

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 18, 2022

Findings Date: January 18, 2022

Project Analyst: Celia C. Inman

Co-Signer: Micheala Mitchell

Project ID #: M-12152-21

Facility: Cape Fear Valley Medical Center

FID #: 943057

County: Cumberland

Applicants: Cumberland County Hospital System, Inc.

Project: Replace an existing linear accelerator

REVIEW CRITERIA

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

Cumberland County Hospital System, Inc., doing business as Cape Fear Valley Health System, referred to hereinafter as "CFVHS" or "the applicant," proposes to replace an existing linear accelerator (LINAC) at Cape Fear Valley Medical Center (CFVMC). CFVMC operates five LINACs. Four of the LINACs are located at the Cape Fear Valley Cancer Treatment & Cyberknife Center on the CFVMC main campus and one is located at the Cancer Center at Health Pavilion North. The proposed project seeks to replace one of the existing linear accelerators on the CFVMC main campus and will not increase CFVMC's complement of LINAC equipment.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2021 SMFP which is applicable to this review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Services Facilities, on page 29 of the 2021 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, Certificate of Need 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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 25, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant states that the renovations to facilitate the installation of the replacement linear accelerator will meet or exceed current North Carolina energy efficiency and water conservation standards and include water conserving fixtures to the extent consistent with clinical needs and patient safety.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Information 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 based on the following reasons:

- The applicant does not propose to develop any beds, services, or equipment for which there is a need determination in the 2021 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to replace an existing LINAC at the cancer treatment center on the main campus of CFVMC.

Patient Origin

On page 324, the 2021 SMFP states:

*“A linear accelerator’s **service area** is one of the 28 multicounty groupings described in the Assumptions of the Methodology.*

...

3. Patient origin data from the current reporting year forms the basis for defining service areas (Table 17C-4). Counties are the basic units for the formation of linear accelerator service areas, based on proximity, utilization patterns, and patient origin data.”

CFVMC is in Cumberland County. Table 17C-4 on page 333 of the 2021 SMFP shows Cumberland County is part of Service Area 18, along with Bladen, Robeson, and Sampson counties. Thus, the service area for this facility is Service Area 18, comprised of Bladen, Cumberland, Robeson, and Sampson counties. Facilities may also serve residents of counties not included in their service area.

The following tables show historical, current and projected patient origin, as provided by the applicant on pages 27 and 29.

CFVMC LINAC Historical and Current Patient Origin

County	FY2019		FY2021 Annualized*	
	# Patients	% of Total	# Patients	% of Total
Cumberland	770	76.2%	776	75.1%
Hoke	68	6.7%	65	6.3%
Bladen	53	5.2%	50	4.8%
Harnett	33	3.3%	52	5.0%
Robeson	29	2.9%	33	3.2%
Sampson	19	1.9%	27	2.6%
Columbus	5	0.5%	4	0.4%
Johnston	0	0.0%	2	0.2%
Scotland	14	1.4%	6	0.6%
Other^	19	1.9%	19	1.8%
Total^^	1,011	100.0%	1,033	100.0%

Source: page 27 of application - the applicant provides the historical patient origin for CFVMC LINAC patients during FY2019 and FY2021 to show that CFVMC's LINAC pre-pandemic patient origin (as a percent of total patients) is consistent with its post-pandemic patient origin.

*Annualized based on 10 months of data (October-August)

^Other includes <1% patient origin from the remaining counties in North Carolina and other states

^^The applicant's calculation of total patients is based on fractions and not the rounded whole numbers that are presented in the table above and on page 27

CFVMC LINAC Projected Patient Origin

County	FY1 – FY2024 10/1/23-9/30/24		FY2 – FY2025 10/1/24-9/30/25		FY3 – FY2026 10/1/25-9/30/26	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Cumberland	873	75.1%	908	75.1%	945	75.1%
Hoke	73	6.3%	76	6.3%	79	6.3%
Bladen	56	4.8%	58	4.8%	60	4.8%
Harnett	58	5.0%	60	5.0%	63	5.0%
Robeson	37	3.2%	39	3.2%	40	3.2%
Sampson	30	2.6%	31	2.6%	33	2.6%
Columbus	5	0.4%	5	0.4%	5	0.4%
Johnston	2	0.2%	2	0.2%	3	0.2%
Scotland	7	0.6%	7	0.6%	8	0.6%
Other*	21	1.8%	22	1.8%	23	1.8%
Total^	1,163	100.0%	1,210	100.0%	1,258	100.0%

Source: Section C, page 29

* Other includes <1% patient origin from the remaining counties in North Carolina and other states

^The applicant's calculation of total patients is based on fractions and not the rounded whole numbers that are presented in the table above and on page 29

In Section C, page 29, the applicant provides the assumptions and methodology used to project patient origin. The applicant states that the projected patient origin is consistent with CFVMC's

historical FY2021 experience providing linear accelerator services. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant projected patient origin based on its historical patient origin.
- The applicant provides the details of how it calculated the number of projected patients in Section Q.

