

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 29, 2014  
PROJECT ANALYST: Celia C. Inman  
TEAM LEADER: Lisa Pittman  
PROJECT I.D. NUMBER: G-10260-14 / 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 2014 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2014 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 119, the applicants state

*"Cone Health is committed to utilizing energy efficient principles in all construction and renovation projects. While this project entails only interior renovation and equipment replacement within an existing 1,100 square foot space, the project will either meet or exceed the NC State Energy Conservation Code."*

Exhibit 16 contains a letter from Little Diversified Architectural Consulting detailing strategies that will be used to meet energy efficiency and water conservation standards. The applicants adequately describe the project's plan to assure improved energy efficiency and improved water conservation.

Therefore, the application is conforming to this criterion subject to Condition 5 in Criterion (4).

- (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 Cone Health system, includes the following separately licensed hospitals:

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

Per Cone Health's 2014 License Renewal Application (LRA), The Moses H. Cone Memorial Hospital Operating Corporation, a wholly owned subsidiary of The Moses H. Cone Memorial Hospital, is licensed to operate The Moses H. Cone Memorial Hospital and Annie Penn Hospital. The Moses H. Cone Memorial Hospital in Guilford County consists of five campuses and seven entities 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.

In addition, there are other facilities that are part of Cone Health, but under individual licenses.

Cone Health owns and operates four linear accelerators at the Cone Health Cancer Center, located on the Wesley Long Hospital campus, at 501 North Elam Avenue in Greensboro. Cone Health also owns and operates two linear accelerators at Cone Health Cancer Center at Alamance Regional at 1240 Huffman Mill Road in Burlington. In addition, Cone Health is a joint venture partner along 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 5776 linear accelerator in CHCC's Vault #3 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.5, pages 57-59, the applicants state that the primary service area for the proposed project is Guilford County, which represents 71.2% of CHCC's radiation therapy patient origin. The applicants further state:

*"The secondary service area comprises Randolph, Rockingham, western Alamance (zip codes 27215 and 27244), and eastern Forsyth (zip codes 27009 and 27284/85) counties. These areas represent 21.7% of the radiation therapy patient origin."*

The applicants provide a service area map in Exhibit 19 highlighting the primary and secondary service areas. The highlighted counties on the map include: Guilford; Randolph; Rockingham; western Alamance; and eastern Forsyth. In Exhibit 15, the applicants provide a list of service area zip codes, by county and city, which are consistent with the counties highlighted in Exhibit 19. The service area counties listed account for 92.9% of Cone Health's total radiation therapy patient origin.

In Exhibit 18, the applicants provide CCHC’s existing and projected radiation therapy patient origin by county of residence, as shown below.

**Cone Health Radiation Therapy Patient Origin**

| County         | Historical    | Projected      |               |                |               |
|----------------|---------------|----------------|---------------|----------------|---------------|
|                | FFY 2013      | Project Year 1 |               | Project Year 2 |               |
|                |               | FFY 2016 #     | FFY 2016 %    | FFY 2017 #     | FFY 2017 %    |
| Guilford       | 71.2%         | 44,429         | 71.2%         | 44,873         | 71.2%         |
| Rockingham     | 12.6%         | 7,862          | 12.6%         | 7,941          | 12.6%         |
| Randolph       | 6.6%          | 4,118          | 6.6%          | 4,160          | 6.6%          |
| Alamance       | 1.8%          | 1,123          | 1.8%          | 1,134          | 1.8%          |
| Forsyth        | 1.7%          | 1,061          | 1.7%          | 1,071          | 1.7%          |
| Virginia       | 1.4%          | 874            | 1.4%          | 882            | 1.4%          |
| Chatham        | 0.7%          | 437            | 0.7%          | 441            | 0.7%          |
| Davidson       | 0.5%          | 312            | 0.5%          | 315            | 0.5%          |
| Stokes         | 0.4%          | 250            | 0.4%          | 252            | 0.4%          |
| Montgomery     | 0.3%          | 187            | 0.3%          | 189            | 0.3%          |
| Mecklenburg    | 0.2%          | 125            | 0.2%          | 126            | 0.2%          |
| South Carolina | 0.2%          | 125            | 0.2%          | 126            | 0.2%          |
| Wake           | 0.1%          | 62             | 0.1%          | 63             | 0.1%          |
| Granville      | 0.1%          | 62             | 0.1%          | 63             | 0.1%          |
| Other*         | 2.2%          | 1,373          | 2.2%          | 1,387          | 2.2%          |
| <b>Total</b>   | <b>100.0%</b> | <b>62,400</b>  | <b>100.0%</b> | <b>63,024</b>  | <b>100.0%</b> |

\*Other is identified as California, Rowan, Beaufort, Cabarrus, Hertford, Brunswick, Catawba, Stanly, Cumberland, Person, Alleghany, and Franklin, each representing less than 0.1% of the patient origin.

As the table above illustrates, the applicants project that the patient origin for radiation therapy services in the project’s first two operating years, FFY 2016 and FFY 2017 is expected to be consistent with the historical FFY 2013 percentages.

The applicants adequately identify the population to be served.

