

ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA – Conditional

NC – Nonconforming

NA = Not Applicable

Decision Date: November 13, 2015

Findings Date: November 13, 2015

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Assistant Chief: Martha J. Frisone

Project ID #: M-11062-15

Facility: Central Harnett Hospital

FID #: 050926

County: Harnett

Applicant: Harnett Health System, Inc.

Project: Acquire one linear accelerator and one CT simulator to develop a comprehensive cancer center

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.

C

Harnett Health System, Inc. (the applicant) proposes to acquire one linear accelerator and one CT simulator to develop a comprehensive cancer center at Central Harnett Hospital in Lillington.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) includes a need determination on page 136 for one linear accelerator for Linear Accelerator Service Area 21. Linear Accelerator Service Area 21 is composed of one county, Harnett County. Harnett Health System, Inc. proposes to acquire one linear accelerator to be located in Harnett County. Therefore, the

application is consistent with the need determination in the 2015 SMFP. Furthermore, Harnett Health System was the only applicant that submitted an application in response to this need determination.

Policies

Policy GEN-3: BASIC PRINCIPLES, page 38 of the 2015 SMFP, is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

The applicant addresses Policy GEN-3 beginning on page 55 of the application.

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section I, pages 11-15; Section II.7, pages 25-26; Section III.2, pages 55-57; Section V.7, pages 68-70; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section III, pages 55-57; Section V, pages 68-70; Section VI, pages 71-73; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section III, pages 55-57; Section V, pages 68-70; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected utilization incorporates the concepts of quality, equitable access and maximum value for resources expended in meeting the need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES, on page 39 of the 2015 SMFP, is applicable to the review of this proposal. Policy GEN-4 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 of 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.”

The proposed capital expenditure for this project is greater than \$2 million. In Section III.2, beginning on page 57, the applicant addresses Policy GEN-4 and the hospital’s plan for energy efficiency and water conservation. The applicant states:

“The proposed Cancer Center @ Central Harnett will provide energy efficiency and water conservation as outlined in a letter from the architect in Exhibit 13 on page 410 and listed below.

...”

The applicant adequately demonstrates the proposal includes a plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4 and conforming to this criterion, subject to Condition (4) in Criterion (4).

Conclusion

In summary, the applicant adequately demonstrates the proposed application is consistent with the need determination in the 2015 SMFP. Additionally, the application is consistent with

Policy GEN-3 and Policy GEN-4 and is conforming to this criterion, subject to Condition (4) 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 applicant proposes to acquire one linear accelerator and one CT simulator to develop a comprehensive cancer center at Central Harnett Hospital in Lillington. In Section I, page 12, the applicant states that Cape Fear Valley Health System (CFVHS) began managing Harnett Health System in 2014. In August of 2014, the CFV Cancer Center (CFVCC) @ Harnett was established, offering medical oncology services. The applicant states that CFVCC is prepared to work with Harnett Health to expand cancer services in Harnett County, creating the proposed comprehensive Cancer Center @ Central Harnett (CCCH) to provide both radiation oncology and medical oncology, modeled after services currently provided at the Cape Fear Valley Health Pavilion North Cancer Center (HPNCC). The applicant will contract with CFVHS to manage services at the proposed CCCH. The applicant refers to the proposed comprehensive cancer center as Cancer Center @ Harnett Health (CCHH) in other areas of the application. The Project Analyst will refer to the comprehensive cancer center as Cancer Center @ Central Harnett or CCCH, as used by the applicant in Section I of the application.

Population to be Served

On page 125, the 2015 SMFP defines the service area for a linear accelerator as the planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I in the SMFP. Thus, the service area for this facility is Linear Accelerator Service Area 21 and consists of Harnett County. Facilities may also serve residents of counties not included in their service area.

In Section III.5, page 61, the applicant provides projected patient origin for the proposed CCCH linear accelerator in the first two years of operation (10/1/18-9/30/20), as shown in the table below.

**Cancer Center @ Central Harnett
Projected Patient Origin, FFY2019 and FFY2020**

County	Percent of Total Patients
Harnett	85.0%
Other Counties	15.0%
TOTAL	100.0%

Other Counties includes Cumberland, Johnston, Sampson, and Wake counties.

In Step 6 of its need methodology, beginning on page 51, the applicant describes its assumptions regarding the patient origin projections. The applicant states that because of its hospital locations, in-migration to Harnett Health from surrounding counties is well over 30% for most services. To estimate in-migration for the proposed CCCH, the applicant reviewed patient origin for radiation therapy, MRI and inpatient admissions and in-migration for 18 cancer centers in counties with only one provider of radiation therapy. The applicant provides this data in Exhibit 10, Table 6. Based on the data it gathered, Harnett Health assumes that 85% of total radiation therapy patients will be from Harnett County and 15% will be from the contiguous counties of Cumberland, Johnston, Sampson, and Wake. A 15-mile radius from the proposed facility encompasses a portion of Cumberland, Johnston and Wake counties, as shown on page 52 of the application.

The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a), pages 39-45, the applicant discusses Harnett County's existing medical oncology program and the county's need for a comprehensive cancer center with both radiation oncology and medical oncology treatment programs and states that the need is based on several factors, including:

- the need determination in the 2015 SMFP,
- lack of access to cancer treatment in Harnett County,
- historical cancer incidence rates in Harnett County,
- projected new cancer cases in Harnett County, and
- population location and growth in Harnett County.

Page 136 of the 2015 SMFP identifies a need for one linear accelerator in Linear Accelerator Service Area 21. Linear Accelerator Service Area 21 is Harnett County.

The CFVCC @ Harnett provides medical oncology services in Harnett County. However, because there is currently no access to linear accelerator services in Harnett County, Harnett County cancer patients who need radiation therapy services must travel out of county to unfamiliar facilities and physicians for those services. In Section III, page 41, the applicant states that Harnett County patients needing radiation therapy services often travel to

Fayetteville, Raleigh and Pinehurst for treatments, sometimes as many as five times each week. The applicant provides data on page 41 identifying where Harnett County residents received radiation treatments from 2010 through 2014, showing a significant percentage of patients receiving treatment in Cumberland, Durham, Johnston, Moore and Wake counties. The applicant also provides the travel times for residents from four population centers in Harnett County to the out-of-county facilities, with drive times ranging from 23 minutes up to 72 minutes. The applicant proposes to locate CCCH and its radiation services in Lillington, which would reduce those travel times by more than 50% to between eleven and 26 minutes. As the applicant notes, patients who need radiation services are often in a weakened physical state which can make travel an issue for the cancer patient. Accessing services in unfamiliar surroundings with unfamiliar physicians can also be an issue for patients.