Analysis of Need

In Section C, pages 31-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, listing the factors as shown below and summarizing them thereafter:

- The existing LA8 linear accelerator has exceeded its useful life and no longer meets the needs of CFVMC's radiation oncology patients. The proposed replacement equipment represents the current clinical standard of care for local patients (pages 32-33)
- Cancer incidence and mortality rates for service area residents (pages 36-40)
- The projected aging of the service area population (pages 34-36)

Existing linear accelerator: On page 32, the applicant states that the existing linear accelerator, LA8, was installed in 2011 and has continuously served CFVMC inpatients and outpatients for over a decade, when the depreciable useful life of a linear accelerator is seven years and 1,500 hours, per the American Hospital Association. The existing linear accelerator has a run time of approximately 1,700 hours. Thus, the equipment has exceeded its useful life. The applicant states that the equipment is no longer state-of-the-art and:

- cannot be upgraded to be compatible with new radiation therapy innovations,
- treatment times are longer compared to current technology, and
- the existing equipment is experiencing significant downtime, requiring the shifting of patients to continue their treatment.

The aging of the residents in Service Area 18: the applicant states that while the service area population is expected to remain stable in the next four years, the service area population age 65 and older is projected to increase rapidly during the next five years. The applicant further states that, over 55% of cancer incidence presents in population age 65 and older.

Cancer incidence and mortality rates for service area residents: the applicant states that cancer is the leading cause of death in North Carolina and that counties in Linear Accelerator Service Area 18 exhibit higher overall cancer incidence rates compared to North Carolina. The applicant further states that incidence rates are impacted by race and ethnicity and that Service Area 18 counties have a higher minority population. The applicant also states that as the population ages, the incidence of cancer will increase as well.

The information is reasonable and adequately supported based on the following:

- The applicant uses data and information from reliable sources and provides those sources in support of the need to replace/upgrade the existing LINAC.
- The applicant provides data to support its assertions about population increases (both countywide and by age groups), changes in life expectancy, and changes in cancer incidence.

Projected Utilization

In Section Q Forms C.2a and C.2b, the applicant provides historical and projected utilization, as illustrated in the table below.

Historical & Projected Utilization				
	Historical	Projected		
	FY2020	FY2024	FY2025	FY2026
# of LINACs	5	5	5	5
Total # ESTV Treatments	17,916	25,259	26,274	27,330

In Section Q Form C.2a and C.2b Utilization - Assumptions and Methodology, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Step 1: Review CFVMC’s historical utilization on its five linear accelerators and calculate the compound average growth rate (CAGR)

	FY2018	FY2019	FY2020	FY2021*	CAGR
Patients	918	1,011	776	1,033	4.0%
ESTVs	17,481	18,611	17,916	22,442	

*Annualized based on 11 months (October through August 2021)
 Source: CFVMC License Renewal Applications (LRAs)

Step 2: Determine projected patient growth rate

The applicant states that the projected growth rate will be the historical CAGR of 4.0% based on:

- the growing and aging population in Service Area 18,
- the statistical data regarding cancer incidence described in Section C,
- increased efficiency and throughput on proposed replacement equipment, and
- support of the CFVMC medical staff.

Step 3: Project CFVMC linear accelerator patients

	CAGR	FY2022	FY2023	FY2024	FY2025	FY2026
Patients	4.00%	1,075	1,118	1,163	1,210	1,258
# of LINACs		5	5	5	5	5
Patients/LINAC		215	224	233	242	252

Step 4: Project CFVMC ESTVs

	FY2021*	FY2022	FY2023	FY2024	FY2025	FY2026
Patients	1,033	1,075	1,118	1,163	1,210	1,258
Treatments	20,988	21,832	22,709	23,622	24,571	25,559
Treatments/Patient	20.3	20.3	20.3	20.3	20.3	20.3
ESTVs	22,442	23,344	24,283	25,259	26,274	27,330
ESTVs/Patient	21.7	21.7	21.7	21.7	21.7	21.7

*Treatments/Patient and ESTVs/Patient are based on FY2021 Annualized reported patients, procedures, and ESTVs

Projected utilization is reasonable and adequately supported based on the following:

- The applicant relied on its historical utilization as the starting point for projecting future utilization.
- The applicant relied on its historical CAGR to project future patients.
- The applicant relied on its historical FY2021 Annualized utilization calculation of treatments per patient and ESTVs per patient to project future treatments and ESTVs per patient.

