REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: December 4, 2025
Findings Date: December 4, 2025

Project Analyst: Cynthia Bradford
Co-Signer: Gloria C. Hale

Project ID #: J-12692-25
Facility: UNC Radiation Oncology at Clayton
FID #: 080619
County: Johnston
Applicant(s): Johnston Radiation Oncology, LLC
Project: Replace existing 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

Johnston Radiation Oncology, LLC ("JRO or JRO Clayton"), the applicant, proposes to replace an existing linear accelerator to be located at UNC Radiation Oncology at Clayton in Johnston County, an existing cancer treatment facility.

Need Determination

The applicant does not propose to acquire a new linear accelerator or any other health service for which there is an applicable need determination in the 2025 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2025 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 30 of the 2025 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 less than $5 million, but greater than $4 million. In Section B, page 27, 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 based on the following:

- The applicant does not propose to acquire more than one linear accelerator to replace an existing linear accelerator.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 based on the following:

- 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 replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

Patient Origin

In Chapter 15, page 312, the 2025 SMFP states, *"A linear accelerator's service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology."* UNC Radiation Oncology at Clayton is located in Johnston County. In Table 15-C4, page 322 of the 2025 SMFP, Johnston County is included in Linear Accelerator Service Area 22. Linear Accelerator Service Area 22 solely includes Johnston County. Thus, the service area for this project is Johnston County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origins for linear accelerator services and for the entire facility of UNC Radiation Oncology at Clayton.

LINAC	UNC Radiation Oncology at Clayton Historical Patient Origin	
	Last Full FY 07/01/2023 to 06/30/2024	
County or other geographic area such as ZIP code	Number of Patients	% of Total
Johnston	159	53.2%
Wake	104	34.8%
Harnett	24	8.0%
Sampson	7	2.3%
Other Counties^	5	1.7%
Total	**299**	**100.0%**

Source: Section C, page 32
^Other includes Cumberland, Wayne, Nash, and New Hanover counties in North Carolina as well as other states.

Entire Facility	UNC Radiation Oncology at Clayton Historical Patient Origin	
	Last Full FY 07/01/2023 to 06/30/2024	
County or other geographic areas such as ZIP code	Number of Patients	% of Total
Johnston	345	51.4%
Wake	209	31.1%
Harnett	58	8.6%
Sampson	27	4.0%
Other Counties^	32	4.8%
Total	**671**	**100.0%**

Source: Section C, page 33

^Other includes Cumberland, Wayne, Nash, New Hanover, Edgecombe counties in North Carolina as well as other states.

In Section C, pages 34-35, the following tables illustrate the applicant's projected patient origin for LINAC services as well as for the entire facility for the first three full fiscal years of operation, as summarized below.

UNC Radiation Oncology at Clayton Projected Patient Origin						
LINAC	FY 1 07/01/2027-06/30/2028		FY 2 07/01/2028-06/30/2029		FY 3 07/01/2029-06/30/2030	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Johnston	201	53.2%	210	53.2%	215	53.2%
Wake	131	34.8%	137	34.8%	141	34.8%
Harnett	30	8.0%	32	8.0%	33	8.0%
Sampson	9	2.3%	9	2.3%	9	2.3%
Other Counties^	6	1.7%	7	1.7%	7	1.7%
Total	**378**	**100.0%**	**395**	**100.0%**	**405**	**100.0%**

Source: Section C, page 34

^Other includes Cumberland, Wayne, Nash, and New Hanover counties in North Carolina.

UNC Radiation Oncology at Clayton Projected Patient Origin						
Entire Facility or Campus	FY 1 07/01/2027-06/30/2028		FY 2 07/01/2028-06/30/2029		FY 3 07/01/2029-06/30/2030	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Johnston	381	51.4%	391	51.4%	401	51.4%
Wake	231	31.1%	237	31.1%	243	31.1%
Harnett	64	8.6%	66	8.6%	67	8.6%
Sampson	30	4.0%	31	4.0%	31	4.0%
Other Counties^	35	4.8%	36	4.8%	37	4.8%
Total	**742**	**100.0%**	**761**	**100.0%**	**780**	**100.0%**

Source: Section C, page 35

^Other includes Cumberland, Wayne, Nash, New Hanover, Edgecombe counties in North Carolina as well as other states.