**Demonstration of Need**

In Section III.1, pages 33-52, the applicants discuss the unmet need served by the proposed project and state that it 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.
- Growth in newly diagnosed cancer cases and utilization of cancer-related services.
- Growing demand for advanced capabilities and improved patient safety mechanisms in radiation therapy technologies to provide more precise, higher quality treatments.
- High utilization of the existing linear accelerators at CHCC and demand for advanced radiation therapy capabilities at Cone Health Cancer Center.

- Inadequacies and technical deficiencies of the existing equipment to be replaced.

Historic and Projected Population Growth

On pages 35-36, the applicants discuss the proposed service area’s projected growth over the next five years, stating the expectation of a 4.1% growth during that period. Table III-1 on page 35 illustrates the growth of the primary service area and the secondary service area, by age group, as illustrated below.

| <b>Projected Service Area Population</b>   |                        |                        |                           |                           |                       |
|--|------------------------|------------------------|---------------------------|---------------------------|-----------------------|
| <b>By Area and Age Group</b>   | <b>2013 Population</b> | <b>2018 Population</b> | <b># Change 2013-2018</b> | <b>% Change 2013-2018</b> | <b>CAGR 2013-2018</b> |
| <b>Primary Service Area - Guilford County</b>  |                        |                        |                           |                           |                       |
| 0-17   | 116,585                | 120,283                | 3,698                     | 3.2%                      | 0.6%                  |
| 18-44  | 190,263                | 193,001                | 2,738                     | 1.4%                      | 0.3%                  |
| 45-64  | 130,698                | 137,301                | 6,603                     | 5.1%                      | 1.0%                  |
| 65+  | 66,581                 | 79,235                 | 12,654                    | 19.0%                     | 3.5%                  |
| <b>Total</b>   | <b>504,127</b>         | <b>529,820</b>         | <b>25,693</b>             | <b>5.1%</b>               | <b>1.0%</b>           |
| <b>Secondary Service Area - Randolph, Rockingham, E. Forsyth, W. Alamance Counties</b> |                        |                        |                           |                           |                       |
| 0-17   | 81,637                 | 81,680                 | 43                        | 0.1%                      | 0.0%                  |
| 18-44  | 118,836                | 118,443                | (393)                     | -0.3%                     | -0.1%                 |
| 45-64  | 100,237                | 101,844                | 1,607                     | 1.6%                      | 0.3%                  |
| 65+  | 57,290                 | 65,884                 | 8,594                     | 15.0%                     | 2.8%                  |
| <b>Total</b>   | <b>358,000</b>         | <b>367,851</b>         | <b>9,851</b>              | <b>2.8%</b>               | <b>0.5%</b>           |
| <b>Total Service Area</b>  |                        |                        |                           |                           |                       |
| 0-17   | 198,222                | 201,963                | 3,741                     | 1.9%                      | 0.4%                  |
| 18-44  | 309,099                | 311,444                | 2,345                     | 0.8%                      | 0.2%                  |
| 45-64  | 230,935                | 239,145                | 8,210                     | 3.6%                      | 0.7%                  |
| 65+  | 123,871                | 145,119                | 21,248                    | 17.2%                     | 3.2%                  |
| <b>Total</b>   | <b>862,127</b>         | <b>897,671</b>         | <b>35,544</b>             | <b>4.1%</b>               | <b>0.8%</b>           |

Source: Truven Health Market Expert Demographics

As the table above shows, the proposed total service area population is projected to grow by 4.1% with a compound annual growth rate (CAGR) from FY 2013 to FY 2018 of 0.8%, according to Truven demographic information provided by the applicants. Of particular note is the growth of the age 65+ cohort for the total service area population, which is projected to increase 17.2% during the five year period.

On page 35, the applicants state, “Nearly 60% of the 35,544 population growth from 2013-2018 will be within the 65+ age cohort.”

On page 36, 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. Today,*

*the rate of hospital stays for the population 65 or older is four (4) times the rate for 15-44 year olds.”<sup>1</sup>*

### Growth in Cancer Cases and Incidence Rates

In Section III.1, page 36, the applicants state:

*“In particular, the incidence of developing cancer, and therefore using oncology services, is directly related to age. According to the National Cancer Institute’s Cancer Statistics, as presented in Table III-2 below the incidence rate for developing invasive cancer increases significantly with age.”*

**Table III-2  
Incidence Rate of Developing Invasive Cancers Over  
Selected Age Intervals by Sex United States(1)**

| All Cancer Sites (2,3) | Male    | Female  |
|------------------------|---------|---------|
| Birth to 19            | 16.6    | 15.0    |
| 20 to 44               | 85.4    | 133.4   |
| 45 to 64               | 683.5   | 656.8   |
| 65 to 74               | 2,463.4 | 1,449.9 |
| 75 and over            | 3,360.5 | 1,873.7 |
| All ages               | 553.2   | 407.7   |

- (1) For people free of cancer at beginning of age interval.
  - (2) All sites exclude basal and squamous cell skin cancers and in situ cancers except urinary bladder.
  - (3) Incidence rates are per 100,000 population
- Source: Surveillance, Epidemiology, and End Results (SEER) Program ([www.seer.cancer.gov](http://www.seer.cancer.gov)) SEER\*Stat Database: Incidence – SEER 9 Regs Research Data, Nov 2012 Sub (1973-2010), National Cancer Institute.

