

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 23, 2019

Findings Date: August 23, 2019

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: G-11719-19

Facility: Wesley Long Community Hospital, Inc.

FID #: 953540

County: Guilford

Applicant: The Moses H. Cone Memorial Hospital

The Moses H. Cone Memorial Hospital Operating Corporation

Project: Replace one existing linear accelerator

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N. C. Gen. Stat. § 131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation, collectively referred to as Cone Health or “the applicant”, proposes to replace one existing linear accelerator located at the Cone Health Cancer Center at Wesley Long (CHCC-WL). CHCC-WL is located on Cone Health’s Wesley Long Hospital campus. The applicant currently owns and operates four linear accelerators at CHCC-WL.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations that are applicable to this review.

Policies

There is one policy in the 2019 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4 on page 31 of the 2019 SMFP states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.11, page 19, the applicant explains why it believes its application is consistent with Policy GEN-4. The applicant states that Cone Health is committed to assuring improved energy efficiency and water conservation in its construction projects. The applicant lists several examples of strategies it may use for energy conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The applicant does not propose to develop any beds, services or equipment for which there is a need determination in the 2019 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4.

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to replace one existing linear accelerator located at CHCC-WL, on Cone Health's Wesley Long Hospital campus.

Per Cone Health's 2019 License Renewal Application (LRA), The Moses H. Cone Memorial Hospital Operating Corporation, a wholly owned subsidiary of The Moses H. Cone Memorial Hospital, is licensed to operate the hospital known as Cone Health, License #H0159. Cone Health, License #H0159, consists of five campuses and seven entities doing business as "facilities." The five campuses and seven facilities are:

- The Moses H. Cone Memorial Hospital and Moses Cone Surgery Center;
- Wesley Long Hospital and Wesley Long Surgery Center;
- MedCenter High Point (freestanding ED and Ambulatory Care Center)
- Women's Hospital; and

- The Behavioral Health Hospital.

In addition, there are other facilities that are part of Cone Health, but under individual licenses.

Cone Health owns and operates four linear accelerators at CHCC-WL on the Wesley Long Hospital campus at 2400 W. Friendly Avenue in Greensboro. Cone Health also owns and operates two linear accelerators at Cone Health Cancer Center at Alamance Regional at 1240 Huffman Mill Road in Burlington. In addition, Cone Health is a joint venture partner along with Randolph Hospital in Randolph Cancer Center, which owns and operates one linear accelerator at 364 White Oak Street in Asheboro.

The applicant proposes to replace the existing TomoTherapy Hi Art, Serial #286 linear accelerator in CHCC-WL's Vault #4 with a new Varian TrueBeam linear accelerator. The existing linear accelerator was acquired pursuant to CON Project ID #G-8209-08 and has been in continuous operation since October 2009.

Patient Origin

In Chapter 9, page 127, the 2019 SMFP states, "*A linear accelerator's service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.*" CHCC-WL is located in Guilford County. In Table 9I, page 136 of the 2019 SMFP, Guilford County is included in Linear Accelerator Service Area 12, along with Rockingham County. Providers may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 30-32, the applicant refers to Exhibit C.2 for the historical patient origin and Exhibit C.3 for the projected patient origin for the first three full fiscal years (FY) following project completion. Exhibit C.2, page 128, provides the historical FY2018 patient origin for radiation oncology, as summarized below.

**CHCC-WL Historical Radiation Oncology
 Patient Origin**

COUNTY/STATE	FY2018 (10/1/17 – 9/30/18)	
	# PATIENTS	% OF TOTAL
Guilford	3,466	75.0%
Rockingham	455	9.9%
Randolph	269	5.8%
Alamance	91	2.0%
Forsyth	82	1.8%
Virginia	79	1.7%
Caswell	51	1.1%
Other*	126	2.7%
Total	4,619	100%

*Other includes 17 NC counties and five other states, each of which represent less than one percent of patient origin
 Source: Cone Health Financial Systems

Exhibit C.2 also provides the historical FY2018 patient origin for the Wesley Long Hospital, which is comparable to the patient percentage by county of the radiation oncology service in the table above.

