

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 27, 2020

Findings Date: May 29, 2020

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: N-11866-20

Facility: Southeastern Regional Medical Center

FID #: 923461

County: Robeson

Applicant: Southeastern Regional Medical Center

Project: Acquire a fixed PET scanner pursuant to the adjusted need determination in the 2020 SMFP for Robeson County

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 (SRMC) is part of Southeastern Health, which the applicant states is a non-profit community-based healthcare system that comprises a 452-bed medical center as well as nursing, rehabilitation and hospice care services. Southeastern Health also operates the Gibson Cancer Center, a comprehensive outpatient cancer center located less than three miles from the SRMC hospital campus in Lumberton. In this application, SRMC proposes to acquire one fixed dedicated PET scanner to be located at the Gibson Cancer Center in Lumberton, Robeson County.

Need Determination

Chapter 17 of the 2020 State Medical Facilities Plan (2020 SMFP) includes a methodology for determining the need for additional fixed PET scanners by service area. Application of the need methodology in the 2020 SMFP did not identify a need for any additional fixed PET scanners in HSA V, the PET Service Area that includes Robeson County. However, the applicant submitted a petition for an adjusted need determination to the State Health Coordinating Council (SHCC) for one fixed dedicated PET scanner in Robeson County. The SHCC approved the petition as stated on page 446 of the 2020 SMFP. Therefore, the application is consistent with the need determination in the 2020 SMFP.

Policies

There are two policies in the 2020 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

Policy GEN-3 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, pages 21 - 23, the applicant explains why it believes its application is conforming to Policy GEN-3. On page 21, the applicant states it operates the Gibson Cancer Center, an outpatient cancer center that provides comprehensive cancer care to cancer patients. The applicant states that the addition of a fixed PET scanner to serve Robeson County patients will enhance quality and safety in the delivery of cancer screening services in the service area.

On page 22, the applicant states: *“SRMC does not discriminate against low-income persons, racial or ethnic minorities, handicapped persons, the elderly, or other underserved persons, including the medically indigent, the uninsured, and the underinsured.”*

On page 23, the applicant states the addition of a fixed dedicated PET scanner in Robeson County *“will provide HSA V with additional capacity and Robeson County its first fixed PET scanner to meet the needs of area patients and improve health equity across the region.”*

Policy GEN-4

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, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety, or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 24, the applicant explains why it believes its application is conforming to Policy GEN-4. On page 24, the applicant states:

“SRMC is committed to energy efficiency and water conservation that balances the need for healthcare services and environmental sustainability in the community it serves.”

The applicant provides supporting documentation in Exhibit B.11 that documents the applicant’s plans for its plumbing, mechanical and electrical systems.

Conclusion

The Agency reviewed the:

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

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

- The applicant does not propose to acquire more fixed PET scanners than are determined to be needed in the service area.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of PET scanner services;
 - The applicant adequately documents how the project will promote equitable access to PET scanner services; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
 - The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

SRMC proposes to acquire one fixed dedicated PET scanner pursuant to an adjusted need determination in the 2020 SMFP, to be located at the Gibson Cancer Center in Lumberton, Robeson County. In Project ID #N-11697-19, the applicant was awarded a certificate of need pursuant to an adjusted need determination in the 2019 SMFP to acquire a second linear accelerator in the Gibson Cancer Center. In Section C, page 27, the applicant states this proposal would be developed in space previously designated as waiting and vestibule space in Project ID #N-11697-19.

Patient Origin

On page 442, the 2020 SMFP defines the service area for a dedicated fixed PET scanner as: “...*the Health Service Area (HSA) in which the scanner is located (Table 17F-1)....*” The applicant proposes to locate the dedicated fixed PET scanner in Robeson County, which is in HSA V. Thus, the service area for this proposal is HSA V.

Facilities may also serve residents of counties not included in their service area.

