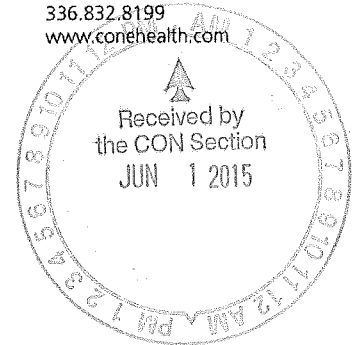




CONE HEALTH
The Network for Exceptional Care

1200 North Elm Street
Greensboro, NC 27401-1020
336.832.8199
www.conehealth.com



June 1, 2015

Ms. Lisa Pittman, Team Leader
Ms. Jane Rhoe-Jones, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation, NC DHHS
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Written Comments for CON Project ID #J-11035-15

Dear Ms. Pittman and Ms. Rhoe-Jones:

In accordance with NCGS § 131E-185(a1)(1), please find enclosed written comments from Alamance Regional Medical Center regarding CON Project ID #J-11035-15, an application filed by University of North Carolina Hospitals at Chapel Hill (UNC Hospitals) to relocate one (1) existing linear accelerator from the main campus in Chapel Hill, NC to a satellite campus in Hillsborough, NC. Please let me know if you have any questions regarding these comments or if I can provide any additional information. Thank you for the opportunity to submit these comments.

Sincerely,

James Roskelly
Executive Vice President, Strategic Development
Cone Health

JR\ec

Attachment

cc: Preston Hammock, President, ARMC and SVP, Cone Health
Skip Hislop, Vice President, Oncology Services, Cone Health Cancer Center

**Written Comments Regarding Certificate of Need Application J-11035-15
to Relocate a Linear Accelerator in Orange County**

**Submitted by Alamance Regional Medical Center
June 1, 2015**

Alamance Regional Medical Center (ARMC), a licensed acute care hospital located in Burlington, NC and part of Cone Health, a six (6) hospital health system, and a provider of both medical oncology and radiation oncology services, submits the following written comments regarding the Certificate of Need application filed on April 15, 2015 by University of North Carolina Hospitals at Chapel Hill (UNC Hospitals, or, alternately, the Applicant) to relocate one (1) existing Siemens Artiste linear accelerator from its current location on the main campus in Chapel Hill, NC to a medical office building on its satellite campus in Hillsborough, NC. It is the position of Alamance Regional Medical Center that the application does not conform to multiple review criteria and should be disapproved. ARMC has organized these comments according to the review criteria found at NCGS § 131E-183.

(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.

The Applicant states that the need for the proposed project is based on several factors, including expansion of geographic access, the need to reduce travel time for radiation therapy patients, and growth and aging of Orange County population.

The Applicant states that the proposed project will satisfy a need for expanded geographic access to Hillsborough residents and surrounding communities that currently lack convenient local access to radiation oncology services. The Applicant also notes that all existing and previously approved radiation oncology services are currently limited to southern Orange County, and the proposed project will expand geographic access to residents of central and northern Orange County. The Applicant states *"The UNC Hospitals Oncology at Hillsborough office opened in 2013. Dr. Timothy Brotherton, a medical oncologist and member of the UNC Department of Medicine, Division of Hematology and Oncology, is the primary provider of medical oncology services in Hillsborough. In the most recent calendar year, Dr. Brotherton provided over 2,400 patient visits at the Hillsborough clinic. Currently, patients of UNC Hospitals Oncology at Hillsborough necessitating radiation therapy services are referred to UNC Hospitals' main campus. Upon completion of the proposed project, the patients of UNC Hospitals Oncology at Hillsborough whose care requires radiation oncology services will be referred to the proposed UNC Hospitals Radiation Oncology, Hillsborough campus.*

*Additionally, Hillsborough and other central Orange County residents currently receiving radiation therapy treatments at UNC Hospitals' main campus will be repatriated as appropriate.*¹

However, there are no specific data provided in the application to indicate how many unique patients were treated at UNC Hospitals Oncology at Hillsborough, and how many were referred for radiation oncology. There are also no specific data provided in the application for the number of patients treated or radiation therapy treatments provided at UNC Hospitals Chapel Hill campus for patients who live in Hillsborough and other central Orange County areas. Absent these data, it is impossible to draw any objective conclusions regarding the reasonableness of projections for the proposed linear accelerator in Hillsborough.

