Cancer Centers of North Carolina

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Received by the
CON Section
31 MAY 2011 2 8 55

Re: Rex Holly Springs Application, Project ID No. J-8669-11

Dear Mr. Smith:

I am writing on behalf of Cancer Centers of North Carolina, P.C. to enclose its comments opposing the radiation oncology portion of the Rex Hospital application to establish a Holly Springs hospital. Thank-you in advance for your consideration of these comments.

Sincerely,

Alan Kritz, M.D.
President

Cancer Centers of North Carolina, P.C.
Comments on Rex Hospital Holly Springs
Project #J-8669-11

Cancer Centers of North Carolina, P.C. ("CCNC") is submitting these comments to oppose the application by Rex Hospitals, Inc. to develop a new acute care hospital, Rex Hospital Holly Springs ("RHHS"), which would include the relocation of one linear accelerator from Rex Hospital Main Campus and the creation of a new cancer center in Holly Springs. This project is currently under review as **Project #J-8669-11.**

The focus of these comments will be on that part of the application that involves the relocation of the linear accelerator and the development of a new cancer center. CCNC believes that it should be denied for a number of reasons:

- The proposed cancer center will unnecessarily duplicate existing services in Wake County, including the recently approved North Carolina Cancer Hospital project on the Rex Hospital Main Campus
- Rex fails to define its service area appropriately for the cancer center.
- Rex fails to demonstrate a need for its project and its utilization projections are faulty and unsupported.
- It is unreasonable to project that the RHHS linear accelerator will reach its projected utilization for radiation oncology or medical oncology patient volume within 3 years of becoming operational.
- The project is not financially feasible because the financial projections are based upon faulty utilization projections and Rex's own financial projections indicate that the cancer services will lose money during each its initial three years of operation.
- The RHHS project will negatively impact existing providers of cancer services in Wake County.

Each of these concerns will be described in detail below, and because of these fundamental problems in the RHHS Application, it should be denied.

I. THE REX HOSPITAL HOLLY SPRINGS CANCER CENTER PROJECT WOULD DUPLICATE EXISTING ONCOLOGY SERVICES.

Review Criteria 131E-183 (a) (4), and (6):

(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.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

Rex proposes to relocate and replace one of its three linear accelerators from the Rex Hospital Main Campus to create a satellite cancer center at the proposed 50-bed RHHS. This center will provide both radiation oncology and infusion services.

Rex was approved in 2010 to construct the North Carolina Cancer Hospital on its Main Campus at a cost of $160 million. The existing linear accelerators and infusion services were part of the overall facility plan for the Cancer Hospital and part of Rex's stated desire to have a facility where patients could receive comprehensive cancer care in one setting. But before it has even begun to implement the approved Cancer Hospital, Rex is proposing in this application to fragment these services by reducing the scope of services on its Main Campus and establishing a new, small cancer center at a site that does not have the same range of diagnostic and treatment services available.

Rex did not present a discussion of alternatives for its Raleigh cancer center project, but balancing the cost of establishing a new program in Holly Springs with achieving economies of scale at a new center not yet constructed is a crucial consideration in evaluating any proposal to create a new radiation oncology treatment center. These costs extend beyond the facilities and equipment to the significant ongoing operating expenses that must be duplicated to operate these specialized services.

Creating a new site for radiation oncology also has implications for existing providers of these services. If a new center changes historical referral patterns, the volumes at existing providers can be reduced. The promotion of the business growth objectives for one provider is not an appropriate basis to justify approval of this application. In fact, this is exactly why Criterion 6 exists.

The principal health planning basis for establishing new locations for delivering radiation oncology services is to remedy problems with access to care. In this case, Rex has failed to demonstrate any problems with access that would warrant the development of a new cancer center offering radiation oncology services.

One difficulty with evaluating the extent of duplication that the RHHS proposal would create is that Rex did not present the capital costs for the cancer center alone in the application. It did present an equipment quote for a new Clinac iX linear accelerator at a cost of $2.375 million which would presumably replace one of Rex's three existing linear accelerators. In its most recent application to establish a cancer center at Panther Creek the total capital costs were $7.25 million. It is clear that the cancer center at RHHS will entail a significant capital investment. Rex has not demonstrated that this expenditure is

necessary, that the proposed project will significantly increase access, or that it will serve an unmet need.