In Section III, page 42, and Exhibit 15, the applicant provides cancer incidence rates for Harnett County and North Carolina. The four-year average incidence rates per 100,000, as published by the North Carolina State Center for Health Statistics (NCSCSHS) show a tremendous fluctuation in the incidence rates for Harnett County over an eight year period and a fairly steady decline for North Carolina as a whole, with Harnett County cancer incidence rates (493.3) surpassing the North Carolina rate (488.9) in the last four-year time frame (2008-2012).

On page 43, the applicant provides the North Carolina Central Cancer Registry's (NCCCR) projected new cancer cases for Harnett County, as shown below.

Year	Projected New Cancer Cases	2008-2015 (7-Yr)	2010-2015 (5-Yr)
2008	422		
2009	470	11.4%	
2010	536	14.0%	
2011	555	3.5%	3.5%
2012	581	4.7%	4.7%
2013	595	2.4%	2.4%
2014	617	3.7%	3.7%
2015	619	0.3%	0.3%
Average Growth Rates		5.7%	2.9%

The Compound Annual Growth Rates (CAGR), as calculated by the Project Analyst, for the seven and five year periods of 5.6% and 2.9%, respectively, are consistent with the applicant's average growth rates shown above.

Harnett County is the fourth fastest growing county in North Carolina, and has a population exceeding 127,000 persons in 2015. The applicant states the growth in Harnett County from 2010 to 2015 can be attributed to the growth in the Triangle area and the growth of Fort Bragg. This growth is projected to continue with population in Harnett County approaching 140,000 by 2019, according to the applicant (page 44), as shown in the table on page 45 and below.

County	Jul-15	Jul-15	Jul-16	Jul-17	Jul-18	Jul-19
Harnett	127,965	127,965	130,209	132,452	134,697	136,942

Source: Office of State Budget and Management, last updated April 30, 2015

The counties of Wake, Durham and Johnston are among the ten counties projected to grow the fastest in the State between 2015 and 2019. On page 45, the applicant states:

“Adding a linear accelerator in Harnett County to meet the need of Harnett County residents will result in available capacity in Durham, Johnston and Wake Counties to meet the needs of their growing population. In addition, the population growth in Wake and Durham Counties will exacerbate the already lengthy travel time for Harnett County residents.”

Projected Utilization

On page 53, the applicant provides CCCH’s projected number of radiation patients and projected radiation treatments, as follows.

**CCCH Linear Accelerator
Projected Patients and Treatments**

	FFY2019	FFY2020	FFY2021
Patients	182	234	288
Simulations	364	468	576
Radiation Treatments	4,006	5,142	6,338

Projected radiation services utilization at the Cancer Center @ Central Harnett is projected to exceed 250 patients in the third year of operation. In addition, the applicant projects 6,338 radiation treatments in FFY2021, Project Year 3.

In Section III, beginning on page 46, the applicant provides the methodology and assumptions used to project the above utilization, as discussed below.

Step 1: Determine the number of new cancer cases for Harnett County in 2015.

Year	Projected New Cancer Cases	5-Yr Growth Rate
2010	536	
2011	555	
2012	581	
2013	595	
2014	617	
2015	619	
Average Growth Rate		2.9%

Assumptions:

- The NCCCR projects 619 new cancer cases for Harnett County in 2015.
- The average five-year growth rate and CAGR from 2010 to 2015 was 2.9%.

Step 2: Estimate the number of new cancer cases in Harnett County in 2016 through 2020 based upon population growth for the population 55 years of age and older and the population less than 55 years of age.

The applicant calculates the number of new cancer cases in Harnett County on page 48 and in Exhibit 10, Table 1, as summarized below:

**Projected Age-Specific New Cancer Cases
Harnett County**

Age Group	2015	2016	2017	2018	2019	2020	2021
<55	136	138	139	141	143	145	146
55+	483	498	513	529	546	562	580
Total	619	636	653	670	688	707	726

Totals may not sum due to rounding.

Assumptions:

- The National Cancer Institute/American Cancer Society (NCI/ACS) predicts 78% of all new cancer cases will be diagnosed in the population 55 years of age and older. See page 47 of the application.
- The new cancer cases in Harnett County will grow at the same rate as the projected CAGR for the population 55 and older (3.07%) and the population under 55 (1.26%). See page 48 of the application.

Step 3: Determine the number of Harnett County cancer cases receiving radiation therapy.

The applicant provides the number of Harnett County cancer patients projected to need radiation therapy on page 49, as shown below.

Total Projected Harnett County Radiation Therapy Cases

	CY2016	CY2017	CY2018	CY2019	CY2020	CY2021
Total Projected Harnett County Cancer Patients	636	653	670	688	707	726
Projected Cases Radiated = 50%	318	326	335	344	353	363
Projected Cases Radiated 2 Times = 13.2%	42	43	44	45	47	48
Projected Total Harnett County Cases Radiated	360	369	379	389	400	411
Convert Calendar Year Volumes to Federal Fiscal Year Cases						
				FFY2019	FFY2020	FFY2021
Projected Total Harnett County Patients Radiated				387	397	408

Assumptions:

- Use NCI/ASRO guidelines to project the number of new cancer cases requiring radiation therapy treatment. See Exhibit 14, page 425 of application.

- Use CFV Cancer Center statistics to determine the number of new cancer cases receiving radiation therapy or requiring a second course of radiation therapy. Note: CFV rate is less than NCI/ASRO guidelines.
- Convert calendar year to federal fiscal year by dividing the calendar year projections by 12 to determine average monthly new cases (FFY2019 = three months of CY2018 and nine months of CY2019).
- Radiation cases equals radiation patients.

Step 4: Estimate CCCH's potential market share of Harnett County new cancer cases requiring radiation therapy.

On pages 49-50, the applicant determines CCCH will command a 60% market share of Harnett County's radiation therapy cases by the third operating year.

