The Prostate Health Center

HAND DELIVERED

December 30, 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-010362-14 Replace Linear Accelerator Cary Radiation Oncology, J-010363-14 Replace Linear Accelerator Duke Cancer Center Macon Pond

Dear Ms. Frisone and Mr. McKillip:

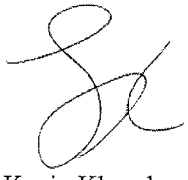
On behalf of Parkway Urology, LLC, thank you for the opportunity to comment on the above referenced applications to replace linear accelerator in service area 20.

We recognize that the Agency decision regarding the proposed linear accelerators will be based upon the statutory review criteria outlined in GS 131E-183. To that end, we have provided detailed written comments addressed to specific review criteria. Because the two applications appear to offer competing service in the same Linear Accelerator Service Area 20 and to the same county population groups, and because both are from the same applicant that operates a linear accelerator in the same counties, we believe the two should be considered competing applications. We also believe that the state should consider these applications in competition with a Certificate of Need application that is under review at this time, J-010322-14 to add a second linear accelerator at the applicant's Duke Raleigh Hospital site. All three applications are for TrueBeam linear accelerators to be owned by Duke University Health System and operated on the license of Duke Raleigh Hospital. Both of the applications in this batch also request permission to operate a second linear accelerator at the Duke Raleigh Hospital during construction of the proposed replacement facilities. However, neither appears to provide information about those operations during the period covered by the applications. As such, both applications appear incomplete.

Those observations notwithstanding, the attached comments address additional inconsistencies in the applications and reasons they are non-conforming with statutory review criteria individually. Because, the two applications are identical in many respects, we combined our comments, addressing differences where they occur.

We believe that neither application should be approved. 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

- **A.** Comments on Cary and Macon Pond Road CON applications
- **B.** Comparison of Provider-based and Freestanding Reimbursement for Linear Accelerators
- **C.** Duke CCNC Petition

COMPETITIVE REVIEW OF - DUKE RALEIGH HOSPITAL, CARY AND MACON POND ROAD REPLACEMENT LINEAR ACCELERATORS J-10363-14 AND J-10362-14

OVERVIEW

Duke University Health System, Inc. d/b/a Duke Raleigh Hospital filed two separate Certificate of Need applications to replace linear accelerators recently acquired from Cancer Centers of North Carolina with new TrueBeam linear accelerators, one at the Macon Pond Road facility and one at the Cary facility. The combined capital expenditure for the applications would be $11.4 million.

The applications are virtually identical in scope, differing only in location, number of patients served, and proposed treatments. Both claim the same DRAH service area (p. 20 both applications). Both include the same request that the Agency permit Duke Raleigh Hospital (DRAH) to operate a second linear accelerator at its main campus, during the construction phase for the proposed replacement project. DRAH would retain the linear accelerator that it had agreed to take out of service when that older unit is replaced. The date to begin use of the second at DRAH is not specified, but the Cary application suggests this would be in March/ April 2015. Cary replacement would be deferred until Macon Pond is complete, but Macon Pond would open only six months after Cary.

The proposed TrueBeam linear accelerators would result in four high cost, high speed linear accelerators owned by the applicant in Linear Accelerator Service Area 20. The CON Section also 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, February 4, 2011. DRAH permission to develop that facility is being contested by Rex Hospital.

The Cary application proposes to take the Cary facility out of operation for partial years FY 16 and FY17, while the replacement project is underway (page 72). According to the schedule (Cary p. 80) the site will be out of service two months in FY 16 (May-June) and two months in FY 17 (July - November). Similarly, Macon Pond would be out of operation June 2015 through March 2016, nine months.

The applications are 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 problems with the referenced applications.

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

Both applications are not conforming to Policies GEN-3 and GEN-4.

POLICY GEN-3

The applications do not address how the proposed volumes incorporate quality, cost effectiveness and access. The applicant, Duke University Health Systems ("DUHS") proposes that because the two locations served more than 250 patients in the prior year, when they were under different ownership, both locations will sustain 80 percent of that level of patient use in 2015 and will increase six percent a year from 2014 through 2018, regardless of the fact that the sites are out of operation much of that time. (Cary p. 30; Macon Pond p. 29). The applications infer that patients will shift toward DRAH when the facilities are closed and back when they open. Neither application provides detail in the explanations of how this will occur. Both are clear that costs to patients will increase, because they will change from CCNC's from freestanding rates to more expensive hospital OPPS provider-based rates.

POLICY GEN-4

Both projects are not conforming to this policy. Both involve a capital expenditure in excess of $2 million and do not include an agreement to develop a water conservation plan as required by GEN-4. Exhibit 17, a letter from Malcom Hawkins, does not include a plan for water conservation.

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 Thompson Reuters cancer incidence rates for five counties, documentation of need is tied to assumptions that: the population of the five counties is growing at 1.1 to 2 percent a year, with the exception of Nash, which is shrinking, that over 65 population will grow, an assertion that it fails to support with data, and a statement that development of the Duke Cancer Institute will directly translate to more referrals to the proposed linear accelerators. Moreover, neither application identifies the counties associated with the patients forecast for "other" or "other states" in section III.

The Cary application argues that the town of Cary has more than 120,000 people and should qualify for its own linear accelerator. This is not a regulatory threshold and the application fails to note that the Cary median age puts it among the younger communities in the state. Cary itself is not a high profile cancer demographic. Its income is higher and it has few African Americans. Data in the State Center for Health Statistics show that African Americans contribute disproportionately to high cancer rates. According to the NC Office of State Budget and Management, its 2014 African American population is only 7.7 percent [1]compared to 21.3 percent for Wake County. (210,266/984,568 = 21.3%).

