

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 27, 2021

Findings Date: May 27, 2021

Project Analyst: Gregory F. Yakaboski

Acting Chief: Lisa Pittman

Project ID #: P-12027-21

Facility: Onslow Radiation Oncology, LLC

FID #: 061343

County: Onslow

Applicants: Onslow Radiation Oncology, LLC

Onslow Memorial Hospital, Inc.

Project: Acquire a replacement LINAC

REVIEW CRITERIA

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

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

C

Onslow Radiation Oncology, LLC (ORO) and Onslow Memorial Hospital, Inc. (OMH) collectively referred to as “the applicant” proposes to acquire a replacement linear accelerator (LINAC) at the ORO facility located at 317 Western Boulevard in Jacksonville, Onslow County.

OMH is the sole member of ORO.

Need Determination

There is no need determination in the 2021 State Medical Facilities Plan (SMFP) that is applicable to this proposed project.

Policy

There is one policy in the 2021 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 page 29 of the 2021 SMFP, states:

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

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, 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 \$2.0 million and less than \$5.0 million. In Section B, page 25, the applicant describes the project’s plan to improve energy efficiency and 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

because 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 its ORO facility located at 317 Western Boulevard in Jacksonville, Onslow County.

Patient Origin

In Chapter 17, page 324, the 2021 SMFP states, “*Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of linear accelerator service areas... .*” ORO is in Onslow County. In Table 17C-4, page 334 of the 2021 SMFP, Onslow County is included in Linear Accelerator Service Area 25. Linear Accelerator Service Area 25 includes only Onslow County. Thus, the service area for this LINAC consists of Onslow county. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	Historical (10/1/2019 to 9/30/2019)		Third Full FY of Operation following Project Completion (10/1/2024 to 9/30/2025)	
	Patients	% of Total	Patients	% of Total
Onslow	156	90.2%	228	90.2%
Duplin	9	5.2%	13	5.2%
Pender	4	2.3%	6	2.3%
Jones	2	1.2%	3	1.2%
Carteret	1	0.6%	1	0.6%
Lenoir	1	0.6%	1	0.6%
Total	173	100.0%	253	100.0%

Source: Tables on pages 27-28 of the application.

In Section C, page 28, the applicant provides the assumptions and methodology used to project its patient origin.

“The proposed project is not expected to have any impact on ORO’s patient origin.”

The applicant’s assumptions are reasonable and adequately supported based on the following reasons:

- ORO's patient origin is not projected to be impacted by the proposed project.
- Projected patient origin for the first three years following project completion is based on historical patient origin of ORO's facility.

Analysis of Need

In Section C, pages 26, and 35, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant identifies reasons to support the need for the proposed service, which are summarized below.

- The existing linear accelerator has reached the end of its useful life and needs to be replaced (page 26)
- Pursuant to the 2021 SMFP, if the only existing LINAC ceases to operate a need for a LINAC would be triggered in Onslow County (page 31);
- The population growth rate and cancer rates in Onslow County (pages 31-34);
- Maintain patient access to radiation oncology services in Onslow County (pages 34-35); and
- The new technology in the replacement equipment expands both the types of treatment and level of care available to patients (pages 34-35).

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

- The existing linear accelerator has reached the end of its useful life and needs to be replaced.
- The ORO LINAC is the only LINAC in Onslow County and if it ceases to operate because its obsolete and not replaced pursuant to the SMFP a need for a LINAC in Onslow County would be generated.
- Cancer rates and population growth in Onslow County support the need to replace the only LINAC in Onslow County.
- The replacement LINAC would incorporate new technology which would expand both the level of care that could be offered as well as the types of treatment allowing Onslow County residents and caregivers to stay and receive treatments in Onslow County as opposed to currently having to leave the county for certain types of treatments.

Projected Utilization

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

	Last FFY2019	Interim FFY2020	Interim FFY2021	1 st OY FFY2023	2 nd OY FFY2024	3 rd OY FFY2025
# of Units	1	1	1	1	1	1
# of ESTV Treatments	5,195	5,255	5,317	5,761	6,243	6,766

Source: Section Q of the application.

*ESTVs means Equivalent Simple Treatment Visits

Note: ORO Fiscal Year is 10/1/20-- to 9/20/20--.

In Section Q, Form C Utilization-Assumptions and Methodology, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Project Population Growth of Onslow County

	2020	2029	CAGR
Total Population	204,357	226,786	1.2%

Source: North Carolina Office of State Budget and Management (NCOSBM).