As noted below in Section II, the Rex proposal fails to show a need for the services proposed. But the same analysis of the defects in the Rex need methodology also shows that it would duplicate the capacity of several other existing cancer center facilities serving the same service area including the medical oncology and radiation oncology services offered by Cancer Centers of North Carolina at both its Macon Pond Road and Cary sites (the former Wake Radiology site denoted in Exhibit 1), as well as the services offered at Duke Raleigh Hospital, Duke University Medical Center, Durham Regional Hospital and at the recently approved Cancer Hospital at the University of North Carolina in Chapel Hill. In addition, Cary Urology was approved to acquire a linear accelerator that would be used in the development of a statewide demonstration projection for the treatment of prostate and urological cancers. All in all, Rex is proposing to fragment its services when there is a great diversity and good distribution of cancer services across the area.

Rex argues in its application that the proposed relocation of the linear accelerator is not duplicative because it will not increase the total number of units operational in service area. This argument is without merit. The RHHS project is clearly duplicative because it will reduce both equipment and staff economies of scale that Rex put forward to justify its recent Cancer Hospital Application, unnecessarily adding costs to the healthcare delivery system, and failing to show any meaningful impact on increasing access to these services. The difficulties of operating a small cancer center are underscored by the fact that Rex projects that oncology services at RHHS will operate at a loss during the first three years of operation (see Section III. below).

Therefore, the RHHS project is not conforming with Criteria 4 and 6 and should be disapproved for these reasons alone.

II. REX HAS FAILED TO DEMONSTRATE A NEED FOR THE RHHS CANCER CENTER, AND HAS ALSO FAILED TO SHOW THAT THE RELOCATION OF THE NEW LINEAR ACCELERATOR WILL NOT ADVERSELY AFFECT THE CURRENT POPULATION BEING SERVED.

Review Criterion 131E-183 (a) (3):

(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.

Rex has taken the position in other CON proceedings that it has excess capacity in its radiation oncology services. Rex's market share of radiation oncology patients has been declining in recent years as other providers in Wake County experience growth. This project appears to be a clear effort by Rex to grab new market share from other radiation oncology providers by placing a facility in a location that might result in some redirection

of patients from its competitors. While such a project may address Rex's strategic objectives, it does serve the needs of the health care system as a whole.

The following discussion will demonstrate that there is no need for the RHHS cancer center and that Rex's projections of utilization for this program are seriously flawed.

A. The project does not improve geographic access.

The Rex Hospital Main Campus is located geographically central to Wake County and is accessible for all portions of the county for specialized cancer treatment. Rex Healthcare operates three radiation therapy centers: Rex Hospital, Rex Healthcare at Wakefield, and Smithfield Radiation Oncology in Johnston County. There is no evidence in the application that the approval of the RHHS project will provide any meaningful enhancement in geographic access to patients Rex serves.

Furthermore, there are numerous existing providers of radiation oncology services both within and surrounding Wake County. The primary justification that Rex offers for the project is that it will enhance access to southern Wake County and Harnett, Lee, and Chatham counties, which do not currently have a radiation oncology provider, but each of these three counties is adjacent to one or more counties that do have such services.

Rex fails to acknowledge that there are other existing providers very conveniently located to serve the residents of its proposed service area. Exhibit 1 presents a map of the RHHS proposed location and the existing providers in Wake County and adjacent counties.. As shown in Exhibit 1, residents of this area have many alternatives to choose from currently in obtaining cancer treatment.

Exhibit 2 presents the RHHS service area for hospital services, which is far smaller than its service area for cancer services, and the locations of existing providers. As can be seen, CCNC's Cary location, the former Wake Radiology site, is located within 10 miles of the RHHS site. Residents of the northern ZIP Codes in RHHS' service area (27502, 27539, and 27606) are as close or closer to radiation oncology providers in Cary and Raleigh as the RHHS site. Residents of 27592 would be as close or closer to the Clayton Radiation Oncology Center at RHHS.

Rex's assumption that residents of Lee, Chatham, and Harnett Counties will come to its RHHS cancer center is without foundation. Many of these residents could access providers in Cary, Raleigh or Fayetteville as easily as the Rex Holly Springs location.

Rex provided no drive time analysis or other evidence of improvements in geographic access that its project would provide, and it is apparent that no material improvement in geographic access will result from this project.

