

**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  
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**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.<sup>1</sup>

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<sup>1</sup> 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

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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.

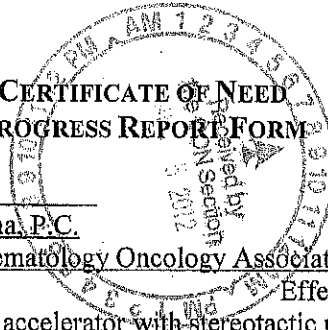
**Evidence that the requested change is consistent with the Basic Principles of Safety and Quality, Access, and Value**

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.

- 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].

	<u>Capital Expense Since Last Report</u>	<u>Total Cumulative Capital Expenditure</u>
<b>Site Costs</b>		
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
<b>Subtotal Site Costs</b>	<b>0</b>	<b>0</b>
<b>Construction Costs</b>		
Construction Contract	0	0
<b>Miscellaneous Costs</b>		
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
<b>Subtotal Misc. Costs</b>	<b>0</b>	<b>0</b>
<b>Total Capital Cost of the Project</b>	<b>0</b>	<b>0</b>

- 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](http://www.ncdhhs.gov/dhsr)

Craig R. Smith, Section Chief  
Phone: 919-855-3873  
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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*



*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.

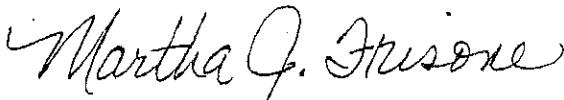
Linear Accelerator (includes couch)	\$57,726.50
Vault	\$79,583.48
Treatment Planning Workstation (online service)	\$5,000.00
Film Processor, film cassettes, viewboxes	\$8,169.45
Patient Monitoring	\$200.00
Positioning Lasers	\$2,257.70
Movable Equipment	\$11,482.31
Landscaping	\$1,000.00
Legal Fees	\$5,346.00
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, Assistant Chief



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