Step 2: ORO LINAC Projected Utilization for Interim Years

	FFY21	FFY22	CAGR
2D/3D & IMRT Treatments	5,124	5,184	1.2%
AFCRs	263	266	1.2%
ESTVs	5,255	5,317	1.2%

Step 3: ORO LINAC Projected Utilization for Project Years

	FFY23	FFY24	FFY25	CAGR*
2D/3D & IMRT Treatments	5,611	6,073	6,574	8.2%
AFCRs	301	340	384	13.0%
ESTVs	5,761	6,243	6,766	

*CAGR is the historical CAGR for the ORO LINAC for FFY2017-FFY2020 as shown in the table below.

	FFY17	FFY18	FFY19	FFY20	CAGR
2D/3D & IMRT Treatments	3,994	4,541	4,211	5,065	8.2%
AFCRs	180	316	367	260	13.0%
ESTVs	4,084	4,699	4,395	5,195	

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

- The applicant relies on data from established and reliable sources and cites to the sources of any data used.

- The applicant relies on historical ORO linear accelerator utilization and population growth to project future growth in utilization.
- The proposed replacement LINAC offers new technology that will allow types of treatments that are currently not available at ORO thus allowing Onslow County residents and their caregivers who currently have to seek certain treatments outside the county to stay within the county for those same treatments.

Access to Medically Underserved Groups

In Section C, page 41, the applicant states, “*ORO provides care to anyone in need of the service ... no patients in need are refused or denied care.*” 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*	%
Racial and ethnic minorities	25.0%
Women	62.0%
Persons with Disabilities*	%
Persons 65 and older	52.8%
Medicare beneficiaries	54.3%
Medicaid recipients	9.8%

*Note: ORO does not maintain data that includes the number of low-income persons or disabled persons it serves.

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

- No patients in need are denied or refused care, including those without the ability to pay.
- ORO is part of the Onslow County healthcare system governed by the Onslow County Hospital Authority, which exists to ensure care to the residents of Onslow County.

Conclusion

The Agency reviewed the:

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will

be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

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

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

CA

The applicant proposes to acquire a replacement LINAC at its ORO facility located at 317 Western Boulevard in Jacksonville, Onslow County.

In Section E, page 50, the applicant states that there are no alternatives available to meet the need described.

On page 50, the applicant states that its proposal is the most effective alternative because

“Given the age of the equipment and its limited technological capabilities compared with modern, up-to-date equipment, there is no alternative for ORO to continue providing the service other than replacing the equipment as proposed.”

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

- The applicant provides credible 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. **Onslow Radiation Oncology, LLC (ORO) and Onslow Memorial Hospital, Inc. (OMH) (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 to be located at Onslow Radiation Oncology, LLC.**
3. **Upon completion of the project, Onslow Radiation Oncology, LLC 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. **Progress reports shall be due on the first day of every third month. The first progress report shall be due on July 1, 2021. The second progress report shall be due on October 1, 2021 and so forth.**
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 its ORO facility located at 317 Western Boulevard in Jacksonville, Onslow County.

Capital and Working Capital Costs

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

Site Costs	\$0
Construction Costs	\$925,885
Miscellaneous Costs	\$2,568,889
Total	\$3,494,774

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

- Cost of equipment (see Exhibit C.1-1).
- Cost of consultants.
- Architect letter providing estimate of construction costs (see Exhibit F.1).

In Section F, page 53, the applicant projects there will be no start-up or initial operating expenses because the project is for a facility which is existing and operational and thus does not need or include working capital.

Availability of Funds

In Section F, page 52, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	ORO	OMH	Total
Loans	\$2,485,089	\$0*	\$2,485,089
Cash and Cash Equivalents, Accumulated reserves or Owners Equity	\$0	\$1,009,685	\$1,009,685
Bonds	\$0	\$0	\$
Other (Specify)	\$0	\$0	\$
Total Financing	\$2,485,089	\$1,009,685	\$3,494,774

* OMH is listed as a co-borrower on the letter regarding the loan from the Bank of America to ORO. ORO will be paying the loan. OMH is intended more as a guarantor with respect to the proposed Bank of America loan in the amount of \$2,485,089.

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

- Exhibit F.2-1 contains a letter from the Bank of America documenting a proposed loan of \$2,485,089; and
- Exhibit F.2-3 contains a copy of the audited financials for OMH showing an excess of revenues of \$3.3 million and cash or cash equivalents of \$18.8 million as of September 30, 2020.
- Exhibit F.2-2 contains a letter from Onslow Memorial Hospital’s Chief Financial Officer and the manager of ORO documenting the use of the loan funds for the proposed project and the payment of OMH’s portion of the capital costs either with accumulated reserves or as an ongoing operational expense.

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 not exceed operating expenses in any of the first three full fiscal years following completion of the project, as shown in the table below.

