

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 20, 2013

PROJECT ANALYST: Kim Randolph
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: G-10055-12 / The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation / Replace existing linear accelerator on the Wesley Long Hospital Campus / Guilford County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

CA

The Moses H. Cone Memorial Hospital and the Moses H. Cone Memorial Hospital Operating Corporation (collectively referred to as Cone Health) currently own and operate four linear accelerators at the Cone Health Cancer Center (CHCC), which is located on the Wesley Long Hospital campus. The applicants propose to replace one existing linear accelerator located at CHCC with a Varian TrueBeam linear accelerator. The applicants do not propose to develop beds, add new health services or acquire medical equipment for which there is a need determination in the 2012 State Medical Facilities Plan (2012 SMFP). Therefore, there are no need determinations in the 2012 SMFP that are applicable to this review.

However, Policy GEN-4 is applicable to this review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, shall

include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

In Section XI.7, page 125, the applicants state "*Cone Health is committed to utilizing energy efficient principles in all construction and renovation projects.*" The applicants state,

"The proposed project will require a new supplemental chilled-water air conditioner to provide cooling to the new monitoring equipment and new mechanical ductwork, piping, controls and plumbing work. These renovations will use energy efficient equipment as much as possible."

The applicants adequately describe the project's plan to assure improved energy efficiency; however, the applicants do not describe the project's plan to assure improved water conservation.

Therefore, the application is conforming to this criterion subject to the following condition.

Prior to issuance of the certificate of need, The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall provide to the Certificate of Need Section a written statement describing the project's plan to assure improved water conservation.

- (2) Repealed effective July 1, 1987.

- (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.

C

The applicants, The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation, collectively doing business as Cone Health, include the following separately licensed hospitals:

- The Moses H. Cone Memorial Hospital in Greensboro (Guilford County); and
- Annie Penn Hospital in Reidsville (Rockingham County).

The licenses for operation of The Moses H. Cone Memorial Hospital and Annie Penn Hospital are issued to The Moses H. Cone Memorial Hospital Operating Corporation, a wholly owned subsidiary of The Moses H. Cone Memorial Hospital. The Moses H. Cone Memorial Hospital in Guilford County consists of five campuses and seven doing business as “facilities.” The five campuses and seven “facilities” are:

- 1) The Moses H. Cone Memorial Hospital and Moses Cone Surgery Center;
- 2) Wesley Long Hospital and Wesley Long Surgery Center;
- 3) MedCenter High Point (emergency services, urgent care, and imaging);
- 4) Women’s Hospital; and
- 5) The Behavioral Health Hospital.

Cone Health owns and operates four linear accelerators at the Cone Health Cancer Center (CHCC), located on the Wesley Long Hospital campus, at 501 North Elam Avenue in Greensboro. (Cone Health is also a joint venture partner with Randolph Hospital in Randolph Cancer Center, which owns and operates one linear accelerator at 364 White Oak Street in Asheboro). The applicants propose to replace the existing Elekta Precise S/N 5770 linear accelerator in CHCC’s Vault #2 with a new Varian TrueBeam linear accelerator. The existing linear accelerator was installed when the cancer center opened and has been in continuous operation since May 2002.

Population to be Served

In Section III, pages 63-64, and Exhibits 14 and 15, the applicants provide actual FY 2012 year-to-date, (October 1, 2011 – August 31, 2012) Cone Health patient origin data by county of residence for the entire facility and the radiation therapy program as illustrated below.

County	Percent of Patients for Entire Facility	Percent of Patients for Radiation Therapy
Guilford	67.2%	68.7%
Rockingham	15.9%	14.6%
Randolph	4.8%	5.9%
Alamance	2.1%	2.2%
Forsyth	2.1%	1.8%
Caswell	1.2%	1.1%
Davidson	0.8%	0.8%
Stokes	0.3%	0.4%
Wake	0.3%	0.0%
Chatham	0.2%	0.5%
Mecklenburg	0.2%	0.0%
Wilkes	0.0%	3.7%
Other*	4.9%	4.0%
Total	100.0%	100.0%

* The other states and counties are identified in Exhibits 14 and 15.