One prevailing factor the Applicant states as a supporting factor for the proposed project is fatigue of patients. The Applicant states: *"One of the primary side effects of radiation therapy is fatigue. Travelling to and from daily and weekly treatments only increases the fatigue. As such, it is prudent to locate these services as close to patient populations as possible."*² The Applicant later reiterates, *"fatigue is a common side effect of radiation therapy services; therefore [sic] reducing the burden of traveling to and from treatments is better for patient care."*³ However, the Applicant does not adequately demonstrate that the travel time will be reduced for the patient population proposed to be served.

As noted above, there are no specific data provided in the application demonstrating the number of patients proposed to be treated from Hillsborough and other central Orange County areas. The Applicant provides projected patient origin in response to Question 5. (c) on page 63 of the application, as excerpted below.

¹ CON Application J-11035-15, page 42

² *Ibid*, pages 40-41

³ *Ibid*, page 52

Table I
Projected Patient Origin for the Relocated Linear Accelerator

County	Year 1: Projected # Treatments	Year 1: % of Total Treatments	Year 2: Projected # Treatments	Year 2: % of Total Treatments
Orange	650	17.8%	711	17.8%
Wake	574	15.7%	628	15.7%
Chatham	332	9.1%	363	9.1%
Alamance	323	8.8%	353	8.8%
Durham	270	7.4%	295	7.4%
Lee	261	7.1%	285	7.1%
Cumberland	168	4.6%	184	4.6%
Harnett	131	3.6%	144	3.6%
Guilford	78	2.1%	86	2.1%
Robeson	58	1.6%	63	1.6%
Wayne	58	1.6%	63	1.6%
Johnston	53	1.5%	58	1.5%
Others ⁽¹⁾	692	19.1%	777	19.1%
Total	3,648	100.0%	3,990	100.0%

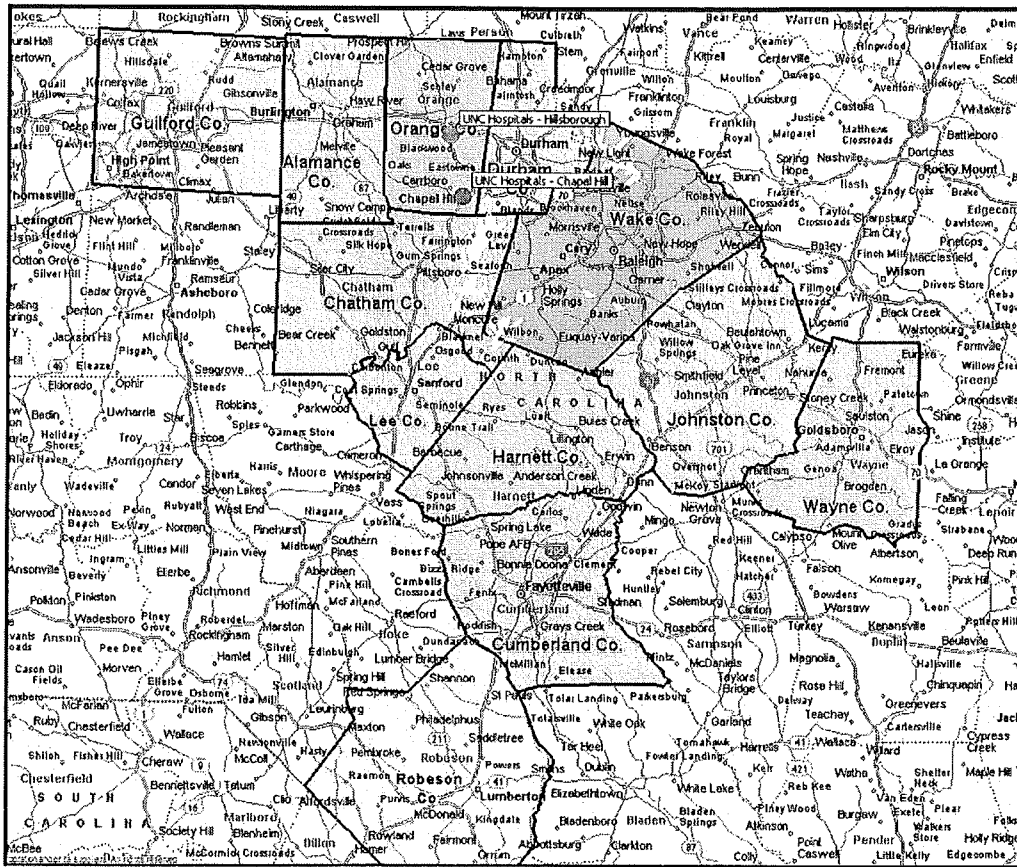
⁽¹⁾ Summed by ARMC from the table on p. 63 of the application in response to Question 5. (c)

