

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 18, 2022

Findings Date: January 18, 2022

Project Analyst: Mike McKillip

Co-Signer: Micheala Mitchell

Project ID #: L-12154-21

Facility: Wilson Medical Center

FID #: 923569

County: Wilson

Applicant: DLP Wilson Medical Center, LLC

Project: Acquire a replacement 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

DLP Wilson Medical Center, LLC, referred to as “the applicant,” proposes to acquire a replacement linear accelerator at the Wilson Radiation Oncology Center.

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 24, the applicant describes the project’s plan for energy efficiency and to conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 linear accelerator at the Wilson Radiation Oncology Center. Wilson Radiation Oncology Center is a freestanding facility, included on the license of Wilson Medical Center, and located approximately one block from the main hospital building.

Patient Origin

In Chapter 17, page 324, the 2021 SMFP states, “A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Wilson Radiation Oncology Center is in Wilson County. In Table 17C-4, page 334 of the 2021 SMFP, Wilson County is included in Linear Accelerator Service Area 26. Linear Accelerator Service Area 26 includes Edgecombe, Halifax, Nash, Northampton and Wilson counties. Thus, the service area for this project consists of those five counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	Historical CY2020		Third Full FY of Operation following Project Completion CY2025	
	Patients	% of Total	Patients	% of Total
Wilson	136	82.4%	116	81.1%
Nash	19	11.5%	13	9.0%
Johnston	5	3.0%	6	4.1%
Out of Area	5	3.0%	8	5.8%
Total	165	100.0%	143	100.0%

Source: Tables on page 26 and 28 of the application.

In Exhibit C.3, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the average historical patient origin from CY2018 to CY2020 for the existing linear accelerator at Wilson Radiation Oncology Center.

Analysis of Need

In Section C.4, pages 30-35, 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 population growth, health status and cancer incidence rates for the applicant’s primary service area counties of Wilson, Nash and Johnston.
- The need to have linear accelerator services located in close proximity to patient residences due to the need to travel frequently to the treatment center and the inconvenience and difficulty of travel for the patient and their caregivers.
- The need to maintain new technology to provide high quality and effective radiation therapy services in an efficient and cost-effective manner.
- The need to maintain high quality technology and equipment to recruit, retain and support the hospital’s physicians and other clinical staff.

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

- The existing 14-year old linear accelerator has reached the end of its useful life and needs to be replaced.
- Cancer rates and population growth in the proposed service area support the need to replace the linear accelerator at the Wilson Radiation Oncology Center.
- The replacement linear accelerator would incorporate new technology which would improve the level of care that could be offered as well as the types of treatment.

Projected Utilization

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

	CY2020	CY2021	Interim CY2022	1st Full OY CY2023	2nd Full OY CY2024	3rd Full OY CY2025
# of Units	1	1	1	1	1	1
# of ESTV Treatments*	1,612	1,548	1,405	1,437	1,452	1,467

Source: Section Q of the application.

*ESTVs = Equivalent Simple Treatment Visits

In Section Q, pages 95-101, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Forecast New Cancer Cases in Primary Service Area: The applicant identifies Wilson, Nash, and Johnston Counties as its primary market based on historical patient origin. The applicant provides new cancer case projections by county through 2021 based on the North Carolina Central Cancer Registry. See the tables on page 95-96 of the application.

Step 2: Estimate Total Cancer Cases in Primary Service Area Treatable with EBRT: The applicant projects that 50% of cancer cases are treatable with EBRT [Electron Beam Radiation Therapy]. See the tables on pages 96-97 of the application.

Step 3: Determine Wilson MC Historical Market Share of EBRT Cases: To forecast utilization, the applicant calculates historical market share by comparing historical Wilson Medical Center cases against estimated total cancer cases treatable with EBRT from Step 2 above. See the table on page 97 of the application.

Step 4: Forecast Wilson Medical Center EBRT Cases, 2022-2025: The applicant states that historical use of the existing linear accelerator has declined, likely due to the age and inefficiency of the equipment. The applicant projects future radiation therapy cases based on the lowest market share of the previous three years. Additionally, the applicant further reduced the Wilson County market share by ten percent and held it consistently through 2025. See the table on page 97 of the application.

Step 5: Determine Wilson MC EBRT Treatments per Patient: The applicant states most patients receive more than one treatment. The applicant determined the historical ratio of treatments per patient to forecast treatments, assuming 1 case = 1 patient. See the table on page 99 of the application.

Step 6: Forecast WROC EBRT Treatments, 2022-2025: The applicant used the annualized 2021 ratio of treatments to cases to project radiation therapy treatments through the first three full fiscal years of operation, as shown in the table on page 99 of the application.

