

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 29, 2018

Findings Date: December 6, 2018

Project Analyst: Tanya M. Saporito

Team Leader: Fatimah Wilson

Project ID #: M-11563-18

Facility: Cape Fear Valley Medical Center – Health Pavilion North

FID #: 030360

County: Cumberland

Applicant: Cumberland County Hospital System, Inc.

Project: Replace existing linear accelerator

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N. C. Gen. Stat. § 131E-183(a) The Agency 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

The applicant, Cumberland County Hospital System, Inc. (CCHS) provides radiation oncology services on a total of five linear accelerators at two locations in Cumberland County: The Cape Fear Valley Cancer Treatment and CyberKnife Center, located on the Cape Fear Valley Medical Center (CFVMC) campus in Fayetteville (four linear accelerators), and The Cancer Center at Health Pavilion North (HPN), also in Fayetteville (one linear accelerator). In this application, the applicant proposes to replace the linear accelerator located at HPN.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, service or equipment for which there is a need determination in the 2018 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations that are applicable to this review.

Policies

There is one policy in the 2018 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4 on page 33 of the 2018 SMFP 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 is 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 but less than \$5 million. In Section B.11, pages 25 - 26, the applicant explains why it believes its application is consistent with Policy GEN-4. The applicant states the existing facility was originally constructed to facility and licensure standards in 2006, and will be upgraded to meet current energy efficiency standards and water conservation methods. The applicant

adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop any beds, services or equipment for which there is a need determination in the 2018 SMFP.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-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, Cumberland County Hospital System, Inc. (CCHS) provides radiation oncology services on a total of five linear accelerators at two locations in Cumberland County: The Cape Fear Valley Cancer Treatment and CyberKnife Center, located on the Cape Fear Valley Medical Center (CFVMC) campus in Fayetteville (four linear accelerators), and The Cancer Center at Health Pavilion North (HPN), also in Fayetteville (one linear accelerator). In this application, the applicant proposes to replace the linear accelerator located at HPN.

Patient Origin

In Chapter 9, page 121, the 2018 SMFP states, “*A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.*” In Table 9I, page 129 of the 2018 SMFP, Cumberland County is included in Linear Accelerator Service Area 18, which also includes Bladen, Robeson and Sampson counties. Providers may serve residents of counties not included in their service area.

In Sections C.2 and C.3, page 28, the applicant provides the historical patient origin for Federal Fiscal Year (FFY) 2017 (October 1, 2016 – September 30, 2017) and the projected patient origin for FFY 2020 (October 2019 – September 2020) – FFY 2022 (October 2021 – September 2022) at HPN, as shown in the following tables:

Historical Patient Origin, Health Pavilion North

COUNTY	LAST FULL FY (10/1/16 – 9/30/17)	
	# PATIENTS	% OF TOTAL
Cumberland	144	65%
Harnett	58	26%
Robeson	7	3%
All Other	14	6%
Total	223	100%

Source: Application Section C, page 28

Projected Patient Origin, Health Pavilion North

County	1 st Full FY 10/1/19 – 9/30/20		2 nd Full FY 10/1/20 – 9/30/21		3 rd Full FY 10/1/21 – 9/30/22	
	# Pts	% of Total	# Pts	% of Total	# Pts	% of Total
Cumberland	129	60%	158	60%	162	60%
Harnett	63	29%	78	29%	79	29%
All Other	22	11%	27	11%	28	11%
Total	214	100%	263	100%	270	100%

Source: Application Section C, page 28

In Section C.3(c), page 29, the applicant states that the patient origin will remain essentially the same as historical patient origin.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.1, page 27, and Section C.4, pages 30 - 32, the applicant explains why it believes the population projected to utilize the proposed linear accelerator services needs those services, summarized below:

- The linear accelerator proposed to be replaced is 12 years old and experiences significant down time for repair. The replacement unit will be located in the same space currently occupied by the unit to be replaced (page 27).
- The existing linear accelerator was acquired pursuant to a need determination in the 2003 SMFP and was installed in 2006. The applicant states that, in the past several years, there have been more than 70 work orders associated with the unit, indicating that its useful life is expired. Additionally, the work orders and down time have resulted in over 275 patient treatments delayed in FY 2017 at HPN (page 30).

