

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 1, 2023

Findings Date: December 1, 2023

Project Analyst: Julie M. Faenza

Co-Signer: Mike McKillip

Project ID #: F-12429-23

Facility: Matthews Radiation Oncology Center

FID #: 190631

County: Mecklenburg

Applicant: Radiation Oncology Centers of the Carolinas, LLC

Project: Replace an existing LINAC

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.

NA

Radiation Oncology Centers of the Carolinas, LLC (hereinafter referred to as "ROCC" or "the applicant") proposes to replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center ("MROC"), its existing cancer treatment facility.

The applicant does not propose to acquire any medical equipment for which there is a need determination in the 2023 State Medical Facilities Plan (SMFP) and does not propose to offer a new institutional health service for which there are any applicable policies in the 2023 SMFP. Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which

all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center (MROC).

Patient Origin

In Chapter 17, page 311, the 2023 SMFP defines a linear accelerator’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 319 shows Anson, Mecklenburg, and Union counties in the Service Area 7 multicounty grouping. Thus, the service area for this project consists of Anson, Mecklenburg, and Union counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

Projected Patient Origin – CHCC-Asheboro – FYs 1-3 (FFYs* 2025-2027)								
Counties	Historical – FFY 2022		FY 1 – FFY 2025		FY 2 – FFY 2026		FY 3 – FFY 2027	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Mecklenburg	610	55.2%	627	55.2%	627	55.2%	627	55.2%
Union	411	37.2%	422	37.2%	422	37.2%	422	37.2%
Other counties/states	85	7.6%	86	7.6%	86	7.6%	86	7.6%
Total	1,106	100.0%	1,136	100.0%	1,136	100.0%	1,136	100.0%

Source: Section C, pages 32-33

*FFY = Federal Fiscal Year (October 1 – September 30)

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

Analysis of Need

In Section C, pages 25 and 37-43, the applicant explains the reasons why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below.

- The existing LINAC is 19 years old, while the average lifespan of a typical LINAC is 10-12 years old. It also lacks the ability to provide stereotactic body radiation therapy, which is now a standard of care for certain types of radiation oncology, and also lacks the ability to provide volumetric modulated arc radiotherapy. Replacing an existing LINAC will allow the applicant to purchase a newer LINAC which has those capabilities. (page 25)

- In both Mecklenburg and Union counties, the population aged 65 and older has historically grown at a faster rate and is projected to grow at a faster rate than any other age cohort. According to information from the North Carolina Central Cancer Registry, there is a much higher incidence rate of cancer and mortality rate from cancer in the population aged 65 and older than there is in any other population cohort. (pages 37-38)
- In both Mecklenburg and Union counties, for the population aged 65 and older, nearly every age cohort broken out by gender and race has experienced an increase in life expectancy as compared to 1990-1992. The applicant states that increase in life expectancy increase the chance of cancer incidence and mortality. (pages 39-41)
- According to the North Carolina Central Cancer Registry, Mecklenburg and Union counties will see an increase in incidence of several types of cancer as well as an increase in mortality from several different types of cancer. The applicant states that an increase in the number of cancer cases has a direct impact on the need for radiation therapy. (pages 41-42)
- Utilization of LINAC services at MROC has increased overall between FFY 2018 and FFY 2023 annualized, even with the COVID-19 pandemic potentially impacting utilization. (page 43)

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

- The applicant provides information to support the need for continued radiation therapy services based on likely increases in population and cancer incidence.
- The applicant’s utilization has been increasing over time.
- The applicant is not proposing to add any new services; rather, the applicant is proposing to replace an existing LINAC with an upgraded model.

Projected Utilization

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

MROC – LINAC Historical & Projected Utilization					
	Historical FFY 2022	FFY 2023 Annualized	FY 1 FFY 2025	FY 2 FFY 2026	FY 3 FFY 2027
# Units*	2	2	2	2	2
# ESTV** Treatments	11,087	13,912	13,912	13,912	13,912

*Forms C.2a and C.2b list only one LINAC; however, MROC has two existing LINACs.

**ESTV = Equivalent Simple Treatment Visits

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

- The applicant examined the historical utilization of Equivalent Simple Treatment Visits (ESTVs) at MROC. The applicant determined that while utilization decreased slightly between FFY 2018 and FFY 2019, utilization has increased each year between FFY 2019 and FFY 2022.
- The applicant projects total ESTVs for FFY 2023 annualized by dividing the number of ESTVs during the first nine months of FFY 2023 to obtain a monthly average and then multiplied that number by 12 months.
- The applicant projected utilization would remain constant during the first three full fiscal years following project completion.

