

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 25, 2023

Findings Date: January 25, 2023

Project Analyst: Ena Lightbourne

Co-Signer: Gloria C. Hale

Project ID #: F-12283-22

Facility: Lake Norman Radiology Oncology - Mooresville

FID #: 220729

County: Iredell

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

Project: Replace linear accelerator

REVIEW CRITERIA

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

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

C

Radiation Oncology Centers of the Carolinas, LLC, referred to as “the applicant” or “ROCC” proposes to acquire a replacement linear accelerator (LINAC) at Lake Norman Radiology Oncology – Mooresville (LNRO-M). LNRO-M is a freestanding facility that provides radiation therapy services.

Need Determination

There is no need determination in the 2022 State Medical Facilities Plan (SMFP) that is applicable to this proposed project.

Policy

There is one policy in the 2022 SMFP applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on pages 30-31 of the 2022 SMFP, states:

“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

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

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

The proposed capital expenditure for this project is greater than \$4 million and less than \$5 million. In Section B, page 24, the applicant describes the project’s plan for energy efficiency and to conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

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

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

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to acquire a replacement LINAC at the LNRO-M.

In Chapter 17, page 321, the 2022 SMFP states, “A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.” LNRO-M is in Iredell County. In Table 17C-4, page 329 of the 2022 SMFP, Iredell County is included in Linear Accelerator Service Area 8. Linear Accelerator Service Area 8 includes Rowan and Iredell counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

County	LNRO-M Radiation Therapy Historical Patient Origin	
	Last Full FY 08/01/2021-07/31/2022	
	Patients	% of Total
Iredell	328	52.1%
Mecklenburg	195	31.0%
Lincoln	43	6.8%
Catawba	23	3.7%
Rowan	15	2.4%
Other Counties and States	25	4.0%
Total	629	100.0%

Source: Section C, page 32

LNRO-M Radiation Therapy Projected Patient Origin						
County	1st Full FY		2nd Full FY		3rd Full FY	
	CY2024		CY2025		CY2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Iredell	307	52.1%	307	52.1%	307	52.1%
Mecklenburg	183	31.0%	183	31.0%	183	31.0%
Lincoln	40	6.8%	40	6.8%	40	6.8%
Catawba	22	3.7%	22	3.7%	22	3.7%
Rowan	14	2.4%	14	2.4%	14	2.4%
Other Counties and States	24	4.0%	24	4.0%	24	4.0%
Total	589	100.0%	589	100%	589	100%

Source: Section C, page 33

In Section C, page 33, the applicant provides the assumptions and methodology used to project its patient origin. On page 33, the applicant states:

“In 2021-2022, each linear accelerator patient averaged 12.25 treatments and LNRO-M assumes no change in its patient origin. The linear accelerator treatments projected in Section Q were divided by 12.25 to project the Radiation Therapy patients for the first three full FYs. The projected patients were then multiplied by the county patient origin percentages...”

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 36-42, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The projected population growth in Iredell County and the extended service area, particularly among those age 45-65+ who account for 94 percent of radiation therapy patients at LNRO-M (pages 37-38).
- Life expectancy has increased in the service area which increases the chance of cancer incidence and mortality, further demonstrating the need for radiation therapy services. (pages 39-41).
- New cancer cases are projected to increase in the service area as well as cancer deaths (pages 40-41).

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

- The applicant adequately demonstrates that projected population growth, increased life expectancy, and the increase in cancer incidence in the service area drives the need for radiation therapy services.

- Although the performance standards do not apply to a replacement LINAC, the applicant projects a total of 6,872 Equivalent Simple Treatment Visit (ESTV) treatments by the third project year, which is above the required standard of 6,750 ESTV treatments.

Projected Utilization

In Section Q, Form C.2a, the applicant provides historical and projected utilization, as illustrated in the following table.

	Last Full FY	Interim Full FY	Interim Full FY	Partial CY	1 st Full FY	2 nd Full FY	3 rd Full FY
	CY2021	CY2022	1/1/23-6/30/23	7/1/23-12/31/23	CY2024	CY2025	CY2026
# of Units	1	1	1	1	1	1	1
# of ESTV Treatments	6,885.5	7,890.8	1,154.5	3,436.0	6,872.0	6,872.0	6,872.0

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

The applicant began with the historical utilization of the existing LINAC at LNRO-M. The applicant states that radiation therapy treatments at LNRO-M remained constant from 2017 through 2021. The applicant calculated the 5-year average number of treatments per day based on 250 days of treatment per year.

