

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 1, 2019

Findings Date: May 1, 2019

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11659-19

Facility: Rex Hospital

FID #: 953429

County: Wake

Applicant: Rex Hospital, Inc.

Project: Acquire a second fixed dedicated PET scanner pursuant to the 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

Rex Hospital, Inc. [**Rex Hospital**] proposes to acquire a second fixed dedicated PET scanner pursuant to the need determination in the 2019 SMFP.

Need Determination

The 2019 State Medical Facilities Plan (SMFP) includes a need determination for one fixed positron emission tomography (PET) scanner for HSA IV, which includes Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, and Warren counties. Rex Hospital proposes to add one fixed dedicated PET scanner to its existing Rex Hospital in Wake County. Therefore, the application is consistent with the 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

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.”

Rex Hospital 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.10, pages 29-32 and Section N.1, pages 130-133, Section O, pages 135-140, 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.10, pages 32-33 and Section C.10, pages 79-84, Section N.1, pages 133-134, 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 health care value in Section B.10, pages 33-34, Section N, pages 129-130, and the applicant's 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 will maximize health care value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the fixed PET scanner equipment need determination in the 2019 SMFP. The application is consistent with Policy GEN-3.

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 Exhibit B.10, pages 35-36, the applicant describes its plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plans to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 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 in HSA IV;
 - The applicant adequately documents how the project will promote equitable access to PET scanner services in HSA IV; 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

The applicant, Rex Hospital, proposes to acquire a second fixed dedicated PET scanner pursuant to the need determination in the 2019 SMFP. In Section C.1, pages 51-52, the applicant describes the project as follows:

“The proposed project involves the renovation of 3,200 square feet of existing space within the hospital co-located with the existing PET scanner. As shown in the project line drawings included in Exhibit C.1, the proposed second fixed PET scanner will be located in space currently occupied by volunteer services and other administrative office space, which will be relocated within the hospital building. The PET control room will be located between the two scanners in its current location with slight configuration modifications.”

Patient Origin

On page 141, the 2019 SMFP defines the service area for a fixed PET scanner as, “A fixed PET scanner's service area is the HSA in which the scanner is located. The HSAs are the six multi-county groupings as defined in Appendix A of the North Carolina 2019 State Medical Facilities Plan.” Table 9N, page 146, of the 2019 SMFP shows a need for one fixed PET scanner in HSA IV. Thus, the service area for this proposal is HSA IV.

In Sections C.1 and C.3, the applicant provides tables showing its historical (FY2018) and projected patient origin for PET scanner services for the first three operating years (FY2021-FY2023) of the proposed project, as summarized in the following table:

County of Origin	Historical Patient Origin (FY2018)	Projected Patient Origin Operating Years 1-3 (FY2021-FY2023)
Wake	68.8%	68.4%
Johnston	7.7%	7.7%
Franklin	4.9%	5.0%
Harnett	4.7%	4.8%
Sampson	2.4%	2.6%
Nash	2.1%	2.2%
Wayne	1.2%	1.3%
Durham	0.8%	0.8%
Other*	7.4%	7.2%
Total**	100.0%	100.0%

Source: Tables on pages 57-63 of the application.

*The applicant provides a list of the counties included in the “Other” category on pages 57-58 and pages 62-63 of the application.

**Totals may not foot due to rounding.

In Section C.3, pages 63-64, the applicant states projected patient origin is based on the historical (FY2018) patient origin for the proposed services. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 64-75, the applicant explains why it believes the population projected to utilize the proposed PET scanner needs the proposed services, including:

- The need for one fixed PET scanner identified in the 2019 SMFP (pages 64-65).
- The need for PET scanner services within HSA IV based on the distribution and utilization of existing PET scanners in the service area (pages 65-71).
- The need for PET scanner services in Wake County based on the utilization of the existing PET scanners located in the county (pages 71-75).