On page 37, the applicants state:

*“About 77% of all cancers are diagnosed in persons aged 55 years and older.<sup>2</sup> As noted in the State Center for Health Statistics “Cancer in North Carolina 2013 Report”, published in January 2014, “Cancer is the leading cause of death in North Carolina. [...] Moreover, cancer incidence rates in North Carolina have been slowly increasing since 1988.”<sup>3</sup>*

The applicants state that the combination of growth and aging of the population results in an increase in both the service area prevalence of cancer (the number of service area residents living with a cancer diagnosis) and the incidence of cancer (the number of new cancer patients diagnosed). According to the following data provided by the applicants on page 38, the number

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<sup>1</sup> Centers for Disease Control and Prevention, National Hospital Discharge Survey. 2010.

<sup>2</sup> American Cancer Society. *Cancer Facts & Figures 2014*. Atlanta: American Cancer Society; 2014. p.1.

<sup>3</sup> State Center for Health Statistics. *Cancer in North Carolina 2013 Report*. Raleigh: State Center for Health Statistics; January 2014. p.2.

of new cancer cases in Cone Health’s service area increased 8.9%, or an average of 2.2% annually from 2006 to 2010, the most current year for which data are available. (Note, the applicants state that the numbers included in the table below include the entire county population because the NC Central Cancer Registry reports the data by county and the applicants therefore were not able to discern the data for the specific zip codes comprising the proposed secondary service area.)

**Table III-3 State and Proposed Project Service Area New Cancer Cases 2006-2010**

| Service Area County | 2006   | 2007   | 2008   | 2009   | 2010   | Change 2006-2010 |       |                  |
|---------------------|--------|--------|--------|--------|--------|------------------|-------|------------------|
|                     |        |        |        |        |        | #                | %     | Average Annual % |
| Guilford            | 2,549  | 2,281  | 2,651  | 2,791  | 2,722  | 173              | 6.8%  | 1.7%             |
| Randolph            | 679    | 738    | 822    | 874    | 811    | 132              | 19.4% | 4.5%             |
| Rockingham          | 587    | 581    | 618    | 607    | 608    | 21               | 3.6%  | 0.9%             |
| Alamance            | 865    | 871    | 845    | 908    | 866    | 1                | 0.1%  | 0.0%             |
| Forsyth             | 1,778  | 1,945  | 1,911  | 1,926  | 2,025  | 247              | 13.9% | 3.3%             |
| Total SA            | 6,458  | 6,416  | 6,847  | 7,106  | 7,032  | 574              | 8.9%  | 2.2%             |
| Total NC            | 44,319 | 46,175 | 47,588 | 49,575 | 49,340 | 5,021            | 11.3% | 2.7%             |

Includes in situ cancers except those of the urinary bladder and female breast.

Source: North Carolina Central Cancer Registry. “Cancer Incidence in NC” reports, 2006-2010.

As the table above shows, all counties in the proposed service area experienced growth in the number of newly diagnosed cancer cases from 2006 to 2010. In addition, portions of the CHCC service area experienced higher growth rates than the state as a whole. The applicants also provide data on the proposed service area’s cancer incidence rates on page 39, which indicates a decline in incidence from 2009 to 2010. The applicants state:

*“Although incidence rates have fluctuated over time, in general they have remained high in the proposed service area. In fact, the incidence rate for the service area was higher than the North Carolina rate for every year from 2006 to 2010.*

...

*It is possible that part of the decline in incidence from 2009 to 2010 can be explained by the nationwide economic recession. As unemployment increased, the number of uninsured individuals also increased.”*

The applicants provide data on unemployment rates in Cone Health’s service area counties, the State and the United States on page 40, illustrating that the service area counties all have higher unemployment rates than the national average from 2010 through 2013. On page 41, the applicants provide the 2011 uninsured rates for each county in the proposed service area, ranging from 16.9% to 17.6%. The applicants suggest that uninsured and/or unemployed individuals are more likely to postpone or forego health care, including primary care and diagnostic screenings that might result in detection and diagnosis of conditions such as cancer. On page 41, the applicants state:

*“As unemployment falls in the service area and a larger percentage of the population ages into Medicare, improved access to primary and specialty health care may result in increasing incidence rates.*

...

*These overall volume and incidence trends for cancer patients consistently exceed growth rates for the service area population. Thus, combined with the previously discussed increase and aging of this population, continued growth and demand for oncology services is a certainty.”*

### Demand for Advanced Radiation Therapy Technologies

On pages 41-44, the applicants state the majority of growth projected in oncology services over the next decade, according to the Advisory Board Company, will be outpatient based. The applicants state that initial outpatient cancer care, such as physician visits, chemotherapy, and radiation therapy treatments are projected to continue to grow. The applicants further state that enhancements in technology, such as minimally invasive surgery, will shift treatments from the inpatient setting to the outpatient setting. On page 42, the applicants state:

*“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 23% from 2012 to 2022.”*

On pages 42-43, the applicants provide Chart III-2, representing The Advisory Board’s projection for outpatient chemotherapy (18%), outpatient radiation oncology (28%), outpatient oncology visits/procedures (23%) and medical oncology inpatient discharges (4%).

