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State Health Coordinating Council  
Medical Facilities Planning Section  
NC Division of Health Service Regulation  
NC Department of Health and Human Services  
Attention: Carol Potter  
701 Barbour Drive  
Raleigh, NC 27603

Dear Ms. Potter,

Thank you for the opportunity to comment on the petition, which was submitted to the State Health Coordinating Council (SHCC), regarding the need for new radiation oncology services. Our comments below pertain to the petition filed by Cary Urology for a new linear accelerator in Service Area 20.

Rex Healthcare strongly opposes the petition because no need exists for an additional linear accelerator in Service Area 20, as reflected by the SMFP and its methodology. We hope that the following information will be useful to the Council as it considers the petition.

If we can provide any further information on linear accelerator utilization, please contact me at (919)-784-3181. Thank you for your consideration.

Sincerely,

Steve Burriss,

Vice President Ambulatory Care, Rex Healthcare

**COMMENTS BY REX HOSPITAL, INC. OPPOSING CARY UROLOGY'S  
PETITION FOR SPECIAL NEED FOR RADIATION ONCOLOGY  
LINEAR ACCELERATOR SERVICE AREA 20  
2009 STATE MEDICAL FACILITIES PLAN**

Rex Hospital, Inc. ("Rex") files the following comments in response to Cary Urology's petition for a special need for a linear accelerator (or "linac") for Service Area 20 to be included in the 2009 State Medical Facilities Plan. Rex currently operates the Rex Prostate Center of Excellence in Raleigh.

**I. Current Service Area 20 Linacs Are Substantially Underutilized**

The Proposed 2009 State Medical Facilities Plan ("SMFP") indicates that Service Area 20 currently has seven (7) linear accelerators in operation. The historical utilization by facility is summarized in the Table 1 below.

**Table 1:**

Total Radiation Oncology Procedures (ESTVs) by Service Area 20 Provider								Ave Ann %
Facility	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005 <sup>2</sup>	FY 2006	FY 2007	Incr. 2003 -2007
Rex Healthcare	28,455	28,133	30,130	25,343	20,113	16,184	18,838	-7.5%
Wake Radiology / Oncology	8,542	7,033	6,764	7,503	7,004	5,960	5,597	-3.5%
Duke Raleigh Hospital	1,594	4,585	4,997	5,201	6,969	7,323	6,923	7.7%
Cancer Centers of NC <sup>1</sup>					2,534	8,924	10,062	99.0%
Totals	38,591	39,751	41,891	38,047	36,620	38,391	41,420	-0.2%

Source: SMFP 2003-2009 and from the Registration and Inventory of Medical Equipment, Linear Accelerator Equipment forms for February 2007.

Notes: <sup>1</sup>The Cancer Centers of North Carolina linear accelerator became operational in 2005, consequently, the average annual percent increase is calculated for 2005-2007.

<sup>2</sup>Effective in FY 2007 SMFP, the need determination methodology was modified by eliminating one of the procedures (77427, Weekly Radiation Therapy Management) thereby reducing procedure (ESTV) counts for freestanding oncology centers like WROS and CCNC.

As the utilization statistics demonstrate, total volumes in Service Area 20 were flat between 2003 and 2007. In fact, two of the four providers experienced an average annual decrease in volumes. Rex's annual volumes decreased by an average of 7.5% per year and Wake Radiology / Oncology Services decreased by an average of 3.5% per year.

In addition to the seven (7) linear accelerators included in the Proposed 2009 SMFP, two (2) additional units are in operation in the service area, but unaccounted for in the SMFP. Betsy Johnson Regional Hospital operates a linear accelerator in Harnett County, and Franklin County Cancer Center operates a linear accelerator in Franklin County. The utilization of these units is unknown.

The 2007 SMFP also identified the need for one (1) additional linear accelerator. This unit is not yet operational. Consequently, there are a total of ten (10) operating and approved linear accelerators in Service Area 20.

Table 2 below shows Service Area 20 linear accelerator utilization by unit for 2007 by facility. The total average use by unit in 2007 was 5,917 ESTVs, which is 12.3% below the SMFP's need threshold of 6,750 ESTVs.