- Radiation therapy services at HPN have increased by the following compound annual growth rates (CAGR) since 2015:

	2015	2016	2017	2018*	CAGR 2015 - 2018
Patients	227	245	223	245	2.5%
Treatments	4,429	5,091	4,796	5,309	6.2%
Treatments per Patient	19.5	20.8	21.5	21.7	3.6%

Source: Application page 31

*In supplemental information, the applicant states this information is annualized based on eight months of data.

- The applicant states the number of patients increased in 2016 as a result of a fire at Southeastern Regional Medical Center (SRMC); HPN treated SRMC’s cancer patients when SRMC could not provide linear accelerator services due to fire damage. The applicant states the calculation of a CAGR from 2015 to 2018 “smooths the variance” such that the CAGR reflected above accounts for the temporary increase in patients from SRMC (page 31).
- The applicant cites the Criteria and Standards for Radiation Therapy Equipment found in 10A NCAC 14C .1900, which requires that proposed new linear accelerators be utilized at 250 patients annually by the third year of operation. The existing linear accelerator at HPN, which the applicant seeks to replace, is currently operating at 98% of that target, even with the down time due to the need for repair. Furthermore, the applicant states the 2018 SMFP does not define capacity for linear accelerators; the applicant defines 100% of capacity for its existing linear accelerator as 286 patients per year, as shown in the following table from page 33:

HPN Capacity Definition

	VARIABLE
Treatments per Day	25
Days per Year*	252
Total Treatments per Year	6,300
Treatments per Patient	22
Total Capacity (Patients)	286
SMFP Planning Target	80%
Patient Planning Volume	229

*Days per year calculated as follows: 5 days / week x 52 weeks / year- 8 holidays)

Thus, utilization of the existing unit at HPN, even with the downtime due to the age of the unit, has been 85.7% of HPN’s capacity in the last year and a half (page 31).

- The applicant cites a study by the American Cancer Society, included in Exhibit C-4, which states that cancer usually develops in older people, and that 87% of all

cancers are diagnosed in persons age 50 or older in the United States. Citing data from the North Carolina Office of State Budget and Management (NCOSBM), the applicant provides information to illustrate that the population of Cumberland County age 50 and over is projected to increase by a CAGR of 0.8% from 2018 – 2022, and by 0.65% from 2018 – 2025. The particular age group of persons 65 and older is projected to increase at an even faster rate: by a CAGR of 3.4% from 2018 – 2022 and 3.72% from 2018 – 2025. The applicant states the projected growth in the older age cohorts in Cumberland County substantiate the need for increased radiation therapy services in the service area.

The information provided by the applicant in the pages referenced above is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates that the existing linear accelerator has passed its useful life, based on the amount of down time for repairs in the past year.
- The older population group in Cumberland County is expected to increase.
- The applicant adequately demonstrates there is a need for increased access to linear accelerator services by the older population group in the service area.
- The applicant demonstrates, through the CAGR calculation, that utilization of HPN’s radiation therapy services have increased over the last three years.

Projected Utilization

In Exhibit C-4 and Form C in Section Q, the applicant provides statistical data and tables showing the historical and projected utilization for the HPN linear accelerator through the first three operating years (OY) following completion of the project, FFY 2020 - FFY 2022, which is summarized as follows:

**HPN
HISTORICAL AND PROJECTED
RADIATION THERAPY TREATMENTS
FFY 2016 – FFY 2022**

FFY	NUMBER OF TREATMENTS	NUMBER OF PATIENTS
2016 Actual	4,907	245
2017 Actual	4,632	223
2018 Actual*	5,129	245
2019 Interim	2,643	126
2020 (OY 1)	4,490	214
2021 (OY 2)	5,523	263
2022 (OY 3)	5,662	270

*The applicant states on page 84 that 2018 data is annualized based on eight months actual data.

In Section Q, pages 84 – 87 and in supplemental information provided at the Agency’s request, the applicant provides its assumptions and methodology for projecting utilization of the replacement linear accelerator, summarized as follows:

