

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: May 29, 2020
Findings Date: May 29, 2020

Project Analyst: Tanya M. Saporito
Team Leader: Fatimah Wilson

Project ID #: O-11856-20
Facility: New Hanover Regional Medical Center
FID #: 943372
County: New Hanover
Applicant: New Hanover Regional Medical Center
Project: Replace one existing linear accelerator

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

New Hanover Regional Medical Center (“NHRMC” or “the applicant”) proposes to replace one existing linear accelerator located at NHRMC Radiation Oncology – 16th Street in Wilmington.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations that are applicable to this review.

Policies

There is one policy in the 2020 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4 on page 31 of the 2020 SMFP states:

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

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

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

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 22, the applicant explains why it believes its application is consistent with Policy GEN-4. The applicant states that NHRMC is committed to environmental responsibility and will manage utility consumption and sustainability. The applicant lists several examples of strategies it may use in support of those plans on page 22. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The applicant does not propose to develop any beds, services or equipment for which there is a need determination in the 2020 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 as stated above.

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to replace one existing linear accelerator located at NHRMC Radiation Oncology – 16th Street in Wilmington. The applicant currently owns and operates four linear accelerators, three of which are located in New Hanover County and one of which is located in Brunswick County.

As reported on NHRMC's 2020 License Renewal Application (LRA), NHRMC is licensed to operate the hospital known as New Hanover Regional Medical Center, License #H0221. NHRMC consists of two separate campuses and 16 entities licensed under the same hospital license, as shown in the following table:

NAME OF FACILITY	LOCATION
NHRMC – Main Campus	2131 South 17 th Street, Wilmington
NRMC Behavioral Health Hospital	2131 South 17 th Street, Wilmington
NHRMC Rehabilitation Hospital	2131 South 17 th Street, Wilmington
NHRMC Orthopedic Hospital	5301 Wrightsville Ave., Wilmington
NHRMC Emergency Department North	151 Scotts Hill Medical Dr., Wilmington
Coastal Family Medicine	2523 Delaney Avenue, Wilmington
Independence Rehabilitation Center	2800 Ashton Dr., Wilmington
NHRMC Medical Hall	2243 S. 17 th Street, Wilmington
NHRMC Health & Diagnostic – Brunswick Forest	1333 S. Dickinson Dr., Leland
NHRMC Health & Diagnostic – Military Cutoff	1135 Military Cutoff Rd., Wilmington
NHRMC Health & Diagnostic – North Campus	151 Scotts Hill Medical Dr., Wilmington
Oleander Rehabilitation Center	5220 Oleander Dr., Wilmington
NHRMC Atlantic Surgicenter	9104 Market Street, Wilmington
NHRMC Heart Center – Outpatient Services	1415 Physicians Dr., Wilmington
NHRMC Physician Specialists	1725 New Hanover Medical Park, Wilmington
NHRMC Radiation Oncology – 16 th Street	1988 S. 16 th Street, Wilmington
NHRMC Radiation Oncology - Supply	545 Ocean Highway W., Supply
NHRMC Health & Diagnostic - Jacksonville	2000 Brabham Avenue, Jacksonville
NHRMC – Nunnelee Pediatric Specialty Clinics	510 Carolina Bay Dr., Wilmington

*Source: NHRMC 2020 Hospital License Renewal Application

NHRMC owns and operates three linear accelerators on two campuses in Wilmington, and one linear accelerator at the Brunswick County campus in Supply.

The applicant proposes to replace the existing linear accelerator at NHRMC Radiation Oncology – 16th Street. That linear accelerator was first installed in 2001 and has operated continuously since then, but has now reached the end of its useful life. The applicant proposes to replace this linear accelerator with a Varian Edge Radiosurgery System.