The following table illustrates current patient origin, from page 29 of the application:

**SRMC PET Services Historical Patient Origin
 Last Full Fiscal Year (10/1/18 – 9/30/19)**

COUNTY	# OF PATIENTS	% OF TOTAL
Robeson	278	79.0%
Bladen	43	12.2%
Columbus	25	7.1%
Cumberland	4	1.1%
Harnett	2	0.6%
Total	352	100.0%

Source: Application page 29
 Percentages may not sum due to rounding

The following table illustrates projected patient origin for the first three full fiscal years (FY) of operation, from page 30 of the application:

SRMC PET Services Projected Patient Origin

COUNTY	1 ST FULL FY (10/1/21 – 9/30/22)		2 ND FULL FY (10/1/22 – 9/30/23)		3 RD FULL FY (10/1/23 – 9/30/24)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Robeson	1,359	81.1%	1,616	81.6%	1,812	81.8%
Bladen	184	11.0%	210	10.6%	232	10.5%
Columbus	98	5.9%	110	5.5%	119	5.4%
Cumberland	19	1.1%	23	1.1%	25	1.1%
Harnett	7	0.4%	7	0.4%	8	0.4%
Other*	9	0.6%	14	0.7%	17	0.8%
Total	1,676	100.0%	1,980	100.0%	2,214	100.0%

Source: Application page 30
 Percentages may not sum due to rounding

In Section C, page 30 and Form C, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because it is based on the historical experience of the applicant in providing similar services to its patients at the Gibson Cancer Center.

Analysis of Need

In Section C.1, page 25, the applicant states it currently provides PET service to its patients through a mobile provider, one-half day each week, which is not sufficient to meet the needs of its patients. In Section C, pages 31 - 49, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states there is need for additional fixed PET scanner capacity in HSA V. The applicant states that, although additional sites in the region have been approved for mobile PET scanners, no fixed PET scanners have been awarded in HSA V since 2003.

- The applicant provides information regarding the ratio of fixed PET scanners per one million residents in the entire state by HSA, and shows that HSA V has the second lowest ratio in the state.
- The applicant states that a significant number of Robeson County residents traveled to other counties in the state in 2018 to receive a PET scan, at times traveling in excess of 130 miles one-way to receive the scan. The applicant explains how the image derived from a fixed PET scanner rather than a mobile PET scanner enables a more precise diagnosis for cancer patients. Furthermore, citing several studies, the applicant states Robeson County has a high level of health disparities, high community health need, and a high mortality rate from cancer than other North Carolina counties.
- The applicant states that the socioeconomic disparities that prevail in Robeson County underscore the need for a dedicated fixed PET scanner at SRMC. SRMC is the only provider of open-heart surgery services without access to a fixed PET scanner for the residents of Robeson County.
- The applicant states Robeson County has higher death rates from heart disease than most North Carolina counties as well. Robeson County is a federally designated healthcare professional shortage area and is recognized as a medically underserved area by the U.S. Department of Health and Human Services. With those health disparities, the existing mobile PET services one-half day per week is simply not enough to meet the need in the county and surrounding area for PET services.
- The applicant discusses the different types of PET scans, including oncology screening, cardiac imaging and other clinical indications that will benefit the residents of Robeson County and SRMC’s service area, that are not currently available.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the proposed dedicated fixed PET scanner through the first three operating years of the proposed project (FY 2022- FY 2024) as summarized in the following table:

Historical and Projected Utilization, SRMC PET Services

	PRIOR FULL FY (FY2019)	INTERIM FULL FY (FY2020)	INTERIM PARTIAL FY (10/1/20 – 3/31/21)	INTERIM FY (4/1/20 – 9/30/21)	1 ST FULL FY (FY 2022)	2 ND FULL FY (FY 2023)	3 RD FULL FY (FY 2024)
Mobile PET scanner (1)	352	376	201	--	--	--	--
Fixed PET scanner (1)	--	--	--	743	1,676	1,980	2,214

The applicant provides its assumptions and methodology for projecting utilization for its proposed services in Section Q, Form C, pages 1 - 5, which is summarized as follows:

Historical Utilization – The applicant provides the overall historical utilization on the mobile PET scanner that serves SRMC one-half day per week, and calculates a compound annual

growth rate (CAGR) from FFY 2015 to FFY 2019, as shown in the following table from page 1:

	FFY 2015	FFY 2016	FFY 2017	FFY 2018	FFY 2019	CAGR
# of PET Scans	271	264	281	269	352	6.8%

As shown above, the applicant reports that the vendor-owned mobile PET scanner utilization increased by a 6.8% CAGR from FFY 2015 to FFY 2019.

