

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 22, 2022

Findings Date: July 22, 2022

Project Analyst: Gregory F. Yakaboski

Co-Signer: Lisa Pittman

Project ID #: P-12209-22

Facility: Carteret General Hospital

FID #: 923076

County: Carteret

Applicant: Carteret County General Hospital Corporation

Project: Acquire no more than one linear accelerator pursuant to the 2022 SMFP need determination for a total of no more than two linear accelerators

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 applicant, Carteret County General Hospital Corporation (CCGHC), proposes to acquire one fixed linear accelerator (LINAC) pursuant to a need determination in the 2022 State Medical Facility Plan (SMFP) to be located at Carteret General Hospital located at 3500 Arendell Street, Morehead City in Carteret County. Following project completion, CCGHC will have two LINAC's, both located at Carteret General Hospital.

Carteret County General Hospital Corporations does business as (d/b/a) Carteret Health Care (CHC).

Need Determination

The 2022 SMFP includes an adjusted need determination for one additional LINAC in Linear Accelerator Service Area 24. Linear Accelerator Service Area 24 consists of Carteret, Craven,

Jones and Pamlico counties. Table 17C-6 of the 2022 SMFP, page 333, states “*The State Health Coordinating Council approved an adjusted need determination for one Linear Accelerator in Service Area 24, designated for Carteret County.*” The applicant proposes to acquire one fixed LINAC to be in Carteret County at Carteret General Hospital.

The applicant does not propose to acquire more LINACs than are determined to be needed in Linear Accelerator Service Area 24 and the applicant proposed to locate the LINAC in Carteret County. Therefore, the application is consistent with the need determination.

Policies

There are two policies in the 2022 SMFP applicable to this review: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3: Basic Principles, on page 30 of the 2022 SMFP, states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 23-27; Section N, pages 107-108; Section O, pages 110-112; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 27 and 29; Section C, pages 60-62; Section L, pages 98-104; Section N, pages 108-109, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 28; Section N, pages 107-108; and referenced exhibits. The information

provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on pages 30-31 of the 2022 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 over \$4 million dollars. In Section B, pages 30-31, 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 based on the following:

- The applicant does not propose to acquire more than one linear accelerator than is determined to be needed in the service area.
- The applicant proposes to situate the linear accelerator in Carteret County consistent with the adjusted need determination in the 2022 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of radiation oncology services in Linear Accelerator Service Area 24;
 - The applicant adequately documents how the project will promote equitable access to radiation oncology services in Linear Accelerator Service Area 24;
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
 - The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 based on the following:
 - 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 acquire one fixed LINAC pursuant to the need determination in the 2022 SMFP to be located at Carteret General Hospital in Morehead City.

Patient Origin

In Chapter 17, page 321, the 2022 SMFP states, “*A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.*” Carteret General Hospital is in Carteret County. In Table 17-C4, page 331 of the 2022 SMFP, Carteret County is included in Linear Accelerator Service Area 24. Linear Accelerator Service Area 24 includes Carteret, Craven, Jones and Pamlico counties. Thus, the service area for this

project consists of those four counties. Facilities may also serve residents of counties not included in their service area.

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

County	Historical (10/1/2020 to 9/30/2021)		Third Full FY of Operation following Project Completion (10/1/2027 to 9/30/2028)	
	Patients	% of Total	Patients	% of Total
Carteret	256	74.9%	385	74.9%
Craven	23	6.7%	35	6.7%
Onslow	58	17.0%	87	17.0%
Out-of-Area	5	1.5%	8	1.5%
Total	342	100.0%	514	100.0%

Source: Pages 41 and 42 of the application.

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

- The applicant bases projected patient origin, in terms of both counties and percent of total, on historical patient origin.
- The applicant bases patient growth on 5-year annual growth rate from FFY17 to FFY21 rounded down from 6.8% to 6.0%.

Analysis of Need

In Section C.4, pages 43-54, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant identifies reasons to support the need for the proposed service, which are summarized below.

