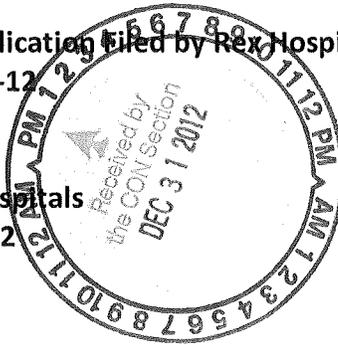


Comments Regarding Certificate of Need Application Filed by Rex Hospital  
Project No. J-10063-12

Submitted by:  
WakeMed Health & Hospitals  
December 31, 2012



**Overview**

In this application, Rex Hospital proposes to replace one of its four units of linear accelerator equipment, specifically the unit located at its Wakefield site in north Raleigh. Because the cost of the proposed replacement equipment is estimated to be more than \$2 million, a certificate of need is required to proceed. Rex cites the age of its existing equipment, as well as the ability to offer "state-of-the-art" radiation therapy to its cancer patients, as the primary reasons for this proposal. However, this application proposes neither the least costly nor most effective alternative, and should be denied, for the reasons discussed below.

**Review Criterion 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.*

Rex proposes to replace the existing linear accelerator at its Wakefield location, a Varian Clinac 21EX, with a Varian TrueBeam-comparable unit. The remaining three linear accelerators at the Rex Cancer Center on the Rex main campus will not be affected by the project. However, the application does not conform with CON Review Criterion 3, as the need for the project is not adequately demonstrated.

Population Growth in Wake County

The recent and projected growth in population in Wake County is not sufficient to demonstrate a need for Rex's proposal. Rex cites the continued rapid growth in population in Wake County as justification for the project. On pages 36-37 of its application, Rex notes the projected growth in both the total and age 65+ populations in Wake County. According to Rex, "...as the population ages, the incidence of cancer rises", yet no reference is provided to substantiate this statement. Rex did not provide any analysis to correlate the growth in Wake County population with an increase in the need for radiation therapy services.

Rex also references a medical journal article, which projects that the number of older adults treated with radiation therapy will increase by 38 percent from 2010-2020. The article provides no discussion or analysis to back up this statement, and is not specific to any geographic region. In fact, the main purpose of the article was to analyze the current supply and project demand for radiation oncologists, not linear accelerators.

On pages 37-40, Rex discusses the growth in population in northern Wake County, as it relates to the need for radiation therapy services at its Wakefield location. Rex's source based its 2012 population estimates and 2017 population projections on the 2000 Census, rather than 2010 Census data. Therefore, it seems likely that these population estimates are outdated and unreasonable, and that Rex did not identify the population to be served.

On pages 39-40, Rex compares the population of the Wakefield service area, a subset of Wake County defined by Rex, to that of several *entire* North Carolina counties. Rex posits that the inventory of linear accelerator equipment at its Wakefield site is justified by the population of the Wakefield service area. However, linear accelerator equipment is allocated in the annual State Medical Facilities Plan based on service areas consisting of one or more *counties*. Service Area 20 consists of Wake and Franklin Counties and has an inventory of 9 linear accelerators. Therefore, to simply imply that the Wakefield service area justifies a linear accelerator based on its population, while ignoring the remainder of the county and Linear Accelerator Service Area 20, is unreasonable.

Historic Utilization of Linear Accelerators at Rex and in Service Area 20

According to the 2009-2012 State Medical Facilities Plans (SMFPs) and Proposed 2013 SMFP, Rex Hospital has an inventory of 4 linear accelerators, all counted under the Rex Hospital license. Three units are located at the Rex Main Campus, and the fourth unit at Rex-Wakefield. According to data provided in Chapter 9 of the annual SMFP, Rex's utilization of its linear accelerator equipment has been flat in recent years, based on calculation of Equivalent Simple Treatment Visits (ESTVs), which weights linear accelerator procedure codes according to complexity. A linear accelerator is assumed to be fully utilized if it performs 6,750 ESTVs per year. Please see the following table.