Projected Utilization

The applicant projects utilization of its mobile PET scanner through six months of FY 2021. The applicant states that the mobile PET scanner FFY 2021 utilization is adjusted by 50%, because the mobile service will only be available for six months in that year, until the proposed fixed dedicated PET scanner is operational, as shown in the following table from page 1:

Projected PET Scan Utilization on Mobile PET Scanner

	FFY 2020	FFY 2021 (OCT. – MAR.)	CAGR
# of PET Scans	376	201	6.8%

The applicant calculates FFY 2021 as follows: $376 \times 1.068 = 401$;
 $401 / 2 = 200.78$.

The applicant projects oncology and cardiac PET scans separately as follows:

Oncology PET Scans

In Section Q, pages 1 - 3, the applicant projects the number of oncology PET procedures through the third full fiscal year. The applicant states that despite the growth in PET scans provided on the mobile PET scanner that has been available, efforts to provide PET services to all patients who need the service has been hampered by the limited availability of the mobile service at SRMC only one-half day per week. The applicant states that its overall analytic cancer cases (defined as patients who were either diagnosed with cancer or received their first treatment at SRMC) procedures grew by a CAGR of 6.7% from FFY 2015 to FFY 2018, as shown in the following table from page 2:

Historical Analytic Cancer Cases, FFY 2015 – FFY 2018

	FFY 2015	FFY 2016	FFY 2017	FFY 2018	CAGR
# of Cases	395	412	446	480	6.7%

Based on its historical experience, the applicant projects analytic cancer cases will grow by 6.7% through the third FFY of operation, as shown in the following table from page 2:

	FFY 2019	FFY 2020	FFY 2021	FFY 2022	FFY 2023	FFY 2024	CAGR
Analytic Cancer Cases	512	547	583	622	664	709	6.7%

To project the number of analytic cancer cases that would be appropriate for PET imaging services, the applicant examined the historical analytic cancer cases that would have been appropriate for PET imaging services. The applicant states that its experience is 98% of historical analytic cancer cases were appropriate for PET imaging services, and therefore multiplies the projected number of analytic cancer cases by 98%, as illustrated in the following table from page 2:

Projected Analytic Cancer Cases Appropriate for PET Imaging Service

	FFY 2019	FFY 2020	FFY 2021	FFY 2022	FFY 2023	FFY 2024
98% of Analytic Cancer Cases	503	537	573	611	652	696

Numbers may not sum due to rounding by Project Analyst

The applicant states that PET scanner appropriate analytic cases are adjusted by 50% for FFY 2021, because the proposed fixed dedicated PET scanner will only be operational for the last six months of FFY 2021, as shown in the following table from page 1:

Projected Analytic Cases Appropriate for PET Imaging

	FFY 2021 (APRIL – SEPT.)	FFY 2022	FFY 2023	FFY 2024
Analytic Cancer Cases Appropriate for PET Imaging	286	611	652	696

The applicant states that, based on its experience, each analytic cancer case that is appropriate for PET imaging is projected to receive two PET scans. The applicant believes the projection is reasonable based on its experience and the fact that Medicare reimburses up to three scans per patient. See the following table that illustrates the number of scans:

Projected # PET Scans per Analytic Cancer Case

	FFY 2021 (APRIL – SEPT.)	FFY 2022	FFY 2023	FFY 2024
Analytic Cancer Case Appropriate for PET Imaging	286	611	652	696
# Scans / Analytic Case	2	2	2	2
Analytic Cancer Case PET Scans	573	1,223	1,3050	1,392

Cardiac PET Scans

The applicant states that PET imaging for cardiac patients provides high diagnostic accuracy, low radiation exposure, rapid imaging responses and greater suitability for ill or higher-risk patients. The applicant projects cardiac imaging procedures on the proposed fixed dedicated PET scanner based on its historical experience.

