspects of their cancer treatment in addition to radiation therapy, as well as their individual risk factors. Some chemotherapy drugs, genetic risk factors, and lifestyle factors (such as smoking) can also increase the risk of late side effects.

When suggesting radiation therapy as part of a patient's cancer treatment, the radiation oncologist will carefully weigh the known risks of treatment against the potential benefits for each patient (including relief of symptoms, shrinking a tumor, or potential cure). The results of hundreds of clinical trials and doctors' individual experiences help radiation oncologists decide which patients are likely to benefit from radiation therapy.

A more comprehensive discussion of acute and late side effects from radiation therapy, as well as ways to cope with these side effects, can be found in the NCI publications *Radiation Therapy and You: Support for People With Cancer* (http://www.cancer.gov/cancertopics/radiation-therapy-and-you) and the *Radiation Therapy Side Effects Fact Sheets* (http://www.cancer.gov/cancertopics/wtk/index).

11. What research is being done to improve radiation therapy?

Doctors and other scientists are conducting research studies called clinical trials to learn how to use radiation therapy to treat cancer more safely and effectively. Clinical trials allow researchers to examine the effectiveness of new treatments in comparison with standard ones, as well as to compare the side effects of the treatments.

Researchers are working on improving image-guided radiation so that it provides real-time imaging of the tumor target during treatment. Real-time imaging could help compensate for normal movement of the internal organs from breathing and for changes in tumor size during treatment.

Researchers are also studying radiosensitizers and radioprotectors, chemicals that modify a cell's response to radiation:

- Radiosensitizers are drugs that make cancer cells more sensitive to the effects of radiation therapy. Several agents are under study as radiosensitizers. In addition, some anticancer drugs, such as 5-fluorouracil and cisplatin, make cancer cells more sensitive to radiation therapy.
- Radioprotectors (also called radioprotectants) are drugs that protect normal cells from damage caused by radiation therapy. These drugs promote the repair of normal cells exposed to radiation. Many agents are currently being studied as potential radioprotectors.

The use of carbon ion beams in radiation therapy is being investigated by researchers, but, at this time, the use of these beams remains experimental. Carbon ion beams are available at only a few medical centers around the world. They are not currently available in the United States. Researchers hope that carbon ion beams may be effective in treating some tumors that are

resistant to traditional radiation therapy.

People with cancer who are interested in taking part in a clinical trial should talk with their doctor. A comprehensive list of current clinical trials is available on NCI's Web site at http://www.cancer.gov/clinicaltrials on the Internet.

NCI's Cancer Information Service (CIS) can also provide information about clinical trials and help with clinical trial searches. Call the CIS at 1–800–4–CANCER (1–800–422–6237).

Selected References

1. Lawrence TS, Ten Haken RK, Giaccia A. Principles of Radiation Oncology. In: DeVita VT Jr., Lawrence TS, Rosenberg SA, editors. *Cancer: Principles and Practice of Oncology*. 8th ed. Philadelphia: Lippincott Williams and Wilkins, 2008.

2. Taylor A, Powell ME. Intensity-modulated radiotherapy—what is it? *Cancer Imaging* 2004; 4(2):68–73. [PubMed Abstract]

3. Gaspar LE, Ding M. A review of intensity-modulated radiation therapy. *Current Oncology Reports* 2008; 10(4):294–299. [PubMed Abstract]

4. Veldeman L, Madani I, Hulstaert F. et al. Evidence behind use of intensity-modulated radiotherapy: A systematic review of comparative clinical studies. *Lancet Oncology* 2008; 9(4):367–375. Erratum in: *Lancet Oncology* 2008; 9(6):513. [PubMed Abstract]

5. Noda SE, Lautenschlaeger T, Siedow MR, et al. Technological advances in radiation oncology for central nervous system tumors. *Seminars in Radiation Oncology* 2009; 19(3):179–186. [PubMed Abstract]

6. Detorie NA. Helical tomotherapy: A new tool for radiation therapy. *Journal of the American College of Radiology* 2008; 5(1):63–66.