<b>Year</b>	<b>Units of Equipment</b>	<b>Total ESTVs<sup>1</sup></b>	<b>Average ESTVs Per Unit</b>	<b>Units Needed [Total ESTVs ÷ 6750]</b>	<b>Surplus/ (Deficit)</b>
2007	4	18,838	4,710	2.79	1.21
2008	4	16,970	4,242	2.51	1.49
2009	4	16,932	4,233	2.50	1.50
2010	4	19,636	4,909	2.91	1.09
2011	4	18,898	4,724	2.80	1.20
CAGR, 2007-2011		0.064%	0.059%		

This utilization data indicates that Rex cannot justify the need for 4 units of linear accelerator equipment – in reality, Rex can barely justify 3 units. If, as Rex states on application page 41, the patient and procedure volume of its Wakefield linear accelerator is growing rapidly (which cannot be verified by the Agency due to the way Rex reports its linear accelerator data) but

<sup>1</sup> Source: Table 9E, 2009-2012 State Medical Facilities Plans, and Proposed 2013 State Medical Facilities Plan.

Rex's overall linear accelerator volume is flat, then linear accelerator patients and/or procedures at the Rex main campus must be *declining*. However, the Rex application provided no information regarding the procedure volumes of its other linear accelerators; its Wakefield volume is combined with its Main Campus volume in the annual Hospital License Renewal applications. Rex should be required to justify the need for all four of its existing linear accelerators to demonstrate the need for the proposed replacement.

#### Projected Utilization of All Rex Linear Accelerators

In this application, Rex expressed its intention to continue operating four linear accelerators following project completion. What remains unclear is how Rex will coordinate the operation of its various cancer-related programs and facilities, following the completion of the following CON projects.

- In 2010, Rex received CON approval to develop the North Carolina Cancer Hospital at Rex (Project No. J-8470-10), a major renovation/expansion project that will add 71,542 square feet to the Rex Cancer Center at the main campus, and "provide cancer patients with one location in which to access the three main disciplines involved in cancer care: medical and radiation oncology, and surgery."<sup>2</sup> Radiation Therapy services are apparently not impacted by this proposal; line drawings indicate that Rex will continue to have space for four linear accelerators following project completion. Rex did not provide volume projections for radiation therapy services in this application, either for the Main Campus or for Wakefield locations.
- In 2011, Rex filed Project No. J-8699-11, a proposal to develop a 50-bed acute care hospital on the campus of Rex Healthcare of Holly Springs. This new facility, which received approval but was under appeal when these comments were developed, proposed a "satellite cancer center"<sup>3</sup> with medical and radiation oncology services, including the relocation and replacement of one linear accelerator from the Rex Hospital main campus to the new hospital. Rex projected linear accelerator volume for the Holly Springs unit following project completion, but not for its Main Campus and Wakefield units. Rex did not indicate in its application specifically which linear accelerator unit it plans to relocate and replace.

Rex did not appeal the CON Section's denial of its 2011 proposed linear accelerator relocation, but it is not clear whether and how Rex's current 2012 proposed linear accelerator replacement interfaces with this 2011 application and whether Rex's representations are consistent in the two applications.

- Project No. J-10063-12, which proposes to replace the linear accelerator at Rex Healthcare of Wakefield. Rex provided historic and projected volumes for the Wakefield unit, but not for linear accelerators at the Main Campus and Holly Springs.

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<sup>2</sup> Source: Project No. J-8470-10, North Carolina Cancer Hospital at Rex, page 43.

<sup>3</sup> Source: Project No. J-8669-11, Rex Hospital Holly Springs, page 33.

These capital projects will expand Rex’s presence in Wake County for oncology services, but because Rex has not developed utilization projections for its four linear accelerators at their respective locations, there is no way for the Agency to determine if the projections for the Wakefield linear accelerator are reasonable.

Rex’s average utilization per unit of its linear accelerators is also below the Service Area 20 average utilization during 2007-2011:

Year	Service Area 20 - All Providers		Rex Hospital Only	
	Units of Equipment	Average ESTVs Per Unit <sup>4</sup>	Units of Equipment	Average ESTVs Per Unit <sup>5</sup>
2007	8	5,178	4	4,710
2008	8	5,254	4	4,242
2009	8	5,104	4	4,233
2010	9	4,927	4	4,909
2011	9	4,944	4	4,724

Based on the table above, Rex’s average utilization of linear accelerator equipment is lower, on a per-unit basis, than the average utilization for Service Area 20. Thus, it can be argued that Rex’s linear accelerator utilization effectively suppresses the need for linear accelerators in Service Area 20.