*“As noted above, radiation therapy is projected to grow 28%, or an average of 2.5% annually, from 2012 to 2022. While all radiation therapy modalities are projected to grow, The Advisory Board Company predicts that growth within radiation therapy will be most striking in the newer, more advanced modalities, such as stereotactic radiosurgery (SRS), stereotactic body radiation therapy (SBRT), and Intensity-Modulated Radiation Therapy (IMRT), as noted in Chart III.3.”*

On page 43, the applicants provide Chart III-3, representing The Advisory Board’s growth projection for HDR brachytherapy (34%), LDR brachytherapy (23%), IMRT (59%) conventional radiation (11%), SBRT (43%) and SRS (27%). The applicants discuss North Carolina hospitals’ use of new, more targeted radiation therapy modalities on page 44, stating:

*“According to the annual survey conducted by the American Hospital Association, the number of hospitals in the U.S. that offer IMRT services increased by 124 from 2007 to 2012. In 2012, 32.5% of North Carolina hospitals offered IMRT services. In fact, North Carolina hospitals appear to be strong adopters of IMRT since just 23.0% of hospitals nationwide offer IMRT.*

...

*According to the NC State Medical Facilities Plan, there has also been significant growth in SRS volumes in North Carolina in recent years.”*

The applicants provide data in Table III-6, page 44, showing that total SRS procedures in NC increased 10.4% from 2010 to 2012. The applicants discuss the benefits, both clinically and operationally, of advanced radiation therapy technologies on pages 43-44, stating:

*“Newer, more technologically advanced radiation therapy modalities provide more treatment options for patients with fewer side effects and decreased morbidity. Cancer treatment has evolved so that “one-size” does not fit all patients. A more customized treatment plan that offers a number of options is more desirable for both physicians and patients. New, more targeted radiation therapy modalities have been shown to reduce side effects of treatment, while also minimizing damage to healthy tissue, which is safer and provides better quality of care to patients.”*

#### High Utilization of Existing Linear Accelerators at Cone Health Cancer Center

In Section III, page 45, the applicants state that service area population growth, the aging of the population, rising incidence rates, and patient preference drive most of the increase in cases and procedures seen at CHCC. The applicants also state that being a regional referral center, CHCC draws patients from geographic areas that lack cancer facilities with the experience and technology provided at CHCC.

On pages 45-46, the applicants discuss the past utilization of CHCC’s four linear accelerators, stating they have historically operated near or above 100% percent of capacity. The table below illustrates CHCC linear accelerator utilization from FFY 2010 through FFY 2014 (annualized).

**Table III-7 ESTV Utilization of CHCC Linear Accelerators**

| ESTVs by Category               | FFY 2010      | FFY 2011      | FFY 2012      | FFY 2013      | FFY 2014 Annualized* | Change FFY 2010-2014A |              |
|---------------------------------|---------------|---------------|---------------|---------------|----------------------|-----------------------|--------------|
|                                 |               |               |               |               |                      | #                     | %            |
| Simple Txt                      | 38            | 47            | 11            | 4             | 12                   | -26                   | -68.4%       |
| Intermediate Txt                | 2,451         | 2,212         | 2,404         | 2,006         | 1,776                | -675                  | -27.5%       |
| Complex Txt                     | 15,245        | 16,009        | 16,936        | 13,869        | 14,391               | -854                  | -5.6%        |
| <b>Conventional RT Subtotal</b> | <b>17,734</b> | <b>18,268</b> | <b>19,351</b> | <b>15,879</b> | <b>16,179</b>        | <b>-1,555</b>         | <b>-8.8%</b> |
| IMRT                            | 6,160         | 6,533         | 7,991         | 5,963         | 8,439                | 2,279                 | 37.0%        |
| Add Field Checks                | 1,295         | 1,220         | 1,243         | 989           | 932                  | -364                  | -28.1%       |
| SRS                             | 567           | 621           | 801           | 1,038         | 1,791                | 1,224                 | 215.9%       |
| <b>Total</b>                    | <b>25,756</b> | <b>26,642</b> | <b>29,386</b> | <b>23,869</b> | <b>27,341</b>        | <b>1,585</b>          | <b>6.2%</b>  |
| <b>% Capacity</b>               | <b>95.4%</b>  | <b>98.7%</b>  | <b>108.8%</b> | <b>88.4%</b>  | <b>101.3%</b>        |                       |              |

\*FFY 2014 is annualized based on four months of data.

As the table above shows, FFY 2013 utilization decreased over 2012's by 5,518 ESTVs or 18.8%. Federal fiscal year 2014's utilization has been annualized based on only four months of procedures, which may or may not be a good forecast for 2014. The compound annual growth rate (CAGR) from 2010 through 2014 (annualized) is 1.5%. Of greater importance, the table demonstrates a shift from conventional radiation therapy treatments to SRS technology, with SRS treatments increasing each year.

On page 46, the applicants state:

*“Although ESTV volumes declined from FY 2012 to FY 2013, FY 2014 year to date volumes annualized indicate an increase in ESTVs over FY 2013. Given the high utilization of Cone Health Cancer Center’s linear accelerators, it is unlikely that volumes could increase significantly without additional incremental capacity.*

*Table III-7 also demonstrates the demand for more advanced radiation therapy procedures at CHCC. From FY 2010 to FY 2014 (annualized), simple, intermediate, and complex conventional radiation therapy volumes declined 8.8%, while IMRT volumes increased 37.0% and SRS volumes increased 215.9%.*

*The shift within categories of treatment appears to be occurring because of changes in radiation therapy technology and newer techniques for improving precision in targeting tumors.*

...