Patient Origin

In Chapter 17, page 400, the 2020 SMFP states, “*Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of a linear accelerator service areas... .*” NHRMC is located in New Hanover County. In Table 17C-1, page 403 of the 2020 SMFP, New Hanover County is included in Linear Accelerator Service Area 19 and is the only county in Linear Accelerator Service Area 19. Thus, the service area is New Hanover County. Facilities may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 32-33, the applicant provides historical and projected patient origin for the first three full fiscal years (FY) following project completion, as illustrated in the following table:

COUNTY	LAST FULL FY (10/1/18 – 9/30/19)		1 ST FULL FY (10/1/21 – 9/30/22)		2 ND FULL FY (10/1/22 – 9/30/23)		3 RD FULL FY (10/1/23 – 9/30/24)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
New Hanover	600	38.8%	701	38.8%	738	38.8%	777	38.8%
Brunswick	563	36.4%	657	36.4%	692	36.4%	729	36.4%
Pender	135	8.7%	158	8.7%	166	8.7%	175	8.7%
Columbus	72	4.7%	84	4.7%	89	4.7%	93	4.7%
Subtotal	1,370	88.7%	1,600	88.7%	1,684	88.7%	1,774	88.7%
In-Migration*	175	11.3%	204	11.3%	215	11.3%	227	11.3%
Total	1,545	100.0%	1,804	100.0%	1,900	100.0%	2,000	100.0%

Source: application pages 32, 33
 Numbers may not sum due to rounding by Project Analyst

In Section C, page 33, the applicant shows calendar years as the three project years. However, in Form C, Utilization, and in the financial Pro Forma forms, the applicant shows fiscal years as its interim and project years. In Section L, the projected payor mix is provided in a table that shows the project years as fiscal years. Additionally, the historical data is provided in fiscal years. Therefore, the Project Analyst concludes that the calendar year references provided in the table on page 33 is a typographical error, and the table above represents the Project Analyst’s correction to reflect the project years as fiscal years.

In Section C, page 33, the applicant provides the assumptions and methodology used to project patient origin, which it states is based on the historical patient origin for radiation oncology services at NHRMC. The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s historical experience providing the same service.

Analysis of Need

In Section C.4, pages 34-39, the applicant explains why it believes the population projected to utilize the proposed linear accelerator service needs that service. On page 34, the applicant states:

“NHRMC proposes to acquire a Varian Edge linear accelerator to meet the internal need of the medical center to replace a 19-year old linear accelerator that has reached the end of its useful life. The proposed system will:

- *Meet the current demand for radiation oncology services and will achieve sufficient volumes to maintain its operation in New Hanover County.*
- *Maintain patient access and throughput to radiation oncology services in the service area.”*

On pages 35-39, the applicant states that the need the patients have for the proposed project results from the following main factors:

- Service area population growth trends – the applicant examined historical population growth of all age groups in New Hanover County and in all of Linear Accelerator Service Area 19, which includes New Hanover, Brunswick, Columbus and Pender counties. The applicant determined that the age groups most likely to need radiation oncology services (45-64 and 65+) are projected to grow faster than other population cohorts from 2020-2025 (pages 35-36).
- Growth in NHRMC physician groups – the applicant states NHRMC actively recruits in selected specialties based on its own internal criteria. The applicant states NHRMC's medical staff has increased from 470 to 678 over the past ten years and anticipates adding 15 physicians in the next six months (page 37).
- NHRMC Accountable Care Organization - The applicant began operating an Accountable Care Organization (ACO) called "*Physician Quality Partners*" in January 2014 to aid in containing healthcare costs and improving healthcare quality. The applicant states that an ACO operates most efficiently when it is formed around strong primary care, specialty and hospital physician-led alliances, and that NHRMC's ACO meets these criteria. A strong ACO will aid in the delivery of quality radiation oncology services (page 38).
- NHRMC radiation oncology utilization – the applicant states NHRMC has experienced utilization growth in all of its inpatient and outpatient services; and a 22.7% increase in radiation oncology treatments from FY 2017 to FY 2019 (page 39).
- NHRMC radiation oncology market share - NHRMC maintains over 90% of the radiation oncology market share in Linear Accelerator Service Area 19, since it is the only hospital in the area and the only provider of radiation oncology services (page 39).