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

- The applicant relies on its own existing utilization to project future utilization.
- The applicant conservatively projects no growth in utilization despite historical growth in utilization.
- The applicant is proposing to provide the same services in the same location as it does now.

Access to Medically Underserved Groups

In Section C, page 49, the applicant states:

“ROCC does not exclude from participation, deny benefits to, or otherwise discriminate against patients, students, or visitors on the basis of race; color; religion; national origin; culture; language; physical or mental disability; age; sex, including pregnancy, childbirth or related medical conditions; marital status; sexual orientation; gender identity or expression; socioeconomic status; source of payment; or any other protected status in admission to, participation in, or receipt of the services and benefits of any of its programs and activities.”

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

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	4.3%
Racial and ethnic minorities	33.8%
Women	47.5%
Persons 65 and older	64.2%
Medicare beneficiaries	54.1%
Medicaid recipients	3.1%

Source: Section C, page 49

On page 49, the applicant states it does not track usage by persons with disabilities.

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

- The applicant provides a statement saying it will provide service to all residents of the service area and that the current level of access by medically underserved groups will not be altered by the proposed project.
- The applicant provides documentation of its existing policies regarding non-discrimination and charity care in Exhibit C.6.

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 replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center (MROC).

In Section E, page 60, the applicant states that there were no alternative methods available to the applicant to meet the need for the proposal. The applicant states:

“..., ROCC began providing radiation therapy services in a freestanding setting, MROC, in 1997. For the last 19 years, a Varian 21EX-d linear accelerator has been providing radiation oncology services. In the United States, the typical life of a linear accelerator is 10-12 years. This existing linear accelerator is increasingly becoming more problematic with replacing original parts and computer boards. If a major part replacement is necessary, then the linear accelerator will be non-operational until the part is replaced, which translates into machine downtime and impacts patient care as all treatments will be cancelled until the machine is once again operational.

...

Replacing the existing linear accelerator is the only alternative available to maintain the linear accelerator unit inventory in Linear Accelerator Service Area 7 and to continue providing radiation therapy at MROC and within the Matthews community.”

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

- The applicant provides reasonable information to explain why it believes it has no other alternative to develop the proposed project.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

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

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

1. **Radiation Oncology Centers of the Carolinas, LLC (herein after “the certificate holder”) shall materially comply with all representations made in the certificate of need application.**
 2. **The certificate holder shall replace an existing linear accelerator with a new linear accelerator.**
 3. **Upon project completion, Matthews Radiation Oncology Center will be licensed for no more than two linear accelerators.**
 4. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project’s proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 5. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **The first progress report shall be due on April 1, 2024.**
 6. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center (MROC).

Capital and Working Capital Costs

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

Construction/Renovation Contract(s)	\$387,415
Architect/Engineering Fees	\$59,600
Medical Equipment	\$1,871,207
Consultant Fees	\$39,402
Physics and SBRT Equipment/Tax	\$178,250
Total	\$2,535,874

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

- In Exhibit F.1, the applicant provides a quote for the linear accelerator which matches the amount listed on Form F.1a (the quote does not include tax; Form F.1a does).
- In Exhibit F.1, the applicant also provides a construction cost breakdown dated August 14, 2023 from Keach Construction, which is equal to the construction cost listed on Form F.1a.

In Section F, page 63, the applicant states that there are no projected start-up expenses or initial operating expenses because the project does not involve a new service. This information is reasonable and adequately supported because MROC is an existing facility that currently offers LINAC services and is only proposing to replace an existing LINAC.

Availability of Funds

In Section F, pages 61-62, the applicant states the entire projected capital expenditure of \$2,535,874 will be funded through a loan.

In Exhibit F.2, the applicant provides a letter dated September 12, 2023 from the president of ROCC, stating that ROCC plans to fund the development of the proposed project with a loan, and committing the loan funding to developing the project.

Exhibit F.2 also contains a letter dated August 24, 2023 from a Senior Vice President at First Citizens Bank, offering to consider providing a loan of up to \$2.6 million to fund the proposed project. The applicant includes an amortization table for the loan immediately following the letter from First Citizens Bank.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from an appropriate ROCC official committing the loan funding to developing the proposed project.
- The applicant provides a letter from an established bank with an offer to consider providing financing and an amortization table.