Access to Medically Underserved Groups

In Section C, page 45, the applicant states:

“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will continue to have access to CFVMD’s linear accelerators, as clinically appropriate.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	% of Total Patients
Low income persons	18.0%
Racial and ethnic minorities	48.9%
Women	50.4%
Persons with disabilities	*
Persons 65 and older	47.9%
Medicare beneficiaries	47.9%
Medicaid recipients	12.6%

Source: Section C, page 46

*CFVHS does not maintain data regarding disabled persons served

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant states that it will provide access to all underserved groups.
- The applicant provides supporting documentation of the access it provides and programs to assist the underserved in Section L.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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 all the reasons described above.

- (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, ... persons [with disabilities], 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, or 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

The applicant proposes to replace an existing LINAC at the cancer treatment center on the main campus of CFVMC.

In Section E, pages 54-55, the provides the following alternatives considered and states why each alternative is not the least costly or most effective alternative to meet the identified need:

- Maintain the status quo – the applicant states that doing nothing will result in delayed treatment for cancer patients and increased operational expenses for CFVHS. Thus, the applicant states that this is not an effective alternative.
- Decommission the existing linear accelerator and utilize the remaining four linear accelerators at CFVMC – the applicant states that shifting patients to the remaining four linear accelerators would increase utilization to more than 250 patients per machine, further stressing the patient load at CFVMC and resulting in a need for

additional equipment, as well as forcing patients to travel for treatment if access to CFVMC linear accelerators is limited. Thus, the applicant states that this alternative would be a more costly and less effective alternative to meeting the identified need.

- Pursue an exemption request – the applicant states that the cost of the proposed replacement equipment is greater than \$2 million, and therefore does not meet the dollar value requirement for an exemption.

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 provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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 all the reasons described above. Therefore, the application is approved subject to the following conditions:

- 1. Cumberland County Hospital System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire no more than one replacement linear accelerator to be located at Cape Fear Valley Medical Center.**
- 3. Upon completion of the project, Cape Fear Valley Medical Center shall have no more than five linear accelerators.**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**

Construction/Renovation Contract	\$551,318
Medical Equipment	\$3,747,965
Non-medical Equipment and Furniture	\$15,500
Other (Consultant fees, Contingency)	\$88,000
Total	\$4,402,783

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit C.1, the applicant provides a quote for the replacement LINAC.
- In Exhibit F.1, the applicant provides a renovation cost estimate signed by an architect which includes a cost break down and which matches the construction cost listed on Form F.1a.

In Section F, page 58, the applicant states there will be no working capital costs because radiation therapy is an existing service at CFVMC.

Availability of Funds

In Section F, pages 56-57, the applicant states the capital cost will be funded through the accumulated reserves of Cumberland County Hospital System, Inc. dba Cape Fear Valley Health System.

Exhibit F.2 contains a letter signed by the Chief Financial Officer of CFVHS, which commits to funding the capital cost from accumulated reserves of CFVHS. Exhibit F.2 also contains the most recent CFVHS audited financial statements documenting the availability of the funds.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides documentation of the commitment to use the necessary funding toward development of the proposed project.
- The applicant provides documentation of the availability of sufficient financial resources to fund the proposed capital cost.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

LINAC Projected Revenue & Expenses – FYs 1-3			
	FY2024	FY2025	FY2026
# of ESTVs	25,259	26,274	27,330
Gross Revenue	\$53,063,311	\$56,024,023	\$59,149,930
Adjustments to Revenue	\$41,646,209	\$43,969,894	\$46,423,231
Net Revenue	\$11,417,102	\$12,054,129	\$12,726,699
Average Net Revenue per ESTV	\$452	\$459	\$466
Operating Costs	\$5,768,584	\$5,898,228	\$6,033,095
Average Operating Costs per ESTV	\$228	\$224	\$221
Net Profit/(Loss)	\$5,648,518	\$6,155,901	\$6,693,604

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in the Section Q Form F.2a and F.2b Revenues and Net Income Assumptions. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant accounts for projected operating expenses and clearly explains the revenue projections.
- Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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 cost is 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 LINAC at the cancer treatment center on the main campus of CFVMC.

On page 324, the 2021 SMFP states:

*“A linear accelerator’s **service area** is one of the 28 multicounty groupings described in the Assumptions of the Methodology.*

...

3. Patient origin data from the current reporting year forms the basis for defining service areas (Table 17C-4). Counties are the basic units for the formation of linear accelerator service areas, based on proximity, utilization patterns, and patient origin data.”

