

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 26, 2018

Findings Date: February 1, 2018

Project Analyst: Bernetta Thorne-Williams

Co-Signer: Lisa Pittman

Co-Signer: Martha J. Frisone

COMPETITIVE REVIEW

Project ID #: J-11384-17

Facility: Duke Raleigh Hospital

FID #: 923421

County: Wake

Applicant(s): Duke University Health System, Inc.

Project: Acquire one fixed PET/CT scanner pursuant to the need determination in the 2017 State Medical Facilities Plan for HSA IV

Project ID #: J-11386-17

Facility: Rex Hospital

FID #: 953429

County: Wake

Applicant(s): Rex Hospital, Inc.

Project: Acquire one fixed PET scanner pursuant to the need determination in the 2017 State Medical Facilities Plan for HSA IV

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 – Both Applications

Duke University Health System (DUHS) proposes to acquire one fixed PET/CT scanner to be located at Duke Raleigh Hospital (DRaH), in Raleigh, Wake County.

Rex Hospital, Inc., (UNC Rex or UNC Rex Healthcare), whose sole member and parent company is the University of North Carolina Health Care System, proposes to acquire one fixed PET scanner to be located at Rex Hospital, in Raleigh, Wake County.

Need Determination

The 2017 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. Two applications were received by the Healthcare Planning and Certificate of Need Section (Agency) to acquire the fixed PET scanner. However, pursuant to the need determination in the 2017 SMFP only one PET scanner can be approved in this review.

DUHS proposes to add one fixed PET/CT scanner to its existing Duke Raleigh Hospital in Wake County. Therefore, the application is consistent with the need determination in the 2017 SMFP.

UNC Rex proposes to add one fixed PET scanner to its existing Rex Hospital in Wake County. Therefore, the application is consistent with the need determination in the 2017 SMFP.

Policies

The following policies are applicable to both applications in this review:

- *POLICY GEN-3: BASIC PRINCIPLES*
- *POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES*

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.”

DUHS 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, page 21, Section N.1, pages 67-68, and Section O, page 69, 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 21-22, Section C.10, page 35, Section N.1, page 67, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section B.10, page 22, Section C.4, page 33, Section N.1, pages 67-68, 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 would maximize healthcare 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 2017 SMFP. The application is consistent with Policy GEN-3.

UNC Rex 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 26-27 and Section N.1, pages 118-119, Section O, pages 121-122, 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 27-28 and Section C.10, pages 72-77, Section N.1, pages 119-120, 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 28-29, Section C.10, pages 74-77, Section N, pages 117-118, 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 2017 SMFP. The application is consistent with Policy GEN-3.

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.”

DUHS addresses Policy GEN-4 as follows:

The proposed capital expenditure for this project is greater than \$5 million. In Section B.11, page 23, and Exhibit K.4 the applicant describes how the proposed project will assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

In summary, the application is consistent with Policy GEN-3, Policy GEN-4 and with the need determination in the 2017 SMFP. Consequently, the application is conforming to this criterion

UNC Rex addresses Policy GEN-4 as follows:

The proposed capital expenditure for this project is greater than \$2 million, but less than \$5 million. In Section B.11, page 30 and Section K.4(c), page 107, the applicant describes how the proposed project will assure improved energy efficiency and water conservation. The

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

Conclusion

DUHS

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant relies on existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policies GEN-3 and GEN-4.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Written comments.
- Response to written comments.
- Information which is publically available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

UNC Rex

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant relies on policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policies GEN-3 and GEN-4.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Written comments.
- Response to written comments.
- Information which is publically available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

In summary, both applicants are conforming with the fixed PET scanner need determination in the 2017 SMFP for HSA IV, Policy GEN-3 and Policy GEN-4. However, there is a limit to the number of fixed PET scanners that can be approved in this review. Only one new fixed PET scanner is needed in HSA IV. Therefore, even if both applications were conforming or conditionally conforming to all statutory and regulatory review criteria, both applications cannot be approved. See the Conclusion following the Comparative Analysis for the decision.

- (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 – Both Applications

DUHS proposes to acquire one fixed PET/CT scanner to be located at Duke Raleigh Hospital in Raleigh, Wake County.

Patient Origin

On page 138, the 2017 SMFP defines the service area for a fixed PET scanner as, “A *fixed PET scanner's service area is the Health Service Area (HSA) in which the scanner is located. The HSAs are the six multi-county groupings as defined in Appendix A of the North Carolina 2017 State Medical Facilities Plan.*” Table 9N, page 173, of the 2017 SMFP shows a need for one fixed PET scanner in HSA IV. Thus, the service area for this proposal is HSA IV.

DRaH does not have a fixed PET/CT scanner, however, the applicant offers PET services through a mobile PET scanner agreement with Alliance for 1.75 days per week. In this application, the applicant proposes to add 3,600 square foot of new construction to connect the existing hospital and Medical Office Building 7, which houses the hospitals oncology services.

In Section C.2, page 25 and in Section Q, the applicant provides the historical patient origin for PET scanners for fiscal year (FY) 2017, (July 1, 2016 - June 30, 2017), as illustrated below.

**PET scanner Patient Origin FY2017
 DRaH Mobile**

County	# of Patients	% of Total Patients
Chatham	1	0.1%
Durham	13	1.4%
Franklin	42	4.6%
Granville	7	0.8%
Johnston	80	8.8%
Lee	3	0.3%
Orange	1	0.1%
Person	3	0.3%
Vance	4	0.4%
Wake	558	61.7%
Warren	3	0.3%
Other	190	21.0%
Total	905	100.0%

**PET scanner Patient Origin FY2017
 DUH Outpatient HSA IV Counties**

County	# of Procedures	% of Total Patients
Chatham	37	0.9%
Durham	735	17.2%
Franklin	37	0.9%
Granville	141	3.3%
Johnston	61	1.4%
Lee	23	0.5%
Orange	153	3.6%
Person	170	4.0%
Vance	84	2.0%
Wake	473	11.0%
Warren	23	0.5%
Total HSA IV	1,937	45.2%
Outside of HSA IV*	2,348	54.8%
Total**	4,285	100.0%

*Total procedures – 1,937/.452 = 4,285

Total Outside of HSA IV – 4,285-1,937 = 2,348

** Note: The number of patients shown in DRaH’s PET patient origin above, from 25 of the application, does not equal the number of PET procedures as shown in Exhibit Q, Step 4a. DRaH states that the some patients receive more than 1 procedure as defined in 10A NCAC 14C .3701

In Section C.3, page 26, the applicant provides the projected patient origin for the first three FYs (July 1 - June 30) for the proposed fixed PET/CT scanner, as illustrated below.

DRaH Projected Patient Origin

County	OY1 FY2020		OY2 FY2021		OY3 FY2022	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Chatham	22	1.4%	27	1.5%	27	1.5%
Durham	14	0.9%	15	0.8%	16	0.8%
Franklin	72	4.7%	81	4.5%	84	4.5%
Granville	10	0.6%	10	0.6%	10	0.6%
Johnston	143	9.3%	163	9.0%	168	9.0%
Lee	29	1.9%	36	2.0%	37	2.0%
Orange	1	0.1%	1	0.1%	1	0.1%
Person	3	0.2%	3	0.2%	3	0.2%
Vance	4	0.3%	4	0.2%	4	0.2%
Wake	1,042	67.8%	1,187	65.9%	1,230	65.9%
Warren	4	0.3%	4	0.2%	4	0.2%
Other	192	12.5%	270	15.0%	280	15.0%
Total	1,537	100.0%	1,802	100.0%	1,866	100.0%

The applicant adequately identifies the population to be served based on the historical patient origin for PET services at DRaH and DUH as well as market projections.

Analysis of Need

In Section C, pages 27-33, the applicant describes the factors which it states supports the need for the proposed project, including:

- *The need determination methodology in the 2017 SMFP (pages 27-28).*

The 2017 SMFP contained a need determination for one additional fixed PET scanner in HSA IV. On pages 27-28, the applicant states, *“This methodology reflects the essential nature of PET scanning in the provision of comprehensive cancer care, as a critical tool for diagnosis and treatment evaluation. ... Duke Raleigh Hospital currently operates two linear accelerators on the hospital campus, and also acquired two oncology treatment facilities from Cancer Centers of North Carolina ... It [DRaH] is the only major cancer center in the state without fixed PET scanning capacity.”*

- Wake County and service area demographics (pages 28-30).

In Section C, page 28, the applicant states that HSA IV is projected to see significant population growth over the next five years with Wake County being the fastest growing county within the HSA. The applicant provides a projected population growth table and a table that illustrates the projected aging of the population in HSA IV on page 29.

- Continued growth in demand for PET services at DUHS facilities (pages 30-32).

On page 30, the applicant states that DRaH is the Wake County site for the Duke Cancer Center. The applicant states that between FY2014 and FY2017, DUHS adult radiation oncology services increased by 32%, from 2,621 to 3,466 patients. DRaH radiation oncology patients increased by 125% during this same timeframe from 394 to 890 patients.

- Growth in Duke Network and physician support (page 32).

The applicant discusses its network of providers within Wake County including Duke Primary Care which currently has 225 providers and recruitment plans to increase the network to 350 providers by 2021. The applicant further discusses plans to develop primary and urgent care sites in Louisburg, Harps Mill (November 2017), Holly Springs and Wake Forest. Duke Health entered into a collaboration with WakeMed Health & Hospitals to create Cancer Care Plus with the goal of easily accessible, value-based cancer care throughout Wake County.

- Patient satisfaction (page 33).

The applicant states a fixed PET/CT scanner at DRaH would increase patient comfort and convenience and allow PET services every weekday at hours more patient friendly than the limited 1.75 hours per week in a mobile PET scanner. The applicant further states that a fixed PET scanner would improve patient comfort as it is challenging using a mobile PET scanner because a patient has to leave the building to go outside into the weather elements usually dressed in a gown.