In Exhibit 15, the applicants project that the patient origin for radiation therapy services in Project Year 1 (FY 2014) and Project Year 2 (FY 2015) will be consistent with the historical FY 2012 percentages shown above.

In Exhibit 16, the applicants provide a map of CHCC’s service area. The highlighted counties on the map include: Guilford; Randolph; Rockingham; western Alamance; and eastern Forsyth. In Exhibit 13, the applicants provide a list of service area Zip Codes, by county and city, which are consistent with the counties highlighted in Exhibit 16. The service area counties listed account for 90.2 percent of Cone Health’s total patient origin and 91.7 percent of Cone Health’s total radiation therapy patient origin.

The applicants adequately identify the population to be served.

Demonstration of Need

In Section III.1, page 40-58, the applicants state that the unmet need served by the proposed project results from the following factors.

- Historical and projected population growth in the proposed service area, especially for the 65+ age group, the most likely group to utilize oncology services.
- Demand for technologically advanced radiation therapy procedures at CHCC that cannot be provided with the current equipment including; cone-beam computed tomography (CBCT), image guided radiation therapy (IGRT), stereotactic radiosurgery (SRS), and stereotactic body radiation therapy (SBRT) procedures.
- High utilization of the existing linear accelerators at CHCC and the growing demand for cancer related services.
- Inadequacies and technical deficiencies of the current equipment including; reduced clinical efficiency, fewer safety mechanisms, and the inability to upgrade due to age.

Historic and Projected Population Growth

On page 42, the applicants project the service area population’s compound annual growth rate (CAGR) from FY 2012 to FY 2017, by age group, as illustrated below.

Age Group	2012 Population	Projected 2017 Population	Change from 2012-2017	% of Change from 2012-2017	CAGR from 2012-2017
0-17	204,662	212,795	8,133	4.0%	0.8%
18-44	315,141	315,197	56	0.0%	0.0%
45-64	225,131	239,302	14,171	6.3%	1.2%
65+	113,131	131,271	20,140	17.8%	3.3%
Total	858,065	900,565	42,500	5.0%	1.0%

On page 42, the applicants state the total population of the service area is projected to grow 1 percent per year for the next 5 years. The applicants state, *“The combined effect of a growing and aging population has significant implications for increasing levels of health care demand from Cone Health’s service area.”*

On page 43, the applicants state,

“In particular, the probability of developing cancer, and therefore using oncology services, is directly related to age. According to the National Cancer Institute’s Cancer Statistics, ... the chance of developing invasive cancer increases significantly with age.”

On page 44, the applicants state,

“About 78% of all cancers are diagnosed in persons aged 55 years and older. As noted in the State Center for Health Statistics ‘Cancer Incidence in North Carolina 2007’ published in April 2010, all cancer rates are at a maximum in the 70+ age categories. Prostate cancer is almost exclusively a disease of older men.”

Demand for Advanced Radiation Therapy Technologies

On pages 46-49, the applicants state the majority of growth projected in oncology services over the next decade, according to the Advisory Board Company, is in outpatient treatment. The applicants state that due to enhancements in technology, such as minimally invasive surgery and demands for continuing care after a cancer diagnosis, the Advisory Board Company projects outpatient radiation therapy volumes to increase 31 percent and outpatient oncology volumes to increase 25 percent from 2011 to 2021.

The applicants state the Advisory Board Company predicts the majority of growth in outpatient radiation therapy volumes will be in the more advanced modalities, which provide more treatment options for residents, with fewer side effects and decreased morbidity, such as intensity-modulated radiation therapy (IMRT), stereotactic body radiation therapy (SBRT), and stereotactic radiosurgery (SRS). On page 49, the applicants state that these

newer treatment options provide more targeted radiation therapy modalities, which reduce side effects and minimize damage to health tissue.

High Utilization of Existing Linear Accelerators and Growing Demand

On pages 51-52, the applicants state CHCC’s four linear accelerators operated at 109.1 percent of capacity in FY 2012 (annualized based on 10 months of actual data), based on the 6,750 Equivalent Simple Treatment Visits (ESTVs) capacity per linear accelerator in the 2012 SMFP. The applicants also state the demand for IMRT and SRS, (SRS was not offered by CHCC until 2010), exceeded the demand for conventional radiation therapy as shown in the following chart.