**Table 2:**

Fiscal Year 2007 Service Area 20 Linear Accelerator Utilization				
Facility	Total ESTVs	ESTVs/ Unit	ESTV Need Threshold	% Over (Under) Threshold
Rex Healthcare	18,838	4,710	6,750	-30.2%
Wake Radiology / Oncology	5,597	5,597	6,750	-17.1%
Duke Raleigh Hospital	6,923	6,923	6,750	2.6%
Cancer Centers of NC	10,062	10,062	6,750	49.1%
Totals	41,420	5,917	6,750	-12.3%

Source: 2009 Draft SMFP.

It is significant to note that two (2) of the four (4) facilities operated at levels significantly below the need threshold in 2007. Rex's average ESTVs per unit was 4,710, or approximately 30.2% below the need threshold. Wake Radiology / Oncology Services' average ESTVs per unit was 5,597 in 2007, or about 17.1% below the need threshold.

In summary, there are currently ten (10) linear accelerators either operational or approved in Service Area 20. The historical data indicates that total oncology procedures have remained flat over the last five years, while the Area 20 linac inventory has increased from 6 to 10. Thus, many of the Area 20 linacs are underutilized. In light of these facts, it is quite unreasonable to petition for a special need for one (1) additional linear accelerator in this service area.

## **II. Dedicated Equipment to Disease Specific Population**

The Proposed 2009 SMFP, page 144 states the following:

*Presently, existing radiation oncology programs are reasonably convenient to the population of the state. The high cost of establishing new programs and the possibilities for achieving further equipment and staff economies of scale are critical considerations in evaluating the need for new radiation oncology treatment center programs.*

Contrary to this policy, the petitioner's requested need adjustment is extremely specific (page 1 of petition):

*. . . one linear accelerator in Service Area 20 to be located in a dedicated prostate health center that is organized to provide multidisciplinary diagnosis, treatment and therapy by practicing urologists, oncologists and others; that has an organized outreach and advisory feedback program designed to address the special needs of African Americans and other high risk groups.*

The petitioner further recommends that Table 9J specifically be modified with a footnote that reads as follows:

*\*To be located in a dedicated Prostate Health Center that is organized to provide multidisciplinary diagnosis, treatment and therapy involving at least 10 urologists practicing in the service area and an organized outreach and feedback program to meet the needs of African Americans and other high risk groups (emphasis added).*

The extreme specificity of the special need adjustment request will, by design, create inefficiency, or a *diseconomy* of scale, related to the cost and use of the linear accelerator. Further, the establishment of a minimum threshold of ten (10) urologists involved, or **50%** of the total number of specialists currently practicing in the service area, creates unreasonable inflexibility in the execution of the plan.

It is also significant to note that this special need determination, if approved, will likely open the door to many disease specific center requests. This will lead to a further erosion in the cost-efficient use of linear accelerators in North Carolina. See Part III below, entitled *Petition Proposes Change in Need Methodology*.

### **III. Petition Proposes Change in Need Methodology**

The petitioner is essentially asking for a change in need methodology for linear accelerators. Consequently, the request was inappropriately submitted as a "special need petition." The idea of creating a disease specific center does not constitute a special need that is unique to Service Area 20. This proposed change in need methodology should be addressed early in the SMFP development process, when changes in need methodology are considered.

As the petitioner states as part of the Q&A on page 15 of the petition:

**Q:** *This project represents a state precedent – what will prevent others from asking for a disease specific center?*

**A:** *In an urban setting, where scarce specialty providers become separated from one another and have little time for essential collaboration, more disease specific centers are a good idea... The state's task will be to monitor distribution, to consider convenient location, a care delivery structure that supports collaborative care protocol development, to set the criteria for such centers and to assure sufficient organized volume to support a single disease focused program."*

This point of view represents a radical departure from the current need methodology employed by the SHCC and the Medical Facilities Planning Section. Approving this proposed "special need adjustment" would have serious, negative, unintended ramifications on the delivery and cost of linear accelerator services in North Carolina.

#### **IV. Lack of Outcome Data/ Impact on Care**

On page 6 of the petition, the petitioner states that "*multidisciplinary approaches generally improve clinical outcomes and involve diminished morbidity.*" However, the petitioner provides no statistical support for this assertion. Further, a multidisciplinary approach can be achieved without investing in dedicated, high cost, in-house equipment. For instance, Cary already has a linear accelerator equipped with IMRT / IGRT at Wake Radiology / Oncology Services, located only two miles south of the proposed center at Cary Urology. This existing center has available capacity to serve additional patients, as the historical utilization statistics above demonstrate.