Exhibit C.3, page 130, provides the projected patient origin for CHCC-WL’s radiation oncology in the first three full fiscal years following project completion, as summarized below.

**Projected Patient Origin
 CCHC-WL Radiation Oncology**

County	1 st Full FY 10/1/20 – 9/30/21		2 nd Full FY 10/1/21 – 9/30/22		3 rd Full FY 10/1/22 – 9/30/23	
	# Pts	% of Total	# Pts	% of Total	# Pts	% of Total
Guilford	3,496	75.0%	3,527	75.0%	3,527	75.0%
Rockingham	461	9.9%	466	9.9%	466	9.9%
Randolph	270	5.8%	273	5.8%	273	5.8%
Alamance	93	2.0%	94	2.0%	94	2.0%
Forsyth	84	1.8%	85	1.8%	85	1.8%
Virginia	79	1.7%	80	1.7%	80	1.7%
Caswell	51	1.1%	52	1.1%	52	1.1%
Other*	126	2.7%	127	2.7%	127	2.7%
Total	4,661	100.0%	4,703	100.0%	4,745[4,703]	100.0%

*Other includes 17 NC counties and five other states, each of which represent less than one percent of patient origin
 Source: Cone Health Financial Systems
 Totals may not sum due to rounding

However, it appears there is an error in the information provided for the third project year. The number of patients by county provided is the same as the second year, but the total provided is 42 patients greater. In supplemental information requested by the Agency in the expedited review of this project, the applicant provides the following updated information for FY2023.

**Projected Patient Origin
 CCHC-WL Radiation Oncology**

County	1 st Full FY 10/1/20 – 9/30/21		2 nd Full FY 10/1/21 – 9/30/22		3 rd Full FY 10/1/22 – 9/30/23	
	# Pts	% of Total	# Pts	% of Total	# Pts	% of Total
Guilford	3,496	75.0%	3,527	75.0%	3,559	75.0%
Rockingham	461	9.9%	466	9.9%	470	9.9%
Randolph	270	5.8%	273	5.8%	275	5.8%
Alamance	93	2.0%	94	2.0%	95	2.0%
Forsyth	84	1.8%	85	1.8%	85	1.8%
Virginia	79	1.7%	80	1.7%	81	1.7%
Caswell	51	1.1%	52	1.1%	52	1.1%
Other*	126	2.7%	127	2.7%	128	2.7%
Total	4,661	100.0%	4,703	100.0%	4,745	100.0%

*Other includes 17 NC counties and five other states, each of which represent less than one percent of patient origin

Source: Supplemental information requested by Agency - Cone Health Financial Systems
 Totals may not sum due to rounding

In Section C.3(c), page 32, the applicant refers to Exhibit C.3 for assumptions and methodology used to project the number of patients by county of origin. Exhibit C.3 provides the table of projected patient origin; however, it does not address the assumptions or methodology for projecting patient origin. In supplemental information requested by the Agency in the expedited review of this project, the applicant states:

“Cone Health does not project any changes to patient origin as a result of this project as it is solely for replacement of existing equipment; therefore, patient origin for the Radiation Oncology Department is expected to remain consistent with actual patient origin in FY 2018.”

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 32-45, the applicant explains why it believes the population projected to utilize the proposed linear accelerator service needs that service. On page 32, the applicant states:

“The proposed equipment is needed to meet the demand for technologically advanced radiation therapy procedures that can treat the growing number of

cancer cases at Cone Health Cancer Center at Wesley Long. The existing unit to be replaced is outdated and has reached the end of its useful life.”

On page 33, the applicant states that the need the patients have for the proposed project results from the following main factors:

- Historical and projected service area population growth, especially for the 65+ age cohort that is most likely to use oncology services (pages 33-35).
- Growth in newly diagnosed service area cancer cases and utilization of cancer-related services (pages 35-37).
- Growing demand for advanced capabilities and improved patient safety to provide more precise and higher quality treatments (pages 37-39).
- High utilization of existing linear accelerators and demand for advanced radiation therapy capacities at CHCC at Wesley Long (pages 40-41).
- Inadequacies and technical deficiencies of the existing outdated equipment to be replaced (pages 41-45).