[1] http://www.townofcary.org/Assets/Planning+Department/Planning+Department+PDFs/populationreport.pdf

The applications assert that Duke market share at these locations will increase at 3.5 to 4 percent annually, with no disruption in net growth rate for the seven months that the facilities are not in operation. To support the projection, the applications indicate that CCNC was historically well used at these locations. However, the number of treatments at the CCNC locations declined in recent years.

Linear Accelerator History CCNC

	FY 2011	FY 2012	FY 2013
Procedures	16,703	15,771	15,429
Linacs open	2	2	2
Per Linear accelerator	8,352	7,886	7,715

Source: Table 9G State Medical Facilities Plans 2013, 2014, 2015

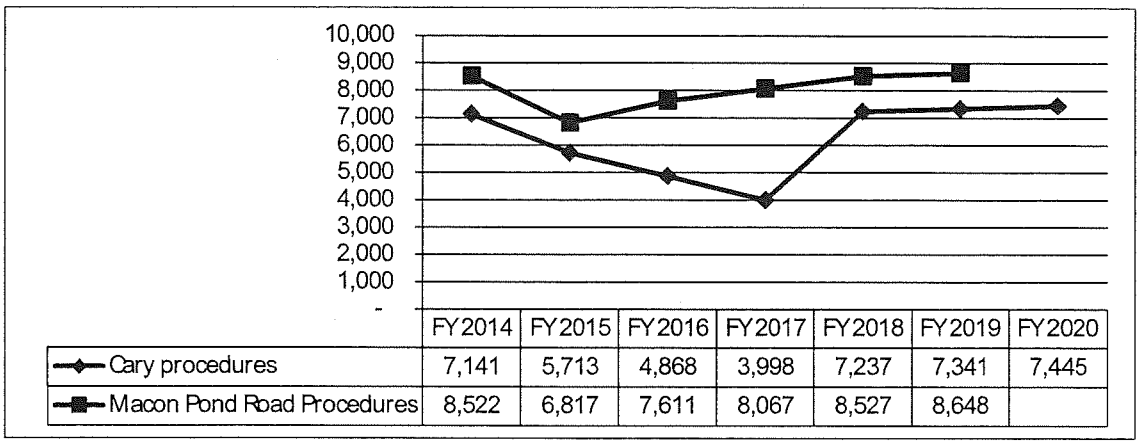
Closer analysis of forecast procedures shows an underlying assumption in the applicant's projections that number of procedures will increase 81 percent in Cary and almost 12 percent at Macon Pond the year the replacement equipment comes on line.

Forecast Linear Accelerator Procedures by FY Cary and Macon Pond

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Cary Procedures	7,141	5,713	4,868	3,998	7,237	7,341	7,445
Percent Change		*-20.0%*	*-14.8%*	*-17.9%*	***81.0%***	*1.4%*	*1.4%*
Macon Pond Procedures	8,522*	6,817	7,611	8,067	8,527	8,648	
Percent Change		*-20.0%*	***11.6%***	*6.0%*	*5.7%*	*1.4%*	

**Estimated at half of the CCNC reported procedures.*

Cary and Macon Pond Procedures



	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
Cary procedures	7,141	5,713	4,868	3,998	7,237	7,341	7,445
Macon Pond Road Procedures	8,522	6,817	7,611	8,067	8,527	8,648	

Forecast Utilization, Cary and Macon Pond Road

	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
Patients both sites	689	551	584	619	656	666	
% change		*-20.0%*	*6.0%*	*6.0%*	*6.0%*	*1.5%*	
Patients Cary	314	251	266	282	299	304	304
% change		*-20.1%*	*6.0%*	*6.0%*	*6.0%*	*1.7%*	0%
Procedures/ pt Cary	22.7	22.8	18.3	14.2	24.2	24.1	24.5
Patients Macon Pond	375	300	318	337	357	362	
%change		-20.0%	6.0%	6.0%	5.9%	1.4%	
Procedures/ pt MPond	22.7	22.7	23.9	23.9	23.9	23.9	22.7

The foundations for such ambitious growth projections are difficult to follow.

The applications include data from Thompson Reuters showing significant increases in cancer cases in of the proposed service area five counties. However, the data are not filtered to remove cancers like melanoma, which are not candidates for radiation therapy. The listed Compound Annual Growth Rates (CAGR) for DRAH patients (Macon Pond p.20) are misleading, because they do not show all counties. As noted earlier, persons in "other" locations identified in the patient origin responses are not identified.

Letters of support for both applications include only three that mention referring patients to the Cary or Macon Pond facility and those letters indicate that the writers' intended referrals also include Duke Raleigh. The applications indicate that DUHS reduced its forecast for Macon Pond and Cary because it may not obtain SRS capability. However, SRS will represent very small number of cases that are appropriate for linear accelerator treatment. Growth is based on the assertion that Duke plans to recruit four more oncologists to Duke Raleigh, but do not quantify the relationship between the recruits and utilization.

On page 20, the Cary application notes that even with two linear accelerators, the Macon Pond site could not serve the Cary patients. Evidence to support the statement is simply that Macon Pond served 385 patients last year. This is inconsistent with the Macon Pond Road application, which indicates that site served 375 in FY 14 (page 33).

Procedures per patient per year change without explanation, with Cary changing by almost 100 percent between FY 2017 and FY 2018.