- There is an adjusted need determination in the 2022 SMFP for one linear accelerator in Linear Accelerator Service Area 24 designated specifically for Carteret County (page 44).
- The demographics of CHC radiation oncology service area and primary service area (page 44).
- Population growth and aging in the CHC service area (pages 44-46).
- Health status of the CHC service area. (pages 47-51).
- Patient choice and distance to treatment (pages 51-52).
- Carteret County as a second home (page 52).
- Outmigration for linear accelerator service area (pages 53-54).

- Role of linear accelerator treatment in cancer care (page 54).

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

- There is a need determination in the 2022 SMFP for one additional linear accelerator in Linear Accelerator Service Area 24, specifically designated for Carteret County.
- Population growth statistics, particularly in the over 65 population for the service area demonstrate an increase in the population most likely to use the LINAC services being proposed.
- The NC State Center for Health Statistics data supports the applicant’s demonstration of need based on cancer statistics and projections in Linear Accelerator Service Area 24.
- The applicant adequately demonstrates the need for a linear accelerator in addition to the existing Linear Accelerator Service Area 24.

Projected Utilization

In Section Q, Form C.2a, pages 117-118, the applicant provides historical and projected utilization, as illustrated in the following tables.

	Last FFFY 10/1/2020 – 9/30/2021	Interim FFY 10/1/2021 – 9/30/2022	Interim FFY 10/1/2022 – 9/30/2023	Interim FFY 10/1/2023 – 9/20/2024	Interim FFY 10/1/2024 – 9/30/2025
# of Units	1	1	1	1	1
# of ESTV Treatments*	6,732	7,252	7,687	8,148	8,637

Source: Section Q of the application.

*ESTV = Equivalent Simple Treatment Visits

	1 st FFY 10/1/2025 – 9/30/2026	2 nd FFY 10/1/2026 – 9/20/2027	3 rd FY 10/1/2027 – 9/30/2028
# of Units	2	2	2
# of ESTV Treatments*	9,155	9,705	10,287

Source: Section Q of the application.

*ESTV = Equivalent Simple Treatment Visits

In Section Q, pages 119-136, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Forecast Need

Step 1: Determine Fiscal Year (See page 120)

Step 2: Determine the CHC radiation oncology service area (See page 120)

Step 3: Determine historical new cancer cases by county by year, FY19-FY22 (See page 121)

Step 4: Determine population by county by year, FY19-FY22. (See page 121)

Step 5: Calculate new cancer case rates per 1,000 population for Service Area 24 counties plus Onslow, FY19-FY22 (See page 122)

Step 6: Determine linear trend equations for new cancer rates, Primary Service Area Counties, FY19-FY22 (See pages 122-123)

Step 7: Project new cancer case rates per 1,000 population by county, FY23-28 (See page 124)

Step 8: Determine Primary Service Area population by year by county, FY23-FY28 (See page 125)

Step 9: Calculate total estimated new cancer cases by county by year for Primary Service Area, FY23- FY28 (See page 125)

Step 10: Determine percentage of new cancer cases eligible for linear accelerator treatment (See page 125)

Step 11: Calculate the number of new cancer cases eligible for linear accelerator treatment for Primary Service Area, FY22-FY28 (See page 126)

Step 12: Determine the percentage of linear accelerator re-treat cases (See page 126)

Step 13: Estimate total linear accelerator cases in the CHC Primary Service Area including re-treats, FY23-FY28 (See pages 127-128)

Forecast Utilization

PATIENTS

Step 14: Determine CHC's 5-year annual growth rate for linear accelerator cases, rounded down to nearest percentage, FY17-FY21 (See page 128)

Step 15: Forecast CHC linear accelerator patients, FY22-FY28 (See page 129)

Step 16: Adjust physician FTEs to accommodate total patient demand (See pages 129-130)

Step 17: Test forecast total patients against Performance Standard in Special Rules for Radiation Therapy Equipment (See page 130)

Sensitivity Test- Market Share Analysis and Patient Origin Forecast

Step 18: Determine CHC historical linear accelerator patient distribution by county, FY21 (See page 131)