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

- The applicant provides information regarding the current and projected population by county for HSA IV from the North Carolina Office of State Budget and Management (NCOSBM) and the distribution of PET scanners within the service area to support the need for additional PET capacity.
- The applicant provides historical utilization data for its existing PET scanner and the other existing Wake County PET scanners to support the need for additional PET scanner capacity in Wake County, generally, and at Rex Hospital, specifically.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the existing and proposed PET scanner through the first three operating years of the proposed project (FY2021-FY2023) as summarized in the following table:

Rex Hospital PET Scanner Utilization			
YEAR	PET Scanner Units	PET Procedures	Percent Change
FY2016 (Actual)	1	2,237	---
FY2017 (Actual)	1	2,776	24.1%
FY2018 (Actual)	1	3,274	17.9%
FY2019 (Projected)	1	3,422	4.5%
FY2020 (Projected)	1	3,551	3.8%
FY2021 Year 1	2	3,764	6.0%
FY2022 Year 2	2	3,990	6.0%
FY2023 Year 3	2	4,229	6.0%

Source: Form C, Section Q of the application.

The applicant provides its assumptions and methodology for projecting utilization for its proposed services in Section Q, Form C, pages 1-7, which is summarized as follows:

Step 1: Historical Utilization – The applicant provides historical utilization of the existing Rex Hospital PET scanner, which is summarized below:

Rex Hospital Historical PET Utilization FY2015-FY2019						
	FY15	FY16	FY17	FY18	FY19**	CAGR FY15-FY19
Cardiac PET Procedures	9	21	472	1,013	1,145	235.8%
Oncology PET Procedures	2,040	2,216	2,304	2,261	2,278	2.8%
Total PET Procedures	2,049	2,237	2,776	3,274	3,422	13.7%
# of Units	1	1	1	1	1	
Capacity per Unit	3,000	3,000	3,000	3,000	3,000	
Total Capacity	3,000	3,000	3,000	3,000	3,000	
% of Unitization*	68.3%	74.6%	92.5%	109.1%	114.1%	

Source: Applicant's internal data

*Total number of PET procedures / Total Capacity

**The applicant states FY2019 is projected based on annualized data from July to November (5 months).

As shown above, the applicant reports that at the end of FY2018, the existing PET scanner at Rex Hospital operated at 109.1 percent of its capacity.

Step 2: Projected Utilization - The applicant provides the projected number of cardiac and oncology procedures separately.

Cardiac PET

In Section Q, pages 3-4, the applicant projects the number of cardiac PET procedures through the third full fiscal year. The applicant states that its combined cardiac imaging procedures grew 10.9 percent overall from FY2015-FY2019. The applicant states in Section Q, page 3, that given the recent development of its cardiac PET program, that it is reasonable to project cardiac PET utilization at 5.5 percent annually, which is half its historical growth rate.

Based on its historical experience, the applicant projects cardiac PET procedures will account for 50 percent of total cardiac imaging procedures, as illustrated below.

Rex Hospital Projected Cardiac PET Procedures Utilization

	FY20	FY21	FY22	FY23
Total Cardiac Imaging Procedures	2,420	2,552	2,691	2,838
% Diagnosed w/ PET	50%	50%	50%	50%
Projected Cardiac PET Procedures	1,210	1,276	1,345	1,419

Source: Section Q, page 4

Oncology PET

The applicant states that oncology PET scanner procedure volume grew by an average rate of 6.3 percent per year from 2015 to 2017, from 2,040 procedures in 2015 to 2,304 procedures in 2017. The applicant projects oncology PET procedures will grow at a rate consistent with that historical utilization of 6.3 percent annually, as shown below.

Rex Hospital Projected Oncology PET Procedures Utilization

	FY20	FY21	FY22	FY23	CAGR
Projected Oncology PET Procedures	2,341	2,488	2,644	2,810	6.3%

Total PET

The applicant combines the projected utilization for its fixed PET scanners for all procedures, in Section Q, page 5, as illustrated below.

Rex Hospital Total Projected PET Utilization by Fiscal Years

	FY20	FY21	FY22	FY23
Cardiac PET Procedures	1,210	1,276	1,345	1,419
Oncology PET Procedures	2,341	2,488	2,644	2,810
Total PET Procedures	3,551	3,764	3,990	4,229
# of Units	1	2	2	2
Capacity per Unit	3,000	3,000	3,000	3,000
Total Capacity	3,000	6,000	6,000	6,000
% of Capacity*	118.4%	62.7%	66.5%	70.5%

Source: Table on page 5 of Section Q.