The applicant calculated a CAGR based on the historical number of cardiac imaging scans that would have been appropriate for PET imaging from FFY 2017 to FFY 2019, as shown in the following table from page 4:

Historical Cardiac Cases Appropriate for PET Imaging

	FFY 2017	FFY 2018	FFY 2019	CAGR
# Procedures	1,326	1,529	1,503	6.5%

Based on its historical experience, the applicant projects PET-appropriate cardiac imaging cases will grow by 6.5% through the third FFY of operation, as shown in the following table from page 4:

Projected PET-Appropriate Cardiac Imaging Cases

	FFY 2020	FFY 2021	FFY 2022	FFY 2023	FFY 2024	CAGR
# Procedures	1,600	1,704	1,814	1,931	2,056	6.5%

The applicant states on page 4 that it assumes that 40% of the PET-appropriate cardiac imaging cases will be performed on the proposed fixed dedicated PET scanner in the third full FFY of operation, and that it will ramp up over time, as illustrated in the following table from page 4:

Projected # PET Scans per Cardiac Case

	FFY 2021 (APRIL – SEPT.)	FFY 2022	FFY 2023	FFY 2024
PET-Appropriate Cardiac Imaging Procedures	852	1,814	1,931	2,056
% Converted to PET Scans	20%	25%	35%	40%
Total Cardiology-Based PET Scans	170	453	676	822

On page 4, the applicant states that the projected number of PET-appropriate cardiac imaging scans are adjusted by 50% for FFY 2021, because the proposed fixed dedicated PET scanner will only be operational for the last six months of FFY 2021.

Total PET Scans

The applicant combines the projected utilization for its proposed PET scanner for all procedures in Section Q, page 5, as illustrated in the following table:

SRMC Total Projected PET Scans

	FFY 2021 (OCT – MAR)	FFY 2021 (APRIL – SEPT.)	FFY 2022	FFY 2023	FFY 2024
# Oncology PET Scans		573	1,223	1,305	1,392
# Cardiology PET Scans		170	453	676	822
# Scans on Fixed PET Scanner		743	1,676	1,980	2,214
# Scans on Mobile PET Scanner	201				
Total PET Scans		944	1,676	1,980	2,214

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

- The applicant’s utilization projections are supported by the historical utilization of the existing mobile PET scanner owned by Alliance.

- The applicant’s utilization projections are supported by advances in technology and capabilities of PET scanners and by the expected increase in demand for both cardiac and oncology PET imaging procedures.
- The applicant’s utilization projections are based on the particular Robeson County demographic and health information of people SRMC serves.

Access

In Section C, page 54, the applicant states SRMC does not discriminate against low-income persons, racial or ethnic minorities, women, handicapped persons, the elderly or other underserved persons, and does and will continue to provide care to all persons regardless of age, race, national or ethnic origin, disability, gender, sexual orientation, income or ability to pay. In Section L, page 87, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table:

PAYOR SOURCE	SRMC	PET SERVICES
Self-pay	10.5%	7.0%
Medicare*	41.9%	47.4%
Medicaid*	22.3%	8.6%
Insurance*	25.2%	36.3%
Other**	0.0%	0.7%
Total	100.0%	100.0%

Numbers may not sum due to rounding.

*Includes managed care plans

**the applicant states on page 87 that workers compensation and TRICARE are included in the Self-Pay category for SRMC, and in the “Other” category for PET services.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services 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 a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

SRMC proposes to acquire one fixed dedicated PET scanner pursuant to an adjusted need determination in the 2020 SMFP, to be located at the Gibson Cancer Center in Lumberton, Robeson County.

In Section E, page 64, 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 – The applicant states this was not an effective alternative because there is limited availability with the mobile PET scanner once weekly, and the patients in Robeson County need the full-time services of a fixed PET scanner.
- Construct new space to house the proposed PET scanner – The applicant states this was not an effective alternative because new construction, rather than adding space to the previously approved project as indicated in the application would unnecessarily increase the capital cost of the project and could create operational efficiencies.

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

- The application is conforming to all statutory and regulatory review criteria.
- The proposal will meet the need for a dedicated fixed PET scanner at SRMC in response to the adjusted need determination in the 2020 SMFP.