Assumptions:

- The applicant states the average market share for all community based linear accelerators is 56.6% overall, and 65.9% when adjusted to remove the two highest and two lowest outliers in the group. See Exhibit 10, Table 6. The Project Analyst calculates an average market share of 59.9% (summed market shares of 1,019% / 17 hospitals) overall and 61.6% (1,019% – [89.9%+88.8%+20.5%+19.4%]) / 13 hospitals) adjusted for the outliers.
- A comparison of community hospitals located in counties like Harnett County, located between two growing metropolitan areas: Alamance Regional Medical Center (64%) and Randolph Medical Center (89.9%). See Exhibit 10, Table 6.
- CCCH will be closer than existing providers for 90% of the population. See page 41 of application.
- CCCH will be associated with the CFV Cancer Centers which the applicant states has a history of providing high quality cancer care. See Exhibit 8.

Steps 5: Project Harnett County radiation cases at CCCH.

The following table from page 51 shows the number of Harnett County patients projected to receive radiation therapy at the proposed cancer center in each of the first three years of operation.

CCCH Projected Harnett County Radiation Cases

	FFY2019	FFY2020	FFY2021
Projected Total Harnett County Cases Radiated	387	397	408
CCCH Market Share of Projected Total Cases Radiated	40%	50%	60%
Harnett County Cases/Patients Radiated at CCCH	155	199	245

Assumption:

- CCCH will start with a 40% market share in year one, increasing to the projected 60% market share by year three.

Step 6: Project CCCH’s potential in-migration of new cases from other counties and project number of total patients expected to receive radiation therapy at CCCH.

On page 52, the applicant projects that 15% of CCCH’s total radiation therapy patients will be from outside of Harnett County from surrounding counties (i.e., Cumberland, Johnston, Sampson, and Wake).

CCCH Total Projected Case/Patient Volume

	FFY2019	FFY2020	FFY2021
Harnett County Cases/Patients Radiated at CCCH	155	199	245
In-migration at 15%	27	35	43
Total Cancer Cases/Patients at CCCH	182	234	288

Assumptions:

- In-migration to Harnett Health is well over 30% for most services. See page 51.
- Average in-migration for radiation therapy at 18 cancer centers, adjusted for outliers, is greater than 30%, ranging from 17% to 63%. See Exhibit 10, Table 6.
- In-migration for radiation therapy services for Alamance and Randolph counties, counties which the applicant states, like Harnett County are sandwiched between two metropolitan areas, averaged greater than 15% in FFY2014. See Exhibit 10, Table 6.

As reflected in the table above, the applicant estimates 288 patients seeking radiation therapy services at CCCH in FFY 2021. On page 53, the applicant states that each patient will receive simulation treatments to plan their course of radiation treatment prior to receiving treatments. The following table shows projected CCCH radiation patients, simulations and treatments.

**CCCH Linear Accelerator
Projected Patients and Treatments**

	FFY2019	FFY2020	FFY2021
Patient	182	234	288
Simulation	364	468	576
Radiation Treatments	4,006	5,142	6,338

Calculations may not foot due to rounding.

Assumptions:

- Based on CFV Cancer Center utilization rates, the applicant projects 2.0 simulations per patient.
- Based on CFV Cancer Center utilization rates, the applicant projects 22 radiation treatments per course of treatment.

Projected utilization is based on reasonable and adequately supported assumptions regarding historical cancer rates, market share and expected growth.

Thus, the applicant adequately identifies the population to be served and adequately demonstrates the need that population has for the proposed services.

Access

In Section III, page 42, the applicant states that the proposed CCCH will provide radiation therapy services for the first time in Harnett County and will expand chemotherapy services such that all residents of Harnett County have improved access to care. In Section VI, page 79, the applicant projects 51.2% of the patients will be covered by Medicare (43.0%) and Medicaid (8.2%). The discussion regarding access found in Criterion (13c) is incorporated herein by reference. The applicant adequately demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project based on reasonable and supported utilization projections and assumptions, and demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the 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.

CA

In Section III.3, pages 59-60, the applicant discusses the alternatives considered prior to the submission of this application. The applicant states:

“Due to the central location of Central Harnett Hospital in Lillington, it was determined initially that the cancer center should be on the Central Harnett campus.”

Based on the need to locate the proposed comprehensive cancer center on the Central Harnett Hospital campus, pursuant to the need determination in the 2015 SMFP for a linear

accelerator in Harnett County, the applicant considered four alternate sites on the campus, which are listed and discussed below.

1. Site A is at the front of the existing hospital. This site was determined not to be the most effective alternative because:
 - The site provides insufficient space for a 16,000 square foot addition to the facility.
 - Additional parking would need to be added and the circumference road would have to be relocated.
 - Existing space in the front of the hospital would have to be demolished.
 - Access to the energy plant would be questionable.
 - Construction would have disrupted the main entrance to the hospital.
 - Total expense was estimated at \$11,260,000, excluding the cost of the equipment.
2. Site B is at the back of the hospital in space adjacent to the existing pharmacy and imaging departments. This location was selected as the most effective alternative because:
 - The proximity to imaging (CT and MRI), pharmacy and the laboratory.
 - Easy access to the existing garden and dining room.
 - Easy access to the energy plant.
 - Limited renovation and addition of employee parking.
 - Total expense was estimated at \$10,270,000, excluding the cost of the equipment.
3. Site C is a new medical office building on the Central Harnett Hospital campus adjacent to the hospital. This site was determined not to be the most effective alternative because:
 - Property would have to be purchased and a medical office building constructed.
 - Lower development costs, but higher operational expenses.
 - Provides physician office space on campus, but total expense was estimated at \$13,840,000, excluding the cost of the equipment.
 - Developers have not shown a firm interest in developing the building.
4. Site D is on the far side of the hospital parking lot. This site was determined not to be viable because:
 - The available property does not offer expansion capability and no physician possibilities.
 - Provides decreased parking availability.
 - Requires separate HVAC.

The applicant includes an analysis of the above alternatives in Exhibit 17. After considering the above alternatives, the applicant states Site B is the most effective alternative.

Furthermore, the application is conforming with all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

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

- 1. Harnett Health System, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Harnett Health System, Inc. shall acquire no more than one linear accelerator and one CT simulator as part of this project.**
 - 3. Harnett Health System, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application and that would otherwise require a certificate of need.**
 - 4. Harnett Health System, Inc. 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 applicant's representations in the written statement as described in paragraph one of Policy GEN-4.**
 - 5. Harnett Health System, Inc. 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

Harnett Health System, Inc. proposes to acquire one linear accelerator and one CT simulator to develop a comprehensive cancer center at Central Harnett Hospital in Lillington.

