REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date:	May 24, 2023
Findings Date:	May 24, 2023
Project Analyst:	Julie M. Faenza
Co-Signer:	Lisa Pittman
Project ID #:	G-12339-23
Facility:	Cone Health Cancer Center – Asheboro
FID #:	230134
County:	Randolph
Applicants:	The Moses H. Cone Memorial Hospital The Moses H. Cone Memorial Hospital Operating Corporation
Project:	Replace and relocate no more than one linear accelerator and no more than one CT simulator to a new cancer center

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") propose to develop a new location for a cancer center by relocating an existing medical oncology cancer center, Cone Health Cancer Center – Asheboro (CHCC-Asheboro) to a new location and combining it with Randolph Cancer Center, a radiation oncology cancer center. The applicant will also acquire and replace the existing linear accelerator and CT simulator owned by Randolph Cancer Center. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

Need Determination

The applicant does not propose to acquire a new linear accelerator or any other health service for which there is an applicable need determination in the 2023 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2023 SMFP applicable to this review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 30 of the 2023 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 capital expenditure of the project is greater than $5 million. In Section B, page 26, the applicant describes its plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

In Section C, pages 27-28, the applicant states that Randolph Cancer Center, LLC was organized in 1999 as a joint venture between Randolph Hospital and the applicant to provide care to residents of Randolph County and surrounding areas. The applicant states that Randolph Cancer Center, LLC applied for and acquired a linear accelerator pursuant to a need determination in the 2006 SMFP (Project ID #G-7460-06) and subsequently applied for and acquired a CT simulator (Project ID #G-8037-08).

In the current application, the applicant proposes to acquire the linear accelerator and CT simulator, replace them, and relocate them to a new location, where they will be combined with a medical oncology treatment center that will also be relocated to the new location. The applicant proposes this project as the result of bankruptcy proceedings for Randolph Hospital.

N.C.G.S. §131E-181(a) states:

> *"A certificate of need shall be valid only for the defined scope, physical location, and person named in the application. A certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c)."*

N.C.G.S. §131E-189(c) states:

> *"The Department may immediately withdraw any certificate of need if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need. …. Transfers resulting from…other good cause, as determined by the Department, shall not result in withdrawal if the Department receives prior written notice of the transfer and finds good cause."*

While Randolph Cancer Center, LLC may indeed be a joint venture between Cone Health and Randolph Hospital, neither Cone Health nor any affiliated entities are certificate holders for either Project ID #G-7460-06 or Project ID #G-8037-08 – the only certificate holders are Randolph Cancer Center, LLC and Randolph Hospital, Inc. To transfer ownership of a certificate of need, the Agency must receive prior written notice and find that good cause exists for the transfer. In Section C, pages 27-28, the applicant states:

> *"On March 6, 2020, Randolph Hospital, Inc. and two affiliated companies, including Randolph Cancer Center, LLC* [RCC]*, filed petitions in the United States Bankruptcy Court for the Middle District of North Carolina seeking relief under Chapter 11 of the US Bankruptcy Code. Through the bankruptcy process, Randolph Hospital, Inc. and its assets were acquired by American Healthcare Systems (AHS), effective January 14, 2021. As RCC's joint-venture partner with Randolph Hospital, Cone Health accepted, in lieu of accumulated debt owed to it by RCC, to assume ownership of the CONs for the linear accelerator and CT Simulator; to relocate medical oncology services to an interim location separate from Randolph Hospital's campus; and, following construction of a new Cancer Center on property owned solely by Cone Health, to combine medical and radiation oncology services. Both joint venture parties agreed that upon acquisition of the services and CONs for the equipment, Cone Health would provide these oncology services to the residents of Randolph County and surrounding areas, and Randolph Cancer Center LLC would wind down operations and dissolve. The "Order Granting Debtors' Motion for Approval of Amended Sale Transaction and Supplementing Prior Sale Order" filed on June 4, 2021 states:*
>
> > *'Subject to Board approval, Cone Health will build a replacement outpatient oncology facility in Randolph County accessible to population centers of Asheboro and Trinity/Archdale and located within 10-miles from the existing hospital facility. When complete, the Cancer Center will cease operations, wind down, and transfer its CONs, G-7460-06 to acquire a linear accelerator and G-8037-08 to acquire a CT simulator, to Cone Health. Cone Health will apply for all CONs required for transfer of the Cancer Center CONs and all CONs required for the new facility, and the Purchaser will not object to the CON applications.'"*

The applicant provides a copy of the bankruptcy order containing this provision in Exhibit C.1.1.