- Cost savings (page 33).

The applicant states that providing PET services on a fixed scanner rather than a mobile scanner would provide cost savings for the provider and the patients. The applicant estimates that it will pay \$1,360,006 during the current fiscal year for its mobile PET services. Furthermore, the mobile PET scanner will be available to serve other providers in rural areas.

The information provided by the applicant in the pages referenced above is reasonable and adequately supported.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the proposed fixed PET/CT scanner. The applicant states factors such as an aging population, improved access to services, clinical practice patterns and population growth will contribute to PET scanner utilization at DRaH and statewide. The applicant describes the assumptions and methodology used to project utilization for the proposed fixed PET/CT scanner in Section Q, as follows:

Step 1: Population projections - The applicant service area for this project is HSA IV which consists of the following counties: Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, and Warren. The applicant identified population projections for the counties listed above by utilizing the Nielsen Claritas population projections from 2016 to 2025. The applicant projects the compound annual growth rate (CAGR) per county for HSA IV, as summarized below.

DRaH Pet Service Area Projected Population

County	2016 Population	2025 Projected Population	10-Year CAGR
Chatham	52,125	58,038	1.2%
Durham	290,677	332,713	1.5%
Franklin	57,246	63,092	1.1%
Granville	51,341	53,628	0.5%
Johnston	151,917	169,884	1.2%
Lee	72,732	80,448	1.1%
Orange	148,089	165,816	1.3%
Person	44,886	45,776	0.2%
Vance	45,584	45,730	0.0%
Wake	1,082,852	1,265,127	1.7%
Warren	17,454	16,922	-0.3%
Total HSA VI	2,014,903	2,297,174	1.5%

Step 2: PET use rate - The applicant calculated the PET utilization rate by using the historical state population data from the North Carolina Office of State Budget Management (NC OSBM) and the total number of PET scans as reported in the 2017 SMFP. The applicant reports that PET utilization rates have remained relatively stable, as illustrated below:

5-Year NC PET Utilization Rates

FY	State Population	Number of Procedures	Use Rate/ 1,000
2011	9,655,990	40,616	4.20
2012	9,761,479	38,300	3.92
2013	9,856,664	39,344	3.99
2014	9,951,630	38,251	3.84
2015	10,056,683	41,663	4.14

Step 3: Service area PET procedures based on PET Use Rate - the applicant used the projected population data in Step 1 and the projected PET use rate in Step 2 to project the total number of PET procedures to be performed in HSA IV from 2016 - 2025. See the table in Section Q of the application.

Step 4: Project DUHS PET volumes before growth in market share - The applicant projected PET scan procedures within DUHS based on population and cancer incidence growth. The applicant then reviewed the historical PET procedures for HSA IV, by counties for Duke University Hospital (DUH) and DRaH for FY2017, as summarized below.

FY2017 Outpatient Procedures DRaH and DUH by Patient County

County	DRaH		DUH	
	# of Procedures	% of Total	# of Procedures	% of Total
Chatham	2	0.2%	37	0.9%
Durham	15	1.4%	735	17.2%
Franklin	47	4.3%	37	0.9%
Granville	10	0.9%	141	3.3%
Johnston	87	8.0%	61	1.4%
Lee	3	0.3%	23	0.5%
Orange	1	0.1%	153	3.6%
Person	3	0.3%	170	4.0%
Vance	4	0.4%	84	2.0%
Wake	671	61.8%	473	11.0%
Warren	4	0.4%	23	0.5%
Total HSA VI	847	78.0%	1,937	45.2%

Step 4b. Projected DUHS PET Volumes at DRaH and DUH - The applicant states DUHS contracts with Sg2, a company nationally recognized for its analytics. Sg2 provided an “Impact of Change” forecast for DUHS based on service area, including demographic, economic, epidemiologic, technological, and policy change factors. Based on the forecast provided by Sg2, the applicant applied a CAGR of 4.5% for outpatient procedures to project PET volume for HSA IV. The applicant states that this rate is “much more” conservative than DRaH’s recent outpatient CAGR of 27.3% over the past 3 years. The applicant does not project inpatient volume as the applicant reports inpatient volume in recent years has been “*de minimis*”.

DRaH Projected Outpatient PET Utilization Based on Service Area Procedure Growth
 (before any shift on procedure volume)

	Actual	Projected							
	2017	2018	2019	2020	2021	2022	2023	2024	2025
Outpatient Scans	1,086	1,134	1,185	1,238	1,293	1,351	1,411	1,474	1,540

The table below reflects the same 4.5% CAGR applied by county to the counties in HSA IV.

DRaH Projected Outpatient PET Procedures by Counties within HSA IV

County	Interim 2018	Interim 2019	OY1 2020	OY2 2021	OY3 2022
Chatham	2	2	2	2	2
Durham	16	16	17	18	19
Franklin	49	51	54	56	58
Granville	10	11	11	12	12
Johnston	91	95	99	104	108
Lee	3	3	3	4	4
Orange	1	1	1	1	1
Person	3	3	3	4	4
Vance	4	4	5	5	5
Wake	701	732	765	799	835
Warren	4	4	5	5	5
Total	885	924	965	1,008	1,053

The applicant applies the same CAGR of 4.5% to outpatient PET procedures performed at DUH for FY 2017 to project future procedures. The applicant noted that this projected growth rate is lower than the 6% CAGR experienced at DUH for outpatient procedures over the past three fiscal years. DUH’s inpatient growth is projected based on a CAGR of 0.1%. The applicant reports that the historical growth for inpatient procedures over the past three fiscal years was 9.7%.

DUH Projected PET Utilization Based on Service Area Procedure Growth
 (before any shift on procedure volume)

PET Type	Actual	Projected							
	2017	2018	2019	2020	2021	2022	2023	2024	2025
Inpatient Scans	4,772	4,963	5,163	5,372	5,590	5,818	6,056	6,305	6,564
Outpatient Scans	1,086	1,134	1,185	1,238	1,293	1,351	1,411	1,474	1,540

Step 4c. Projected Shift in DUH Outpatient PET Volume from Service Area - The applicant projects an increase in the number of outpatient procedures that will shift from DUH to DRaH. The applicant states that the mobile PET scanner currently at DRaH has reached its functional capacity, and is limited by a service contract, therefore service expansion is not an option. As a result of this, many HSA IV patients travel to DUH to receive PET scans when DRaH would be a more convenient geographic location. The applicant reports that the shift in procedures from DUH to DRaH is based on the following factors:

- Increased capacity at DRaH resulting from the shift from mobile to a fixed PET scanner with expanded hours resulting in more time and convenient access for patients. The current wait time for scheduling procedures is seven days so urgent procedures are referred to other providers due to capacity restraints.
- Reduction in travel burdens for patients seeking timely PET scanner services.
- Close proximity to Duke Primary Care and Private Diagnostic Clinic physicians

located within Wake County and coordinated cancer services at DRaH.

The applicant projects the following percentage of outpatient procedures, by county in HSA IV, to shift from DUH to DRaH, as shown below. The assumptions vary by county based on relative proximity to DRaH and DUH.

Percentage of Outpatient Procedures to Shift to DRaH

HSA IV County	PY1 FY2019	PY2 FY2020	PY3 FY2021	PY4 FY2022
Chatham	30%	35%	40%	40%
Durham	-	-	-	-
Franklin	30%	35%	40%	40%
Granville	-	-	-	-
Johnston	30%	35%	40%	40%
Lee	30%	35%	40%	40%
Orange	-	-	-	-
Person	-	-	-	-
Vance	-	-	-	-
Wake	20%	25%	30%	30%
Warren	-	-	-	-

The applicant notes that in this table’s project year (PY) 1 refers to FY2019 which is when the PET scanner is projected to become operational and PY4 is FY2022 the third full operational year after project development. The applicant then applied those percentages to project the number of outpatient procedures projected to shift from DUH to DRaH as illustrated below:

DRaH Outpatient PET Utilization from Redirected PET Procedures

County	PY1 FY2019	PY2 FY2020	PY3 FY2021	PY4 FY2022
Chatham	12	15	18	18
Durham	-	-	-	-
Franklin	12	15	18	18
Granville	-	-	-	-
Johnston	20	24	29	30
Lee	8	9	11	11
Orange	-	-	-	-
Person	-	-	-	-
Vance	-	-	-	-
Wake	103	135	169	176
Warren	-	-	-	-
Total	155	198	245	253

Step 5: Project incremental PET market share for DRaH - The applicant projected additional PET utilization based on incremental market share growth from having mobile for PET services 1.75 days per week to having one of three fixed (full-time) PET scanners in Wake County. The applicant projects that its market share will grow “*just as its volume increased significantly when it was able to add slots on its mobile PET scanner in recent years.*” The

table below demonstrates the market share that DRaH currently has providing PET services on a mobile scanner less than two full days a week.

**Existing (FY17) DRaH Outpatient
 PET Market Share in HSA IV Service Area**

County	Current DRaH Market Share
Chatham	0.9%
Durham	1.2%
Franklin	19.6%
Granville	4.7%
Johnston	13.7%
Lee	1.0%
Orange	0.2%
Person	1.6%
Vance	2.1%
Wake	14.7%
Warren	5.6%
Total HSA VI	10.0%

The applicant states that because DUHS has no fixed PET scanners in Wake County, its ability to accommodate the increasing demand for PET services is limited. The applicant states as a result of the proposed project, DUHS has the potential to operate one of three fixed PET scanners in the county, thus, the applicant anticipates an increase in its market share. Incremental market share projections are based on several factors in HSA IV, including, but not limited to the following:

- The need determination identified in the 2017 SMFP for increased access to fixed PET services in HSA IV.
- Growth in historic utilization combined with the constraints on current capacity.
- The availability of a fixed PET scanner coordinated with other DUHS oncology services at DRaH.
- The historic and projected growth of the Duke Primary Care and Specialist Physician network in Wake and Franklin counties, including the development of several new physician offices.
- Collaboration with WakeMed for Cancer Care+, a collaboration to enhance delivery of easily accessible value-based cancer care throughout Wake County.
- Letters of support from local providers

The applicant states that because of the reasons listed above, DUHS projects to gain incremental market share in PET services in Wake and adjacent counties. The table below reflects an incremental market share increase over the current market share and not a year-over-year increase in market share.