- The applicant uses historical utilization data for the specific unit at HPN to project interim and future utilization of the replacement unit.
- The applicant states utilization of the existing linear accelerator at HPN increased slightly in FY 2016 and part of FY 2017 as a result of the fire at SRMC that closed SRMC's linear accelerator during that time; the temporary increase in Robeson County patients skewed HPN patient numbers during that time.
- The applicant calculates two CAGRs of historical patient growth at HPN: one that includes the temporary influx of Robeson County patients from SRMC, and one that excludes those patients. The applicant determined that the CAGR that includes the Robeson County patients was 2.5%, while the CAGR that excludes the Robeson County patients was 3.4%.
- The applicant conservatively utilizes the lower CAGR of 2.5% to project future utilization at HPN.
- In Section Q assumptions, the applicant states FY 2018 utilization, which the applicant annualized based on eight months of data, is a more accurate indication of future patient origin at HPN. Therefore, in Sections C and Q and in supplemental information, the applicant utilizes the annualized FY 2018 patient volume data as its base year from which to project future utilization. The applicant projects patient volume by applying the 2.5% CAGR to project future patient volume.
- In Section C and in supplemental information, the applicant states the replacement linear accelerator will be down for six months in FY 2019 to allow time for renovation, installation and calibration of the replacement linear accelerator.
- During the down time, the applicant states approximately one-half of projected HPN patients will receive radiation therapy services at CFVMC ($251 / 2 = 125.5$; in the first half of the interim year).
- Once the replacement unit is operational in the second half of the interim year, HPN patients will begin to return to HPN, so that at the end of the interim year, HPN is projected to serve all but 43 of the patients who were temporarily being served at CFVMC.
- Thereafter, the applicant states patient volume will ramp up slowly as the remaining 43 patients return to HPN.
- In supplemental information, the applicant states:

“...patient volumes during the first fiscal year were decreased by 43 patients based upon discussion and direction from the Corporate Director

*of the Cancer Center and Imaging Services who was directly involved in preparation of the CON. The volume decrease represents the equivalent of two months of patients at HPN (257 / 12 * 2 = 43) per her recommendation.*

...

Final projected volume for PY 1 ... reflects projected volume of 257 patients minus a decrease for ramp up of 43 patient OR 257 – 43 = 213 [sic] patients in PY 1.

...Once the new equipment is in place at HPN beginning October 2019, HPN patient volumes will shifted [sic] back to HPN from CFVMC, however, to assure the equipment is accurately installed and calibrated, patient volume in the first year will shift back at an adjusted rate, or ramped up slowly, resulting in an estimated 43 HPN patients being treated at CFVMC in PY1....”

Therefore, based on information from the Corporate Director of the Cancer Center at HPN, the applicant projects that approximately 82 patients [125 – 43 = 82] will return to HPN in the beginning of the first full fiscal year after the linear accelerator is fully operational.

See the following table, from Section Q, page 85 and from supplemental information:

	BASE YEAR	INTERIM		PROJECTED			AVG. ANNUAL GROWTH RATE 2018 – 2022
	10/2017 – 9 2018	10/2018 – 9/2019	PY 1 10/19 – 9/20	PY 1 10/20 – 9/21	PY 1 10/21 – 9/22		
Projected HPN Patients	245	251		257	263	270	
HPN Projected Volume CAGR				2.5%	2.5%	2.5%	
		10/18 – 3/19	4/19 – 9/19	PY 1 Ramp Up			
Temporary Pt. Shift to CFVMC	0	--	125	43	0	0	
HPN Pt. Volume Adjusted for Ramp Up	245	126	--	214	263	270	
Projected HPN Patients	245	251		214	263	270	

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected utilization is based on the applicant’s historical experience with the existing linear accelerator at HPN.

- The applicant used population data from the North Carolina Office of State Budget and Management to project growth in the population groups more likely to receive a cancer diagnosis in the project years.
- The applicant accounted for the temporary influx of patients from SRMC as a result of a fire at SRMC. Even without the extra SRMC patients, and using the lower CAGR, the applicant demonstrates that the replacement linear accelerator will be well utilized.
- The applicant accounted for down time initially during the installation and calibration period for the replacement linear accelerator.

Access

In Section C, page 36, the applicant states that it is the policy of Cape Fear Valley Hospital System to provide all services to “*all patients upon the request of physicians with appropriate privileges, regardless of race, sex, income status, ability to pay, disability, age or other underserved characteristics.*” In Section L, page 66, the applicant projects the following payor mix during the two full fiscal years of operation following completion of the project, as illustrated in the following table:

Projected Payor Mix, FFY 2020 - 2022

PAYOR CATEGORY	CFVMC SERVICES AS % OF TOTAL	LINAC SERVICES AS % OF TOTAL
Self-Pay	3.1%	1.0%
Charity Care	3.1%	0.02%
Medicare	47.2%	49.7%
Medicaid	20.7%	8.3%
Insurance	18.1%	20.7%
Workers Compensation	0.6%	0.0%
TRICARE	7.0%	20.1%
Other (undetermined)	0.2%	0.0%
Total	100.0%	100.0%

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the replacement linear accelerator proposed in this application.
- Projected utilization is reasonable and adequately supported.
The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(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

The applicant does not propose to:

- reduce a service
- eliminate a service
- relocate a facility or service

Therefore, Criterion (3a) is not applicable to this review.

