

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 9, 2016

Findings Date: February 9, 2016

Project Analyst: Celia C. Inman

Assistant Chief: Martha J. Frisone

Project ID #: P-11117-15

Facility: Lenoir Memorial Hospital, Inc.

FID #: 933304

County: Lenoir

Applicant: Lenoir Memorial Hospital, Inc.

Project: Replace existing linear accelerator

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Lenoir Memorial Hospital, Inc. (LMH), currently owns and operates a linear accelerator located at the Lenoir Memorial Cancer Center at 703 Doctors Drive in Kinston, across the street from the hospital's main campus. The applicant proposes to replace its existing linear accelerator.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2015 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2015 SMFP that is applicable to this review: Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES.

Policy GEN-4 states:

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

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section 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 are required to submit a plan of 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 million and less than \$5 million. In Section III.2, pages 36-37, the applicant addresses Policy GEN-4 and the project’s plan for energy efficiency and water conservation. The applicant states:

“LMH has designed the proposed equipment replacement project to be in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including Policy GEN-4. ... The hospital’s cancer center facility was constructed to ensure energy efficiency and cost effective utilities.

...

LMH will work with experienced architects and engineers to develop this proposed project to ensure energy efficient systems are an inherent part of the proposed project, to the degree appropriate with the proposed renovations.”

The applicant adequately demonstrates the proposal 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

In summary, the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to replace the existing linear accelerator that it currently owns and operates at Lenoir Memorial Cancer Center at 703 Doctors Drive, across the street from the hospital's main campus.

Population to be Served

On page 125, the 2015 SMFP defines a linear accelerator's service area as "*the linear accelerator planning area in which the linear accelerator is located. The linear accelerator planning areas are the 28 multicounty groupings shown in Figure 9I.*" Table 9I on page 133 of the SMFP shows Lenoir County in Linear Accelerator Service Area 23, along with the contiguous counties of Duplin and Wayne.

Thus, the service area for this facility's project is Linear Accelerator Service Area 23, consisting of Lenoir, Duplin and Wayne counties. Facilities may also serve residents of counties not included in their service area.

In Section III.4(a and b), pages 40-41, the applicant identifies its historical patient origin for services provided at LMH. The applicant states that historically, Lenoir, Duplin and Greene counties account for approximately 90 percent of LMH's linear accelerator patient origin as shown in the table on page 41 and below.

**LMH Linear Accelerator Services
Historical Patient Origin
FFY2015**

County	Service
Lenoir	74.0%
Duplin	10.1%
Greene	5.3%
Craven	4.7%
Wayne	3.0%
Pitt	1.8%
Jones	1.2%
Total	100.0%

The applicant provides a geographical map on page 42 showing the project's proposed primary market of Lenoir County, and secondary market of Greene County to the north and Duplin County to the south.

On page 43, the applicant provides the projected patient origin by county of residence for linear accelerator services for the first two years of operation following completion of the project.

**LMH Linear Accelerator Services
Projected Patient Origin
FFY2017 – FFY2018**

County	Service
Lenoir	74.0%
Duplin	10.1%
Greene	5.3%
Craven	4.7%
Wayne	3.0%
Pitt	1.8%
Jones	1.2%
Total	100.0%

The applicant states that its assumptions for the projected patient origin are based on LMH's historical experience providing linear accelerator services and physician support letters committing to continue to refer patients.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to replace the existing Varian 2100CD linear accelerator with a new Varian TrueBeam linear accelerator. In Section III.1, pages 24-33, the applicant discusses the

need for the proposed project and states that the need is based on numerous qualitative and quantitative factors, including:

- the existing linear accelerator is technologically obsolete,
- the proposed replacement represents the current clinical standard of care,
- the aging and economic demographics of the service area population increases the demand for healthcare, and
- cancer incidence rates for service area residents are high compared to statewide statistics.

Existing Equipment

LMH's existing linear accelerator was purchased in 1999 to provide standard 3-dimensional therapy using custom cerrobend blocking. LMH upgraded for multi-leaf collimation in 2001 and began performing intensity-modulated radiation therapy (IMRT) in 2004. In 2009, LMH upgraded the equipment to provide on-board imaging. The applicant states that the unit has served LMH patients continuously for the past 16 years and has far exceeded its depreciable useful life. While the equipment was considered state-of-the-art in 1999, it can no longer be upgraded to be compatible with new radiation therapy innovations and technological advances.

