

RECEIVED

By K Fisk at 2:28 pm, Aug 17, 2012



Cancer Centers of North Carolina

Medical Oncology

Neeraj Agrawal, M.D.
William R. Berry, M.D.
Elizabeth E. Campbell, M.D.
Roy Cromartie, M.D.
Margaret A. Deutsch, M.D.
Shaun C. Donegan, M.D.
Charles F. Eisenbeis, MD., Ph.D.
Maha A. Elkordy, M.D.
Alan D. Kritz, M.D.
Virgil L. Rose, M.D.
Paramjeet Singh, M.D.
Stephen J. Tremont, M.D.
Mark Yoffe, M.D.

Radiation Oncology

Andrew S. Kennedy, M.D., FACRO
John F. Reilly, Jr., M.D.
Scott L. Sailer, M.D.

ENT Surgical Oncology

Scott D. Meredith, M.D.

Gynecologic Oncology

Monica B. Jones, M.D.
Jennifer Rubatt, M.D.

August 17, 2012

VIA E-MAIL (DHSR.SMFP.Petitions-Comments@dhhs.nc.gov)
VIA FACSIMILE (919-715-4413)

North Carolina Division of Health Service Regulation
Medical Facilities Planning Section
Edgerton Building
809 Ruggles Drive
Raleigh, NC 27603

RE: Comments re: Petition submitted by Duke University Health System, Inc. d/b/a Duke Raleigh Hospital for Adjustment to Need Determination in Service Area 20 for Additional Linear Accelerator

To Whom It May Concern:

Cancer Centers of North Carolina ("CCNC") submits this letter in response to the above-referenced petition in which Duke University Health System, Inc. d/b/a Duke Raleigh Hospital ("Duke Raleigh") proposes that the need for linear accelerators in Service Area 20 in the 2013 State Medical Facilities Plan be increased to one additional linear accelerator. For the reasons stated below, CCNC contends that Duke Raleigh's petition does not paint an accurate picture of linear accelerator usage in Service Area 20, and therefore its conclusions are based on a number of factual inaccuracies and/or faulty assumptions.

1. Although Duke Raleigh's ESTV volume in 2011-2012 increased over the 2010-2011 volume in by approximately 25%, the chart on page 3 of Duke Raleigh's petition reveals that this is an unprecedented increase and that historically Duke Raleigh's ESTV volume has experienced zero growth. In fact, the 2011-2012 growth spike is merely an aberration reflecting the fact that Duke Cancer Center in Durham underwent renovations during that time period, thus requiring Duke patients who normally received treatments in Durham to receive them at Duke Raleigh. As a result, Duke Raleigh's purported concern that it does not have the capacity to treat its patients is unfounded and predicated on a situation that no longer exists.

www.cancercentersofnc.com

Raleigh
4101 Macon Pond Road
Raleigh, NC 27607

Phone (919) 781-7070
Fax (919) 571-9352

North Raleigh
10010 Falls of Neuse Road
Suite 203
Raleigh, NC 27614

Phone (919) 431-9201
Fax (919) 431-9213

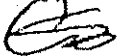
Clayton
555 Medical Park Place
Suite 108
Clayton, NC 27520

Phone (919) 781-7070
Fax (919) 571-9352

2. Duke Raleigh's annual cancer center report (a copy of which is attached) reveals its plans to initiate high-dose rate ("HDR") and prostate seed implant brachytherapy procedures by the end of 2012. The implementation of these procedures will lessen linear accelerator demand, as they do not rely on external beam radiation therapy.
3. Duke Raleigh's petition correctly notes that CCNC acquired Wake Radiology Oncology Services in Cary, North Carolina in 2011. However, that acquisition has not impacted CCNC's radiation treatment procedure volumes at its Raleigh location. Treatment volumes have remained consistent, and as recently reported, the ESTV volume at CCNC's Raleigh location was 11,223.5 in 2012; a copy of our report is attached.
4. The delay in the development of CCNC's new linear accelerator is not without precedent, as projects approved by CON are routinely delayed for a variety of reasons. CCNC's justification for the delay is rational and does not justify a complete departure from the established need determination methodology or ignorance of the actual confirmed ESTV procedure volumes.

