

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 26, 2020

Findings Date: March 26, 2020

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: F-11822-19

Facility: Matthews Radiation Oncology Center

FID #: 190631

County: Mecklenburg

Applicant(s): Radiation Oncology Centers of the Carolinas, LLC

Project: Acquire and replace a refurbished linear accelerator for a total of no more than two linear accelerators upon project completion

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

Radiation Oncology Centers of the Carolinas, LLC d/b/a Matthews Radiation Oncology Center (MROC), referred to hereinafter as “the applicant”, proposes to acquire and replace a refurbished linear accelerator for a total of no more than two linear accelerators at Matthews Radiation Oncology Center upon project completion.

Need Determination

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

Policies

There is one policy in the 2019 SMFP which is applicable to this review:

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities. Policy GEN-4 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, 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 proposed capital expenditure for this project is greater than \$5 million.

In Section B, page 14, the applicant explains why it believes its application is consistent with Policy Gen-4. On page 14, the applicant states:

“MROC will strive to obtain the most cost-effective materials that promote energy efficiency and water conservation. The applicant will monitor utility usage and energy consumption in order to ensure that the efficient and environmentally responsible mechanisms in place are effective.

...

The applicant will accept a CON condition of approval requiring the applicant to submit an Energy Efficiency and Sustainability Plan to the Agency’s Construction Section....”

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficient and water conservation.

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 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 2019 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy *Gen-4* based on the following:
 - The applicant describes the practices that will be implemented to sustainably manage energy efficiency and water conservation.
 - The applicant states that upon CON approval, it will submit an Energy Efficiency and Sustainability Plan to the Agency's Construction Section.

(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 acquire and replace a refurbished linear accelerator for a total of no more than two linear accelerators at Matthews Radiation Oncology Center.

The applicant states that Presbyterian Hospital, a subsidiary of Novant Health, has invested in a joint venture with Southeast Radiology Oncology (SERO), a large single specialty radiation oncology physician practice, to create Radiation Oncology of the Carolinas, LLC. The joint venture is part of Novant Health an MROC's efforts in providing high quality and comprehensive care to patients in the service area seeking cancer treatments. Radiation Oncology of the Carolinas, LLC., operates both MROC and Lake Norman Radiation Oncology Center. The applicant states that MROC currently has one highly utilized existing linear accelerator that is causing considerable capacity constraints at the facility. As part of the new joint venture and in order to address these capacity constraints, Novant Health has agreed to sell a grandfathered refurbished linear accelerator that is currently not in use to MROC.

In Chapter 9, page 127, the 2019 SMFP states, “A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.” In Table 9I, page 135 of the 2019 SMFP, Mecklenburg County is included in Linear Accelerator Service Area 7, which also includes Anson and Union counties. Providers may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin for the entire facility.

County	Last full FY 10/01/2017-9/30/2018		3 rd Full FY 1/1/2023-12/31/2023	
	Patients	% of Total	Patients	% of Total
Mecklenburg	275	54.78%	348	54.78%
Union	196	39.04%	249	39.04%
Other	31	6.18%	39	6.18%
Total	502	100.00%	635	100.00%

Source: Section C, pages 17-18

Note: On page 18, the projected patient origin table states that the first three operating years of the project is CY 2021, CY2022, and CY 2023. However, in Section Q, the applicant states that the first three operation years of the project are CY 2022, CY 2023, and CY 2024. However, based on the application in its entirety, it appears that the first three project years are CY 2022-CY2024.

In Section C, page 18, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states that the projected patient origin is based on the historical patient origin for radiation oncology services at MROC. The applicant does not anticipate any changes to patient origin during the first three years of the project.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 21-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, with the specific need for the project being comprised of several factors, including:

Service Area Aging and Population Growth (pages 21-23)

The applicant states that based on 2017 data from the North Carolina Office of State Budget and Management (NCOSBM), Mecklenburg and Union county population, the service area for the proposed project, is expected to grow at compound annual growth rate (CAGR) of 1.9 and 1.7 percent from 2019 to 2024, respectively. The applicant states that the 65 and older population is projected to grow at a 4.7 percent CAGR annually from 2019-2024.