Capital and Working Capital Costs

In Section VIII, page 88, the applicant projects that the total capital cost of the project will be \$11,999,000 as shown in the table below.

Project Capital Costs

Site Costs	\$ 713,000
Construction Contract	\$ 4,809,500
Equipment/Furniture	\$ 5,739,322
Consultant Fees	\$ 463,000
Other	\$ 274,178
Total Capital Cost	\$11,999,000

Exhibit 13 contains a letter from the architect which states that total estimated construction costs, including site work, are \$5,399,500. This is different from the information in Section VIII, which provides site work and construction costs totaling \$5,499,500 (\$690,000 + \$4,809,500), a difference of \$100,000. However, the applicant has projected higher costs than the architect and has also allowed an additional undesignated “Other” in the amount of \$224,178 for contingencies. On page 89, the applicant states that the capital cost will be financed with a no interest loan from CFVHS.

In Section IX.1-4, page 92, the applicant states start-up and initial operating expenses required for the project will total \$135,000 and that the working capital of \$135,000 will come from CFVHS.

Availability of Funds

Exhibit 30 contains a letter dated August 17, 2105, from CFVHS CFO which states:

“Cape Fear Valley Health System is positioned financially to fund the capital expenditure for the full project cost of \$11,999,000 through operations and/or accumulated cash reserves of CFVHS. In addition, CFVHS will fund the initial operating expenses in the amount of \$135,000. These funds are available and CFVHS commits to using these funds for this project as indicated in this letter, in addition to several other projects which have been approved or are under review by the Agency as reflected in the Cape Fear Valley Health System’s 2013 Audited Financial Statements, which are included as part of this Application.”

Exhibit 31 contains the financial statements for CFVHS for the years ending September 30, 2014 and 2013. As of September 30, 2014, CFVHS had cash and cash equivalents of \$69,915,000, total current assets of \$252,789,000 and total net assets of \$446,857,000 (total assets – total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three years of the project. The applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

Radiation Therapy Services	Project Year 1	Project Year 2	Project Year 3
Projected Number of Patients	182	234	288
Projected Average Charge (Gross Patient Revenue / Projected # Pts)	\$ 69,923.57	\$ 72,124.68	\$ 74,265.10
Gross Patient Revenue	\$12,750,768.94	\$16,885,661.15	\$21,405,822.75
Deductions from Gross Patient Revenue	\$ 9,944,555.25	\$13,169,432.46	\$16,694,788.22
Net Patient Revenue	\$ 2,806,213.68	\$ 3,716,228.69	\$ 4,711,034.53
Total Expenses	\$ 2,095,472.75	\$ 2,630,228.26	\$ 2,676,290.10
Net Income	\$ 710,740.93	\$ 1,086,000.43	\$ 2,034,744.43

The applicant also projects a positive net income for Harnett Health System, and the comprehensive cancer center, CCCH, in each of the first three operating years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See pages 113-114 in the Pro Formas Section for the assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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

The applicant proposes to acquire one linear accelerator and one CT simulator to develop a comprehensive cancer center at Central Harnett Hospital in Lillington.

On page 125, the 2015 SMFP defines the service area for a linear accelerator as the planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I of the SMFP. Thus, the service area for this facility is Linear Accelerator Service Area 21 and consists of Harnett County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to acquire one linear accelerator and one CT simulator to develop a comprehensive cancer center at Central Harnett Hospital in Lillington. There are currently no linear accelerators operating in Harnett County.

In Section V.7, pages 68-70, the applicant discusses the impact of the proposed project on competition in the service area as it relates to existing or approved health service capabilities or facilities. The applicant states:

“Currently, residents of Harnett County must leave the county and travel five days a week for radiation therapy. The proposed Cancer Center will be the only treatment facility offering medical and radiation oncology in the service area. However, patients will continue to have a choice and can elect to go out of the service area. Harnett Health and its partner CFVHS have carefully designed the project for to [sic] provide high quality care at a competitive price in a more geographically assessable [sic] location.”

The information provided by the applicant is reasonable and adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Harnett County. 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 80-81, the applicant provides the proposed staffing for the proposed comprehensive cancer center, including radiation oncology services, for the second year of operation (FFY2020), as shown below in the table.

Position	Proposed FTEs Year 2
Physician	2.00
RN	3.00
LPN	1.00
Aides/Orderlies/MOA's	1.00
Cancer Center Nurse Mgr	0.20
Tumor Registrar	0.50
Social Worker	0.80
Dietician	0.60
Pharmacist	1.00
Pharmacy Tech	1.00
Tech-MLT	1.00
Phlebotomist	1.00
Radiation Therapist	2.00
Dosimetrist	1.00
Physicist	0.80
Aides-housekeeper	0.50
Administrator	0.20
Business and Office Mgr	1.00
Clerical	2.00
Financial Counselor/ Reimbursement Analyst	1.00
Registration	1.00
Total	22.60

As shown in the table above, the applicant proposes 22.6 full-time equivalent (FTE) positions at the proposed cancer center. The table and the documentation letter from CFV Cancer Center Service Line Director identify some of the positions as contract consulting services. In Section VII.3, pages 81-82, and Section VII.6, pages 83-84, the applicant describes its recruitment and retention procedures, and indicates that it expects to be successful in identifying, hiring, and retaining qualified staff for the proposed project. In Section VII.8, page 85, the applicant identifies Olalehan Folarin, MD as the Medical Director for Harnett Health and Hugh Bryan, MD as the Medical Director of the Radiation Oncology Department at CFV Cancer Treatment & CyberKnife Center. Exhibit 21 contains a copy of a letter from Dr. Bryan expressing his support for the project and willingness to be involved in the development of the proposed project. Dr. Bryan states that he will be involved in the medical direction of the new proposed comprehensive cancer center. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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.2, pages 16-23, the applicant discusses the scope of the services it proposes. On pages 23-24, the applicant identifies the necessary ancillary and support services required for the proposed project and states that the projected staff and the existing ancillary and support services at Central Harnett Hospital and Harnett Health are sufficient to meet the needs of the proposed project. Exhibits 4 and 11 contain documentation of the availability of the necessary ancillary and support services. The applicant provides and discusses the projected services in Section VII, pages 80-86. In Section V.2, pages 65-66, the applicant identifies the facilities with which it currently has transfer agreements. Exhibits 11, 20 and 21 contain copies of letters from physicians expressing support for the proposed project. Exhibits 22, 23 and 35 contain letters of support from other medical providers and the community. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming 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.