CFVMC is in Cumberland County. Table 17C-4 on page 333 of the 2021 SMFP shows Cumberland County is part of Service Area 18, along with Bladen, Robeson, and Sampson counties. Thus, the service area for this facility is Service Area 18, comprised of Bladen, Cumberland, Robeson, and Sampson counties. Facilities may also serve residents of counties not included in their service area.

There are eight LINACs in Linear Accelerator Service Area 18. The following table identifies the provider, number of LINACs, and average utilization of each LINAC during FFY 2019, per page 328 of the 2021 SMFP.

Linear Accelerator Service Area 18 Utilization				
Facility	County	# of LINACs	Total # of Procedures	Average # of Procedures/Unit
Cape Fear Valley Medical Center	Cumberland	5	18,611	3,722
Southeastern Regional Medical Center	Robeson	2	7,591	3,796
North Carolina Radiation Therapy Management Services-Clinton	Sampson	1	2,933	2,933
Total		8	29,135	10,451

Source: Table 17C-1, page 328, 2021 SMFP

In Section G, page 64, the applicant explains why the proposal would not result in the unnecessary duplication of existing or approved LINAC services in LINAC Service Area 18. The applicant states that the robust growth of radiation therapy services at CFVMC supports the need for CFVMC to replace its existing linear accelerator. The proposed project does not increase the number of linear accelerators in the service area.

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

- The applicant uses its historical utilization to support the need to replace its existing asset.
- The applicant does not propose to increase the number of LINACs in Linear Accelerator Service Area 18.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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 all the reasons described 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

The applicant proposes to replace an existing LINAC at the cancer treatment center on the main campus of CFVMC.

In Section Q Form H, the applicant provides the current and projected full-time equivalent (FTE) positions for its LINAC services, as illustrated in the following table.

CFVMC LINAC FTE Staffing – Current and Projected				
	Current	Projected		
	FY2021	FY2024	FY2025	FY2026
Registered Nurse	4.0	4.0	4.0	4.0
Social Worker	1.0	1.0	1.0	1.0
Dietician	1.5	1.5	1.5	1.5
Supervisor	2.0	2.0	2.0	2.0
Radiation Therapist	12.0	12.0	12.0	12.0
Physicist	3.0	3.0	3.0	3.0
Clerical	3.0	3.0	3.0	3.0
Dosimetrist	4.0	4.0	4.0	4.0
Total	30.5	30.5	30.5	30.5

The assumptions and methodology used to project staffing are provided on Form H. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 66-67, the applicant describes its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant currently has sufficient staff to operate the replacement LINAC once it is operational.
- The applicant provides supporting documentation of its existing training and continuing education programs in Exhibit H.3.

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 all the reasons described 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

The applicant proposes to replace an existing LINAC at the cancer treatment center on the main campus of CFVMC.

Ancillary and Support Services

In Section I, page 68, the applicant identifies the necessary ancillary and support services for the proposed services, explains how each ancillary and support service is currently available, and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because it is already providing all of the necessary ancillary and support services necessary for the proposed replacement LINAC.

Coordination

In Section I, page 69, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant is already coordinating services 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 for all the reasons described above.

- (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

The applicant proposes to replace an existing LINAC at the cancer treatment center on the main campus of CFVMC.

In Section K, page 72, the applicant states that the project involves renovating 794 square feet of existing space. Line drawings are provided in Exhibit K.2.

In Section K, page 72, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal. The applicant states that the project manager based the renovation cost on a detailed review of the project, upon published construction costing data, and upon CFVMC's experience with similar projects. Exhibit F.1 contains a cost certification letter.

In Section K, page 73, 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. The applicant states that using existing space results in lower costs and less duplication.

On page 73, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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 all the reasons described above.

- (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 ... persons [with disabilities], 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, page 76, the applicant provides the historical payor mix during FY2021 for all services at CFVMC. On page 77, the applicant provides the payor mix during FY2021 for LINAC services at CFVMC, as shown in the table below.

CFVMC Historical LINAC Payor Mix FY2021	
Payor Category	Percent of Total Patients Served
Self-Pay	3.2%
Charity Care	
Medicare*	48.9%
Medicaid*	11.0%
Insurance*	22.2%
TRICARE	14.7%
Total	100.0%

*Including any managed care plans

In Section L, page 78, the applicant provides the following comparison for its radiation therapy services.