In Section C, page 23, the applicant states:

“The growth of the 65 and older population is important because it is well known that the growth in older populations lead to increased demand for healthcare services, including cancer care service, like radiation therapy, as incidence rates of disease increase with age.... In fact, nearly 60 percent of the patients seen by MROC are aged 65 and older. Thus, it is anticipated that the significant growth and aging of the service area population will continue to increase demand for radiation therapy services.”

The applicant assumes that the significant growth and aging of the service area population will continue to increase demand for radiation therapy services.

MROC’s Primary Service Area and Population Growth (pages 23-25)

The applicant identified the primary service area as the area where over 75 percent of MROC patients reside, which consist of eight ZIP codes in Mecklenburg and Union County. The applicant used 2017 data from NCOSBM to determine that the 65 and older population in the primary service area ZIP codes is projected to increase by 4.73 percent and 4.66 percent annually, respectively, between 2019 and 2024. However, this population is projected to grow at a CAGR of 5.27 percent. The applicant assumes the demand for cancer services in the primary service area will likely grow at a faster rate than the service area as a whole.

Existing Providers in the Service Area (pages 25-26)

The applicant states the MROC is the only provider of radiation therapy services in southeast Mecklenburg County. The next closest provider is an approximate 40-minute drive from MROC. The applicant states that as the only provider in the immediate area, it is important that MROC has the capacity to meet the growing demand.

Cancer Incidence Rates in the Service Area are Rapidly Rising (pages 26-28)

The applicant states that based on 2016 data from the Centers for Disease Control and Prevention (CDC), those age 55-74 has seen the newest cancer cases. In addition, Mecklenburg County has one of the highest rates of cancer incidents in the North Carolina. The applicant states that the with highest incidence of cancer and overall growth occurring among the elderly population, it is important for MROC to have sufficient capacity to accommodate anticipated growth in demand.

Utilization of Existing Linac at MROC (pages 28-29)

The applicant states that MROC’s historical utilization of the existing linac in FY 2015 to FY 2018 has seen a 5.25 percent annual growth of unweighted treatments performed. In addition, weighted treatments have grown 6.9 percent annually, as illustrated in the tables below (Section C, page 28).

FY 2015-2018 Trend in Unweighted Treatments Performed					
	2015	2016	2017	2018	CAGR
Number of Procedures	9,556	10,173	10,191	11,141	5.25%

Source: 2015-2019 Medical Equipment Registration Forms
Note: Reporting periods are 10/01 through 9/31.

FY 2015-2018 Trend in weighted Treatments Performed					
	2015	2016	2017	2018	CAGR
Number of Weighted Procedures	8,978	9,808	10,015	10,929	6.77%

Source: 2016-2019 SMFPs, 2020 draft SMFP, and 2015-2019 Medical Equipment Forms
Note: CPT Code 77417 is weighted at 0.5 so procedures reflected here are lower than gross procedures performed.

The applicant states that in 2018, the existing linac performed a total of treatments that almost meets the performance standards for two linacs and is currently experiencing constraints on operations. The applicant states that if the growing need continues, the existing linac will not be able to accommodate this growth.

New Joint Venture with Novant Health will Increase Demand for Services (page 29)

The applicant states the MROC has partnered with Novant Health for the purpose of providing comprehensive continuum cancer care to service area residents and provide enhanced continuity of care. The applicant states that the affiliation with Novant Health will result in MROC becoming a part of Novant Health's in-network employee health plan. The applicant states that this will increase the number of patients who radiation oncology treatments are covered under MROC. The applicant states:

“Without additional capacity, MROC will continue to face capacity restraints and will be limited in its ability to accommodate existing demand, let alone the growth in demand anticipated by its new ownership structure and affiliation with Novant Health. It is clear that the proposed project will alleviate existing capacity constraints and will allow for the additional capacity necessary to accommodate the anticipated increased demand radiation oncology services at MROC.”

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

- The applicant adequately demonstrates that the existing linear accelerator cannot support the growing need for radiation treatments at MROC.
- The applicant adequately demonstrates that the aged population in Mecklenburg County has the highest incidents of new cancer cases and exhibiting significant growth in population and demand.
- The applicant adequately demonstrates a high utilization rate for the existing linear accelerator at MROC.

- The applicant demonstrates that additional linear accelerator capacity would enhance quality and continuum care.