Cary Procedures per Patient

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Cary procedures	7141	5713	4868	3998	7237	7341	7445
Patients Cary	314	251	266	282	299	304	304
Procedures/ patient	22.7	22.8	18.3	14.2	24.2	24.1	24.5

Source: Cary pages 32 and 33

In Section III, page 33, the Cary application takes the position that if the equipment is installed, patients will come. With no evidence and incomplete historic patient origin information, the application simply makes an assertion that growth will happen, half will go to the Cary site, and that 10 percent of Duke University Medical Center Comprehensive Cancer Center (DUMCCCC) patients from Wake, Johnston, Franklin, Harnett and Nash will go to these two freestanding facilities "because they are closer." Macon Pond is similarly deficient. The applications provide no evidence that they are closer. Given the significant capital invested in DUMCCC, this argument indicates that both projects would unnecessarily duplicate the investment in DUMCCC.

The applications have no methodology for patient origin, only vague assumptions of consistency with past. To achieve the forecasts, patients from Nash, Johnston, Harnett and Franklin Counties would bypass closer Duke Raleigh to reach Cary or Macon Pond. Many Franklin County residents are actually closer to DUMCCC than to the proposed Wake County locations. Thus if proximity is the sole criterion for choice of service, the need argument is unsupported.

On page 35, the Cary application indicates that the projected volume can be accommodated at DUH or Duke Raleigh, while the project is under construction, again indicating that the projects would unnecessarily duplicate existing capacity. The applications attempt to offset this with an assertion that Duke's CFO conducted a breakeven analysis for different multiples of linear accelerators. Both applications lack supporting documentation for that calculation, rendering it questionable.

The applications frequently rely on general statements to justify need of the population to be served. The applications contain no letters from patients or potential patients supporting the proposed replacements. The applications argue for patient convenience, but provide no information from patients confirming this assumption.

The applications fail to make a case that all three linear accelerators will be fully utilized by Project Year 3. The methodology contains several logical flaws:

- Both applications assume that under DUHS ownership the historic number of CCNC cases will decrease only 20 percent in 2015 and rebound will begin immediately upon opening the replacement equipment. As illustrated in Table 9G of the *2013, 2014 and Proposed 2015 State Medical Facilities Plan*, CCNC ESTV's declined over the past three years. CCNC history does not support the rebound pattern. Utilization dropped after FY 2011.

Linear Accelerator History CCNC

	FY2009	FY2010	FY2011	FY2012	FY2013
Procedures	11,923	11,506	16,703	15,771	15,429
Linacs	2	2	2	2	2

- Furthermore, while CCNC had 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 transferred to DRAH (five medical oncologists and one gynecologic oncologist). The caseload is more likely to drop by 60 percent (100 -40 = 60). Such a drop would give the two sites substantially more excess capacity than the current CON applications present. 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 had substantial excess capacity.

  Page 3 of the DUHS 2013 petition acknowledged the declining level of activity on the CCNC equipment, see Attachment C.

- During construction, The Cary application shows that Cary procedures continue to drop but patients will not (See page 4 of these comments). The Cary application provides no support for the forecasts.

- In developing the need, the DUHS application makes no reference to the fact that when DUHS acquired CCNC; the charge structure for the two linear accelerator locations shifted from freestanding to hospital-based. This is much more costly to patients, as demonstrated in Attachment B to these comments. In FY2015, patients who have high deductible and co-insurance burdens may be deterred by the higher DUHS charge structure. Multiple recent reports are showing that high deductibles are a major factor in patient decisions not to use health care services.[2]

[2] High Deductibles Weigh Down More Employees, New York Times, September 1, 2014 http://www.nytimes.com/2014/09/02/business/increasingly-high-deductible-health-plans-weigh-down-employees.html

The applications assert that patients from the proposed service area are going to DUMCCC because DRAH has reached capacity. They do 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 applications mention addition of medical oncologists and GYN surgeons, to the DRAH medical staff, but do not tie these to an unserved need in the proposed service area population for the services of these physicians. Indeed, these physicians had been practicing at or referring to CCNC, and the applications may double count their impact.

The applications indicate that DRAH provides "free healthcare services to members of Project Access" and "laboratory" services to the Open Door Clinic. Neither relate to the proposed linear accelerators.

The competing applications fail to provide a complete picture of need for and use of linear accelerators licensed to operate as part of DRAH.

Also, the applications fall short with regard to need of the population for a second linear accelerator at DRAH. For these reasons and more, both are non-conforming to Criterion 3.

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 applications propose to relocate services provided at Duke University Medical Center Comprehensive Cancer Center in Durham to DRAH, which is not a Comprehensive Cancer Center. The applications do not discuss the effect of the relocation 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. They do not discuss the impact on the viability of the DUMCCC.

The applications are 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.

The applications consider only one alternative, replacement of existing equipment at the two locations. However, the discussions overlook a significant alternative that would involve the same or less capital and potentially much lower cost to patients, operation of these locations as freestanding facilities. The freestanding charge structure and the physicians associated with CCNC produced the history on which the applications rely. As noted above, the applications do not independently demonstrate that the new owner can sustain the patient demand, or the increased demand associated with the increased market shares that both applications forecast.

Footnotes to the Income and Expense Statements (Cary p. 84, Macon Pond p. 83) assume that each site will shift from Freestanding to Provider-based reimbursement. Expenses and Revenues exclude the costs associated with the Radiation Oncologists who are employees of the applicant and are essential to operation of the facility. Thus, the applications fail to show the whole picture of costs of the service to either the applicants or patients under the proposed new arrangement. The applications fail to demonstrate the much lower cost that would be associated with operating the proposed equipment as freestanding centers, as demonstrated in data provided in Parkway Urology's application for an additional linear accelerator and referenced here in Attachment B.

Without independent verification of need for the linear accelerators, it is impossible to determine that it is reasonable to replace them.

The applications fail to mention or provide a mechanism for transferring the planning and simulation information from DUMCCC for the patients who would shift from the Durham location to the DRAH facilities. Normally, this requires additional software and cabling that are not included in the application. Otherwise, the patients would require new planning and simulation they transfer to Cary or Macon Pond; this would be a redundant expense.