*The proposed project to replace an existing outdated, technologically inadequate linear accelerator with an up-to-date Varian TrueBeam linear accelerator will allow*

*CHCC to meet future demand for improved conventional radiation therapy, IMRT, SRS, and SBRT.”*

### Inadequate and Technical Deficiencies of Existing Linear Accelerator

On pages 47-52, the applicants compare the existing Elekta Precise S/N 5776 (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 skin damage.
- 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 visits.
- Incapable of providing cone-beam computed tomography (CBCT), a key localization technology for a variety of tumor diseases and sites.
- 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 patient respiration. Treatment with gated 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 the respiration cycle.
- Incapable of directly interfacing with the existing stereoscopic 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.
- Treatment couch constructed with reinforced metal bars and plastic bars which interfere with the radiation dose and can cause a 20 percent reduction in dosage.
- Current treatment planning system does not allow for dose corrections for the presence of the couch in the beam. This could result in reduction in expected dose to the tumor.
- The Elekta has 1 cm leaves in the Multileaf Collimator, which limit its ability to achieve more precise dose conformality.
- Incapable of modulated arc treatments which spread the toxicity of radiation over 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.

Because of the above listed limitations, the applicants are proposing to replace the Elekta with the highly advanced Varian system, which provides 3D conventional radiation therapy, IMRT, SRS, and SBRT using a 120-leaf Multileaf Collimator and the On-Board Images with cone-beam CT for real-time image guidance during treatment. The applicants adequately demonstrate the need to replace the existing Elekta linear accelerator in Vault 3.

**Projected Utilization**

In Section IV.1, pages 62-68, the applicants project linear accelerator and radiation oncology department utilization at CHCC for the interim years and the first three fiscal years after completion of the project, as illustrated in the table below.

**Projected Utilization**

|                     | Interim Years |          | Project Years |          |          |
|---------------------|---------------|----------|---------------|----------|----------|
|                     | FFY 2014      | FFY 2015 | FFY 2016      | FFY 2017 | FFY 2018 |
| Linear Accelerators | 4             | 4        | 4             | 4        | 4        |
| ESTV Treatments     | 27,341        | 27,341   | 27,614        | 27,890   | 28,169   |
| Projected Increase  | 0             | 0        | 1.0%          | 1.0%     | 1.0%     |
| Capacity            | 101.3%        | 101.3%   | 102.3%        | 103.3%   | 104.3%   |

The assumptions and methodology used for determining CHCC’s projected utilization begin on page 63 and are summarized as follows:

- The first year of operation following completion of the project is FFY 2016 (October 1, 2015 through September 30, 2016).
- FFY 2014 volumes are annualized based on the first four months of FFY 2014.
- CCHC is operating at 101.3% of capacity in FFY2014 with 27,341 ESTVs and four linear accelerators, based on the 2014 SMFP definition of capacity as 6,750 ESTVs per linear accelerator.
- The annual growth rate is 1.0% beginning in FFY 2016, with no growth in FFY2015. The applicant determines this growth rate to be a conservative rate based on the following factors:
  - Service area total population is projected to grow 0.8% annually over the next five years.
  - The 65+ age group, which is most likely to utilize oncology health care services, is projected to grow 3.2% annually.
  - New cancer cases in the service area counties increased 2.2% annually from 2006 to 2010.
  - Outpatient radiation therapy volumes are projected to increase 2.5% annually from 2012 to 2022.
  - Cone Health Cancer Center ESTV volumes had an average annual growth rate of 1.2% from FFY 2010 to FFY 2014.
  - The Project Analyst calculated the CHCC CAGR at 1.5% during the same period.
- Radiation oncology department procedures include linear accelerator treatments, exams with physicians, simulations, CT guidance scans, brachytherapy procedures,

seed implants, physics consults, and treatment planning procedures. Total radiation oncology department procedures are provided as shown below:

**Projected Utilization Total Radiation Oncology Department Procedures**

|                               | Interim Years |          | Project Years |          |          |
|-------------------------------|---------------|----------|---------------|----------|----------|
|                               | FFY 2014      | FFY 2015 | FFY 2016      | FFY 2017 | FFY 2018 |
| Radiation Oncology Procedures | 61,782        | 61,782   | 62,400        | 63,024   | 63,654   |
| Projected Increase            | 0             | 0        | 1.0%          | 1.0%     | 1.0%     |

On page 63, the applicants show the four existing linear accelerators performed an average of 6,835 ESTVs per linear accelerator during FFY 2014 (annualized based on four months of data) [27,341 / 4 = 6,835]. In Project Year 3, the applicants project the four CCHC linear accelerators will perform an average of 7,042 ESTVs per linear accelerator [28,169 / 4 = 7,042]. The applicants adequately demonstrate projected utilization is based on reasonable, credible, and supported assumptions.

**Access**

In Section V, page 79, the applicants state that Cone Health has demonstrated a long-standing commitment to the underserved residents of its community. The applicants further state:

*“CHCC Radiation Oncology program projects to provide nearly 57% of its services to the Medicare and Medicaid populations and at least 5% of its services to the self-pay/uninsured population. CHCC will continue to provide free cancer screenings and community education /outreach programs that benefit underserved and uninsured individuals.”*

The applicants further address access to its services in Section VI, pages 81-82 and provides the following payor mix for the second full fiscal year of the proposed project.