Projected Utilization

In Section Q, Form C, the applicant provides statistical data and tables showing the linear accelerator utilization for MROC, which is summarized as follows:

Matthews Radiation Oncology Center Projected Utilization			
	1st Full FY 1/1/2022-12/31/2022	2nd Full FY 1/1/2023-12/31/2023	3rd Full FY 1/1/2024-12/31/2024
# of Linacs	2	2	2
# of Equivalent Simple Treatment Visits (ESTVs)	12,785	13,297	13,829

In Section C, pages 30-34, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

In Section C, page 30, the applicant states that when determining projected utilization for the existing and proposed linear accelerators, certain factors were analyzed, such as cancer incidence rates, growth and aging of the service area population, and historical utilization.

Step 1: Determine the cancer incidence rates by age group for the below 65 and 65 and over population in Mecklenburg and Union Counties.

Using 2012-2016 data from the CDC’s State Cancer Registry and NCOSBM, the applicant analyzed the average cancer count by age group below 65 and 65 and over population for Mecklenburg and Union Counties, and the average population by the same age group in Mecklenburg and Union counties. The applicant calculated the county cancer incidence rate by dividing the average cancer count by the average population, as illustrated in the table below.

2012-2016 Service Area County Incidence Rates by age Group per 100,000 Population		
	Below 65	65+
Mecklenburg County	239.42	1,981.5
Union	250.9	1,934.3

Source: Section C, page 30

Step 2: Estimate the number of cancer cases in MROC’s Primary Service Area Zip Codes in 2019 and 2024.

The applicant identified the primary service area as the area where 77 percent of patients reside, which consist of eight ZIP codes in Mecklenburg and Union County. The applicant determined the 2019-2024 primary service area population by age group under 65 and 65+ (Figure 4, page 25) and applied the incidence of cancer rates, determined in Step 1 above, to the respective

population by ZIP code and age group to determine the estimate total number of cancer cases in the primary service area ZIP codes in 2019-2024. The applicant projects that the number of cancer cases in MROC’s primary service area was 250 cases between 2019-2024.

Step 3: Compare the projected annual growth in population and cancer incidence in the primary service area zip codes from 2019 to 2024.

The applicant compared the 2019-2024 projected annual growth in population and cancer incidence in the primary service area ZIP codes to demonstrate that the cancer incidents rates are projected to grow faster the population rates due to the aging of the population. Based on data from the CDC and NCOSBM, the applicant projects the CAGR of cancer cases in the primary service area, as illustrated in the table below.

MROC Primary Service Area ZIP Code Total Populations and Cancer Incidence Growth Rates 2019-2024			
County	ZIP Code	Population CAGR	Cancer Incidence CAGR
Mecklenburg	28105	1.44%	3.33%
Mecklenburg	28227	1.50%	3.22%
Mecklenburg	28270	1.43%	3.51%
Mecklenburg	28277	1.68%	3.87%
Union	28079	1.58%	2.97%
Union	28104	1.66%	3.59%
Union	28110	1.25%	2.58%
Union	28173	1.78%	3.86%
	Total	1.56%	3.44%

Source: Section C, page 32

Step 4: Analyze MROC’s historical trend in utilization

As demonstrated in the applicant’s analysis of need, the applicant analyzed MROC’s historical growth in the number of patients, unweighted treatments, and weighted treatments between FY 2015 and FY 2018. The applicant states the MROC experienced a significant growth in patient and treatment volume that outpaced the population growth trends. The applicant states that MROC also experienced a growth in the complexity of treatment. There was a 5.25 percent growth for unweighted treatments and a 6.77 percent growth in weighted treatments. The following table illustrates the growth in patients and treatment volume.

	2015	2016	2017	2018	CAGR
# of Patients	431	468	459	502	5.21%
# of Unweighted Procedures	9,556	10,173	10,191	11,141	5.25%
#of Weighted Procedures (ESTVs)	8,978	9,808	10,015	10,929	6.77%

Source: Section C, pages 32-33

Step 5: Determine projected growth rate for interim year and project years 1,2, and 3

The applicant used MROC’s historical growth rates in ESTVs from FY 2015 and FY 2018, the primary service area population growth, and the cancer incidence growth rate to project a conservative growth rate of 4 percent.