Exhibit 1

Proposed Rex Hospital Holly Springs and Existing Providers

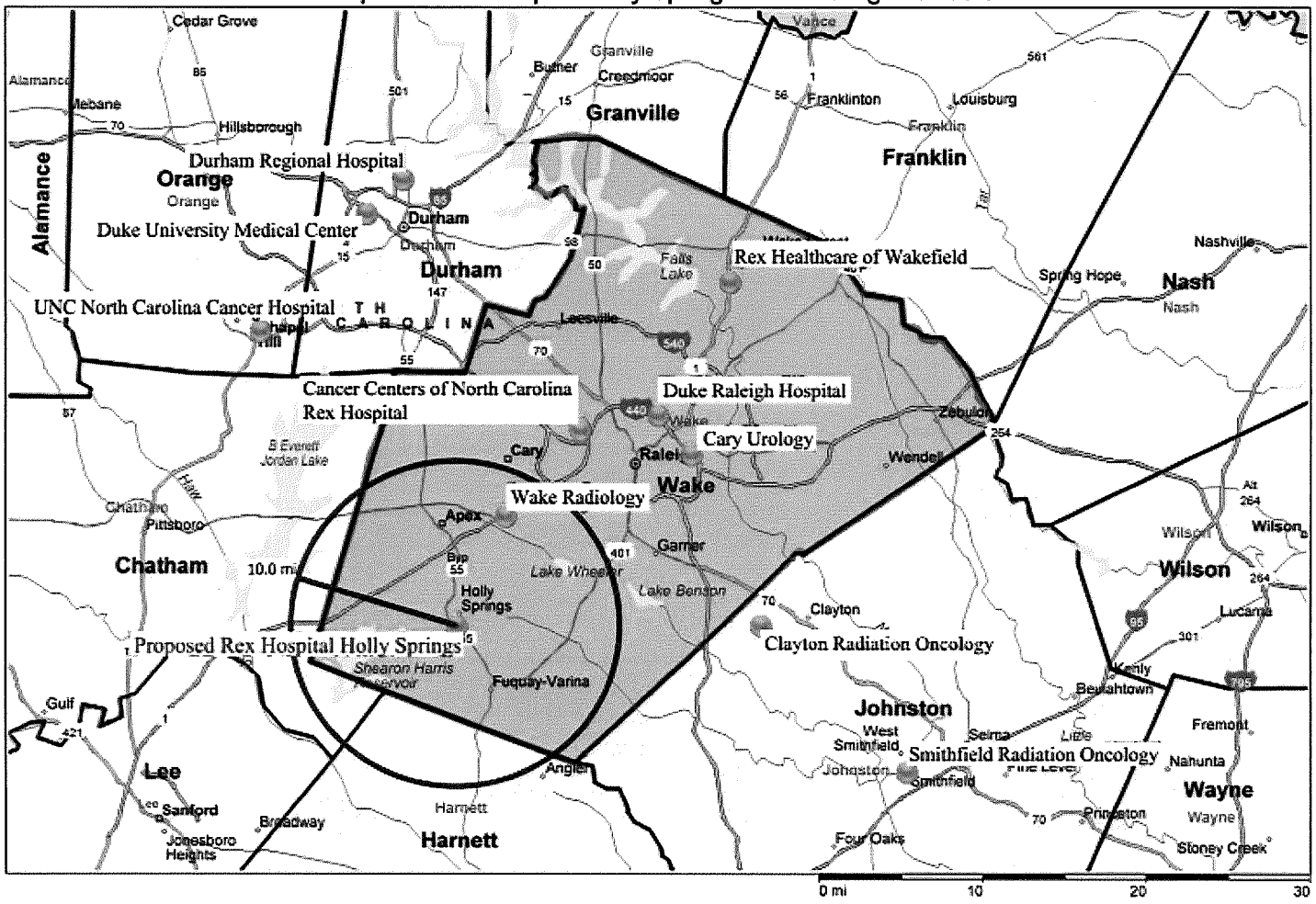
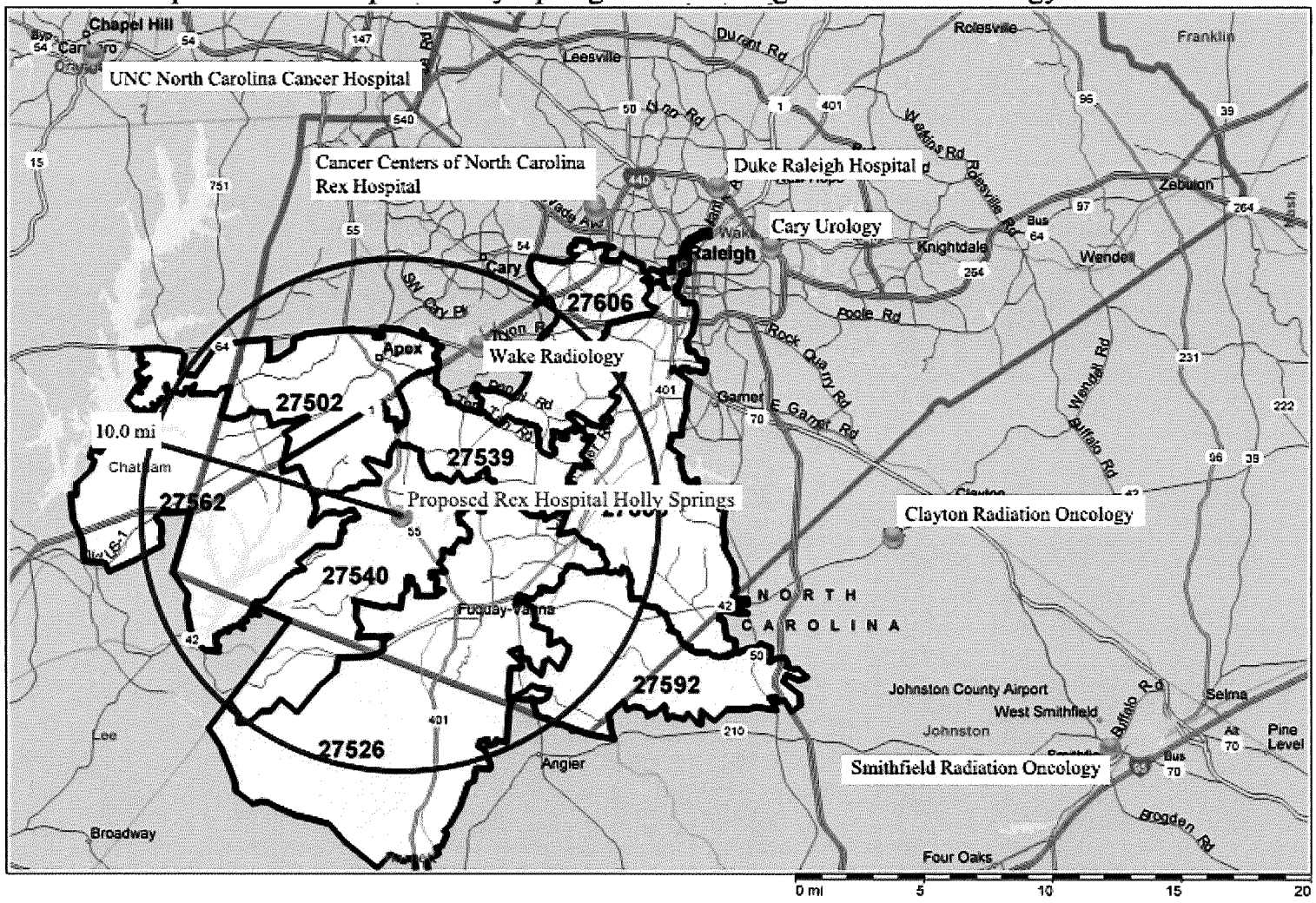