ESTVs by Category	FY 2009	FY 2010	FY 2011	FY 2012 Annualized	Change from FY 2009 - 2012	
					#	%
Simple Treatment Delivery	141	38	47	11	(130)	-92.9%
Intermediate Treatment Delivery	3,688	2,451	2,212	2,276	(1,412)	-38.3%
Complex Treatment Delivery	16,126	15,245	16,009	16,914	788	4.9%
Conventional Radiation Therapy Subtotal	19,955	17,734	18,268	19,201	(754)	-3.8%
IMRT	2,964	6,160	6,533	8,249	5,285	178.3%
Additional Field Check Radiographs	1,735	1,295	1,220	1,217	(518)	-29.9%
SRS	0	567	621	796	796	100.0%
Total	24,654	25,756	26,642	29,463	4,809	19.5%
% of Capacity	91.3%	95.4%	98.7%	109.1%		

On page 44, the applicants state that the combination of population growth and the aging population results in an increase in the residents with an existing or new diagnosis of cancer. The applicants state the number of new cancer cases in the Cone Health service area increased 17 percent or an average of 4 percent per year from 2005 – 2009, which grew faster than the state percentage of 14.4 percent or 3.4 percent per year.

Inadequate and Technically Deficient Existing Linear Accelerator

On pages 53-58, the applicants compare the existing Elekta Precise C/M 5770 (Elekta) linear accelerator installed in 2002 with the proposed state-of-the-art Varian TrueBeam linear accelerator. The applicants state that deficiencies with the existing Elektra include the following:

- Difficulty maintaining the energy calibration setup for beam delivery of photons at a precise depth in the patient.

- Inability to deliver the new 15 MV photon technology, rather than 18 MV photon technology, which delivers half the amount of neutrons and limits damage to pacemakers or defibrillators and the risk of a secondary malignancy years after treatment.
- Inability to meet the standard of care for treating tumors because the Elekta cannot provide image-guided radiation therapy (IGRT), which allows for higher daily doses, and results in fewer treatments.
- Incapable of providing cone-beam computed tomography (CBCT), a key localization technology for a variety of tumor diseases and sites.
- Outdated portal imaging, which provides images to view treatment portals during patient set-up and treatment.
- Degraded mechanical performance with regard to its isocentricity, which affects the equipment's ability to target a small point in space to the less than the two millimeters standard adopted by Cone Health and recommended by The American Association of Physicists in Medicine Task Group 40.
- Incapable of gated treatment delivery, which allows the radiation beam to be modulated on and off with the patient's breathing. Gated treatment delivery is used to reduce irradiation of healthy tissue by focusing on the tumor when movement of the tumor in the breast, mediastinum, lung, and abdomen can be significant (up to 2-5 cm) during breathing.
- Incapable of directly interfacing with the camera system in the vault that positions the couch the patient lies on during treatment and terminates the radiation beam if the patient moves out of position. Currently the radiation therapist must monitor the treatment machine console, the camera system, and manually enter couch adjustments and interrupt the treatment if the patient moves out of position.
- Outdated construction material on the treatment couch which interferes with the radiation dose and can cause a 20 percent reduction in dosage.
- Outdated and unsupported treatment planning system, which does not allow for dose corrections for the presence of the couch in the beam.
- Incapable of providing a more precise dose than 1 cm.
- Incapable of modulated arc treatments that spreads the toxicity of radiation to a larger area of normal tissue, which reduces side effects.
- Obsolete machine repair parts with less than one year of stock remaining.
- Outdated motorized physical wedge that requires mechanical upkeep and precise calibration, which causes treatment delivery delays and additional data management in the treatment planning system.
- Unable to be upgraded.

The applicants adequately demonstrate the need to replace the existing Elekta linear accelerator in Vault 2.

Projected Utilization

In Section IV.1, pages 68-69, the applicants project linear accelerator utilization at CHCC for the first three fiscal years after completion of the project, as illustrated in the table below.