Step 19: Calculate CHC linear accelerator patients by county, FY22-FY28 (See page 131)

Step 20: Determine CHC market share of estimated linear accelerator patients by county, FY23-FY28 (See pages 132-133)

Forecast ESTVs

Step 21: Determine CHC historical linear accelerator treatments and patients (See page 134)

Step 22: Calculate CHC historical ESTVs per patient (See page 134)

Step 23: Determine CHC forecast linear accelerator patients, FY22-FY28 (See page 135)

Step 24: Forecast CHC ESTVs, FY22-FY28 (See page 135)

Step 25: Test forecast ESTVs for reasonableness (See pages 135-136)

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 relies on historical linear accelerator utilization at Carteret General Hospital to project future utilization.
- The applicant provides letters of support from physicians and the community for the proposed project in Exhibit I.2 of the application.
- The applicant in Step 14 provides five years of historical patient data from Carteret General Hospital, calculates the 5-year average growth rate to be 6.8%, rounds the growth rate down to 6.0% and then in Step 15 projects the number of patients from FFY 2023 through FFY 2028, the third year after project completion.
- The applicant projects to add an additional full-time radiation oncologist in January 2023.
- The proposed LINAC offers new technology that will allow Carteret General Hospital to serve an existing and projected patient population in Linear Accelerator Service Area 24.
- There is a need determination in the 2022 SMFP for one additional linear accelerator in Linear Accelerator Service Area 24 and specifically designated for Carteret County.

- Population growth statistics, particularly in the over 65 population for the service area demonstrate an increase in the population most likely to use the LINAC services being proposed.
- The NC State Center for Health Statistics data supports the applicant’s demonstration of need based on cancer statistics and projections in Linear Accelerator Service Area 24.
- The projected utilization of 257 patients per LINAC during the third full year of operation following completion of the project exceeds the 250 patients per LINAC threshold for the third full year of operation following completion of the project, as required by 10A NCAC 14C .1903 (5)(b).

Access to Medically Underserved Groups

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

“CHC accepts patients regardless of gender, gender preference, race, ethnicity, age, or income, it can and does also serve most people who have disabilities.”

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

Medically Underserved Groups	Percentage of Total Patients
Low income persons	5.1%
Racial and ethnic minorities	15.9%
Women	58.2%
Persons with Disabilities	100.0%
Persons 65 and older	69.0%
Medicare beneficiaries	67.4%
Medicaid recipients	4.7%

Source: Table on page 62 of the application.

The applicant adequately describes, on page 62, the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based, in part, on the following:

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

Conclusion

The Agency reviewed the:

- Application

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

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

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

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to acquire one fixed LINAC pursuant to the need determination in the 2022 SMFP to be located at Carteret General Hospital in Morehead City.

In Section E, pages 71-73, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo*- The applicant states that maintaining the status quo would not meet current patient demand nor would it fulfill the adjusted need determination for a linear accelerator in the 2022 SMFP for Linear Accelerator Service Area 24 specifically in Carteret County. Therefore, the applicant determined that this alternative was not the most effective.
- *Extend Hours on the Existing Equipment*- The applicant states that simply extending the hours for the existing linear accelerator would not address the problems of when the piece of equipment was down for repair or maintenance, the fact that it is problematic for many patients, especially elderly patients, to travel after dark, and the fact that cancer patients need weekend recovery breaks from the effects of the treatment. In addition, extending hours does not double capacity. Therefore, the applicant determined that this alternative was not the most effective.
- *Replacement of the Existing Equipment Alone*- The applicant states that replacing the existing linear accelerator does not address the lack of capacity issues nor adequately

address patient need, both current and projected. Therefore, the applicant determined that this alternative was not the most effective.

- *Create a Freestanding Cancer Center with a New Linear Accelerator-* The applicant states that this alternative would have higher overhead costs, be less efficient and overall more costly, including having to purchase a simulator, having to organize ambulance transport, and fail to take advantage of existing ancillary and support services. Therefore, the applicant determined that this alternative was neither the least costly nor the most effective.