In addition to technologic limitations, the applicant states that the age of the existing linear accelerator limits LMH's ability to provide an efficient radiation therapy service because treatment times are significantly longer compared to current technology. IMRT treatments at LMH require at least 10 to 15 minutes beam treatment time with the existing equipment, with an overall treatment time of 20 to 30 minutes for most patients. New technology enables the beam treatment to be completed in less than two minutes with total treatment time of only 10 minutes. Thus, the applicant states that patient treatment time will be significantly shortened with the proposed replacement and patient throughput could be doubled or tripled.

The applicant also discusses the hardship caused by equipment downtime happening on a regular basis. During FFY2015, LMH's linear accelerator was down on 14 separate occasions, affecting the daily treatment of 113 patients.

Proposed Replacement Equipment

The proposed Varian TrueBeam linear accelerator upgrades LMH's clinical treatment capabilities, and the applicant states this will increase treatment accuracy, increase patient throughput, enhance patient safety, improve patient experience, and increase physician and patient satisfaction. The new capabilities include image-guided radiation therapy (IGRT), CT reconstruction, soft-tissue imaging, 3D laser positioning, Rapidarc, and improved accuracy.

Demographics

The applicant’s proposed primary market for this project is Lenoir County (74% of projected patient population), whose overall population is projected to remain flat during the next four years. However, as the following table illustrates, the population age 65 and older is projected to grow at a compound annual growth rate (CAGR) of 1.9%.

	2015	2019	4-Yr CAGR
Total Population	58,777	58,576	-0.1%
Population Age 65+	10,650	11,473	1.9%

The applicant states that the 65+ age cohort currently comprises 18.1% of the total population in Lenoir County, which is comparatively higher than the statewide average of 15%.

According to the National Cancer Institute, over half of all cancer incidence occurs in individuals age 65 and older. Therefore, the applicant states that the local aging data indicates there is a great need for timely access to state-of-the-art radiation therapy services as the average age of the local population ages at a steady rate.

The applicant also discusses the lack of financial resources among local residents (pages 30-31) and how this hampers their ability to travel long distances to access radiation therapy services. The applicant provides information that shows the County’s median annual household income was \$10,500, 25% lower than the State average, and the population below the poverty level was 23.7%, 6.2% higher than the State average.

The applicant states that because LMH is the only provider of radiation therapy services in Lenoir County, it is particularly important that LMH have adequate access to state-of-the-art radiation therapy equipment to accommodate the needs of local residents.

Cancer Incidence Rate

According to the Centers for Disease Control and Prevention, cancer is the leading cause of death in North Carolina¹ and according to the North Carolina State Center for Health Statistics (NCSCHS), Lenoir County has a higher overall cancer incidence rate compared to North Carolina, as shown below.

**2008-2012 Cancer Incidence Rate
per 100,000**

	All Cancers
Lenoir County	552.7
North Carolina	488.9

¹ www.cdc.gov/nchs/fastats/deaths.htm

In addition to higher cancer incidence rates, according to the NCSCHS, Lenoir County also has a significantly higher cancer mortality rate than the State.

As cancer increases with age, it also varies by gender and race. For example, African Americans exhibit disproportionately higher cancer incidence rates compared to Caucasians. According to the American Cancer Society, African Americans have the highest death rate and shortest survival of any racial and ethnic group in the US for most cancers. The applicant states that this is relevant to the need for radiation therapy services in Lenoir County because 41% of the total population in Lenoir County is African American, compared to only 22.1% Statewide.

Projected Utilization

In Section III.1, pages 34-36, the applicant describes the specific methodology used to project radiation therapy utilization at LMH.

Methodology Step 1: Identify historical linear accelerator utilization

The applicant provides historical utilization for LMH’s existing linear accelerator on page 34, as shown below.

**Lenoir Memorial Hospital
 Historical Linear Accelerator Utilization**

	FFY2011	FFY2012	FFY2013	FFY2014	FFY2015	4-Yr CAGR
Linear Accelerator Procedures	8,289	8,312	8,632	8,539	8,482	0.58%
Linear Accelerator ESTVs	6,522	6,349	6,623	6,562	6,650	0.49%

Totals may not foot due to rounding

Methodology Step 2: Project Future linear accelerator utilization

The applicant provides projected utilization for LMH’s linear accelerator services on page 35 as shown below.