Based on the information provided in the application as submitted, the Agency finds that Randolph Cancer Center, LLC, and Randolph Hospital, Inc., via Cone Health, have provided prior written notice of their intent to transfer ownership of the certificates of need for Project I.D. #G-7460-06 and Project ID #G-8037-08 and that good cause exists for the transfer.

Patient Origin

In Chapter 17, page 311, the 2023 SMFP defines a linear accelerator's service area as "…*one of the 28 multicounty groupings described in the Assumptions of the Methodology."* Table 17C-4 on page 320 shows Randolph County is the only county in Service Area 13. Thus, the

service area for this project consists of Randolph County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin.

Current Patient Origin – CHCC-Asheboro and Randolph Cancer Center – FFY 2022*						
Counties	CHCC-Asheboro - Medical		Randolph Cancer Center - Radiation		Combined	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Randolph	5,317	85.9%	125	80.6%	5,442	85.8%
Guilford	206	3.3%	2	1.3%	208	3.3%
Montgomery	196	3.2%	2	1.3%	198	3.1%
Davidson	184	3.0%	6	3.9%	190	3.0%
Chatham	178	2.9%	5	3.2%	183	2.9%
Other counties	110	1.8%	15	9.7%	125	2.0%
Total	**6,191**	**100.0%**	**155**	**100.0%**	**6,346**	**100.0%**

Source: Section C, page 33
*FFY = Federal Fiscal Year (October 1 – September 30)

Projected Patient Origin – CHCC-Asheboro – FYs 1-3 (FFYs* 2025-2027)						
Counties	FY 1 – FFY 2025		FY 2 – FFY 2026		FY 3 – FFY 2027	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Randolph	5,555	85.7%	5,611	85.7%	5,669	85.7%
Guilford	210	3.2%	212	3.2%	214	3.2%
Montgomery	204	3.1%	206	3.1%	208	3.1%
Davidson	195	3.0%	197	3.0%	200	3.0%
Chatham	188	2.9%	190	2.9%	194	2.9%
Other counties	134	2.0%	131	2.0%	133	2.0%
Total**	**6,486**	**100.0%**	**6,547**	**100.0%**	**6,618**	**100.0%**

Source: Section C, page 35
*FFY = Federal Fiscal Year (October 1 – September 30)
**There is a mathematical error in the calculation of total number of patients during FY 1 (FFY 2025). The error is minor and does not impact the outcome of this review in any way.

In Section C, page 34, the applicant provides the assumptions and methodology used to project its patient origin. The applicant does not expect changes to patient origin patterns of current patients. 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 in a nearby location.

Analysis of Need

In Section C, pages 36-40, 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 applicant is required to build a new cancer center located within 10 miles of the existing facility; the applicant already owns land that meets those requirements. (page 36)

- While the overall population of Randolph County is expected to remain flat between 2022 and 2027, the population of some age groups will decline, and others will grow. The population aged 65 and older in Randolph County is the only age cohort projected to grow between 2022 and 2027. Additionally, according to the National Cancer Institute, advanced age is the most important risk factor for cancer overall. (pages 37-38)

- The National Cancer Institute's Surveillance, Epidemiology, and End Results Program provides data that is used by The Advisory Board to generate a Cancer Incidence Estimator. Based on The Advisory Board's estimates for the population aged 65 and older, total cancer incidence for all tumor sites except the brain is projected to increase at a 5-year Compound Annual Growth Rate (CAGR) of 2.7%. (page 38)

- While utilization of services at Randolph Cancer Center decreased during 2020 and 2021, likely due to the pandemic, utilization rates have rebounded significantly in 2022, and despite the decrease in utilization during the pandemic, the 5-year CAGR for radiation oncology procedures is 1.7% (including the time period where utilization was lower due to the pandemic). Medical oncology visits followed a similar decrease and rebound and have a 5-year CAGR of 4.5%. (pages 38-39)

- The SMFP considers a linear accelerator fully utilized for purposes of generating a need determination when it performs 6,750 Equivalent Simple Treatment Visits (ESTVs) per year. Based on utilization in the 2023 SMFP, the linear accelerator at Randolph Cancer Center is at 59% of capacity and is not projected to use less capacity after the proposed project is fully developed. (pages 39-40)

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

- The applicant is required to develop a new cancer center pursuant to bankruptcy proceedings and a court order.