(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

CCHS proposes to replace an existing linear accelerator located at Cape Fear Valley Medical Center – Health Pavilion North in Fayetteville.

In Section E, page 43, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Do nothing
- Close the radiation oncology program at HPN

On page 43, the applicant states that its proposal is the most effective alternative because the existing linear accelerator will continue to fail, causing delayed treatment to cancer patients and increased operational expense for CFVHS. In addition, the cancer treatment center at HPN is a comprehensive treatment program, and forcing patients to receive

treatment at the Cyberknife Center at CFVMC would create unnecessary patient throughput issues and inconvenience existing cancer patients who receive treatment at HPN.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The applicant demonstrates the existing linear accelerator at HPN has outlived its useful life and needs replacing to treat cancer patients.
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Cumberland County Hospital System, Inc. shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Cumberland County Hospital System, Inc. shall materially comply with the last made representation.**
- 2. Cumberland County Hospital System, Inc. shall acquire no more than one linear accelerator to replace one existing linear accelerator located at Cape Fear Valley Medical Center – Health Pavilion North. The applicant shall dispose of the existing linear accelerator being replaced by removing it from North Carolina.**
- 3. Cumberland County Hospital 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 Q of the application and that would otherwise require a certificate of need.**
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Cumberland County Hospital System, Inc. shall submit, on the form**

provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:

- a. Payor mix for the services authorized in this certificate of need.
- b. Utilization of the services authorized in this certificate of need.
- c. Revenues and operating costs for the services authorized in this certificate of need.
- d. Average gross revenue per unit of service.
- e. Average net revenue per unit of service.
- f. Average operating cost per unit of service.

5. Cumberland County Hospital System, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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

CCHS proposes to replace an existing linear accelerator located at the Cape Fear Valley Medical Center – Health Pavilion North in Fayetteville.

Capital and Working Capital Costs

In Section Q, page 93, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	COST
Construction / Renovation Contract	\$ 473,814.00
Architect / Engineering Fees	\$ 95,000.00
Medical Equipment	\$2,750,000.00
Non-Medical Equipment	\$ 15,000.00
Furniture	\$ 8,000.00
Consultant Fees (CON, Physicist)	\$ 62,340.00
Other (Project Contingency)	\$ 75,000.00
Total	\$3,479,154.00

In Section F.3, page 47, the applicant states that there are no start-up or initial operating expenses, as this is not a new service.

In Section Q, the applicant provides the assumptions used to project the capital cost.

Availability of Funds

In Section F, page 45, the applicant states that the capital cost will be funded as shown in the table below.

SOURCES OF CAPITAL COST FINANCING

TYPE	TOTAL
Loans	\$0.00
Accumulated reserves or OE *	\$3,479,154.00
Bonds	\$0.00
Other (Specify)	\$0.00
Total Financing	\$3,479,154.00

* OE = Owner’s Equity

In Exhibit F.2, the applicant provides an August 15, 2018 letter from the Chief Financial Officer that confirms the availability of the funds and the commitment of the funds to the project. The applicant also provides Cape Fear Valley Health System’s consolidated financial statements from FFY 2017 that confirm the availability of the funds necessary to finance the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4, page 100, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1 ST FULL FISCAL YEAR	2 ND FULL FISCAL YEAR	3 RD FULL FISCAL YEAR
Total Radiation Therapy Patients	214*	263	270
Total Gross Revenues (Charges)	\$9,445,961	\$11,840,998	\$12,399,280
Total Net Revenue	\$2,127,412	\$2,666,895	\$2,792,635
Average Net Revenue per Patient	\$9,942	\$10,140	\$10,343
Total Operating Expenses (Costs)	\$1,188,151	\$1,487,277	\$1,642,225
Average Operating Expense per Patient	\$5,552	\$5,655	\$6,082
Net Income	\$939,321	\$1,179,618	\$1,150,410

Totals may not sum due to rounding and use of spreadsheets

*214 patients represents the projected ramp up following the interim year patient shift to CFVMC (renovation, installation and calibration of the replacement linear accelerator at HPN).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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 replace an existing linear accelerator located at the Cape Fear Valley Medical Center – Health Pavilion North in Fayetteville

On page 121, the 2018 SMFP states, “A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.” In Table 9I, page 129 of the 2018 SMFP, Cumberland County is included in Linear Accelerator Service Area 18, which also includes Bladen, Robeson and Sampson counties. Providers may serve residents of counties not included in their service area.

