

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 28, 2024

Findings Date: June 28, 2024

Project Analyst: Chalice L. Moore

Co-Signer: Gloria C. Hale

Project ID #: H-12513-24

Facility: FirstHealth Moore Regional Hospital

FID #: 943358

County: Moore

Applicant(s): FirstHealth of the Carolinas, Inc.

Project: Acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators upon project completion

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

FirstHealth of the Carolinas, Inc. (“FirstHealth”), the applicant, proposes to acquire no more than one linear accelerator pursuant to the 2024 State Medical Facilities Plan (SMFP) to be located at FirstHealth Moore Regional Hospital (FMRH) Pinehurst, Moore County. Following project completion, FirstHealth will have a total of three linear accelerators (LINACs), located at FirstHealth Moore Regional Hospital.

Need Determination

The 2024 SMFP includes an adjusted need determination for one additional LINAC in Linear Accelerator Service Area 17. Linear Accelerator Service Area 17 consists of Moore, Hoke, Lee, Montgomery, Richmond, and Scotland counties. Table 15C-6 of the 2024 SMFP, page

327, states *“In response to a petition, the State Health Coordinating Council approved an adjusted need determination for one linear accelerator that can only be approved for a cancer center in Service Area 17.”* The applicant proposes to acquire one fixed LINAC to be located in Moore County at FirstHealth Moore Regional Hospital, which it states, in Section B, page 24, has a cancer center. The applicant does not propose to acquire more LINACs than are determined to be needed in Linear Accelerator Service Area 17 and the applicant proposes to locate the LINAC in Moore County in a cancer center. Therefore, the application is consistent with the adjusted need determination.

Policies

There are two policies in the 2024 SMFP applicable to this review: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3: Basic Principles, on page 29 of the 2024 SMFP, states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 24-25; Section N, pages 106-107; Section O, pages 109-112; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 24; Section C, pages 60; Section L, pages 101-102; Section N, page 107, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 24; Section N, page 106; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 30 of the 2024 SMFP, states:

“Any person proposing a capital expenditure greater than \$4 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 \$5 million. In Section B, pages 26-29, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

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:

- The applicant does not propose to acquire more than one linear accelerator than is determined to be needed in the service area.

- The applicant proposes to situate the linear accelerator in Moore County consistent with the adjusted need determination in the 2024 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-

3 and Policy GEN-4 based on the following:

- The applicant adequately documents how the project will promote safety and quality in the delivery of radiation oncology services in Linear Accelerator Service Area 17;
- The applicant adequately documents how the project will promote equitable access to radiation oncology services in Linear Accelerator Service Area 17;
- The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
- 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

FirstHealth proposes to acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators at FMRH upon project completion.

Patient Origin

In Chapter 15, page 315, the 2024 SMFP states, "*A linear accelerator's service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.*" FMRH is in Moore County. In Table 15-C4, page 324 of the 2024 SMFP, Moore County is included in Linear Accelerator Service Area 17. Linear Accelerator Service Area 17 includes Moore, Hoke, Lee, Montgomery, Richmond, and Scotland counties. Thus, the service area for this project consists of those six counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for the linear accelerator.

County	Historical (10/1/2022 to 9/30/2023)		Third Full FY of Operation following Project Completion (10/1/2028 to 9/30/2029)	
	# of Patients	% of Total	# of Patients	% of Total
Moore	361	39.9%	447	39.9%
Richmond	127	14.0%	157	14.0%
Lee	100	11.1%	124	11.1%
Hoke	64	7.1%	79	7.1%
Montgomery	55	6.1%	68	6.1%
Cumberland	47	5.2%	58	5.2%
Robeson	37	4.1%	46	4.1%
Harnett	36	4.0%	45	4.0%
Scotland	29	3.2%	36	3.2%
Chatham	15	1.7%	19	1.7%
Randolph County	9	1.0%	11	1.0%
Other Counties and States	24	2.7%	30	2.7%
Total	904	100.0%	1120	100.0%

Source: Pages 40 and 42 of the application.