Currently, UNC Radiation Oncology at Clayton operates one linear accelerator at the facility in Johnston County. In Section Q, pages 34-35, the applicant provides the assumptions and methodology used to project its patient origin. The applicant projects patient origin for its LINAC services based on patient origin for its LINAC services from the State Fiscal Year (SFY)2023-SFY2024. The assumptions and methodology used to project patient origin and growth are reasonable and adequately supported because they are based on the historical patient origin for the same services already being offered at the same location.

Analysis of Need

In Section C, pages 36-43, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services as summarized below.

- Johnston County's population grew by over 38,000 residents, or 17.4 percent over the past five years. Johnston County added over 8,500 residents age 65 and older from 2020 to 2025, equating to a population CAGR of 5.3 percent for this cohort. Johnston County's age 65 and older population is projected to grow third-fastest among all North Carolina counties.
- Cancer rates for Johnston County are significantly higher than those for North Carolina overall. Johnston County's high cancer incidence rate is also associated with a higher rate of cancer deaths.
- Johnston Radiation Oncology is the sole provider of linear accelerator services in SA 22 and Johnston County, operating two linear accelerators at locations in Smithfield and Clayton, respectively. The linear accelerator at Clayton, the only linear accelerator in Johnston County's largest municipality, has been in operation at that facility since 2010. If the existing linear accelerator at UNC Radiation Oncology at Clayton is not replaced, the current unit will only continue to wear with daily use, which puts it at risk for failure and an end to operability.

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

- Population growth statistics, particularly in the over 65 population for the service area demonstrate an increase in the population most likely to use the LINAC services being proposed.
- The NC State Center for Health Statistics data supports the applicant's demonstration of need based on cancer statistics and projections in Linear Accelerator Service Area 22.
- The applicant adequately demonstrates the need for a linear accelerator in addition to the existing LINAC in Linear Accelerator Service Area 22.

Projected Utilization

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

UNC Radiation Oncology – Clayton LINAC Historical and Projected Utilization				
Projected Medical Equipment Utilization Upon Project Completion	Last FFY 7/1/2023-6/30/2024	**1st FFY 7/1/2027 – 6/30/2028**	**2nd FFY 7/1/2028 – 6/20/2029**	**3rd FY 7/1/2029 – 6/30/2030**
# of Units	1	1	1	1
# of ESTV Treatments*	5,614	7,323	7,615	7,808

Source: Section Q, Forms C.2a and C.2b, pages 97-98.
*ESTV = Equivalent Simple Treatment Visits

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

Step 1:

To project utilization for the proposed replacement linear accelerator at the Clayton facility, the applicant analyzed historical utilization of the existing linear accelerator across treatment delivery types, patients, and equivalent simple treatment visits (ESTVs).

Using JRO internal data for 2D/3D and IMRT treatments, the applicant calculated yearly ratios representing the average number of treatments per patient. From FY 2022 to FY 2025 the number of total ESTVs rose from 5,736 ESTVs to 6,389 ESTVs, growing at a compound annual growth rate (CAGR) of 3.7 percent. It should be noted that more recent growth in ESTVS, from FY 2024 to FY 2025, demonstrates annual growth of 13.8 percent, more than triple the FY 2022 to FY 2025 CAGR. The applicant conservatively projects that linear accelerator procedures at UNC Radiation Oncology at Clayton will grow at the projected Johnston County population growth rate of 2.5%.

The applicant assumes that the number of treatments per patient will remain constant through the third project year, based on the FY 2022 to FY 2025 average ratio of treatments per patient (19.76 treatments per patient). The applicant projects the number of AFCRs to remain flat through the third project year (45 AFCRs per year), which is reasonable given the minimal impact of these procedures on overall utilization. To calculate the facility's total number of ESTVs, the applicant multiplied the number of treatments for each delivery type by the corresponding weight factor assigned in the *SMFP* (2D/3D and IMRT treatments x 1.0; AFCRs x 0.5), as shown in the table below.