	Project Year 1 FY 2014 10/01/13 –09/30/14	Project Year 2 FY 2015 10/01/14 –09/30/15	Project Year 3 FY 2016 10/01/15 – 09/30/16
# of Linear Accelerators	4	4	4
# of ESTV Treatments	30,055	30,356	30,659

On page 69, the applicants show the four existing linear accelerators performed an average of 7,366 ESTVs per linear accelerator during FY 2012 (annualized based on 10 months of data) [29,463 / 4 = 7,366]. In Project Year 3, the applicants project the four existing linear accelerators will perform an average of 7,665 ESTVs per linear accelerator [30,659 / 4 = 7,665].

In Section IV.1, pages 69-74, the applicants summarize the assumptions and methodology used to project utilization of radiation therapy at CHCC as follows.

Radiation Therapy Utilization Methodology	
Step	Description
1	Define CHCC’s proposed service area.
2	Project increases in population by service area and age group for CHCC.
3	Project increases in cancer cases for CHCC’s service area.
4	Project CHCC’s linear accelerator utilization.

Step 1: Define CHCC’s proposed service area.

On page 41, and Exhibit 13, the applicants define CHCC’s proposed service area as Guilford, Randolph, and Rockingham counties, plus specific zip codes identified in eastern Forsyth and western Alamance Counties. The applicants state the proposed service area is consistent with the current patient origin of Cone Health and the radiation therapy program.

The applicants adequately demonstrate the proposed service area is based on reasonable, credible, and supported assumptions.

Step 2: Project increases in population by service area and age group for CHCC.

On page 42, utilizing historic experience in CHCC’s service area, the applicants project a 1.0 percent population growth rate per year from FY 2012 - FY 2017. The applicants also project a 3.3 percent growth rate per year in the 65 + age group, the group most likely to utilize oncology health care services.

The applicants adequately demonstrate that it is reasonable to use projected population growth rate and population growth rates by age group to project the growth in oncology health care services.

Step 3: Project increases in cancer cases for CHCC’s service area.

On page 44, the applicants state the service area experienced a 4.0 percent increase per year in new cancer cases from 2005 – 2009 compared to a 3.4 percent growth rate per year for the state of North Carolina. For the same time period, on page 45, the applicants state that new cancer cases increased 1.0 percent per year. On page 46, the applicants state increases in new cancer cases consistently exceed the population growth in the service area.

The applicants adequately demonstrate that it is reasonable to project increases in new cancer cases based on current population growth rates for the state of North Carolina.

Step 4: Project CHCC’s linear accelerator utilization.

On page 48, the applicants state radiation therapy is projected to increase 31 percent or an average of 2.7 percent per year, from 2011 – 2021, with the most growth projected for the newer advanced modalities. On page 71, the applicants indicate ESTV volumes at CHCC experienced an average growth rate of 6.1 percent per year from FY 2009 – FY 2012. According to the annual survey conducted by the American Hospital Association, from 2005 – 2009, the number of hospitals in the United States that offer IMRT services increased 25 percent compared to the increase of 21.9 percent in North Carolina. The applicants state that according to the 2012 SMFP, total SRS procedures have increased 32.1 percent in the last two years. Additionally, on page 47, the applicants state that *“According to the Advisory Board’s forecast for outpatient oncology volumes, which accounts for population growth, use rates, aging of the population, technology trends, and reimbursement changes, total outpatient oncology volumes are projected to increase 25% from 2011 to 2021.”*

After reviewing all the growth rates, both historical and projected in the previous steps, the applicants state on page 71, *“Cone Health decided to utilize a conservative 1.0 percent annual growth rate to project ESTV volumes for FY 2013 through FY 2016.”* CHCC’s historical and projected ESTV Treatments are show in the table below.