7. Fenwick JD, Tomé WA, Soisson ET, et al. Tomotherapy and other innovative IMRT delivery systems. *Seminars in Radiation Oncology* 2006; 16(4):199–208. [PubMed Abstract]

8. Kavanagh BD, Timmerman RD. Stereotactic radiosurgery and stereotactic body radiation therapy: An overview of technical considerations and clinical applications. *Hematology/Oncology Clinics of North America* 2006; 20(1):87–95. [PubMed Abstract]

9. Schulz-Ertner D, Jäkel O, Schlegel W. Radiation therapy with charged particles. *Seminars in Radiation Oncology* 2006; 16(4):249–259. [PubMed Abstract]

10. Brada M, Pijls-Johannesma M, De Ruysscher D. Proton therapy in clinical practice: Current clinical evidence. *Journal of Clinical Oncology* 2007; 25(8):965–970.

11. Olsen DR, Bruland OS, Frykholm G, Norderhaug, IN. Proton therapy—a systematic review of clinical effectiveness. *Radiotherapy and Oncology: Journal of the European Society for*

Therapeutic Radiology and Oncology 2007; 83(2):123–132. [PubMed Abstract]

12. Patel RR, Arthur DW. The emergence of advanced brachytherapy techniques for common malignancies. *Hematology/Oncology Clinics of North America* 2006; 20(1):97–118. [PubMed Abstract]

13. Lam MG, de Klerk JM, van Rijk PP, Zonnenberg, BA. Bone seeking radiopharmaceuticals for palliation of pain in cancer patients with osseous metastases. *Anti-cancer Agents in Medicinal Chemistry* 2007; 7(4):381–397. [PubMed Abstract]

14. Connell PP, Hellman S. Advances in radiotherapy and implications for the next century: A historical perspective. *Cancer Research* 2009; 69(2):383–392.

15. Calvo FA, Meirino RM, Orecchia R. Intraoperative radiation therapy first part: Rationale and techniques. *Critical Reviews in Oncology/Hematology* 2006; 59(2):106–115. [PubMed Abstract]

16. Travis LB, Hodgson D, Allan JM, Van Leeuwen FE. Second Cancers. In: DeVita VT Jr., Lawrence TS, Rosenberg SA, editors. *Cancer: Principles and Practice of Oncology*. 8th ed. Philadelphia: Lippincott Williams and Wilkins, 2008.

Related Resources

Cancer Clinical Trials

- How To Find a Doctor or Treatment Facility If You Have Cancer
- Follow-up Care After Cancer Treatment
- Radiation Therapy Side Effects Sheets
- Radiation Therapy and You: Support for People With Cancer

This is the most current Fact Sheet on the National Cancer Institute website on September 30, 2014

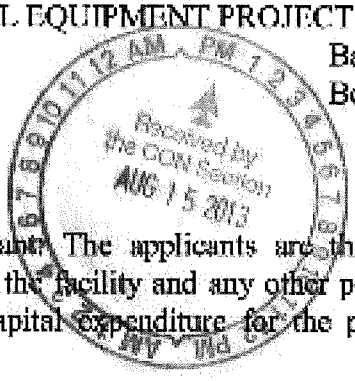
Attachment H

Excerpts from Duke Raleigh Replacement Linear Accelerator CON Project ID# J-10164-13

Comments: CON Project ID# J-010320-14

Certificate of Need Application
ACUTE CARE FACILITY/
MEDICAL EQUIPMENT PROJECT

Project I. D. Number: J-10164-13 Batch Category: _____
Proposal Type: _____ Beginning of Review: _____



I. IDENTIFICATION

1. Legal Name of the Applicant: The applicants are the legal entities (i.e., persons or organizations) that will own the facility and any other persons who will offer, develop or incur an obligation for a capital expenditure for the proposed new institutional health service.