UNC Radiation Oncology at Clayton Projected Utilization					
	FY26	***FY27****	***FY28 (PY1)***	***FY29 (PY2)***	***FY30 (PY3)***
2D/3D & IMRT Patients	336	201	354	363	372
Existing Treatments per Patient	19.76	19.76	19.76	19.76	19.76
2D/3D & IMRT Treatments	6,594	3,945	6,950	7,127	7,305
AFCRs	45	26	45	45	45
ESTVs for Existing Services	6,616	3,958	6,972	7,150	7,328

Source: Section Q, page 101

*Replacement of the linear accelerator will require a 20-week or 5-month downtime; therefore, projections illustrate the volumes for both a 7-month period of operation and a full 12-month period.

Step 2:

The existing linear accelerator at UNC Radiation Oncology at Clayton does not currently support more complex radiation therapy procedure types such as stereotactic body radiation therapy (SBRT). The proposed replacement linear accelerator will have the necessary capabilities to perform SBRT procedures. In the absence of relevant historical data for the Clayton facility, the applicant analyzed historical volumes for the linear accelerator at UNC Radiation Oncology at Smithfield, which currently provides SBRT. Internal data demonstrating growth trends across 2D/3D and IMRT treatments, SBRT treatments, and patients by treatment type are provided in the table below.

UNC Radiation Oncology at Smithfield Historical Utilization						
	FY22	**FY23**	**FY24**	**FY25**	**FY22-FY25 Average**	**FY22-FY25 CAGR**
2D/3D & IMRT Treatments	4,779	5,506	4,618	5,438		4.4%
2D/3D & IMRT Patients	231	279	254	275		6.0%
SBRT Patients	4	9	16	24		81.7%
SBRT to Traditional Patient Ratio		0.032	0.063	0.087		
SBRT Procedures per Patient	4.50	4.67	5.63	4.58	4.84	0.6%
SBRT Treatments	18	42	90	110		82.8%

Source: Section Q, page 101

Step 3:

To project SBRT utilization at the Clayton location, the applicant first calculated the number of SBRT patients by applying the FY 2025 ratio of SBRT to traditional treatments (0.087) to the projected numbers of Clayton traditional patients. The applicant assumes that the provision of SBRT at UNC Radiation Oncology at Clayton will involve a ramp-up period, operating at 50 percent in the first year of operation (FY 2027) then increasing to 75 percent in the first full project year (FY 2028) and 100 percent in project years two and three (FY 2029 and FY 2030).

To determine UNC Radiation Oncology at Clayton's total number of SBRT treatments, the applicant calculated the average ratio of traditional treatments per patient and holding it constant through FY 2030, JRO calculated the FY 2022 to FY 2025 average ratio of SBRT

procedures per Smithfield patient (4.84 procedures per patient) and multiplied it by the projected number of Clayton SBRT patients, as shown in the table below.

UNC Radiation Oncology at Clayton Projected SBRT Procedures					
	FY27	***FY27****	***FY28 (PY1)***	***FY29 (PY2)***	***FY30 (PY3)***
2D/3D & IMRT Patients	345	201	354	363	372
SBRT to Traditional Patient Ratio	0.087	0.087	0.087	0.087	0.087
Ramp Up	0.50	0.29	0.75	1.00	1.00
SBRT Patients	16	6	24	32	33
SBRT Procedures per Patient	4.84	4.84	4.84	4.84	4.84
SBRT Treatments	78	30	117	155	160

Source: Section Q, page 102

*Replacement of the linear accelerator will require a 20-week or 5-month downtime; therefore, projections illustrate the volumes for both a 7-month period of operation and a full 12-month period.

Step 4:

The applicant calculated SBRT ESTVs by multiplying the projected procedures shown in the preceding table by the 3.0 weighting factor assigned in the 2025 SMFP, which is indicative of these procedures' greater complexity relative to other treatment delivery types. By summing the ESTVs associated with projected 2D/3D and IMRT treatments, AFCRs, and SBRT procedures, UNC Radiation Oncology at Clayton is expected to perform a total of 7,323 ESTVs in FY 2028, reaching 7,808 ESTVs in FY 2030, accounting for the ramp-up period in SBRT. The number of total patients was calculated by summing the number of total SBRT patients and 2D/3D and IMRT patients. The applicant anticipates that the proposed replacement linear accelerator at UNC Radiation Oncology will serve a total of 378 patients in FY 2028, 395 patients in FY 2029, and 405 patients in FY 2030, as shown in the table below.