	FY 2009	FY 2010	FY 2011	FY 2012*	FY 2013 Projected	FY 2014 Projected	FY 2015 Projected	FY 2016 Projected
CHCC ESTV Treatments	24,654	25,756	26,642	29,463	29,758	30,055	30,356	30,659
% of Change		4.5%	3.4%	10.6%	1.0%	1.0%	1.0%	1.0%
# of Linear Accelerators	4	4	4	4	4	4	4	4
% Capacity	91.3%	95.4%	98.7%	109.1%	110.2%	111.3%	112.4%	113.6%

* Annualized

On page 73, the applicants state *“The methodology used to project growth in linear accelerator ESTV volumes accounts for projected population growth, historical cancer incidence rates, and historical Cone Health volumes.”*

On page 74, the applicants provide the CHCC historical and projected total radiation oncology procedures, as show in the table below.

	FY 2009	FY 2010	FY 2011	FY 2012*	FY 2013 Projected	FY 2014 Projected	FY 2015 Projected	FY 2016 Projected
CHCC Radiation Oncology Procedures	44,175	52,047	56,073	61,918	62,537	63,162	63,794	64,432
% of Change		17.8%	7.7%	10.4%	1.0%	1.0%	1.0%	1.0%

* Annualized

The applicants state the total radiation oncology procedures include linear accelerator volumes, exams with radiation oncology physicians, simulations, CT guidance scans, brachytherapy procedures, seed implants, physics consults, and treatment planning procedures. The applicants adequately demonstrate projected utilization is based on reasonable, credible, and supported assumptions.

In summary, the applicants adequately identify the population to be served and demonstrate the need to replace the existing linear accelerator. Therefore, the application is conforming to this criterion.

- (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.

NA

- (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.

C

In Section III.3, page 62, the applicants discuss the alternatives considered prior to the submission of this application, which include:

- 1) Maintaining the Status Quo – The applicants state that maintaining the status quo is not an effective alternative because it does not improve the scope and quality of radiation therapy services available to CHCC. Additionally, it does not eliminate the current quality, efficiency, and service problems caused by the existing outdated and technologically inadequate linear accelerator.
- 2) Purchasing Different Equipment – The applicants state that purchasing a non-SRS/SBRT capable linear accelerator is not an effective alternative due to the current and projected future demand for more advanced technologies, such as SRS and SBRT.

The applicants state that purchasing a Varian TrueBeam linear accelerator is the most effective alternative to address the current and future demand for more advanced technology within radiation therapy modalities.

Furthermore, the application is conforming or conditionally conforming to all other statutory review criteria. Therefore, the application is approvable. An application that cannot be approved is not an effective alternative.

In summary, the applicants adequately demonstrate that their proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall materially comply with all representations made in the certificate of need application.**

- 2. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall acquire no more than one linear accelerator to replace the existing Elekta Precise S/N 5770 linear accelerator in Vault #2 for a total of no more than four linear accelerators upon project completion.**
 - 3. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall dispose of the Elekta Precise S/N 5770 linear accelerator by removing it from North Carolina.**
 - 4. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application that would otherwise require a certificate of need.**
 - 5. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicants' representations in the written statement as described in paragraph one of Policy GEN-4.**
 - 6. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (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.

C

In Section VIII.1, page 109, the applicants project the total capital cost will be \$5,835,841, which includes \$330,000 for renovation costs, \$5,469,341 for fixed equipment, and \$36,500 for architect and engineering fees.

In Section IX, page 116, the applicants state there will be no start-up or initial operating expenses for this project. In Section VIII.3, page 112, the applicants state that the total capital cost will be funded with the accumulated reserves of Cone Health. Exhibit 23 contains a letter from the Chief Financial Officer of Cone Health which states,

“This letter confirms that Cone Health plans to use its unrestricted net assets to fund the replacement of a linear accelerator in Vault #2 at Cone Health Cancer Center on the Wesley Long Hospital campus. Total capital project costs are budgeted at \$5,835,841.”

Exhibit 24 contains the audited financial statements for Cone Health for years ending September 30, 2010 and 2011. According to the financial statements, as of September 30, 2011, Cone Health had \$22,024,000 in cash and cash equivalents, \$291,706,000 in total current assets, \$1,635,229,000 in total assets and \$987,973,000 in total net assets (total assets less total liabilities). The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project.

The applicants project a positive net income for the CHCC Radiation Oncology Department in each of the first three operating years of the project as shown in the table below.