CCNC remains committed to the acquisition and installation of its new CON Section-approved linear accelerator in a reasonably expedited timeframe. In the meantime, though, CCNC respectfully requests that the CON Section reject Duke Raleigh's petition as without merit.

Sincerely,



Alan Kritz, MD

President



[Home](#) > [Services](#) > [Cancer Center](#) > [About Us](#) > [2011 Reports](#) > Radiation Oncology Report

Cancer Center

Radiation Oncology Report



Carol A. Hahn, MD
Medical Director Radiation Oncology

Share

Radiation oncology services at Duke Raleigh Hospital have continued to grow in the last year. We've seen increases in the numbers of patients and in the complexity of treatments delivered. In the last year, we have completed technological upgrades to our Linear Accelerator to allow for On Board Imaging (OBI) and Cone Beam CT (CBCT). These imaging technologies allow for increased precision in targeting radiation treatments and have furthered the utilization of Image Guided Radiotherapy (IGRT) to provide improved precision in treatment delivery.

Additionally, these technological upgrades allow accurate delivery of complex Intensity Modulated Radiotherapy (IMRT). This will also be available to be delivered in a more rapid fashion using Rapid Arc technology that will be available in January 2012 to improve patient convenience and comfort.

Following the Linear Accelerator upgrade, upgrades to the CT simulator were also completed in the last year, and we installed a large-bore multi-slice helical CT scanner with superior image speed and resolution. This new equipment allows us to perform 4-dimensional CT to plan and deliver radiation synchronized to patient respiration.

This technology is important for patients with tumors in the chest and abdomen, which can exhibit significant movement during the respiratory cycle. Use of respiratory monitoring and timing radiation delivery to certain portions of a patient's respiratory cycle helps protect the hearts of our patients with left-sided breast cancer. The new CT simulator has the largest field of imaging view within the Duke University Health System, allowing patients up to 650 pounds to have the option of CT-based planning for precise localization of their treatment. Additional upgrades to both hardware and software are planned in early 2012.

Duke Raleigh continues to be the only center in Wake County to offer multidisciplinary subspecialty clinics. The Thoracic Oncology multidisciplinary clinic is held in the Duke Raleigh Radiation Oncology Clinic and is a combined effort of Duke Radiation Oncology, staffed by Dr. Catherine Chang, along with Duke Thoracic Surgery and Duke Medical Oncology. This clinic is held every Friday and is coordinated by Patient Navigator, Brenda Wilcox, RN. Patients seen in the Thoracic Multidisciplinary Clinic are evaluated by three subspecialty physicians in the same clinic to determine optimal therapy and assess their eligibility for therapy on Duke clinical trials. Imaging slots are held in Duke Raleigh diagnostic radiology specifically for the multidisciplinary clinic patients to expedite patient evaluation and initiation of therapy. With expansion of Duke Gastrointestinal (GI) Oncologic Surgery at Duke Raleigh Hospital, we have also added a multidisciplinary clinic for our patients with colorectal cancers, held every Thursday morning and staffed by Dr. Carol Hahn, Medical Director of Radiation Oncology, along with Duke Medical Oncology and Duke colorectal tumor surgeons.

We are expanding our brachytherapy services in Wake County. With the expansion of the GU Oncology Service at Duke Raleigh, we will provide services in prostate brachytherapy - seed implants for prostate cancer - beginning in January 2012. Plans are under development for installation of a High Dose Rate (HDR) afterloader in a dedicated brachytherapy suite to be opened in the fall of 2012. This facility will provide additional treatment options for both our gynecologic oncology patients with vaginal brachytherapy and our breast cancer patients with accelerated partial breast radiotherapy (APBI) delivered with balloon catheter techniques.

Along with the growth in patient treatment, radiation oncology continues to provide our patients with the highest level of customer satisfaction. Patient satisfaction scores of more than 97% on Press Ganey surveys were reported in November 2011 with Radiation Oncology consistently leading outpatient satisfaction scores at Duke Raleigh.