**Lenoir Memorial Hospital
 Projected Linear Accelerator Utilization**

	FFY2016	FFY2017	FFY2018	FFY2019
Linear Accelerator Procedures	8,482	8,641	8,804	8,969
Linear Accelerator ESTVs	6,650	6,774	6,902	7,031

Totals may not foot due to rounding

Assumptions:

- demand for radiation therapy services at LMH is expected to continue to increase based on projected aging population growth and the related impact on future cancer incidence rates for local residents

- the new linear accelerator will become operational October 1, 2016
- FFY2016 linear accelerator utilization will remain constant with FFY2015 utilization
- Linear accelerator utilization will grow at the same rate as the population growth rate for Lenoir County residents age 65 and older (1.9%)

The applicant states that the projected utilization is reasonable and conservative, based on the limitations on utilization created by the downtime of the existing equipment and the increased productivity of the proposed equipment with faster procedure times and improved patient throughput. Furthermore, the applicant states that in the third project year, FFY2019, the LMH linear accelerator will be utilized at an average of 7,031 ESTVs per unit, which exceeds the 6,750 ESTVs per unit threshold.

The applicant demonstrates the projected utilization is based on reasonable and adequately supported assumptions. Thus, the applicant adequately demonstrates the need the identified population has for the proposed services.

Access

In Section VI.2, page 55, the applicant states:

“LMH will continue to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. Specific to this project, radiation therapy services at LMH will continue to be available to and accessible by any patient having a clinical need for those services.”

In Section VI.15, page 66, the applicant projects that 54% of patients to be served will be Medicare beneficiaries and 14% will be Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

Conclusion

In summary, the applicant adequately identifies the population to be served; adequately demonstrates the need the population to be served has for the proposed services; and adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services. Therefore, the application is conforming to this criterion.

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

NA

- (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

In Section III.3, pages 37-39, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant states that maintaining the status quo would not be in the best interest for LMH’s patients because the existing equipment is no longer state-of-the-art. Therefore, this option was rejected.
- 2) Replace and Update Components of the Existing Linear Accelerator – The applicant states that this alternative would only serve as a temporary solution, and there are several clinical limitations inherent to the age and specifications of the existing equipment. Therefore, this option was rejected.
- 3) Pursue the Proposed Project – The applicant states that the proposed project, as presented in this application, meets all the needs of its patients, physicians, staff and community. While LMH will incur the capital costs of replacing the equipment, the applicant states that the new equipment will be state-of-the-art and will enable LMH to more effectively and efficiently treat patients.

The applicant demonstrates that the proposed project to replace its existing linear accelerator with state-of-the-art equipment is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory review criteria. Therefore, the application is approvable. An application that cannot be approved is not an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Lenoir Memorial Hospital, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Lenoir Memorial Hospital, Inc. shall acquire no more than one linear accelerator to replace the existing linear accelerator located at Lenoir Memorial Cancer Center. Upon project completion, Lenoir Memorial Hospital shall own and operate no more than one linear accelerator.**

3. **Lenoir Memorial Hospital, Inc. shall dispose of the existing Lenoir Memorial Hospital linear accelerator by removing it from North Carolina.**
 4. **Lenoir Memorial Hospital, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application, and that would otherwise require a certificate of need.**
 5. **Lenoir Memorial Hospital, Inc. 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 its existing linear accelerator. The project involves minor renovations to the vault space at Lenoir Memorial Cancer Center to house the replacement equipment.

Capital and Working Capital Costs

In Section VIII, page 76, the applicant projects the total capital cost of the proposed project will be \$3,438,692, including:

Costs	Total Costs
Construction Contract	\$ 172,192
Fixed Equipment	\$ 3,135,000
Equipment/Furniture	\$ 60,000
Consultant Fees	\$ 71,500
Total Capital Costs	\$ 3,438,692

In Section IX, page 83, the applicant states there are no start-up or initial operating expenses for this project.

Availability of Funds

In Section VIII.3, page 79, the applicant states that the total capital cost will be funded with Lenoir Memorial Hospital, Inc. accumulated reserves. Exhibit 7 contains a letter from the Chief Financial Officer of LMH which documents its commitment to fund the proposed project and the availability of funds. Exhibit 7 also contains the audited financial statements for Lenoir Memorial Hospital for years ending September 30, 2014 and 2013. According to the financial statements, as of September 30, 2014, LMH had \$15,896,635 in cash and cash equivalents, \$32,133,437 in total current assets, \$185,300,846 in total assets and \$145,111,508 in total net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicant projects a positive net income for the project in each of the first three operating years of the project, as shown in the table below.