Duke University Health System d/b/a Duke Raleigh Hospital
(Name of Applicant)

3400 Wake Forest Road
(Street & Number)

Raleigh	NC	27609	Wake
(City)	(State)	(Zip)	(County)

I.2. Name and Address of Parent Company (if applicable):

Not applicable.

I.3. Person to whom all correspondence and questions regarding this application should be directed:

Catharine W. Cummer	Regulatory Counsel, Strategic Planning
(Name)	(Title)

3100 Tower Blvd., Suite 1300
(Street & Number)

Durham	NC	27707	(919) 668-0857
(City)	(State)	(Zip)	(Area Code & Phone Number)

catharine.cummer@duke.edu
(email address)

4. Name of Lessor (If applicable):

Not Applicable

XII. PROPOSED DEVELOPMENT SCHEDULE

Project the specific dates (**i.e., month, day, and year**) for each of the following milestones. If a milestone is not applicable, please enter NA and explain why it is not applicable on a separate page.

Note that the schedule which you propose is extremely important. The timetable you provide determines (1) the period of time during which the project must be developed, and (2) the time(s) at which the Agency shall request a progress report(s). Therefore, this schedule should reflect the actual dates each milestone is anticipated to be completed. If the CON decision is made on a later date than the one identified in 1.(a) in the timetable below, the schedule will be adjusted accordingly by the Certificate of Need Section.

1.	Certificate of Need		
	(a)	Anticipated Date of Decision (90 to 150 days from beginning date of review period)	January 28, 2014
	(b)	Date of Issuance of the Certificate of Need (Date may not be less than 31 days following the decision date)	March 1, 2014
2.	Financing		
	(a)	Obtaining construction financing	_____
	(b)	Obtaining permanent financing	_____
	(c)	Obtaining funds necessary to undertake project	_____
3.	Design		
	(a)	Completion of preliminary drawings	_____
	(b)	Completion of final drawings and specifications	_____
	(c)	Approval of final drawings and specifications by the Construction Section, DHSR	_____
4.	Construction		
	(a)	Approval of Site by Construction Section, DHSR	_____
	(b)	Contract award (Notice to Proceed)	_____
	(c)	25% completion of construction (25% of the dollar value of the contract in place)	September 15, 2014
	(d)	50% completion of construction	March 1, 2015
	(e)	75% completion of construction	August 31, 2015
	(f)	Completion of construction *includes renovation and relocation of CT simulator	January 31, 2016*
	(g)	Occupancy/offering of service(s)	September 30, 2015
5.	Acquisition of Medical Equipment (Repeat as needed for each major project component)		
	(a)	Ordering equipment	March 1, 2015
	(b)	Arrival of equipment	June 1, 2015
	(c)	Operation of equipment	September 30, 2015
6.	Other Milestones		
	(a)	Licensure of Facility	NA _____
	(b)	Certification of beds	NA _____
	(c)	Other (Specify)	NA _____

Attachment I

Additional Letters of Support

Comments: CON Project ID# J-010320-14

August 18, 2014

Dr. John Leung
Dr. Michael Garafalo
The Prostate Health Center
117 Sunnybrook Dr.
Raleigh, N.C. 27610

Dear Dr. Leung and Dr. Garafalo,

I am writing to thank you both for the very caring and excellent professional care you afforded me while undergoing radiotherapy treatment this Summer in your facility in Raleigh. I've always been a person interested in how things work and why, and your willingness to patiently discuss with me some of the more arcane details of my treatment course is no small part of my appreciation for the care I received.

And even more importantly, I want to individually thank by name the Staff members that I directly interacted with each and every day for eight weeks time, specifically: Ray Thompson, Laura Salley, Bill Stevens, Lindsey Barclay, Ashley Broadway, and Melissa Jessup.

I really appreciate how you welcomed me each day, accompanied me down the hall to each treatment, and always maintained a relaxed yet efficient environment in the building. You probably have no idea how our brief daily interactions did such a great deal to dissipate the mental and emotional stresses of coming for treatment day after day. I became very comfortable and relaxed being there, even on those occasional days when I really didn't want to be there, and only because of you.