2017-2021 LNRO-M Linear Accelerator Treatment						
	2017	2018	2019	2020	2021	5-Year Average TX per day
1.0 ESTV Treatment	6,536	6,597	6,446	6,410	6,631	26.1
0.5 ESTV Treatment	680	815	862	614	509	2.8
Total Treatments	7,216	7,412	7,308	7,024	7,140	28.9

The applicant projects the 2022 LINAC volume by annualizing (January 2022-August 2022) the volume of 5,112 1.0 ESTV treatments and 297 0.5 ESTV treatments. The applicant states that LNRO-M experienced an increase in volume due to the downtime of the Novant Health Huntsville Medical Center’s LINAC.

- 1.0 ESTV treatments = [5,112 treatments / 8 months x 12 = 7,668 treatments]
- 0.5 ESTV treatments = [297 treatments / 8 months x 12 = 446 treatments]

The applicant projects that during interim 2023, the average number of treatments will be consistent with average number of treatments experience in the previous years. The applicant states that the existing LINAC will be out of service from March 1, 2023, through June 30, 2023. Treatments will be performed at Novant Health Huntersville Medical Center.

- 1.0 ESTV treatments = [42 days x 26.1 treatments per day = 1,096 treatments]
- 0.5 ESTV treatments = [42 days x 2.8 treatments per day = 117 treatments]

2022 – June 2023 Linear Accelerator Treatments				
	Last Full Year	Interim Full Year	Interim Partial Year	
	2021	2022	1/2023-2/2023	3/2023-6/2023
Days			42	83
1.0 ESTV Treatment	6,631	7,668	1,096	0
0.5 ESTV Treatment	509	446	117	0
Total Treatments	7,140	8,114	1,213	0

The applicant projects the partial 6-month utilization (7/2023-12/2023) will equal the 5-year average treatments per day. For the first three operating years of the project, the applicant projects utilization will double the partial year volume as follows:

- 1.0 ESTV treatments = [250 days x 26.1 treatments per day = 6,524 treatments]
- 0.5 ESTV treatments = [125 days x 2.8 treatments per day = 348 treatments]

	1 st Full FY	2 nd Full FY	3 rd Full FY
	CY2024	CY2025	CY2026
# of Units	1	1	1
1.0 ESTV Treatment	6,524	6,524	6,524
0.5 ESTV Treatment	348	348	348
Total Treatments	6,872	6,872	6,872

Totals may not foot due to rounding.

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

- The historical utilization of the existing LINAC.
- The projected population growth in Iredell County and the extended service area, particularly among key age groups that account for the majority of LNRO-M patients.

Access to Medically Underserved Groups

In Section C, page 48, the applicant states:

“Services are available to all persons including: (a) low-income persons, (b) racial and ethnic minorities, (c) women, (d) handicapped persons, (e) elderly, and (f) other underserved persons, including medically indigent referred by their attending physicians.”

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	4.6%
Racial and ethnic minorities	9.2%
Women	52.6%
Persons with Disabilities	Not Tracked
Persons 65 and older	57.1%
Medicare beneficiaries	51.6%
Medicaid recipients	3.6%

Source: Section C, page 48

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. The applicant is an existing provider in the service area currently providing services to the underserved.

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.

C

The applicant proposes to acquire a replacement LINAC at the LNRO-M.

In Section E, page 60, the applicant states that there were no other alternatives considered that will accommodate replacing the existing LINAC.

On page 60, the applicant states that the proposal to replace the existing LINAC is the only effective alternative because of the following factors:

- The existing LINAC has exceeded the average lifespan of a LINAC.
- Replacing original parts and computer boards have become problematic because it would require the equipment to temporarily become non-operational, which can affect patient care.
- The existing LINAC lacks the technology to deliver radiation oncology services efficiently.

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 age and lack of advanced technology of the existing LINAC can affect access to care.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire a replacement linear accelerator at Lake Norman Radiology Oncology – Mooresville.**
- 3. Upon completion of the project, Lake Norman Radiology Oncology – Mooresville shall be licensed for no more than one linear accelerator.**
- 4. 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 June 1, 2023.
5. 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.
6. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
- a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
7. 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 acquire a replacement LINAC at the LNRO-M.