Radiation Therapy Services	PY 1	PY 2	PY 3
Projected Procedures	8,641	8,804	8,969
Projected Average Charge (Gross Patient Revenue / Projected # of procedures)	\$ 1,150	\$ 1,195	\$ 1,242
Gross Patient Revenue	\$ 9,938,806	\$10,520,384	\$11,135,994
Deductions from Gross Patient Revenue	\$ 6,366,103	\$ 6,738,622	\$ 7,132,938
Net Patient Revenue	\$ 3,572,702	\$ 3,781,762	\$ 4,003,056
Total Expenses	\$ 2,713,569	\$ 2,806,578	\$ 2,904,200
Net Income	\$ 859,134	\$ 975,184	\$ 1,098,856

* Source: Pro Forma Financial Statements' Form C, Form D and Form E

The applicant did not include a Form B in the ProForma Financial Section to show Lenoir Memorial Hospital total facility income. However, based on the audited financial statements included in Exhibit 7, LMH experienced a net excess of revenues over expenses of \$845,676 in FFY2013 and \$2,726,639 in FFY2014. It is therefore not unreasonable to expect LMH total revenues to exceed total expenses in each of the first three operating years of the project.

The assumptions used by the applicant in preparation of the proforma financial statements are reasonable, including projected utilization, costs and charges. See the related assumption notes in the ProForma Section for the assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (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 its existing linear accelerator located at Lenoir Memorial Cancer Center in Kinston.

On page 125, the 2015 SMFP defines a linear accelerator’s service area as *“the linear accelerator planning area in which the linear accelerator is located. The linear accelerator planning areas are the 28 multicounty groupings shown in Figure 9I.”* Table 9I on page 133 of the SMFP shows Lenoir County in Linear Accelerator Service Area 23, along with the contiguous counties of Duplin and Wayne.

Thus, the service area for this facility’s project is Linear Accelerator Service Area 23, consisting of Lenoir, Duplin and Wayne counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the existing and approved linear accelerators located in Linear Accelerator Service Area 23, as reported in the 2016 SMFP. The data is for FFY 2014.

Service Provider	County	Licensed Linacs	ESTVs FFY2014	Average ESTVs / Unit	Percent of Capacity
Lenoir Memorial Hospital	Lenoir	1	6,562	6,562	97.2%
NC Radiation Therapy-Goldsboro	Wayne	1	5,852	5,852	86.7%

As shown in the table above, the two radiation therapy providers in Linear Accelerator Service Area 23 are operating just below the State defined capacity threshold of 6,750 ESTVs.

In Section III.6(b), page 44, the applicant states that the identified need is internal to LMH, because it involves replacement of an existing linear accelerator and no other provider can or should provide for the internal radiation therapy needs of LMH’s patients.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing and approved linear accelerator services. The discussions regarding analysis of need, including projected utilization, and access found in Criterion (3) are incorporated herein by reference. Therefore, the application is conforming to this criterion.

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

C

In Section VII.1, pages 67-68, the applicant provides the current and proposed staffing, as shown in the table below.

Position	Current FTE Positions FFY2015	PY2 FTE Positions FFY2018
Administrative Director	0.5	0.5
Radiation Therapist	2.8	2.8
Registered Nurse	1.0	1.0
Social Worker	0.5	0.5
Receptionist/Patient Registration	2.0	2.0
Dosimetrist	0.5	0.5
Total	7.3	7.3

The applicant states that the replacement project does not require any additional staffing. In Section VII.6, page 70, the applicant describes its experience and its process for recruiting and retaining staff. Ron Allison, MD, is LMH's Medical Director of Radiation Oncology. Exhibit 14 contains a copy of a letter from Dr. Allison expressing his support for the replacement project and his commitment to continue serving as the Medical Director for radiation therapy services at LMH. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section II.2, page 14, the applicant identifies the ancillary and support services that are required for the proposed project as including business office/registration, medical records, medical supplies, administrative services, laundry, maintenance, housekeeping and radiology. The applicant discusses coordination with the existing health care system in Section V, pages 49-52. The applicant provides supporting documentation in Exhibits 8, 9, 15. The information provided in the application is reasonable and supports a finding of conformity with this criterion.

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

NA

- (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 develop the replacement project, with minimal renovation, in existing space located in the Lenoir Memorial Cancer Center building across the street from the LMH hospital facility. Exhibit 6 contains a letter from a licensed engineer that estimates the construction cost at \$172,192 and professional fees at \$26,500, which corresponds to the capital cost projections provided by the applicant in Section VIII.1, page 76. In Section XI.7, page 93, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.12 and VI.13, pages 63-64, the applicant provides the payor mix during FFY 2014 for Lenoir Memorial Hospital and its linear accelerator services, as illustrated in the table below:

**Lenoir Memorial Hospital
FFY 2014 (10/1/13-9/30/14)
Patient Days /Procedures as a Percent of Total Utilization**

	Entire Facility	Linear Accelerator
Self-Pay	3.8%	11.0 %
Medicare	69.0%	54.0%
Medicaid	16.8%	14.0%
Managed Care/Blue Cross	7.0%	12.0%
Commercial Insurance	3.0%	6.0%
Other (SEHP, Vocational Rehab)	0.4%	3.0%
Total	100.0%	100.0%

Totals may not sum due to rounding

In Section VI.2, page 55, the applicant states:

“LMH will continue to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.