- Utilization of existing radiation and medical oncology services are steadily increasing.

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.

Linear Accelerator & CT Simulator Historical & Projected Utilization				
	Historical FFY 2022	FY 1 FFY 2025	FY 2 FFY 2026	FY 3 FFY 2027
Linear Accelerator				
# Units	1	1	1	1
# ESTV* Treatments	3,985	4,229	4,314	4,400
CT Simulator				
# Units	1	1	1	1
# of Procedures	164	174	177	181

*ESTV = Equivalent Simple Treatment Visits

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

- The applicant calculated historical growth rates for radiation oncology procedures and medical oncology visits and compared them with projected growth rates for the Randolph County population overall, the Randolph County population aged 65 and older, and The Advisory Board's Cancer Incidence estimate. The applicant determined that, based on those varying growth rates, it would project an annual growth rate of 2.0% for radiation oncology services and 1.0% for medical oncology services.

- The applicant states that it assumes the projected growth of radiation oncology services will be higher than the historical growth rate based on the following factors:

  - Cancer incidence is expected to increase in Randolph County.

  - The current linear accelerator is more than 15 years old, not as technically advanced as the model proposed in this application, and the replacement linear accelerator combined with an entirely new cancer center combining medical and radiation oncology services will encourage patients being treated outside of Randolph County to return to Randolph County for services.

- The applicant states that it assumes the projected growth of medical oncology services will be lower than the historical growth rate based on the following factors:

  - There was a large increase in medical oncology volumes between FFY 2021 and 2022, which was not consistent with historical patterns.

  - The historical growth rate prior to FFY 2021 to 2022 was relatively flat and the applicant wants to be conservative in its projections.

- The applicant applied the projected growth rate to the procedures, visits, patients, and ESTVs to determine projected utilization.

The applicant's assumptions and methodology are summarized in the table below.

Radiation and Medical Oncology Historical and Projected Utilization						
	Historical	Interim		Projected		
	FFY 2022	FFY 2023	FFY 2024	FY 1 – FFY 2025	FY 2 – FFY 2026	FY 3 – FFY 2027
Radiation Oncology Procedures	5,279	5,385	5,492	5,602	5,714	5,828
Growth rate		2.0%	2.0%	2.0%	2.0%	2.0%
Radiation Oncology Unique Pts	155	158	161	164	168	171
Growth rate		2.0%	2.0%	2.0%	2.0%	2.0%
Medical Oncology Visits/Cases	6,191	6,253	6,315	6,379	6,442	6,507
Growth rate		1.0%	1.0%	1.0%	1.0%	1.0%
# of ESTV Treatments	3,985	4,065	4,146	4,229	4,313	4,399
Growth rate		2.0%	2.0%	2.0%	2.0%	2.0%

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

- The applicant relies on data from its own operating experience and other reliable sources for its assumptions.

- The applicant considers a number of possible growth rates and provides support for the chosen projected growth rates.

Access to Medically Underserved Groups

In Section C, page 45, the applicant states:

> *"Cone Health is a private, not-for-profit organization established to serve the community by providing high quality, affordable, and comprehensive health care services to all patients, regardless of their economic status.*
>
> *Cone Health does not discriminate against low-income persons, racial and ethnic minorities, women,* [disabled] *persons, the elderly, or other underserved persons, including the medically 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. Access to hospital services for disadvantaged groups is provided in an organized setting through Cone Health's hospital-based outpatient clinics. Cone Health's well-established community education and screening programs are available to the general public and ensure adequate access to Cone Health services for medically underserved persons. The proposed project will not alter the current level of accessibility to patients of Cone Health."*

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	4.1%
Racial and ethnic minorities	12.6%
Women	67.3%
Persons 65 and older	60.8%
Medicare beneficiaries	66.1%
Medicaid recipients	8.2%

Source: Section C, page 46

On page 46, the applicant states it does not track usage by persons with disabilities.

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 patient financial support in Exhibits C.6.1 and L.2.a.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

In Section D, page 51, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. The applicant states that only radiation oncology services and medical oncology services will be relocated and all other services will remain in the same location. The applicant states the relocated services will still be available to the population presently utilizing the services following completion of the project.

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

- The proposed site is 3.7 miles away from the current location of radiation oncology services.