	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Total treatments	5,761	6,243	6,766
Total Gross Revenues (Charges)	\$8,749,879	\$9,766,347	\$10,901,442
Total Net Revenue	\$2,091,864	\$2,334,875	\$2,606,246
Average Net Revenue per treatment	\$363	\$374	\$385
Total Operating Expenses (Costs)	\$2,879,681	\$2,937,917	\$2,997,750
Average Operating Expense per treatment	\$500	\$471	\$443
Net Income	(\$787,817)	(\$603,043)	(\$391,505)

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

- OMH deems radiation oncology services vital for the residents of Onslow County. ORO has historically experienced a net loss and, as shown in the table above, is projected to

continue to experience a net loss. However, OMH has historically covered ORO's losses through its own funds and intends to continue to cover any losses by ORO in the future. See letter dated February 15, 2021 by the Chief Financial Officer of OMH in Exhibit F.2-2.

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all of the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all of 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 its ORO facility located at 317 Western Boulevard in Jacksonville, Onslow County.

In Chapter 17, page 324, the 2021 SMFP states, "*Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of linear accelerator service areas... .*" ORO is in Onslow County. In Table 17C-4, page 334 of the 2021 SMFP, Onslow County is included in Linear Accelerator Service Area 25. Linear Accelerator Service Area 25 includes only Onslow County. Thus, the service area for this LINAC consists of Onslow county. Facilities may also serve residents of counties not included in their service area.

There is one LINAC in Linear Accelerator Service Area 25. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators from 10/1/2018 – 9/30/2019, as summarized from Table 17C-1, page 328 of the 2021 SMFP.

	# LINEAR ACCELERATORS	COUNTY	TOTAL PROCEDURES*	AVERAGE ESTVS* PER LINEAR ACCELERATOR
Onslow Radiation Oncology, LLC	1	Onslow	4,395	4,395

*The 2021 SMFP equates ESTVs with procedures in Table 17C-1.

In Section G, page 60, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing LINAC services in Linear Accelerator Service Area 25. The applicant states:

“The proposed project involves the replacement of an existing linear accelerator, which is the sole unit in the service area ... the proposed replacement of the linear accelerator will not result in unnecessary duplication but will maintain the only existing radiation oncology service in the county.”

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 reasons:

- The project involves the replacement of the only LINAC in Linear Accelerator Service Area 25.
- The existing LINAC in Linear Accelerator Service Area 25 performed 5,195 treatments in the last FFY (10/1/2019 to 9/30/2020).
- The proposal would not result in an increase in the number of LINACs in Linear Accelerator Service Area 25.
- The applicant adequately demonstrates that the proposed replacement LINAC is needed in addition to the existing or approved LINACs in Linear Accelerator Service Area 25.

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 its ORO facility located at 317 Western Boulevard in Jacksonville, Onslow County.

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

Position	Current FTE Staff	Projected FTE Staff
	<i>(9/30/020)</i>	2nd Full Fiscal Year (FFY24)
Registered Nurses	1.0	1.0
Clerical	2.0	2.0
Other (Chief Therapist)	1.0	1.0
Other (Therapist)	2.2	2.2
TOTAL	6.2	6.2

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H.2 and H.3, pages 62-63, 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 reasons:

- Projected staffing is based on historical staffing at ORO.
- ORO utilizes the services of OMH, its sole member and one of the largest employers in Onslow County, to meet recruitment and staffing needs, if necessary.

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 its ORO facility located at 317 Western Boulevard in Jacksonville, Onslow County.

Ancillary and Support Services

In Section I.1, page 64, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 64-65, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because ORO is an existing facility that currently already provides all the identified ancillary and support services.

Coordination

In Section I.2, page 65, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following reasons:

- ORO is an existing radiation oncology provider and the sole radiation oncology provider in Onslow County with extensive working relationships with area healthcare providers and social service providers.
- The community hospital, Onslow Memorial Hospital, is the sole member of ORO.

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 its ORO facility located at 317 Western Boulevard in Jacksonville, Onslow County.

In Section K, page 67, the applicant states that the project involves renovating 1,000 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 67, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following reasons:

- Existing fixtures and casework will be reused, to the extent possible, to reduce design and construction costs.
- The project was designed to renovate existing space as opposed to construct new space to minimize project costs.
- To upgrade the vaults shielding the renovations were designed to use concrete rather than more expensive construction materials.

On pages 67-68, 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 following reasons:

- ORO does not anticipate any increase in charges despite the expenditure of capital to acquire a replacement LINAC.
- Replacing the existing LINAC allows ORO to continue to offer access to radiation oncology services in Onslow county thus maintaining local access and allowing patients to avoid the costs in time and money from traveling out of the area for care.
- To avoid undue costs of care ORO delayed replacing the LINAC until such replacement was necessary.

On page 68, 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 70, the applicant provides the historical payor mix during the last Full FY (10/1/2019 to 9/30/2020) for the proposed services, as shown in the table below.

Payor Category	Percent of Total Patients Served
Self-Pay	2.3%
Medicare*	54.3%
Medicaid*	9.8%
Insurance*	20.2%
Other**	13.3%
Total	100.0%

Source: Table on page 70 of the application.