Step 7: Determine the Number of Treatments by Linear Accelerator CPT Code: To project ESTVs, the applicant analyzed historical Wilson Medical Center linear accelerator treatments by CPT code. The applicant then projected the procedure mix based on the capabilities of the new equipment. See the tables on page 100 of the application.

Step 8: Forecast Number of Treatments by Linear Accelerator CPT Code, 2022-2025: The applicant multiplies the projected treatments by the CPT code percentages from Step 7 to arrive at treatments by CPT code as shown in the table on 101 of the application.

Step 9: Forecast Total Wilson MC ESTVs, 2022-2025: To forecast the number of ESTVs, the applicant multiplies the estimated treatments by CPT code in Step 8 by its corresponding ESTV factor as listed in the 2021 SMFP. See the table on page 101 of the application.

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

- The applicant relies on data from its own operating experience and other reliable sources for its assumptions.
- The applicant relies on historical linear accelerator utilization at Wilson Radiation Oncology Center to project future utilization.
- The applicant provides letters of support from physicians for the proposed project in Exhibit I.2 of the application.

Access to Medically Underserved Groups

In Section C.6, page 40, the applicant states, “*Wilson Radiation Oncology Center accepts patients regardless of gender, gender preference, race, ethnicity, age, income, or disability status.*” On page 41 of the application, 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*	14.6%
Racial and ethnic minorities	75.0%
Women	40.0%
Persons with Disabilities	NA*
Persons 65 and older	61.0%
Medicare beneficiaries	61.0%
Medicaid recipients	11.2%

*On page 41 of the application, the applicant states, “*By definition, all patients of the hospital are disabled.*”

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:

- The applicant commits to provide services to all patients referred for services.
- The applicant’s facilities have 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 acquire a replacement linear accelerator at the Wilson Radiation Oncology Center. Wilson Radiation Oncology Center is a freestanding facility, included on the license of Wilson Medical Center, and located approximately one block from the main hospital building.

In Section E, page 49, the applicant states that there are no alternatives available to meet the need described. The applicant states,

“The applicant has sustained use of the existing equipment as long as is reasonable. Continuing to offer the service requires replacing the linear accelerator. For all of the reasons discussed in Section C.4, radiation oncology services are needed and will be needed in the service area for the foreseeable future. Wilson Radiation Oncology Center has an existing vault that can accommodate the replacement equipment without disrupting service and, after installation, the replaced equipment can use all of the existing infrastructure with no additional capital investment required. In the absence of such a vault, project costs would be higher and time delay to implementation would be longer.”

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. DLP Wilson Medical Center, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

- 2. The certificate holder shall acquire a replacement linear accelerator to be located at Wilson Radiation Oncology Center.**
 - 3. Upon completion of the project, Wilson Radiation Oncology Center 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 fourth month. The first progress report shall be due on June 1, 2022. The second progress report shall be due on October 1, 2022 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 linear accelerator at the Wilson Radiation Oncology Center.

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.

Construction/Renovation Costs	\$700,000
Architecture/Engineering Fees	\$134,000
Medical Equipment	\$4,039,000
Nonmedical Equipment	\$20,000
Interest During Construction	\$35,000
Contingency	\$70,000
Total	\$4,998,000

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 as documented in Exhibits F.1 and K.3.

In Section F.3, page 53, the applicant projects there will be no start-up or initial operating expenses because Wilson Radiation Oncology Center is existing and operational.

Availability of Funds

In Section F.2, page 50, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	DLP Wilson Medical Center, LLC
Loans	\$0
Cash and Cash Equivalents, Accumulated reserves or Owners Equity	\$4,998,000
Bonds	\$
Other (Specify)	\$
Total Financing	\$4,998,000

Exhibit F.2 contains a copy of an October 5, 2021 letter from LifePoint Corporate Services, a corporate affiliate of DLP Wilson Memorial Hospital, LLC, documenting the funding of the proposed project with accumulated reserves. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

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

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Treatments	1,437	1,452	1,467
Total Gross Revenues (Charges)	\$17,058,755	\$18,038,726	\$19,074,047
Total Net Revenue	\$3,093,216	\$3,180,718	\$3,267,903
Net Revenue per Treatment	\$2,153	\$2,191	\$2,228
Total Operating Expenses (Costs)	\$2,867,078	\$2,899,742	\$2,933,004
Operating Expense per Treatment	\$1,995	\$1,997	\$1,999
Net Income	\$226,138	\$280,976	\$334,899

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to acquire a replacement linear accelerator at the Wilson Radiation Oncology Center.