Financial Feasibility

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

Revenues and Operating Expenses – MROC			
	FY 1 (FFY 2025)	FY 2 (FFY 2026)	FY 3 (FFY 2027)
Total Patients	1,136	1,136	1,136
Total Gross Revenues (Charges)	\$31,062,174	\$31,994,039	\$32,953,860
Total Net Revenue	\$11,716,652	\$12,068,152	\$12,430,196
Total Net Revenue per Patient	\$10,314	\$10,623	\$10,942
Total Operating Expenses (Costs)	\$7,401,045	\$7,561,873	\$7,725,920
Total Operating Expenses per Patient	\$6,515	\$6,657	\$6,801
Net Profit/(Loss)	\$4,315,608	\$4,506,279	\$4,704,276

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center (MROC).

In Chapter 17, page 311, the 2023 SMFP defines a linear accelerator’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 319 shows Anson, Mecklenburg, and Union counties in the Service Area 7 multicounty grouping. Thus, the service area for this project consists of Anson, Mecklenburg, and Union counties. Facilities may also serve residents of counties not included in their service area.

According to Table 17C-1 on page 314 of the 2023 SMFP, there are seven facilities with 11 existing and approved LINACs in Service Area 7. Information about each facility is shown in the table below.

Service Area 7 Existing and Approved Linear Accelerators				
Facility	County	# of LINACs	Total ESTVs	Average ESTVs per LINAC
Atrium Health Pineville	Mecklenburg	1	11,783	11,783
Atrium Health University City	Mecklenburg	1	8,089	8,089
Carolinas Medical Center	Mecklenburg	3	18,235	6,078
Matthews Radiation Oncology Center	Mecklenburg	2	11,071	5,535
Novant Health Huntersville Medical Center	Mecklenburg	1	9,013	9,013
Novant Health Presbyterian Medical Center	Mecklenburg	2	12,895	6,448
Atrium Health Union	Union	1	8,080	8,080
Total		11	79,166	7,197

In Section G, page 71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Service Area 7. The applicant calculates the number of LINACs that are “needed” based on the amount of ESTVs performed at each facility divided by the number of LINACs at each facility (as reported in the Proposed 2024 SMFP). The applicant concludes, based on its calculations, that the proposal would not result in the unnecessary duplication of existing linear accelerator services in Service Area 7 because each facility operates an appropriate number of LINACs based on how many ESTVs are performed at each facility.

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

- The applicant is not proposing to add any new linear accelerators to Service Area 7.

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

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center (MROC).

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.

MROC Current & Projected FTE Staffing		
	Current (as of 7/12/2023)	FYs 1-3 – FFYs 2025-2027
Administrative	1.0	1.0
Secretary	2.0	2.0
Oncology Nurse	2.0	2.0
Medical Dosimetrist	2.0	2.0
Radiation Therapist	7.2	7.2
Total	14.2	14.2

The assumptions and methodology used to project staffing are provided at the end of Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 73-74, the applicant states existing staff will continue to work at the facility and describes its existing training and continuing education programs. Supporting documentation is provided in Exhibit H.3.

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

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.

- The applicant accounts for projected salaries and other costs of employment for FTEs in its projected operating expenses found on Form F.3b in Section Q.
- The applicant provides its policies related to education and staff qualifications in Exhibit H.3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center (MROC).

Ancillary and Support Services

In Section I, page 76, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 77-78, the applicant explains how each ancillary and support service is made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant is currently providing the necessary ancillary and support services for the same services it will continue to offer.
- In Exhibit I.1, the applicant provides a letter dated September 10, 2023, from the president of ROCC, attesting to the existence of the necessary ancillary and support services at MROC and committing to continue to provide the necessary ancillary and support services for the proposed project.

Coordination

In Section I, page 78, the applicant describes its existing relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed

services will be coordinated with the existing health care system because the applicant operates an existing facility that has established relationships in the community.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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.

NA

The applicant does not propose to construct any new space or to make more than minor renovations to existing space. Therefore, Criterion 12 is not applicable to this review.

- (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 85, the applicant provides the historical payor mix during the last full fiscal year at MROC, as shown in the table below.

Historical Payor Mix – MROC – FFY 2022	
Self-Pay	0.9%
Charity Care	0.2%
Medicare*	54.1%
Medicaid*	3.1%
Insurance*	39.8%
Other Governmental	1.9%
Total	100.0%

*Including any managed care plans.