DRaH Projected Incremental PET Market Share Gain

	PY1 FY2019	PY2 FY2020	PY3 FY2021	PY4 FY2022
Chatham	3%	4%	5%	5%
Franklin	5%	7%	9%	9%
Johnston	5%	7%	9%	9%
Lee	5%	7%	9%	9%
Wake	5%	7%	9%	9%

The following table in Section Q labeled *Outpatient PET Procedures from Incremental PET Market Share Gain* illustrates the projected additional PET procedures based on incremental market gain in the proposed service area, by applying the percentages in the previous table to the projected total HSA procedures in step 3, as shown in the table below.

Outpatient PET Procedures from Incremental PET Market Share Gain

County	FY2019	FY2020	FY2021	FY2022
Chatham	7	9	11	12
Franklin	12	17	23	23
Johnston	33	46	60	61
Lee	16	22	29	29
Wake	235	335	439	447
Total HSA IV	302	430	562	571

(Step 3 x Step 5)

Step 6: Total projected volumes and market share in HSA IV – The applicant combined the projected DRaH PET volumes based on the service area utilization in Step 4b with the estimated shift of procedures from DUH to DRaH in Step 4c plus the incremental market share increases discussed in Step 5. The table below provides the overall market projections for procedures in HSA IV for PET services at DRaH for the first three full project years.

Outpatient PET Procedures/Market Share within HSA IV at DRaH

Total Projected DRaH PET Procedures					Total Projected DRaH PET Market Share				
County	FY 2019	FY 2020	FY 2021	FY 2022	FY 2019	FY 2020	FY 2021	FY 2022	
Chatham	21	26	31	32	9.4%	11.5%	13.7%	14.0%	
Durham	16	17	18	19	1.3%	1.3%	1.4%	1.4%	
Franklin	76	86	96	100	30.9%	34.6%	38.4%	39.4%	
Granville	11	11	12	12	5.1%	5.2%	5.4%	5.7%	
Johnston	147	170	193	199	22.6%	25.7%	28.8%	29.5%	
Lee	26	35	43	44	8.5%	11.0%	13.6%	13.7%	
Orange	1	1	1	1	0.2%	0.2%	0.2%	0.2%	
Person	3	3	4	4	1.7%	1.8%	1.9%	2.0%	
Vance	4	5	5	5	2.3%	2.4%	2.5%	2.6%	
Wake	1,071	1,235	1,407	1,458	22.8%	25.8%	28.9%	29.4%	
Warren	4	5	5	5	6.1%	6.4%	6.7%	7.0%	
Total	1,381	1,593	1,814	1,879	15.9%	18.1%	20.3%	20.7%	

Step 7: In-migration and total combined volumes - The applicant states that the proposed PET scanner will draw from a wide geographic region, as reflected in the multi-county service areas established in the SMFP. According to the 2017 patient origin data, approximately 22% of DRaH’s PET procedures originated from patients residing out of HSA IV and more than 50% of DUH’s PET procedures are for patients who reside outside of HSA IV. The applicant concludes that it is reasonable to assume that the proposed PET scanner will also attract patients from outside HSA IV. The applicant states there are only six PET scanners in HSAs V and VI combined. Additionally, there is no PET scanner in Harnett County, which is adjacent to Wake County. The applicant projects that in-migration will represent up to 15% of the procedures performed on the proposed PET scanner during PY3 which is more conservative than DRaH’s current in-migration of 22%.

DRaH In-Migration by Project Year

	2019	2020	2021	2022
In-migration %	10.0%	12.5%	15.0%	15.0%

The applicant provides a table labeled in Section Q, as shown below.

DRaH PET in-migration labeled DRaH PET Total Volumes by Project Year

County	Interim 2019	OY1 2020	OY2 2020	OY3 2022	Step
Existing Service Area Utilization Growth	924	965	1,008	1,053	4b
Procedures Shifted from DUHS	155	198	244	255	4c
Market Share Growth	302	430	562	571	5
Sub-Total	1,381	1,593	1,814	1,879	
In-migration %	10.0%	12.5%	15.0%	15.0%	
In-migration	153	228	320	332	6 x In-mig %
Total Procedures	1,535	1,821	2,134	2,211	

(In-migration 2019 = $[(1381/1-.10) + 1381=1381/.9 = 1534.44]$ Total differs because of rounding.

Step 8: Total DUHS System PET Utilization - the applicant provides the total number of projected PET procedures to be performed at DRaH and DUH for the first three full project years. The applicant projects an average of 2,591 procedures will be performed per fixed PET scanner by PY 3 (FY2022), based on 7,774 procedures divided by three fixed PET scanners ($7,774/3 = 2,591.33$). This exceeds the threshold of 2,080 as promulgated in 10A NCAC 14C .3703 of the performance standards for PET scanners, as illustrated below.

Total DUHS PET Procedures by Project Year

Site	# of Scanners	Interim 2019	OY1 2020	OY2 2021	OY3 2022
DUH	2	5,008	5,174	5,346	5,563
DRaH	1	1,535	1,821	2,134	2,211
Total	3	6,543	6,995	7,481	7,774
Average number of procedures pre scanner		2,181	2,332	2,494	2,591

Projected utilization of the existing and proposed fixed PET scanners is based on reasonable and adequately supported assumptions.

Based on review of the information provided by the applicant in Section C, pages 24-34, Section Q, and referenced exhibits, the comments received during the first 30 days of the review cycle, and the applicant’s response to the comments received at the public hearing, the applicant adequately documents the need to acquire one fixed PET/CT scanner to be located at DRaH.

Access

In Section C.10, page 35, the applicant states, “*The services of Duke Raleigh Hospital are open to all area and non-area residents for inpatient, outpatient and other healthcare services on a walk-in, emergency, appointment, or referral basis. There is no discrimination on the basis of race, ethnicity, age, gender, or disability. Policies to provide access to services by low income, medical indigent, uninsured, or underinsured patients are described and provided elsewhere in the application.*” In Section L, page 63, the applicant projects that 61.8 percent of patients projected to receive PET services at DRaH in OY2 (7/1/20 to 6/30/21) will have all or part of their services paid for by Medicare or Medicaid as illustrated in the table below.

Projected Payor Source PY2

Payor Source	Duke Raleigh Hospital	Fixed PET Services
Private Payor/Managed Care	31.8%	32.4%
Medicare	53.6%	58.5%
NC Medicaid	6.6%	3.3%
TRICARE	1.2%	1.7%
Workers Comp.	0.4%	0.0%
Other*	2.7%	2.1%
Self Pay**	3.8%	1.9%
Total	100.0%	100.0%

Source: Table page 63

*Other: includes commercial, Duke Select and other government payors

**Self pay includes charity care

On page 63, the applicant states that the projected payor mix is based on FY2017 YTD actual mobile PET procedures payor mix and a shift of 2% from managed care to Medicare because of an aging population. The applicant adequately demonstrated the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population projected to be served has for the proposed project, and demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant adequately describes the methodology and assumptions used to project utilization.
- The applicant provides historical data, projected demographics, clinical practice patterns and verifiable sources which support its projections.
- The applicant relies on historical data and its experience to project the extent to which all residents, including underserved groups, will have access to the proposed services.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

UNC Rex proposes to acquire one fixed PET scanner to be located at Rex Hospital, in Raleigh, Wake County.

Patient Origin

On page 138, the 2017 SMFP defines the service area for a fixed PET scanner as, *“A fixed PET scanner's service area is the Health Service Area (HSA) in which the scanner is located. The HSAs are the six multi-county groupings as defined in Appendix A of the North Carolina 2017 State Medical Facilities Plan.”* Table 9N, page 173, of the 2017 SMFP shows a need for one Fixed PET scanner in HSA IV. Thus, the service area for this proposal is HSA IV. Facilities may also serve residents of counties not included in their service area.

UNC Rex currently operates one fixed PET scanner which operates Monday through Friday with extended hours of operations from 6:00 a.m. to 9:30 p.m. (see page 46). In this application, the applicant proposes to renovate 3,200 square foot of existing space to house the existing and proposed PET scanners. In Section C.2, pages 49-52, the applicant provides its historical patient origin for its fixed PET scanner services for fiscal year (FY) 2017, (July 1, 2016 - June 30, 2017), as illustrated below.

FY2017 Projected Patient Origin

County	# of Procedures	% of Total
Wake	2,011	72.4%
Johnston	226	8.1%
Franklin	143	5.2%
Harnett	109	3.9%
Sampson	47	1.7%
Nash	37	1.3%
Wayne	25	0.9%
Wilson	21	0.8%
Granville	20	0.7%
Cumberland	15	0.5%
Vance	15	0.5%
Durham	14	0.5%
Edgecombe	9	0.3%
Chatham	8	0.3%
Orange	8	0.3%
Duplin	7	0.3%
Lee	6	0.2%
Robeson	4	0.1%
Warren	4	0.1%
Carteret	3	0.1%
Lenoir	3	0.1%
Moore	3	0.1%
New Hanover	3	0.1%
Northampton	3	0.1%
Person	3	0.1%
Alamance	2	0.1%
Halifax	2	0.1%
Onslow	2	0.1%
Beaufort	1	0.0%
Burke	1	0.0%
Columbus	1	0.0%
Craven	1	0.0%
Guilford	1	0.0%
Iredell	1	0.0%
Mecklenburg	1	0.0%
Watauga	1	0.0%
Wilkes	1	0.0%
Other States	14	0.5%
Total	2,776	100.0%

The applicant states on page 52, that each procedure is projected to represent one patient.