- The applicant provides reasonable and supported information to explain why it believes the proposed project is the most effective alternative to meet the need for a PET scanner in Robeson County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Southeastern Regional Medical Center shall materially comply with all representations made in the certificate of need application.**
 - 2. Southeastern Regional Medical Center shall acquire no more than one dedicated fixed PET scanner for a total of no more than one dedicated fixed PET scanner at the hospital.**
 - 3. Southeastern Regional Medical Center, as part of this project, shall not acquire 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 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 shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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

SRMC proposes to acquire one fixed dedicated PET scanner pursuant to an adjusted need determination in the 2020 SMFP, to be located at the Gibson Cancer Center in Lumberton, Robeson County.

Capital and Working Capital Costs

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

Construction Costs	\$1,100,000
Medical Equipment	\$2,787,422
Miscellaneous Costs	\$185,618
Total	\$4,073,040

Source: Application Section Q

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

In Section F, page 68, the applicant states there will be no start-up costs or initial operating expenses since the hospital is operational.

Availability of Funds

In Section F, page 66, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	SRMC	TOTAL
Loans	\$0	\$0
Accumulated reserves or OE *	\$4,073,040	\$4,073,040
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$4,073,040	\$4,073,040

* OE = Owner's Equity

Exhibit F.2-1 contains a letter dated February 17, 2020 from the Chief Reimbursement Officer for Southeastern Regional Medical Center documenting the availability of sufficient accumulated reserves for the capital needs of the proposed project. Exhibit F.2-2 contains the audited financial statements of Southeastern Regional Medical Center and Related Organizations, which show that as of December 31, 2019, the applicant had \$13.2 million in cash and cash equivalents and \$77.1 million in total assets.

Financial Feasibility

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

SRMC Revenue Projections, First Three Full Fiscal Years			
	1ST FULL FISCAL YEAR 10/1/21 – 9/30/22	2ND FULL FISCAL YEAR 10/1/22 – 9/30/23	3RD FULL FISCAL YEAR 10/1/23 – 9/30/24
Total Procedures	1,676	1,980	2,214
Total Gross Revenues (Charges)	\$6,123,317	\$7,452,842	\$8,583,665
Total Net Revenue	\$1,590,746	\$1,919,063	\$2,221,709
Average Net Revenue per Procedure	\$949.13	\$969.22	\$1,003.47
Total Operating Expenses (Costs)	\$1,496,952	\$1,892,279	\$2,161,119
Average Operating Expense per Procedure	\$893.17	\$955.70	\$976.12
Net Income	\$93,784	\$26,784	\$60,590

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

SRMC proposes to acquire one fixed dedicated PET scanner pursuant to an adjusted need determination in the 2020 SMFP, to be located at the Gibson Cancer Center in Lumberton, Robeson County.

On page 442, the 2020 SMFP defines the service area for a fixed dedicated PET scanner as, “A dedicated fixed PET scanner’s service area is the Health Service Area (HSA) in which the scanner is located.” SRMC is located in Robeson County, which is in HSA V. Thus, the service area for this proposal is HSA V.

Table 17F-1, on page 444 of the 2020 SMFP shows the following PET scanners in HSA V:

FACILITY	PLANNING INVENTORY	# PROCEDURES (2017 – 2018)	UTILIZATION RATE
Cape Fear Valley Medical Center	1	953	31.77%
First Imaging of the Carolinas	1	1,113	37.10%
New Hanover Regional Medical Center	1	2,163	72.10%

In Section G, pages 73-74, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET scanners services in HSA V. The applicant states:

“There are three existing fixed PET scanners in HSA V; however, as described in Section C.4, HSA V has the second lowest ratio of fixed PET scanners per one million residents, significantly below the statewide ratio and just under one-half the ratio in HSA II. Further, while the populations of HSAs II, III, and IV may be higher than those of HSAs I, V, and VI, the more populous HSAs are smaller geographically; that is, they cover less area than HSAs I, V, and VI. SRMC believes that this is an important consideration, as patients already must travel longer distances in HSAs I, V, and VI. The lower number of fixed PET scanners covering a larger geography places an even greater burden on these residents.”