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

MROC	% of Total Patients Served During FFY 2022	% of Population of Service Area
Female	47.5%	51.3%
Male	52.5%	48.7%
Unknown	0.0%	0.0%
64 and Younger	35.8%	87.4%
65 and Older	64.2%	12.6%
American Indian	0.0%	0.9%
Asian	2.0%	6.3%
Black or African-American	10.7%	29.8%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	66.2%	49.1%
Other Race	4.6%	13.9%
Declined / Unavailable	16.5%	0.0%

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 87, the applicant states it has no such obligation.

In Section L, page 87, the applicant states that no patient civil rights access complaints have been filed against MROC during the 18 months immediately prior to submission of the application.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

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

Projected Payor Mix – MROC – FFY 2027	
Self-Pay	1.2%
Medicare*	54.1%
Medicaid*	3.1%
Insurance*	39.8%
Other Governmental	1.9%
Total	100.0%

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 1.2% of services will be provided to self-pay patients, 54.1% of services to Medicare patients, and 3.1% of services to Medicaid patients.

In Section L, page 89, the applicant states it makes no distinction between charity care and reduced cost patients. The applicant states that the projected payor mix includes patients who will receive reduced cost services.

In Section L, pages 88-89, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year following project completion. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects its payor mix based on its historical payor mix.
- The applicant will continue to offer the same services it offered historically after project completion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 89, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center (MROC).

In Section M, page 91, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant states it has existing clinical education agreements with health professional training programs in the area.
- MROC is an established facility that will continue to offer the same services after project completion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center (MROC).

In Chapter 17, page 311, the 2023 SMFP defines a linear accelerator's service area as "...one of the 28 multicounty groupings described in the Assumptions of the Methodology." Table 17C-4 on page 319 shows Anson, Mecklenburg, and Union counties in the Service Area 7 multicounty grouping. Thus, the service area for this project consists of Anson, Mecklenburg, and Union counties. Facilities may also serve residents of counties not included in their service area.

According to Table 17C-1 on page 314 of the 2023 SMFP, there are seven facilities with 11 existing and approved LINACs in Service Area 7. Information about each facility is shown in the table below.

Service Area 7 Existing and Approved Linear Accelerators				
Facility	County	# of LINACs	Total ESTVs	Average ESTVs per LINAC
Atrium Health Pineville	Mecklenburg	1	11,783	11,783
Atrium Health University City	Mecklenburg	1	8,089	8,089
Carolinas Medical Center	Mecklenburg	3	18,235	6,078
Matthews Radiation Oncology Center	Mecklenburg	2	11,071	5,535
Novant Health Huntersville Medical Center	Mecklenburg	1	9,013	9,013
Novant Health Presbyterian Medical Center	Mecklenburg	2	12,895	6,448
Atrium Health Union	Union	1	8,080	8,080
Total		11	79,166	7,197

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 93, the applicant states:

“ROCC expects the replacement of the existing linear accelerator to have a positive effect on competition in the service area because it will maintain the current capacity of linear accelerator services at MROC and thus the service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 93, the applicant states:

“To make the project operational, ROCC will purchase the Varian TrueBeam linear accelerator through an agreement with Varian, which it has a long-term relationship [sic].”

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

Regarding the impact of the proposal on quality, in Section N, pages 93-94, the applicant states:

“Quality at MROC is derived from its commitment to excellence in all aspects of care throughout the healthcare system. Quality care at the organization is provided by highly skilled and compassionate teams using advanced technology, treatment protocols, and carefully outlined safety and quality assurance standards based on the tenets that care is patient-centered, safe, timely, effective, efficient, and equitable.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 94, the applicant states:

“ROCC addresses the barriers to access in its daily operation. ROCC does not discriminate against any class of patient based on age, sex, religion, race, [disability], ethnicity, or ability to pay.

ROCC actively participates in both the Medicaid and Medicare programs. ...”

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

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center (MROC).

On Form O in Section Q, the applicant identifies the facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of two radiation oncology centers with LINACs located in North Carolina.

In Section O, page 97, the applicant states that during the 18 months immediately preceding the submittal of the application there were no incidents resulting in findings of immediate jeopardy at either of the two radiation oncology facilities identified in Form O. After reviewing and considering information provided by the applicant and considering the quality of care

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

(21) Repealed effective July 1, 1987.

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

NA

The applicant proposes to replace an existing linear accelerator (LINAC) at Matthews Radiation Oncology Center (MROC).

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