UNC Radiation Oncology at Clayton Projected ESTVs						
	FY26	***FY27***	***FY27****	***FY28 (PY1)***	***FY29 (PY2)***	***FY30 (PY3)***
2D/3D & IMRT & AFCRs ESTVs	6,616	6,794	3,958	6,972	7,150	7,328
SBRT Treatments ESTVs	0	234	90	351	465	480
Total ESTVs	6,616	7,028	4,048	7,323	7,615	7,808
Total Patients	336	361	207	378	395	405

Source: Section Q, page 102

*Including down time

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

- The applicant relies on its historical utilization from both its LINAC units, one in Clayton and one in Smithfield, to project future utilization.
- The applicant uses an annual growth rate that is less than its historical compound annual growth rate over the last three years.

Access to Medically Underserved Groups

In Section C.6, page 49, the applicant states,

> *"…UNC Health and its affiliated entities, which include JRO, prohibit the exclusion of services to any patient based on the patient's ability to pay, in addition to the patient's age, race, sex, creed, religion, or disability. JRO's commitment to treating all patients regardless of their ability to pay is evidenced by its payor mix. JRO has a long and proud history of serving patients who require care, regardless of their ability to pay."*

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	21.9%
Women	66.2%
Persons with Disabilities	
Persons 65 and older	55.0%
Medicare beneficiaries	54.9%
Medicaid recipients	4.0%

Source: Section C, page 49

The applicant adequately describes, on page 49 and in Exhibit C.6, the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based, in part, on the following:

- The applicant provides written statements about providing access to all residents of the service area, including underserved groups.
- The applicant's facility has historically provided care to all in need of radiation oncology services, including underserved persons.

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.

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

NA

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

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

CA

The applicant proposes to replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

In Section E, pages 57-58, 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

JRO considered maintaining the status quo by continuing to operate the existing linear accelerator at UNC Radiation Oncology at Clayton. The existing linear accelerator is more than fifteen years old, well beyond the typical ten-to-twelve-year lifespan for such equipment in the United States. The unit has already experienced performance challenges, service requests, and intermittent downtimes that have caused treatment delays. As the equipment continues to age, these issues will worsen, leading to increased maintenance costs and increased risk of complete equipment failure. Given that this linear accelerator represents half of Johnston County's linear accelerator inventory, a total failure would significantly reduce accessible services in the county. Therefore, this was not the most effective alternative.

Develop the Proposed Replacement Linear Accelerator at Smithfield Radiology

JRO considered instead developing the replacement linear accelerator at Smithfield Radiation Oncology. The linear accelerator at UNC Radiation Oncology at Clayton is nearing the end of its useful life and cannot currently deliver standard of care linear accelerator procedures; in contrast, the linear accelerator at Smithfield Radiation Oncology is able to perform SRS and SBRT procedures. Developing the linear accelerator at Smithfield would concentrate linear accelerator resources in one geographical area of the county rather than evenly distributing access across the county and service area. Therefore, this was not the most effective alternative.

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

- The applicant provides reasonable information to explain why it believes 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. **Johnston Radiation Oncology, LLC (herein after "the certificate holder") shall materially comply with all representations made in the certificate of need application.**

2. **The certificate holder shall replace an existing linear accelerator with a new linear accelerator at UNC Radiation Oncology at Clayton.**

3. **Upon project completion, UNC Radiation Oncology at Clayton will be licensed for no more than one linear accelerator.**

4. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**

5. **Progress Reports:**
   a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.**
   b. **The certificate holder shall complete all sections of the Progress Report form.**
   c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
   d. **The first progress report shall be due on May 1, 2026.**

6. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

Capital and Working Capital Costs

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

Construction/Renovation Contracts	$610,500
Architect/ Engineering Fees	$54,000
Medical Equipment	$3,534,149
Other (Contingency)	$100,000
Total	**$4,298,649**

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

- In Section Q, Form F.1a and Exhibit C.1-2., the applicant provides its assumptions which are based on the experience of UNC Radiation Oncology and its members with similar projects in addition to a vendor quote for the linear accelerator.
- In Exhibit F.1, the applicant provides a construction cost breakdown dated July 9, 2025, from Johnson & Johnson Crabtree Architects, P.C.