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

- There is an adjusted need determination in the 2020 SMFP for the proposed fixed dedicated PET scanner pursuant to a petition submitted by the applicant.
- The applicant adequately demonstrates that the proposed fixed dedicated PET scanner is needed in addition to the existing or approved PET scanners in HSA V.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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 Form H, Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services for the first three full fiscal years (FY) of operation, as illustrated in the following table:

POSITION	1 ST FULL FY (10/1/2021 -9/30/2022)	2 ND FULL FY (10/1/2022 -9/30/2023)	3 RD FULL FY (10/1/2023 -9/30/2024)
Aides/Orderlies	0.50	1.00	1.00
Radiology Technologists	1.00	1.50	2.00
Business Office	0.25	0.50	1.00
Patient Navigator	0.25	0.50	1.00
Total	2.00	3.50	5.00

The applicant has no current staff since it does not currently own or operate a PET scanner.

The assumptions and methodology used to project staffing for the PET scanner services are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 75 and 76, respectively, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section I.3, page 78, the applicant identifies the current medical director of radiology services at SRMC, who will continue in that capacity following project completion. In Exhibit I.3, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibit I.2, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 77, the applicant states that the following ancillary and support services are necessary for the proposed services and are currently available at the hospital:

- Laboratory
- Radiology
- Pharmacy
- Dietary
- Housekeeping
- Maintenance
- Administration

The applicant states there are other services that are and will continue to be provided at SRMC, including vendor-provided radiotracers for use in cardiac imaging PET scans.

On page 77, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.2.

In Section I, page 77, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 81, the applicant states that this project would be developed in space previously designated as waiting and vestibule space in Project ID #N-11697-19, and that 2,703 square feet of new space will be added to accommodate waiting and administrative space for the linear accelerator and the PET scanner.

On page 82, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 82, 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.

In Exhibit B.11, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, page 86, the applicant provides the historical payor mix during fiscal year 2019 for the hospital and for mobile PET services, as shown in the table below:

PAYOR SOURCE	SRMC	PET SERVICES
Self-pay	10.5%	5.1%
Medicare*	41.9%	46.6%
Medicaid*	22.3%	7.7%
Insurance*	25.2%	40.3%
Other**	0.0%	0.3%
Total	100.0%	100.0%

Numbers may not sum due to rounding.

*Includes managed care plans

**the applicant states on page 86 that workers compensation and TRICARE are included in the Self-Pay category for SRMC, and in the "Other" category for PET services.

In Section L.1, page 85, the applicant provides the following comparison:

	Percentage of Total Patients Served by the Facility or Campus during FY2019	Percentage of the Population of Robeson County
Female	63.9%	51.8%
Male	36.1%	48.2%
Unknown	NA	NA
64 and Younger	65.8%	84.8%
65 and Older	34.2%	15.2%
American Indian	27.5%	41.7%
Asian	0.9%	0.7%
Black or African-American	27.3%	23.8%
Native Hawaiian or Pacific Islander	0.3%	0.2%
White or Caucasian	41.1%	30.9%
Other Race	1.1%	2.7%
Declined / Unavailable	1.8%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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 86, the applicant states it is not under any obligation.

In Section L.2, page 87, the applicant states that during the last five years, no patient civil rights access complaints have been filed against SRMC.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 87, the applicant provides the projected payor mix for the third operating year (FY 2024) for the proposed project, as shown in the table below:

PAYOR SOURCE	SRMC	PET SERVICES
Self-pay	10.5%	7.0%
Medicare*	41.9%	47.4%
Medicaid*	22.3%	8.6%
Insurance*	25.2%	36.3%
Other**	0.0%	0.7%
Total	100.0%	100.0%

Numbers may not sum due to rounding.

*Includes managed care plans

**the applicant states on page 87 that workers compensation and TRICARE are included in the Self-Pay category for SRMC, and in the "Other" category for PET services.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 7.0% of PET scanner services will be provided to self-pay patients, 47.4% to Medicare patients, and 8.6% to Medicaid patients.