**Patient Days/Procedures as a Percent of Total Utilization  
 October 1, 2016- September 30, 2017**

| Payor Category                      | Cone Health Facility | CCHC Radiation Oncology |
|-------------------------------------|----------------------|-------------------------|
| Self Pay/ Indigent/ Charity         | 7.8%                 | 5.0%                    |
| Medicare/ Medicare Managed Care     | 45.8%                | 51.4%                   |
| Medicaid                            | 13.1%                | 5.3%                    |
| Managed Care / Commercial Insurance | 30.0%                | 35.6%                   |
| Other *                             | 3.3%                 | 2.7%                    |
| Total                               | 100.0%               | 100.0%                  |

\* Includes other Government payors and worker’s compensation.

The applicant adequately demonstrates 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.

In summary, the applicants adequately identify the population to be served, adequately demonstrate the need to replace the existing linear accelerator, and adequately demonstrate all residents of the area will have access to the proposed services. 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 56, the applicants discuss the alternatives considered prior to the submission of this application, which include:

- 1) Maintain 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 patients at CHCC. Additionally, it does not eliminate efficiency and quality problems caused by the existing outdated and technologically inadequate linear accelerator for which replacement parts will no longer be available. Therefore, this option was rejected.
- 2) Purchase 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. Therefore, this option was rejected.
- 3) Replace the Elekta with a Varian TrueBeam - The applicants state that replacing an outdated linear accelerator with an advanced Varian TrueBeam linear accelerator will improve the scope and quality of radiation therapy services provided to patients at the comprehensive cancer center.

The applicants demonstrate that purchasing a Varian TrueBeam linear accelerator is an effective alternative to address the current and future demand at CHCC 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 5776 linear accelerator in Vault #3 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 5776 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 105, the applicants project the total capital cost will be \$5,870,000, which includes \$330,000 for renovation costs, \$5,500,000 for fixed equipment, and \$40,000 for architect and engineering fees and reimbursables. In Section IX, page 110, the applicants state there will be no start-up or initial operating expenses for this project.

In Section VIII.3, page 106, the applicants state that the total capital cost will be funded with the accumulated reserves of Cone Health. Exhibit 26 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 #3 at Cone Health Cancer Center on the Wesley Long Hospital campus. Total capital project costs are budgeted at \$5,870,000.”*

Exhibit 27 contains the audited financial statements for Cone Health for years ending September 30, 2013 and 2012. According to the financial statements, as of September 30, 2013, Cone Health had \$11,895,000 in cash and cash equivalents, \$328,888,000 in total current assets, \$2,210,298,000 in total assets and \$1,411,467,000 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.

| <b>CHCC<br/>Radiation Oncology Department</b> | <b>Project Year 1<br/>10/1/15 - 09/30/16</b> | <b>Project Year 2<br/>10/1/16 - 09/30/17</b> | <b>Project Year 3<br/>10/1/17 - 09/30/18</b> |
|---|--|--|--|
| Projected Radiation Oncology Procedures       | 62,400                                       | 63,024                                       | 63,654                                       |
| Projected Average Charge per Procedure        | \$908.84                                     | \$917.93                                     | \$927.11                                     |
| Gross Patient Revenue                         | \$56,711,285                                 | \$57,851,182                                 | \$59,013,990                                 |
| Deductions from Gross Patient Revenue         | \$35,389,739                                 | \$36,101,073                                 | \$36,826,705                                 |
| Net Patient Revenue                           | \$21,321,546                                 | \$21,750,109                                 | \$22,187,286                                 |
| Total Expenses                                | \$12,143,043                                 | \$12,503,791                                 | \$12,580,023                                 |
| Net Income                                    | \$9,178,502                                  | \$9,246,317                                  | \$9,607,262                                  |

\* Source: Form C.

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.

| <b>The Moses H. Cone Memorial Hospital<br/>Entire Facility</b> | <b>Project Year 1<br/>10/1/15 - 09/30/16</b> | <b>Project Year 2<br/>10/1/16 - 09/30/17</b> | <b>Project Year 3<br/>10/1/17 - 09/30/18</b> |
|--|--|--|--|
| Net Patient Service Revenue                                    | \$1,371,157,000                              | \$1,405,450,000                              | \$1,438,406,000                              |
| Total Revenue  | \$1,423,938,000                              | \$1,457,184,000                              | \$1,490,140,000                              |
| Total Expenses   | \$1,377,722,000                              | \$1,411,818,000                              | \$1,453,335,000                              |
| Income from Operations   | \$46,216,000                                 | \$45,366,000                                 | \$36,805,000                                 |
| Net Nonoperating Revenue                                       | \$29,195,000                                 | \$31,368,000                                 | \$33,462,000                                 |
| Excess of Revenue over Expenses                                | \$75,411,000                                 | \$76,734,000                                 | \$70,267,000                                 |

\* Source: Form B.

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 on the Wesley Long Hospital campus. The applicants propose to replace the existing Elekta Precise S/N 5776 linear accelerator in Vault #3 with a new Varian TrueBeam linear accelerator. The applicants are not proposing to add beds, other medical equipment or new services in Guilford County.