There are seven existing linear accelerators in Linear Accelerator Service Area 18. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators, as summarized from Table 9G, page 126 of the 2018 SMFP.

	# LINEAR ACCELERATORS	TOTAL PROCEDURES*	AVERAGE ESTV* PER LINEAR ACCELERATOR
Cape Fear Valley Medical Center	5	21,769	4,354
Southeastern Regional Medical Center	1	4,099	4,099
NC Radiation Therapy - Sampson	1	2,863	2,863

*The 2018 SMFP equates Equivalent Simple Treatment Visits (ESTVs) with procedures in Table 9G.

The applicant proposes to replace one existing linear accelerator located at Cape Fear Valley Medical Center-North Health Pavilion; therefore, the applicant does not propose to increase the inventory of linear accelerators in the service area.

In Section G, page 52, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved linear accelerator services in linear accelerator service Area 18. The applicant states:

“The proposed project is being developed to replace an existing highly utilized asset at CFVMC’s Cancer Center @HPN to meet the needs of patients specific to Cape Fear Valley Medical Center’s cancer program and HPN’s growing linear accelerator volume.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant proposes to replace an existing, antiquated, well-utilized linear accelerator with comparable equipment to serve its oncology patients.
- The proposal would not result in an increase in number of linear accelerators in the service area.
- The applicant adequately demonstrates that the proposed replacement linear accelerator is needed in addition to the existing or approved linear accelerators.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Q, Form H.2, the applicant provides the historical and projected staffing for HPN radiation therapy services, summarized as follows:

Staffing – HPN Radiation Therapy Services

POSITION	CURRENT FY 2018	PROJECTED		
		1 ST FULL FISCAL YEAR	2 ND FULL FISCAL YEAR	3 RD FULL FISCAL YEAR
RN	1.0	1.0	1.0	1.0
Social Worker	0.5	0.5	0.5	0.5
Dietician	0.5	0.5	0.5	0.5
Radiation Therapist	2.5	2.5	2.5	2.5
Physicist	0.5	0.5	0.5	0.5
Clerical	0.5	0.5	0.5	0.5
TOTAL	5.5	5.5	5.5	5.5

In Section Q, Form H, the applicant provides its staffing-related assumptions. Since the project is for a replacement linear accelerator, staff is in place and the applicant does not project to add additional full-time equivalent (FTE) positions as a result of this project. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 54 - 55, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 56, the applicant identifies the current medical director. In Exhibit H-4.b, the applicant provides a letter from the medical director committing to continue to serve as medical director following replacement of the existing linear accelerator. In Exhibit H-3 and H-4.a, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 I, page 57, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Clinical Laboratory Services
- Radiology Services
- Plant Engineering Services
- Human Resources
- Employee Occupational Health
- Legal Services
- Facilities Planning, Accounting
- Interpreter Services
- Public Safety
- Pharmaceutical Services
- Housekeeping Services
- Business Office Services
- Corporate Education & Training
- Information Technology
- Design & Construction
- Risk Management
- Marketing & Communications

On page 57, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.

In Section I, page 58, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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

In Section K, page 61, the applicant states that the project involves renovating 1,480 square feet of existing space to install the replacement linear accelerator. The replacement unit will be installed in the same space as the existing unit; renovation is to update the space where the 12-year old existing linear accelerator was located. Line drawings are provided in Exhibit K-2.

On pages 61 - 62, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K-4.a.

On page 61, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibit K-4.a.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

In Section L.1(b), page 65, the applicant provides the following payor mix for both CFVMC's combined inpatient and outpatient services and for HPN's radiation therapy services for FY 2017 (10/1/16 – 9/30/17):

Historical Payor Mix, FFY 2017

PAYOR CATEGORY	CFVMC SERVICES AS % OF TOTAL	RADIATION THERAPY SERVICES AS % OF TOTAL
Self-Pay	3.1%	1.0%
Charity Care	3.1%	0.02%
Medicare	47.2%	49.7%
Medicaid	20.7%	8.3%
Insurance	18.1%	20.7%
Workers Compensation	0.6%	0.0%
TRICARE	7.0%	20.1%
Other (undetermined)	0.2%	0.0%
Total	100.0%	100.0%

As shown in the table above, the applicant states that 8.3% of its radiation therapy services were reimbursed by Medicaid and 49.7% were reimbursed by Medicare in FY 2017.