You turned each treatment into a visit, and I miss my visits with each of you. Thank you all.

Best Regards,

Bill Lyons

William C. Lyons, JR

August 1, 2014

Kevin P. Khoudary, M.D.
The Prostate Health Center

RE: Additional Linear accelerator, Wake County, The Prostate Health Center, Colo - Rectal Cancer

Dear Dr. Khoudary:

I am writing this letter to express my support for The Prostate Health Center's proposed CON application to expand services to include an additional linear accelerator in Wake County.

With an additional linear accelerator The Center's services beyond prostate and related cancers will increase healthcare access, and offer important care options. The Center is a great asset and I am pleased to fully support your application for an additional linear accelerator. The Center has a strong reputation for delivering quality services, and putting priority on the patients' best interests. I understand that it is organized as an interdisciplinary program that offers medical and radiation oncology services, with regular interdisciplinary case conferences and emphasizes screening for diverse populations. Wake County is a central location, close to large populations who need the service, and the expansion is welcomed.

I estimate that, on a monthly basis, based on my experience, I will refer 10 patients to The Prostate Health Center.

Regards,

Stephen Furs,MD
Cary Gastroenterology Associates, PA
1000 Crescent Green Drive Suite 102
Cary, NC 27518

Specialty: Gastroenterology

August 1, 2014

Kevin P. Khoudary, M.D.
The Prostate Health Center

RE: Additional Linear accelerator, Wake County, The Prostate Health Center, Colo - Rectal Cancer

Dear Dr. Khoudary:

I am writing this letter to express my support for The Prostate Health Center's proposed CON application to expand services to include an additional linear accelerator in Wake County.

With an additional linear accelerator The Center's services beyond prostate and related cancers will increase healthcare access, and offer important care options. The Center is a great asset and I am pleased to fully support your application for an additional linear accelerator. The Center has a strong reputation for delivering quality services, and putting priority on the patients' best interests. I understand that it is organized as an interdisciplinary program that offers medical and radiation oncology services, with regular interdisciplinary case conferences and emphasizes screening for diverse populations. Wake County is a central location, close to large populations who need the service, and the expansion is welcomed.

I estimate that, on a monthly basis, based on my experience, I will refer 20 patients to The Prostate Health Center.

Regards,

Michael Brody, MD
Cary Gastroenterology Associates, PA
1000 Crescent Green Drive Suite 102
Cary, NC 27518

Specialty: Gastroenterology

August 1, 2014

Kevin P. Khoudary, M.D.
The Prostate Health Center

RE: Additional Linear accelerator, Wake County, The Prostate Health Center, Colo - Rectal Cancer

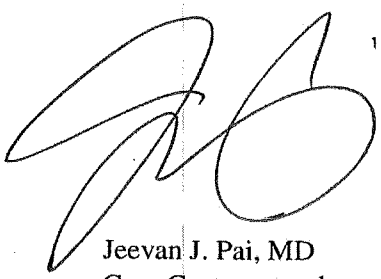
Dear Dr. Khoudary:

I am writing this letter to express my support for The Prostate Health Center's proposed CON application to expand services to include an additional linear accelerator in Wake County.

With an additional linear accelerator The Center's services beyond prostate and related cancers will increase healthcare access, and offer important care options. The Center is a great asset and I am pleased to fully support your application for an additional linear accelerator. The Center has a strong reputation for delivering quality services, and putting priority on the patients' best interests. I understand that it is organized as an interdisciplinary program that offers medical and radiation oncology services, with regular interdisciplinary case conferences and emphasizes screening for diverse populations. Wake County is a central location, close to large populations who need the service, and the expansion is welcomed.

I estimate that, on a monthly basis, based on my experience, I will refer 15 patients to The Prostate Health Center.