- The proposed site is 5.6 miles away from the current location of medical oncology services.

- In Exhibit C.1.1, the bankruptcy order requires that the new facility be developed within 10 miles of the hospital.

Access to Medically Underserved Groups

In Section D, page 51, the applicant states:

> *"The services relocated from Randolph Hospital will be offered at the new location of the proposed project and the relocation is not expected to result in any change in the services offered to the listed groups. …, the proposed project will serve Medicare, Medicaid, and Self-Pay patients."*

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use radiation and medical oncology services will be adequately met following completion of the project for the following reasons:

- The applicant provides a statement which states that medically underserved patients currently using the proposed services will be served at the new location.

- The new location for the proposed services is no more than 5.6 miles away from the current location of the 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 for the following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.

- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

(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 combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

In Section E, page 55, the applicant states that there were no alternative methods available to the applicant to meet the need for the proposal. The applicant states:

> *"Due to the nature of the bankruptcy agreement between Randolph Cancer Center, LLC, and Cone Health, the applicant is required to move all oncology services off the Randolph Hospital campus. Specific language in the document eliminates alternatives besides removing and replacing the existing Oncology Services provided by Randolph Cancer Center, LLC. The medical oncology service was immediately relocated to an interim location and will be relocated to the new location proposed in the application.*
>
> *The only alternative available to Cone Health was relocation to a different address than 1271 Spero Road, or perhaps to an existing building. However, the bankruptcy agreement states that the new cancer center must be "in Randolph County accessible to population centers of Asheboro and Trinity/Archdale and located within 10-miles from the existing hospital facility." There were a limited number of available sites within this geographic requirement that met Cone Health's required criteria with adequate access for patients. Because the proposed project includes radiation therapy, there are very specific construction elements for the linear accelerator vault; none of those construction elements were available in an existing building. Therefore, Cone Health has no alternative but to build a new cancer center with a vault that meets the radiation protection guidelines for a linear accelerator."*

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

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

- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 develop a new cancer center by relocating an existing medical oncology treatment center to a new location, acquiring, replacing, and relocating an existing radiation oncology treatment center with one linear accelerator and one CT simulator, and combining the two treatment centers in a new location.**

3. **Upon project completion, Cone Health Cancer Center – Asheboro will be licensed for no more than one linear accelerator and no more than one CT simulator.**

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, 2023.**

7. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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.

8. 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 combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

Capital and Working Capital Costs

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

Site Preparation	$2,634,888
Construction/Renovation Contract(s)	$12,911,164
Landscaping	$172,659
Architect/Engineering Fees	$3,635,390
Medical Equipment	$8,474,170
Non-Medical Equipment	$1,550,271
Furniture	$702,195
Consultant Fees	$153,481
Other	$2,281,440
Total	**$32,515,658**

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 February 10, 2023 from an architectural firm which projects a total cost to develop the cancer center as $18,153,632 – which is the combined total cost listed above for site preparation, construction/renovation contracts, landscaping, consultant fees, and "other."

- In Exhibits F.1.2a and F.1.2b, the applicant provides quotes for the linear accelerator and CT simulator, respectively.

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 currently provides the existing services and is planning only to relocate the services and relocate and replace the associated equipment.

Availability of Funds

In Section F, page 56, the applicant states the entire projected capital expenditure of $32,515,658 will be funded with The Moses H. Cone Memorial Hospital's accumulated reserves.

In Exhibit F.2.1, the applicant provides a letter dated February 15, 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.

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-Asheboro			
	FY 1 (FFY 2025)	**FY 2 (FFY 2026)**	**FY 3 (FFY 2027)**
Total Patients	6,486	6,547	6,618
Total Gross Revenues (Charges)	$68,189,131	$71,716,370	$75,426,482
Total Net Revenue	$22,931,193	$24,117,872	$25,366,103
Total Net Revenue per Patient	$3,535	$3,684	$3,833
Total Operating Expenses (Costs)	$19,633,741	$20,383,863	$21,163,798
Total Operating Expenses per Patient	$3,027	$3,113	$3,198
Net Profit/(Loss)	**$3,297,452**	**$3,734,009**	**$4,202,305**

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

- The applicant clearly details the sources of data used to project revenues and expenses.
- The applicant bases projections on its own historical experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

In Chapter 17, page 311, the 2023 SMFP defines a linear accelerator's service area as "…*one of the 28 multicounty groupings described in the Assumptions of the Methodology."* Table 17C-4 on page 320 shows Randolph County is the only county in Service Area 13. Thus, the service area for this project consists of Randolph County. Facilities may also serve residents of counties not included in their service area.