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

- The service area population 65+ age cohort is projected to grow 18.5% between 2018 and 2023.
- The incidence rate for developing invasive cancer increases significantly with age, with over half of all new cancer cases being diagnosed in patients over 65.
- The number of new cancer cases in Linear Accelerator Service Area 12 is projected to increase over 6%, or an average of 1.5% annually from 2015 to 2019.
- Radiation therapy is projected to grow nearly 17%, or an average of 1.7% annually, from 2018 to 2028, with the most striking growth in the newer, advanced modalities, such as stereotactic body radiation therapy (SBRT) and intensity-modulated radiation therapy (IMRT).
- Table C-5, page 40, shows CHCC-WL has operated near or above 100% capacity for the last five years, with the most noticeable growth in procedures in the more advanced modalities, such as SBRT and IMRT.
- The existing Accuray TomoTherapy S/N 286 can no longer meet the contemporary requirements of a linear accelerator operating in a major cancer center; the unit experiences efficiency and quality issues associated with outdated older units.

Projected Utilization

In Section Q, Form C, page 104, the applicant provides a table showing the historical and projected utilization for the CHCC-WL linear accelerators through the first three full fiscal

years following completion of the project, FY2021 - FY2023, which is summarized as follows:

**CHCC-WL
 HISTORICAL AND PROJECTED
 RADIATION THERAPY TREATMENTS
 FFY 2018– FFY 2023**

	LAST FULL FY FY2018	INTERIM FY2019	INTERIM FY2020	1 ST FULL FY FY2021	2 ND FULL FY FY2022	3 RD FULL FY FY2023
# of Linacs	4	4	4	4	4	4
# of ESTV Treatments	29,379	29,279	29,279	29,543	29,808	30,077

* FY2019 data is annualized based on six months actual data (page 40)

In Section Q, pages 107-108, the applicant provides its assumptions and methodology for projecting utilization of the existing linear accelerators and the proposed replacement linear accelerator. The applicant projects flat ESTV volumes for FY2020 and an annual growth rate of 0.9% for ESTV volumes for FY2021-FY2023, based on the following assumptions:

- Service area total population is projected to grow 0.9% annually over the next five years, with the 65+ age group, projected to grow 3.4% annually,
- Total new cancer cases in the service area counties increased 1.5% annually from 2015-2019,
- Outpatient radiation therapy volumes are projected to increase 1.7% annually from 2018-2028,
- CHCC-WL ESTV volumes increased 14.2%, or 4.2% annually, from FY2015-FY2019 (annualized),
- The inability to serve a significant increase in patients without additional, incremental capacity, and
- Replacing a linac in FY2019-FY2020 will temporarily reduce capacity during construction and installation.

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

- Projected utilization is based on the applicant’s historical experience with the existing linear accelerators at CHCC-WL.
- The applicant uses the 0.9% growth rate of the total population for projecting growth in ESTV treatments, which is conservative as compared to the growth rates of the 65+ population, total new cancer cases, outpatient radiation therapy volumes, and CHCC-WL ESTV historical volume increases.
- The projections allow for expected limited capacity during construction and installation for the replacement linear accelerator.

Access

In Section C, page 51, the applicant states:

“Cone Health does not discriminate against low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent, the uninsured and the underinsured.”

In Section L.3, page 88, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table:

Projected Payor Mix, FY2022

PAYOR CATEGORY	WESLEY LONG HOSPITAL SERVICES AS % OF TOTAL	RADIATION ONCOLOGY SERVICES AS % OF TOTAL
Self-Pay	5.3%	2.1%
Charity Care	NA	NA
Medicare	60.5%	57.9%
Medicaid	8.3%	5.4%
Insurance	24.1%	33.3%
Workers Compensation	0.4%	0.1%
TRICARE	0.7%	0.0%
Other (Specify)	0.8%	1.2%
Total	100.0%	100.0%

Totals may not sum due to rounding

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- supplemental information requested by the Agency, and
- Information which was publicly available during the review and used by the Agency.

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the replacement linear accelerator proposed in this application.
- Projected utilization is reasonable and adequately supported.