CHCC Radiation Oncology Department	Project Year 1 10/1/13 - 09/30/14	Project Year 2 10/1/14 - 09/30/15	Project Year 3 10/1/15 - 09/30/16
Gross Patient Revenue	\$56,480,840	\$59,897,931	\$63,521,756
Deductions from Gross Patient Revenue	\$33,396,766	\$35,417,271	\$37,560,015
Net Operating Revenue	\$23,084,074	\$24,480,660	\$25,961,741
Total Expenses	\$13,953,836	\$14,257,231	\$14,569,204
Net Income	\$9,130,238	\$10,223,429	\$11,392,537

* Source: Form C, page 135.

The applicants also project a positive net income for the entire facility in each of the first three operating years of the project as illustrated in the table below.

The Moses H. Cone Memorial Hospital Entire Facility	Project Year 1 10/1/13 - 09/30/14	Project Year 2 10/1/14 - 09/30/15	Project Year 3 10/1/15 - 09/30/16
Net Patient Service Revenue	\$1,123,844,000	\$1,180,036,000	\$1,239,038,000
Total Revenue	\$1,151,148,000	\$1,207,886,000	\$1,267,445,000
Total Expenses	\$1,110,907,000	\$1,166,852,000	\$1,223,322,000
Income from Operations	\$40,241,000	\$41,034,000	\$44,123,000
Total Non-Operating Gains and Losses	(\$7,043,000)	(\$7,646,000)	(\$8,841,000)
Income Attributable to Minority Interests	(\$253,000)	(\$253,000)	(\$253,000)
Increase in Unrestricted Net Assets	\$32,945,000	\$33,135,000	\$35,029,000

* Source: Form B, page 130.

The assumptions used by the applicants in preparation of the pro forma financial statements, including projected utilization, are reasonable. See the Pro Forma Section for the pro formas and the applicants’ assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this 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.

C

Cone Health currently owns and operates four linear accelerators at CHCC, which is located on the Wesley Long Hospital campus. The applicants propose to replace the existing Elekta Precise S/N 5770 linear accelerator in Vault #2 with a new Varian TrueBeam linear accelerator. The applicants are not proposing to add beds, equipment or new services in Guilford County.

In Section III.1, pages 40-59, the applicants adequately demonstrate the demand for state-of-the-art enhanced radiation therapy services in the service area, which is based on current utilization. In Section IV, page 69, the applicants project that the four linear accelerators will average 7,665 ESTVs per unit ($30,659 \text{ ESTVs} / 4 = 7,665$) in the third project year (FFY 2016). Additionally, in Section III.6, pages 64-65, the applicants state that based on the inventory in the 2012 SMFP, the other providers of radiation therapy services in Cone Health’s service area are High Point Regional Health System, Randolph Cancer Center and Morehead Memorial Hospital, as shown in the table below.

Facility	SMFP Service Area	FFY 2011 # of Linear Accelerators	FFY 2011 Average ESTVs per unit	FFY 2011 Total ESTVs	% of Capacity*
High Point Regional Health System	12	2	4,167	8,334	61.7%
Randolph Cancer Center	13	1	4,824	4,824	71.5%
Morehead Memorial Hospital	12	1	6,137	6,137	90.9%
Cone Health Cancer Center	12	4	6,660	26,642	98.7%

* The applicants calculate the percent of capacity by dividing the Average ESTVs per unit by the 6,750 ESTVs capacity defined on page 133 of the 2012 SMFP.

As shown in the table above, Cone Health’s four existing linear accelerators operated at 98.7 percent of capacity. The applicants state the other providers would be unable to meet the identified need based on their current capacity.

The applicants adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved linear accelerators in Service Area 12. Therefore, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1, pages 100-101, the applicants provide the current and projected staffing for CHCC’s Radiation Oncology Department, during the second operating year (FY 2015), as shown in the following table.