On page 7, the petitioner states that "*Treating urologic cancers requires highly skilled and finely tuned techniques.*" In fact, treating **any** cancer with a linear accelerator requires "highly skilled and finely tuned techniques" and prostate cancer is not unique. Damage to surrounding tissue as a result of linear accelerator treatments is **always** a concern and consideration, regardless of the type of cancer being treated. Again, the petitioner does not provide any data to support the improved efficiency, cost, or outcomes related to the housing of dedicated, high cost equipment at a disease-specific center. On the contrary, patients who have complications or require chemotherapy, surgery, or whose cancer has spread to other organs, a comprehensive cancer center would be the more effective treatment setting.

#### **V. Failure to Establish Need in Service Area 20**

The petitioner fails to establish a need for the proposed service in Service Area 20. According to the Proposed 2009 SMFP, in determining whether an additional linear accelerator is needed in a service area, two of the following three criteria must be met:

1. The linear accelerators in existing radiation oncology centers should be performing greater than 6,750 procedures (ESTVs) per accelerator per year.
2. The population that lives in the radiation oncology service area is sufficiently great to support the addition of another accelerator (population per accelerator greater than 120,000).
3. The patient origin data shows that over 45 percent of the patients come from outside of the service area.

Service Area 20 does not meet any of the above criteria. A discussion of the failure to meet the first criterion is included in Part I above. To reiterate, the average Area 20 ESTVs per linac in 2007 was 5,917, well below the SMFP's 6750-ESTV threshold for establishing need

Service Area 20 also does not meet the second criterion. Table 3 below summarizes an analysis of the population per unit when the two linear accelerators that are not currently included in the Service Area 20 inventory are considered (Harnett and Franklin Counties):

**Table 3:**

<b>Adjusted Population Per Linear Accelerator in Service Area 20</b>	
2008 Civilian Population	1,033,705
SMFP Linacs	8
SMFP Population/Linac	129,213
Total Actual Linacs	10
Adjusted Actual Population/Linac	103,371
<b>Source:</b> 2009 Draft SMFP, licensure applications and published literature on Franklin Cancer Center.	

When the two additional units are factored into the calculation, the population per linear accelerator becomes 103,371. This population per linear accelerator is well below the threshold of 120,000 population per unit.

The Proposed 2009 SMFP indicates that 16.32% of the patients treated in Service Area 20 reside outside of Service Area 20. Consequently, Service Area 20 does not meet the third criterion since fewer than 45% of its patients reside outside of the service area.

In order to establish a case for a particular need for a linear accelerator in Service Area 20, one of the arguments that the petitioner offers (on page 8) is as follows:

*Using SEER data, the State Center for Health Statistics estimates that Service Area 20 had approximately 500 new prostate cancer cases in 2007. With half of them candidates for linear accelerator treatment, the area has enough prostate cancer patients in its boundaries to satisfy the standard of 250 patients for a linear accelerator. In fact, fewer than 180 patients can make a program viable.*

There are several errors in this logic. First, this unreasonably assumes that the new linear accelerator would capture 100% of the prostate cancer cases. There will always be a significant portion of the population that will be treated at comprehensive cancer centers either by referral or by choice. As discussed previously, patients who have complications or require chemotherapy, surgery, or whose cancer has spread to other organs will be more effectively treated at a comprehensive cancer center.

Second, the current inventory of linear accelerators is already underutilized. As the petitioner states on page 3, "*Based on the 2007 projections from the North Carolina Cancer Registry, male urologic cancers represent 21.4 percent of all cancers diagnosed . . .*" If all of these patients were to be treated at the new center, the utilization of the existing linear accelerators would further erode. While the petitioner stresses that these are new patients, the average treatment cycle for a prostate patient is 2 to 3 months. When the 2 to 3 month treatment cycle is complete, the capacity becomes available to treat new patients. Consequently, the ongoing diagnosis of new patients is essential to the utilization of existing equipment over time.