In Section F, page 61, the applicant states that there are no projected start-up expenses or initial operating expenses because the project does not involve a new service. This information is reasonable and adequately supported because JRO Clayton is an existing facility that currently offers LINAC services and is only proposing to replace an existing LINAC.

Availability of Funds

In Section F, page 59, the applicant states the entire projected capital expenditure of $4,298,649 will be funded through accumulated reserves of Johnston Radiation Oncology, LLC.

In Exhibit F.2, the applicant provides a letter dated September 15, 2025, from the Vice President of UNC Health Johnston, stating that it plans to fund the development of the proposed project through accumulated cash reserves.

Exhibit F.2-2 contains a balance sheet for JRH Ventures, LLC ending May 31, 2025 demonstrating that adequate funds are available.

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

- The applicant provides a letter from an appropriate UNC Health Johnston official committing the accumulated reserves for developing the proposed project.
- The applicant provides financial statements to demonstrate that adequate funds are available for the proposed project.

Financial Feasibility

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

UNC Radiation Oncology - Clayton LINAC Revenues and Operating Expenses			
	FY 1 (FFY 2027)	**FY 2 (FFY 2028)**	**FY 3 (FFY 2029)**
Total Patients	7,323	7,615	7,808
Total Gross Revenues (Charges)	$25,979,170	$27,961,972	$29,529,966
Total Net Revenue	$7,022,475	$7,558,449	$7,982,296
Total Net Revenue per Patient	$959	$993	$1,022
Total Operating Expenses (Costs)	$3,998,089	$4,165,592	$4,311,866
Total Operating Expenses per Patient	$546	$547	$552
Net Profit/(Loss)	**$3,024,386**	**$3,392,857**	**$3,670,430**

Source: Section Q, Forms C.2b & F.2b

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.

- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

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

C

The applicant proposes to replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

In Chapter 15, page 312, the 2025 SMFP states, *"A linear accelerator's service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology."* UNC Radiation Oncology at Clayton is located in Johnston County. In Table 15-C4, page 322 of the 2025 SMFP, Johnston County is included in Linear Accelerator Service Area 22. Linear Accelerator Service Area 22 solely includes Johnston County. Thus, the service area for this project is Johnston County. Facilities may also serve residents of counties not included in their service area.

There are two LINACs in Linear Accelerator Service Area 22. The following table identifies the provider, number of linear accelerators, and average utilization of each of the LINACs in FFY2023, as summarized from Table 15C-1, page 316 of the 2025 SMFP.

Provider	# of LINACs	County	Total Procedures	Average ESTV* per LINAC
UNC Radiation Oncology at Clayton**	1	Johnston	5,931	5,931
Smithfield Radiation Oncology	1	Johnston	5,555	5,555

*The 2025 SMFP equates ESTV's with procedures in Table 15C-1.

**Listed in the 2025 SMFP as Johnston Health Clayton Professional Plaza

In Section G, page 69, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Linear Accelerator Service Area 22. The applicant states:

> *"The proposed project involves the replacement of an existing linear accelerator and therefore does not involve the addition of any linear accelerators to linear accelerator in Service Area 22."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the proposed project involves the replacement of an existing LINAC in Service Area 22 and thus, will not increase the inventory.

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.

