

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 26, 2019

Findings Date: July 26, 2019

Project Analyst: Celia C. Inman

Assistant Chief: Lisa Pittman

Project ID #: N-11697-19

Facility: Southeastern Regional Medical Center Gibson Cancer Center

FID #: 001329

County: Robeson

Applicant: Southeastern Regional Medical Center, Inc.

Project: Acquire a 2nd linear accelerator pursuant to an adjusted need determination in the 2019 SMFP

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N. C. Gen. Stat. § 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

Southeastern Regional Medical Center, Inc. (SRMC), the applicant, currently owns and operates one linear accelerator at the Gibson Cancer Center (GCC), which is licensed as part of Southeastern Regional Medical Center. The applicant proposes to acquire a second linear accelerator (linac) pursuant to an adjusted need determination in the 2019 State Medical Facilities Plan (SMFP).

Need Determination

Table 9K on page 139 of the 2019 SMFP shows an adjusted need determination for one additional linear accelerator for Service Area 18, to be developed in Robeson County. The

applicant proposes to acquire one linear accelerator and develop it at SRMC's Gibson Cancer Center in Robeson County. Therefore, the proposed project is consistent with the adjusted need determination in the 2019 SMFP.

Policies

There are two policies in the 2019 SMFP which are applicable to this review: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3 on page 31 of the 2019 SMFP states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

In Section B.10, pages 28-31, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 28-29, Section N, pages 99-100, Section O, pages 102-103, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B, pages 29-30, Section C, pages 55-56, Section L, pages 93-94, Section N, pages 100-101, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B, page 30, Section E.2, page 65, Section N, pages 98-99, and the pro forma financial statements in Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

Policy GEN-4 on page 31 of the 2019 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, 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 is 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 \$5 million. In Section B.11, page 31, the applicant explains why it believes its application is consistent with Policy GEN-4. The applicant states that SRMC is committed to energy efficiency and water conservation that balances the need for healthcare services and environmental sustainability. Exhibit B.11 contains a statement from the project architect describing the project’s plan to assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- application, and
- 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 does not propose to develop more linear accelerators than are determined to be needed in the 2019 SMFP.
 - The applicant adequately demonstrates that the proposal is consistent with Policies GEN-3 and GEN-4.
- (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 acquire one linear accelerator and develop it at SRMC's Gibson Cancer Center in Robeson County, pursuant to the adjusted need determination in the 2019 SMFP. In addition, the applicant proposes to construct additional space in the Gibson Cancer Center to house the proposed linear accelerator adjacent to the existing linear accelerator.

Patient Origin

In Chapter 9, page 127, the 2019 SMFP states, "*A linear accelerator's service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.*" In Table 9I, page 136 of the 2019 SMFP, Robeson County is included in Linear Accelerator Service Area 18, which also includes Bladen, Cumberland and Sampson counties. Providers may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 36-37, the applicant provides the historical patient origin for the last full fiscal year (FY), October 1, 2017 – September 30, 2018, and the projected patient origin for FY2022 (October 2021 – September 2022) through FY2024 (October 2023 – September 2024) at GCC, as shown in the following tables:

**Historical Patient Origin
 Gibson Cancer Center
 FY2018**

COUNTY/STATE	LAST FULL FY (10/1/17 – 9/30/18)	
	# PATIENTS	% OF TOTAL
Robeson	226	62.8%
Columbus	62	17.2%
Bladen	55	15.3%
Cumberland	4	1.1%
South Carolina	4	1.1%
Hoke	3	0.8%
Guilford	2	0.6%
Other States	2	0.6%
Scotland	2	0.6%
Total	360	100.0%

**Projected Patient Origin
 Gibson Cancer Center**

COUNTY/STATE	1 st Full FY FY2022		2 nd Full FY FY2023		3 rd Full FY FY2024	
	# Pts	% of Total	# Pts	% of Total	# Pts	% of Total
Robeson	303	62.8%	326	62.8%	351	62.8%
Columbus	82	17.2%	89	17.2%	96	17.2%
Bladen	74	15.3%	79	15.3%	85	15.3%
Cumberland	5	1.1%	6	1.1%	6	1.1%
South Carolina	5	1.1%	6	1.1%	6	1.1%
Hoke	4	0.8%	4	0.8%	5	0.8%
Guilford	3	0.6%	3	0.6%	3	0.6%
Other States	3	0.6%	3	0.6%	3	0.6%
Scotland	3	0.6%	3	0.6%	3	0.6%
Total	483	100%	519	100%	559	100%

In Section C.3(c), page 38, the applicant states that the projected patient origin reflects the historical patient origin for linear accelerator services and the projected number of linear accelerator patients as shown in the assumptions and methodology for Form C.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 38-50, the applicant explains why it believes the population projected to utilize the proposed linear accelerator services needs those services, with the specific need for the project being comprised of several factors, including:

- The need for additional capacity at SRMC (pages 39-46).