The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce or eliminate a service or relocate a health service facility or health service. The applicant proposes to replace an existing linear accelerator. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to replace one existing linear accelerator located at CHCC-WL on the Wesley Long Hospital campus.

In Section E, pages 61-62, 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, and
- acquire a linear accelerator that does not have advanced capabilities.

On page 61, the applicant states that maintaining the status quo does not improve the scope and quality of radiation therapy services at CHCC-WL or eliminate the efficiency and quality issues caused by an older linear accelerator. The applicant further states that purchasing a linac without advanced capabilities would result in lower capital costs but would not meet CHCC-WL's need to provide additional capacity in complex radiation treatment. For these reasons these two alternatives were rejected as less effective alternatives.

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

- The applicant demonstrates the existing linear accelerator at CHCC-WL is outdated, has outlived its useful life, and needs replacing to provide additional capacity at CHCC-WL.
- The applicant demonstrates that CHCC-WL needs additional capacity that allows the provision of complex radiation treatment, IMRT, and SBRT types of treatment.
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- application,
- supplemental information requested by the Agency, and
- 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. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall materially comply with the last made representation.**
- 2. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall acquire no more than one linear accelerator to replace one existing linear accelerator located on the Wesley Long Hospital campus. The applicant shall dispose of the existing linear accelerator being replaced by removing it from North Carolina.**
- 3. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 4. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall submit, on the form**

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

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

5. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to replace one existing linear accelerator located at CHCC-WL on the Wesley Long Hospital campus.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 109, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	COST
Construction / Renovation Contract/ Site Prep	\$ 510,000
Architect / Engineering Fees	\$ 102,000
Medical Equipment	\$ 3,900,000
Non-Medical Equipment	\$ 25,000
Other (Project Contingency)	\$ 61,200
Total	\$ 4,598,200

In Section F.3, page 66, the applicant states that there are no start-up or initial operating expenses, as this is not a new service.

In Section Q, the applicant provides the assumptions used to project the capital cost. Exhibits C.4 and F.1 contain supporting documentation.

Availability of Funds

In Section F, page 64, the applicant states that the capital cost will be funded as shown in the table below.

SOURCES OF CAPITAL COST FINANCING	
TYPE	TOTAL
Loans	
Accumulated reserves or OE *	\$4,598,200
Bonds	
Other (Specify)	
Total Financing	\$4,598,200

* OE = Owner's Equity

In Exhibit F.2-1, the applicant provides a June 13, 2019 letter from Cone Health's Chief Financial Officer that confirms the availability of the funds and the commitment of the funds to the project. The applicant also provides The Moses H. Cone Memorial Hospital and Affiliates' consolidated financial statements from FY2018 in Exhibit F.2-2.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, page 114, the applicant projects that revenues will exceed operating expenses for the radiation oncology department in the first three operating years of the project, as shown in the table below.

	1ST FULL FY FY2021	2ND FULL FY FY2022	3RD FULL FY FY2023
Total ESTV Treatments (Txt)	29,543	29,808	30,077
Total Gross Revenues (Charges)	\$73,979,405	\$77,631,029	\$81,462,896
Total Net Revenue	\$28,544,683	\$29,354,575	\$30,187,447
Average Net Revenue per ESTV Txt	\$966	\$985	\$1,004
Total Operating Expenses (Costs)	\$14,316,799	\$14,743,993	\$15,190,934
Average Operating Expense per ESTV Txt	\$485	\$495	\$505
Net Income	\$14,227,884	\$14,610,582	\$14,996,513

Totals may not sum due to rounding

Form F.2, page 110, for The Moses H. Cone Memorial Hospital system also shows revenues exceed expenses in each of the first three full fiscal years following completion of the project.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to replace one existing linear accelerator located at CHCC-WL on the Wesley Long Hospital campus.

In Chapter 9, page 127, the 2019 SMFP states, “A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.” CHCC-WL is located in Guilford County. In Table 9I, page 136 of the 2019 SMFP, Guilford County is included in Linear Accelerator Service Area 12, along with Rockingham County. Providers may serve residents of counties not included in their service area.