Source: Patient Origin Table provided by on page 63 of the CON Application in response to Section III, Question 5. (c)

As demonstrated in Table I above, the top twelve (12) counties of the projected patient origin account for 80.9% of the total patient origin for the proposed relocated linear accelerator in Hillsborough. Map I below shows the location of these twelve (12) counties in relation to UNC Hospitals' existing Chapel Hill linear accelerators and the proposed Hillsborough linear accelerator.

Map I

Proposed Hillsborough Linear Accelerator Top 80% Patient Origin



Source: Patient Origin Table provided by on page 63 of the CON Application in response to Section III, Question 5. (c)

Given the Applicant's reliance on travel time to and from treatment as a primary factor in requesting approval for the proposed project, a drive time analysis was conducted to determine the difference in both driving time and driving distance between the existing site in Chapel Hill and the proposed site in Hillsborough. Microsoft MapPoint 2013 was used to calculate the driving time and driving distance from the population center of each county listed in the Applicant's patient origin table to both the current location of the linear accelerator at 101 Manning Drive, Chapel Hill, NC, and the proposed location at 460 Waterstone Drive, Hillsborough, NC. The results are summarized in Table II below.

Table II
Driving Distance and Time Comparison
UNC Hospitals and Proposed Location

County	% of Total Treatments	Closer Driving Distance	Shorter Drive Time
Orange	17.8%	Chapel Hill	Chapel Hill
Wake	15.7%	Chapel Hill	Chapel Hill
Chatham	9.1%	Chapel Hill	Chapel Hill
Alamance	8.8%	Hillsborough	Hillsborough
Durham	7.4%	Hillsborough	Hillsborough
Lee	7.1%	Chapel Hill	Chapel Hill
Cumberland	4.6%	Chapel Hill	Chapel Hill
Harnett	3.6%	Chapel Hill	Chapel Hill
Guilford	2.1%	Hillsborough	Hillsborough
Robeson	1.6%	Chapel Hill	Chapel Hill
Wayne	1.6%	Chapel Hill	Chapel Hill
Johnston	1.5%	Chapel Hill	Chapel Hill

Source: Microsoft MapPoint 2013 and CON Application #J-11035-15

As indicated in Table II, patients receiving up to 62.6% of the proposed treatments could actually have to travel a further distance and for a longer time on a regular basis for radiation therapy services. The projected patient origin for the proposed relocated linear accelerator does not support the Applicant's assertion that the project will reduce the travel burden for patients.

The Applicant states that *"the proposed relocation of an existing linear accelerator is not projected to have any impact on UNC Hospitals' projected patient origin for its radiation oncology service."*⁴ The relocation of a service from a primary site to a secondary site may not alter the patient origin for the service as a whole, but should impact the patient origin for the secondary site. The Applicant states in the application, "a five-mile travel distance affected patients' use of radiation oncology services and suggested that greater distances may create a more significant impact in utilization of these particular services."⁵ There is no tangible acknowledgement of this principle in the identification of the population being served. Therefore, there are no specific data provided related to travel times and distances that demonstrate the projected volumes for the proposed relocated linear accelerator project are reasonable.