The applicant states that based on the reported ESRVs in the 2019 SMFP, SRMC operates the third busiest linear accelerator in North Carolina. SRMC has only one linear accelerator and it currently operates at a rate of 8,788 ESTVs per year based on the most recent SMFP data available. The applicant further states that the next closest linear accelerator is 30 miles away.

In Section G, page 76, the applicant states:

“The 2019 SMFP [emphasis in original] includes a need determination for one additional linear accelerator in Robeson County, which is the result of an approved petition submitted by SRMC in July 2018. As described in the assumptions and methodology for Form C, as the only provider of linear accelerator services in a county with a population of over 130,000 people, SRMC needs additional capacity to meet the growing demand for linear accelerator services by patients at its facility.”

- The unique demographic factors in Robeson County (pages 46-48).

The applicant states that the National Cancer Institute (NCI) discusses cancer disparities among population groups and identifies Robeson County as ranking last (100th) in the 100 North Carolina counties in both the 2017 health factors and health outcomes County Health Rankings. The State Center for Health Statistics found cancer to be the second leading cause of death in Robeson County (see Exhibit C.4). In addition, Robeson County has a higher incidence rate of colon/rectum and lung cancer than North Carolina as a whole. Also of relevance, income statistics suggest that Robeson County residents are more likely to smoke, be overweight, and lead a sedentary lifestyle – all risk factors for developing preventable cancers.

- The need to promote quality, access, and value (pages 48-50).

The applicant states that the addition of a second linear accelerator would clearly enhance quality and safety of SRMC’s cancer services. Operating at as high a utilization level as SRMC increases the likelihood of machine failure which results in lack of access for patients. The applicant states that additional linear accelerator capacity is needed to provide sufficient access for SRMC patients to better serve patients and potentially reduce the number of patients that leave Robeson County

for care. The applicant also states that a second linear accelerator will promote value in convenient scheduling, shorter wait times and less missed or forgone treatments. Additional capacity will ensure patients have a higher probability of uninterrupted treatments by receiving care in a timely manner, preventing time away from patients' home and community, and delays in needed treatment.

The information provided by the applicant in the pages referenced above is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates that the existing linear accelerator cannot support the future need for radiation treatments at SRMC.
- The population group in Robeson County exhibits high levels of health disparity which predisposes it to cancer and the need for cancer treatments.
- The applicant demonstrates that additional linear accelerator capacity would enhance quality, safety, and value.

Projected Utilization

In Section Q, Form C, the applicant provides statistical data and tables showing the historical and projected linear accelerator utilization for Gibson Cancer Center, which is summarized as follows:

**GIBSON CANCER CENTER
HISTORICAL AND PROJECTED
RADIATION THERAPY TREATMENTS
FY 2016 – FY 2024**

	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
# of Linacs	1	1	1	1	1	1	2	2	2
# of Patients	165	380	360	387	417	448	483	519	559
# of ESTVs*	4,099	8,788	7,823	8,417	9,057	9,745	10,486	11,282	12,140
ESTV per Patient	24.8	23.1	21.7	21.7	21.7	21.7	21.7	21.7	21.7

*# of ESTVs = # of patients x ESTVs per patient in projection years

In Section Q, Form C Utilization – Assumptions and Methodology, the applicant provides the assumptions and methodology for projecting utilization of the proposed and existing linear accelerators, summarized as follows:

- SRMC's linear accelerator patient volume grew at a compound annual growth rate (CAGR) of 5.6% from FY2014 through FY2018, as shown in Section Q, Table 1 and below.

	FY2014	FY2015	FY2016	FY2017	FY2018	CAGR
# of Patients	289	210	165	380	360	5.6%
ESTV Treatments	7,475	5,910	4,099	8,788	7,823	1.1%
ESTV per Patient	25.9	28.1	24.8	23.1	21.7	

The applicant states that this growth was in spite of three major catastrophic events severely impacting its linear accelerator utilization in FY2015, FY2016, and FY2018, including a fire in 2015, Hurricane Matthew in late 2016, and Hurricane Florence in FY2018. Therefore, the applicant believes it is more relevant to analyze the growth trend from FY2014 to FY2017 (the year prior to the first event through the year prior to the third event), as shown in Section Q, Table 2 and below.