Regards,



Jeevan J. Pai, MD
Cary Gastroenterology Associates, PA
1000 Crescent Green Drive Suite 102
Cary, NC 27518

Specialty: Gastroenterology

August 1, 2014

Kevin P. Khoudary, M.D.
The Prostate Health Center

RE: Additional Linear accelerator, Wake County, The Prostate Health Center, Colo - Rectal Cancer

Dear Dr. Khoudary:

I am writing this letter to express my support for The Prostate Health Center's proposed CON application to expand services to include an additional linear accelerator in Wake County.

With an additional linear accelerator The Center's services beyond prostate and related cancers will increase healthcare access, and offer important care options. The Center is a great asset and I am pleased to fully support your application for an additional linear accelerator. The Center has a strong reputation for delivering quality services, and putting priority on the patients' best interests. I understand that it is organized as an interdisciplinary program that offers medical and radiation oncology services, with regular interdisciplinary case conferences and emphasizes screening for diverse populations. Wake County is a central location, close to large populations who need the service, and the expansion is welcomed.

I estimate that, on a monthly basis, based on my experience, I will refer 10 patients to The Prostate Health Center.

Regards,

Juliana Miller, MD
Cary Gastroenterology Associates, PA
1000 Crescent Green Drive Suite 102
Cary, NC 27518

Specialty: Gastroenterology

Attachment J

Alternative Scenarios Duke / CCNC Linear Accelerators

Comments: CON Project ID# J-010320-14

ALTERNATIVE SCENARIOS TO CCNC AND DRAH UTILIZATION FORECASTS

The following scenarios illustrate more reasonable estimated CCNC linear accelerator use:

DUHS Application Exhibit 19 Step 6 indicates that CCNC patient volume will decrease 20 percent based on a combination of factors:

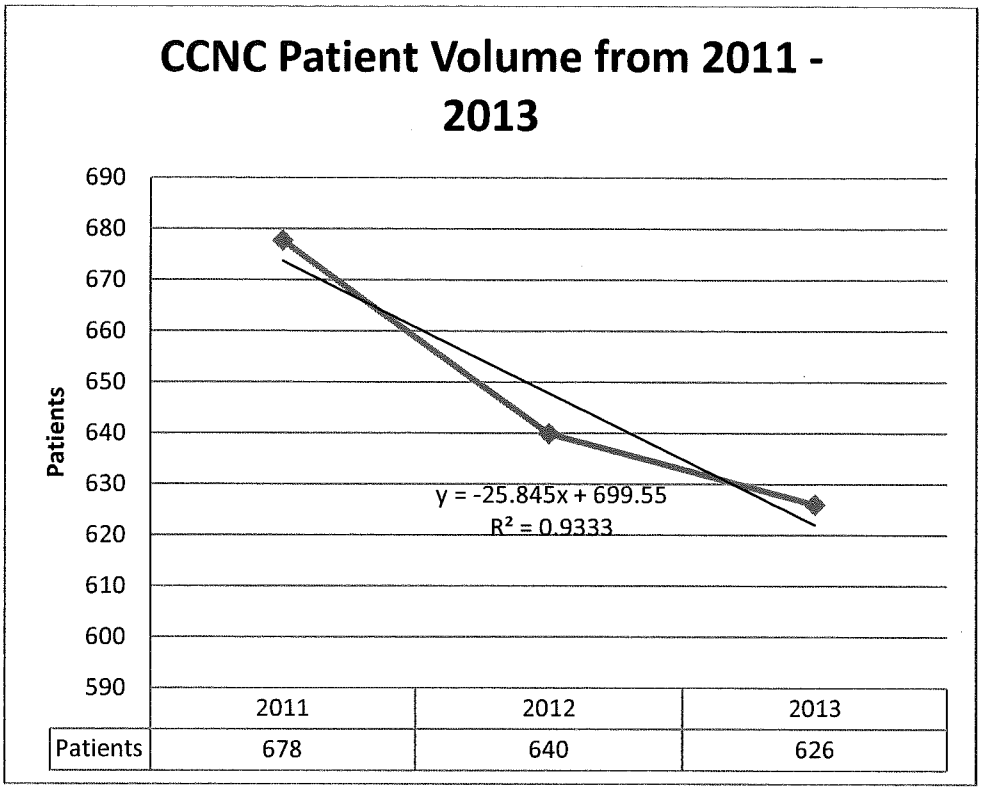
"Regardless of whether the CCNC asset transaction is concluded, ***six of the CCNC medical oncologists will be joining the Duke Cancer Institute in Wake County this fall.*** *Duke is also aware that some of the current CCNC medical oncologists will be joining UNC Healthcare and/or retiring. Therefore, to project FY2015 patient market share, DRAH assumes a 20 percent decrease in FY2014 patient volume at CCNC to reflect this change. Assuming the CCNC transaction is concluded, Duke Cancer Institute physicians are anticipated to refer patients to the existing operational CCNC linear accelerators. Given the pent up demand for DUHS radiation therapy services in Wake County, the CCNC equipment will provide additional capacity for Duke Cancer Institute physicians. Additionally, other non-Duke or CCNC referring providers in the market and local patients are familiar with the existing CCNC locations in Raleigh and Cary and may prefer to use radiation therapy services at these convenient locations. For these reasons,* ***DRAH determined a 20 percent decrease in patient volume at CCNC during FY2015 was reasonable and conservative.*** *" – Exhibits, pg. 303*