On page 73, the applicant states that its proposal is the most effective alternative because *“it will provide a better continuum of care for patients, improve efficiency of operations, and prevent unnecessary patient travel costs and time loss. Patient need and physician capacity to deliver services both support this proposal.”*

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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. Carteret County General Hospital Corporation (herein after “the certificate holders”) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holders shall acquire no more than one fixed linear accelerator pursuant to the need determination in the 2022 State Medical Facility Plan to be located at Carteret General Hospital located at 3500 Arendell Street, Morehead City in Carteret County for a total of no more than two fixed linear accelerators.**
- 3. The certificate holders 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. **The certificate holders 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.**
 5. **The certificate holders shall provide third party documentation of proof of funds for the capital and working capital needs of the project.**
 6. **Progress Reports:**
 - a. **Pursuant to G.S. § 131E-189(a), the certificate holders 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 holders shall complete all sections of the Progress Report form.**
 - c. **The certificate holders 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, 2022.**
 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 holders 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 holders 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.

The applicant proposes to acquire one fixed LINAC pursuant to the need determination in the 2022 SMFP to be located at Carteret General Hospital in Morehead City.

Capital and Working Capital Costs

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

Site Costs	\$0.00
Construction Costs	\$1,144,000
Miscellaneous Costs	\$4,754,311
Total	\$5,898,311

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions as documented in Form F.1a Capital Cost Assumptions and Exhibits F.1 and K.3.

In Section F.3, page 76, the applicant projects there will be no start-up or initial operating expenses because the Carteret General Hospital radiation oncology program is existing and operational

Availability of Funds

In Section F.2, page 74, the applicant states that the capital cost will be funded, as shown in the table below.

Type	Sources of Capital Cost Financing	
	<i>Carteret County General Hospital Corporation</i>	Total
Loans	\$	\$
Accumulated reserves or OE *	\$5,898,311	\$5,898,311
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$5,898,311	\$5,898,311

* OE = Owner's Equity

Exhibit F.2 contains a copy of an April 10, 2022 letter from the VP of Finance of Carteret County General Hospital Corporation, documenting the funding of the proposed project with cash reserves. However, the applicant does not provide third party documentation of proof of funds. See Condition #5 in Criterion (4).

Financial Feasibility

The applicant provided pro forma financial statements for Carteret General Hospital's Radiation Oncology program for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed

operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

	1st Full Fiscal Year (FFY 2026)*	2nd Full Fiscal Year (FFY 2027)	3rd Full Fiscal Year (FFY 2028)
Total Treatments	9,155	9,705	10,287
Total Gross Revenues (Charges)	\$23,426,810	\$24,832,418	\$26,322,364
Total Net Revenue	\$5,409,250	\$5,758,638	\$6,130,478
Average Net Revenue per Treatment	\$591	\$593	\$596
Total Operating Expenses (Costs)	\$5,055,791	\$5,666,980	\$5,846,265
Average Operating Expense per Treatment	\$552	\$584	\$568
Net Income	\$353,459	\$91,658	\$284,213

*1st Full Fiscal Year is 10/1/2025 to 9/30/2026)

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

- The applicants base their projections on Carteret General Hospital’s entire oncology program’s historical experience and adequately account for projected operating expenses, such as salaries, equipment maintenance and administrative support, consistent with projections elsewhere in the application.
- 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, subject to the applicant complying with Condition #5 in Criterion (4) prior to issuance of the Certificate, 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 subject to the applicant complying with Condition #5 in Criterion (4) prior to issuance of the Certificate.

- 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 acquire one fixed LINAC pursuant to the need determination in the 2022 SMFP to be located at Carteret General Hospital in Morehead City.

In Chapter 17, page 321, the 2022 SMFP states, “A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Carteret General Hospital is in Carteret County. In Table 17-C4, page 331 of the 2022 SMFP, Carteret County is included in Linear Accelerator Service Area 24. Linear Accelerator Service Area 24 includes Carteret, Craven, Jones and Pamlico counties. Thus, the service area for this project consists of those four counties. Facilities may also serve residents of counties not included in their service area.