In Section III.1, pages 33-52, the applicants adequately demonstrate, based on current utilization, the demand for state-of-the-art enhanced radiation therapy services in the service area. In Section IV, page 63, the applicants project that the four linear accelerators will average 7,042 ESTVs per unit (28,169 ESTVs / 4 = 7,042) in the third project year, FFY 2018. Additionally, in Section III.6, pages 58-59, the applicants state that based on the inventory in the 2014 SMFP, the other providers of radiation therapy services in Cone Health's service area are High Point Regional Health System, Morehead Memorial Hospital, Randolph Cancer Center, Novant Health Kernersville Medical Center, and Cone Health Cancer Center at Alamance Regional Medical Center as shown in the table below.

| Facility                                | SMFP Service Area | FFY 2012 # of Linear Accelerators | FFY 2012 Total ESTVs | FFY 2012 Average ESTVs per unit | % of Capacity* |
|---|-------------------|-----------------------------------|----------------------|---------------------------------|----------------|
| Cone Health Cancer Center               | 12                | 4                                 | 29,386               | 7,347                           | 108.8%         |
| Cone Health CC at ARMC                  | 15                | 2                                 | 9,165                | 4,583                           | 67.8%          |
| High Point Regional Health System       | 12                | 2                                 | 7,449                | 3,724                           | 55.2%          |
| Morehead Memorial Hospital              | 12                | 1                                 | 5,288                | 5,288                           | 78.3%          |
| Randolph Cancer Center                  | 13                | 1                                 | 4,055                | 4,055                           | 60.1%          |
| Novant Health Kernersville <sup>^</sup> | 12                | 1                                 | NA                   | NA                              | NA             |

\* The applicants calculate the percent of capacity by dividing the Average ESTVs per unit by the 6,750 ESTVs capacity defined on page 125 of the 2014 SMFP.

<sup>^</sup>Novant Health Kernersville became operational in September 2013; therefore, no volumes were reported for 2012.

As shown in the table above, Cone Health’s four existing linear accelerators located at CCHC operated at 108.8% of capacity. In Section III.6(b), page 59, the applicants state:

*“The proposed project seeks to replace an existing, outdated piece of radiation therapy equipment at Cone Health Cancer Center with a new, more technologically advanced linear accelerator that can adequately meet demand for safer, more effective treatments. Therefore, other providers in the area cannot meet this need. With 29,386 ESTVs in FY 2013, CHCC provided three (3) to seven (7) times as many treatments as any other provider in the service area. By virtue of its depth and breadth of clinical and support services, CHCC occupies a unique role in its service area. Hence, existing providers are unable to meet the identified need.”*

The applicants adequately demonstrate that the proposed project will not result in the unnecessary duplication of existing or approved linear accelerators in the Service Area. 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 94-95, the applicants provide CHCC’s Radiation Oncology Department current and projected staffing for the second operating year, FFY 2017, as shown in the following table.

**CHCC's Current and Projected Staffing**

|   | <b>Current Staff<br/>FY 2014</b>                           | <b>Projected Staff<br/>Year 2<br/>FY 2017</b>              |
|---|--|--|
| <b>Functional Area and Position</b>           | <b>Total # of Full Time<br/>Equivalent (FTE) Positions</b> | <b>Total # of Full Time<br/>Equivalent (FTE) Positions</b> |
| <b>Nursing</b>                                |  |  |
| Radiation Therapy Nurse Manager               | 1.0  | 1.0  |
| RN Level II                                   | 4.1  | 4.1  |
| <b>Total Nursing</b>                          | 5.1  | 5.1  |
| <b>Administration</b>                         |  |  |
| Radiation Oncology Director                   | 1.0  | 1.0  |
| <b>Total Administration</b>                   | 1.0  | 1.0  |
| <b>Financial/Business Office</b>              |  |  |
| Financial Counselor                           | 2.0  | 2.0  |
| <b>Total Financial/Business Office</b>        | 2.0  | 2.0  |
| <b>Other Clinical</b>                         |  |  |
| Chief Physicist                               | 1.0  | 1.0  |
| Senior Medical Physicist                      | 0.8  | 0.8  |
| Physicist                                     | 4.2  | 4.2  |
| Dosimetrist                                   | 3.6  | 3.6  |
| Registered Radiation Therapist                | 15.9   | 15.9   |
| Radiation Therapist Navigator                 | 1.0  | 1.0  |
| Chief Radiation Therapist                     | 1.0  | 1.0  |
| Radiation Oncology Technician II              | 2.0  | 2.0  |
| Radiology Tech                                | 0.1  | 0.1  |
| Radiation Therapy and Dosimetry<br>Supervisor | 1.0  | 1.0  |
| <b>Total Other Clinical</b>                   | 30.6   | 30.6   |
| <b>Other Non-Clinical</b>                     |  |  |
| Secretary II                                  | 1.0  | 1.0  |
| Medical Secretary                             | 5.0  | 5.0  |
| <b>Total Other Non-Clinical</b>               | 6.0  | 6.0  |
| <b>Total Staff</b>                            | 44.7   | 44.7   |

In Section VII.3, pages 96-97, 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 among the largest employers in the Triad region of North Carolina.” The applicants further state that Cone Health has a human resources staff dedicated to recruitment and retention of employees, has not experienced difficulty hiring staff and does not anticipate any problems filling future positions.

In Section VII.8, pages 101-102, the applicants identify the Medical Director of Radiation Oncology for Cone Health and provide a list of Cone Health’s active medical staff.

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.