	FY2014	FY2015	FY2016	FY2017	CAGR
# of Patients	289	210	165	380	9.6%
ESTV Treatments	7,475	5,910	4,099	8,788	5.5%
ESTV per Patient	25.9	28.1	24.8	23.1	

To remain conservative, SRMC elects to use the average of the FY2014 to FY2018 CAGR of 5.6% and the FY2014 to FY2017 CAGR of 9.6%, which is 7.6% to project future utilization.

- Projected linear accelerator patients using a 7.6% annual increase (Section Q, Table 3)

	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
# of Patients	387	417	448	483	519	559

- The applicant states that ESTV treatments per patient is expected to remain constant at the FY2018 ratio of 21.7 ESTV treatments per patient, resulting in the following ESTV treatments. (Section Q, Table 4)

	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
# of Patients	387	417	448	483	519	559
ESTVs per Patient	21.7	21.7	21.7	21.7	21.7	21.7
ESTV Treatments	8,417	9,057	9,745	10,486	11,282	12,140

Totals may not sum due to rounding

- The applicant states that the proposed linear accelerator is projected to become operational on April 1, 2021, making the third full year of operation April 1, 2023 through March 31, 2024 (OY3). The applicant converts fiscal year patients to operating year patients as summarized below:

OY3 patients = (0.5 x FY2023) + (0.5 x FY2024) = (0.5 x 519) + (0.5 x 559) = 259 + 280 = 539 patients

The applicant provides Table 5 in Section Q to demonstrate that each linear accelerator at SRMC’s Gibson Cancer Center will be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment (539 patients / 2 linacs = 269 patients per linac), thus meeting the performance standards in *10A NCAC 14 C .1903 Performance Standards*.

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected utilization is based on the applicant’s historical experience with the existing linear accelerator at GCC.
- The applicant uses a reasonable growth rate to project future growth in the number of patients at GCC.

Access

In Section C.11, pages 55-56, the applicant states:

“SRMC does not discriminate against low-income persons, racial or ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent, the uninsured and the underinsured.”

In Section L, page 93, the applicant projects the payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table:

**Projected Payor Mix
FY2023**

PAYOR CATEGORY	FACILITY SERVICES AS % OF TOTAL	LINAC SERVICES AS % OF TOTAL
Self-Pay	4.5%	2.5%
Charity Care^	0.0%	0.0%
Medicare*	44.5%	62.0%
Medicaid*	36.5%	10.1%
Insurance*	14.6%	25.5%
Workers Compensation^^	0.0%	0.0%
TRICARE	0.0%	0.0%
Other^^^	0.0%	0.0%
Total	100.0%	100.0%

*including any managed care plans

^SRMC’s internal data does not include Charity Care as a payor source

^^Workers Compensation and TRICARE are included in the insurance payor category and cannot be provided separately.

^^^Other is included in Self-Pay

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- Information which was 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 the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the replacement linear accelerator proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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

The applicant does not propose to reduce or eliminate a service or relocate a health service facility or health service. The applicant proposes to establish a new diagnostic center. 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 one linear accelerator and develop it at SRMC's Gibson Cancer Center in Robeson County, pursuant to the adjusted need determination in the 2019 SMFP.

In Section E, page 65, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- maintain the status quo, and
- develop an additional linear accelerator, as proposed.

On page 65, the applicant states that without the proposed project, SRMC will be forced to attempt to support its growing patient volume with capacity limited to one linear accelerator. Therefore, patients may be forced to delay treatment, travel for treatment, or forgo radiation therapy treatment altogether. Furthermore, the applicant states that continued overuse of the one linear accelerator will likely lead to catastrophic equipment failure. Thus, the applicant determined that maintaining the status quo is a less effective alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the more effective alternative to meet the need for the following reasons:

- The applicant demonstrates the existing linear accelerator cannot meet the utilization requirements projected for the future.
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the more effective alternative.

Conclusion

The Agency reviewed the:

- application, and
- 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. Southeastern Regional Medical Center, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Southeastern Regional Medical Center, Inc. shall acquire no more than one linear accelerator for a total of two linear accelerators.**
- 3. Southeastern Regional Medical Center, Inc. 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.

- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Southeastern Regional Medical Center, Inc. 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.**
- 5. Southeastern Regional Medical Center, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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 one linear accelerator and develop it at SRMC's Gibson Cancer Center in Robeson County, pursuant to the adjusted need determination in the 2019 SMFP.

Capital and Working Capital Costs

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

ITEM	COST
Construction Contract / Site Prep	\$ 4,748,000
Architect / Engineering Fees	\$ 379,840
Medical Equipment	\$ 2,685,000
Furniture	\$ 80,000
Total	\$ 7,892,840

In Section F.3, pages 69-70, the applicant states that there are no start-up or initial operating expenses, as this is not a new service.

In Section Q, the applicant provides the assumptions used to project the capital cost.

Availability of Funds

In Section F, page 68, the applicant states that the capital cost will be funded as shown in the table below.

SOURCES OF CAPITAL COST FINANCING	
TYPE	TOTAL
Loans	\$ 0
Accumulated reserves or OE *	\$ 7,892,840
Bonds	\$ 0
Other (Specify)	\$ 0
Total Financing	\$ 7,892,840

* OE = Owner's Equity

In Exhibit F.2-1, the applicant provides an April 15, 2019 letter from the Chief Financial Officer that confirms the availability of the funds and the commitment of the funds to the project. The applicant also provides SRMC's audited financial statements for FY2018 that confirm the availability of the funds necessary to finance the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4, the applicant projects that revenues will exceed operating expenses in the first three fiscal years of the project, as summarized in the table below.

	1ST FULL FISCAL YEAR	2ND FULL FISCAL YEAR	3RD FULL FISCAL YEAR
Total Radiation Therapy Patients	483	519	559
Total Gross Revenues (Charges)	\$21,152,973	\$23,443,377	\$25,981,780
Total Net Revenue	\$5,464,253	\$6,055,912	\$6,711,634
Average Net Revenue per Patient	\$11,313	\$11,668	\$12,007
Total Operating Expenses (Costs)	\$4,543,553	\$5,026,523	\$4,998,109
Average Operating Expense per Patient	\$9,407	\$9,685	\$8,941
Net Income	\$920,700	\$1,029,389	\$1,713,525

Totals may not sum due to rounding

Form F.3 shows that the entire SRMC facility revenues also exceed expenses during each of the first three fiscal years of the project.

Conclusion

The Agency reviewed the:

- application, and
- 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.

C

The applicant proposes to acquire one linear accelerator and develop it at SRMC's Gibson Cancer Center in Robeson County, pursuant to the adjusted need determination in the 2019 SMFP.

In Chapter 9, page 127, the 2019 SMFP states, "*A linear accelerator's service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.*" In Table 9I, page 136 of the 2019 SMFP, Robeson County is included in Linear Accelerator Service Area 18, which also includes Bladen, Cumberland and Sampson counties. Providers may serve residents of counties not included in their service area.

There are seven existing linear accelerators in Linear Accelerator Service Area 18. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators, as summarized from Table 9G, page 132 of the 2019 SMFP.

	# LINEAR ACCELERATORS	TOTAL PROCEDURES*	AVERAGE ESTV* PER LINEAR ACCELERATOR
Cape Fear Valley Medical Center	5	19,268	3,854
Southeastern Regional Medical Center	1	8,788	8,788
NC Radiation Therapy – Sampson	1	2,975	2,975

*The 2019 SMFP equates Equivalent Simple Treatment Visits (ESTVs) with procedures in Table 9G.

In Section G, page 76, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved linear accelerator services in linear accelerator service Area 18. The applicant states:

“The 2019 SMFP [emphasis in original] includes a need determination for one additional linear accelerator in Robeson County, which is the result of an approved petition submitted by SRMC in July 2018. As described in the assumptions and methodology for Form C, as the only provider of linear accelerator services in a county with a population of over 130,000 people, SRMC needs additional capacity to meet the growing demand for linear accelerator services by patients at its facility.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant proposes to acquire one additional linear accelerator, pursuant to an adjusted need determination for one additional linear accelerator in Robeson County.
- The applicant adequately demonstrates that the proposed linear accelerator is needed in addition to the existing or approved linear accelerators.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information which was 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 the reasons stated above.