*Total number of PET procedures / Total Capacity

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 PET scanner at Rex Hospital.
- 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 procedures.
- The applicant provides letters from physicians expressing support for the proposed project and their intention to refer patients to the PET scanner services at Rex Hospital in Exhibit I.2 of the application.

Access

In Section C.11, page 79, the applicant states Rex Hospital will continue to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental condition, age, ability to pay, or any other factor. In Section L.3, page 125, the applicant projects the following payor mix for Rex Hospital’s PET scanner services during the second year of operation (FY2022) following completion of the project, as shown in the following table.

Payment Source	PET Scanner Services Percent of Total Procedures
Self-Pay	2.5%
Medicare	64.8%
Medicaid	3.2%
Insurance	29.4%
Total*	100.0%

Source: Table on page 87 of the application.
*Totals may not foot due to rounding.

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 the reduction or elimination of a 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

Rex Hospital proposes to acquire a second fixed dedicated PET scanner pursuant to the need determination in the 2019 SMFP.

In Section E.2, pages 94-95, 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 due to the fact that the existing fixed PET scanner at Rex Hospital is already operating above capacity, which is resulting in scheduling delays and patient and physician inconvenience.
- Utilize mobile PET scanner services – The applicant states this was not an effective alternative because it would be difficult to provide the volume of services needed on a mobile PET unit, and the existing mobile PET scanner units in the state are already operating over capacity.

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 alternative will meet the need for additional PET scanner capacity at Rex Hospital.
- The alternative does not rely on the availability of mobile PET scanner services, which are already operating above capacity.

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. Rex Hospital, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Rex Hospital, Inc. shall acquire no more than one additional fixed PET scanner for a total of no more than two fixed PET scanners at the hospital.**
 - 3. Rex Hospital, Inc., 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, Rex Hospital, 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. Rex Hospital, Inc. 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.

Rex Hospital proposes to acquire a second fixed dedicated PET scanner pursuant to the need determination in the 2019 SMFP. The applicant proposes to renovate space near the existing fixed PET scanner to accommodate the proposed fixed PET scanner.

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	\$1,328,000
Miscellaneous Costs	\$2,878,352
Total	\$4,206,352

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

In Section F.3, page 99, the applicant states the project does not involve a new service and there will be no start-up costs or initial operating expenses required.

Availability of Funds

In Section F, page 98, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing		
Type	Rex Hospital, Inc.	Total
Loans	\$	\$
Accumulated reserves or OE *	\$4,206,352	\$4,206,352
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$4,206,352	\$4,206,352

* OE = Owner's Equity

Exhibit F.2 contains a letter dated February 15, 2019 from the Chief Financial Officer for Rex Hospital documenting its intention to provide accumulated reserves for the capital needs of the proposed project. Exhibit F.2 contains the audited financial statements of Rex Healthcare, Inc. which show that as of June 30, 2018, the applicant had \$140 million in cash and cash equivalents, \$1.1 billion in total assets, and \$576 million in net assets (total assets less total liabilities).

Financial Feasibility

The applicant provided pro forma financial statements for UNC Rex Healthcare for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

Rex Hospital PET Scanner Services

	1st Fiscal Year	2nd Fiscal Year	3rd Fiscal Year
Total Procedures	3,764	3,990	4,229
Total Gross Revenues (Charges)	\$24,243,338	\$26,468,174	\$28,897,570
Total Net Revenue	\$7,079,051	\$7,728,703	\$8,438,086
Net Revenue per Procedure	\$1,881	\$1,937	\$1,995
Total Operating Expenses (Costs)	\$3,909,375	\$4,461,623	\$4,707,360
Operating Expense per Patient	\$1,038	\$1,118	\$1,113
Net Income	\$3,169,676	\$3,267,080	\$3,730,727

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.