There are three LINAC’s in Linear Accelerator Service Area 24. The following table identifies the provider, number of linear accelerators, and average utilization of each of the LINAC’s in FFY2020, as summarized from Table 17C-1, page 325 of the 2022 SMFP.

Provider	# of LINAC’s	County	Total Procedures	Average ESTV* per LINAC
Carteret General Hospital	1	Carteret	6,870	6,870
CarolinaEast Medical Center	2	Craven	9,650	4,825

*The 2022 SMFP equates ESTV’s with procedures in Table 17C-1.

In Section G, pages 83-84 , the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Linear Accelerator Service Area 24. The applicant states:

“CHC’s single linear accelerator is not sufficient to keep up with patient need. ... Although the other linear accelerator providers located in CHC’s Primary Service Area have extra capacity, neither CarolinaEast nor Onslow Radiation Oncology can relieve the capacity pressures specific to CHC. CarolinaEast is not convenient for CHC patients... Onslow Radiation Oncology is not conveniently located for CHC patients. ... Far from representing unnecessary duplication, a second linear accelerator at CHC will represent essential added capacity to respond to growing demand for radiation therapy treatment at CHC Cancer Center.”

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

- There is an adjusted need determination in the 2022 SMFP for the proposed linear accelerator in Linear Accelerator Service Area 24, specifically Carteret County.
- The applicant adequately demonstrates that the proposed linear accelerator is needed in addition to the existing or approved linear accelerators in Linear Accelerator Service Area 24.

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 acquire one fixed LINAC pursuant to the need determination in the 2022 SMFP to be located at Carteret General Hospital in Morehead City.

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

Position	Current FTE Staff	Projected FTE Staff
	<i>(3/28/2022)</i>	<i>3rd Full Fiscal Year (10/1/2027 – 9/30/2028)</i>
Registered Nurses	2.2	3.6
Radiology Technologists	4.5	5.9
Director of Radiation Oncology	1.0	1.0
TOTAL	7.7	10.5

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form 3.b. In Sections H.2 and H.3, pages 87-88, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

- (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 acquire one fixed LINAC pursuant to the need determination in the 2022 SMFP to be located at Carteret General Hospital in Morehead City.

Ancillary and Support Services

In I.1, page 89, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 90-91, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits F.1, I.1 and I.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because Carteret General Hospital is an existing facility that offers radiation oncology services including currently providing all the identified ancillary and support services.

Coordination

In Section I.2, page 92, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system since Carteret General Hospital is an existing radiation oncology provider with extensive working relationships with area healthcare providers and social service providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. 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 acquire one fixed LINAC pursuant to the need determination in the 2022 SMFP to be located at Carteret General Hospital in Morehead City.

In Section K, page 94, the applicant states that the project involves constructing 1,430 square feet of new space. Line drawings are provided in Exhibit K.1.

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

“The architect and design team based the construction / renovation design and costs on a detailed review of the project, actual costs of similar projects, and construction costing data, as well as the design team’s own experience. ... The product will be a cost-effective and energy efficient facility that will maximize operational efficiency and enhance the patient experience. This will maximize the accessibility of health care resources to the local community and surrounding areas.”

On page 96, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. The applicant states,

“CHC has taken steps to maximize use of existing resources as it adds a second linear accelerator. ... CHC has worked with its radiation oncologist to accelerate recruitment of a second radiation oncologist. This person would enable CHC to maximize use of the existing linear accelerator and expand hours as much as the patient population will tolerate. ... The project will alleviate capacity constraints on the existing linear accelerator. This increased demand and maximum use of existing resources will provide efficiencies. Funding with cash rather than with debt will contain costs. ... projected revenue will continue to exceed expense. Radiation therapy treatment by linear accelerator involves protocols of daily treatments over one or more months. Thus, maintaining local access represents substantial savings for patients who would otherwise travel out of the area for the linear accelerator treatment. ... CHC does not anticipate the need to increase its charges because of the proposed project.’