C

In Section II.1, pages 27-28, 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 to 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 69-80. The applicants provide supporting documentation in Exhibits 7 and 20. 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.

NA

- (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;

C

The following table illustrates CHCC's payor mix for FFY 2013 as reported by the applicants in Section VI, page 90.

**Patient Days/Procedures as a Percent of Total Utilization  
October 1, 2012- September 30, 2013**

| <b>Payor Category</b>               | <b>Cone Health Facility</b> | <b>CCHC Radiation Oncology</b> |
|-------------------------------------|-----------------------------|--------------------------------|
| Self Pay/ Indigent/ Charity         | 7.4%                        | 5.0%                           |
| Medicare/ Medicare Managed Care     | 45.4%                       | 51.5%                          |
| Medicaid                            | 13.5%                       | 5.1%                           |
| Managed Care / Commercial Insurance | 29.9%                       | 35.6%                          |
| Other *                             | 3.8%                        | 2.8%                           |
| Total                               | 100.0%                      | 100.0%                         |

\* Includes Champus and Worker's Compensation.

In Section VI.4, page 83, 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 23, which contains copies of Cone Health’s patient accounting policies and procedures.

On page 85, the applicants state they provide extensive outreach and education services targeting generally underserved groups. The applicants provide supporting documentation in Exhibits 21 and 22. In Section VI.8, page 86, the applicants state Cone Health provided 5.77% and 3.43% of net revenue in charity care and bad debt, respectively, in FFY 2013. On page 87, the applicants estimate CHCC Radiation Oncology Department will provide 4.93% and 4.32% of net revenue in charity care and bad debt, respectively, in FFY 2017, the second year after completion of the proposed project.

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. The following table illustrates those percentages for Guilford County and statewide.

|                 | <b>Total # of Medicaid Eligibles as % of Total Population</b> | <b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b> | <b>% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center) *</b> |
|-----------------|---|--|---|
| Guilford County | 15%   | 5.9%   | 19.5%   |
| Statewide       | 17%   | 6.7%   | 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;

C

In Section VI.11, pages 89-90, 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 persons.*" The applicants state they are dedicated to providing care to all members of the community, regardless of ability to pay. See Exhibit 23 for Cone Health's "*Ability to Pay*" and "*Credit & Collection*" policies. In Section VI.10, page 89, the applicants state "*There have been no civil rights equal access complaints filed against Cone Health in the last five years.*" 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

C

In Sections VI.14 – VI.15, pages 91-92, the applicants project the payor mix for the second operating year following completion of the proposed project, FFY 2017, as shown in the following table.

**Patient Days/Procedures as a Percent of Total Utilization  
October 1, 2016- September 30, 2017**

| <b>Payor Category</b>               | <b>Cone Health Facility</b> | <b>CCHC Radiation Oncology</b> |
|-------------------------------------|-----------------------------|--------------------------------|
| Self Pay/ Indigent/ Charity         | 7.8%                        | 5.0%                           |
| Medicare/ Medicare Managed Care     | 45.8%                       | 51.4%                          |
| Medicaid                            | 13.1%                       | 5.3%                           |
| Managed Care / Commercial Insurance | 30.0%                       | 35.6%                          |
| Other *                             | 3.3%                        | 2.7%                           |
| Total                               | 100.0%                      | 100.0%                         |

\* Includes other Government payors and worker's compensation.

The applicants state:

*“Actual FY 2014 year-to-date (October 2013 – January 2014) payer mix levels are used as the basis for projecting future percentages for patient volumes and revenues by payer under the assumption that these current ratios will remain essentially unchanged.”*

In Section VI.2, page 81, 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.

C

In Section VI.9, pages 88-89, the applicants document the range of means by which patients have access to the linear accelerator services provided at CHCC. The applicants state that patients typically gain access to CHCC via physician referral following a cancer diagnosis. The applicants further state that referrals typically 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.

C

In Section V.1, pages 69-71, 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 applicants provide a list of the health professional training programs that currently utilize the training opportunities at Cone Health on page 70. 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.

C

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 5776 linear accelerator in Vault #3 with a new Varian TrueBeam linear accelerator. The applicants are not proposing to add beds, other medical equipment or new services in Guilford County. In Section V.7, pages 78-80, 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:

*“Cone Health is a leader in the cost effectiveness and quality of hospital-based inpatient and outpatient services delivered to the residents of its service area. Moreover, Cone Health, as a fundamental part of its community service mission, makes these services accessible to all community residents. The proposed project will result in upgraded services that will more effectively serve patients.*

...

*The ability to provide a higher level of complex care in a more efficient manner without significant price increases presents the opportunity to deliver the best value for patients and Cone Health.*

...

*By replacing an outdated, inadequate linear accelerator with an advanced linear accelerator, CHCC will improve the quality of care provided to patients.*

...

*Cone Health has a long-standing demonstrated commitment to the underserved residents of its community.”*

See also Sections II, III, V, VI, and VII; and Exhibits 21 and 22. The information provided by the applicants in each of these sections and exhibits 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 outdated 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 adequately demonstrate they will continue to provide quality services (see Section II and VII of the application);
- The applicants adequately demonstrate they 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; the licensed inventory of linear accelerators will remain the same. Therefore the Criteria and Standards for Radiation Therapy Equipment, promulgated in 10A NCAC 14C.1900, are not applicable to this review.