In Section C, page 42, and Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant states, on page 42, that it assumes no change in its patient origin.
- The applicant calculated the number of patients by county of patient origin using historical data projected forward.

Analysis of Need

In Section C, pages 44-54, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services as summarized below.

- There is an adjusted need determination in the 2024 SMFP for one linear accelerator in Linear Accelerator Service Area 17 that can only be approved for a cancer center. Linear Accelerator Service Area 17 consists of the following counties: Hoke, Lee, Moore, Montgomery, Richmond, and Scotland counties (pages 45-46).
- The demographics of FMRH’s service area and primary service area. From 2019 to 2024, the population of Service Area 17 which includes Hoke, Lee, Montgomery, Moore, Richmond, and Scotland counties, grew by 6.0 percent. Service Area 17 represents 81.4 percent of projected linear accelerator patients at FMRH. (page 46).
- Population growth and aging in FMRH’s service area. The 45-64 population grew by 2.5 percent from 2019 to 2024, representing 24.3 percent of Service Area 17’s population. The elderly population (65+ years old) grew by 14.5 percent from 2019 to 2024, to represent 21.2 percent of Service Area 17’s total population. (pages 48-51).
- Health status of FMRH’s service area. The overall number of new cancer cases is projected to increase, and the number of cancer deaths are projected to increase with the exception of lung/bronchus cancers over the 5-year period from 2018 to 2023. The

increase in the number of cases has a direct relationship to the need for radiation therapy services. (pages 48-51).

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

- There is an adjusted need determination in the 2024 SMFP for one additional linear accelerator in Linear Accelerator Service Area 17 to be located in a cancer center. FMRH has a cancer center, and it is located in Moore County, one of the counties in Linear Accelerator Service Area 17.
- Population growth statistics, particularly in the over 65 population for the service area demonstrate an increase in the population most likely to use the LINAC services being proposed.
- The NC State Center for Health Statistics data supports the applicant’s demonstration of need based on cancer statistics and projections in Linear Accelerator Service Area 17.
- The applicant adequately demonstrates the need for a linear accelerator in addition to the existing LINACs in Linear Accelerator Service Area 17.

Projected Utilization

In Section Q, Form C.2a, the applicant provides historical and projected utilization, as illustrated in the following tables.

FMRH LINACs Historical and Projected Utilization				
Projected Medical Equipment Utilization Upon Project Completion	Last FFY 10/1/2022- 9/30/2023	1 st FFY 10/1/2026 – 9/30/2027	2 nd FFY 10/1/2027 – 9/20/2028	3 rd FY 10/1/2028 – 9/30/2029
# of Units*	2	3	3	3
# of ESTV Treatments**	16,685	19,107	19,721	20,354

Source: Section Q of the application.

*The Project Analyst notes that there was a typo showing a total of only one LINAC for each of the first three project years following project completion. FMRH will have three LINACs.

**ESTV = Equivalent Simple Treatment Visits

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant examined the historical linear accelerator treatments at FMRH from FY2018 through FY2024 annualized. The applicant stated that while radiation therapy treatments slightly decreased during the global pandemic, it fully recovered.
- The applicant calculated the 3-year Compound Annual Growth Rate (CAGR) for radiation therapy treatments using the following formula: $3\text{-Year CAGR} = (17,379/15,345)^{(1/3)} - 1 = 6.42\%$
- The applicant utilized 50% of the calculated 3-year CAGR in projecting future radiation therapy treatments.

- The applicant projected the interim years and Year 1- Year 3 therapy by multiplying the previous year’s radiation therapy treatments by 50% of the 3-year CAGR.

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

- The applicant relies on its historical utilization to project future utilization.
- The applicant uses an annual growth rate that is less than its historical compound annual growth rate over the last three years.

Access to Medically Underserved Groups

In Section C.6, page 60, the applicant states,

“FMRH does not exclude from participation, deny benefits to, or otherwise discriminate against patients, students, or visitors on the basis of race; color; religion; national origin; culture; language; physical or mental disability; age; sex, including pregnancy, childbirth or related medical conditions; marital status; sexual orientation; gender identity or expression; socioeconomic status; source of payment; or any other protected status in admission to, participation in, or receipt of the services and benefits of any of its programs and activities.”

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

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	5.1%
Racial and ethnic minorities	27.7%
Women	50.4%
Persons with Disabilities	FMRH does not track this category
Persons 65 and older	72.2%
Medicare beneficiaries	68.9%
Medicaid recipients	5.1%

Source: table on page 60 of the application.

The applicant adequately describes, on page 60 and in Exhibit C.6, the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based, in part, on the following:

- The applicant provides written statements about providing access to all residents of the service area, including underserved groups.
- The applicant’s facility has historically provided care to all in need of radiation oncology services, including underserved persons.

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.

- (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

- (4) 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. 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

FirstHealth proposes to acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators at FMRH upon project completion.

In Section E, page 71, the applicant states,

“There are no alternatives to consider that will accommodate the increased workload on the existing linear accelerators at FMRH. FMRH has maxed out the reasonable number of daily procedure hours on the two existing linear accelerators and requires a third linear accelerator to accommodate any additional growth. Currently, FMRH has the highest average number of procedures per unit in North Carolina at 8,682 ESTVs. Service Area 17 consists of two linear accelerator providers, FirstHealth and Scotland Memorial Hospital. The presence of the underutilized linear accelerator at Scotland Memorial Hospital has consistently eliminated any linear accelerator deficit needed to meet SMFP Criterion 3 in Service Area 17 over the past five SMFPs. Scotland Memorial Hospital provides fewer advanced radiation therapy treatment options compared to FirstHealth. Scotland Memorial Hospital is not a reasonable alternative for the oncology patients treated at FMRH, which leaves FMRH as the only option to increase the number of linear accelerators that it operates.”

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

- The applicant provides reasonable information to explain why it believes it has no other alternative than to develop the proposed project.
- 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

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. FirstHealth of the Carolinas, Inc. (herein after “the 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 linear accelerator for a total of no more than three linear accelerators at FirstHealth Moore Regional Hospital.**
- 3. Upon project completion, FirstHealth Moore Regional Hospital will be licensed for no more than three linear accelerators.**
- 4. The certificate holder 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.**
- 5. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 6. 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.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on January 1, 2025.**

7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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

FirstHealth proposes to acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators at FMRH upon project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects the total capital cost of the project, as shown in the table below.

Site Preparation (Permits & Testing)	\$20,000
Construction/Renovation Contracts + Contingency	\$5,620,817
Architect/ Engineering Fees	\$130,000
Medical Equipment	\$3,537,638
FF&E*	\$62,500
Consultant Fee (CON Preparation and CON Fee)	\$69,000
Other	\$1,168,663
Total	\$10,608,618

*Furniture, fixtures, and equipment

The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Section Q, Form F.1a and Exhibits F.1., the applicant provides its assumptions and a quote for the linear accelerator.
- In Exhibit F.1, the applicant also provides a construction cost breakdown dated March 1, 2024, from Brasfield & Gorrie General Contractors.

In Section F, page 63, the applicant states that there are no projected start-up expenses or initial operating expenses because the project does not involve a new service. This information is reasonable and adequately supported because FMRH is an existing facility that currently offers LINAC services and is only proposing to add an additional LINAC.

Availability of Funds

In Section F, page 72, the applicant states the entire projected capital expenditure of \$10,608,618 will be funded through accumulated reserves of FirstHealth.

In Exhibit F.2, the applicant provides a letter dated April 12, 2024, from the CEO of FirstHealth of the Carolinas, Inc., stating that it plans to fund the development of the proposed project through assets limited as to use, internally designated by the Board.

Exhibit F.2 also contains financial statements for FirstHealth and affiliates for 2023 through September demonstrating that adequate funds are available.

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

- The applicant provides a letter from an appropriate FirstHealth official committing the accumulated reserves for developing the proposed project.
- The applicant provides financial statements to demonstrate that adequate funds are available for the proposed project.

Financial Feasibility

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

Revenues and Operating Expenses – FMRH Radiation Therapy			
	FY 1 (FFY 2027)	FY 2 (FFY 2028)	FY 3 (FFY 2029)
Total Patients	19,107	19,721	20,354
Total Gross Revenues (Charges)	\$70,803,450	\$75,269,036	\$80,016,268
Total Net Revenue	\$15,505,955	\$16,483,919	\$17,523,563
Total Net Revenue per Patient	\$812	\$836	\$861
Total Operating Expenses (Costs)	\$5,684,106	\$5,837,983	\$5,997,082
Total Operating Expenses per Patient	\$297	296	\$295
Net Profit/(Loss)	\$9,821,850	\$10,645,936	\$11,526,481

The assumptions used by the applicant in preparation of the pro forma financial statements are provided at the end of Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant clearly details the sources of data used to project revenues and expenses.
- The applicant bases projections on its own historical experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (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

FirstHealth proposes to acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators at FMRH upon project completion.

The applicant proposes to acquire one LINAC pursuant to the need determination in the 2024 SMFP to be located at FirstHealth Moore Regional Hospital in Pinehurst, Moore County. In Chapter 15, page 315, the 2024 SMFP states, “A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.” In Table 15C-4, page 324 of the 2024 SMFP, Moore County is included in Linear Accelerator Service Area 17. Linear Accelerator Service Area 17 includes Hoke, Lee, Montgomery, Moore, Richmond, and Scotland counties. Thus, the service area for this project consists of those six counties. Facilities may also serve residents of counties not included in their service area. There are three LINACs in Linear Accelerator Service Area 17. The following table identifies the provider, number of linear accelerators, and average utilization of each of the LINACs in FFY2022, as summarized from Table 15C-1, page 319 of the 2024 SMFP.

Provider	# of LINACs	County	Total Procedures	Average ESTV* per LINAC
FH Moore Regional Hospital	2	Moore	17,364	8,682
Scotland Memorial Hospital	1	Scotland	2,991	2,991

*The 2024 SMFP equates ESTV’s with procedures in Table 15C-1.

In Section G, page 82, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Linear Accelerator Service Area 17. The applicant states:

“Linear Accelerator Service Area 17 has two radiation therapy providers that operate three linear accelerators. Based on the ESTV procedures calculated from the treatments reported in the 2024 SMFP, FMRH needs a third linear accelerator, as the following table

highlights. FMRH is a Comprehensive Cancer Center and requires the additional capacity for advanced radiation therapy services.”

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:

- There is an adjusted need determination in the 2024 SMFP for the proposed linear accelerator in Linear Accelerator Service Area 17, that can only be approved for a cancer center.
- The applicant adequately demonstrates that the proposed linear accelerator is needed in addition to the existing or approved linear accelerators in Linear Accelerator Service Area 17.

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.

- (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

FirstHealth proposes to acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators at FMRH upon project completion.

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

Position	Projected FTE Staff			
	Current Staff as of 3/15/2024	1 st FFY	2 nd FFY	3 rd FFY
Management	1.8	1.80	1.80	1.80
Secretary	2.7	2.73	2.73	2.73
Oncology Nurse	3.3	5.00	5.00	5.00
Physician Assistant	0.7	1.00	1.00	1.00
Radiation Therapist	12.0	19.50	19.50	19.50
Total	20.5	30.03	30.03	30.03

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form 3.b. In Sections H.2 and H.3, pages 84-85, the applicant describes the methods used to recruit or fill new positions and 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:

- Projected staffing is based on historical staffing at the existing facility.
- The applicant provides documentation of its methods to recruit, train and retain staff in Section H of the application.

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

FirstHealth proposes to acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators at FMRH upon project completion.

Ancillary and Support Services

In Section I.1, pages 88-89, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 88-89, the applicant explains how each ancillary and support service is or will be made 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 FirstHealth Moore Regional Hospital is an existing facility that offers radiation oncology services including currently providing all the identified ancillary and support services.

Coordination

In Section I.2, page 89, 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 since FirstHealth Moore Regional Hospital is an existing radiation oncology provider with extensive working relationships with area healthcare providers and social service providers.

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.

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

NA

- (11) Repealed effective July 1, 1987.

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

C

FirstHealth proposes to acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators at FMRH upon project completion.

In Section K, page 92, the applicant states that the project involves constructing 3,500 square feet of new space and renovating 500 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 95, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant states,

“The project architect reviewed the necessary construction/renovations, and the general contractor has estimated project construction/renovation costs to total \$5.6 million.”

On page 93, 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,

“FirstHealth proposes to construct approximately 3,500 [sic] SF and renovate 500 SF. Exhibit F.1 includes a cost estimate from the project architect that estimates construction/renovation costs for the 4,000 SF to be \$5.6 million, which is consistent with Form F.1a Capital Costs in Section Q of the CON application. Based on the expertise of the project architect, the proposed construction/renovations are needed in relation to the addition of a third linear accelerator.”

On page 93, the applicant adequately explains any applicable energy saving features that will be incorporated into the construction/ renovation plans. The applicant states,

*“FirstHealth is committed to the environmental responsibility for its team members, patients, visitors, and the communities it serves...
If the CON is granted, FirstHealth will submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of DHSR.”*

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 98, the applicant provides the historical payor mix during the last full fiscal year (10/1/2022 to 9/30/2023) for FMRH, as shown in the table below.

Payor Category	Percent of Total Served
Self-Pay	2.8%
Charity Care	
Medicare*	50.3%
Medicaid*	14.8%
Insurance*	26.5%
Other (Governmental)	5.6%
Total	100.0%

Source: Table on page 98 of the application.

*Including any managed care plans.

In Section L, page 99, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY (10/1/2022 to 9/30/2023)	Percentage of the Population of the Service Area
Female	50.4%	51.1%
Male	49.6%	48.9%
Unknown	N/A	0.0%
64 and Younger	27.8%	76.1%
65 and Older	72.2%	23.9%
American Indian	2.6%	1.2%
Asian	0.1%	1.8%
Black or African American	21.8%	11.1%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	72.3%	77.0%
Other Race	2.1%	8.7%
Declined / Unavailable	0.2%	0.0%

Source: United States Census Bureau's QuickFacts

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 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 100, the applicant states it has no obligation.

In Section L, page 100, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

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 101, the applicant projects the following payor mix for FirstHealth Moore Regional Hospital's radiation oncology services during the third full fiscal year of operation following completion of the project, as shown in the table below.

FMRH Radiation Oncology Services	
Payor Category	Percent of Total Patients Served
Self-Pay	1.2%
Medicare*	68.9%
Medicaid*	5.3%
Insurance*	17.8%
Other (Governmental)	6.8%
Total	100.0%

Source: Table on page 101 of the application.

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.2% of total radiation oncology services will be provided to self-pay patients, 68.9% to Medicare patients and 5.3% to Medicaid patients.

On page 101, the applicant provides the assumptions and methodology 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 its historical payor mix for linear accelerator treatments for FY2022.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reason stated 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.5, page 102, the applicant adequately describes the range of means by which patients will have access to 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.

- (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

FirstHealth proposes to acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators at FMRH upon project completion.

In Section M, page 104, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- FirstHealth maintains ongoing relationships with area schools and training programs to support clinical training needs.
- In Exhibit M.1, the applicant includes a list of training programs it has agreements with.

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

FirstHealth proposes to acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators at FMRH upon project completion.

In Chapter 15, page 315, the 2024 SMFP states, “A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.” In Table 15C-4, page 324 of the 2024 SMFP, Moore County is included in Linear Accelerator Service Area 17. Linear Accelerator Service Area 17 includes Hoke, Lee, Montgomery, Moore, Richmond, and Scotland counties. Thus, the service area for this project consists of those six counties. Facilities may also serve residents of counties not included in their service area. There are three LINACs in Linear Accelerator Service Area 17. The following table identifies the provider, number of linear accelerators, and average utilization of each of the LINACs in FFY2022, as summarized from Table 15C-1, page 319 of the 2024 SMFP.