In Section C.3, pages 53-54, the applicant provides the projected patient origin for the first three FYs for cardiac and oncology PET procedures individually. On pages 55-56, the applicant provides the combined projected patient origin for the proposed fixed PET scanner, as illustrated below.

Projected Patient Origin

County	OY1 (7/1/2019-6/30/2020) # of Procedures		OY2 (7/1/2020-6/30/2021) # of Procedures		OY3 (7/1/2021-6/30/2022) # of Procedures	
	# of Procedures	% of Total	# of Procedures	% of Total	# of Procedures	% of Total
Wake	2,657	71.4%	2,987	70.8%	3,179	70.8%
Johnston	294	7.9%	327	7.8%	348	7.7%
Franklin	190	5.1%	214	5.1%	228	5.1%
Harnett	151	1.0%	173	4.1%	185	4.1%
Sampson	77	2.1%	96	2.3%	102	2.3%
Nash	49	1.3%	56	1.3%	59	1.3%
Wayne	40	1.1%	49	1.2%	52	1.2%
Wilson	35	0.9%	44	1.0%	47	1.0%
Granville	34	0.9%	43	1.0%	46	1.0%
Vance	23	0.6%	28	0.7%	30	0.7%
Cumberland	21	0.6%	25	0.6%	26	0.6%
Durham	19	0.5%	22	0.5%	24	0.5%
Edgecombe	13	0.4%	16	0.4%	17	0.4%
Duplin	12	0.3%	15	0.3%	16	0.3%
Orange	10	0.3%	12	0.3%	12	0.3%
Lee	9	0.2%	11	0.2%	11	0.2%
Chatham	10	0.3%	10	0.2%	11	0.2%
Lenoir	6	0.2%	8	0.2%	9	0.2%
Robeson	6	0.2%	7	0.2%	7	0.2%
Onslow	4	0.1%	5	0.1%	6	0.1%
Warren	5	0.1%	5	0.1%	5	0.1%
Halifax	3	0.1%	4	0.1%	4	0.1%
Carteret	4	0.1%	4	0.1%	4	0.1%
Moore	4	0.1%	4	0.1%	4	0.1%
New Hanover	4	0.1%	4	0.1%	4	0.1%
Northampton	4	0.1%	4	0.1%	4	0.1%
Person	4	0.1%	4	0.1%	4	0.1%
Burke	2	0.1%	3	0.1%	3	0.1%
Iredell	2	0.1%	3	0.1%	3	0.1%
Alamance	2	0.1%	3	0.1%	3	0.1%
Beaufort	1	<0.1%	1	<0.1%	1	<0.1%
Columbus	1	<0.1%	1	<0.1%	1	<0.1%
Craven	1	<0.1%	1	<0.1%	1	<0.1%
Guilford	1	<0.1%	1	<0.1%	1	<0.1%
Mecklenburg	1	<0.1%	1	<0.1%	1	<0.1%
Watauga	1	<0.1%	1	<0.1%	1	<0.1%
Wilkes	1	<0.1%	1	<0.1%	1	<0.1%
Other States	22	0.6%	26	0.6%	28	0.6%
Total	3,723	100.0%	4,218	100.0%	4,490	100.0%

The applicant states on page 56 that projected patient origin for the proposed fixed PET scanner is based on historical patient origin for cardiac, oncology and other PET procedures, adjusted to reflect the differing growth rates for cardiac, oncology and other PET procedures. The applicant adequately identified the population it proposes to serve.

Analysis of Need

In Section C, pages 57-69, the applicant describes the factors which it states supports the need for the proposed project, including:

- *2017 SMFP need determination (pages 57-58)*

The 2017 SMFP identifies a need determination for one additional fixed PET scanner in HSA IV. The applicant notes on page 58 that although the need generated by Part 2 of the methodology for fixed PET scanners is based on a major cancer treatment facility, program or provider that does not own or operate a fixed PET scanner, the need may be met by any applicant.

- *Need for Fixed PET within HSA IV (pages 58-60)*

In Section C, page 58, the applicant states that HSA IV consists of 11 counties and currently has six existing PET scanners. The applicant states on page 59, that it looked at several factors that support the need for additional fixed PET scanners services in HSA IV including, “*population, distribution of fixed PET scanners, utilization of radiation oncology services, and utilization of cardiac catheterization.*”

- *Need for fixed PET scanner within Wake County (pages 60-69)*

The applicant provides a table on page 60, which illustrates the population of the 11 counties that comprise HSA IV for 2017 and the projected population as of 2022. The table shows that Wake County is the largest county in HSA IV. The projected growth of Wake County represents more than 62 percent of the total projected growth for the service area. (page 60)

The information provided by the applicant in the pages referenced above is reasonable and adequately supported.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the proposed fixed PET scanner. The applicant states factors such as historical utilization and growth and an increase in demand for both cardiac and oncology PET procedures will contribute to projected PET scanners utilization. See projections below:

UNC Rex Projected Number of Procedures

	Interim FY2018	Interim FY2019	OY1 FY2020	OY2 FY2021	OY3 FY2022
# of PET scanners	1	1/2^	2	2	2
Projected # of Procedures	2,952	3,274	3,723	4,218	4,490

^The proposed fixed PET is projected to be operational on January 1, 2019, six months after the start of FY2019

The applicant describes the assumptions and methodology used to project utilization for the proposed fixed PET scanner in Section Q, pages 1-9, as follows:

Step 1: Historical Utilization - As stated on page 34, PET scanners, including UNC Rex’s scanner, initially were used in clinical oncology. In October 2016, UNC Rex started performing perfusion cardiac PET procedures during limited timeslots each day which resulted in a CAGR 16.4 percent in total PET procedures, as illustrated below:

UNC Rex Historical PET Utilization FY2015-FY2017

	FY15	FY16	FY17	CAGR FY15-FY17
Cardiac PET Procedures	9	21	472	624.2%
Oncology PET Procedures	2,040	2,216	2,304	6.3%
Total PET Procedures	2,049	2,237	2,776	16.4%
# of Units	1	1	1	
Capacity per Unit	3,000	3,000	3,000	
Total Capacity	3,000	3,000	3,000	
% of Unitization*	68.3%	74.6%	92.5%	

Source: Applicant’s internal data

*Total number of PET procedures / Total Capacity

The applicant reports that at the end of FY2017, the existing PET scanner at UNC Rex operated at 92.5 percent of its capacity. Scheduling for the existing PET scanner typically takes two weeks which is inconvenient for patients and physicians and demonstrates a need for the unit. (Section Q, page 1)

Step 2: Projected Utilization - The applicant provides the projected number of cardiac and oncology procedures separately. Because more patients and providers are choosing cardiac PET procedures over other diagnostic imaging options, the applicant projects that cardiac PET procedures will continue to increase at UNC Rex which is the only provider of cardiac PET services in Wake County. The applicant further states that UNC Rex’s growth in cardiac PET procedures is supported by UNC Rex’s “robust cardiology program” as well as the Heart and Vascular Hospital and the proposed addition of a fifth cardiac catheterization lab. (Section Q, pages 2-3)

Cardiac PET

In Section Q, pages 2-3, 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 13.7 percent overall from FY2015-FY2017. In FY2017, the UNC Rex performed a total of 1,961 cardiac imaging procedures, including 472 cardiac PET procedures (24%).

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 6.9 percent annually which is half its historical growth rate ($13.7/2 = 6.85$).

The applicant also projects cardiac PET procedures will continue to account for 24 percent of total cardiac imaging procedures in FY2018 growing to 50% in FY2021, as illustrated below.

UNC Projected Cardiac PET Procedures Utilization

	FY17 Actual	FY18	FY19	FY20	FY21	FY22	CAGR FY17-FY22
Total Cardiac Imaging Procedures	1,961	2,096	2,240	2,393	2,558	2,733	6.9%
% Diagnosed w/ PET	24%	24%	30%	40%	50%	50%	
Projected Cardiac PET Procedures	472	503	672	957	1,279	1,367	23.7%

Source: Section Q, Table 3, page 3

UNC Rex believes its growth assumptions are reasonable because of the following:

- Superior benefits of cardiac PET.
- The proposed addition of a 2nd PET to provide sufficient capacity.
- Expertise of clinical and operational staff.
- Declining growth of cardiac SPECT and cardiac stress echo procedures.
- Letters of support from UNC Rex’s cardiologist.

Oncology PET

The applicant states that UNC Rex’s oncology PET procedures have grown consistently over a longer time period than cardiac PET procedures. For example, UNC Rex has experienced a 5.0 percent annual growth in oncology patient volumes across all sites of care in the past two years and a 6.3% CAGR from FY15-FY17. In addition to continued internal growth and new diagnostic uses, the applicant recently purchased the facility formerly known as The Prostate Health Center and renamed it UNC Rex Cancer Care of East Raleigh. Moreover, the applicant reports that UNC Rex’s affiliate, UNC Hospitals, is developing a linear accelerator in Holly Springs in southern Wake County which will also increase the use of PET services in Wake County. (Section Q, page 4) The applicant projects oncology PET procedures will grow at a rate consistent with its historical utilization of 6.3% annually.

The applicant projects oncology PET procedures will grow at a rate consistent with its historical utilization of 6.3 percent annually as shown below.

UNC Rex Projected Oncology PET Procedures Utilization

	FY2017 Actual	FY18	FY19	FY20	FY21	FY22	CAGR
Projected Oncology PET Procedures	2,304	2,449	2,602	2,765	2,939	3,123	6.3%

Total PET

The applicant combines the projected utilization for its fixed PET scanners for all procedures, in Section Q, page 6, as illustrated below.