Another argument offered by the petitioner is as follows:

*At present, Service Area 20 has more than 20 urologists and eight radiation centers. In the three counties, chemotherapy is delivered in hospitals, radiation centers and in hematology/oncology offices. All of these providers have different medical record systems. Their service location are scattered over a 1.5 – hour travel radius. This presents more than 160 different possible medical records for prostate cancer patients. There is no practical way to have effective tumor boards and multidisciplinary approaches to this disease entity with such a structure. The sheer number of treatment locations works against any effective coordination among physician specialists treating the same patient.*

This argument actually serves to **discourage** the addition of another treatment facility in the area. Adding another center in Service Area 20 will further fragment the delivery of services. While the petitioner envisions the clustering of services in one location, the reality would be to merely add another option to the current complex network of services.

In summary, Service Area 20 does not meet the standard criteria as set forth in the Proposed 2009 SMFP to establish a need for a new linear accelerator. Further, the petitioner does not establish a case for a special need in Service Area 20.

#### **VI. Not Most Effective Alternative**

The petitioner did not select the most effective alternative. On page 11, the petitioner discusses the option of working with existing radiation therapy providers. The petitioner argues:

*"Already in short supply, the 20 urologists in Service Area 20 do not have the time to continuously observe individual patients among the eight (8) treatment centers."*

However, the petitioner does not discuss the opportunity for the urologists to network or joint venture with an existing service area provider, such as the Rex Prostate Cancer Center of Excellence or Wake Radiation Oncology (fewer than two miles away).

Coordination with an existing provider would serve to consolidate resources, offer a broader complement of services, improve equipment utilization and lower costs.

## VII. Proposed Service Will Result in Unnecessary Duplication of Services

Since the current equipment is underutilized (see Part I), it can be safely assumed that no 'pent up' demand is present due to lack of access to services. Thus, adding equipment should not generally result in an overall increase in number of treatments in the service area. Consequently, the addition of another linear accelerator in Service Area 20 will only serve to dilute the utilization of the current equipment. Table 4 below summarizes the impact of adding an 11<sup>th</sup> linear accelerator to Service Area 20.

**Table 4:**

Criteria	2009 SMFP	Additional Unit
Number of Units <sup>1</sup>	10	11
Adjusted Actual Pop/Linac	103,371	93,973
ESTVs/Unit <sup>2</sup>	5,917	4,602
Notes:		
<sup>1</sup> Includes units operating in Harnett and Franklin counties.		
<sup>2</sup> Based on 2007 reported procedures for 7 inventoried linear accelerators.		

Adding another linear accelerator to Service Area 20 would result in an average utilization of 4,602 ESTVs per linac, based on 2007 reported procedures. This is **31.8% below** the per unit threshold of 6,750, which is required to establish need for a new linear accelerator (1 - 4,602 / 6,750).

It is also important to note that several area providers offer prostate cancer services. Rex Cancer Center is a 2007 recipient of the Jimmy V Foundation grant in the amount of \$500,000 to create the Rex Prostate Center of Excellence. The grant will enable the Center to expand four components of their comprehensive prostate center program:

- Outreach and education
- Community screenings
- Clinical treatment and follow up
- Survivorship.

The goal of Rex's program is to reduce the mortality rate in men due to prostate cancer. It is significant to note that these specific strategies aimed at early intervention are the appropriate and proven avenues to influence outcomes/mortality rates. Conversely, the petitioner's proposal to provide additional linear accelerator services in a service area where the service is readily accessible and equipment is already underutilized is unlikely to have an impact on mortality rates.

Also, the Duke Raleigh Cancer Center offers a multidisciplinary approach to prostate center treatment. The treatment team consists of a urologist, radiation oncologist,



and , if necessary, a medical oncologist. The physicians coordinate care by meeting with the patient in sequence and then conferring collaboratively to determine the optimal care plan for the patient.

### **VIII. Conclusion**

Rex opposes Cary Urology's petition for a special adjustment to need for a Linear Accelerator for Service Area 20. The current linacs in Service Area 20 are already substantially underutilized and the addition of another accelerator would exacerbate this problem. Further, Cary Urology did not prove its case for a specific need for a dedicated linear accelerator at a disease-specific center in Service Area 20. Also, the petitioner is, in essence, proposing a change in the Statewide SMFP need determination methodology, not allowed at this stage in the process. Finally, other similar disease-specific programs are already offered in Service Area 20, such as the Rex Prostate Cancer Center of Excellence and Duke Raleigh Cancer Center's multidisciplinary approach to prostate cancer treatment.