C

The applicant, Rex Hospital, proposes to acquire a second fixed dedicated PET scanner pursuant to the need determination in the 2019 SMFP.

On page 141, the 2019 SMFP defines the service area for a fixed PET scanner as, “A *fixed PET scanner's service area is the HSA in which the scanner is located. The HSAs are the six multi-county groupings as defined in Appendix A of the North Carolina 2019 State Medical Facilities Plan.*” Table 9N, page 146, of the 2019 SMFP shows a need for one fixed PET scanner in HSA IV. Thus, the service area for this proposal is HSA IV.

Table 9L, page 144, of the 2019 SMFP provides an inventory with utilization of fixed PET scanners in HSA IV, which is summarized in the table below:

Fixed PET Scanners in HSA IV by County and Facility

County	Facility	# of Fixed Pet Scanners	FY2017 Procedures	FY2017 Utilization Rate
Wake	UNC REX	1	2,556	85.20%
Orange	UNC Hospitals	2	4,152	69.20%
Wake	Wake PET Services	1	469	15.63%
Durham	Duke University Hospital	2	4,774	79.57%
Wake	Duke Raleigh Hospital*	1	NA	NA

Source: Table 9L, page 144, 2019 SMFP

*CON was issued (Project I.D. J-11384-17) on August 21, 2018 for a fixed PET scanner at Duke Raleigh Hospital.

In Section G.3, pages 106-107, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET scanner services in the service area. The applicant states:

“The 2019 SMFP includes a need determination for one additional fixed PET scanner in HSA IV, which was generated by UNC REX. As described in the assumptions and methodology for Form C, UNC REX needs additional capacity to meet the growing demand for PET services by patients at its facility. ... As discussed in the assumptions and methodology in Form C, UNC REX’s existing PET scanner has been performing a rapidly growing number of cardiac PET procedures. The proposed fixed PET scanner at UNC REX is expected to relieve current capacity constraints and enable UNC REX to perform more cardiac PET procedures, in addition to oncology and other PET procedures.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed fixed dedicated PET scanner is needed in addition to the existing or approved services.

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 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 projected full-time equivalent (FTE) staffing in the first three operating years (FY2021-FY2023) for the proposed PET scanner services. The assumptions and methodology used to project staffing are provided in Section Q. 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 Sections H.2 and H.3, pages 109-110, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H.4, page 111, the applicant identifies the proposed medical director and provides supporting documentation in Exhibit H.4.

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.1, page 113, the applicant states UNC REX is an existing full-service hospital, as such, the hospital currently has all necessary ancillary and support services in place. In Section I.2, pages 113-114, the applicant states it has established relationships with other local health care and social service providers and provides which will continue following completion of the proposed project. The applicant 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
- 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 HSA IV where 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

- (11) The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.
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.3, page 116, the applicant states that the project requires renovations to 3,200 square feet of space in the existing PET scanner department of the hospital. Line drawings are provided in Exhibit C.1.

In Section K.4, page 117, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.4, page 117, 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 Section K.4, page 117, 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.1, page 123, the applicant provides the historical payor mix during FY2018 for the PET scanner services at Rex Hospital, as shown in the table below.

Payor Category	Percent of PET Scanner Procedures
Self-Pay	2.5%
Medicare	64.8%
Medicaid	3.2%
Insurance	29.4%
Total	100.0%

Source: Table on page 123 of the application.

In Section L.1, pages 121-122, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the FY2018	Percentage of the Population of the Orange County Service Area
Female	63.7%	51.9%
Male	36.3%	48.1%
Unknown	NA	NA
64 and Younger	61.8%	86.0%
65 and Older	38.2%	14.0%
American Indian	0.2%	0.0%
Asian	1.9%	6.6%
Black or African-American	22.0%	22.2%
Native Hawaiian or Pacific Islander	0.1%	Included in Asian
White or Caucasian	68.7%	67.3%
Other Race	4.7%	2.7%
Declined / Unavailable	2.5%	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;

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 123, the applicant states Rex Hospital complies with all the relevant regulatory requirements with regard to uncompensated care, community service and access by minorities and handicapped persons.