...

LMH has historically provided substantial care and services to all of the above categories of medically underserved persons. Specifically, as a certified provider under Title XVIII (Medicare), LMH provides a full

range of services to the elderly. Services to low income persons are provided by LMH as a certified provider under Title XIX (Medicaid)."

Exhibit 12 contains copies of LMH's financial policies.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available. The following counties comprise the projected counties of residence for the patients to be served by the proposed services.

	2010 Total # of Medicaid Eligibles as % of Total Population	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population	2009 % Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Lenoir	24.6%	11.0%	21.10%
Duplin	20.3%	7.6%	24.6%
Greene	21.1%	7.6%	24.6%
Craven	15.1%	6.5%	19.6%
Wayne	20.2%	8.3%	20.3%
Pitt	16.3%	6.7%	21.3%
Jones	20.5%	9.8%	20.9%
Statewide	16.5%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the imaging services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age,

race or gender does not include information on the number of elderly, minorities, women, or handicapped persons utilizing health services.

The applicant demonstrates that medically underserved populations currently have adequate access to the services offered at LMH. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 62, the applicant states:

“LMH is not obligated under public regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. However, as previously stated, LMH does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay.”

The applicant states that it will continue providing services to the community, as described above. See Exhibit 12 for LMH’s financial policies. In Section VI.10, page 62, the applicant states that it is not aware of any documented civil rights access complaints filed against LMH during the last five years. 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 VI.15, page 66, the applicant provides the projected payor mix for radiation therapy services for the second full operating year following project completion, as shown in the following table.

**LMH Linear Accelerator Services
Projected Utilization as a Percent of Total
FFY 2018**

Payor Category	% of Total Utilization
Self Pay	11.0%
Medicare	54.0%
Medicaid	14.0%
Blue Cross	12.0%
Commercial Insurance	6.0%
Other (SEHP, Vocational Rehab)	3.0%
Total	100.0%

Totals may not sum due to rounding

On page 66, the applicant provides the assumptions and methodology used to project payor mix. The applicant states that it does not anticipate any change in payor mix for the proposed service for the second year of operation. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (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 VI.9, page 61, the applicant describes the range of means by which a person will have access to the proposed services, including via physician referrals and the hospital emergency department. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, 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

In Section V.1, pages 49-50, the applicant describes how the facility will accommodate the clinical needs of area health professional training programs. See page 49 for a listing of LMH clinical training affiliations. See Exhibit 9 for examples of clinical training agreements. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to replace an existing linear accelerator located at Lenoir Memorial Cancer Center.

On page 125, the 2015 SMFP defines a linear accelerator's service area as *"the linear accelerator planning area in which the linear accelerator is located. The linear accelerator planning areas are the 28 multicounty groupings shown in Figure 9I."* Table 9I on page 133 of the SMFP shows Lenoir County in Linear Accelerator Service Area 23, along with the contiguous counties of Duplin and Wayne.

Thus, the service area for this facility's project is Linear Accelerator Service Area 23, consisting of Lenoir, Duplin and Wayne counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the existing and approved linear accelerators located in Linear Accelerator Service Area 23, as reported in the 2016 SMFP. The data is for FFY 2014

Service Provider	County	Licensed Linacs	ESTVs FFY2014	Average ESTVs / Unit	Percent of Capacity
Lenoir Memorial Hospital	Lenoir	1	6,562	6,562	97.2%
NC Radiation Therapy-Goldsboro	Wayne	1	5,852	5,852	86.7%

In Section V.7, pages 54-55, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services.

See also Sections II, III, V, VI, VII and XI where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to replace the existing linear accelerator. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

The application is conforming to this criterion.

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

C

In Section II and Exhibit 2, the applicant states that LMH is the only hospital it owns, leases or manages in North Carolina. Exhibit 2 lists the other medical entities that LMH owns and operates. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by Lenoir Memorial Hospital in North Carolina. 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 LMH facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to replace an existing linear accelerator; the licensed inventory of linear accelerators will remain the same. Therefore the Criteria and Standards for Radiation Therapy Equipment, promulgated in 10A NCAC 14C .1900, are not applicable to this review.