Overall, Duke Raleigh Radiation Oncology continues to grow in volume, services and patient satisfaction, and we anticipate continued growth in 2012. As active and full participants in the Duke University Medical Center Department of Radiation Oncology, we continue to work closely with both Duke Raleigh administration as well as Duke Health System and Duke Cancer Institute leadership to further the growth of Duke cancer care in Wake County.



Registration and Inventory of Medical Equipment
Linear Accelerator Equipment
January 2012

Instructions

This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for linear accelerator equipment. Please complete all sections of this form and return to the Medical Facilities Planning Branch by **Friday, January 27, 2012**.

1. Complete and sign the form
2. Return the form by one of two methods:
 - a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov
 - b. Mail the form to Kelli Fisk, Medical Facilities Planning Branch, 2714 Mail Service Center, Raleigh, NC 27699-2714.

Note: Fixed equipment operated in a facility licensed under a hospital should be reported on that hospital's license renewal application, and not duplicated on this form.

If you have questions, call Kelli Fisk in the Medical Facilities Planning Branch at (919) 855-3865 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Section 1: Contact Information

1. Full legal name of corporation, partnership, individual, or other legal entity that acquired the equipment by purchase, donation, lease, transfer, or comparable arrangement:

Cancer Centers of North Carolina, P.C.
 (Legal Name)

2. Address of the corporation, partnership, individual, or other legal entity that acquired the equipment:

4101 Macon Pond Road
 (Street and Number)

Raleigh
 (City)

NC 27607
 (State) (Zip)

(919) 781-7070
 (Phone Number)

3. Chief Executive Officer or approved designee who is certifying the information in this registration form:

Thomas A. Grates
 (Name)

Executive Director
 (Title)

4000 WestChase Bld., Suite 300
 (Street and Number)

Raleigh
 (City)

NC 27607
 (State) (Zip)

(919) 829-4458
 (Phone Number)

Tom.Grates@USOncology.com
 (Email)

4. Information Compiled or Prepared by: Don Brelsford
 (Name)

(919) 829-4448
 (Phone Number)

Don.Brelsford@USOncology.com
 (Email)



Registration and Inventory of Medical Equipment
Linear Accelerator Equipment – January 2012

Page 2 of 6

Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2010 – 9/30/2011 Other time period: _____

(Please make additional copies of pages of this form as needed.)

	Linear Accelerator Number 1	Linear Accelerator Number 2	Total Units
Serial or I.D. Number	1009	M2896	2
Model Number	2100 CD	Primus	
Manufacturer	Varian	Siemens	
Certificate of Need Project ID	None	J5464-96 (see note below)	
Date of Purchase	3/16/2005	7/01/1998	
Purchase Price	\$325,460.58	\$1,460,426.00	
Service Site Information: Please include all of the information requested for each location.	Service Site <u>CCNC-Macon Pond</u> Address <u>4101 Macon Pond Rd</u> City, State, Zip <u>Raleigh, NC 27607</u> County <u>Wake</u>	Service Site <u>CCNC - Cary Rad</u> Address <u>300 Ashville Ave</u> <u>Suite 110</u> City, State, Zip <u>Cary, NC 27518</u> County <u>Wake</u>	
Configured for stereotactic radiosurgery?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Total Units
Number of unduplicated patients* who received radiation oncology treatment on the linear accelerator	470	330	Total Patients 800

- Patients shall be counted once if they receive one course of radiation oncology treatment using the linear accelerator 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. The number of patients reported here should match the number of patients reported in the Linear Accelerator Treatment Patient Origin chart on page 4 of this report.

Note: Cancer Centers of North Carolina, P.C., acquired Wake Radiology/Oncology Services effective May 9, 2011. The number of unduplicated patients and procedures listed on this report reflect the full year activities, combining data from WROS from 10/01/2010 through 5/08/2011, with the data from CCNC from 5/09/2011 through 9/30/2011.