In Section L.2, page 124, the applicant states that during the last five years, no patient civil rights access complaints have been filed against Rex Hospital.

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 125, the applicant provides the projected payor mix for the second operating year (FY2022) for the proposed project, as shown in the table below.

Payor Category	Percent of PET Scanner Procedures
Self-Pay	2.5%
Medicare	64.8%
Medicaid	3.2%
Insurance	29.4%
Total	100.0%

Source: Table on page 125 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.5 percent of PET scanner services will be provided to self-pay patients, 64.8 percent to Medicare patients, and 3.2 percent to Medicaid patients.

In Section L.3, page 125, 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.

- (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 126, 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.1, pages 127-128, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes.

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

The applicant, Rex Hospital, proposes to acquire a second fixed dedicated PET scanner pursuant to the need determination in the 2019 SMFP.

On page 141, the 2019 SMFP defines the service area for a fixed PET scanner as, “A *fixed PET scanner's service area is the HSA in which the scanner is located. The HSAs are the six multi-county groupings as defined in Appendix A of the North Carolina 2019 State Medical Facilities Plan.*” Table 9N, page 146, of the 2019 SMFP shows a need for one fixed PET scanner in HSA IV. Thus, the service area for this proposal is HSA IV.

Table 9L, page 144, of the 2019 SMFP provides an inventory with utilization of fixed PET scanners in HSA IV, which is summarized in the table below:

Fixed PET Scanners in HSA IV by County and Facility

County	Facility	# of Fixed Pet Scanners	FY2017 Procedures	FY2017 Utilization Rate
Wake	UNC REX	1	2,556	85.20%
Orange	UNC Hospitals	2	4,152	69.20%
Wake	Wake PET Services	1	469	15.63%
Durham	Duke University Hospital	2	4,774	79.57%
Wake	Duke Raleigh Hospital*	1	NA	NA

Source: Table 9L, page 144, 2019 SMFP

*CON was issued (Project I.D. J-11384-17) on August 21, 2018 for a fixed PET scanner at Duke Raleigh Hospital.

In Section N.2, pages 129-134, 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 130, the applicant states,

“The proposed project will be developed in existing space that will be renovated to accommodate the second fixed PET scanner as well as additional support space. As an existing PET provider, UNC REX has all necessary ancillary and support services in place including a Rubidium generator, which allow it to produce the radiotracer required for cardiac PET imaging. As such, the cost of the project is significantly lower

than if the hospital were to develop a new PET service or develop new construction to house the proposed equipment.”

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

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.3, page 136, the applicant states The University of North Carolina Health Care System (UNC Health Care System) is the sole member and parent of Rex Healthcare, Inc., which is the parent of Rex Hospital. The applicant states UNC Health Care System owns or manages ten licensed healthcare facilities in North Carolina, including Rex Hospital.

In Section O, pages 137-140, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred at six UNC Health Care System facilities. In Section O.2, page 140, the applicant states that all of the facilities are back in compliance with all Medicare Conditions of Participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, all of the facilities are back in compliance with all Medicare Conditions of Participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, and considering the quality of care provided at all ten facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

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 C, page 87 and Section Q, page 5, the applicant projects to have an annual rate of 2,114 PET procedures on each of its two units (4,229 PET procedures / 2 PET scanner units = 2,114 procedures/unit) 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 number of procedures projected is based on reasonable and adequately supported assumptions. 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*

-C- In Section C, page 87 and Section Q, Form C, the applicant states the one fixed PET scanner operated by Rex Hospital performed 3,274 procedures in FY2018. The discussion found in Criterion (3) regarding historical utilization is incorporated herein by reference.

- (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.*

- C- In Section C and Section Q, Form C of the application, the applicant provides its assumptions and methodology concerning the projected PET scanner utilization. The applicant projects that the two fixed PET scanners (the existing and the proposed PET scanner) will perform a total of 4,229 procedures for an average of 2,114 procedures by the third year following project completion which exceeds the projected threshold as set forth by this rule. The discussion found in Criterion (3) regarding projected utilization is incorporated herein by reference.

(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.