Population Growth Rate for Primary Service for Area Zip Codes	1.56%
Cancer Incidence Growth Rate for Primary Service Area Zip Codes	3.44%
Historical Growth Rate in ESTVs 2015-2018	6.7%
Projected Growth Rate	4%

Step 6: Determine the projected utilization for interim years and project years 1,2, and 3

The applicant states that MROC has experienced significant capacity restraints in FY 2019 and struggled to accommodate the demand as utilization continued to grow. The applicant projects utilization with a constant in the interim years to account for the capacity constraints experience in FY 2019. The applicant then projects utilization if the facility had the capacity to meet the demand and continued with historical trend in utilization. The applicant compares the projected utilization to illustrate that the facility’s utilization will increase significantly in the first year of operation if the existing capacity restraints are alleviated, as illustrated in the tables below.

MROC’s Projected Utilization									
Historical Utilization					Projected at Historical Growth Rate				
2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
8,978	9,808	10,015	10,929	10,333	10,333	10,333	12,785	13,297	13,829

Source: Section C, page 33

MROC’s Trend Using Historical Growth Rate										
Historical Utilization					Projected at Historical Growth Rate					
2015	2016	2017	2018	CAGR	2019	2020	2021	2022	2023	2024
8,978	9,808	10,015	10,929	6.8%	11,669	12,460	13,205	14,205	15,168	16,195

Source: Section C, page 34

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

- Projected utilization is based on the applicant’s historical experience with the existing linear accelerator at MROC.
- The applicant used population data from the North Carolina Office of State Budget and Management and the Centers for Disease Control and Preventions to project growth in the population groups more likely to receive a cancer diagnosis in the project years.

- The applicant accounts for the capacity constraints experienced during FY 2019.

Access

In Section C, page 39, the applicant states:

“MROC’s policies that ensure that there is no denial, restriction, or limitation of access to minorities or handicapped persons. MROC does not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay.”

In Section L, page 70, 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. The applicant states that MROC is not expected to see a change in payor mix.

Projected Payor Mix 3rd FY 1/1/2024-12/31/2024	
Payor Source	Linear Accelerator Services as Percent of Total
Self-Pay/Charity Care	0.41%
Medicare*	58.25%
Medicaid*	3.34%
Insurance*	34.43%
Other (Hospice, Workers Comp, VA)	3.57%
Total	100.00%

Source: Section L, page 70

*Including any managed care plans

The projected payor mix is reasonable and adequately supported based on the applicant’s assumption that the payor mix is not expected to change during the first three operating years.

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 following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services 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 (payer 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 acquire and replace a refurbished linear accelerator for a total of no more than two linear accelerators at Matthews Radiation Oncology Center upon project completion.

In Section E, page 49, 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 this option was less effective because the existing linear accelerator is at peak capacity. The applicant states that not replacing the linear accelerator will not address the issues that have arisen by the increase in demand.

Purchase and Install Refurbished Linear Accelerator -The applicant states that this was not a viable option because the age and limitations of a refurbished linear accelerator. The applicant states that these limitations can pose a risk to patient safety.

Purchase and Replace Refurbished Linear Accelerator-The applicant states that this was the most cost-effective alternative because it would reduce capacity restraints and provide patients with the most advanced radiation therapy technology.

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 application is conforming to all statutory and regulatory review criteria.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The applicant adequately demonstrated that the propose project will meet the growing demand, reduce capacity restraints, and provide the most advance technology.

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. Radiation Oncology Centers of the Carolinas, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Radiation Oncology Centers of the Carolinas, LLC shall acquire and replace a refurbished linear accelerator for a total of no more than two linear accelerators at Matthews Radiation Oncology Center upon project completion.**
- 3. Radiation Oncology Centers of the Carolinas, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Radiation Oncology Centers of the Carolinas, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
- 5. Radiation Oncology Centers of the Carolinas, LLC shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**

- 6. Radiation Oncology Centers of the Carolinas, LLC shall provide written documentation of the efforts made by the applicant to establish relationships with local training institutions.**
 - 7. Radiation Oncology Centers of the Carolinas, LLC 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 acquire and replace a refurbished linear accelerator for a total of no more than two linear accelerators at Matthews Radiation Oncology Center upon project completion.

Capital and Working Capital Costs

In Section Q, page 87, the applicant projects the total capital cost of the project, as shown in the table below.