CHCC’s Current and Projected Staffing

	Current Staff FY 2012	Projected Staff Year 2 FY 2015
Functional Area and Position	Total # of Full Time Equivalent (FTE) Positions	Total # of Full Time Equivalent (FTE) Positions
Nursing		
Radiation Therapy Nurse Supervisor	1.0	1.0
RN Level II	5.0	5.0
Total Nursing	6.0	6.0
Administration		
Office Manager	1.0	1.0
Radiation Oncology Director	1.0	1.0
Total Administration	2.0	2.0
Financial/Business Office		
Patient Account Representative	1.0	1.0
Financial Counselor	2.0	2.0
Total Financial/Business Office	3.0	3.0
Other Clinical		
Sr. Physicist	1.0	1.0
Lead Clinical Physicist	1.0	1.0
Physicist	5.9	5.9
Dosimetrist	6.0	6.0
Registered Radiation Therapist	19.0	19.0
Radiation Therapist Navigator	1.0	1.0
Chief Radiation Therapist	1.0	1.0
Radiation Oncology Technician II	2.0	2.0
Total Other Clinical	36.9	36.9
Other Non-Clinical		
Clerical Assistant II	1.0	1.0
Medical Secretary	5.9	5.9
Total Other Non-Clinical	6.9	6.9
Total Staff	54.8	54.8

In Section VII.3, page 102, the applicants state that no additional staff will be added as the result of the acquisition of a replacement linear accelerator.

The applicants state Cone Health is one of the largest employers in the Triad region with the human resources staff dedicated to recruitment and retention of employees. The applicants state Cone Health has not experienced difficulty hiring staff and does not anticipate any problems filling future positions.

In Section VII.8, page 107, the applicants identify the Medical Director of Radiation Oncology for Cone Health.

The applicants adequately demonstrate the availability of sufficient health manpower to continue providing radiation therapy services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In Section II.1, page 35, and Exhibit 5, the applicants identify the ancillary and support services that are currently available to the Radiation Oncology Department. The applicants state,

“The ancillary and support services required to provide radiation therapy services include physics, dosimetry, laboratory, pharmacy, radiology, social work and pastoral care, environmental services, and business office for registration, scheduling, billing, and medical records. As an established provider, Cone Health Cancer Center maintains all of these required support services; moreover, no incremental expansion of these support services will be necessary for the operation of the proposed equipment.”

The applicants state that Project I.D. #G-8124-08 (expand and renovate the Cancer Center), which was proposed for the purpose of improving the applicants’ ability to provide ancillary and support services, was completed in January 2012. The applicants discuss coordination with the existing health care system in Section V, pages 75-86. The applicants provide supporting documentation in Exhibits 6 and 17. The information provided in these sections and exhibits is reasonable and credible and supports a finding of conformity with this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.

- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (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;

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The following table illustrates the current payor mix for CHCC, as reported by the applicants in Section VI, page 96.

Payor Category	Entire Cone Health Facility Patient Days/Procedures as Percent of Total Utilization	Radiation Oncology Department Patient Days/Procedures as Percent of Total Utilization
Self Pay/ Indigent/ Charity	7.7%	3.0%
Medicare/ Medicare Managed Care	44.9%	53.3%
Medicaid	12.6%	5.8%
Managed Care / Commercial Insurance	32.2%	36.7%
Other *	2.5%	1.1%
Total	100.0%	100.0%

* Includes other Government payors and worker's compensation.

In Section VI.4, page 89, the applicants state *“All patients will have access to the health care services provided by Cone Health and CHCC upon completion of this project regardless of their ability to pay.”* The applicants also state, *“The Hospital accepts responsibility for providing quality hospital care without regard to the individual patient’s financial circumstances.”* The applicants provide supporting documentation in Exhibit 20.

On page 88, the applicants state they provide outreach and education services targeting generally underserved groups. The applicants provide supporting documentation in Exhibits 18 and 19. In Section VI.8, page 92, the applicants state CHCC provided 9.68 percent of net revenue in charity care and bad debt in FY 2011. In Section V.7, page 85, the applicants state the *“CHCC Radiation Oncology Program projects to provide at least 58% of its services to the Medicare and Medicaid populations and at least 4% to the self-pay/uninsured population.”*

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina, as shown in the following table.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center) *
Guilford County	15%	5.90%	18.3%
Statewide	17%	6.71%	19.7%

* More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the health services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicants demonstrate that medically underserved populations currently have adequate access to linear accelerator services provided at CHCC. Therefore, the application is conforming to this criterion.