In Section B, pages 30-31, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section L, page 98, the applicant provides the historical payor mix during the last full fiscal year (10/1/2020 to 9/30/2021) for Carteret County General Hospital, as shown in the table below.

Payor Category	Percent of Total Served
Self-Pay	14.0%
Charity Care	0.7%
Medicare*	25.3%
Medicaid*	11.5%
Insurance*	36.8%
Workers Compensation	0.4%
TRICARE	8.9%
Other (VA, Hospice, Other Gov't & Liability)	2.4%
Total	100.0%

Source: Table on page 98 of the application.

*Including any managed care plans.

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

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY (10/1/2020 to 9/30/2021)	Percentage of the Population of the Service Area
Female	58.2%	49.6%
Male	41.8%	50.4%
Unknown	n/a	n/a
64 and Younger	69.0%	85.0%
65 and Older	31.0%	15.0%
American Indian	0.1%	0.7%
Asian	0.4%	2.5%
Black or African American	7.6%	14.3%
Native Hawaiian or Pacific Islander	0.1%	n/a
White or Caucasian	84.1%	78.4%
Other Race	5.9%	4.1%
Declined / Unavailable	1.8%	n/a

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 101, the applicant states,

“CHC is a CMS certified hospital and therefore subject to EMTALA rules. It is in full compliance with CMS certification for Medicare and Medicaid, and by extension in compliance with EMTALA requirements.

Furthermore, as a tax-exempt not-for-profit hospital, CHC is subject to compliance with Internal Revenue Service Section 501(r) and all requirements imposed by the Affordable Care Act. ... CHS files reports as required and is in full compliance with these requirements.”

In Section L, page 101, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 102, the applicant projects the following payor mix for both Carteret County General Hospital and specifically the radiation oncology services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Carteret County General Hospital: Overall

Payor Category	Percent of Total Served
Self-Pay	14.0%
Charity Care	0.7%
Medicare*	26.9%
Medicaid*	11.5%
Insurance*	35.2%
Workers Compensation	0.4%
TRICARE	8.9%
Other (VA, Hospice, Other Gov't & Liability)	2.4%
Total	100.0%

Source: Table on page 102 of the application.

*Including any managed care plans.

Carteret County General Hospital: Radiation Oncology

Payor Category	Percent of Total Served
Self-Pay	2.4%
Medicare*	69.0%
Medicaid*	4.7%
Insurance*	14.0%
Other (Champus, TRICARE, VA)	9.8%
Total	100.0%

Source: Table on page 102 of the application.

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.4% of total radiation oncology services will be provided to self-pay patients, 69.0% to Medicare patients and 4.7% to Medicaid patients.

On page 102, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on historical payor mix (FFY 2021) for both the entire facility and the radiation oncology services.
- Insurance and Medicare were adjusted to account for the change in percentage of the primary service area population that will be over 65 by the third project year, Medicare was increased by 1.6% and Insurance was decreased by 1.6%.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the 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.5, page 104, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

The applicant proposes to acquire one fixed LINAC pursuant to the need determination in the 2022 SMFP to be located at Carteret General Hospital in Morehead City.

In Section M, pages 105-106, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- CHC has program to train third year Medical Students from Campbell University
- CHC has relationships with the nursing programs at East Carolina University, Barton College, Craven Community College, Pitt Community College, Carteret Community College, Beaufort County Community College and Coastal Carolina Community College.
- The applicant states that all appropriate trainees will have opportunity to observe/train in the external beam radiation treatment program.

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 acquire one fixed LINAC pursuant to the need determination in the 2022 SMFP to be located at Carteret General Hospital in Morehead City.