There are seven existing linear accelerators in Linear Accelerator Service Area 12. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators, as summarized from Table 9G, page 131 of the 2019 SMFP.

	# LINEAR ACCELERATORS	TOTAL PROCEDURES*	AVERAGE ESTV* PER LINEAR ACCELERATOR
Cone Health	4	27,175	6,794
High Point Regional Health	2	12,658	6,329
UNC Rockingham Health Care	1	4,614	4,614

*The 2019 SMFP equates Equivalent Simple Treatment Visits (ESTVs) with procedures in Table 9G.

The applicant proposes to replace one existing linear accelerator located at Cone Health's Wesley Long campus; therefore, the applicant does not propose to increase the inventory of linear accelerators in the service area.

In Section G, page 71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved linear accelerator services in linear accelerator service Area 12. 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 with a newer, more advanced linear accelerator. Because this project proposes replacement equipment for patients already seeking treatment at Cone Health Cancer 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 for the following reasons:

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- supplemental information requested by the Agency, and
- Information which was publicly available during the review and used by the Agency.

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section Q, Form H, page 116, the applicant provides the historical and projected staffing by full-time equivalent (FTE) position for CHCC-WL radiation therapy services, as summarized below.

Staffing – CHCC-WL Radiation Therapy Services

POSITION	CURRENT AS OF APRIL 30, 2019	PROJECTED		
		1 ST FULL FY FY2021	2 ND FULL FY FY2022	3 RD FULL FY FY2023
Administrative Assistant	1.00	1.00	1.00	1.00
Medical Secretary	5.00	5.00	5.00	5.00
Financial and Administrative Support Specialist	2.00	2.00	2.00	2.00
Radiation Oncology Tech II	2.02	2.04	2.06	2.08
Radiation Therapist	18.28	18.44	18.61	18.78
Physicist Assistant	1.00	1.00	1.00	1.00
Dosimetrist	4.83	4.87	4.91	4.96
Certified Therapeutic Physicists	5.00	5.00	5.00	5.00
Radiation Therapy Imaging Specialist	1.00	1.00	1.00	1.00
TOTAL	40.13	40.35	40.58	40.81

As can be seen in the table above, projected staffing FTE positions are comparable to the current positions. In Section Q, Form H, pages 116-118, the applicant provides its staffing-related assumptions. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.2, which is found in Section Q. In Section H, pages 73-74, 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.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 75, the applicant states that the following ancillary and support services are necessary to provide radiation therapy services:

- physics
- dosimetry
- laboratory
- pharmacy
- scheduling/registration
- billing
- medical records
- radiology
- social work
- pastoral care
- environmental services

On page 75, the applicant adequately explains that each ancillary and support service is already available at CHCC-WL and provides supporting documentation in Exhibit I-1.

In Section I, pages 75-76, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-3.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The proposed project does not involve any new construction. In Section K, page 81, the applicant states that the project involves renovating 1,375 square feet of existing space to install the replacement linear accelerator in the same space as the existing unit (Vault 4). Line drawings are provided in Exhibit K-2.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such

as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.1(b), page 87, the applicant provides the following payor mix for Wesley Long Hospital and the radiation oncology department for FY 2018 (10/1/17 – 9/30/18):

CHCC-WL Historical Payor Mix, FY2018

PAYOR CATEGORY	WESLEY LONG SERVICES AS % OF TOTAL	RADIATION ONCOLOGY SERVICES AS % OF TOTAL
Self-Pay	5.3%	2.1%
Charity Care	NA	NA
Medicare	60.5%	57.9%
Medicaid	8.3%	5.4%
Insurance	24.1%	33.3%
Workers Compensation	0.4%	0.1%
TRICARE	0.7%	0.0%
Other (Specify)	0.8%	1.2%
Total	100.0%	100.0%

*Other includes hospice, automobile indemnity and other unclassified payors

As shown in the table above, the applicant states that 5.4% of its radiation oncology services were reimbursed by Medicaid and 57.9% were reimbursed by Medicare in FY2018.

In Section L.1, page 86, the applicant provides the following comparison.