- (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;

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In Section VI.11, page 96, the applicants state "*Cone Health has no obligation under applicable Federal regulations to provide uncompensated care, community service, or access to care by minorities and handicapped person.*" The applicants state they are dedicated to providing care to all members of the community. In Section VI.10, page 95, the applicants state "*There has been one civil rights equal access complaint filed against Cone Health in the last five years.*" The applicants state the complaint was dismissed in February 2008. The application is conforming to this criterion.

- (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

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In Sections VI.14 – IV.15, pages 97-98, the applicants project the payor mix for the second operating year, (FY 2015) as shown in the following table.

Payor Category	Entire Cone Health Facility Patient Days/Procedures as Percent of Total Utilization	Radiation Oncology Department Patient Days/Procedures as Percent of Total Utilization
Self Pay/ Indigent/ Charity	8.1%	4.3%
Medicare/ Medicare Managed Care	45.2%	51.1%
Medicaid	12.8%	7.5%
Managed Care / Commercial Insurance	30.8%	35.1%
Other *	3.2%	2.0%
Total	100.0%	100.0%

* Includes other Government payors and worker’s compensation.

The applicants state they based the projected payor mix levels shown above on actual payor mix levels for FY 2012 (year-to-date through August 2012) using the assumption that these current ratios will remain essentially unchanged.

In Section VI.2, page 87, the applicants describe the policy for providing access to the facility, as follows:

“Cone Health, including the Cancer Center, does not discriminate against low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent, the uninsured and the underinsured. In general, the health services of Cone Health are available to any patient in need without restriction of any kind.”

The applicants demonstrate that medically underserved populations will continue to have adequate access to linear accelerator services at CHCC. Therefore, the application is conforming to this criterion.

- (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.

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In Section VI.9, page 94, the applicants document the range of means by which patients have access to the linear accelerator services provided at CHCC. The applicants state that referrals may come from local hospitals, hospitals throughout the state, primary care physicians, American Cancer Society, home health agencies, hospice agencies, and other healthcare providers. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

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In Section V.1, pages 75-76, Cone Health documents that they accommodate the clinical needs of health professional training programs in the service area and that they will continue to do so. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (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.

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Cone Health currently owns and operates four linear accelerators at CHCC, located on the Wesley Long Hospital campus. The applicants propose to replace the existing Elekta Precise S/N 5770 linear accelerator in Vault #2 with a new Varian TrueBeam linear accelerator. The applicants are not proposing to add beds, equipment or new services in Guilford County. In Section V.7, pages 84-86, the applicants discuss the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality, and access. The applicants state *“The proposed project will result in upgraded services that will more effectively serve patients.”* See also Sections II, III, V, VI, and VII. The information provided by the applicants in each of these sections is reasonable, credible, and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost effectiveness, quality, and access to linear accelerator services in Guilford County.

This determination is based on a review of the information in the sections of the application referenced above and the following analysis:

- The applicants adequately demonstrate the need to replace an existing linear accelerator at CHCC with a Varian TrueBeam linear accelerator;

- The applicants adequately demonstrate that the proposal is a cost-effective alternative to meet the need (see Section III of the application);
- The applicants will continue to provide quality services (see Section II and VII of the application);
- The applicants will continue to provide adequate access to medically underserved populations (see Section III and VI of the application); and
- The proposal will have a positive impact on competition by providing residents with increased access to quality services (see Section II and VI of the application).

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

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Cone Health is a licensed, acute care hospital and is accredited by the Joint Commission. CHCC has been designated as a Community Hospital Comprehensive Cancer Program by the American College of Surgeons Commission on Cancer. According to the records in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents have occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) 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.

NA

The applicants propose to replace an existing linear accelerator, not acquire an additional linear accelerator. Therefore the Criteria and Standards for Radiation Therapy Equipment, promulgated in 10A NCAC 14C.1900, are not applicable to this review.