The applications do not choose the least costly or most effective. Hence, both are 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 applications appear consistent with Revenue presented in Form C. The treatments listed on Forms D and E appear consistent with the treatment counts presented in Section IV. However, as noted above, Cary treatments per patient vary significantly from one year to the next and the differences are not explained. Moreover, the Expenses presented on Form C for both applications appear to be incomplete.

- The applications fail to explain what happens to staff in the months when the sites are out of service. They disappear from expenses.
- On Form C Macon Pond has a gap from June 30, 2015 to April 1, 2016 and Cary has a gap from April 1, 2016 to December 1, 2016.
- The assumptions include no supporting table for staffing in the interim years, so the reviewer must back into incremental staffing.
- Depreciation on Form C 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, Depreciation associated with the recent purchase of CCNC is excluded in all three Interim Years.
- Other Indirect Expenses drop inexplicably in Year 3 of the Cary application. These expenses include billing, which should increase with the increase in treatments and cases. These expenses are understated.
- Expenses on Form C for Cary include no maintenance for Interim FY 2017, even though the proformas assume operation of the existing equipment during that year. Macon Pond has a similar problem.

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

The financial statements are clearly inconsistent with operational projections in. Hence financial statements are not reliable.

The applications are 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.

The applications propose to increase market share and assert that "other providers would not be able to meet the need to replace the equipment that serves Duke's patients." (Cary p 28; Macon Pond p 27) The applications fail to demonstrate the foundation for increasing market share, and indicate that referrals could come from outside the Duke system. In the unsubstantiated event that this would occur, the patients would not be Duke's patients and without one or both projects, could be referred to another center. In fact, if the number of cases were to stay at levels projected for the interim periods, other providers would have absorbed the cases.

Moreover, in proposing to redirect patients from DUMCCC, the applications fail to acknowledge the fact that that DUMCCC'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 applications. The eight linear accelerators met neither the 6,750 ESTV requirement nor the 250 patient requirement.

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

DUMCCC 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 reported $180 million outstanding principal in 2014[3]. 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[4]). The small percentage (5 percent) suggests that patients are going to DUMCCC for particular reasons associated with faculty, equipment, clinical trials or other programs.

The applications provide no information to demonstrate that the asserted transfer of patients would occur. Moreover, partial treatment at DUMCCC would reduce the number of treatments provided and/or add cost for new treatment planning for the patients. The applications do not indicate that all DUMCCC patients are treated on a TrueBeam linear accelerator.

The applications are 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 applications:

- Project additional staff members but provide no rationale for either location.
- Indicate that Duke Raleigh has eight radiation oncologists, but do not indicate how many will use either facility.
- Make no provision for the cost of commissioning in the capital cost.

The applications are non-conforming to Criterion 7.

[3]Medical Care Commission 2014Annual Report page 28
http://www.ncdhhs.gov/dhsr/ncmcc/pdf/2014/annualreport2014.pdf
4 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 applications appear 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 the Cary and Macon Pond Road linear accelerators will serve a closed medical staff – limited to DRAH; neither makes provision for coordination of care with non-DRAH physicians or physicians who are not on the Duke medical staff.

Duke Health System uses the Epic medical record system which is incompatible with the North Carolina Health Information Exchange (NCHIE) program and Duke has refused to exchange information with the NCHIE.

The applications are, at best, comparatively inferior in this area hence represents less effective alternatives and would be 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.

Neither application discuss the impact of acquisition of the second CCNC linear accelerator at Macon Pond Road. That alone makes it difficult to evaluate projections. Absent those projections or projections for DRAH hospital campus linear accelerator(s), it is impossible to verify that neither project will duplicate the capabilities of the other linear accelerators that DRAH has or has requested. Moreover, both applications propose charges that are higher than the Medicare freestanding rate structure, which DUHS in its request to "transfer for good cause" the second Macon Pond Road linear accelerator Certificate of Need from CCNC. Thus the construction will increase the cost of providing the service. Forecasts for Macon Pond Road do not show sufficient procedures or patients to justify two linear accelerators.

The proposed construction/ renovation will unduly increase the costs of providing health services by Duke University Health System.

Charges in Proforma Forms D increase at six percent a year, which is higher than current medical inflation.

The applications are 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;**

The applications provide no specific information on charity care provided to linear accelerator patients of Duke Raleigh Hospital. In Section VI.13 of both applications, charity and self -pay are combined in a single payor class and there are no data on charity care provided.

Duke University Health System 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. Neither application provides a copy of the 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).

The applications are non-conforming to Criterion 13(b).

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 projects will not increase competition. They will replace two existing linear accelerators at DUHS locations in Service Area 20.

COST EFFECTIVENESS

The applications fail to demonstrate that purchasing the replacement equipment is cost effective. The proposed solutions will involve higher Medicare and Medicaid payments and contribute to long-term high costs to patients and to Medicare.

Very few cancer patients have tumors of the type that justify SRS treatments. DUHS with more than 1800 patients provided only 939 such treatments at DUMCCC (2.5 percent of total) in 2013.

The applications are non-conforming to Criterion 18a.

Attachment B

XIV. Comparison of Regimens based on Place of Service

The following tables demonstrate the comparison of various regimens between hospital-based centers with a fee for service physician, and the freestanding center.

These comparisons reflect the national unadjusted rates.

Hospital & Fee for Service vs. Global

Hospitals are paid under OPPS [Outpatient Prospective Payment System]. Under OPPS, each code is assigned an APC [Ambulatory Payment Classification] that corresponds to a code. Each APC category can have multiple CPT codes, but they are paid under the same value.