Capital Costs	Radiation Oncology Centers of the Carolinas, LLC d/b/a Matthews Radiation Oncology Center
Site Preparation	\$15,000
Construction/Renovation Contract(s)	\$2,429,776
Landscaping	\$2,500
Architect/Engineering Fees	\$190,000
Medical Equipment	\$3,894,464
Furniture	\$31,553
Consultant Fees (CON) Consultant	\$50,000
Financing Costs	\$25,527
Information Technology	\$438,561
Low Voltage (nurse call, overhead paging, CATV)	\$30,000
Security	\$5,000
DHSR Review Cost	\$2,134
Special Inspections	\$20,000
Project Contingency	\$701,935
Fair Market Value of Refurbished Linear Accelerator	\$2,400,000
Total Capital Cost	\$10,236,450

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 52, the applicant states that because MROC’s radiation therapy service is an ongoing operation, there are no start-up or initial operating expenses.

Availability of Funds

In Section F, page 50, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Radiation Oncology Centers of the Carolinas, LLC d/b/a Matthews Radiation Oncology Center	Total
Loans	\$10,236,450	\$10,236,450
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$10,236,450	\$10,236,450

* OE = Owner’s Equity

Exhibit F-2.1 contains a letter from the Senior Vice President of Commercial Banking at First Citizens Bank confirming that a line of credit will be made available to MROC to cover the capital costs of the proposed project.

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.

	1st Full FY 1/1/2022-12/31/2022	2nd Full FY 1/1/2023-12/31/2023	3rd Full FY 1/1/2024-12/31/2024
Total ESTV Treatments	12,785	13,297	13,829
Total Gross Revenues (Charges)	\$24,904,480	\$25,898,227	26,931,724
Total Net Revenue	\$10,270,230	\$10,678,607	\$11,103,320
Average Net Revenue per ESTV Treatment	\$803.30	\$803.08	\$802.90
Total Operating Expenses (Costs)	\$7,288,808	\$7,418,705	\$7,553,306
Average Operating Expense per ESTV Treatment	\$570.10	\$557.93	\$546.19
Net Income	\$2,981,422	\$3,259,902	\$3,550,014

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 based on the following:

- 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 acquire and replace a refurbished linear accelerator for a total of no more than two linear accelerators at Matthews Radiation Oncology Center upon project completion.

In Chapter 9, page 127, the 2019 SMFP states, “A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.” In Table 9I, page 135 of the 2019 SMFP, Mecklenburg County is included in Linear Accelerator Service Area 7, which also includes Anson and Union counties. Providers may serve residents of counties not included in their service area.

There are 10 existing linear accelerators in Linear Accelerator Service Area 7. The following table identifies the provider, number of linear accelerators, and average number of procedures for each unit performed during October 1, 2016-September 30, 2017, as summarized from Table 9G, page 131 of the 2019 SMFP.

Facility Name	County	# of Linear Accelerators	# of Procedures (ESTVs) 10/1/2016-9/30/2017	Average** ESTV per Linear Accelerator
Carolinas HealthCare System University*	Mecklenburg	1	7,420	7,420
Carolinas Medical Center	Mecklenburg	3	18,946	6,315
Matthews Radiation Oncology Center	Mecklenburg	1	10,015	10,015
Novant Health Huntersville Medical Center	Mecklenburg	1	599	599
Novant Health Presbyterian Medical Center	Mecklenburg	2	9,746	4,873
Pineville Radiation Therapy Center	Mecklenburg	1	10,070	10,070
Carolinas HealthCare System Union	Union	1	8,072	8,072

Source: Table 9G, page 131, of the 2019 SMFP

*University radiation Therapy Center provided services from October 1-November 30, 2016. Beginning December 1, 2016, the equipment became licensed under Carolinas HealthCare System University.

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

The applicant proposes to acquire and replace an existing refurbished linear accelerator currently located at MROC, therefore, the applicant does not propose to increase the inventory of linear accelerators in the service area.

In Section G, page 56, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved emergency services in Linear Accelerator Service Area 7. The applicant states:

“The next closest providers of radiation therapy in the service area are Pineville Radiation Therapy Center and Carolinas Medical Center, both of which are also well utilized. Given the growth in demand resulting from the growing and aging service area population, the proposed linac is needed and will not duplicate existing providers.”