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

C

In Section Q, Form H, the applicant provides the historical and projected staffing for linear accelerator services, summarized as follows:

**Staffing – SRMC Linear Accelerator Services
Full-Time Equivalent (FTE) Positions**

POSITION	LAST FULL FY 2018	PROJECTED		
		1 ST FULL FISCAL YEAR	2 ND FULL FISCAL YEAR	3 RD FULL FISCAL YEAR
Radiation Therapist	3.6	6.3	6.3	6.3
TOTAL	3.6	6.3	6.3	6.3

In Section Q, Form H, the applicant provides its staffing-related assumptions. The Physicist and Dosimetrist positions are contract positions. Adequate costs for the health manpower and contract positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 78-79, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 79, the applicant identifies Thomas Walden, MD as the current medical director. In Exhibit I.2, the applicant provides a letter from Dr. Walden committing support for the project.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section I, page 81, the applicant identifies the necessary ancillary and support services and discusses how the services are made available, stating that patients may require the use of any of SRMC's existing ancillary and support services, including:

- laboratory
- radiology
- pharmacy
- dietary
- housekeeping
- maintenance
- administration
- other

In Section I, page 81, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I.1 and I-2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

In Section K, page 84, the applicant states that the project involves the construction of 7,377 square feet of space to install the proposed linear accelerator at GCC. The new unit will be installed in adjacent space to the existing unit. Line drawings are provided in Exhibit C.1.

On page 85, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Section Q and Exhibit C.1.

On page 85, 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 and provides supporting documentation in Exhibit C.1.

On page 86, the applicant refers to Exhibit B.11 for a statement regarding energy saving features to be incorporated into the proposed construction.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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 L.1(b), page 92, the applicant provides the following payor mix for the last full fiscal year.

**Historical Payor Mix
 FY2018**

PAYOR CATEGORY	FACILITY SERVICES AS % OF TOTAL	LINAC SERVICES AS % OF TOTAL
Self-Pay	4.5%	2.5%
Charity Care [^]	0.0%	0.0%
Medicare*	44.5%	62.0%
Medicaid*	36.5%	10.1%
Insurance*	14.6%	25.5%
Workers Compensation ^{^^}	0.0%	0.0%
TRICARE	0.0%	0.0%
Other ^{^^^}	0.0%	0.0%
Total	100.0%	100.0%

*including any managed care plans

[^]SRMC's internal data does not include Charity Care as a payor source

^{^^}Workers Compensation and TRICARE are included in the insurance payor category and cannot be provided separately.

^{^^^}Other is included in Self-Pay

As shown in the table above, the applicant states that 2.5%, 10.1%, and 62.0% of its linear accelerator services in FY 2018 were provided to self-pay patients, Medicaid patients, and Medicare patients, respectively.

In Section L.1(a), pages 90-91, the applicant provides the following comparison for the patients served during the last fiscal year.

	% OF TOTAL PATIENTS SERVED BY SRMC	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	50.4%	51.3%
Male	49.5%	48.7%
Unknown	0.1%	0.0%
64 and Younger	45.4%	85.1%
65 and Older	54.9%	14.9%
American Indian	25.0%	39.7%
Asian	0.6%	0.6%
Black or African-American	26.1%	23.8%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	43.7%	27.2%
Other Race	2.0%	5.5%
Declined / Unavailable	2.5%	0.0%

The Agency reviewed the:

- application, and
- 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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 92, the applicant states it is not under an obligation to provide uncompensated care. The applicant states that it provided \$76 million (8.3% of gross revenue) in bad debt and charity care in FY2018.

In Section L, page 93, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- application, and
- 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 93, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table:

**Projected Payor Mix
 FY2023**

PAYOR CATEGORY	FACILITY SERVICES AS % OF TOTAL	LINAC SERVICES AS % OF TOTAL
Self-Pay	4.5%	2.5%
Charity Care [^]	0.0%	0.0%
Medicare [*]	44.5%	62.0%
Medicaid [*]	36.5%	10.1%
Insurance [*]	14.6%	25.5%
Workers Compensation ^{^^}	0.0%	0.0%
TRICARE	0.0%	0.0%
Other ^{^^^}	0.0%	0.0%
Total	100.0%	100.0%

^{*}including any managed care plans

[^]SRMC's internal data does not include Charity Care as a payor source

^{^^}Workers Compensation and TRICARE are included in the insurance payor category and cannot be provided separately.

^{^^^}Other is included in Self-Pay

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.5% of linear accelerator services will be provided to self-pay patients, 62.0% to Medicare patients and 10.1% to Medicaid patients.