UNC Rex Total Projected PET Utilization by Fiscal Years

	FY18	FY19	FY20	FY21	FY22
Cardiac PET Procedures	503	672	957	1,279	1,367
Oncology PET Procedures	2,449	2,602	2,765	2,939	3,123
Total PET Procedures	2,952	3,274	3,723	4,218	4,490
# of Units	1	1.5	2	2	2
Capacity per Unit	3,000	3,000	3,000	3,000	3,000
Total Capacity	3,000	4,500	6,000	6,000	6,000
% of Unitization*	98.4%	72.8%	62.0%	70.3%	74.8%

*Total number of PET procedures / Total Capacity

UNC Rex’s fiscal year is the State fiscal year (SFY), July 1st through June 30th. The applicant projects that the proposed fixed PET scanner will become operational on January 1, 2019. The applicant converted utilization to project year (calendar year) utilization based on the following formula from Section Q, page 8:

- Calendar Year (CY) 2019 = FY2019 x 0.5 + FY2020 x 0.5
- CY2020 = FY2020 x 0.5 + FY2021 x 0.5
- CY2021 = FY2021 x 0.5 + FY2022 x 0.5

The applicant projects to perform 4,354 PET procedures by the third operating year following completion of the proposed project or 2,177 procedures per PET scanner, as illustrated below.

UNC Rex Projected Fixed PET Utilization by CY

	CY2019 PY1	CY2020 PY2	CY2021 PY3
Total PET Procedures	3,498	3,970	4,354
# of Units	2	2	2
Utilization Percentage (Procedures/Capacity)	1,749	1,985	2,177

Source: Section Q, page 5

Based on a review of the information provided by the applicant in Section C, pages 45-72, Section Q, and referenced exhibits; comments received during the first 30 days of the review cycle; and the applicant’s response to the comments received at the public hearing, the applicant adequately documents the need to acquire one fixed PET scanner to be located at Rex Hospital.

Access

In Section C.10, page 72, the applicant states, “*UNC REX prohibits the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability, or the ability to pay.*” In Section L, page 113, the applicant projects that 64.6 percent of total patient days at UNC

Rex and 65.4 percent of patients who will receive PET services at UNC Rex in OY2 (7/1/20 to 6/30/21) will have all or part of their services paid for by Medicare or Medicaid as illustrated in the table below

Payor Source	UNC Rex: Total Patient Days	UNC Rex: Fixed PET Services
Medicare	57.2%	62.1%
Medicaid	7.4%	3.3%
Commercial/Managed Care	31.8%	31.1%
Self-Pay	2.8%	3.1%
Other*	0.8%	0.4%
Total	100.0%	100.0%

Source: Table page 113

*Other: includes workers comp. and other government

On page 114, the applicant states that the projected payor mix is consistent with FY2017 payor mix.

The applicant adequately demonstrated the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the proposed project, and demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant adequately describes the methodology and assumptions used to project utilization.
- The applicant provides historical data, projected demographics, clinical practice patterns and verifiable sources which support its projections.
- The applicant relies on historical data and its experience to project the extent to which all residents, including underserved groups, will have access to the proposed services.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

NA – Both Applications

DUHS. The applicant does not propose the reduction or elimination of a service. Therefore, Criterion 3a is not applicable to this review.

UNC Rex. 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.

C – Both Applications

DUHS. In Section E, page 41, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- **Maintain the Status Quo** – The applicant states that maintaining the status quo is not the most effective alternative because DRaH has limited use (1.75 days per week) of the mobile PET services. Although DRaH has requested additional hours, Alliance Imaging has been unable to provide additional time. Moreover, given the high utilization at DRaH, a mobile PET scanner is inefficient, inconvenient and is not cost effective. Therefore, maintaining the status quo is not the least costly or most effective alternative.
- **Locate the proposed fixed PET scanner at a different site** – The applicant states there is no other realistic alternative for locating the proposed equipment to meet the identified need in the 2017 SMFP. The applicant states that DRaH is the only major cancer center in the state that does not have a fixed PET scanner. Therefore, the applicant concludes that offering the services off-site would not be in the best interest of patients or physicians.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is its most effective alternative to meet the identified need.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

UNC Rex. In Section E, pages 87-88, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- **Maintain the Status Quo** – The applicant states that maintaining the status quo is not the most effective alternative because PET services at UNC Rex have experienced significant growth and operated at 92.5 percent of the standard capacity in FY2017. Therefore, maintaining the status quo is not the least costly or most effective alternative.
- **Utilize other PET capacity in Wake County** – The applicant states Wake PET services offers services for oncology patients, but not for cardiac patients. Furthermore, the applicant states that the Wake PET services is a part of another system of care. Therefore, utilizing other fixed PET scanners in the county is not an effective alternative for UNC Rex. Note: Wake Radiology's website states that UNC Rex is its hospital partner and David I Schulz, MD is its Director of PET-CT services. Dr. Schulz is also the Medical Director for PET services at UNC Rex. (Exhibit H.4 and <http://WakeRad.com/physicians/david-shulz>.) This is not a persuasive argument for not using Wake Pet's services.
- **Utilizing mobile PET scanner services** – The applicant states that utilizing mobile PET services, might provide some relief, however, mobile PET scanners in North Carolina are operating over capacity and have actually created a need in the 2018 SMFP for one additional mobile PET scanner in North Carolina. Given the lack of capacity, UNC Rex would likely only be able to contract for a limited amount of mobile PET services, which would not meet the growing need for additional PET services at UNC Rex.

After considering the above alternatives, the applicant determined the proposed project as represented in the application to acquire one fixed PET scanner, pursuant to the need determination in the 2017 SMFP, is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is its most effective alternative to meet the identified need.

This determination is based on a review of the:

- Information in the application, including any exhibits

- Written comments
 - Remarks made at the public hearing
 - Responses to comments
 - Information which was publicly available during the review and used by the Agency.
- (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 – Both Applications

DUHS proposes to acquire one fixed PET/CT scanner to be located at DRaH in Raleigh, Wake County.

Capital and Working Capital Costs

In Section Q, Form F.1, the applicant provides the total capital cost for the proposed project, as follows:

DRaH Projected Capital Cost

Site Preparation	\$410,000
Construction/Renovation Contract – Building Shell	\$875,000
Construction/Renovation Contract – PET suite upfit	\$2,200,000
Landscaping	\$15,000
Architect/Engineering Fees	\$237,000
Medical Equipment	\$3,199,247
Other (CON filing fee, utilities, permits, inspection and project contingency)	\$965,910
TOTAL CAPITAL COST	\$7,902,157

In Section F, pages 43-44, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Availability of Funds

In Section F, the applicant states the capital costs for the proposed project will be funded with accumulated reserves/owner equity of DUHS. Exhibit F.2 contains a letter dated August 9, 2017 from the Senior Vice President, Chief Financial Officer and Treasurer committing up to \$8,000,000 in accumulated reserves to the capital costs of the proposed project. Exhibit F.2 also contains the Consolidated Financial Statements for Duke University Health System, Inc. and Affiliates for June 30, 2016 and 2015. As of June 30, 2016, DUHS had \$281,143,000 in cash and cash equivalents, \$5,164,925,000 in total assets, and \$2,394,892,000 in net assets. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

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

	1st Full Fiscal Year FY2020	2nd Full Fiscal Year FY2021	3rd Full Fiscal Year FY2022
Total Procedures	1,821	2,134	2,211
Total Gross Revenues (Charges)	\$13,132,625	\$15,397,300	\$15,949,023
Total Net Revenue	\$3,428,646	\$4,032,670	\$4,190,474
Average Net Revenue per procedure	\$1,882.84	\$1,889.72	\$1,895.28
Total Operating Expenses (Costs)	\$1,708,114	\$1,875,386	\$1,905,577
Average Operating Expense per procedure	\$983.01	\$878.81	\$861.86
Net Income	\$1,720,532	\$2,157,285	\$2,284,897

The applicant also projects a positive net income for the entire facility in each of the first three operating years. 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 applicant adequately demonstrates sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

UNC Rex proposes to acquire one fixed PET scanner to be located at Rex Hospital in Raleigh, Wake County.

Capital and Working Capital Costs

In Section F, page 91, and Form F.1a in Section Q, the applicant projects the total capital cost of the project will be \$3,978,339, which includes:

UNC Rex Projected Capital Cost

Construction/Renovation Contract	\$1,024,400
Architect/Engineering Fees	\$162,494
Medical Equipment	\$2,495,445
Non-Medical Equipment	\$30,000
Furniture	\$15,000
Consultant Fees	\$84,000
Other (projected contingency and IT costs)	\$167,000
TOTAL CAPITAL COST	\$3,978,339

In Section F, page 92, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Availability of Funds

In Section F, page 91, the applicant states that the proposed project will be financed through the accumulated reserves of UNC Rex. In Exhibit F.2-1, the applicant provides a letter dated August 15, 2017 from the Chief Financial Officer of UNC Rex Healthcare committing up to \$3,978,339 to the capital costs of the proposed project.

Exhibit F.2 also contains the audited consolidated balance sheet for Rex Healthcare, Inc. and Subsidiaries for June 30, 2016 and 2015. As of June 30, 2016, Rex Healthcare had \$91,014,000 in cash and cash equivalents, \$950,320,000 in total assets, and a total net position of \$426,412,000. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. The applicant adequately designates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

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

	1st Full Fiscal Year FY2020	2nd Full Fiscal Year FY2021	3rd Full Fiscal Year FY2022
Total Procedures	3,723	4,218	4,490
Total Gross Revenues (Charges)	\$22,984,238	\$26,821,604	\$29,409,142
Total Net Revenue	\$7,890,945	\$9,129,359	\$10,007,873
Average Net Revenue per procedure	\$2,119.51	\$2,164.38	\$2,227.35
Total Operating Expenses (Costs)	\$4,433,261	\$4,835,997	\$5,110,172
Average Operating Expense per procedure	\$1,190.78	\$1,146.50	\$1,138.12
Net Income	\$3,457,684	\$4,293,362	\$4,897,701

The applicant also projects a positive net income for the entire facility in each of the first three operating years. 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 applicant adequately demonstrates sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C – Both Applications

Table 9L, page 141, of the 2017 SMFP provides an inventory with utilization of fixed PET scanners in North Carolina by HSA. More recent utilization data was obtained from the 2017 LRAs. DUH and UNC each have one fixed PET scanner which was acquired pursuant to Policy AC-3. Both provide clinical scans and were approved prior to January 1, 2012, therefore the scanners are included in the PET inventory. However, UNC's AC-3 PET scanner utilization has not consistently been included in the SMFP. Based on previous LRA's, the table below correctly includes AC-3 utilization for each year shown.