Name of entity that acquired the equipment (from page 1) Cancer Centers of North Carolina, P.C.


 Registration and Inventory of Medical Equipment
 Linear Accelerator Equipment – January 2012

Page 3 of 6

Section 2: Equipment and Procedures Information continued

	Treatment Simulator** Number 1	Treatment Simulator Number 2	Total Units
Serial or I.D. Number	919787USCT	4125	2
Model Number	Lightspeed Qx/I CT Scanner	SimView 3000	
Manufacturer	GE	Siemens	
Certificate of Need Project ID	None	J5464-96 (see note below)	
Date of Purchase	3/08/2005	7/01/1998	
Purchase Price	\$402,841.00	\$464,658.00	
Service Site Information: Please include all of the information requested for each location.	Service Site <u>CCNC – Macon Pond</u> Address <u>4101 Macon Pond Rd</u> City, State, Zip <u>Raleigh, NC 27607</u> County <u>Wake</u>	Service Site <u>CCNC – Cary Rad</u> Address <u>300 Ashville Ave</u> <u>Suite 110</u> City, State, Zip <u>Cary, NC 27518</u> County <u>Wake</u>	
Number of unduplicated patients who receive treatment simulation	488	319	Total Patients 807

** "... [m]achine that produces high quality diagnostic radiographs and precisely reproduces the geometric relationships of megavoltage radiation therapy equipment to the patient." (GS 131E-176 (24b))

Note: Cancer Centers of North Carolina, P.C., acquired Wake Radiology/Oncology Services effective May 9, 2011. The number of unduplicated patients and procedures listed on this report reflect the full year activities, combining data from WROS from 10/01/2010 through 5/08/2011, with the data from CCNC from 5/09/2011 through 9/30/2011.

Name of entity that acquired the equipment (from page 1) Cancer Centers of North Carolina, P.C.



Registration and Inventory of Medical Equipment
Linear Accelerator Equipment – January 2012

Page 4 of 6

Section 3: Linear Accelerator Treatment Data (including Cyberknife® & Similar Equipment)

In the chart below, write the number of procedures, by CPT Code provided by the entity's linear accelerator(s) during the time period of this report.

CPT Code	Description	Number of Procedures	
		Linac 1	Linac 2
Simple Treatment Delivery			
77401	Radiation treatment delivery		
77402	Radiation treatment delivery (<=5 MeV)		
77403	Radiation treatment delivery (6-10 MeV)	15	250
77404	Radiation treatment delivery (11-19 MeV)	99	86
77406	Radiation treatment delivery (>=20 MeV)		
Intermediate Treatment Delivery			
77407	Radiation treatment delivery (<=5 MeV)		
77408	Radiation treatment delivery (6-10 MeV)		32
77409	Radiation treatment delivery (11-19 MeV)		19
77411	Radiation treatment delivery (>=20 MeV)		
Complex Treatment Delivery			
77412	Radiation treatment delivery (<=5 MeV)		
77413	Radiation treatment delivery (6-10 MeV)	2,000	2,617
77414	Radiation treatment delivery (11-19 MeV)	5,183	1,138
77416	Radiation treatment delivery (>= 20 MeV)		132
Other Treatment Delivery Not Included Above			
77418	Intensity modulated radiation treatment (IMRT) delivery	3,160	525
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multisource Cobalt 60 based (Gamma Knife)		
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		
G0340	(Image-guided) robotic linear accelerator-based stereotactic radiosurgery, fractionated treatment, 2nd-5th fraction		
	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		
Imaging Procedures Not Included Above			
77417	Additional field check radiographs	1,533	1,361
Total Procedures		11,990	6,160

Name of entity that acquired the equipment (from page 1) Cancer Centers of North Carolina, P.C.



Registration and Inventory of Medical Equipment
Linear Accelerator Equipment – January 2012

Page 5 of 6

Section 4: Linear Accelerator Treatment Patient Origin Data

Please provide the county of residence for unduplicated patients (see note on page 2) served by your facility's linear accelerators during the time period of this report. The total number served should be the same as on page 2 of this report. This data is needed to calculate linear accelerator service areas.