C

The applicant proposes to locate the proposed linear accelerator in 14,623 square feet of new space at the back of Central Harnett Hospital, adjacent to the existing pharmacy and imaging departments. Exhibit 13 of the application contains line drawings and a copy of a letter from a Perkins + Will's architect which estimates the construction costs for the proposed project and includes a discussion of its energy conservation efforts. The exhibit also contains a narrative of the proposed structural systems by Mulkey Engineers & Consultants which discusses a 14,250 square foot addition with drop off canopy adjacent to the existing hospital structure. Section XI.4, page 99, includes 373 square feet more than indicated in the engineer's preliminary document. This is a 2.6% variance and would appear to be insignificant to the total project. In addition, the applicant has allowed costs to cover the larger number of square feet. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

Central Harnett Hospital does not currently provide radiation therapy services. In Section VI.12, page 77, the applicant reports the payor mix for Central Harnett Hospital for FFY2014, which is summarized in the following table.

**Central Harnett Hospital
FFY2014**

Payer Category	Days/Procedures as Percent of Total
Self-Pay/Indigent/Charity	6.9%
Medicare/Medicare Managed Care	52.9%
Medicaid	23.8%
Commercial Insurance	5.7%
Managed Care	1.8%
Other (Specify)	8.9%
Total	100.0%

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. More current data, particularly with regard to the estimated uninsured percentages, was not available. The following table illustrates those percentages for Harnett, Cumberland, Johnston, Sampson and Wake counties and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	CY2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Harnett County	16.9%	6.2%	20.3%
Cumberland County	18.2%	7.4%	20.3%
Johnston County	17.5%	6.7%	20.0%
Sampson County	25.4%	10.1%	24.0%
Wake County	3.3%	0.0%	18.4%
Statewide	16.5%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the linear accelerator 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 payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 77, the applicant states:

"Harnett Health has no obligation under any applicable Federal regulation to provide uncompensated care. However, Harnett Health provided \$70,455,099 in charity care and bad debt during FY 2014. As a responsible member of the community, Harnett Health will continue to provide uncompensated care."

In Section VI.2, page 71, in reference to describing how each of the medically underserved groups in (a) through (f) will have access to the proposed services, the applicant states:

"Each of the groups in (a) through (f) above will continue to have access to services at Harnett Health. Harnett Health does not deny medical care to any person regardless of race, creed, religion, handicap, economic status, social status, or ability to pay. Please see the financial policies in Exhibit 16."

In Section VI.10, page 77, the applicant states that it is not aware of any documented civil rights equal access complaints or violations filed against Harnett 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 Section VI.15, page 79, the applicant provides the projected payor mix for the second full fiscal year of operation for CCCH's linear accelerator services, as shown in the table below.

CCCH Linear Accelerator Services

Payor Category	FFY2020 Percent of Total
Self-Pay/Indigent/Charity	2.0%
Medicare/Medicare Managed Care	43.0%
Medicaid	8.2%
Commercial Insurance/Managed Care	35.0%
Managed Care	0.0%
Other (Specify)	11.9%
Total	100.0%

Totals may not sum due to rounding.

Other is not specified by the applicant. CFVMC, management for Harnett Health facilities, identify "Other" as Tricare and Worker's Comp on its 2015 LRA.

On page 79, the applicant states:

"Payor mix for radiation therapy and chemotherapy for the Cancer Center @ Central Harnett was calculated based upon FFY 2014 payor mix for cancer patients at the CFV Cancer Centers and Cancer Center @ Health Pavilion North."

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. 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, page 76, the applicant describes the range of means by which a person will have access to the proposed services. The information provided is reasonable and supports a finding of conformity to 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, page 65, the applicant states Harnett Health has existing relationships with several professional training programs, including Campbell University, Central Carolina Community College, and Pitt Community College; and that the proposed cancer center will be available as a clinical training site for health professional training programs. Exhibit 18 contains letters of support and examples of existing training agreements. The information provided in Section V.1 and Exhibit 18 is reasonable and supports a finding of conformity to 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

The applicant proposes to acquire one linear accelerator and one CT Simulator to develop a comprehensive cancer center in Harnett County. There are no other linear accelerators operating in Harnett County.

On page 125, the 2015 SMFP defines the service area for a linear accelerator as the planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I of the SMFP. Thus, the service area for this facility is Linear Accelerator Service Area 21 and consists of Harnett County. Facilities may also serve residents of counties not included in their service area.

In Section V.7, pages 68-70 the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services, stating:

“Currently, residents of Harnett County must leave the county and travel five days a week for radiation therapy. The proposed Cancer Center will be the only treatment facility offering medical and radiation oncology in the service area. However, patients

will continue to have a choice and can elect to go out of the service area. Harnett Health and its partner CFVHS have carefully designed the project for [sic] to provide high quality care at a competitive price in a more geographically assessable [sic] location.”

The applicant further states that the proposed project will promote cost effectiveness by decreasing patient travel time which will decrease out-of-pocket expenses; financing the project with a no interest loan from CFVHS; providing a consolidated multi-disciplinary approach for cancer care; and providing competitive pricing.

In reference to quality, the applicant states it adheres to external quality standards and the proposed project will be held to the same quality standards as existing Harnett Health services. The applicant also states that the cancer center will be held to Joint Commission quality standards and seek certification as a community cancer center within five years.

In regard to access, the applicant states that Harnett Health is the only acute care provider in Harnett County and the proposed cancer center will facilitate increased geographic access to services by permitting patients to remain within their home county for diagnosis and treatment. The applicant further states, *“Harnett Health serves all patients regardless of their payment source or ability to pay.”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13) are incorporated herein by reference.

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.

C

In Section I, page 10, the applicant states that Harnett Health System, Inc., the applicant, currently owns two hospitals in North Carolina; Betsy Johnson Hospital and Central Harnett Hospital. Cape Fear Valley Health System manages Harnett Health System, Inc. CFVHS owns and/or operates the following health care facilities in North Carolina.