Fixed PET scanners in HSA IV by Facility

Center	# of Fixed Pet Scanners	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Duke University Hospital*	2	4,474	4,447	4,084	4,220	4,643
UNC Hospitals**	2	1,940	3,255	3,472	3,702	3,934
Rex Hospital (owned by UNC Health Care System)	1	1,729	1,857	1,918	2,085	2,231
Wake PET Services, Wake Oncology, Wake Radiology (hospital partner is UNC Rex)	1	683	635	544	465	518
Total***	6	8,826	10,194	10,018	10,472	11,326
Average Utilization Rate in HSA IV		49.0%	56.6%	55.7%	58.2%	62.9%

*Including 1 AC-3 fixed PET scanner approved in 2002 (clinical)

**Including 1 AC-3 fixed PET scanner approved in 2000 (clinical)

***Average utilization for 2016 was calculated based on the total number of procedures (inclusive of data from AC-3 scanner) divided by the number of PET scanners divided by 3,000 (annual capacity per SMFP, page 139).
 [11,326 / 6 / 3,000 = 1,888 / 3,000= 62.9%]

DUHS explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanner services in HSA IV in Section G of the application. The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved PET scanner services in HSA IV based on the following analysis:

1. The State Health Coordinating Council and Governor determined that one new fixed PET scanner was needed in HSA IV. See Table 9N, page 143 of the 2017 SMFP. DUHS submitted its application in response to the need determination in the 2017 SMFP.
2. DRaH currently offers PET services on a mobile PET scanner 1.75 days per week. The mobile PET scanner will be available for other providers. The proposed project does not create a duplication in those services, but rather allows DRaH to provide more efficient and convenient coordination of oncology services and meet the growing need for the service.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Consequently, the applicant adequately demonstrates that the application is conforming to this criterion.

UNC Rex explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanner services in HSA IV in Section G of the application. The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved PET scanner services in HSA IV based on the following analysis:

1. The State Health Coordinating Council and Governor determined that one new fixed PET scanner was needed in HSA IV. See Table 9N, page 143 of the 2017 SMFP. UNC Rex submitted its application in response to the need determination in the 2017 SMFP.
2. UNC Rex currently offers PET services on one fixed PET scanner, thus the proposed project does not create a duplication in those services, but rather allows UNC Rex to provide more efficient and convenient coordination of oncology and cardiology services, and meet the growing need for the service.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Consequently, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C – Both Applications

DUHS. In Section Q, Form H, the applicant states DRaH currently employs 0.64 full time equivalent (FTE) positions in connection with the mobile PET scanner services currently provided. The applicant provides the proposed staffing for the first two operating years of the proposed project in Section Q, Form H. The applicant projects to hire 4.48 new FTE positions beginning in November 2018 (FY2019), as illustrated below.

- 3.36 FTEs PET Technologists
- 1.12 FTEs Financial Care Counselors

The applicant provides its assumptions for staffing in Section Q, Form H. In Section H.2, page 50, the applicant discusses its process for recruiting staff. In Section H.4, page 51, the applicant states one additional nuclear medicine radiologist has been recruited to join the faculty as of January 2018. On page 51, the applicant identifies Dr. Michael Spiritos as the Chief Medical Officer of DRaH.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of adequate health manpower and management personnel for the provision of the proposed services.
- The applicant documents support from the current and continuing Chief Medical Officer at DRaH.
- The applicant documents the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

UNC Rex. In Section Q, Form H, the applicant states Rex Hospital currently employs 4.00 full time equivalent (FTE) positions for its PET services. The applicant provides proposed staffing for the first three operating years of the proposed project in Section Q, Form H. The applicant projects to hire one new FTE position beginning in January 2019 (six months after the start of FY2019), as illustrated below.

- 4.00 FTEs Nuclear Medicine Technologists
- 1.00 FTE Coordinator/Diagnostic Services

The applicant provides its assumptions for staffing on Form H. In Section H.2, pages 100-101, the applicant discusses its process for recruiting staff. In Section H.4, page 101, the applicant identifies Dr. David Schulz as the Medical Director for PET services at UNC Rex.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of adequate health manpower and management personnel for the provision of the proposed services.
- The applicant documents support from the current and continuing Medical Director at Rex Hospital.

- The applicant documents the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C – Both Applications

DUHS. In Section I, page 53, the applicant states DRaH is a part of the Duke University Health System, and as such, has the support of departments within DUHS that provide existing PET services in Durham County. The applicant states that those departments have sufficient existing staff to provide support services for DRaH. The applicant further states on page 53, that professional interpretations for radiology procedures, including PET procedures, are currently and will continue to be provided by the Private Diagnostic Clinic (PDC). PDC is a Duke School of Medicine faculty practice with a full range of specialty physician services which are billed separately to the patient. On page 54, the applicant states that DRaH provides cancer services as part of the Duke Cancer Institute (DCI). Additionally, on page 53, the applicant states Duke Health (DH) entered into a collaboration with WakeMed Health to create Cancer Care Plus+. Cancer Care Plus+ will be anchored at DRaH. Exhibit C.4 contains forty-eight letters of support including a letter from the Medical Director of DRaH, the CEO of Maria Parham Health, physicians associated with Duke Cancer Institute, departments of radiology, pulmonology and thoracic surgery. Additionally Exhibit I.2 contains letters of support from the Program Manager of Project Access of Wake County and the President/CEO of WakeMed.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of necessary ancillary and support services for the provision of the proposed dialysis services.
- The applicant documents ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

UNC Rex. In Section I, page 103, 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. Exhibit I.1 contains a letter dated August 15, 2017 from the President of Rex Hospital, Inc., documenting the current availability of all necessary ancillary and support services for the proposed project. Exhibit I.2 contains 91 letters of support, including a letter of support from the President of Chatham Hospital and the President and CEO of UNC Johnston Health.

The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of necessary ancillary and support services for the provision of the proposed dialysis services.
- The applicant documents ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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

DUHS. Although DRaH projects some in-migration from outside of HSA IV, it does not project to provide the proposed services to a substantial number of person residing in 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.

UNC Rex. Although UNC Rex projects some in-migration from outside of HSA IV, it does not project to provide the proposed services to a substantial number of person residing in 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

Neither applicant is an HMO.

- (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 – Both Applications

DUHS. In Section K, page 57, the applicant states it proposes to construct 3,600 square foot of new space to connect the existing hospital building and Medical Office Building 7, which houses the hospital's oncology services. The applicant states in Section K.4(c), that the proposed project will be designed in accordance with the 2012 North Carolina Energy Conservation Code and will make use of water conserving plumbing fixtures, LED lamps for energy efficiency, reduced heat loads and an energy recovery ventilator. Exhibit F.1, contains a cost estimate from Studio Forty Architecture & Space Planning for the proposed construction project which includes the costs for materials and labor for the building shell and the upfit of the building totaling \$3,500,000. This information is consistent with the cost projections in Section Q, Form F.1, as shown below:

• Site Preparation Costs	\$410,000
• Construction/Renovation Contract – Building Shell	\$875,000
• Landscaping	\$15,000
• Construction/Renovation Contract – PET suite upfit	\$2,200,000
Total	\$3,500,000

Costs and charges are described by the applicant in the financials section of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

In Section K.4, pages 57-58, the applicant states that DRaH separately decided to build a structure connecting the existing main hospital with Medical Office Building (MOB) 7. MOB 7 houses the hospital's oncology services, including radiation oncology and chemotherapy. Once DRaH decided to connect these two buildings, this connecting structure became the most effective location for installation of the proposed PET scanner. Because the proposed location is also contiguous with the hospital's existing radiology department, the existing outpatient imaging waiting and registration area can be used and the radiology department management can provide oversight for the PET services. The applicant further states that the construction will maximize coordination with other oncology services, thereby allowing for greater patient and provider convenience. The connection between the main hospital and MOB 7 will create a route for transporting patients to those oncology services and allow for more patient comfort, efficiency, privacy and flexibility. (page 57)

Conclusion

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the proposed fixed PET scanner and that the construction cost will not unduly increase costs and charges for health services. Furthermore, the applicant adequately documents that applicable energy savings features have been incorporated into the construction plans. Therefore, the application is conforming to this criterion.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing

- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

UNC Rex. In Section K, pages 106-107, the applicant proposes to renovate 3,200 square feet of existing space to accommodate the proposed new PET scanner and additional support space. The applicant states that as an existing provider of PET services, UNC Rex has the necessary support services in place, including a hot lab and a Rubidium generator which will allow it to produce the radiotracer required for cardiac PET imaging. (page 107)

Exhibit F.1, contains a cost estimate from WHR Architects for the proposed renovations totaling \$1,024,000. This information is consistent with the cost projections in Section Q, Form F.1, as shown below:

Construction/Renovation Contract	\$1,024,400
Total	\$1,024,400

Costs and charges are described by the applicant in the financials section of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

Conclusion

The applicant adequately demonstrates that the cost, design and means of renovation represent the most reasonable alternative for the proposed fixed PET scanner and that the renovation cost will not unduly increase costs and charges for health services. Furthermore, the applicant adequately documents that applicable energy savings features have been incorporated into the renovation plans. Therefore, the application is conforming to this criterion.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 – Both Applications

DUHS. In Section L.1 of the application, the applicant provides the information required by this criterion. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The following table illustrates the actual payer mix for the entire hospital and PET services during FY2017.