a. The 20 percent decrease is neither reasonable nor conservative.

b. Only six of 15 CCNC medical oncologists will be joining the Duke Cancer Institute in Wake Country this fall.

c. The application provides no foundation for the 20 percent estimate.

d. Moreover, the projection does not recognize that the number of patients at CCNC has decreased in recent years, as evident by data in Table 9G of respective State Medical Facilities Plans.



Source: 2013, 2014 and Proposed 2015, Tables 9G, SMFP

Annual CCNC Patient Decline: 25.845

The following scenarios consider a range of possible impact of the historical trend and the actual proportion of CCNC physicians who will transfer to Duke. All demonstrate that CCNC will not reach either 250 patients per linear accelerator or 6,750 ESTVs per linear accelerator. Clearly, the Duke application far overestimates the utilization of the CCNC linear accelerators.

Scenario 1: Recent 3-Year CCNC Trend Continues Through Duke Acquisition in October 2014

Cancer Centers of North Carolina
Service Area 20, Wake Country

Scenario 1: 2011 – 2013 CCNC Procedure Trend Extended Through 2018

FY	Number of Linear Accelerators	Number of Procedures (ESTVs)	Number of Patients[1]	Patients/ Linear Accelerator	ESTVs / Linear Accelerator
2011	3	16,703	678	226	5,568
2012	3	15,771	640	213	5,257
2013	3	15,429	626	209	5,143
2014	3	14,792	600	200	4,931
2015	3	5,662	230	77	1,887
2016	3	5,025	204	68	1,675
2017	3	4,388	178	59	1,463
2018	3	3,751	152	51	1,250

[1] *The State Medical Facilities Plan reports only ESTVs. To convert ESTVs to Patients, use the following ratio:*

Number of Procedures (ESTVs) in 2013[1]:	15,429
Number of Patients in 2013[2]:	626
Ratio of Patients to Procedures (ESTVs) in 2013:	4.1percent
Ratio of Procedures (ESTVs) to Patients in 2013:	24.65

[2] *Only 40 percent of CCNC medical oncologists will join the Duke Cancer Center in Wake County[3]. If each CCNC medical oncologist refers the same number of patients to the CCNC linear accelerator, then only 40 percent of patients will stay with the Duke CCNC program.*

Current CCNC Medical Oncologists[4]: 15

[1] *Source: http://www.ncdhhs.gov/dhsr/mfp/pdf/2014/shcc/0521_table9g.pdf*
[2] *Source: Duke CON Application, Exhibit 19, Step 6, page 293*
[3] *Source: Duke CON Application, Exhibit 19, page 303*
[4] *Source: http://cancercentersofnc.com/physicians/*