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

- The service area population 65+ age cohort is projected to grow 15.9% between 2020 and 2025.
- The population group of 65+ who utilize the proposed services experiences a higher cancer diagnosis than younger patients.
- The population growth for the 65+ cohort in Linear Accelerator Service Area 19 is projected to be 17% from 2020 to 2025.
- The applicant determined that radiation oncology treatments at NHRMC increased by an average annual change rate of 10.6% from FY 2017 to FY 2019.

- The existing linear accelerator has reached the end of its useful life after 19 years, despite software and hardware upgrades.

Projected Utilization

In Section Q, Form C, the applicant provides a table showing the historical and projected utilization for the NHRMC linear accelerators through the first three full fiscal years following completion of the project, FY 2022 – FY 2024, summarized as follows:

NHRMC Historical Radiation Oncology Treatments

LOCATION	HISTORICAL			AVERAGE ANNUAL CHANGE	50% OF AVERAGE ANNUAL CHANGE
	FY 2017	FY 2018	FY 2019		
NHRMC Main Campus	1,024			10.6%	5.3%
NHRMC 16 th Street	18,961	19,920	21,046		
NHRMC Brunswick County	4,005	6,609	8,380		
Total	23,990	26,529	29,426		
Annual Change		10.6%	10.7%		

In clarifying information, the applicant states the linear accelerator that was on the NHRMC main campus was relocated to the NHRMC-16th Street location in 2016; therefore, there is no utilization data for the main campus location after FY 2017.

The applicant projects future utilization based on on-half of the average annual change rate (AACR) calculated above, as illustrated in the following table from page 44:

NHRMC Projected Radiation Oncology Treatments

	50% OF HISTORICAL AACR	INTERIM YEAR 1	INTERIM YEAR 2	PY 1	PY 2	PY 3
		FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Radiation Oncology Treatments	5.3%	30,986	32,628	34,357	36,178	38,095

In Section C, pages 43-44, the applicant provides its assumptions and methodology for projecting utilization of the existing linear accelerators and the proposed replacement linear accelerator.

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

- Projected utilization is based on the applicant’s historical experience with the existing linear accelerators at NHRMC campuses.
- The applicant documents the projected population growth in the population groups most likely to need radiation oncology services.

- The applicant uses one-half of the actual average annual change rate experienced by NHRMC radiation oncology services from FY 2017 to FY 2019 to project future radiation oncology utilization.
- NHRMC is the only provider of radiation oncology services in Linear Accelerator Service Area 19.

Access

In Section C, page 45, the applicant states NHRMC does not discriminate against any class of patient based on ability to pay, race, ethnicity, sex, handicap or age. In Section L, page 81, 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:

NHRMC Projected Payor Mix, FY 2024

PAYOR CATEGORY	NHRMC ENTIRE CAMPUS SERVICES AS % OF TOTAL	RADIATION ONCOLOGY SERVICES AS % OF TOTAL
Self-Pay	9.7%	2.3%
Medicare*	28.2%	47.5%
Medicaid*	17.6%	5.8%
Insurance*	36.7%	39.4%
TRICARE	2.8%	1.0%
Other	4.9%	4.0%
Total	100.0%	100.0%

*Includes Managed Care plans
Totals may not sum due to rounding

The projected payor mix is reasonable and adequately supported because it is based on the applicant’s historical payor mix for the same 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 identifies the population to be served.
- The applicant adequately explains why the population to be served needs the replacement linear accelerator proposed in this application.
- Projected utilization is reasonable and adequately supported.

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

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

NA

The applicant does not propose to reduce 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 replace one existing linear accelerator located at NHRMC Radiation Oncology – 16th Street in Wilmington that has reached the end of its useful life after 19 years of operation.

In Section E, page 57, the applicant states it is one of three providers of radiation oncology services in the state with three or more linear accelerators that are highly utilized. The unit proposed to be replaced has reached the end of its useful life; and since it is not located on the main hospital campus, a certificate of need is required. Therefore, there were no alternatives considered for this application.