DRaH Historical Payor Mix FY2017		
Payor Source	Entire Hospital	Mobile PET Procedures
Private Pay/ Managed Care	34.5%	35.1%
Medicare	50.9%	55.8%
NC Medicaid	6.6%	3.3%
TRICARE	1.2%	1.7%
Worker Comp.	0.4%	0.0%
Other*	2.7%	2.1%
Self-Pay**	3.8%	1.9%
Total	100.0%	100.0%

*Includes Commercial, Duke Select and other government payors,
 **Self pay includes charity care

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

UNC Rex. In Section L.1 of the application, the applicant provides the information required by this criterion. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The following table illustrates the actual payer mix for the entire hospital and PET services during FY2017.

Rex Hospital Payor Mix FY2017		
Payor Source	UNC Rex Total Patient Days	UNC Rex Fixed PET Services
Medicare	57.2%	62.1%
Medicaid	7.4%	3.3%
Commercial/Managed Care	31.8%	31.1%
Self-Pay	2.8%	3.1%
Other*	0.8%	0.4%
Total	100.0%	100.0%

Source: Table page 112

*Other: includes workers comp. and other government

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits
 - Written comments
 - Remarks made at the public hearing
 - Responses to comments
 - Information which was publicly available during the review and used by the Agency.
- (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 – Both Applications

DUHS. In Section L.2(a), page 62, the applicant states DUHS has satisfied its Hill Burton requirements to provide uncompensated care and has no obligation to provide uncompensated care, community service, access by minorities and handicapped persons other than those obligations which apply to all acute care hospitals which participate in the Medicare, Medicaid and Title V programs. On page 63, the applicant states that no civil rights equal access complaints have been filed against the facility in the last five years.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

UNC Rex. In Section L.2, page 112, the applicant states UNC Rex has no obligations to provide uncompensated care, community service or access to care by medically underserved, minorities or handicapped persons during the last three years. The applicant further states on page 112, that in order to maintain UNC Rex's §501(c)(3) tax-exempt status that it is necessary to fulfill a general obligation to provide access to services for all patients in need of care regardless of their ability to pay. On page 113, the applicant states UNC Rex is in compliance Title III of the Americans with Disabilities ACT, the Civil Rights Act and all federal mandated regulations concerning minorities and handicapped persons.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits
 - Written comments
 - Remarks made at the public hearing
 - Responses to comments
 - Information which was publicly available during the review and used by the Agency.
- (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 – Both Applications

DUHS. In Section L.3 of the application, the applicant provides the information required by this criterion.

The following table illustrates the projected payor mix during the second full fiscal year.

DRaH Projected Payor Mix OY2 FY2021 Based on Procedures		
Payor Source	Entire Hospital	Mobile PET Services
Private Pay/ Managed Care	31.8%	32.4%
Medicare	53.6%	58.5%
NC Medicaid	6.6%	3.3%
TRICARE	1.2%	1.7%
Worker Comp.	0.4%	0.0%
Other*	2.7%	2.1%
Self-Pay**	3.8%	1.9%
Total	100.0%	100.0%

*Includes Commercial, Duke Select and other government payors,

**Self pay includes charity care

The applicant states that the projected pay source is based on FY 2017 actual mobile PET procedures with the only adjustment to the payor source being a 2% annual shift from Managed Care to Medicare due to the aging of the population. The applicant

adequately demonstrated the extent to which the elderly and medically underserved groups will have access to the proposed PET services.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

UNC Rex. In Section L.3 of the application, the applicant provides the information required by this criterion.

The following table illustrates the projected payor mix during the second full fiscal year.

Rex Hospital Payor Mix OY FY2021		
Payor Source	UNC Rex Total Patient Days	UNC Rex Fixed PET Services
Medicare	57.2%	62.1%
Medicaid	7.4%	3.3%
Commercial/Managed Care	31.8%	31.1%
Self-Pay	2.8%	3.1%
Other*	0.8%	0.4%
Total	100.0%	100.0%

On page 114, the applicant states that it projects the payor mix for fixed PET services will remain consistent with FY2017 payor mix. The applicant adequately demonstrated the extent to which the elderly and medically underserved groups will have access to the proposed PET services.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

- (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 – Both Applications

DUHS. In Section L.5, page 64, the applicant provides a range of means by which

patients will have access to the proposed fixed PET scanner services at DRaH which include referrals from Duke affiliated and other community physicians. The applicant adequately demonstrates that it will offer a range of means for access to the proposed PET services. Therefore, the application is conforming to this criterion.

UNC Rex. In Section L.5, page 114, the applicant provides the range of means by which patients will have access to the proposed fixed PET services at UNC Rex which include referrals from physicians on the medical staff and through the emergency department. The applicant adequately demonstrates that it will offer a range of means for access to the proposed PET services. Therefore, the application is conforming to this criterion.

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

C – Both Applications

DUHS. In Section M, page 65, the applicant states Duke Department of Radiology provides professional services for PET procedures at DRaH offering training to diagnostic radiology residents and nuclear medicine fellows. DUHS also provides training opportunities for radiology technologist students from Wake Technical Community College and other local programs for nursing students. The information provided in Section M is reasonable and adequately supported. Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

UNC Rex. In Section M, page 115, the applicant states that UNC Rex has more than 60 agreements with health professional training programs through the Southeast. The applicant states it has training agreements with the University of North Carolina (UNC), Duke University, East Carolina University, Durham Technical College and Western Carolina University. See Exhibit M.1 for a list of healthcare training programs. On page 115, the applicant states that UNC Rex serves as a Wake Area Health Education Center affiliated training site for the American Heart Association. See page 115 for a list of those programs sanctioned by the American Heart Association. The information provided in Section M is reasonable and adequately supported. Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

demonstrate that its application is for a service on which competition will not have a favorable impact.

C – Both Application

Table 9L, page 141, of the 2017 SMFP provides an inventory with utilization of fixed PET scanners in North Carolina by HSA. More recent utilization data was obtained from the 2017 LRAs. DUH and UNC each have one fixed PET scanner which was acquired pursuant to Policy AC-3. Both provide clinical scans and were approved prior to January 1, 2012, therefore the scanners are included in the PET inventory. However, UNC’s AC-3 PET scanner utilization has not consistently been included in the SMFP. Based on previous LRAs the table below correctly includes AC-3 utilization for each year shown.

Fixed PET scanners in HSA IV by Facility

Center	# of Fixed Pet Scanners	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Duke University Hospital*	2	4,474	4,447	4,084	4,220	4,643
UNC Hospitals**	2	1,940	3,255	3,472	3,702	3,934
Rex Hospital (owned by UNC Health Care System)	1	1,729	1,857	1,918	2,085	2,231
Wake PET Services, Wake Oncology, Wake Radiology (hospital partner is UNC Rex)	1	683	635	544	465	518
Total***	6	8,826	10,194	10,018	10,472	11,326
Average Utilization Rate in HSA IV		49.0%	56.6%	55.7%	58.2%	62.9%

*Including 1 AC-3 fixed PET scanner approved in 2002 (clinical)

**Including 1 AC-3 fixed PET scanner approved in 2000 (clinical)

***Average utilization for 2016 was calculated based on the total number of procedures (inclusive of data from AC-3 scanner) divided by the number PET scanners divided by 3,000 (annual capacity per SMFP, page 139). [$11,326 / 6 / 3,000 = 1,888 / 3,000 = 62.9\%$]

On page 138, the 2017 SMFP defines the service area for a fixed PET scanner as, “A fixed PET scanner’s service area is the Health Service Area (HSA) in which the scanner is located. The HSAs are the six multi-county groupings as defined in Appendix A of the North Carolina 2017 State Medical Facilities Plan.” Table 9N, page 173, of the 2017 SMFP shows a need for one Fixed PET scanner in HSA IV. Thus, the service area for this proposal is HSA IV. Facilities may also serve residents of counties not included in their service area.

DUHS proposes to acquire one fixed PET/CT scanner pursuant to the need determination in the 2017 State Medical Facilities Plan for HSA IV. The applicant proposes to locate the PET scanner at Duke Raleigh Hospital in Raleigh, Wake County.

In Section N of the application, pages 67-68, 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.

In Section N, pages 67-68, the applicant states:

“Duke Raleigh Hospital is the only major cancer center in the state without a fixed dedicated PET scanner. In Wake County there are currently two fixed PET scanners; Rex Hospital (part of the UNC network) has one fixed PET scanner, and Wake Radiology operates the other. Rex and Wake Radiology have recently entered into a joint venture pursuant to which Wake Radiology now provides all of Rex’s outpatient imaging interpretations. Therefore, allowing Duke Raleigh Hospital to develop a fixed PET scanner will create a new alternative for patients and providers for fixed PET scanning services in Wake County and surrounding parts and provide patients with more choice for their oncology services.

... In addition, Duke Raleigh Hospital will be able to eliminate the ongoing cost of its mobile PET contract with Alliance by developing its own fixed PET scanner. It will be able to expand hours of operation to meet demand as needed without further capital investment and without paying for additional time under the services agreement. The charges for the services will not be adversely affected by this project as reimbursement for PET services is established by government payors or by existing contracts with private payors. Charges and reimbursement for the hospital are the same for fixed and mobile procedures.

... It will enhance the patient’s experience. Patient comfort is challenging at a mobile site because the patient must leave the building to go outside into the weather elements... Placing a fixed-PET within an established Radiology suite provides continuity of care in a setting that is appealing and more comfortable for patients.