According to Table 17C-1 on page 315 of the 2023 SMFP, the linear accelerator that is part of the proposed project is the only existing or approved linear accelerator in Randolph County.

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

> *"…, the proposed project will relocate and consolidate Cone Health's medical oncology and radiation oncology services into one location and replace the linear accelerator and CT simulator. The existing linear accelerator and CT simulator have surpassed their useful life and the co-location of services will allow for better patient care close to home and efficiencies for staff and providers. Thus, the proposed project is not expected to result in unnecessary duplication of existing or approved health service facilities."*

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

- The applicant is not proposing to add any new linear accelerators or CT simulators to Randolph County.

- The applicant adequately demonstrates that it is necessary to replace the existing equipment and the replacement equipment will not be an unnecessary duplication of existing or approved services.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

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

CHCC-Asheboro Projected FTE Staffing			
	FY 1 – FFY 2025	**FY 2 – FFY 2026**	**FY 3 – FFY 2027**
Administrative	7.3	7.4	7.4
Clinical Support Staff	5.1	5.1	5.2
Nurse	10.4	10.5	10.6
Physicians	On-call	On-call	On-call
Physician Extenders	2.2	2.2	2.3
Pharmacists	0.3	0.3	0.3
Radiation Oncology	4.2	4.3	4.4
Total	**29.4**	**29.8**	**30.1**

The assumptions and methodology used to project staffing are provided 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

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 combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

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 proposes to offer at the new location.

- In Exhibit I.1, the applicant provides a letter dated February 15, 2023, from the Chief Operating Officer of Cone Health, attesting to the existence of the necessary ancillary and support services 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 Cone Health's existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit O.8. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- Cone Health is an existing provider of healthcare services in Randolph County and thus has established many relationships with area healthcare providers.

- The applicant provides letters of support from local physicians and healthcare providers documenting their support for the proposed project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction

project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

In Section K, page 73, the applicant states that the project involves constructing 23,936 square feet of new space in an existing medical office building. Line drawings are provided in Exhibit K.1.

In Section K, pages 75-76, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. Supporting documentation is provided in Exhibits K.4.b and K.4.c.1. The site appears to be suitable for the proposed cancer center based on the applicant's representations and supporting documentation.

In Section K, pages 73-74, 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 plans to develop the new cancer center on property already owned by Cone Health.

- The applicant states the consolidation of resources will allow for efficiencies, especially when a patient's treatment plan involves both medical and radiation oncology.

- Because of the requirements imposed on the applicant by the bankruptcy order, the applicant determined this was the only reasonable alternative to develop the proposed project.

In Section K, 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 the project is financially feasible and will not negatively impact Cone Health's overall financial stability.

- The applicant states the proposed project will not unduly increase the costs and charges to the public.

In Section K, 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

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, pages 77-78, the applicant provides the historical payor mix during the last full fiscal year for all services at CHCC-Asheboro and Randolph Cancer Center, as shown in the table below.

Historical Payor Mix – CHCC-Asheboro and Randolph Cancer Center FFY 2022		
	CCHC-Asheboro (Medical)	**Randolph Cancer Center (Radiation)**
Self-Pay	2.6%	3.9%
Medicare*	64.2%	58.8%
Medicaid*	8.4%	2.0%
Insurance*	23.1%	35.3%
Other	1.7%	0.0%
Total	**100.0%**	**100.0%**

*Including any managed care plans.

In Section L, page 78, the applicant states charity care is not considered a separate payor category and that charity care is offered to qualifying patients in all payor categories.

In Section L, page 78, the applicant provides the following comparison.

CHCC-Asheboro	% of Total Patients Served During FFY 2021	% of Population of Randolph County
Female	67.3%	50.3%
Male	32.7%	49.7%
Unknown	0.0%	0.0%
64 and Younger	40.0%	81.8%
65 and Older	60.0%	18.2%
American Indian	0.3%	1.2%
Asian	0.3%	1.7%
Black or African-American	8.3%	7.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	85.2%	88.1%
Other Race	3.8%	2.0%
Declined / Unavailable	2.3%	0.0%

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the 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 79, the applicant states it has no such obligation.