Capital and Working Capital Costs

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

Capital Costs	
Construction/Renovation Contract(s)	\$354,450
Architect/Engineering Fees	\$78,270
Medical Equipment	\$2,125,645
Consultant Fees (CON Prep and CON Fee)	\$43,000
Other (Physics and SBRT Equipment)	\$117,426
Other (Tax)	\$170,052
Other (DHSR Review Cost)	\$2,500
Other (Contingency)	\$35,500
Total	\$2,926,843

In Section Q, Form.1a, page 1, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Vendor equipment quotes and renovation cost estimates.
- The applicant includes depreciation and amortization in its capital cost projections.

In Section F, page 63, the applicant states that there will be no projected working capital costs because radiation therapy is an existing service at LNRO-M.

Availability of Funds

In Section F, page 61, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	First Citizens Bank	Total
Loans	\$2,926,843	\$2,926,843
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,926,843	\$2,926,843

*OE = Owner's Equity

In Exhibit F.2, the applicant provides a letter from the president of Radiation Oncology Centers of the Carolinas, LLC, stating the project will be funded through a commercial loan. The applicant provides a letter from the Senior Vice-President of First Citizens Bank, stating their intention to fund the project through a commercial loan upon project approval.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that

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

LNRO-M	1 st Full FY CY 2024	2 nd Full FY CY 2025	3 rd Full FY CY 2026
Total ESTV Treatments	6,872	6,872	6,872
Total Gross Revenues (Charges)	\$16,187,338	\$16,672,958	\$17,173,147
Total Net Revenue	\$6,436,086	\$6,629,168	\$6,828,043
Average Net Revenue per Treatment	\$937	\$965	\$994
Total Operating Expenses (Costs)	\$4,770,246	\$4,847,566	\$4,926,405
Average Operating Expense per Treatment	\$694	\$705	\$717
Net Income	\$1,665,840	\$1,781,602	\$1,901,638

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions 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 acquire a replacement LINAC at the LNRO-M.

In Chapter 17, page 321, the 2022 SMFP states, “A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.” LNRO-M is in Iredell County. In Table 17C-4, page 329 of the 2022 SMFP, Iredell County is included

in Linear Accelerator Service Area 8. Linear Accelerator Service Area 8 includes Rowan and Iredell counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

There are four linear accelerators in Linear Accelerator Service Area 8. The following table identifies the provider, number of linear accelerators, number of total procedures, and average utilization of each of the linear accelerators in FFY2020, as summarized from Table 17C-1, page 324 of the 2022 SMFP.

	# Linear Accelerators	County	Total Procedures*	Average ESTVs* Per Linear Accelerator
Iredell Memorial Hospital	2	Iredell	6,245	3,123
Lake Norman Radiology Oncology-Mooresville	1	Iredell	6,937	6,937
Novant Health Rowan Medical Center	1	Rowan	6,139	6,139

*The 2022 SMFP equates ESTVs with procedures in Table 17C-1.

In Section G, page 71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved LINAC services in Service Area 8. The applicant states it has historically provided the volume of ESTV procedures needed to meet the performance standard as shown in Table 17C-1 of the 2022 SMFP; 6,937 exceeded the threshold of 6,750. In Section Q, Form C.2a, the applicant projects it will exceed that threshold all three full fiscal years of the project at 6,872 ESTVs.

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 proposal would not result in an increase in the number of linear accelerators in Linear Accelerator Service Area 8.
- The applicant adequately demonstrates that the proposed replacement linear accelerator is needed in addition to the existing or approved linear accelerators in Linear Accelerator Service Area 8.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to acquire a replacement LINAC at the LNRO-M.

In Section Q, Form H, pages 1-2, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 08/30/2022	2nd Full Fiscal Year (CY 2025)
Director	1.0	1.0
Medical Secretary	0.8	0.8
Oncology/Nurse	0.8	0.8
Radiation Therapist	5.4	5.4
TOTAL	8.0	8.0

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 73-74, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- LNRO-M is an existing facility with radiation therapy staff already in place.
- The facility allocates funds to cover staff training needs and license and certification maintenance.
- Clinical and non-clinical education programs are structured to encourage participation.
- The applicant provides supporting documentation 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 acquire a replacement LINAC at the LNRO-M.

Ancillary and Support Services

In Section I, page 76, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 77-78, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 78, the applicant describes its existing and proposed 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 based on ROCC's 17-year established relationships with local health care and social service providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

C

The applicant proposes to acquire a replacement LINAC at the LNRO-M.