Conclusion

The Agency reviewed the:

- application
- exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. New Hanover Regional Medical Center shall materially comply with all representations made in the certificate of need application.**
 - 2. New Hanover Regional Medical Center shall acquire no more than one linear accelerator to replace one existing linear accelerator located on the NHRMC Radiation Oncology-16th Street campus. The applicant shall dispose of the existing linear accelerator being replaced by removing it from North Carolina.**
 - 3. Upon completion of the project, New Hanover Regional Medical Center shall be licensed for no more than four linear accelerators.**
 - 4. New Hanover Regional Medical Center shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
 - 5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, New Hanover Regional Medical Center 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.**
 - 6. New Hanover Regional Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to replace one existing linear accelerator located at NHRMC Radiation Oncology – 16th Street in Wilmington.

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:

ITEM	COST
Site Costs	\$0
Construction Costs	\$64,500
Medical Equipment	\$2,844,619
Miscellaneous Costs	\$188,900
Total	\$3,098,019

In Section F.3, page 61, the applicant states that there are no start-up or initial operating expenses, as this is not a new service.

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

Availability of Funds

In Section F.2, page 59, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	TOTAL
Loans	
Cash / Investments or OE *	\$3,098,019
Bonds	
Other (Specify)	
Total Financing	\$3,098,019

*OE = Owner's Equity

In Section F, page 60, the applicant states it will use cash and investments to fund the capital cost of the project. In Exhibit F.2, the applicant provides a February 10, 2020 letter from NHRMC's Chief Financial Officer that confirms the availability of the funds and the commitment of the funds to the project. The applicant also provides NHRMC's audited financial statements from years ending 2018 and 2019 in Exhibit F.2.

Financial Feasibility

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

	1 ST FULL FY FY 2022	2 ND FULL FY FY 2023	3 RD FULL FY FY 2024
Total ESTV Treatments (From Form C)	33,240	35,002	36,857
Total Gross Revenues (Charges)	\$115,566,781	\$127,338,321	\$140,308,901
Total Net Revenue	\$22,870,666	\$23,513,021	\$24,175,224
Average Net Revenue per ESTV Txt	\$688	\$672	\$656
Total Operating Expenses (Costs)	\$1,7789,551	\$18,162,100	\$18,543,138
Average Operating Expense per ESTV Txt	\$535	\$519	\$503
Net Income	\$5,081,115	\$5,350,921	\$5,632,086

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) 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.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

The applicant proposes to replace one existing linear accelerator located at NHRMC Radiation Oncology – 16th Street in Wilmington.

In Chapter 17, page 400, the 2020 SMFP states, “*Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of a linear accelerator service areas... .*” NHRMC is located in New Hanover County. In Table 17C-1, page 403 of the 2020 SMFP, New Hanover County is included in Linear Accelerator Service Area 19 and is the only county in Linear Accelerator Service Area 19. Thus, the service area is New Hanover County. Facilities may serve residents of counties not included in their service area.

There are four existing linear accelerators in Linear Accelerator Service Area 19, all of which are owned by the applicant. The following table identifies the number of linear accelerators and average utilization of each of the linear accelerators, as shown in Table 17C-5, page 410 of the 2020 SMFP:

LINEAR ACCELERATOR SERVICE AREA	# LINEAR ACCELERATORS	2017 – 2018 ESTV PROCEDURES	# PROCEDURES PER ACCELERATOR
Service Area 19	4	27,747	6,937

The applicant proposes to replace one existing linear accelerator located at the NHRMC Radiation Oncology – 16th Street campus; therefore, the applicant does not propose to increase the inventory of linear accelerators in the service area.

In Section G, page 65, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved linear accelerator services in in linear accelerator service Area 19. The applicant states:

“NHRMC must replace an existing linear accelerator because it has reached the end of its useful life and NHRMC is the only provider of radiation oncology services in Service Area 19.”