Facility	Location
Cape Fear Valley Medical Center	Fayetteville
Highsmith Rainey Specialty Hospital	Fayetteville
CFV Bladen County Hospital	Elizabethtown
Roxie Avenue Center (Detox/MH Facility)	Fayetteville
CFV Hoke Hospital	Raeford
Harnett Health System, Inc. (Betsy Johnson Hospital and Central Harnett Hospital)	Dunn/Lillington

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned or operated by Harnett Health or Cape Fear Valley Medical Center in North Carolina.

After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all seven facilities, the applicant provided sufficient evidence that quality care has been provided in the past. 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.

C

The application is conforming to all applicable Criteria and Standards for Radiation Therapy Equipment promulgated in 10A NCAC 14C .1900. The specific criteria are discussed below.

SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT

10A NCAC 14C .1902 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire radiation therapy equipment shall use the Acute Care Facility/Medical Equipment application form.

-C- The applicant used the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to acquire radiation therapy equipment shall provide the following information:

(1) a list of all the radiation therapy equipment to be acquired and documentation of the capabilities and capacities of each item of equipment;

-C- The applicant identifies the radiation therapy equipment to be acquired in Exhibit 3 of the application. The equipment's capabilities are discussed in Section II.1, pages 16-18. With regard to the capacity of the equipment, in Section IV.2, page 64, the applicant states:

“Both the capacity of linear accelerators and CT simulators are defined in Chapter 9 of the annual State Medical Facilities Plan.

Capacity of a linear accelerator is defined as 6,750 ESTVs.

Capacity of a CT Simulator is defined as one simulator for up to three linear accelerators.”

(2) documentation of the purchase price and fair market value of each piece of radiation therapy equipment, each simulator, and any other related equipment proposed to be acquired;

-C- The applicant documents the purchase price of the equipment with the vendor quotes provided in Exhibit 3 of the application. The quotes in Exhibit 3 agree with the equipment costs as provided in Section VIII.

(3) the projected number of patient treatments by intensity modulated radiation treatment (IMRT); stereotactic radiosurgery; simple, intermediate and complex radiation treatments to be performed on each piece of radiation therapy equipment for each of the first three years of operation following the completion of the proposed project and documentation of all assumptions by which utilization is projected;

- C- In Section II.8, page 30, the applicant provides the projected number of patient treatments by type for each of the first three years of operation for the proposed linear accelerator. The applicant’s projections are summarized in the table below:

Projected Linear Accelerator Utilization by Treatment Type

Treatment Type	Percent Distribution	PY 1 FFY2019	PY 2 FFY2020	PY 3 FFY2021
Simple	0.83%	33	43	53
Intermediate	0.00%	0	0	0
Complex	73.64%	2,950	3,787	4,667
IMRT	16.03%	642	824	1,016
Additional Field Checks	9.50%	381	489	602
Total Treatments	100.00%	4,006	5,142	6,338

Totals may not sum due to rounding.

The applicant states:

“Projected distribution by treatment type is based upon the historical CPT utilization at the Cancer Center @ HPN, upon which the Cancer Center @ Central Harnett is being modeled. ESTVs per patient are based upon CFVHS actual experience with cancer patients reflected in the 2015 LRA included in Exhibit 12.”

Exhibit 12 contains the 2015 Hospital License Renewal Application (LRA) for Harnett Health System, Inc. (Betsy Johnson Hospital and Central Harnett Hospital). Exhibit 12 does not contain any documentation for Equivalent Simple Treatment Visits (ESTVs) per patient for CFVHS. CFVHS’ 2015 LRA, which is on file with the Agency, shows approximately 21 ESTVs per patient on its five linear accelerators. The table above shows the applicant is projecting approximately 21 ESTVs per patient based on the 2015 SMFP’s methodology for calculating ESTVs.

The applicant provides additional assumptions for the projections in Section III.1(a and b) and Exhibit 10. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (4) *documentation that the proposed radiation therapy equipment shall be operational at least seven hours per day, five days a week;*

- C- In Section II.8, page 31, the applicant refers to Exhibit 11 for a letter from CFV Cancer Center’s Clinical Nurse Manager, in which she states the proposed linear accelerator will operate from 8:00 a.m. to 5:00 p.m., Monday through Friday.

- (5) *documentation that no more than one simulator is available for every two linear accelerators in the applicant's facility, except that an applicant that has only one linear accelerator may have one simulator;*

-C- In Section II.8, page 31, the applicant states Central Harnett does not currently operate a linear accelerator or a simulator. The applicant is proposing to acquire one linear accelerator and one CT simulator in this application. Exhibit 3 contains a vendor quote for one linear accelerator and one CT simulator.

(6) *documentation that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;*

-C- In Section II.8, page 31, the applicant refers to the architect’s letter in Exhibit 13 which states, “the preliminary planning and design for the physical environment of the facility is intended to conform to requirements of federal, state and local regulatory bodies”.

(7) *the projected total number of radiation treatment patients by county that will be treated in the facility in each of the first three years of operation following completion of the proposed project;*

-C- In Section II.8, page 31, the applicant provides a table showing the projected total number of radiation treatment patients by county to be treated at the proposed Central Harnett facility in each of the first three years of operation. The applicant’s table on page 31 erroneously shows the first three years of operation as FFY2018, FFY2019 and FFY2020. The table below summarizes the applicant’s data using the correct dates, according to Step 5, page 51, of its methodology; Exhibit 10, Tables 2 and 3; and the pro forma financial statements.

**Cancer Center @ Central Harnett
Projected Patient Origin for Radiation Treatments**

<i>County</i>	Percent of Linac Patients	PY 1 FFY2019 10/1/18-9/30/19	PY 2 FFY2020 10/1/19-9/30/20	PY 3 FFY2021 10/1/20-9/30/21
Harnett	85.0%	155	199	245
Other Counties	15.0%	27	35	43
TOTAL	100.0%	182	234	288

Other Counties include Cumberland, Johnston, Sampson and Wake counties.