In Chapter 17, page 324, the 2021 SMFP states, “A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Wilson Radiation Oncology Center is in Wilson County. In Table 17C-4, page 334 of the 2021 SMFP, Wilson County is included in Linear Accelerator Service Area 26. Linear Accelerator Service Area 26 includes Edgecombe, Halifax, Nash, Northampton and Wilson counties. Thus, the service area for this project consists of those five counties. Facilities may also serve residents of counties not included in their service area.

There are four linear accelerators in Linear Accelerator Service Area 26. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators in FFY2019, as summarized from Table 17C-1, page 328 of the 2021 SMFP.

	# LINEAR ACCELERATORS	COUNTY	TOTAL PROCEDURES*	AVERAGE ESTVS* PER LINEAR ACCELERATOR
NC Radiation Therapy Management-Roanoke Rapids	1	Halifax	2,163	2,163
Wilson Medical Center	1	Wilson	2,104	2,104
Nash General Hospital	2	Nash	8,494	4,247

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

In Section G, pages 59-60, 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 26. The applicant states:

“Nash General Hospital has capacity to absorb patients from Wilson County. However, Nash County is growing and aging; over time it cannot absorb all of its own growth, plus the Wilson County need without reaching capacity. ... Roanoke Rapids is an hour and five minutes from Wilson by the fastest route, I-95. Many rural people avoid Interstate travel. And, this would represent a two-hour daily trip for patients and their supporters.”

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 proposal would not result in an increase in the number of linear acceleratoes in Linear Accelerator Service Area 26.
- The applicant adequately demonstrates that the proposed replacement linear accelerator is needed in addition to the existing or approved linear accelerators in Linear Accelerator Service Area 26.

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.

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The applicant proposes to acquire a replacement linear accelerator at the Wilson Radiation Oncology Center.

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		
	(9/17/2021)	1 st Full Fiscal Year	2nd Full Fiscal Year	3 rd Full Fiscal Year
Registered Nurses	1.0	1.0	1.0	1.0
Clerical	2.0	2.0	2.0	2.0
Director of Oncology Services	1.0	1.0	1.0	1.0
Patient Navigator	1.0	1.0	1.0	1.0
Dosimetrist	1.0	1.0	1.0	1.0
Radiation Therapist	3.0	3.2	3.3	3.4
TOTAL	9.0	9.2	9.3	9.4

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 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.

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The applicant proposes to acquire a replacement linear accelerator at the Wilson Radiation Oncology Center.

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 Wilson Radiation Oncology Center 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 fact that Wilson Radiation Oncology Center is an existing radiation oncology provider with extensive 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. 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 linear accelerator at the Wilson Radiation Oncology Center.

In Section K, page 68, 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 69, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The application states,

“The project involves minimal square feet because it takes advantage of an existing linear accelerator vault in a freestanding radiation oncology facility. It will involve no additional site cost, no additional support spaces, and no expansion of mechanical, electrical, or plumbing capacity. The construction cost is in line with construction costs for this type of renovation. The cost also reflects the relatively small scale of the project. Wilson Medical Center will be able to provide higher-quality and more efficient radiation oncology services with considerably less down-time at project end.”

On page 69, 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,

“As explained in Section C.4, the proposed project is necessary to continue offering access to radiation oncology services in Wilson County. As such, maintaining local access prevents patients from traveling out of the area for care, which minimizes their cost of obtaining care. Wilson Medical Center has delayed replacing the equipment until it was absolutely necessary in order to avoid undue costs for the service. Despite the need to expend capital to acquire a replacement linear accelerator, Wilson Medical Center does not anticipate the need to increase its charges as a result of the proposed project.”

On page 69, 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.1, page 72, the applicant provides the historical payor mix for Wilson Medical Center during the last full fiscal year (CY2020), as shown in the table below.

Payor Category	Percent of Total Patients Served
Self-Pay	17.1%
Charity	0.4%
Medicare*	43.0%
Medicaid*	19.2%
Insurance*	19.2%
Workers Compensation, TRICARE	1.1%
Total	100.0%

Source: Table on page 72 of the application.

*Including any managed care plans.