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 proposes to replace an existing, well-utilized 19-year old linear accelerator that has reached the end of its useful life with comparable equipment to serve its oncology patients.
- The proposal would not result in an increase in the number of linear accelerators in the service area.
- The applicant adequately demonstrates that the proposed replacement linear accelerator is needed in addition to the existing or approved linear accelerators.

Conclusion

The Agency reviewed the:

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

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

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

C

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

POSITION	HISTORICAL # FTEs	PROJECTED # FTEs		
	10/1/18 – 9/30/19	PY 1 (10/1/21 – 9/30/22)	PY 2 (10/1/22 – 9/30/23)	PY 3 (10/1/23 – 9/30/24)
Mgr Radiation Therapy	1.00	1.00	1.00	1.00
Coord Cash Applications	1.01	0.86	0.86	0.86
Staff Nurse	7.60	6.75	6.75	6.75
Chief Radiation Therapist	2.00	2.04	2.04	2.04
Radiation Therapist	15.80	14.82	14.82	14.82
Radiology Tech	0.02	0.00	0.00	0.00
Dosimetrist	5.00	4.45	4.45	4.45
Simulation Technologist	1.01	1.13	1.13	1.13
Physicist I	0.60	0.56	0.56	0.56
Physicist II	2.00	3.12	3.12	3.12
Physicist II – Radiation Safety	1.00	0.94	0.94	0.94
Lead Dosimetrist	1.00	0.94	0.94	0.94
Cash Applications Tech	2.05	1.72	1.72	1.72
Info. Release Specialist	1.06	0.86	0.86	0.86
Patient Accounts Tech	0.66	0.86	0.86	0.86
Patient Access Tech	4.93	4.64	4.64	4.64
Radiation Therapy Liaison	1.12	0.86	0.86	0.86
Financial Counselor	2.03	2.06	2.06	2.06
Medical Assistant	0.50	0.00	0.00	0.00
Total	50.39	47.61	47.61	47.61

The assumptions and methodology used to project staffing are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 67 and 68, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 72, the applicant identifies the current medical director. In Exhibit I.3, the applicant provides a letter from the medical director in which he indicates an interest in continuing to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 for the reasons stated above.

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

C

In Section I, page 70, the applicant states that the following ancillary and support services are necessary for the proposed services

- Billing, Accounts Payable, General Accounting
- Business Office/Admitting
- Facility Management
- Human Resources/Wage and Benefits
- Information Management
- Legal Services
- Materials Management
- Medical Record Services
- Planning and Marketing
- Precertification and Insurance
- Purchasing
- Quality Management and Infection Control
- Risk Management and Utilization Review
- Scheduling

- Staff Education

On page 70, the applicant adequately explains that each ancillary and support service is already available at NHRMC and provides supporting documentation in Exhibit I.1.

In Section I, pages 71-72, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibits I.2 and I.3.

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

Conclusion

The Agency reviewed the:

- application
- exhibits to the application

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;

- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

C

In Section K, page 75, the applicant states that the project involves renovating 576 square feet of existing space to accommodate the new linear accelerator. Line drawings are provided in Exhibit K.2.

On page 75 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal, and 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.

On page 76, 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.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and

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

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

C

In Section L, page 80, the applicant provides the historical payor mix during FY 2018 for the proposed services, as shown in the table below:

NHRMC Historical Payor Mix

PAYOR SOURCE	ENTIRE NHRMC CAMPUS	RADIATION ONCOLOGY
Self-Pay	9.7%	2.3%
Medicare*	28.2%	47.5%
Medicaid*	17.6%	5.8%
Insurance*	36.7%	39.4%
TRICARE	2.8%	1.0%
Other	4.9%	4.0%
Total	100.0%	100.0%

*Includes managed care plans

Totals may not sum due to rounding

In Section L, page 79, the applicant provides the following comparison.