	% of Total LINAC Patients Served FY2021	% of the Population of the Service Area
Female	48.0%	50.4%
Male	52.0%	49.6%
Unknown		
64 and Younger	48.0%	87.8%
65 and Older	52.0%	12.2%
American Indian	3.0%	1.9%
Asian	2.0%	2.7%
Black or African-American	41.0%	39.1%
Native Hawaiian or Pacific Islander	1.0%	0.4%
White or Caucasian	47.0%	51.1%
Other Race	6.0%	4.8%
Declined / Unavailable		

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

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 ... persons [with disabilities] 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 78, the applicant states it has no such obligation.

In Section L, page 79, the applicant states that the question is not applicable and did not identify any patient civil rights equal access complaints filed in the 18 months immediately preceding the application deadline against the facility, stating.

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.

- (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 79, the applicant projects the following payor mix for the proposed LINAC services during the third full fiscal year of operation following completion of the project, as shown in the table below.

CFVMC Projected Payor Mix FY2026

Payor Category	Percent of Total Patients Served
Self-Pay	3.2%
Charity Care	
Medicare*	48.9%
Medicaid*	11.0%
Insurance*	22.2%
TRICARE	14.7%
Total	100.0%

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.2% of total LINAC services will be provided to self-pay patients, 48.9% and 11.0% of total LINAC services will be provided to Medicare and Medicaid patients, respectively.

On page 79, the applicant provides the assumptions used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix from FY2021.

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 all the reasons described above.

- (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 81, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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.

- (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

The applicant proposes to replace an existing LINAC at the cancer treatment center on the main campus of CFVMC.

In Section M, pages 82-85, 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. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes because the applicant currently provides access to the facility for training purposes for health professional training programs in the area and provides a listing of the programs on pages 83-84.

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 all the reasons described above.

- (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 LINAC at the cancer treatment center on the main campus of CFVMC.

On page 324, the 2021 SMFP states:

“A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.

...

3. Patient origin data from the current reporting year forms the basis for defining service areas (Table 17C-4). Counties are the basic units for the formation of linear accelerator service areas, based on proximity, utilization patterns, and patient origin data.”

CFVMC is in Cumberland County. Table 17C-4 on page 333 of the 2021 SMFP shows Cumberland County is part of Service Area 18, along with Bladen, Robeson, and Sampson counties. Thus, the service area for this facility is Service Area 18, comprised of Bladen, Cumberland, Robeson, and Sampson counties. Facilities may also serve residents of counties not included in their service area.

There are eight LINACs in Linear Accelerator Service Area 18. The following table identifies the provider, number of LINACs, and average utilization of each LINAC during FFY 2019, per page 328 of the 2021 SMFP.

Linear Accelerator Service Area 18 Utilization				
Facility	County	# of LINACs	Total # of Procedures	Average # of Procedures/Unit
Cape Fear Valley Medical Center	Cumberland	5	18,611	3,722
Southeastern Regional Medical Center	Robeson	2	7,591	3,796
North Carolina Radiation Therapy Management Services-Clinton	Sampson	1	2,933	2,933
Total		8	29,135	10,451

Source: Table 17C-1, page 328, 2021 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 86, the applicant states:

“The proposed project is replacing an existing piece of equipment currently in operation. Therefore, the proposed project will continue to foster competition by continuing to promote cost effectiveness, quality, and access to services in the proposed service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 86, the applicant states:

“The proposed project will continue CFVMC’s efforts to promote cost effectiveness in several ways. The replacement equipment will be located in existing space, and the new equipment will be more efficient and effective, decreasing downtime and patient

delays. This will result in assuring CFVMC's ability to achieve economies of scale, scope, and expertise and will ensure that CFVHS continues to be a strong and viable competitor in the broader health care marketplace."

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 87, the applicant states:

"CFVHS adheres to external quality standards. . . . The project will also be held to the same quality standards as existing CFVHS surgical services."

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 87, the applicant states:

"CFVHS has existing strategies with specific activities designed to assure services will be accessible by indigent patients without regard to ability to pay. CFVMC will not discriminate in the provision of services on the basis of age, race, religion, disability, or the patient's ability to pay."

See also Sections C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and & the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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 all the reasons described 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

The applicant proposes to replace an existing LINAC at the cancer treatment center on the main campus of CFVMC.

In Section Q Form O, the applicant identifies the hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of three hospitals located in North Carolina.

In Section O, page 90, the applicant states that, it is not aware of any deficiencies in quality of care at its licensed facilities in the 18 months immediately preceding the submittal of the application. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care and resulting in immediate jeopardy occurred in any of these hospitals. 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 three hospitals, 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.

G.S. 131E-183 (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 LINAC. The Criteria and Standards for Radiation Therapy Equipment, which are promulgated in 10A NCAC 14C .1900, are not applicable to this review because they do not apply to proposals to replace existing LINACs.