County in which service was provided: Wake

Patient County	# of Patients		Patient County	# of Patients		Patient County	# of Patients	
	Lin 1	Lin2		Lin 1	Lin2		Lin 1	Lin2
1. Alamance	2	1	37. Gates			73. Person		
2. Alexander			38. Graham			74. Pitt		
3. Alleghany			39. Granville			75. Polk		
4. Anson			40. Greene			76. Randolph		1
5. Ashe			41. Guilford		1	77. Richmond		
6. Avery			42. Halifax	1	2	78. Robeson	1	
7. Beaufort			43. Hamett	27	20	79. Rockingham		
8. Bertie			44. Haywood			80. Rowan		
9. Bladen			45. Henderson			81. Rutherford		
10. Brunswick			46. Hertford			82. Sampson	1	4
11. Buncombe			47. Hoke			83. Scotland		
12. Burke			48. Hyde			84. Stanly		
13. Cabarrus			49. Iredell			85. Stokes		
14. Caldwell			50. Jackson			86. Surry		
15. Camden			51. Johnston	42	11	87. Swain		
16. Carteret	1		52. Jones			88. Transylvania		
17. Caswell			53. Lee		7	89. Tyrrell		
18. Catawba		1	54. Lenoir			90. Union		
19. Chatham		4	55. Lincoln			91. Vance		
20. Cherokee			56. Macon			92. Wake	342	263
21. Chowan			57. Madison			93. Warren	2	
22. Clay			58. Martin		1	94. Washington		
23. Cleveland			59. McDowell			95. Watauga		
24. Columbus			60. Mecklenburg			96. Wayne	4	1
25. Craven			61. Mitchell			97. Wilkes		
26. Cumberland		1	62. Montgomery			98. Wilson	4	1
27. Currituck			63. Moore			99. Yadkin		
28. Dare			64. Nash	4	1	100. Yancey		
29. Davidson			65. New Hanover	1				
30. Davie		1	66. Northampton	1		101. Georgia		
31. Duplin			67. Onslow	1		102. South Carolina		
32. Durham	3	4	68. Orange	3	1	103. Tennessee		
33. Edgecombe		1	69. Pamlico	1		104. Virginia		
34. Forsyth	1	1	70. Pasquotank			105. Other (specify)	8	2
35. Franklin	20		71. Pender			Linac 1: FL 4, KS, PA, OH, AZ Linac 2: NY, VA		
36. Gaston			72. Perquimans			Total Number of Patients	470	330

Section 5: Reimbursement/Payment Source

Name of entity that acquired the equipment (from page 1) Cancer Centers of North Carolina, P.C.



Registration and Inventory of Medical Equipment
Linear Accelerator Equipment – January 2012

Page 6 of 6

Please provide the source of reimbursement/payment for linear accelerator treatment procedures. Total procedures should equal the total number of procedures reported on page 2 of this form.

Primary Payer Source	Number of Procedures	
	Linac 1	Linac 2
Self Pay	349	21
Medicare & Medicare Managed Care	5,278	2,574
Medicaid	402	192
Commercial Insurance	972	--
Managed Care	4,964	3,255
Unreimbursed Care (Indigent/Charity)	25	--
Other (Specify) WakeMed Inpatient, paid by WakeMed	--	105
Total	11,990	6,160

Section 6: Certification and Signature

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Signature Thomas A. Grates

Print Name Thomas A. Grates

Date signed 1/27/12

Please complete all sections of this form and return to the Medical Facilities Planning Branch by **Friday, January 27, 2012**.

1. Complete and sign the form
2. Return the form by one of two methods:
 - a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov
 - b. Mail the form to Kelli Fisk in the Medical Facilities Planning Branch, 2714 Mail Service Center, Raleigh, NC 27699-2714.

If you have questions, call Kelli Fisk in the Medical Facilities Planning Branch at (919) 855-3865 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Section 5: Reimbursement/Payment Source

Name of entity that acquired the equipment (from page 1) Cancer Centers of North Carolina, P.C.