The Applicant states *"Orange County is the fifteenth fastest growing county in North Carolina based on numerical growth and the fifteenth fastest county based on percentage growth."*⁶ As shown by the Applicant in the projected patient origin, only

⁴ Ibid, page 65

⁵ Ibid, page 47

⁶ Ibid, page 43

17.8% of treatments will be performed on patients from Orange County.⁷ There is no discussion of the need based on population growth for over 80% of the proposed patient origin. Additionally, there are no data provided in the application to demonstrate that the proposed project is needed *in this area of Orange County* instead of the area where it is currently located. As this project is not increasing the inventory of linear accelerators in Orange County, any population growth would be served by the existing complement of linear accelerators regardless of geographic location within the county. Again, there are no specific data provided in the application related to population growth within the proposed area within Orange County where the linear accelerator will be relocated that demonstrate a need that is not already being served.

In conclusion, the Applicant has neither identified the population to be served by the proposed project nor demonstrated the need that this population has for the services proposed, and is, therefore, non-conforming with Criterion 3.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

As discussed above in response to Criterion 3, the Applicant does not adequately identify the population to be served by the proposed project and does not demonstrate the need that this population has for the services proposed. Therefore, the Applicant also has not demonstrated that the needs of the population presently served would continue to be met adequately following the proposed relocation of one (1) linear accelerator. The Applicant has not demonstrated that the linear accelerators in Chapel Hill would be able to continue to serve patients at that site under reasonable utilization projections.

(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.

The Applicant describes two alternatives to the proposed project in the application: Maintain the Status Quo, and Relocate to Another Site in Orange County.

The Applicant states "As discussed previously, fatigue is a common side effect of radiation therapy services; therefore reducing the burden of traveling to and from treatments is better for patient care." However, as discussed previously in these

⁷ Ibid, page 63

comments, the Applicant has not reasonably demonstrated that the burden of travel would be reduced for the majority of patients proposed to be served.

The application is non-conforming to other review criteria, specifically Criterion 3, 3a, and 18a. A project that cannot be approved is not an effective alternative. As such, the proposed project is non-conforming to Criterion 4.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how 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 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 Applicant has identified Orange County as the primary service area and the remainder of the State of North Carolina as the secondary service area for its clinical operations.⁶ Section III, Question 6. (a) asks the Applicant to "Identify all providers of each service component included in the proposed project located in the service area and provide the utilization at each of these providers during the last full fiscal year prior to submission of this application." Section III, Question 6. (b) asks the Applicant to "Explain and provide specific documentation of the inadequacy or inability of the existing providers to meet the identified need."

The Applicant has declined to provide any information on the presence or availability of other providers in the service area, which includes all counties in North Carolina, to meet the need proposed to be met by the proposed project. The basis for this refusal is NCGS § 131E-183(b). This statute states:

The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

The Applicant's reliance on this statute is erroneous in several ways. First, the exemption is only applicable to an academic medical center teaching hospital as defined by the current State Medical Facilities Plan. The Applicant explicitly states that

⁶ Ibid, page 62

*"the proposed facility is not an Academic Medical Center Teaching Hospital."*⁹

Consequently, the exemption claimed is unreasonably and inappropriately applied and wholly not applicable to the proposed project. Moreover, the statute refers to rules adopted by the Department. The rules are understood to be those criteria and standards as codified in the North Carolina Administrative Code, more specifically those in Title 10A, Chapter 14. The review criteria above are statutes as contained within the North Carolina General Statutes, specifically in Chapter 131E, Section 183(a), not criteria and standards as codified in Title 10A, Chapter 14. As such, the exemption claimed by the Applicant is not applicable to fulfilling the review criteria nor is it applicable anywhere in this application as the Applicant has not responded to any criteria and standards for the proposed project. As a result, the Applicant does not demonstrate the expected effects of the proposed services on competition in the proposed service area.

The Applicant states that "the proposed project is not specifically being developed to foster competition per se, but rather to enhance the provision of timely, quality patient care."¹⁰ As demonstrated earlier in the analysis of Criterion 3, the proposed project does not promote timely access to care as the majority of patients identified for the proposed project must actually travel longer distances and times in order to access services at the proposed location.

In conclusion, Alamance Regional Medical Center (ARMC) contends that the Applicant's CON application to relocate one (1) linear accelerator from its Chapel Hill campus to a medical office building on the Hillsborough campus does not conform to multiple review criteria and should be disapproved.

⁹ CON Application J-11035-15, page 53

¹⁰ Ibid, page 82