In Section K, page 81, the applicant states that the project involves renovating 944 square feet of existing space. Line drawings are provided in Exhibit C.1.

On page 82, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the architect's determination of necessary renovations to the linear accelerator vault, control room, and support space.

On page 82, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the applicant's proposal to renovate a small space within the radiation oncology service, minimizing cost.

On page 82, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 85, the applicant provides the historical payor mix during FY 2022 for the proposed services, as shown in the table below.

LNRO-M Historical Payor Mix 08/01/2021-07/31/2022	
Payor Category	Percent of Total
Self-Pay	0.8%
Charity Care	
Medicare*	51.6%
Medicaid*	3.6%
Insurance*	41.1%
Other (Government)	1.6%
Total	100.0%

*Including any managed care plans.

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

LNRO-M	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	52.6%	50.5%
Male	47.4%	49.5%
Unknown	0.0%	0.0%
64 and Younger	42.9%	83.8%
65 and Older	57.1%	16.2%
American Indian	0.3%	0.6%
Asian	0.8%	2.7%
Black or African American	6.2%	12.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	89.5%	81.8%
Other Race	1.9%	2.3%
Declined / Unavailable	1.3%	0.0%

*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.

The Agency reviewed the:

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

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

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

C

In Section L, page 87, the applicant states that the facility or campus is not obligated under any applicable federal regulations to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 87, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility 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 88, 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.

LNRO-M Projected Payor Mix (LINAC) CY2026	
Payor Category	Percent of Total
Self-Pay	0.8%
Charity Care	
Medicare*	51.6%
Medicaid*	3.6%
Insurance*	41.1%
Other (Government)	2.9%
Total	100.0%

*Including managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.8% of total services will be provided to self-pay patients, 51.6% to Medicare patients and 3.6% to Medicaid patients. On page 89, the applicant projects to serve 28 charity care patients a year for the first three full fiscal years of the project.

On page 88, 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 by the actual payor mix for LINAC treatments performed at LNRO-M during FY 2022.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire a replacement LINAC at the LNRO-M.

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 have access to the facility for training purposes based on ROCC's established clinical agreements with area health education programs that include access to LNRO-M.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

The applicant proposes to acquire a replacement LINAC at the LNRO-M.

In Chapter 17, page 321, the 2022 SMFP states, “*A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.*” LNRO-M is in Iredell County. In Table 17C-4, page 329 of the 2022 SMFP, Iredell County is included in Linear Accelerator Service Area 8. Linear Accelerator Service Area 8 includes Rowan and Iredell counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

There are four linear accelerators in Linear Accelerator Service Area 26. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators in FFY2020, as summarized from Table 17C-1, page 324 of the 2022 SMFP.

	# Linear Accelerators	County	Total Procedures*	Average ESTVs* Per Linear Accelerator
Iredell Memorial Hospital	2	Iredell	6,245	3,123
Lake Norman Radiology Oncology-Mooresville	1	Iredell	6,937	6,937
Novant Health Rowan Medical Center	1	Rowan	6,139	6,139

*The 2022 SMFP equates Equivalent Simple Treatment Visits (ESTVs) with procedures in Table 17C-1.

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

“...it will maintain the current capacity of linear accelerator services at LNRO-M and thus the service area. The Varian TruBeam linear accelerator will allow more complex radiation therapy treatments to once again be performed in the Mooresville community.”

Regarding the impact of the proposal on cost effectiveness, in Section K, page 82, the applicant states it will minimize cost by renovating a small space within the radiation oncology service, and as stated in Section E, page 60, the replacement LINAC will be more efficient.

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:

“The objective is to make certain a mechanism is in place, which ensures the occurrence of ongoing evaluation of various aspects of LNRO-M’s operation, both clinical and non-clinical.

...

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:

“The ROCC radiation oncology service is readily accessible to any resident of the service area with access to the Iredell County Area Public Transit...”

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, handicap, ethnicity, or ability to pay.”

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

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

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section O, Form O, page 1, the applicant identified the imaging centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of two of this type of facility located in North Carolina.

In Section O, page 97, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents resulting in a finding of immediate jeopardy had not occurred in any of these facilities. On pages 96-97, the applicant describes ROCC's programs regarding quality care, risk management, and infection control. The applicant provides supporting documentation in Exhibit O.2. After reviewing and considering information provided by the applicant at both 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 acquire a replacement linear accelerator. Therefore, there are no administrative rules that apply to this proposal.