Radiation Therapy Referrals to Main Campus

On page 31, Rex addresses the anecdotal need for the project, including the age and relative speed of its existing linear accelerator equipment at the Wakefield location. Rex also states:

*As a result, Rex Healthcare of Wakefield must send more complex patients to Rex Hospital to receive treatment on one of its three linear accelerators at that location. Approximately five to six cases per year are sent to Rex Hospital for treatment.*

This equates to one patient referral to the Main Campus every 8-10 weeks, a volume which hardly seems large enough to justify the proposed project. Rex discusses the undue burden of travel for patients from the Wakefield service area to its main campus; however, patients from locations such as Garner, Holly Springs and Knightdale, which are equally distant from the Rex Hospital main campus, apparently do not share this hardship.

For these reasons, the Rex application does not conform to Criterion 3.

<sup>4</sup> Source: Table 9F, 2009-2012 SMFPs, and Proposed 2013 SMFP.

<sup>5</sup> Source: Table 9E, 2009-2012 SMFPs, and Proposed 2013 SMFP.

#### **Review Criterion 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.*

#### Centralized vs. Decentralized Cancer Services

In Sections I and II, Rex provides an extensive description of its Cancer services capabilities, including its relationship with the UNC Health Care System. Rex recently completed a three-phase renovation of the Rex Cancer Center at its main campus, including replacement of a linear accelerator, in mid-2010. Also in 2010, Rex requested and received Agency approval to develop the North Carolina Cancer Hospital at Rex (Project No. J-8470-10), with a total capital cost of \$60 million, including approximately \$3 million in radiation therapy equipment. This proposed project, which is currently under development, was touted as a plan to centralize cancer services in one facility at the Rex main campus.

Concurrently, however, Rex has been taking steps to *decentralize* its cancer services. Rex has developed radiation and medical oncology at Rex Healthcare of Wakefield (Project No. J-7452-05) and also proposed, in two separate applications, to develop medical and radiation oncology – by relocating a unit of linear accelerator equipment – at a location in the Panther Creek area of Cary (Project Nos. J-8006-07 and J-8265-08). In 2011, Rex proposed to offer medical and radiation therapy, by relocating and replacing one unit of equipment from the main campus, in a “satellite cancer center” at an acute care hospital proposed for development in Holly Springs (Project No. J-8669-11)<sup>6</sup>. By continuing to invest heavily in cancer services at the Wakefield location and proposing to do the same in Holly Springs, the question of whether Project No. J-8470-10 is needed is not certain.

#### Proposed Replacement Equipment

The equipment proposed in this application, a Varian TrueBeam-comparable unit, is described as state-of-the-art, having only been recently approved for use in the United States. This equipment would, at least in cursory review, be the most advanced linear accelerator in the Rex inventory. It is not discussed in the application why Rex did not propose to acquire equipment with this level of clinical capability for the main Rex Cancer Center, and simply opt to relocate a piece of its existing equipment to Rex Healthcare of Wakefield, which would have been a more effective alternative.

In response to Question III.3, Rex outlines the various alternatives considered in addition to the proposed project. These included taking no action, acquiring replacement equipment for under \$2 million, and developing the project as proposed. Perhaps the most pertinent question, and one not addressed among these alternatives, is why Rex did not propose to replace a unit of linear accelerator equipment at Rex Cancer Center on the main campus, and relocate a linear accelerator to Rex-Wakefield? Given that Rex Cancer Center is the flagship of Rex’s cancer

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<sup>6</sup> At the time these comments were being developed, the Rex Hospital of Holly Springs project was under appeal.

services, it would seem logical to offer the newest, most technologically advanced radiation therapy equipment at that location.

On page 53, Rex discusses the alternative of replacing existing equipment for under \$2 million:

*After considering the scope of services that could be provided on such equipment and the needs of Rex's patients, Rex determined that such an option would result in replacement equipment that is not as effective as the chosen alternative. Rex believes its patients should not be forced to choose between traveling to receive state-of-the-art care or staying close to home and receiving less than optimal care.*

Such a statement sounds noble, but for the fact that Rex has recently replaced two linear accelerators at Rex Cancer Center, per Project Nos. J-6944-03 and J-8009-07 that also cost more than \$2 million to replace. The proposed equipment for Rex-Wakefield, as described in the application, will be the most technologically advanced linear accelerator in the Rex system, which "will allow Rex to be on the leading edge of this technology" (page 20), with capabilities that "allows clinicians to tailor patients' treatments for their particular type of cancer" (page 54).