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

C

The applicant proposes to replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

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	UNC Radiation Oncology at Clayton Projected FTE Staff			
	Current Staff as of 6/30/2024	1st FFY	2nd FFY	3rd FFY
Manager	0.3	0.3	0.3	0.3
Senior Medical Office Specialist	1.0	1.0	1.0	1.0
Medical Office Specialist	0.3	1.0	1.0	1.0
Billing Coordinator	0.5	0.9	0.9	0.9
Dosimetrist	1.0	1.0	1.0	1.0
Physicist	1.0	1.0	1.0	1.0
Coordinator	1.0	1.3	1.3	1.3
Radiation Therapist	3.6	3.5	3.5	3.5
Registered Nurses	1.1	1.0	1.0	1.0
Chief Physicist	0.0	0.1	0.1	0.1
Director	0.0	0.1	0.1	0.1
Revenue Cycle Manager	0.0	0.2	0.2	0.2
Total	**9.8**	**11.4**	**11.4**	**11.4**

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q immediately following Form H. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form 3.b.

In Sections H.2 and H.3, pages 71-72, 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:

- Projected staffing is based on historical staffing at the existing facility.
- The applicant provides documentation of its methods to recruit, train and retain staff in Section H of the application.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

Ancillary and Support Services

In Section I.1, page 73, the applicant identifies the necessary ancillary and support services for the proposed services. On page 74, 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 UNC Radiation Oncology at Clayton is an existing facility that offers radiation oncology services including currently providing all the identified ancillary and support services.

Coordination

In Section I.2, page 74, 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 since Johnston Radiation Oncology is an existing radiation oncology provider with established working relationships with area healthcare providers 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.

(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

(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 replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

In Section K, page 77, the applicant states that the project involves renovating 1,550 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

On pages 77-78, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant states,

> *"The replacement linear accelerator will occupy existing space at UNC Radiation Oncology at Clayton, which already has the necessary systems infrastructure in place to accommodate the new unit. The design and upfit costs will therefore be significantly lower than if the replacement linear accelerator were to be housed in newly constructed space or space not originally designed to support the provision of radiation therapy services. In addition to being more cost-effective, the minor renovation that is required for the space can be carried out in a more efficient manner, reducing potential disruptions to timely care delivery."*

On page 78, 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. The applicant states,

> *"…the proposed project is necessary to continue offering access to radiation oncology services in Johnston County. As such, maintaining local access prevents patients from travelling out of the area for care, which minimizes the cost of obtaining care. Despite the need to expend capital to acquire a replacement linear accelerator, the capital expenditures for the proposed project are relatively minimal. Additionally, UNC Radiation Oncology at Clayton does not anticipate the need to increase its charges as a result of the proposed project."*

On page 78, the applicant adequately explains any applicable energy saving features that will be incorporated into the construction/ renovation plans. The applicant states,

> *"…all existing spaces necessary for the proposed project will conform to or exceed the energy efficiency and water conservation standards incorporated into the latest edition of the North Carolina State Building Codes and will focus on reducing energy consumption associated with lighting, heating, and air distribution, as well as reducing water usage."*

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 81, the applicant provides the historical payor mix during the last full fiscal year (07/01/2023 to 6/30/2024) for UNC Radiation Oncology at Clayton, as shown in the table below.

Payor Category	Percent of Total Served
Self-Pay	1.2%
Medicare*	54.9%
Medicaid*	4.0%
Insurance*	39.0%
Other (other Gov't, TRICARE, Worker's Comp)	1.0%
Total	**100.0%**

Source: Table on page 81 of the application.
*Including any managed care plans.

In Section L, page 82, the applicant provides the following comparison.

UNC Radiation Oncology at Clayton	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY (07/01/2023 to 6/30/2024)	Percentage of the Population of the Service Area
Female	66.2%	50.4%
Male	33.8%	49.6%
Unknown	0.0%	0.0%
64 and Younger	45.0%	86.4%
65 and Older	55.0%	13.6%
American Indian	0.6%	0.7%
Asian	0.5%	0.8%
Black or African American	16.5%	13.9%
Native Hawaiian or Pacific Islander	0.2%	0.0%
White or Caucasian	78.1%	58.9%
Other Race	4.1%	29.1%
Declined / Unavailable	0.0%	0.0%

Source: United States Census Bureau's QuickFacts

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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 83, the applicant states it has no obligation.

In Section L, page 83, 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.

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 85, the applicant projects the following payor mix for UNC Radiation Oncology at Clayton's radiation oncology services during the third full fiscal year of operation following completion of the project, as shown in the table below.