In Section L.3, page 87, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.5, page 88, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 89, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

Conclusion

The Agency reviewed the:

- Application
- 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

SRMC proposes to acquire one fixed dedicated PET scanner pursuant to an adjusted need determination in the 2020 SMFP, to be located at the Gibson Cancer Center in Lumberton, Robeson County.

On page 442, the 2020 SMFP defines the service area for a fixed dedicated PET scanner as, “A dedicated fixed PET scanner’s service area is the Health Service Area (HSA) in which the scanner is located.” SRMC is located in Robeson County, which is in HSA V. Thus, the service area for this proposal is HSA V.

Table 17F-1, on page 444 of the 2020 SMFP shows the following PET scanners in HSA V:

FACILITY	PLANNING INVENTORY	# PROCEDURES (2017 – 2018)	UTILIZATION RATE
Cape Fear Valley Medical Center	1	953	31.77%
First Imaging of the Carolinas	1	1,113	37.10%
New Hanover Regional Medical Center	1	2,163	72.10%

In Section N.2, pages 90 - 93, 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 91 the applicant states,

“...SRMC currently provides services through a vendor-provided mobile service, which is on site one half-day per week. While the mobile service has provided some local access to PET services, it does not and cannot meet the need for PET services in Robeson County and the surrounding area. As a result, and under the status quo, patients in need of a PET scan must either travel a significant distance to another site, must delay diagnosis, staging, and treatment for their cancer until the mobile PET is on site with available appointments, or forgo a PET scan and rely on another, less-effective diagnostic procedure.

...Further, there are increased socioeconomic challenges for underserved populations such as lack of funds to seek treatment outside of their home town or inadequate transportation. For these reasons, PET services must be available to patients of all demographic and socioeconomic statuses affording them the same access to safe and effective diagnosis and treatment courses.”

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 B, N, F and Q of the application and any exhibits)

- Quality services will be provided (see Sections B, N and O of the application and any exhibits)
- Access will be provided to underserved groups (see Sections B, C, N and L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 Q, Form A, the applicant identifies the hospital located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant is the only hospital located in North Carolina owned, operated or managed by SRMC.

In Section O, page 95, the applicant states that, during the 18 months immediately preceding the submittal of the application, two incidents related to quality of care occurred in the hospital, one of which involved multiple deficiencies and a finding of “*immediate jeopardy*”. The applicant states that all of the problems have been corrected, and provides supporting documentation in Exhibit I.1. 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, two incidents related to quality of care occurred in the hospital. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification, 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.

C

The application is conforming with all applicable Criteria and Standards for Positron Emission Tomography Scanners. The specific criteria are discussed below.

SECTION .3700 - CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER

10A NCAC 14C .3703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that:

(1) the proposed dedicated PET scanner, including a proposed mobile dedicated PET scanner, shall be utilized at an annual rate of at least 2,080 PET procedures by the end of the third year following completion of the project;

-C- In Section Q, Form C, and the assumptions and methodology in Section Q, pages 1 – 5, the applicant projects to have an annual rate of 2,097 PET procedures on the proposed fixed dedicated PET scanner by the end of the third year following completion of the project. The projected number of procedures exceeds the annual rate of 2,080 procedures as set forth in this rule. The discussion found in Criterion (3) regarding projected utilization is incorporated herein by reference.

(2) if an applicant operates an existing dedicated PET scanner, its existing dedicated PET scanners, excluding those used exclusively for research, performed an average of at least 2,080 PET procedures per PET scanner in the last year; and

-NA- The applicant does not currently operate an existing dedicated fixed PET scanner.

(3) its existing and approved dedicated PET scanners shall perform an average of at least 2,080 PET procedures per PET scanner during the third year following completion of the project.

-NA- The applicant does not currently operate an existing dedicated fixed PET scanner. In Section Q, Form C, and the assumptions and methodology in Section Q, pages 1 – 5, the applicant projects to perform 2,097 PET procedures on the proposed fixed dedicated PET scanner by the end of the third year following completion of the project.

(b) The applicant shall describe the assumptions and provide data to support and document the assumptions and methodology used for each projection required in this Rule.

-C- The applicant provides its assumptions and methodology in Section Q, Form C. The discussion found in Section C regarding projected utilization is incorporated herein by reference.