In Section L, page 79, the applicant states that no patient civil rights access complaints have been filed against Cone Health during the 18 months immediately prior to submission of the application. The applicant states it is unaware of any patient civil rights access complaints that may have been filed against Randolph Cancer Center.

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 80, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Projected Payor Mix – CHCC-Asheboro – FY 3 (FFY 2027)			
	Medical	**Radiation**	**Total**
Self-Pay	2.6%	3.9%	2.6%
Medicare*	64.2%	58.8%	64.1%
Medicaid*	8.4%	2.0%	8.2%
Insurance*	23.1%	35.3%	23.4%
Other	1.7%	0.0%	1.7%
Total	**100.0%**	**100.0%**	**100.0%**

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 2.6% of medical oncology services, 3.9% of radiation oncology services, and 2.6% of total services will be provided to self-pay patients, 64.2% of medical oncology services, 58.8% of radiation oncology services, and 64.1% of total services to Medicare patients, and 8.4% of medical oncology services, 2.0% of radiation oncology services, and 8.2% of total services to Medicaid patients. The applicant's projected patient origin appears to be consistent with its historical patient origin.

In Section L, page 80, the applicant states charity care is not considered a separate payor category and that charity care is offered to qualifying patients in all payor categories.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conditionally conforming to this criterion, subject to Condition #6 in Criterion (4), based on the reasons stated above.

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

C

In Section L, page 82, 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 combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

In Section M, pages 83-84, 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 will have access to the facility for training purposes based on the following:

- The applicant describes the existing opportunities it provides for area health professional training programs.

- The applicant provides a list of some of the existing health professional training programs that utilize Cone Health for the clinical needs of those programs.

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 combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

In Chapter 17, page 311, the 2023 SMFP defines a linear accelerator's service area as "…*one of the 28 multicounty groupings described in the Assumptions of the Methodology."* Table 17C-4 on page 320 shows Randolph County is the only county in Service Area 13. Thus, the service area for this project consists of Randolph County. Facilities may also serve residents of counties not included in their service area.

According to Table 17C-1 on page 315 of the 2023 SMFP, the linear accelerator that is part of the proposed project is the only existing or approved linear accelerator in Randolph County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 85, the applicant states:

> *"Currently, there is one linear accelerator in Randolph County, which also comprises the boundaries of Linear Accelerator Service Area 13 in the North Carolina State Medical Facilities Plan. This linear accelerator is currently operated by Randolph Cancer Center, a joint venture between Cone Health and Randolph Health. Cone*

> *Health will continue to operate the only linear accelerator in LinAcc Service Area 13 upon completion of the proposed project. There should be no effect on competition in the service area. As approximately eighty (80) percent of the patients served by the existing linear accelerator originate in Randolph County, it is not expected that the proposed project will significantly impact competition in Service Area 13 or surrounding linear accelerator service areas. The upgraded linear accelerator will, however, offer an enhanced alternative to Randolph County residents who may be currently leaving the service area for advanced radiation oncology services."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 85, the applicant states:

> *"By combining medical and radiation oncology services in a single location, Cone Health Cancer Center – Asheboro will be able to take advantage of efficiencies of scale and maintain the same high standards of care offered at other Cone Health cancer center locations. For patients, multiple trips to separate locations will be reduced as they will be able to receive their care in one location."*

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

Regarding the impact of the proposal on quality, in Section N, page 85, the applicant states:

> *"…, Cone Health has many years of experience in operating a cancer center with radiation oncology services. Cone Health Cancer Center has been recognized for its quality by multiple organizations."*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 86, the applicant states:

> *"Cone Health is committed to being a leader in providing cost-efficient, high-quality health care services to citizens in its service area in both inpatient and outpatient settings. As part of this commitment, it makes these services available to all community residents, without regard for ability to pay."*

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

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

1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.

3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion 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 combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

On Form O in Section Q, the applicant identifies the facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of six additional cancer centers located in North Carolina.

In Section O, page 89, the applicant states that during the 18 months immediately preceding the submittal of the application there were no incidents resulting in findings of immediate jeopardy at any of the six identified in Form O. After reviewing and considering information provided by the applicant and considering the quality of care provided at all six 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.

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 combine existing medical oncology and radiation oncology treatment centers by relocating an existing medical oncology treatment center to a new location and acquiring an existing linear accelerator and CT simulator. Upon project completion, CHCC-Asheboro will provide both medical and radiation oncology treatment and services.

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.