The applicant provides additional assumptions for the projections in Section III.1(a and b) and Exhibit 10. In Step 6 of its methodology, beginning on page 51, the applicant describes its assumptions regarding the patient origin projections. The applicant states that because of its hospital locations, in-migration to Harnett Health from surrounding counties is well over 30% for most services. To estimate in-migration for the proposed Cancer Center @ Central Harnett, the applicant reviewed patient origin for radiation therapy, MRI and inpatient admissions and in-migration for 18 cancer centers in counties with only one provider of radiation therapy. The applicant provides this data in Exhibit 10, Table 6. Based on the data it gathered, Harnett Health assumes that 15% of total radiation therapy patients will be from outside of Harnett County from the contiguous counties of Cumberland, Johnston, Sampson and Wake.

The applicant further discusses the projected patient origin by county in Section III.5, pages 60-62.

(8) *the projected number of radiation treatment patients that will be treated for palliation in each of the first three years of operation following completion of the proposed project; and*

-C- In Section II.8, page 32, the applicant provides a table showing the projected total number of radiation treatment patients that will be treated for palliation (32.2%) at the proposed facility in each of the first three years of operation. The applicant states that the percent distribution for palliation and curative treatments is based upon actual patients treated at CFV Cancer Centers.

(9) *the projected number of radiation treatment patients that will be treated for cure in each of the first three years of operation following completion of the proposed project.*

-C- In Section II.8, page 32, the applicant provides a table showing the projected total number of radiation treatment patients that will be treated for cure (67.7%) at the proposed facility in each of the first three years of operation. The applicant states that the percent distribution for palliation and curative treatments is based upon actual patients treated at CFV Cancer Centers.

(c) *An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall provide the following information:*

(1) *description of all services to be provided by the proposed multidisciplinary prostate health center, including a description of each of the following services:*

- (A) *urology services,*
- (B) *medical oncology services,*
- (C) *biofeedback therapy,*
- (D) *chemotherapy,*
- (E) *brachytherapy, and*
- (F) *living skills counseling and therapy;*

(2) *documentation that urology services, medical and radiation oncology services, biofeedback therapy, brachytherapy and post-treatment living skills counseling and therapy will be provided in the same building;*

(3) *description of any services that will be provided by other facilities or in different buildings;*

(4) *demographics of the population in the county in which the proposed multidisciplinary prostate health center will be located, including:*

- (A) *percentage of the population in the county that is African American,*
- (B) *the percentage of the population in the county that is male,*
- (C) *the percentage of the population in the county that is African American male,*
- (D) *the incidence of prostate cancer for the African American male population in the county, and*

- (E) *the mortality rate from prostate cancer for the African American male population in the county;*
- (5) *documentation that the proposed center is located within walking distance of an established bus route and within five miles of a minority community;*
- (6) *documentation that the multiple medical disciplines in the center will collaborate to create and maintain a single or common medical record for each patient and conduct multidisciplinary conferences regarding each patient's treatment and follow-up care;*
- (7) *documentation that the center will establish its own prostate/urological cancer tumor board for review of cases;*
- (8) *copy of the center's written policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay;*
- (9) *copy of written strategies and activities the center will follow to assure its services will be accessible by patients without regard to their ability to pay;*
- (10) *description of the center's outreach activities and the manner in which they complement existing outreach initiatives;*
- (11) *documentation of number and type of clinics to be conducted to screen patients at risk for prostate cancer;*
- (12) *written description of patient selection criteria, including referral arrangements for high-risk patients;*
- (13) *commitment to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall include:*
 - (A) *the total number of patients treated;*
 - (B) *the number of African American persons treated;*
 - (C) *the number of persons in other minority populations treated; and*
 - (D) *the number of insured, underinsured and uninsured patients served by type of payment category;*
- (14) *documentation of arrangements made with a third party researcher to evaluate, during the fourth operating year of the center, the efficacy of the clinical and outreach initiatives on prostate and urological cancer treatment, and develop recommendations regarding the advantages and disadvantages of replicating the project in other areas of the State. The results of the evaluation and recommendations shall be submitted in a report to the Medical Facilities Planning Section and Certificate of Need Section in the first quarter of the fifth operating year of the demonstration project; and*
- (15) *if the third party researcher is not a historically black university, document the reasons for using a different researcher for the project.*

-NA- The applicant does not propose to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

- (a) *An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met:*
- (1) *an applicant's existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted;*
- NA- The applicant does not own a linear accelerator.
- (2) *each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment; and*
- C- In Section II.8, page 34, the applicant projects the new linear accelerator will treat 288 patients during the third year of operation. The applicant's table erroneously shows the third project year as FFY2020. Other areas in the application, the Pro Formas Section and Exhibit 10, Tables 2 and 3 document the third year of operation is FFY2021, October 1, 2020 – September 30, 2021.
- (3) *an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.*
- NA- The applicant does not own a linear accelerator.
- (b) *A linear accelerator shall not be held to the standards in Paragraph (a) of this Rule if the applicant provides documentation that the linear accelerator has been or will be used exclusively for clinical research and teaching.*
- NA- The applicant does not proposes to use the linear accelerator exclusively for clinical research and teaching.
- (c) *An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the following information:*
- (1) *the number of patients that are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and*
 - (2) *the maximum number and type of procedures that the proposed equipment is capable of performing.*
- NA- The applicant is not proposing to acquire radiation therapy equipment other than one linear accelerator and one CT simulator to serve the patients as projected in Section III.1, page 53 and above in 10A NCAC 14C .1902(b) and 10A NCAC 14C .1903(2).

(d) *The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.*

-C- In Section III.1(a and b), pages 39-55 and Exhibit 10, the applicant documents its assumptions and provides data supporting the methodology used to determine its utilization projections. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

10A NCAC 14C .1904 SUPPORT SERVICES

(a) *An applicant proposing to acquire radiation therapy equipment shall document that the following items shall be available; and if any item shall not be available, the applicant shall provide substantive information obviating the need for that item:*

- (1) *an organized program of radiation therapy continuing education for radiation therapists, technologists and medical staff;*
- (2) *a program for the collection of utilization data relative to the applicant's provision of radiation therapy services;*
- (3) *medical laboratory services;*
- (4) *pathology services; and*
- (5) *pharmaceutical support services.*

-C- In Section II.8, page 36, the applicant states that it provides documentation regarding the services above in Exhibit 11. Exhibit 11 contains a letter from the CFV Cancer Centers' Clinical Nurse Manager, who will also serve in that capacity at CCCH, which states:

"In my role as Clinical Nurse Manger, it is my responsibility to ensure that all necessary ancillary services will be provided to support the Radiation Therapy Program at the Cancer Center @ Central Harnett, including the following as required by 10A NCAC 14C .1904(a)."