In Chapter 17, page 321, the 2022 SMFP states, “A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Carteret General Hospital is in Carteret County. In Table 17-C4, page 331 of the 2022 SMFP, Carteret County is included in Linear Accelerator Service Area 24. Linear Accelerator Service Area 24 includes Carteret, Craven, Jones and Pamlico counties. Thus, the service area for this project consists of those four counties. Facilities may also serve residents of counties not included in their service area.

There are three LINAC’s in Linear Accelerator Service Area 24. The following table identifies the provider, number of linear accelerators, and average utilization of each of the LINAC’s in FFY2020, as summarized from Table 17C-1, page 325 of the 2022 SMFP.

Provider	# of LINAC’s	County	Total Procedures	Average ESTV* per LINAC
Carteret General Hospital	1	Carteret	6,870	6,870
CarolinaEast Medical Center	2	Craven	9,650	4,825

*The 2022 SMFP equates ESTV’s with procedures in Table 17C-1.

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

“CHC needs a second linear accelerator to continue to meet current and future demand from patients and referring physicians. The proposed project will allow CHC to remain competitive and thus maintain patient attractiveness in the service area. A second linear accelerator will position CHC for long-term patient access. With sufficient capacity, CHC can continue to support the high-quality professionals that patients have come to expect.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 107-108, the applicant states:

“The proposed CHC project... will require only small staff additions. Because the project will not involve debt, CHC will be able to minimize new capital and operating costs. Because it will operate as part of an existing program, the project will require few expenses...”

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

Regarding the impact of the proposal on quality, in Section N, page 108, the applicant states:

“Placing this linear accelerator at CHC assures the state and residents of the service area that services will meet the standards of the American College of Surgeons, the Mayo Clinic, the UNC Lineberger Cancer Network, the Quality Oncology Practice Initiative, The Joint Commission, and the state of North Carolina. The program will operate as part of a licensed facility subject to licensure oversight.”

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, pages 108-109, the applicant states:

“Access to radiation oncology is available only through an order by a radiation oncologist or physician authorized by CHC. All eligible candidates will have access to the proposed services. CHC does not discriminate based on income, gender, nationality, race, creed, or any other unmentioned group.

See also Section L and C 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

In Section Q, Form O, page 147, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one, Carteret General Hospital, of this type of facility located in North Carolina.

In Section O, page 111, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care resulting in a finding of immediate jeopardy did not occur in Carteret General Hospital.

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care did not occur in this facility. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at Carteret General Hospital, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

SECTION .1900 - CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT

10A NCAC 14C .1903 PERFORMANCE STANDARDS

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

- (1) identify the existing LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;
- C- The applicant and related entities own one existing LINAC located on the main campus of Carteret General Hospital on Arendell Drive in Morehead City.
- (2) identify the approved LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;
- C- The applicant and related entities own one existing LINAC located on the main campus of Carteret General Hospital on Arendell Drive in Morehead City. The applicant and related entities do not have any approved, but non-operational, LINAC's in Linear Accelerator Service Area 24.
- (3) provide projected utilization of the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC during each of the first three full fiscal years of operation following completion of the project;
- C- In Section C, page 64 and Section Q, the applicant provided projected utilization of its existing and proposed LINAC during each of the first three full fiscal years of operation following completion of the project.

	1st FFY 2026	2nd FFY 2027	3rd FFY 2028
# of LINAC's	2	2	2
Total Patients	458	485	514
Total ESTVs	9,155	9,705	10,287

- (4) provide the assumptions and methodology used for the projected utilization required by Item (3) of this Rule;
- C- The applicant provided the assumptions and methodology used for the projected utilization required by Item (3) of this Rule in Section Q, Form C.2
- (5) project that the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC shall perform during the third full fiscal year of operation following completion of the project either:
 - (a) 6,750 or more ESTVs per LINAC; or
 - (b) serve 250 or more patients per LINAC.
- C- In Section Q, the applicant projected that each of the existing identified in Items (1) and (2) of this Rule and the proposed LINAC shall serve 257 or more patients per LINAC during the third full fiscal year of operation following completion of this project which exceeds the requirement to serve 250 or more patients per LINAC during the third full fiscal year of operation as required by this Rule.