For these reasons, the Rex proposal is neither the least costly nor most effective alternative and does not conform with Review Criterion 4.

#### **Review Criterion 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 Rex application fails to demonstrate the financial feasibility of the project because its financial statements are not based on reasonable volume projections. The financial projections for the project are based on unrealistic and unsupported projections for utilization of the Wakefield linear accelerator. Please see the discussion under Review Criterion 3.

In order to demonstrate the financial feasibility of this project, Rex would need to provide volume and financial projections for all four of its linear accelerators at their respective locations.

### **Review Criterion 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 Rex proposal does not conform with Review Criterion 6. Please see the discussion under Review Criterion 3. Rex Hospital is licensed for 4 linear accelerators, but its historical procedure volume justifies only 3 units. Moreover, Rex has sought Agency approval for capital projects in the past on the basis of centralizing cancer services but in this application proposes to decentralize the newest and most sophisticated equipment at a separate location. Furthermore, Rex's proposal appears to detract from its flagship program on its main campus and to diminish effective utilization of existing or already approved expensive current technology at its main location.

### **Review Criterion 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:*

- a. The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;*
- 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;*
- c. That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and*
- d. That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.*

In its application, Rex describes the need to replace outmoded linear accelerator equipment at Rex Healthcare of Wakefield, and how doing so will eliminate the undue burden of travel for Rex-Wakefield patients to the main campus of Rex Hospital. However, Rex did not describe how cancer patients at Rex Hospital or other Rex locations would access the newest, most technologically advanced radiation therapy equipment in the Rex system, which was only made publicly available by the manufacturer in the last 18 months (page 20). Is this equipment being

made available for *all* Rex cancer patients originating within and outside Service Area 20, or just for patients at Rex Healthcare of Wakefield?

Missing from the application is any description of how other Rex patients might be referred to Rex-Wakefield, and what modes of transport might be made available for low-income persons, or persons who have no independent means of travel. Rex Healthcare of Wakefield is not served by the Capital Area Transit or Triangle Transit bus systems.

### **Review Criterion 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 a service on which competition will not have a favorable impact.*

The Rex application does not propose to increase the inventory of linear accelerators in Service Area 20. However, as discussed in response to Review Criterion 3, Rex's historic utilization indicates that it had a surplus of 1.2 linear accelerators in 2011, indicative of excess capacity. Rex's description of the need to replace its accelerator at the Wakefield location, aside from the age of the equipment, does not justify the expense associated with the project. In essence, the linear accelerator equipment Rex proposes for its Wakefield location is more advanced than the existing equipment currently offered at Rex Cancer Center on the main campus but will be placed in a location that provides access to fewer patients than its primary flagship cancer program on the main Rex campus.

According to information provided on page 31, Rex refers "[a]pproximately five to six cases per year [from Rex-Wakefield]...to Rex Hospital for treatment." This is not congruent with Rex's argument that its existing linear accelerator equipment at Rex-Wakefield is incapable of meeting the needs of most radiation therapy patients at Rex-Wakefield. Many more patients would be referred to the main campus if the current linear accelerator at Rex-Wakefield really were inadequate.

The Rex project cannot demonstrate a positive effect on competition for linear accelerator services in Service Area 20 if the need for the proposed replacement is not shown and access is not increased. As mentioned above, Rex has not addressed how it may assist patients with limited or no transportation to access radiation therapy services on the new linear accelerator at the Wakefield location. Furthermore, the proposal is not likely to have a positive effect on competition between Rex and other providers but rather appears likely to have a negative impact on Rex overall by facilitating a shift of volume from an expensive, flagship program on Rex's main campus to a satellite location with consequent duplication of services and cost. According to information provided in the Rex application, its ESTV procedures at Rex-Wakefield



are growing at a rate of 28.5 percent per year. However, the overall Rex ESTV volume is nearly flat. This suggests that the growth in volume at Wakefield has been at the expense of volume at the main Rex Cancer Center.

For these reasons, the Rex application does not conform to Review Criterion 18a.

### **Summary**

In conclusion, WakeMed understands the need to periodically replace medical equipment, but believes that the Rex proposal is neither the least costly nor most effective alternative, given Rex's other pending cancer-related capital projects and the utilization of their existing linear accelerator equipment. Therefore, the Rex application should be denied.