Patients Served During Last Full Fiscal Year

	% OF TOTAL PATIENTS SERVED BY WESLEY LONG	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	57.3%	52.3%
Male	42.7%	47.7%
Unknown	0.0%	0.0%
64 and Younger	69.0%	84.2%
65 and Older	31.0%	15.8%
American Indian	0.3%	0.5%
Asian	0.8%	4.25%
Black or African-American	41.7%	31.5%
Native Hawaiian or Pacific Islander	>0.1%	Included in Asian
White or Caucasian	52.6%	57.1%
Other Race	2.8%	6.6%
Declined / Unavailable	0.8%	0.0%

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 87, the applicant states it is not under an obligation to provide uncompensated care. The applicant further states that Cone Health is dedicated to providing care for all in its community regardless of ability to pay.

In Section L, page 88, the applicant states that during the last five years Cone Health has had one patient civil rights access complaint filed against the facility. The applicant lists no other complaints filed against any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- application, and
- 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 88, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Projected Payor Mix, FY2022

PAYOR CATEGORY	WESLEY LONG HOSPITAL SERVICES AS % OF TOTAL	RADIATION ONCOLOGY SERVICES AS % OF TOTAL
Self-Pay	5.3%	2.1%
Charity Care	NA	NA
Medicare	60.5%	57.9%
Medicaid	8.3%	5.4%
Insurance	24.1%	33.3%
Workers Compensation	0.4%	0.1%
TRICARE	0.7%	0.0%
Other (Specify)	0.8%	1.2%
Total	100.0%	100.0%

Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.1% of total services will be provided to self-pay patients, 57.9% to Medicare patients and 5.4% to Medicaid patients.

On page 89, the applicant provides the assumptions and methodology used to project payor mix following project completion. The projected payor mix is reasonable and adequately supported and is based on the historical payor mix for existing linear accelerator services at CHCC-WL.

Conclusion

The Agency reviewed the:

- application, and
- 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 90, the applicant adequately describes the range of means by which patients will have access to the proposed services, which is by physician referral.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, pages 91-93, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and lists the programs that currently utilize the training opportunities at Cone Health.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
 - (16) Repealed effective July 1, 1987.
 - (17) Repealed effective July 1, 1987.
 - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to replace one existing linear accelerator located at CHCC-WL on the Wesley Long Hospital campus.

In Chapter 9, page 127, the 2019 SMFP states, “A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.” CHCC-WL is located in Guilford County. In Table 9I, page 136 of the 2019 SMFP, Guilford County is included in Linear Accelerator Service Area 12, which also includes Rockingham County. Providers may serve residents of counties not included in their service area.

There are seven existing linear accelerators in Linear Accelerator Service Area 12. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators, as summarized from Table 9G, page 131 of the 2019 SMFP.

	# LINEAR ACCELERATORS	TOTAL PROCEDURES*	AVERAGE ESTV* PER LINEAR ACCELERATOR
Cone Health	4	27,175	6,794
High Point Regional Health	2	12,658	6,329
UNC Rockingham Health Care	1	4,614	4,614

*The 2019 SMFP equates Equivalent Simple Treatment Visits (ESTVs) with procedures in Table 9G.

In Section N, pages 94-96, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 94, the applicant states the project involves replacing an existing outdated linear accelerator and is not expected to have a significant impact on competition in the service area. The applicant further states that the proposed project will have a positive impact on the

cost effectiveness, quality, and access to radiation therapy services, which will generally increase competition.

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

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- Information which was publicly available during the review and used by the Agency.

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form A Facilities, page 103, in addition to Cone Health, which consists of five campuses and seven facilities, the applicant identifies three other facilities located in North Carolina owned, operated or managed by the applicant or a related entity: Annie Penn Hospital, Alamance Regional Medical Center, and Randolph Cancer Center.

In Section O, page 100, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of the facilities identified above. 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, there have been no incidents related to quality of care at any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all

five facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to replace an existing linear accelerator on Cone Health's Wesley Long Hospital campus. The Criteria and Standards for Radiation Therapy Equipment, which are promulgated in 10A NCAC 14C .1900, are not applicable to this review because the applicant does not propose to acquire a new linear accelerator. Therefore, Criterion (21) is not applicable to this review.