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 acquire and replace an existing and antiquated linear accelerator with comparable equipment to serve its patients.
- The proposal would not result in an increase in 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 based on 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, page 90, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Matthews Radiation Oncology Center Current and Projected FTE Staff			
	Current As of 9/30/2019	1st Full FY 1/1/2022-12/31/2022	2nd Full FY 1/1/2023-12/31/2023	3rd Full FY 1/1/2024-12/31/2024
Oncology Nurse	1.00	2.00	2.00	2.00
Clerical Staff (Secretary)	2.00	2.00	2.00	2.00
Dosimetrist	1.00	2.00	2.00	2.00
Radiation Therapists	5.40	7.00	7.00	7.00
Administrator (Director)	1.00	1.00	1.00	1.00
TOTAL	10.40	14.00	14.00	14.00

The assumptions and methodology used to project staffing are provided in Section Q. 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 58 and 59, respectively, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H, page 59, the applicant identifies the current medical director. In Exhibit H-3.3, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-3.1 and H-3.2, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 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 60, the applicant states that the following ancillary and support services are necessary for the proposed services:

Ancillary/Support Services	Facility Paid Contractor	Contractor	Specify Date Service Available
Professional and Administrative Services	X	Southeast Radiation Oncology Group, P.A.	Currently Available, and Ongoing
Human Resources	X	ADP TotalSource	Currently Available, and Ongoing with Annual Renewals
Physiatrist, Treatment Planning and Safety Services	X	HannLeb, Inc.	Currently Available, and Ongoing with Annual Renewals
Maintenance Service on Linear Accelerator	X	RS&A, Inc.	Currently Available, and Ongoing
Maintenance Service on CT	X	Network Imaging Systems, Inc.	Currently Available, and Ongoing
Service and Support for AlignRT	X	Vision RT, Inc.	Currently Available, and Ongoing
Maintenance and Service for Aria, InSightive, Eclipse	X	Varian Medical Systems	Currently Available, and Ongoing
Managed Care Contract Negotiation	X	Fulcrum Strategies, LLC	Currently Available, and Ongoing

In Section I, page 61, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-3.

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

Conclusion

The Agency reviewed the:

- Application
- 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.

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 64, the applicant states that the project involves constructing 2,164 square feet of new space. Line drawings are provided in Exhibit K-1.

On page 64, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K-3.

On page 65, 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.

On page 65, 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 69, the applicant provides the historical payor mix during last full fiscal year for the proposed services, as shown in the table below.

Historical Payor Mix Last Full FY 10/1/2017-9/30/2018	
Payor Source	Linear Accelerator Services as Percent of Total
Self-Pay/Charity Care	0.41%
Medicare*	58.25%
Medicaid*	3.34%
Insurance*	34.43%
Other (Hospice, Workers Comp, VA)	3.57%
Total	100.00%

Source: Section L, page 69

*Including any managed care plans

In Section L, page 68, the applicant provides the following comparison.

Radiation Oncology Centers of the Carolinas, LLC d/b/a Matthews Radiation Oncology Center	Percentage of Total Patients Served	Percentage of the Population of the Service Area*
Female	60.63%	51.74%
Male	39.37%	48.26%
Unknown	0.00%	0.00%
64 and Younger	41.40%	88.25%
65 and Older	58.60%	11.75%
American Indian	Unavailable**	0.46%
Asian	Unavailable**	5.73%
Black or African-American	Unavailable**	29.40%
Native Hawaiian or Pacific Islander	Unavailable**	0.08%
White or Caucasian	Unavailable**	57.51%
Other Race	Unavailable**	6.81%
Declined / Unavailable	Unavailable**	0.00%

*The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

**MROC’s billing software does not account for race; therefore, no data is available for the race/ethnicity of patients treated at MROC.

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 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 69, the applicant states:

“MROC is not obligated to provide uncompensated care, community service, or access by minorities and handicapped persons.”

In Section L, page 69, 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
- 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 70, 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. The applicant states that charity care is deducted from revenue and is not a payor source. It is combined with self-pay for presentation purposes only.

Projected Payor Mix	
3rd Full FY-1/1/2024-12/31/2024	
Payor Source	Linear Accelerator Services as Percent of Total
Self-Pay/Charity Care	0.41%
Medicare*	58.25%
Medicaid*	3.34%
Insurance*	34.43%
Other (Hospice, Workers Comp, VA)	3.57%
Total	100.00%

Source: Section L, page 70

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.41% of total services will be provided to self-pay patients, 58.25% to Medicare patients and 3.34% to Medicaid patients.