In Section L.1, page 74, 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	60.62%	51.6%
Male	39.38%	48.4%
Unknown	0.0%	0.0%
64 and Younger	65.65%	84.0%
65 and Older	34.35%	16.0%
American Indian	0.05%	0.9%
Asian	0.12%	1.0%
Black or African-American	49.62%	27.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	43.87%	58.2%
Other Race	2.13%	11.9%
Declined / Unavailable	0.11%	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;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 76, the applicant states that it is obligated under applicable federal regulations to provide uncompensated care, community service, and access by minorities and persons with disabilities. The applicant states,

“Wilson Medical Center is a CMS certified hospital and therefore subject to EMTALA rules. It is in full compliance with CMS certification for Medicare and Medicaid, and by extension in compliance with EMTALA requirements. See Exhibit L.4 for Wilson Medical Center’s EMTALA Policy. Furthermore, Wilson Medical Center is subject to compliance with Internal Revenue Service Section 501(r) and all requirements imposed by the Affordable Care Act.”

In Section L.2b, page 76, 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 77, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation (CY2025) following completion of the project, as shown in the table below.

Payor Category	Percent of Total Patients Served
Self-Pay	0.5%
Charity	3.3%
Medicare*	61.0%
Medicaid*	11.2%
Insurance*	22.6%
Workers Compensation, TRICARE	1.3%
Total	100.0%

Source: Table on page 77 of the application.

*Including any managed care plans.

As shown in the table above, during third full fiscal year of operation, the applicant projects that 0.5% of total services will be provided to self-pay patients, 3.3% to charity patients, 61% to Medicare patients and 11.2% to Medicaid patients.

On pages 77, 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 (CY2020) payor mix for Wilson Radiation Oncology Center.

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 79, 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 linear accelerator at the Wilson Radiation Oncology Center.

In Section M, page 80, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1 of the application. The applicant adequately demonstrates that health professional training programs in the area have access to the facility.

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 linear accelerator at the Wilson Radiation Oncology Center.

In Chapter 17, page 324, the 2021 SMFP states, “*A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology.*” Wilson Radiation Oncology Center is in Wilson County. In Table 17C-4, page 334 of the 2021 SMFP, Wilson County is included in Linear Accelerator Service Area 26. Linear Accelerator Service

Area 26 includes Edgecombe, Halifax, Nash, Northampton and Wilson counties. Thus, the service area for this project consists of those five counties. Facilities may also serve residents of counties not included in their service area.

There are four linear accelerators in Linear Accelerator Service Area 26. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators in FFY2019, as summarized from Table 17C-1, page 328 of the 2021 SMFP.

	# LINEAR ACCELERATORS	COUNTY	TOTAL PROCEDURES*	AVERAGE ESTVS* PER LINEAR ACCELERATOR
NC Radiation Therapy Management-Roanoke Rapids	1	Halifax	2,163	2,163
Wilson Medical Center	1	Wilson	2,104	2,104
Nash General Hospital	2	Nash	8,494	4,247

*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 82, the applicant states:

“Wilson Radiation Oncology Center in need of a new linear accelerator to continue to meet current and future demand for patients and physician referrals. The proposed project will allow the applicant to remain competitive and thus maintain the strong competition in the service area. It will also allow Wilson Radiation Oncology Center to remain prepared for long-term success by serving patients' needs and providing them with an excellent experience.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 82, the applicant states:

“The proposed project will expand and enhance services at a growing community hospital in a service area with a population also growing and aging. Wilson Radiation Oncology Center proposes to replace its existing linear accelerator with newer equipment in its radiation oncology department. Upgrading its equipment, and subsequently its service, will enable Wilson Radiation Oncology Center to serve patients more efficiently and with higher quality care.”

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 83, the applicant states:

“The replacement equipment will be acquired from quality vendors who will be held accountable for meeting current safety regulations at the time of sale; and Wilson Radiation Oncology Center will adhere to the maintenance program that supports sustained standards. Staff will be pre-trained in use and care of the equipment.”

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 83, the applicant states:

“The location, ADA compliant building design, and willingness to accept Medicare, Medicaid, hardship patients, and uninsured will all increase access for patients and promote competition in the proposed service area. More than 72 percent of expected patients will be Medicare and Medicaid beneficiaries.”

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 Form O, page 115 of the application, the applicant identifies nine facilities in North Carolina owned, operated or managed by the applicant or a related entity. In Section O.1, page 85, the applicant states four of the facilities operate a linear accelerator.

In Section O.4, page 87 the applicant states that, during the 18 months immediately preceding the submittal of the application, neither Wilson Medical Center, nor any North Carolina LifePoint Health, Inc. managed hospitals, have had any situation resulting in finding of immediate jeopardy. According to the files in the Acute and Home Care Licensure and Certification Section, DHHS, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred 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 nine facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

NA

The applicant proposes to acquire a replacement linear accelerator. There are no administrative rules that are applicable to this proposal.