*Including any managed care plans.

**Other: Includes government payors such as TRICARE and Veteran’s Administration.

In Section L, page 71, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	62.0%	44.4%
Male	38.0%	55.6%
Unknown	0.0%	0.0%
64 and Younger	47.2%	90.5%
65 and Older	52.8%	9.5%
American Indian	0.0%	0.6%
Asian	1.0%	2.1%
Black or African-American	19.7%	14.6%
Native Hawaiian or Pacific Islander	0.0%	0.0%
White or Caucasian	75.0%	75.3%
Other Race	4.3%	0.8%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 72, the applicant states that it 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.2b, page 72, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 73, 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.

Payor Category	Percent of Total Patients Served
Self-Pay	2.3%
Medicare*	54.3%
Medicaid*	9.8%
Insurance*	20.2%
Other**	
Total	100.00%

Source: Table on page 73 of the application.

*Including any managed care plans.

**Other: Includes government payors such as TRICARE and Veteran's Administration.

As shown in the table above, during third full fiscal year of operation, the applicant projects that 2.3% of total services will be provided to self-pay patients, 54.3% to Medicare patients and 9.8% to Medicaid patients.

On pages 70 and 73, 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 because it is based on the historical payor mix for ORO.

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 74, 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 its ORO facility located at 317 Western Boulevard in Jacksonville, Onslow County.

In Section M, page 76, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following reasons:

- The applicant states that ORO “regularly hosts students in radiation therapy technology from Pitt Community College in Greenville.”
- The applicant states that ORO is available to students across the UNC System through its relationship with OMH, which is managed by UNC Health.

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 its ORO facility located at 317 Western Boulevard in Jacksonville, Onslow County.

In Chapter 17, page 324, the 2021 SMFP states, “*Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of linear accelerator service areas... .*” ORO is in Onslow County. In Table 17C-4, page 334 of the 2021 SMFP, Onslow County is included in Linear Accelerator Service Area 25. Linear Accelerator Service Area 25 includes only Onslow County. Thus, the service area for this LINAC consists of Onslow county. Facilities may also serve residents of counties not included in their service area.

There is one LINAC in Linear Accelerator Service Area 25. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators from 10/1/2018 – 9/30/2019, as summarized from Table 17C-1, page 328 of the 2021 SMFP.

	# LINEAR ACCELERATORS	COUNTY	TOTAL PROCEDURES*	AVERAGE ESTVs* PER LINEAR ACCELERATOR
Onslow Radiation Oncology, LLC	1	Onslow	4,395	4,395

*The 2021 SMFP equates ESTVs with procedures in Table 17C-1.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 77, the applicant states:

“As the only provider of radiation oncology services in the service area, Onslow County, the proposed project will improve competition by sustaining the service in the county and providing local access and choice to an in-county provider for Onslow County residents. ... Further, the proposed equipment will improve ORO’s competitiveness with providers in other counties in the region by allowing SRS and SBRT treatments for the first time in Onslow County.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 77-78, the applicant states:

“The proposed project will positively impact cost effectiveness primarily in three ways. First ... the need or repairs outside of routine maintenance is expected to be rare. Second ... improved throughput ... Finally, ... the equipment enhancements will minimize the need for patients to leave the county for care as they sometimes do.”

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

Regarding the impact of the proposal on quality, in Section N, page 78, the applicant states:

“The quality of radiation oncology services will be enhanced by ... the improvement in technology from the replacement equipment. ... Further, the proposed equipment will offer SRS and SBRT capabilities for the first time in Onslow County; these treatment types will allow clinicians to prescribe more effective treatments for certain cancer sites that are optimally treated using these techniques.”

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 78, the applicant states:

“Access by the medically underserved groups will be enhanced in multiple ways. ... Without the service available locally, the medically underserved in particular will have more barriers to care, geographically, temporally and financially.”

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

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section O, pages 79-80, the applicant identifies the radiation oncology facilities located in the service area owned, operated or managed by the applicant or a related entity. The applicant states that this is the only radiation oncology facility owned, operated or managed by the applicant or a related entity in North Carolina.

In Section O, page 79, the applicant states that the State of North Carolina does not license freestanding (non-hospital based) cancer centers such as ORO. In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, ORO provided quality care as evidenced by its "*continuous certification by Medicare and Medicaid and its role as the radiation oncology component of the American College of Surgeon's Commission on Cancer's accreditation for OMH.*" See also Exhibit I.1 containing a letter dated February 15, 2021 from the Senior Vice President, Support Services of Onslow Memorial Hospital attesting to ORO's certification and accreditation status. After reviewing and considering information provided by the applicant, 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 LINAC. There are no administrative rules that are applicable to this proposal.