On pages 93-94, the applicant provides the assumptions and methodology used to project payor mix following project completion. The projected payor mix is

reasonable and adequately supported because it is based on the historical FY2018 payor mix.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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 L, page 94, the applicant adequately describes the range of means by which patients will have access to the proposed services, which is by physician referral.

The Agency reviewed the:

- application, and
- 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

In Section M, page 96, 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.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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 acquire one linear accelerator and develop it at SRMC’s Gibson Cancer Center in Robeson County, pursuant to the adjusted need determination in the 2019 SMFP.

In Chapter 9, page 127, the 2019 SMFP states, “A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.” In Table 9I, page 136 of the 2019 SMFP, Robeson County is included in Linear Accelerator Service Area 18, which also includes Bladen, Cumberland and Sampson counties. Providers may serve residents of counties not included in their service area.

There are seven existing linear accelerators in Linear Accelerator Service Area 18. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators, as summarized from Table 9G, page 132 of the 2019 SMFP.

	# LINEAR ACCELERATORS	TOTAL PROCEDURES*	AVERAGE ESTV* PER LINEAR ACCELERATOR
Cape Fear Valley Medical Center	5	19,268	3,854
Southeastern Regional Medical Center	1	8,788	8,788
NC Radiation Therapy – Sampson	1	2,975	2,975

*The 2019 SMFP equates Equivalent Simple Treatment Visits (ESTVs) with procedures in Table 9G.

In Section N, pages 98-101, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in

the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 98, the applicant states:

“The proposed project will foster competition by promoting cost effectiveness, quality, and access to services in Robeson County and surrounding areas and will thus be in compliance with the spirit and legislative intent of the Certificate of Need Law. Although SRMC provides care for a majority of Robeson County residents, some choose to leave the county for care elsewhere. The additional equipment to be purchased in the proposed project is leading-edge, state-of-the-art technology which will greatly improve the delivery of radiation oncology services in Robeson County, resulting in enhanced competition between SRMC and other facilities that serve Robeson County patients.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- Information which was 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 the reasons stated above.

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

C

In Section O, page 103, the applicant states that SRMC is the only acute care facility in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O, page 103, the applicant states that it has continually maintained all relevant licensure, certification, and accreditation during the 18 months immediately preceding the submittal of the application. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care at SRMC. 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 SRMC, 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.

(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 one linear accelerator and develop it at SRMC's Gibson Cancer Center in Robeson County, pursuant to the adjusted need determination in the 2019 SMFP.

The Criteria and Standards for Radiation Therapy Equipment, which are promulgated in 10A NCAC 14C .1900, are applicable to this review.

**SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY
EQUIPMENT**

10A NCAC 14C .1903 PERFORMANCE STANDARDS

- (a) *An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met:*
- (1) *an applicant's existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted;*
- C- As demonstrated in Section Q, Form C Utilization - Methodology and Assumptions, the applicant shows SRMC's existing linear accelerator performed in excess of 6,750 ESTV treatments and served more than 250 patients in the last full fiscal year, FY2018. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (2) *each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment; and*
- C- The applicant provides Table 5 in Section Q, Form C Utilization - Methodology and Assumptions to demonstrate that the proposed and existing linear accelerators at SRMC's Gibson Cancer Center will be utilized at an annual rate of more than 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment (539 patients / 2 linacs = 269 patients per linac), thus meeting the performance standards in *10A NCAC 14 C .1903 Performance Standards*. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (3) *an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.*
- C- The applicant provides Table 5 in Form C Utilization - Methodology and Assumptions to demonstrate that the proposed and existing linear accelerators at SRMC's Gibson Cancer Center will be utilized at an annual rate of more than 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment (539 patients / 2 linacs = 269 patients per linac), thus meeting the performance standards in *10A NCAC 14 C .1903 Performance Standards*. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (b) *A linear accelerator shall not be held to the standards in Paragraph (a) of this Rule if the applicant provides documentation that the linear accelerator has been or will be used exclusively for clinical research and teaching.*
- NA- The applicant does not propose to use the linear accelerator exclusively for clinical research and teaching.
- (c) *An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the following information:*
- (1) *the number of patients that are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and*
 - (2) *the maximum number and type of procedures that the proposed equipment is capable of performing.*
- NA- The applicant does not propose to acquire radiation therapy equipment other than a linear accelerator.
- (d) *The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.*
- C- In Section Q, Form C Utilization - Methodology and Assumptions, the applicant documents its assumptions and provides data supporting the methodology used to determine its utilization projections. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.