UNC Radiation Oncology at Clayton Projected Payor Mix PY3 (2030)	
Payor Category	**Percent of Total Patients Served**
Self-Pay	1.2%
Charity Care**	
Medicare*	54.9%
Medicaid*	4.0%
Insurance*	39.0%
Other (other Gov't, TRICARE, Worker's Comp)	1.0%
Total	**100.0%**

Source: Table on page 85 of the application.
*Including any managed care plans.
**The applicant states, on page 84, that it doesn't include charity care as a payor source, but patients in any payor category receive charity care.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.2% of total radiation oncology services will be provided to self-pay patients, 54.9% to Medicare patients and 4.0% to Medicaid patients.

On pages 84-85, the applicant provides the assumptions and methodology used to project payor mix, including charity care, 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 its historical payor mix for linear accelerator treatments for FY2024.

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 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.5, page 86, 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 replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

In Section M, page 87, 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 because UNC Health Johnston maintains long standing agreements with area schools and training programs to support clinical training needs, including Johnston Community College.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

In Chapter 15, page 312, the 2025 SMFP states, *"A linear accelerator's service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology."* UNC Radiation Oncology at Clayton is located in Johnston County. In Table 15-C4, page 322 of the 2025 SMFP, Johnston County is included in Linear Accelerator Service Area 22. Linear Accelerator Service Area 22 solely includes Johnston County. Thus, the service area for this project is Johnston County. Facilities may also serve residents of counties not included in their service area.

There are two LINACs in Linear Accelerator Service Area 22. The following table identifies the provider, number of linear accelerators, and average utilization of each of the LINACs in FFY2023, as summarized from Table 15C-1, page 316 of the 2025 SMFP.

Provider	# of LINACs	County	Total Procedures	Average ESTV* per LINAC
UNC Radiation Oncology at Clayton**	1	Johnston	5,931	5,931
Smithfield Radiation Oncology	1	Johnston	5,555	5,555

*The 2025 SMFP equates ESTV's with procedures in Table 15C-1.

**Listed in the 2025 SMFP as Johnston Health Clayton Professional Plaza

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 88, the applicant states:

> *"The proposed project will foster competition by promoting cost effectiveness, quality, and access to services in Johnston County and surrounding areas. The replacement equipment to be purchased for the proposed project features advanced capabilities which*

will greatly expand and improve the delivery of radiation therapy services in Johnston County, resulting in enhanced competition and a higher quality of care among providers of these services."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 88, the applicant states:

"…the development of a replacement linear accelerator as detailed in this application can be accomplished in a resource responsible manner. JRO will upfit existing space in UNC Radiation Oncology at Clayton to accommodate the replacement linear accelerator without new construction or major renovation. As an existing provider of radiation therapy, JRO has all necessary ancillary and support services in place to continue supporting these services. Additionally, UNC Radiation Oncology at Clayton does not anticipate the need to increase its charges as a result of the proposed project. As such, JRO believes the replacement unit can be developed at a reasonable cost and in an efficient manner."

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

Regarding the impact of the proposal on quality, in Section N, page 89, the applicant states:

"JRO believes the proposed replacement project will promote safety and quality in the provision of radiation therapy services to patients of Johnston County and surrounding areas. UNC Health Rex and UNC Health Johnston, the members of JRO, are known for providing high-quality services and expect the proposed project to provide significant benefits to patients through the development of advanced equipment and an expanded scope of care delivery."

See also Sections B and O the application and exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 91, the applicant states:

"…UNC Health Johnston, including JRO, prohibits the exclusion of services to any patient based on the patient's ability to pay, in addition to the patient's age, race, sex, creed, religion, or disability"

See also Sections B, C, and L of the application and exhibits.

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

1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not

result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.

3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant proposes to replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

In Section Q, Form O, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 14 of this type of facility located in North Carolina. In Section O, page 94, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care resulting in a finding of immediate jeopardy occurred in any of its facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care did not occur in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all four of the applicant's hospitals, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

NA

The applicant proposes to replace an existing linear accelerator located at UNC Radiation Oncology at Clayton.

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