CCNC Medical Oncologists Transferring to Duke in 2014[5]: 6
Percent Transferring to Duke: 40%

Scenario 2: Recent 3-Year CCNC Trend Stabilizes Following Duke Acquisition in October 2014 and Remains Constant After 2016

Cancer Centers of North Carolina
Service Area 20, Wake Country

Scenario 2: Market Loss Stabilized in 2015

FY	Number of Linear Accelerators	Number of Procedures (ESTVs)	Number of Patients	Patients/ Linear Accelerator	ESTVs / Linear Accelerator
2011	3	16,703	678	226	5,568
2012	3	15,771	640	213	5,257
2013	3	15,429	626	209	5,143
2014	3	14,792	600	200	4,931
2015	3	5,917	240	80	1,972
2016	3	5,280	214	71	1,760
2017	3	5,280	214	71	1,760
2018	3	5,280	214	71	1,760

Assume the same medical oncologist impact as in Scenario 1.

[5] *Source: Duke CON Application, Exhibit 19, page 304*
NOTE: Amit Metha is not a CCNC physician.

Scenario 3: Recent 3-Year CCNC Trend Stabilizes Following Duke Acquisition in October 2014 and Increases at Rates Predicted in Step 8 of CCNC Patient Projection Methodology, Exhibit 19

Cancer Centers of North Carolina Service Area 20, Wake Country

Scenario 3: Market Loss Stabilized in 2015 and Predicted Market Growth per Exhibit 19

FY	Number of Linear Accelerators	Number of Procedures (ESTVs)	Number of Patients	Patients/ Linear Accelerator	ESTVs / Linear Accelerator
2011	3	16,703	678	226	5,568
2012	3	15,771	640	213	5,257
2013	3	15,429	626	209	5,143
2014	3	14,792	600	200	4,931
2015	3	5,917	240	80	1,972
2016	3	6,364	258	86	2,121
2017	3	7,107	270	90	2,220
2018	3	8,122	281	94	2,310

a. Assume the same medical oncologist impact as in Scenario 1.
b. Calculate annual increase in patients from Step 8, Exhibit 19, CCNC Linear Accelerator Patients

Annual Patient Increase from Step 8 Exhibit 19

	FY2015	FY2016	FY2017	FY2018
Total Patients [6]	551	595	651	718
Annual Increment		44	56	67

c. Add the Step 8 Annual Increment to the Patients from Scenario 2.
d. Apply 2013 ESTVs to Patient from Scenario 1. NOTE: This is more generous than the ratio used in Step 12 of the Duke application.

[6] *Source: Duke CON Application, Exhibit 19, Step 8, page 306*

Adding the Duke estimate of "redirected DUH patients" from the CON application, Exhibit 19 Step 10 does not rescue the number of patients treated on CCNC equipment. The true estimate remains far below the Duke CON estimate. This is illustrated in the following table: More reasonable estimates of patients served at the CCNC locations are less than half the cases the applicant estimated. The CCNC equipment does not reach 250 patients per linear accelerator by the third year.

Comparison of Duke Forecast to Adjusted Scenario Forecasts
(Includes Duke Assumption regarding Redirected DUH Patients)

Source		FY2014	FY2015	FY2016	FY2017	FY2018
Redirected from DUH to CCNC in Step 10		0	0	37	38	38
CCNC without redirection	Scenario 1	600	230	204	178	152
	Scenario 2	600	240	214	214	214
	Scenario 3	600	240	258	270	281
Totals Compared						
Duke CON Step 11		**689**	**551**	**632**	**688**	**756**
CCNC with redirection	Scenario 1	**600**	**230**	**241**	**216**	**190**
	Scenario 2	**600**	**240**	**251**	**252**	**252**
	Scenario 3	**600**	**240**	**295**	**308**	**319**