Exhibit 11 also contains a letter from the Administrator for Central Harnett Hospital and VP, Support Services at Harnett Health documenting that all ancillary services necessary for the proposed cancer services are available on-site at Central Harnett Hospital.

(b) *An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall provide a written description of the center's plans and strategies to establish:*

- (1) *an African American Prostate Cancer Education/Outreach Program that will partner with and complement existing support groups, such as the N.C. Minority Prostate Cancer Awareness Action Team; and*
- (2) *an Advisory Board composed of representatives of prostate cancer advocacy groups, prostate cancer patients and survivors that will meet regularly to provide feedback to*

the center regarding outreach practices which are effective or which need to be changed.

- NA- The applicant is not proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan.

10A NCAC 14C .1905 STAFFING AND STAFF TRAINING

- (a) *An applicant proposing to acquire radiation therapy equipment shall document the number and availability of staff or provide evidence that obviates the need for staff in the following areas:*

- (1) *Radiation Oncologist;*

- C- In Section II.8, page 36, the applicant states that the proposed program will have one radiation oncologist. See Exhibit 11 for a letter from Cape Fear Valley Health System's Medical Director for Radiation Oncology Services documenting CFV Cancer Center's intent to recruit an additional radiation oncologist to work at CCCH full-time.

- (2) *Radiation Physicist;*

- C- In Section II.8, page 36, the applicant states that the radiation physicists from the CFV Cancer Treatment & CyberKnife Center and the Cancer Center @ Health Pavilion North will also fill this role at CCCH. Exhibit 11 contains a letter from the CFV Cancer Centers' Service Line Director, who will be the Administrator in charge at CCCH, which states:

"Initially, the Cape Fear Valley Cancer Treatment & CyberKnife Center in Fayetteville and Cape Fear Valley Cancer Center at Health Pavilion North in north Fayetteville will provide consulting services for social work, dietary services, dosimetry and other areas as needed until the volume at Cancer Center at Central Harnett is sufficient to support these specialists full time."

Exhibit 11 also contains letters from CFV Cancer Centers' physicists stating their support for the project.

- (3) *Dosimetrist or Physics Assistant;*

- C- In Section II.8, page 37, the applicant states the dosimetrists from the CFV Cancer Treatment & CyberKnife Center and the Cancer Center @ Health Pavilion North will also fill this role at the CCCH. Exhibit 11 contains a letter from the CFV Cancer Centers' Service Line Director, who will be the Administrator in charge of the CCCH, which states:

"Initially, the Cape Fear Valley Cancer Treatment & CyberKnife Center in Fayetteville and Cape Fear Valley Cancer Center at Health Pavilion North in north Fayetteville will provide consulting services for social work, dietary services,

dosimetry and other areas as needed until the volume at Cancer Center at Central Harnett is sufficient to support these specialists full time.”

Exhibit 11 also contains a letter of support from a CFV Cancer Centers medical dosimetrist.

(4) *Radiation Therapist;*

- C- In Section VII, page 80, the applicant projects 2.0 FTE radiation therapists for the second full fiscal year at CCCH.

Recruitment of staff is discussed in Section VII.3 and VII.6, pages 81-82 and 83-84. Exhibit 11 contains letters of support from five radiation therapists at CFV Cancer Centers.

(5) *Radiation-Oncology Administrator;*

- C- In Section II.8, page 37, the applicant refers to Exhibit 11 which contains a letter from the CFVCC Service Line Director agreeing to be the Administrator at CCCH.

(6) *Registered Nurse or LPN;*

- C- In Section VII, page 80, the applicant projects 3.0 FTE RN positions and 1.0 FTE LPN positions for the second full fiscal year at CCCH. Recruitment of staff is discussed in Section VII.3 and VII.6, pages 81-82 and 83-84.

(7) *Physical Therapist;*

- C- In Section II.8, page 37, the applicant states Harnett Health will provide physical therapy services through existing staff at the hospital's physical therapy department.

(8) *Dietician;*

- C- In Section II.8, page 37, the applicant states the dieticians from the CFV Cancer Treatment & CyberKnife Center and the Cancer Center @ Health Pavilion North will also fill this role at CCCH. Exhibit 11 contains a letter from the CFV Cancer Centers' Service Line Director, who will be the Administrator in charge of the CCCH, which states:

“Initially, the Cape Fear Valley Cancer Treatment & CyberKnife Center in Fayetteville and Cape Fear Valley Cancer Center at Health Pavilion North in north Fayetteville will provide consulting services for social work, dietary services, dosimetry and other areas as needed until the volume at Cancer Center at Central Harnett is sufficient to support these specialists full time.”

(9) *Pharmacist;*

- C- In Section VII, page 80, the applicant projects 1.0 FTE pharmacist positions and 1.0 FTE pharmacy tech positions for the second full fiscal year at CCCH. Recruitment of staff is discussed in Section VII.3 and VII.6, pages 81-82 and 83-84.

(10) *Social Worker; and*

- C- In Section II.8, page 38, the applicant states the social workers from the CFV Cancer Treatment & CyberKnife Center and the Cancer Center @ Health Pavilion North will also fill this role at CCCH. Exhibit 11 contains a letter from the CFV Cancer Centers' Service Line Director, who will be the Administrator in charge of the CCCH, which states:

“Initially, the Cape Fear Valley Cancer Treatment & CyberKnife Center in Fayetteville and Cape Fear Valley Cancer Center at Health Pavilion North in north Fayetteville will provide consulting services for social work, dietary services, dosimetry and other areas as needed until the volume at Cancer Center at Central Harnett is sufficient to support these specialists full time.”

(11) *Maintenance Engineer.*

- C- In Section II.8, page 38, the applicant states CFVCC has a service contract with Varian to maintain all its linear accelerators, which will be extended to the CCCH linear accelerator. The applicant states that the contract also applies to the CT simulator.
- (b) *An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall document that the center will have:*
- (1) *a medical director who is either a urologist certified by the American Board of Urology, a medical oncologist certified by the American Board of Internal Medicine, or a radiation oncologist certified by the American Board of Radiology; and*
 - (2) *a multidisciplinary team consisting of medical oncologists, radiation oncologists, urologists, urologic pharmacologists, pathologists and therapy specialists.*
- NA- The applicant is not proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan.