

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 28, 2025

Findings Date: April 4, 2025

Project Analyst: Crystal Kearney

Co-Signer: Micheala Mitchell

Project ID #: G-12566-24

Facility: Wesley Long Hospital

FID #: 933540

County: Guilford

Applicant(s): The Moses H. Cone Memorial Hospital

The Moses H. Cone Memorial Hospital Operating Corporation

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

The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation (hereinafter referred to as “Cone Health” or “the applicant”) proposes to replace an existing linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”), its existing cancer treatment facility upon project completion.

The applicant does not propose to acquire any medical equipment for which there is a need determination in the 2024 State Medical Facilities Plan (SMFP) and does not propose to offer

a new institutional health service for which there are any applicable policies in the 2024 SMFP. Therefore, Criterion (1) is not applicable to this review.

Policies

There is one policy in the 2024 SMFP which is applicable to this review. *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, page 27, the applicant describes the project’s plan to improve energy efficiency and conserve water.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 develop any beds or services or acquire any medical equipment for which there is a need determination in the 2024 SMFP.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant states it will conform to the energy efficiency and water conservation rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation and required by North Carolina State Building Code.
- (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 linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”).

Patient Origin

In Chapter 15, page 315, the 2024 SMFP defines a linear accelerator’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 15C-1 on page 319 shows Guilford and Rockingham counties in the Service Area 12 multicounty grouping. Thus, the service area for this project consists of Guilford and Rockingham Counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

Projected Patient Origin – Cone Health Cancer Center-Wesley Long Hospital								
Counties	Historical – FFY 2023		FY 1 – FFY 2026		FY 2 – FFY 2027		FY 3 – FFY 2028	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Guilford	1,209	73.5%	1,245	73.5%	1,258	73.5%	1,270	73.5%
Rockingham	199	12.1%	205	12.1%	207	12.1%	209	12.1%
Randolph	93	5.7%	97	5.7%	98	5.7%	98	5.7%
Other counties/states	143	8.8%	149	8.8%	151	8.8%	152	8.8%
Total	1,644	100.0%	1,694	100.0%	1,711	100.0%	1,728	100.0%

Source: Section C, pages 32-34

In Section C, pages 33-34, the applicant provides the assumptions and methodology used to project its patient origin. The applicant does not project changes from its historical patient origin. The applicant’s assumptions and methodology used to project patient origin are reasonable and adequately supported because they are based on the current patient origin for the same services already being offered and which will continue to be offered upon project completion.

Analysis of Need

In Section C, pages 35 and 37-43, the applicant explains the reasons why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below.

- The existing LINAC is more than 13 years old, while the average lifespan of a typical LINAC is 10 years of use. The proposed equipment is needed to continue to meet the demand for technologically advanced radiation procedures that can treat the growing number of cancer cases at Cone Health Center at Wesley Long. (page 35)
- Historical and projected service area population growth, especially for the 65+ age cohort that is most likely to use oncology services. The population in the service is projected to grow 3.0% over the next five (5) years. The 65+ age cohort is projected to experience strong growth with an 11.3% increase over five (5) years. (page 36)
- Growth in newly diagnosed cancer cases and utilization of cancer-related services. The applicant states that the combination of growth in the population and the aging of the population results in an increase in both the service area prevalence of cancer – the number of residents in the service area living with a cancer diagnosis- and the incidence of cancer – the number of new cancer patients diagnosed. (page 37)
- Growing demand for advanced capabilities in radiation therapy technologies to provide more precise and higher quality treatments. The applicant proposes that as cancer cases increases, utilization of cancer services, particularly for outpatient services, is projected to increase significantly. The applicant states that the more technologically advanced radiation therapy modalities provide more treatment options for patients with fewer side effects and decreased morbidity. (page 38)
- High utilization of existing linear accelerators and demand for advanced radiation therapy capabilities at Cone Health Cancer Center at Wesley Long. The applicant states that service area population growth, aging of the population, rising numbers of people diagnosed with cancer, and patient preference drive most of the increase in cases and procedures seen at CHCC-WL. (page 39)
- An existing linear accelerator that has reached the end of its useful life and is not as advanced in imaging capabilities for tumors and patient anatomy than what is currently available. The applicant states that the existing linear accelerator is no longer optimal for meeting the needs of a major cancer center due to the wear-and-tear that arises from the use of a linear accelerator for over 10 years, as well as outdated components. The applicant states that the downtime caused by maintenance concerns of an older linear accelerator would significantly limit Cone Health's ability to serve patient demand. (page 40)

The information is reasonable and adequately supported based on service area growth and demand for complex radiation therapy treatments, combined with increasing utilization of more advanced radiation therapy procedures at CHCC-WL and the technological limitations of the existing, outdated equipment demonstrate the need to replace an existing linear accelerator with a Varian Edge linear accelerator.

Projected Utilization

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

CHCC-WLH – LINAC Historical & Projected Utilization					
	Historical FFY 2023	FFY 2025 Interim FY	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
# Units*	4	4	4	4	4
# ESTV** Treatments	31,893	31,122	31,748	32,066	32,366

*Forms C.2a and C.2b list only one LINAC; however, CHCC-WLH has three existing LINACs.

**ESTV = Equivalent Simple Treatment Visits

In the Utilization Assumptions and Methodology subsection of Section Q, found immediately after Form C.2b, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Step 1: Projected Population Growth in the Service Area: The applicant states that the service area total population is projected to grow at a 0.6% compound growth rate over the next five years, The 65+ age group, which is most likely to utilize oncology health care services, is projected to grow 2.2% annually.

Table C-1 Projected Service Area Population 2024-20249					
Age Cohort	2024 Population	Projected 2029 Population	Projected # Change 2024-2029	Projected % Change 2024-2029	5-Year CAGR
0-17	128,572	129,217	645	0.5%	0.1%
18-44	241,921	249,147	7,226	3.0%	0.6%
45-64	157,603	155,996	-1,607	-1.0%	-0.2%
65+	116,498	129,640	13,142	11.3%	2.2%
Total	644,594	664,000	19,406	3.0%	0.6%

Source: NC OSBM, Section C, page 36

Table C-2 Cancer Incidence Rates Linear Accelerator Service Area 12 and North Carolina 2022	
Service Area County	Incidence Rate
Guilford	492.3
Rockingham	499.2
Total service area	495.8
Total NC	474.6

Source: North Carolina State Center for Health Statistics, Cancer Incidence Rates, 2018-2022, Section C, page 37

Step 2: Historical Growth in Service Area Cancer Cases The applicant states that the total number of new cancer cases in service area counties are estimated to have increased 1.8% annually from 2020 to 2024.

Table C-3 Number of New Cancer Cases Linear Accelerator Service Area 12 and North Carolina 2020-2024								
Service Area County	2020	2021	2022	2023	2024	#	%	CAGR
Guilford	3,138	3,204	3,266	3,283	3,390	252	8.0%	1.9%
Rockingham	649	655	661	671	679	39	4.6%	1.1%
Total Service Area	3,787	3,859	3,927	3,953	4,069	282	7.4%	1.8%
Total NC	64,274	65,730	65,706	67,357	70,040	5,766	9.0%	2.25%

Source: North Carolina Center for Health Statistics, Cancer Projections, 2020-2024, Section C, page 37

Step 3: Projected Demand for Radiation Therapy Treatment: The applicant states that the outpatient radiation therapy volumes in Service Area 12 are projected to increase 1.3% annually from 2023 to 2033. The modalities projected to experience the highest growth include more technologically advanced modalities, such as IMRT and SBRT which are projected to grow at a compound annual growth rate of 4.0% during the same time period.

Table C-4 Outpatient Oncology Volume Projections National and Linear Accelerator Service Area 12 2023-2033					
	National Projections			Service Area 12 Projections	
	10-Year Growth Rate	10-Year CAGR		10 -Year Growth Rate	10-Year CAGR
Total Outpatient Oncology	13.8%	1.3%		15.5%	1.5%
Radiation Therapy	12.7%	1.2%		14.2%	1.3%
Advanced Radiation Therapy (IMRT, SRS, SBRT)	45.9%	3.9%		48.4%	4.0%

Source: The Advisory Board Company, Market Scenario Planner, section C, page 38

Step 4: Cone Health Cancer Center Historical Radiation Therapy Utilization: Cone Health Cancer Center ESTV volumes increased 15.1%, or 4.8% annually, from FY2020 to FY2023. CHCC-WL linear accelerators are highly utilized, operating above 100% capacity since 2020.

Table C-5						
ESTV Utilization of CHCC-WL Linear Accelerators¹						
FY 2020- FY 2023						
ESTVs by Category	FY 2020	FY 2021	FY 2022	FY 2023	Change FY2020- FY 2023	
					#	%
Simple Treatment Delivery	8	9	8	12	4	50.0%
Intermediate Treatment Delivery	1	0	0	0	-1	-100.0%
Complex Treatment Delivery	15,825	15,728	16,420	16,910	1,085	6.9%
Conventional Radiation Therapy Subtotal	15,834	15,737	16,428	16,922	1,088	6.9%
IMRT	9,835	10,465	11,371	11,849	2,014	20.5%
Additional Field Check Radiographs	148	120	129	81	-67	-45.3%
SRS	58	57	59	57	-1	-1.7%
SBRT	598	695	809	970	372	62.2%
Total Procedures	26,473	27,074	28,796	29,879	3,406	12.9%
Total ESTVs²	27,711	28,509	30,468	31,893	4,182	15.1%
% Capacity³	102.6%	105.6%	112.8%	118.1%		

¹ Cone Health currently owns and operates four (4) linear accelerators at CHCC-WL

² Procedures converted to ESTVs per Table 15C-3 of the 2024 NC SMFP

³Capacity defined as 6,750 ESTVs per linear accelerator in 10A NCAC 14C.1903

Source: License Renewal Applications, Section C, page 39

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

- The applicant relies on its existing utilization to project future utilization.
- The applicant cites growth in the number of new cancer cases and demand for advanced radiation technology.
- The applicant states that the 65+ age cohort within the service area is expected to increase 11.3% in the next five years, and the risk of developing cancer is directly related to increased age.

Access to Medically Underserved Groups

In Section C, page 46, the applicant states:

Low-income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, Medicare and Medicaid patients, or other underserved persons, including the medical indigent, the uninsured and the underinsured in general, the health services of Cone Health are available to any patient in need without restriction of any kind.”

The 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	16.2%
Racial and ethnic minorities	41.4%
Women	57.55
Persons 65 and older	38.9%
Medicare beneficiaries	42.3%
Medicaid recipients	16.2%

Source: Section C, page 47

On page 47, the applicant states, “Cone Health does not maintain data that includes the number of persons with disabilities it serves, they are not denied access to the proposed services.”

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 provides a statement saying it will provide service to all residents of the service area and that the current level of access by medically underserved groups will not be altered by the proposed project.
- The applicant provides documentation of its existing policies regarding non-discrimination and charity care in Exhibits C.6.1 and C.6.2 .

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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.

C

The applicant proposes to replace an existing linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”).

In Section E, page 55, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo: The applicant states that by not replacing the equipment. The applicant states that this option has the benefit of eliminating the necessary capital cost. The applicant states that this option does not eliminate the efficiency and maintenance problems caused by a linear accelerator that is more than 13 years old. Therefore, this option was rejected.
- Purchase different equipment: The applicant states that considering purchasing a linear accelerator that did not have advanced capabilities, such as SRS or SBRT. The applicant states that this option may have resulted in lower capital costs. The applicant states that the growth for radiation therapy services is in the advanced modalities. The applicant states that CHCC-WL’s own volume trends show growth in the complex radiation treatment, IMRT, and SBRT types of treatment. Therefore, this option was rejected.

The applicant states that since neither of the above options were deemed superior, Cone Health elected to pursue the proposed project. The applicant states that by replacing an outdated linear accelerator with an advanced, Varian Edge linear accelerator, Cone Health will maintain state of the art radiation therapy services provided to patients at Cone Health Center at Wesley Long.

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 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

- Remarks made at the public hearing

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. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation (herein after “the certificate holder”) shall materially comply with all representations made in the certificate of need application.**
 - 2. The certificate holder shall replace an existing linear accelerator with a new linear accelerator.**
 - 3. Upon project completion, Cone Health Cancer Center - Wesley Long Hospital will be licensed for no more than four 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 October 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

The applicant proposes to replace an existing linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”).

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.

Capital Cost	Applicant 1 The Moses H. Cone Memorial Hospital	Applicant 2 The Moses H. Cone Memorial Hospital Operating Corporation	Total
Construction/Renovation Contract(s)	\$2,187,145		\$2,187,145
Architect/Engineering Fees	\$80,000		\$80,000
Medical Equipment	\$4,502,089		\$4,502,089
Non Medical Equipment	\$12,000		\$12,000
Furniture	\$1,600		\$1,600
Total	\$6,782,834	0	\$6,782,834

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

- In Exhibit F.1.1, the applicant provides a letter dated October 9, 2024, from an architectural firm which projects a total cost to develop the cancer center as \$ 6,782,834 which is the combined total cost listed above for construction/renovation contracts, architect/engineering fees, medical and non-medical equipment, and furniture.

In Section F, page 58, 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 Cone Health is replacing an existing, operational linear accelerator that is part of an existing, operational cancer center.

Availability of Funds

In Section F, page 60, the applicant states the entire projected capital expenditure of \$6,782,834 will be funded with The Moses H. Cone Memorial Hospital’s accumulated reserves.

In Exhibit F.2.1, the applicant provides a letter dated October 14, 2023, from the Chief Financial Officer for Cone Health, stating that Cone Health has sufficient accumulated reserves to fund the projected capital cost and committing to providing that funding to develop the proposed project.

Exhibit F.2.2 contains a copy of Cone Health’s Consolidated Financial Statements for the year ending September 30, 2022. According to the Consolidated Financial Statements, as of September 30, 2022, Cone Health had adequate cash and assets to fund all the capital needs of the proposed project.

In Exhibit F.2.2, the applicant provides the Long-Term Investments line item in Cone Health’s FY 2023 audited financial statements. The applicant states that the statements contain the consolidated financial statements for The Moses H. Cone Memorial Hospital and its subsidiaries, including but not limited to The Moses H. Cone Memorial Hospital Operating Corporation.

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 the appropriate Cone Health official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the 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 – CHCC-Wesley Long Radiation Oncology			
	FY 1 (FFY 2026)	FY 2 (FFY 2027)	FY 3 (FFY 2028)
Total Treatments	31,748	32,066	32,386
Total Gross Revenues (Charges)	\$156,384,142	\$164,265,902	\$172,544,904
Total Net Revenue	\$41,076,113	\$42,283,420	\$43,526,215
Total Net Revenue per Patient	\$1,294	\$1,319	\$1,344
Total Operating Expenses (Costs)	\$20,390,899	\$20,938,883	\$21,756,949
Total Operating Expenses per Patient	\$642	\$653	\$672
Net Income	\$20,685,214	\$21,344,537	\$21,769,266

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
- Remarks made at the public hearing

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

The applicant proposes to replace an existing linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”).

In Chapter 15, page 314, the 2025 SMFP defines a linear accelerator’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 15C-4 on page 323 shows Guilford and Rockingham County are in Service Area 12. Thus, the service area for this project consists of Guilford and Rockingham Counties. Facilities may also serve residents of counties not included in their service area.

Service Area 12 Existing and Approved Linear Accelerators			
Facility	# of Linear Accelerators	# of ESTVs	Capacity
Cone Health	4	31,893	118.1%
Atrium Health Wake Forest Baptist High Point Medical Center	2	9,723	72.0%
UNC Rockingham Healthcare	1	2,684	39.8%

Source: Proposed 2025 State Medical Facilities Plan

In Section G, page 64, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved linear accelerator services in Guilford County. The applicant states:

“The proposed project will not result in unnecessary duplication of services as the project is a replacement of an existing, operational linear accelerator that is at the end

of its functional life, with a newer, up-to-date linear accelerator. Because this project proposes replacement equipment for patients already seeking treatment at Cone Health Center at Wesley Long, no other provider can meet the need for this project.”

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 proposal would not result in an increase in the number of linear accelerators in Service Area 12.
- The applicant adequately demonstrates that the proposed replacement linear accelerator is needed in Service Area 12, and that the replacement will not be an unnecessary duplication of existing or approved linear accelerator services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”).

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

Cone Health Cancer Center at Wesley Long				
Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff	Projected FTE Staff
	8/31/2024	1 st Full FY	2 nd Full FY	3 rd Full FY
Financial and Administrative Support	8.9	10.0	10.0	10.0
Radiation Oncology Technician	2.0	2.0	2.1	2.1
Radiation Therapist	17.0	18.2	18.3	18.5
Certified Therapeutic Physical	4.4	4.4	4.4	4.4
Physicist Assistant	0.9	0.9	0.9	0.9
Dosimetrist	5.6	5.6	5.6	5.6
Software Engineer	1.0	2.0	2.0	2.0
Radiation Therapy Imaging Specialist	1.0	1.0	1.0	1.0
Clinical Services Manager	0.6	0.6	0.6	0.6
TOTAL	41.4	44.7	44.9	45.1

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in at the end of Section Q. 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 the methods used to recruit or fill new positions and its proposed training and continuing education programs. Supporting documentation is provided in Exhibits H.2 and H.3.

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

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.
- The applicant accounts for projected salaries and other costs of employment for FTEs in its projected operating expenses found on Form F.3b in Section Q.
- The applicant provides its policies related to staff training in Exhibit H.3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”).

Ancillary and Support Services

In Section I, page 69, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, page 69, the applicant explains how each ancillary and support service is 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 based on the following:

- The applicant is currently providing the necessary ancillary and support services for the same services it will continue to offer.
- In Exhibit I.1, the applicant provides a letter dated October 14, 2024, from the vice president of Oncology and Southern Region, Cone Health, attesting to the existence of the necessary ancillary and support services at the Radiation Oncology Department at Cone Health Cancer Center and committing to continue to provide the necessary ancillary and support services for the proposed project.

Coordination

In Section I, page 70, the applicant describes its existing 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 operates an existing facility that has established relationships in the community.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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

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 linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”).

In Section K, the applicant states that the project involves renovating 1,200 square feet of existing space. Line drawings showing the area to be renovated are provided in Exhibit K.2.

On page 73, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that Cone Health contracted CPL: Architecture, Engineering, Planning Firm to develop the preliminary renovation plans for the proposed project.
- The applicant states that CPL worked with Cone Health stakeholders, including construction management team members and radiation oncology management and staff to explore the most reasonable alternative for minor renovations to the existing vault, control rooms, and support space.
- The applicant states that the work of these experts led to the selection of the most reasonable alternative for the proposed project.

On page 74, 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 based on the following:

- The applicant states that the proposed project is financially feasible and will not negatively impact Cone Health's financial stability.
- The applicant states that the proposed project will not unduly increase the costs and charges to the public for the proposed services.

On page 74, 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
- Remarks made at the public hearing

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 the last full fiscal year at Wesley Long Hospital for the proposed services, as shown in the table below.

Wesley Long Hospital 10/01/2022 to 9/30/2023	
Payor Source	Percentage of Total Patients Served
Self-Pay	9.4%
Charity Care	0%
Medicare *	41.3%
Medicaid *	14.3%
Insurance *	31.6%
Workers Compensation	0%
TRICARE	0%
Other	3.4%
Total	100.0%

*Including any managed care plans
 Source: Table on page 76 of the application

In Section L, page 77, the applicant provides the following comparison.

Wesley Long Hospital	% of Total Patients Served During FFY 2022	% of Population of Service Area
Female	57.5%	52.6%
Male	42.5%	47.4%
Unknown	0%	0%
64 and Younger	61.1%	83.6%
65 and Older	38.9%	16.4%
American Indian	0.4%	0.8%
Asian	0.9%	5.7%
Black or African American	40.1%	36.3%
Native Hawaiian of Pacific Islander	0.1%	0.1%
White or Caucasian	52.6%	54.2%
Other Race	5.0%	2.8%
Decline/ Unavailable	1.0%	0%

Source: Table on page 77 of the application

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 78, the applicant states that no patient civil rights access complaints have been filed against Wesley Long Hospital during the 18 months immediately prior to submission 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.

- (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 services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Wesley Long Radiation Oncology	
Payor Source	% of Total Patients Served
Self-Pay	2.0%
Medicare*	57.2%
Medicaid*	4.1%
Insurance*	33.3%
Other	3.4%
Total	100.0%

Source: Table on page 79 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 2.0% of total services will be provided to self-pay patients, 57.2% to Medicare patients and 4.1% to Medicaid patients.

On page 79, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years 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 FY 2022.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 79, 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 linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”).

In Section M, page 82, 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:

- The applicant maintains ongoing relationships with area schools and training programs to support clinical training needs.
- On pages 82-83, the applicant includes a list of training programs it has agreement 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

The applicant proposes to replace an existing linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”).

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, Guilford County is included in Linear Accelerator Service Area 12. Linear Accelerator Service Area 12 includes Guilford and Rockingham counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

There are 7 LINACs in Linear Accelerator Service Area 12. 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
Cone Health	4	Guilford	30,468	7,617
High Point Medical Center	2	Guilford	9,977	4,988
UNC Rockingham Hospital	1	Rockingham	2,505	2,505

*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 84, the applicant states:

“The proposed project is not expected to have a significant impact on competition in the proposed service area.

...the proposed project will have positive impact on the cost effectiveness, quality and access to radiation therapy services, which will generally increase competition. With a demonstrated history of providing cost-effective, high-quality, and accessible care, Cone Health provides the best option for fostering competition for radiation therapy services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 84, the applicant states:

“The proposed project is cost effective because, as demonstrated in the proforma in Section Q, the replacement of an existing linear accelerator in its current location ensures that patients can continue to access the high quality, technologically up-to-date services without significant price increases. The proposed project is financially feasible.”

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

Regarding the impact of the proposal on quality, in Section N, page 84, the applicant states:

“Replacing the outdated linear accelerator with a technologically up-to-date piece of equipment ensures the quality of care for patients continues.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 84, the applicant states:

“Cone Health has a longstanding, demonstrated commitment to the underserved residents of its communities. As demonstrated in Section L of this application, Cone Health expects to provide 61.3% of linear accelerator services to Medicare and Medicaid recipients and 2.0% to self-pay patients in the third year of operation.”

See also Section B, 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

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

The applicant proposes to replace an existing linear accelerator (LINAC) at Cone Health Cancer Center at Wesley Long (“CHCC-WL”).

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 of this type of facility located in North Carolina.

In Section O, page 88, 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.

NA

The applicant proposes to replace an existing linear accelerator (LINAC) at Wesley Long Hospital.

The Criteria and Standards for Radiation Therapy Equipment, promulgated in 10A NCAC 14C .1900, are not applicable to this review because the applicant does not propose to acquire a linear accelerator pursuant to a need determination.