On page 70, 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 historical payor mix and the applicant's assumption that the payor mix is not expected to change during the first three operating years of the project.

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 based on the reason stated above.

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

C

In Section L, page 70, 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.

CA

In Section M, page 71, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. On page 71, the applicant states that MROC does not currently have relationships with health professional training programs, however, it is open to discussions with local health professional training programs in the area for training opportunities for clinicians such as nurses and technologists.

Conclusion

The Agency reviewed the:

- Application

- 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 conditionally 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 acquire and replace a refurbished linear accelerator for a total of no more than two linear accelerators at Matthews Radiation Oncology Center upon project completion.

In Chapter 9, page 127, the 2019 SMFP states, “A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.” In Table 9I, page 135 of the 2019 SMFP, Mecklenburg County is included in Linear Accelerator Service Area 7, which also includes Anson and Union counties. Providers may serve residents of counties not included in their service area.

There are 10 existing linear accelerators in Linear Accelerator Service Area 7. The following table identifies the provider, number of linear accelerators, and average number of procedures for each unit performed during October 1, 2016-September 30, 2017, as summarized from Table 9G, page 131 of the 2019 SMFP.

Facility Name	County	# of Linear Accelerators	# of Procedures (ESTVs) 10/1/2016-9/30/2017	Average** ESTV per Linear Accelerator
Carolinas HealthCare System University*	Mecklenburg	1	7,420	7,420
Carolinas Medical Center	Mecklenburg	3	18,946	6,315
Matthews Radiation Oncology Center	Mecklenburg	1	10,015	10,015
Novant Health Huntersville Medical Center	Mecklenburg	1	599	599
Novant Health Presbyterian Medical Center	Mecklenburg	2	9,746	4,873
Pineville Radiation Therapy Center	Mecklenburg	1	10,070	10,070
Carolinas HealthCare System Union	Union	1	8,072	8,072

Source: Table 9G, page 131, of the 2019 SMFP

*University radiation Therapy Center provided services from October 1-November 30, 2016. Beginning December 1, 2016, the equipment became licensed under Carolinas HealthCare System University.

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

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 72, the applicant states:

“The proposed project will promote cost-effectiveness approaches, expand availability of radiation therapy treatments, and encourage quality health care services by improving timely access to services for the patient population serviced by MROC and coordination of care delivery with existing providers.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 72, the applicant states:

“Further, the addition of a second linac at MROC will eliminate capacity constraints and create a more efficient operational flow with reasonable scheduling and hours of operation.

...

Additionally, by replacing the existing refurbished linac with a new linac, MROC will be incorporating the most advanced technology in its radiation therapy treatments.”

Regarding the impact of the proposal on quality, in Section N, page 72, the applicant states:

...MROC is committed to providing high quality care to its patients. This is evidenced by its compliance with risk management programs in radiation safety and overall

quality management, each of which are reviewed on an annual basis with continual efforts towards error prevention and reduction.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 73, the applicant states:

“MROC is committed to being accessible to all groups regardless of age, sex, race, or payor status. MROC will continue to provide services to uninsured, charity, and Medicaid patients.”

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 L and N of the application and any exhibits)

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 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, page 82, the applicant identifies the healthcare facilities with Linear Accelerators located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of seven of this type of facility located in North Carolina.

In Section O, pages 74-75, the applicant states,

“As a diagnostic center, MROC is not a licensed facility, however, MROC holds an active Radioactive Materials License and Accelerator License for its existing linac as

required by the N.C. Department of Health and Human Services North Carolina Radiation Protection Section...the applicant has provided sufficient evidence that quality of care has been provided in the past at MROC.”

In Section O, page 75, the applicant states that during the 18-month look-back period, neither DHSR nor CMS has determined that the hospitals listed in Section Q, Form A, operated out of compliance with Medicare Conditions of Participation. According to the files in the Acute Care 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 has occurred in one of these facilities. However, the issues were corrected, and the facility was back in compliance on December 4, 2019. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at all 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 acquire and replace an existing refurbished linear accelerator at the Matthews Radiation Oncology Center. 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.