- In the hospital setting, the APC (yellow) and Professional (blue) Medicare rate are added together.
- In the freestanding center, a single global rate (purple) is reported.

Prostate Reimbursement Comparisons

Prostate	APC	APC RVU	Medicare Pro	RVU Pro	Medicare Global	RVU Global
205b Prostate 3D/3D	$14,740.53	378.83	$3,504.54	97.83	$17,112.19	477.69
205c Prostate 3D/IMRT Boost	$19,268.68	473.44	$3,676.85	102.64	$20,673.70	577.11
205d Prostate IMRT	$24,103.30	538.71	$2,839.67	79.27	$22,174.67	619.01
205db Prostate IMRT w Boost	$24,791.20	544.59	$3,033.12	84.67	$22,578.75	630.29
205d-c Prostate IMRT Arc w IGRT	$23,644.70	590.56	$3,493.08	97.51	$24,685.49	689.10
205e Prostate 2D-Seeds	$15,030.08	263.38	$4,175.15	116.55	$13,647.05	380.96
206 Prostate SBRT-3D Plan	$16,220.59	237.94	$2,546.64	71.09	$11,140.89	311.00

Breast Reimbursement Comparisons

Breast	APC	APC RVU	Medicare Pro	RVU Pro	Medicare Global	RVU Global
152 Breast 4-3D/ e-	$12,280.78	289.38	$3,035.98	84.75	$13,439.28	375.16
152a Breast 2-3D/ e-	$11,395.20	281.56	$2,752.98	76.85	$12,876.15	359.44
152b Breast 2-3D/ Photon Boost	$11,526.62	276.02	$2,836.45	79.18	$12,761.16	356.23
153 Breast 2-IMRT	$17,703.10	437.20	$2,988.34	83.42	$18,145.32	506.53
153A Breast: 2-IMRT with Electron Boost*	$20,114.59	476.23	$2,963.26	82.72	$20,060.05	559.98
153B Breast: 2-IMRT with Photon Boost*	$20,246.01	469.50	$3,046.73	85.05	$19,902.43	555.58

Lung Reimbursement Comparisons

Lung	APC	APC RVU	Medicare Pro	RVU Pro	Medicare Global	RVU Global
182 Lung 2-3D/3-3D	$13,774.07	358.93	$3,288.17	91.79	$16,182.95	451.75
183 Lung 3-IMRT/R-IMRT	$25,141.63	564.17	$3,052.10	85.20	$23,299.15	650.40
184 Lung 3-IMRT/3-IMRT	$26,604.04	633.81	$3,830.17	106.92	$26,571.92	741.76

Head & Neck Reimbursement Comparisons

Head & Neck	APC	APC RVU	Medicare Pro	RVU Pro	Medicare Global	RVU Global
170 H&N TI Larynx	$9,290.27	250.38	$2,049.06	57.20	$11,000.47	307.08
171 H&N 3C/4C/2C	$15,446.04	355.00	$3,541.44	98.86	$15,985.57	446.24
172 H&N 3C/4C/3-3D	$16,843.15	365.73	$4,145.77	115.73	$17,235.78	481.14
173 H&N 2-3D/4-3D	$12,334.57	286.13	$2,997.65	83.68	$13,284.53	370.84
174 H&N 3-3D/2-3D/2-3D	$14,915.45	329.64	$3,665.03	102.31	$15,510.56	432.98
174a H&N 3-3D/2-3D	$13,999.78	326.61	$3,351.22	93.55	$15,088.21	421.19
175 H&N 4-IMRT BID	$36,090.59	793.83	$3,628.85	101.30	$32,102.96	896.16
176 H&N 7-IMRT	$24,636.94	507.14	$3,549.32	99.08	$21,791.37	608.31
177 H&N Field in Field	$12,969.64	291.73	$3,260.95	91.03	$13,748.43	383.79

XV. Comparing Reimbursement Based on POS

The following demonstrates the reimbursement differential based on place of service (POS).

The freestanding center receives less reimbursement than the combined hospital and fee for service

Prostate	**Freestanding**	**APC & MD**	**Differential**
205b Prostate 3D/3D	$17,112.19	$18,245.07	($1,132.88)
205c Prostate 3D/IMRT Boost	$20,673.70	$22,945.53	($2,271.83)
205d Prostate IMRT	$22,174.67	$26,942.97	($4,768.30)
205db Prostate IMRT w Boost	$22,578.75	$27,824.32	($5,245.57)
205d-c Prostate IMRT Arc w IGRT	$24,685.49	$27,137.78	($2,452.29)
205e Prostate 2D-Seeds	$13,647.05	$19,205.23	($5,558.18)
206 Prostate SBRT-3D Plan	$11,140.89	$18,767.23	($7,626.34)
Breast	**Freestanding**	**APC & MD**	**Differential**
152 Breast 4-3D/ e-	$13,439.28	$15,316.76	($1,877.48)
152a Breast 2-3D/ e-	$12,876.15	$14,148.18	($1,272.03)
152b Breast 2-3D/ Photon Boost	$12,761.16	$14,363.07	($1,601.91)
153 Breast 2-IMRT	$18,145.32	$20,691.44	($2,546.12)
153A Breast: 2-IMRT with Electron Boost	$20,060.05	$23,077.85	($3,017.80)
153B Breast: 2-IMRT with Photon Boost	$19,902.43	$23,292.74	($3,390.31)
Lung	**Freestanding**	**APC & MD**	**Differential**
182 Lung 2-3D/3-3D	$16,182.95	$17,062.24	($879.29)
183 Lung 3-IMRT/R-IMRT	$23,299.15	$28,193.73	($4,894.58)
184 Lung 3-IMRT/3-IMRT	$26,571.92	$30,434.21	($3,862.29)
Head & Neck	**Freestanding**	**APC & MD**	**Differential**
170 H&N TI Larynx	$11,000.47	$11,339.33	($338.86)
171 H&N 3C/4C/2C	$15,985.57	$18,987.48	($3,001.91)
172 H&N 3C/4C/3-3D	$17,235.78	$20,988.92	($3,753.14)
173 H&N 2-3D/4-3D	$13,284.53	$15,332.22	($2,047.69)
174 H&N 3-3D/2-3D/2-3D	$15,510.56	$18,580.48	($3,069.92)
174a H&N 3-3D/2-3D	$15,088.21	$17,351.00	($2,262.79)
175 H&N 4-IMRT BID	$32,102.96	$39,719.44	($7,616.48)
176 H&N 7-IMRT	$21,791.37	$28,186.26	($6,394.89)
177 H&N Field in Field	$13,748.43	$16,230.59	($2,482.16)