Exhibit 2

Proposed Rex Hospital Holly Springs and Existing Radiation Oncology Providers



B. RHHS' utilization projections are unrealistic.

While it is undisputed that Wake County, generally, and southern Wake County, specifically are experiencing population growth, Rex has failed to identify the population in need of cancer services in its proposed service area or to make reasonable assumptions about its ability to attract patients to its RHHS cancer center. Thus, Rex has failed to document the reasonableness of its projected utilization.

1. Rex does not define a reasonable service area for the proposed project.

As discussed above, Rex assumed that the RHHS cancer center would serve patients from southern Wake County and Lee, Chatham, and Harnett Counties. Rex provided no evidence other than noting that portions of these counties were proximate to southern Wake. Rex presented no evidence regarding the number of patients from any part of this proposed service area who have received cancer treatment at Rex Hospital in the past. It provided no evidence of relationships with physicians in this broad geographic region who are the primary referral sources for cancer patients.

As a result, Rex has failed to reasonably identify the population of cancer patients that would be served by the RHHS project.

2. Rex's projected utilization is unreasonable..

Rex fails to present a detailed analysis of the need for radiation therapy services in its proposed service area. The "need" methodology that is presented in the application is nothing more than a projection model for its proposed facility. It did not identify with specificity the size of the population in need of cancer treatment currently and the projected number of such patients who would require the services RHHS proposes.

The methodology that Rex presents is not a reasonable approach to project utilization for the proposed RHHS cancer program. The following summarizes the Rex projection model in the RHHS application.

1. *Obtain 2009 and 2011 projected new cancer cases, by county, from the North Carolina Central Cancer Registry and calculate the compound annual growth rate (CAGR) projected by the State data.*

2. *Project total new cancer cases by county from 2012 through 2017, using one-half the CAGR from step 1.*

3. *Adjust total cancer cases by county for calendar years to match the three project years, FFY 2015-2017.*

4. *Calculate the expected number of new cancer cases appropriate for linear accelerator treatment by multiplying total cancer cases by 50 percent.*

5. *Calculate the expected number of cancer cases needing retreatment on a linac by multiplying the number of linac appropriate cases from step 4 by 15 percent.*

6. *Calculate the total number of cancer cases appropriate for a linac by county for each year by adding the result of steps 4 and 5.*

7. *Estimate the number of linac treatments, or procedures, per case, which is assumed to be 22.*

8. *Calculate the total number of linac treatments as the product of steps 6 and 7.*

9. *Project the market share for each county for the linac proposed to be relocated to Holly Springs.*

10. *Calculate the total number of projected linac treatments as the product of steps 8 and 9.*

11. *Calculate the number of linac patients as the quotient of steps 10 and 7.*

12. *Estimate the number of non-treatment procedures per patient, assumed to be limited to field-check radiographs and an average of five per patient (approximately one per week).*

13. *Calculate the projected ESTVs as the sum of step 10 and one-half the sum of step 12 (since field-check radiographs are weighted at 0.5 ESTVs).*

14. *Adjust projected utilization to account for ramp-up during the first three project years.*

What is most apparent in this methodology is that the projections of radiation patients are performed at the county level rather than based on the specific population of the RHHS service area. This approach fails to account for the actual service area characteristics that influence the new for cancer services.

This approach also assumes that the need for radiation oncology is evenly distributed across the county despite differences in age, sex, and health status. A more appropriate approach would have been to develop age-specific cancer incidence rates and apply these rates to the population in the service area.

One of the most critical assumptions in any projection model is the expected market share for a facility. Rex presents a convoluted approach to market share estimation that has no relationship to what a new cancer program in Holly Springs could expect to capture.

The starting point was Rex's market share of all radiation oncology patients in Wake County, which estimates to be 35.3% in 2010. Rex must have detailed patient origin data available by ZIP Code for its radiation oncology program that would provide a direct measure of its historical market share in the proposed RHHS service area, but it chose not to present this information. Instead, Rex adjusts its overall county market share to 30% for the RHHS project and then multiplies this figure by 14.3% to 14.5% between 2015 and 2017 to reflect the proportion of Wake County's population that is in RHHS' Wake County service area to yield an estimated market share for RHHS of 4.3% to 4.4% during the projection period. This market share is applied to all radiation oncology patients in Wake County to derive the Wake patients that RHHS will serve.

Using a countywide approach is highly imprecise in projecting radiation oncology utilization for a new facility that will serve a limited geographic area. Rex's overall market share that was derived primarily by its large program on its Main Campus is not a reasonable basis for what a new facility on the campus of a much smaller start-up hospital can reasonably be projected to achieve.

Rex's market share assumptions for the other counties are similarly flawed.

- In Harnett County, Rex estimated that 34% of Harnett radiation oncology patients receive care in Wake County and Rex serves 44.3% of these patients, which means that Rex serves approximately 15% of the Harnett County radiation oncology market (44.3% x 34.0% = 15.0%). Rex assumes that the new program at RHHS will capture 30% of all Harnett County radiation oncology patients, which is double the market share that Rex has currently. Such a result is not supportable based solely on opening a new cancer in Holly Springs.