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	48.3%	52.3%
Male	51.7%	47.7%
Unknown	0.0%	0.0%
64 and Younger	37.1%	82.3%
65 and Older	62.9%	17.7%
American Indian	0.1%	0.6%
Asian	0.3%	1.6%
Black or African-American	11.7%	13.7%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	84.7%	77.45
Other Race	1.8%	6.6%
Declined / Unavailable	1.4%	0.0%

The Agency reviewed the:

- application
- exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 80, the applicant states: "*NHRMC is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access my minorities and handicapped persons.*"

In Section L, page 80, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L, page 81, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below:

NHRMC Projected Payor Mix FY 2024

PAYOR SOURCE	ENTIRE NHRMC CAMPUS	RADIATION ONCOLOGY
Self-Pay	9.7%	2.3%
Medicare*	28.2%	47.5%
Medicaid*	17.6%	5.8%
Insurance*	36.7%	39.4%
TRICARE	2.8%	1.0%
Other	4.9%	4.0%
Total	100.0%	100.0%

*Includes managed care plans

Totals may not sum due to rounding

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 9.7% of total services and 2.3% of radiation oncology services will be provided to self-pay patients, 28.2% and 47.5% respectively to Medicare patients and 17.6% and 5.8% respectively to Medicaid patients.

On page 81, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project, stating that the payor mix is not projected to change. The projected payor mix is reasonable and adequately supported because it is based on the applicant's experience providing radiation oncology services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L, page 82, the applicant adequately describes the range of means by which patients will have access to the proposed services, which is by physician referral.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section M, page 84, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

The applicant proposes to replace one existing linear accelerator located at NHRMC Radiation Oncology – 16th Street in Wilmington.

In Chapter 17, page 400, the 2020 SMFP states, “*Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of a linear accelerator service areas... .*” NHRMC is located in New Hanover County. In Table 17C-1, page 403 of the 2020 SMFP, New Hanover County is included in Linear Accelerator Service Area 19 and is the only county in Linear Accelerator Service Area 19. Thus, the service area is New Hanover County. Facilities may serve residents of counties not included in their service area.

There are four existing linear accelerators in Linear Accelerator Service Area 19, all of which are owned by the applicant. The following table identifies the number of linear accelerators and average utilization of each of the linear accelerators, as shown in Table 17C-5, page 410 of the 2020 SMFP:

NHRMC Linear Accelerators

LINEAR ACCELERATOR SERVICE AREA	# LINEAR ACCELERATORS	2017 – 2018 ESTV PROCEDURES	# PROCEDURES PER ACCELERATOR
Service Area 19	4	27,747	6,937

The applicant proposes to replace one existing linear accelerator located at the NHRMC Radiation Oncology – 16th Street campus; therefore, the applicant does not propose to increase the inventory of linear accelerators in the service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 86, the applicant states:

“NHRMC expects the development of the replacement of the existing linear accelerator to have a positive or at least neutral effect on competition in the service area [because t]he linear accelerator will be located in NHRMC, which is the only hospital in New Hanover County and the only hospital in the service area that offers radiation therapy.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 86, the applicant states:

“The cost effectiveness would be an easy measure if radiation oncology providers reported their charges and costs per treatment, etc. However, this data is not publicly reported and usually only available when a provider or potential provider submits a CON application in North Carolina.”

Regarding the impact of the proposal on quality, in Section N, pages 86-87, the applicant states:

“Quality at NHRMC is derived from its commitment to excellence in all aspects of are throughout the healthcare system. ... Quality goals, measures, and efforts are disseminated and decided during hospital board retreats and education sessions.

...

Quality is a core value at NHRMC. Its mission statement, read at the beginning of every meeting of the Board of Trustees and its subcommittees, features a commitment to quality.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 87, the applicant states:

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

Considering all the information in the application, 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 (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q, Form A, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three hospitals located in North Carolina.

In Section O, page 92, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. 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, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all NHRMC facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

NA

The applicant proposes to replace an existing linear accelerator on NHRMC's Radiation Oncology – 16th Street campus. The Criteria and Standards for Radiation Therapy Equipment, which are promulgated in 10A NCAC 14C .1900, are not applicable to this review because the applicant does not propose to acquire a new linear accelerator. Therefore, Criterion (21) is not applicable to this review.