Attachment C

RECEIVED
By K Fisk at 3:45 pm, Aug 01, 2012

NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

PETITION FOR ADJUSTMENT TO NEED DETERMINATION IN SERVICE AREA 20 FOR ADDITIONAL LINEAR ACCELERATOR

Petitioner Duke University Health System, Inc. d/b/a Duke Raleigh Hospital ("Duke Raleigh") hereby submits this petition to adjust the need determination for linear accelerators in Service Area 20 in the 2013 State Medical Facilities Plan for one additional linear accelerator.

Petitioner

Duke University Health System, Inc. d/b/a Duke Raleigh Hospital
3400 Wake Forest Road
Raleigh, NC 27609-7373

Contact: Catharine W. Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd.
Suite 1300
Durham, NC 27707
(919) 668-0857
catharine.cummer@duke.edu

Statement of the Proposed Change

Duke Raleigh proposes that the need for linear accelerators in Service Area 20 (Wake, Franklin, and Harnett Counties) be increased to one additional linear accelerator, to reflect the unmet demand for additional linear accelerator capacity in the service area.

Reasons for Proposed Change

The existing need determination that no additional linear accelerators for Service Area 20 are needed results from a methodology reflecting the total number of existing and approved number of linear accelerators in the Service Area. However, two factors at play in the service area are not fully recognized in this methodology:

1) Cancer Centers of North Carolina obtained a certificate of need for a second linear accelerator pursuant to a need determination set forth in the 2007 State Medical Facilities Plan. After all appeals were completed, the certificate of need was issued in

February 2011. Since that time, Cancer Centers of North Carolina has made no progress towards the implementation of this asset and has not provided a timetable for expected completion. Therefore, this need has not been met.

2) Utilization over the past several years reflects an imbalance between highly utilized and underutilized equipment that has not corrected over several years, suggesting that apparent capacity in the service area may not be available as a practical matter to alleviate demand.

These factors are discussed at greater length below.

1. Cancer Centers of North Carolina linear accelerator certificate of need

A need for an additional linear accelerator was recognized in the 2007 State Medical Facilities Plan, reflecting 36,620 ESTVs performed on a total of 7 linear accelerators. Several applicants, including Duke Raleigh Hospital, applied to acquire equipment pursuant to this need determination. After a competitive review, the CON Section issued a decision approving the application of Cancer Centers of North Carolina ("CCNC") to acquire a linear accelerator capable of performing stereotactic radiosurgery. After appeals of the decision, a CON was issued to CCNC in February 2011.

In the interim, however, CCNC acquired Wake Radiology Oncology Services and thereby gained access to a second linear accelerator. Since the issuance of its CON in February 2011, CCNC has not spent any money, nor taken any material steps toward the development of the equipment for which it has a CON. In its March 28, 2012 progress report to the CON Section (attached as Exhibit A), CCNC cited developments in available technology and its acquisition of Wake Radiology Oncology Services as reasons for its delay: "We have been analyzing the impact to these developments to identify the optimal way to implement the project, but we will fully intend to proceed with this project, once our analysis is complete." CCNC did not, however, indicate when its analysis would be complete, and provided no updated project timetable. Therefore, equipment found to be needed five years ago has yet to be added to the inventory, and there is no prospect for when it will be.

It is true that an additional office-based linear accelerator was put into service in Franklin County in 2006. This linear accelerator was acquired without a certificate of need under a prior version of the certificate of need statute, which regulated "oncology treatment centers" but not linear accelerators if the total cost of the equipment and construction was less than $250,000. Accordingly, the Franklin County Cancer Center began serving patients in Louisburg on a linear accelerator (purchased for $57,726.50) on May 1, 2006. (See May 9, 2011 correspondence from CON Section attached as Exhibit B.) Although the volumes on this linear accelerator were not reported in the SMFP until this year, its reported utilization for 2010-11 (5 year after it began service) remained at only 1407 ESTVs, or 20.84% of capacity.[1]

[1] In addition, Parkway Urology, PA d/b/a Cary Urology PA has been awarded a certificate of need for a dedicated linear accelerator for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, which is not counted in the regular inventory of linear accelerators. Because this is a dedicated-use

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.

linear accelerator under the control of a different provider in times of high demand on the equipment on which they began treatment. As a result, Duke Raleigh is facing increasing difficulty in meeting the needs of its patients on its single linear accelerator. Since February 2012 it has extended hours of operation in Radiation Oncology from an average of 8.5 hours per day to almost 10 hours per day, with the equipment in use some days for 12 hours or more. This increased utilization also causes stress on the machine, and is reflected in an increase in maintenance issues. The downtime needed to address these maintenance issues can cause scheduling delays and further exacerbates the capacity pressures on Duke Raleigh's sole linear accelerator.