Provider	# of LINAC’s	County	Total Procedures	Average ESTV* per LINAC
FH Moore Regional Hospital	2	Moore	17,364	8,682
Scotland Memorial Hospital	1	Scotland	2,991	2,991

*The 2024 SMFP equates ESTVs with procedures in Table 15C-1.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 107, the applicant states:

“FirstHealth expects the development of the third linear accelerator to have a positive or at least neutral effect on competition in the service area because the linear accelerator will be located at FMRH, which is the only comprehensive cancer center in Service Area 17 and the only hospital in the service area that offers advanced radiation therapy. As one of the busiest radiation therapy programs in North Carolina, as measured by ESTVs per linear accelerator, FirstHealth requires additional linear accelerator capacity in order to treat patients in a timely manner during an extremely challenging time.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 106, the applicant states:

“To make the project operational, FirstHealth will purchase the Varian TrueBeam linear accelerator through an agreement with Varian, which it has a long-term relationship.”

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

Regarding the impact of the proposal on quality, in Section N, page 106, the applicant states:

“FirstHealth is committed to carrying out its QualityFirst Plan. The objective is to make certain a mechanism is in place, which ensures the occurrence of ongoing evaluation of various aspects of FMRH’s operation, both clinical and non-clinical. The program provides a methodology to monitor, analyze, and improve performance. Quality care at the organization is... based on the tenets that care is patient-centered, safe, timely, effective, efficient, and equitable.”

See also Sections B and O the application and exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 107, the applicant states:

“FirstHealth addresses the barriers to access in its daily operation. FirstHealth does not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay.”

See also Sections B, C, and L of the application and 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 based on 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

FirstHealth proposes to acquire no more than one linear accelerator pursuant to the 2024 SMFP need determination for a total of no more three linear accelerators at FMRH upon project completion.

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 four of this type of facility located in North Carolina. In Section O, page 111, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care resulting in a finding of immediate jeopardy did not occur in any of its hospitals. 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, incidents related to quality of care did not occur in any of these facilities. 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 four of the applicant's 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.

C

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

SECTION .1900 - CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT 10A NCAC 14C .1903 PERFORMANCE STANDARDS

An applicant proposing to acquire a LINAC pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;
- C- The applicant owns two existing LINACS located on the main campus of FirstHealth Moore Regional Hospital on Memorial Drive in Pinehurst.
- (2) identify the approved LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;
- NA- The applicant and related entities do not have any approved, but non-operational, LINACs in Linear Accelerator Service Area 17. Therefore, this Rule is not applicable to this review.
- (3) provide projected utilization of the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC during each of the first three full fiscal years of operation following completion of the project;
- C- In Section Q, Form C. 2b, the applicant provided projected utilization of its existing LINACs and proposed LINAC during each of the first three full fiscal years of operation following completion of the project as follows:

	1st FFY 2027	2nd FFY 2028	3rd FFY 2029
# of LINACs	3	3	3
Total ESTVs	19,107	19,721	20,354

- (4) provide the assumptions and methodology used for the projected utilization required by Item (3) of this Rule;
- C- The applicant provided the assumptions and methodology used for the projected utilization required by Item (3) of this Rule in Section Q, following Form C.2b.
- (5) project that the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC shall perform during the third full fiscal year of operation following completion of the project either:
 - (a) 6,750 or more ESTVs per LINAC; or

(b) serve 250 or more patients per LINAC.

- C- In Section Q, the applicant projected that each of the existing LINACs identified in Item (1) of this Rule and the proposed LINAC shall perform 6,785 ESTVs per LINAC (20,354 ESTVs/3 LINACs = 6,785 ESTVs) during the third full fiscal year of operation following completion of this project which exceeds the requirement to perform 6,750 or more ESTVs per LINAC during the third full fiscal year of operation as required by this Rule.