- In Chatham County, Rex estimated that only 12.7% of Chatham radiation oncology patients received care in Wake County at all programs. Without further analysis or support, Rex estimated that RHHS alone would capture 5% of Chatham radiation oncology patients in the future, which is not reasonable.

- In Lee County, Rex estimates that only 7% of Lee radiation oncology patients received care in Wake County, but because RHHS will be closer to 59% of the Lee County residents than the Moore County providers where Lee patients currently go, it expects RHHS to achieve a market share of 10%. Rex gives no consideration to the historical referral patterns and relationships that are in place in Lee County or that a cancer center at a small hospital is not likely to significantly alter these relationships.

Taken together, Rex has made wholly unreasonable projections of market share for radiation oncology services at RHHS. The unreasonableness of these assumptions is further demonstrated by the projected utilization that results for RHHS. In 2017, the third year of operation, RHHS is projected to provide 6,915 ESTVs on its linear accelerator. Yet in 2009, at its established program on its Main Campus, Rex averaged just 4,233 ESTVs per linear accelerator. The flawed projection methodology yielded the

unreasonable result that the RHHS linear accelerator would have 50% greater utilization within three years of opening than Rex's existing radiation oncology program that offers more comprehensive services.

The Rex infusion therapy volumes are based upon its projections of radiation oncology treatments. Given the unreasonableness of the radiation therapy projections, the infusion projections are also unreliable.

C. Rex cannot meet its projections without adversely impacting existing providers.

Rex frankly acknowledges that the purpose of this cancer center project at RHHS is to capture market share from other providers. On p. 235 of the application, it states:

> *Specifically, since the projected infusion volume is related to the radiation volume projected for Holly Springs, and the radiation oncology assumptions project that the relocated linac will be more effectively utilized in Holly Springs than it is in Raleigh, the infusion therapy volume is similarly beyond the volume projected for the North Carolina Cancer Hospital at Rex.*

The extent of the impact cannot be determined because Rex failed to disclose its current utilization derived from the RHHS service area, but any adverse impact on existing providers is unjustified because the project does not address a need or any demonstrated access problems.

For all these reasons, the RHHS project is not conforming with Criterion 3.

III. THE REX PROPOSAL IS NOT FINANCIALLY FEASIBLE.

Review Criteria 131E-183 (a) (5):

(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 reasonableness of the financial projections for any project is dependent on the reasonableness of the utilization projections on which the revenues and expenses are based. As demonstrated under Section II above, Rex has not presented reasonable utilization projections. As a consequence, the financial projections it presents are fundamentally flawed.

Even if Rex's utilization projections were accepted, Rex's own financial projections demonstrate that the project is not financially feasible. Exhibit 3 presents Rex's projection of financial performance for the Oncology Component of the RHHS project, which includes both radiation and infusion.

Exhibit 3
Projected Net Income for RHHS' Oncology Component

	FY 2015	FY 2016	FY 2017
Net Income	($2,762,121)	($2,325,273)	($1,754,868)

Source: RHHS Application, p. 349

For these reasons, the RHHS project is not conforming with Criterion 5.

IV. THE REX PROPOSAL WILL NOT OFFER ANY ENHANCEMENTS TO COMPETITION THAT WOULD JUSTIFY ITS APPROVAL.

Review Criterion131E-183 (a) (18a):

(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.*

As described throughout these comments, Rex's proposed RHHS cancer center duplicates services offered by other existing and approved oncology providers in Wake and surrounding counties including its own Rex Hospital location. Rex fails to present any concrete basis for determining that this proposal would have a positive impact on cost effectiveness or quality. If Rex believes that the replacement of an existing linear accelerator unit may have a favorable impact on quality, this improvement could be achieved more effectively and at a considerably lower cost, by locating the replacement linear accelerator at the hospital.

Rex has not demonstrated that the proposed facility will have a favorable impact on access to any underserved communities. Its utilization projections are unsubstantiated and can only be achieved through significant increases in market share that would be achieved only with a significant adverse impact on other providers. Such an impact is

unnecessary since Rex's proposal is not needed. Oncology services and radiation oncology services in particular are costly to offer in terms of equipment and highly specialized staff. Rex will duplicate expensive equipment and staff both from its own hospital location and that of other existing providers. The proposed project will thus not have a favorable impact on cost effectiveness.

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