Adverse effect on providers and consumers without change:

Without the requested adjustment to the need determination, patients will have increasing challenges in finding access to linear accelerator treatment. Although providers with high utilization such as Duke Raleigh may further expand hours of treatment to try to meet patient needs, such expansion is not feasible indefinitely.

Alternatives considered

The only alternative to adjusting the need is to leave the determination as it currently stands, which does not provide sufficient access to services in the Service Area 20.

Evidence that the proposed change would not result in unnecessary duplication of health resources in the area

As set forth above, some existing providers appear to have capacity on their existing equipment, but the experience of several years demonstrates that this apparent capacity has not relieved the high utilization on other providers. Therefore, while the proposed change would increase the number of linear accelerators in the Service Area, the expansion is necessary to provide adequate access.

Evidence that the requested change is consistent with the Basic Principles of Safety and Quality, Access, and Value

The requested change will improve value by allowing potential providers to pursue cost-effective and efficient expansions of services. It is not a tenable long-term solution to have certain providers continue to provide services well above capacity, as it makes scheduling procedures for patients difficult, leads to increased maintenance costs and delays, and may require more frequent replacement of equipment.

Conclusion

For all the reasons set forth herein, Duke Raleigh respectfully requests that the need determination for linear accelerators in Service Area 20 be adjusted to find a need for a single additional linear accelerator.

CERTIFICATE OF NEED PROGRESS REPORT FORM

County: Wake Date of Progress Report: March 28, 2012
Facility: Cancer Centers of North Carolina, P.C. Facility I.D. #: 050382
formerly known as Raleigh Hematology Oncology Associates, P.C.
Project I.D. #: #J-7941-07 Effective Date of Certificate: February 4, 2011
Project Description: Acquire a second linear accelerator with stereotactic radiosurgery capabilities to be located at the Macon Pond Road facility in Raleigh/Wake County.

A. Status of the Project

(a) Describe in **detail** the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

Up to this point, no capital expenditures have been obligated. The certificate of need for this project was issued on February 4, 2011, about three years from the date of the project's original approval by the CON Section, and there have been intervening developments affecting the Varian Trilogy technology which we are analyzing. The proponent also has acquired another linear accelerator that already was in operation in the service area. We have been analyzing the impact of these developments to identify the optimal way to implement the project, but we still fully intend to proceed with this project, once our analysis is complete.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete **until** *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS). Not Applicable now.

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

PROJECT MILESTONES	Projected Completion Date from certificate	Actual completion date	Proposed completion date
	Month/day/year	Month/day/year	Month/day/year
Obtained Funds for the Project	01/15/2011		
Final Drawings and Specifications Sent to DHSR	03/01/2011		
Acquisition of land/facility	N/A		
Construction Contract Executed	04/01/2011		
25% completion of construction	05/01/2011		
50% completion of construction	05/21/2011		
75% completion of construction	06/12/2011		
Completion of construction	07/07/2011		
Ordering of medical equipment	01/15/2011		
Operation of medical equipment	07/07/2011		
Occupancy/offering of services	07/07/2011		
Licensure	07/07/2011		
Certification	N/A		

2. If the project is experiencing significant delays in development: Please see the response above in Section A.

EXHIBIT A

a. explain the reasons for the delay; and
b. provide a revised timetable for the CON Section to consider.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired. Not Applicable at present.

D. Capital Expenditure

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	**Total Cumulative Capital Expenditure**
Site Costs		
Purchase price of land	0	0
Closing costs	0	0
Legal Fees	0	0
Site preparation costs	0	0
Landscaping	0	0
Other site costs (identify)	0	0
Subtotal Site Costs	**0**	**0**
Construction Costs		
Construction Contract	0	0
Miscellaneous Costs		
Moveable Equipment	0	0
Fixed Equipment	0	0
Furniture	0	0
Consultant Fees	0	0
Financing Costs	0	0
Interest during Construction	0	0
Other Misc. Costs (identify)	0	0
Subtotal Misc. Costs	**0**	**0**
Total Capital Cost of the Project	**0**	**0**

2. What do you project to be the remaining capital expenditure required to complete the project? $4,336,603.00

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference. Not expected at present.

E. CERTIFICATION – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer:	
Name and Title of Responsible Officer	Alan Kritz, MD President
Telephone Number of Responsible Officer	919-781-7070

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ▸ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

May 9, 2011

Robert McLaurin, M.D., President
Precision Radiation Oncology Systems, Inc.
d/b/a Franklin County Cancer Center
113 Jolly Street
Louisburg, NC 27549

RE: Inquiry / Precision Radiation Oncology Systems, Inc. d/b/a Franklin County Cancer Center / Acquire a linear accelerator prior to August 26, 2005 / Franklin County

Dear Dr. McLaurin:

The purpose of this letter is to notify you of the Certificate of Need Section's determination regarding the above referenced inquiry.

Pertinent portions of the Certificate of Need Law are summarized below:

1. Prior to August 26, 2005 and as of the date of this letter, G.S. 131E-178(a) states in part *"No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department."*
2. Prior to August 26, 2005 and as of the date of this letter, "new institutional health service" is defined in part in G.S. 131E-176(16)a as *"The construction, development, or other establishment of a new health service facility."*
3. Prior to August 26, 2005, "health service facility" was defined in G.S. 131E-176(9b) as *"a hospital; psychiatric facility; rehabilitation facility; nursing home facility; adult care home; kidney disease treatment center, including freestanding hemodialysis units; intermediate care facility for the mentally retarded; home health agency office; chemical dependency treatment facility; diagnostic center; oncology treatment center; hospice, hospice inpatient facility, hospice residential care facility; and ambulatory surgical facility."* (Emphasis added.)
4. Prior to August 26, 2005, "oncology treatment center" was defined in G.S. 131E-176(18a) as *"a facility, program, or provider, other than an existing health service facility that provides services for diagnosis, evaluation, or treatment of cancer and its aftereffects or secondary results and for which the total cost of all the medical equipment utilized by the center, exceeds two hundred fifty thousand dollars ($250,000). In determining whether costs are more than two hundred fifty thousand dollars ($250,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the facility, program, or provider shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater."*
5. Prior to August 26, 2005 and as of the date of this letter, "new institutional health service" is defined in part in G.S. 131E-176(16)b as *"Except as otherwise provided in G.S. 131E-184(e), the obligation by any*

EXHIBIT B

person of a capital expenditure exceeding two million dollars ($2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars ($2,000,000)."