In Section L.1, page 64, the applicant provides the following comparison.

Patients Served During Last Full FY (10/1/16 – 9/30/17)

	% OF TOTAL PATIENTS SERVED BY CFVMC	% OF CANCER PATIENTS SERVED AT HPN	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	61%	59%	51%
Male	39%	41%	49%
Unknown	0%	0%	0%
64 and Younger	76%	48%	88%
65 and Older	24%	52%	12%
American Indian	2%	2%	2%
Asian	1%	2%	3%
Black or African-American	46%	46%	38%
Native Hawaiian or Pacific Islander	0%	0%	0%
White or Caucasian	42%	46%	52%
Other Race	8%	4%	5%
Declined / Unavailable	1%	0%	0%

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 65, the applicant states it is not under an obligation to provide uncompensated care. The applicant provides a table that shows CFVMC provided 3.1% of services to charity care, 47.2% to Medicare recipients, and 20.7% to Medicaid recipients.

In Section L, page 65, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L, page 66, the applicant projects the following payor mix for the proposed services during the first two full fiscal years of operation following completion of the project, as shown in the table below.

Projected Payor Mix, FFY 2020 - 2022

PAYOR CATEGORY	CFVMC SERVICES AS % OF TOTAL	LINAC SERVICES AS % OF TOTAL
Self-Pay	3.1%	1.0%
Charity Care	3.1%	0.02%
Medicare	47.2%	49.7%
Medicaid	20.7%	8.3%
Insurance	18.1%	20.7%
Workers Compensation	0.6%	0.0%
TRICARE	7.0%	20.1%
Other (undetermined)	0.2%	0.0%
Total	100.0%	100.0%

As shown in the table above, during the second and third full fiscal years of operation, the applicant projects that 3.1% of total services will be provided to self-pay patients, 3.1% to charity care patients, 47.2% to Medicare patients and 20.7% to Medicaid patients.

On page 66, the applicant provides the assumptions and methodology used to project payor mix following project completion. The projected payor mix is reasonable and adequately supported because it is entirely based on the historical payor mix for linear accelerator services at HPN.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L, page 66, the applicant adequately describes the range of means by which patients will have access to the proposed services, which is by physician referral.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming 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 M, pages 68 - 70, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming 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 replace an existing linear accelerator located at the Cape Fear Valley Medical Center – Health Pavilion North in Fayetteville.

On page 121, the 2018 SMFP states, “A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.” In Table 9I, page 129 of the 2018 SMFP, Cumberland County is included in Linear Accelerator Service Area 18, which also includes Bladen, Robeson and Sampson counties. Providers may serve residents of counties not included in their service area.

There are seven existing linear accelerators in Linear Accelerator Service Area 18. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators, as summarized from Table 9G, page 126 of the 2018 SMFP.

	# LINEAR ACCELERATORS	TOTAL PROCEDURES*	AVERAGE ESTV* PER LINEAR ACCELERATOR
Cape Fear Valley Medical Center	5	21,769	4,354
Southeastern Regional Medical Center	1	4,099	4,099
NC Radiation Therapy - Sampson	1	2,863	2,863

*The 2018 SMFP equates Equivalent Simple Treatment Visits (ESTVs) with procedures in Table 9G.

In Section N, page 73, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 73, the applicant states the project involves replacing an existing critical piece of equipment at the Health Pavilion North. It will continue to foster competition by continuing to promote cost effectiveness and access to radiation therapy in the service area.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 O, page 76, the applicant identifies five hospitals and cancer treatment facilities located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 76, and in supplemental information provided to the Agency, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all five 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.

NA

The applicant proposes to replace an existing linear accelerator at the CFVMC Health Pavilion North. The Criteria and Standards for Radiation Therapy Equipment, which are promulgated in 10A NCAC 14C .1900, are not applicable to this review because the applicant does not propose to acquire a new linear accelerator. Therefore, Criterion (21) is not applicable to this review.