The CON Section has determined the following:

1. On July 21, 2005, Precision Radiation Oncology Systems, Inc. (PROS) and RSA executed a contract whereby PROS purchased a linear accelerator from RSA.
2. Raleigh Development Company (RDC) proposed to buy the Perry-Medders Building and lease it to PROS. There was no common ownership or other relationship between PROS and RDC.
3. On August 22, 2005, RDC entered into a contract to purchase the Perry-Medders Building.
4. The total capital cost to acquire and make operational the linear accelerator acquired by PROS on July 21, 2005 was $181,495.45, as shown in the following table.

Linear Accelerator (includes couch)	$57,726.50
Vault	$79,583.48
Treatment Planning Workstation (online service)	$5,000.00
Film Processor, film cassettes, viewboxes	$8,169.45
Patient Monitoring	$200.00
Positioning Lasers	$2,257.70
Movable Equipment	$11,482.31
Landscaping	$1,000.00
Legal Fees	$5,346.00
Architect & Engineering Fees	$10,730.01
Total	$181,495.45

6. When PROS acquired the linear accelerator, the threshold for an oncology treatment center was $250,000. The total capital cost to acquire and make operational the linear accelerator acquired by PROS on July 21, 2005 was less than $250,000. Therefore, as of July 21, 2005 when PROS acquired the linear accelerator, the proposal was not a new institutional health service which required a certificate of need.
7. During the 2005 Session, the General Assembly ratified Senate Bill 740 which:
   a. deleted "oncology treatment center" from the definition of "health service facility" in G.S. 131E-176(9b);
   b. deleted the definition of "oncology treatment center" in G.S. 131E-176(18a);
   c. added a definition of "linear accelerator" in G.S. 131E-176(14b1); and
   d. added "linear accelerator" to G.S. 131E-176(16)f1.
   e. Section 7 of Senate Bill 740 provides that the change in the law regarding hospices and hospice offices would be effective December 31, 2005 and the remainder of the act would be effective when it became law. Senate Bill 740 was signed by the Governor on August 26, 2005. As a result, effective August 26, 2005, the acquisition of a linear accelerator requires a certificate of need regardless of the cost to acquire and make it operational.
8. RDC and PROS were unable to agree on the terms of the lease and RDC and PROS "terminated" the lease on September 9, 2005.

9. Jolly Holdings, LLC was created on September 20, 2005. There is significant common ownership between Jolly Holdings, LLC and PROS. Jolly Holdings, LLC is wholly-owned by Robert McLaurin, MD, who owns approximately 98% of the outstanding shares in PROS.
10. Jolly Holdings, LLC purchased the Perry-Medders Building for $271,250 on November 14, 2005.
11. The linear accelerator acquired by PROS on July 21, 2005 was installed in a vault added to the Perry-Medders Building. The linear accelerator began serving patients on May 1, 2006 and has continued to serve patients since then.
12. Including the cost to purchase the Perry-Medders Building, the total capital cost to acquire and make operational the linear accelerator acquired by PROS on July 21, 2005 was $452,745.45.
13. PROS already owned the linear accelerator before the law changed on August 26, 2005, having acquired a vested interest as of July 21, 2005, including the cost to install it in the Perry-Medders Building which was to be leased from RDC, an unrelated third party.
14. The plans for RDC to acquire the Perry-Medders Building and lease it to PROS fell through after the law changed on August 26, 2005.
15. As of November 14, 2005, the applicable threshold for determining if the acquisition of the Perry-Medders Building resulted in a new institutional health service which required a certificate of need was $2,000,000. Including the cost to purchase the Perry-Medders Building, the total capital cost to acquire and make operational the linear accelerator acquired by PROS on July 21, 2005 was only $452,745.45. Therefore, acquisition of the Perry-Medders Building by Jolly Holdings, LLC on November 14, 2005 did not result in the development of a new institutional health service which required a 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,

Martha J. Frisone

Martha J. Frisone, Assistant Chief

Craig R. Smith

Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR
Lee M. Whitman, Wyrick Robbins Yates & Ponton, LLP

Duke Raleigh Hospital
Linear Accelerator Volumes
FY 11 and FY 12

Charge Code Description	CPT CODE	FY11	FY12
RAD TX DEL SIMPLE 6-10	77403	83	-
RAD TX DEL SIMPLE 11-19	77404	49	104
RAD TX DEL INTRMD 6-10	77408	-	-
RAD TX DEL CMPLX TO 5	77412	-	-
RAD TX DEL CMPLX 6-10	77413	1,024	1,100
(M) 11-19 MeV	77414	-	-
11-19 MeV	77414	4,336	5,818
RAD TX DEL CMPLX 11-19	77414	-	-
(M) 20 MeV OR GREATER	77416	-	10
THER RAD PORT FILM	77417	1,920	2,663
IMRT TX	77418	1,034	1,447
TOTAL ESTVs		7,486	9810.5

EXHIBIT C