Finally, this project will greatly enhance access to PET services in the service area. It will add access to services, and a new alternative for fixed PET services... Currently, patients seeking cancer care at Duke Raleigh Hospital are limited to 1.75 days per week availability for PET procedures, creating scheduling delays... Providing this service may be particularly of benefit to medically underserved groups, who may have more difficulty in traveling to other locations for services due to transportation and other barriers.”

Conclusion

The application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative.
- The applicant adequately demonstrates it will provide quality services.
- The applicant adequately demonstrates that it will provide access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits

- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

UNC Rex proposes to acquire one fixed PET scanner pursuant to the need determination in the 2017 State Medical Facilities Plan for HSA IV. The applicant proposes to locate the PET scanner at Rex Hospital in Raleigh, Wake County.

In Section N of the application, pages 117-120, 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.

In Section N, pages 117-120, the applicant states:

“The proposed project will enhance competition in the service are for cardiac catheterization services by promoting value, safety and quality, and access to services ... the proposed project would provide additional capacity to UNC REX, which offers the lowest cost PET procedures among all HSA IV providers according to the average claims data shared by Blue Cross Blue Shield (BCBS) on its Health Care Cost Estimator tool. [See table on page 117]. ...

[A]s a member of UNC Health Care, UNC REX benefits from significant cost saving measures through the consolidation of multiple services and large economies of scale. This efficiency results in lower costs that are passed to patients in the form of lower charges.

... PET is now considered a gold standard in diagnostic cardiac imaging based on its high diagnostic accuracy, low radiation exposure, fast image acquisition times, and suitability for ill or higher-risk patients as well as those with larger bodies. UNC REX is the only provider of cardiac PET services in Wake County. ...

UNC REX is committed to providing medical care to all patients ... UNC REX is a leading provider of care to the elderly population in Wake County...

UNC REX offers a comprehensive cancer program that serves patients across Wake County as well as Johnston County. ... In Johnston County, UNC REX is a joint venture partner with Johnston Health in the ownership and operation of Smithfield Radiation and Clayton Radiation Oncology. ...

Increasing UNC REX’s PET capacity will also expand access for oncology and cardiology patients across a broad region, including areas where no fixed PET capacity exists.”

Conclusion

The application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative.
- The applicant adequately demonstrates it will provide quality services. .
- The applicant adequately demonstrates that it will provide access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

(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 – Both Applications

DUHS. In Section O, page 69, the applicant states that DRaH coordinates a hospital-wide continuous quality improvement program. On page 70, the applicant states that on December 4, 2015, DRaH received a conditional deficiency related to immediate use sterilization process. A subsequent plan of correction was accepted by CMS and the facility was determined to be back in compliance effective February 24, 2016.

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision none of the facilities were found to be out of compliance with one or more Medicare conditions of participation. All eight facilities operated by DUHS are 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 eight facilities, the applicant provided sufficient evidence that quality care has been provided in the past.

UNC Rex. In Section O, pages 121-122, the applicant states that UNC Rex has quality policies and procedures in place that encompass all of its facilities. See Exhibit O, for UNC Rex's Quality and Performance Improvement Policies.

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision one of the ten facilities operated by UNC Health Care System was found to be out of compliance with one or more Medicare conditions of participation. Nash Healthcare is awaiting a follow-up survey for its EMTALA deficiency cited during a survey on 8/16/2017. The other nine facilities operated by UNC Rex Health Care are 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 eight facilities, the applicant provided sufficient evidence that quality care has been provided in the past.

- (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 – Both Applications

The applications are 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- **DUHS.** In Section C, page 36 and Form C, Methodology and Assumptions the applicant projects to have an annual rate of 2,211 PET procedures 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.

-C- **UNC Rex.** In Section C, page 80 and Section Q, page 5, the applicant projects to have an annual rate of 2,177 PET procedures on each of its two units 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- **DUHS.** In Section C, page 36 and Form C, Methodology and Assumptions, the applicant states the two fixed PET scanners operated by DUHS performed 4,774 procedures in FY 2017 for an average of 2,387 procedures per scanner.
 - C- **UNC Rex.** In Section C, page 81 and Section Q, Form C, the applicant states the one fixed PET scanner operated by UNC Rex performed 2,776 procedures in FY2017.
 - (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- **DUHS.** In Section C, page 36 and Section Q, Form C of the application, the applicant provides its assumptions and methodology concerning the projected PET scanner utilization. In Step 8, the applicant projects that each of the three (includes the proposed PET scanner at DRaH) fixed PET scanners will perform a total of 7,774 procedures for an average of 2,591 procedures by the third year following project completion which exceeds the projected threshold as set forth by this rule.
 - C- **UNC Rex.** In Section C, page 81 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 4,354 procedures for an average of 2,177 procedures by the third year following project completion which exceeds the projected threshold as set forth by this rule.
- (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- **DUHS.** 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.
 - C- **UNC Rex.** 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.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2017 SMFP, no more than one fixed Positron Emission Tomography (PET) Scanner can be approved for HSA IV in this review. Because each of the two applicants propose to acquire one fixed PET scanner, both applicants cannot be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst also conducted a comparative analysis of the proposals. For the reasons set forth below and in the remainder of the findings, the application submitted by Duke Raleigh Hospital is approved and the application by UNC Rex is not approved.

Conformity with Applicable Statutory and Regulatory Review Criteria

DRaH and UNC Rex both adequately demonstrated that their proposals are conforming to all applicable statutory and regulatory review criteria. Therefore, the applications submitted by DRaH and UNC Rex are both effective alternatives with regard to conformity with review criteria.

Geographic Accessibility

The 2017 SMFP identifies the need for one fixed PET scanner in HSA IV, which includes Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, and Warren counties. Both applicants propose to locate the fixed PET scanner in Wake County. Therefore, with regard to geographic accessibility both proposed projects are comparable.

Patient Access to Alternative Providers

According to the 2017 SMFP there are four Providers of fixed PET services in HSA IV with a total of six fixed PET scanners. Of those fixed PET scanners, two are located in Wake County, two in Durham County, and two in Orange County, as illustrated in the table below.

Center	# of Fixed Pet Scanners	County
Duke University Hospital	2	Durham
UNC Hospitals (part of UNC Health Care System)	2	Orange
Rex Hospital (owned by UNC Health Care System)	1	Wake
Wake PET Services, Wake Oncology, Wake Radiology (hospital partner is UNC Rex)	1	Wake
Total	6	

The 2017 SMFP identified a need for one fixed PET scanner in HSA IV based on the *Methodology Part 2, Step 7*, which states: “A need is determined for one additional fixed PET scanner if a major cancer treatment facility, program or provider identified in Step 6 is hospital-based and does not own or operate a fixed dedicated PET scanner...”

The need generated by this part of the methodology may be met by any applicant, and not just a major cancer treatment facility, program, or provider that does not own or operate a fixed dedicated PET scanner.”

The need determination in the 2017 SMFP was triggered by Duke Raleigh Hospital which now meets the definition of a major cancer center, but does not operate a fixed PET scanner. Thus, DUH applied to operate the proposed fixed PET at DRaH which is located in Raleigh, Wake County. DRaH currently provides PET services through a mobile PET scanner available 1.75 days per week through a service agreement with Alliance Healthcare. UNC Rex currently provides PET services through a fixed PET scanner that operates Monday through Friday with extended hours of operations from 6:00 a.m. to 9:30 p.m. As shown in the table above, Rex Hospital is currently the only provider of hospital-based fixed PET services in Wake County. If UNC Rex’s application is approved, UNC Rex would remain the only provider of hospital-based fixed PET services. If DRaH’s application is approved that would create a second provider of hospital-based fixed PET services in Wake County and third provider of fixed PET services in Wake County.

DUH entered into a joint collaboration with WakeMed Health and Hospitals to create Cancer Care Plus which is anchored at Duke Raleigh Hospital. However, that collaboration does not include PET services via Wake Radiology (Wake PET Services). The hospital partner of Wake PET Services is UNC Rex. Furthermore, the Director of PET-CT Services at Wake Radiology (Wake PET) is also the Medical Director for PET services at UNC Rex. UNC Rex acknowledges on page 88 of its application, that it has the options of utilizing the fixed PET scanner operated through Wake PET Services.

Therefore, with regard to providing HSA IV residents, specifically Wake County patients (as identified by both applicants as being in need of additional fixed PET scanner services) with access to an alternative provider of fixed PET services the proposal submitted by Duke University Health System is the most effective alternative.

Access by Underserved Groups

Projected Charity Care

DRaH combines its self-pay and charity care revenue, therefore it is not possible to determine how much is actually charity care. UNC Rex does not provide a revenue item for charity care, rather it deducts it from revenue. Because the applicants define charity care differently, it is not possible to compare projected charity care.

Projected Access by Medicare Recipients

For the applicants in this review, the following table compares Project Year 2 projections for the total number of procedures, the number of Medicare patients and Medicare procedures as a percentage of total patients. Generally, the application proposing either the higher percentage or number of Medicare procedures is the more effective alternative with regard to this comparative factor. See the table below.

Applicant	# of Fixed PET Scanners	Total Number of Procedures Per Machine	Projected Number of Medicare Procedures Per Machine	Medicare Procedures as a Percentage of Total Procedures
DRaH	1	2,134	1,249	58.5%
UNC Rex*	2	2,109	1,310	62.1%

Source: Section L and Section Q of the applications.

*Procedures per machine (4,218 / 2 = 2,109), Medicare procedures per machine (2,619 / 2= 1,309.5)

As shown in the table above, UNC Rex projects to serve the highest percentage and highest number of Medicare patients in Project Year 2. The application submitted by UNC Rex is the most effective alternative with regard to projected access by Medicare recipients.

Projected Access by Medicaid Recipients

For the applicants in this review, the following table compares Project Year 2 projections for the total number of procedures, the number of Medicaid procedures and Medicaid procedures as a percentage

of total patients. Generally, the application proposing either the higher percentage or the higher number of Medicare patients is the more effective alternative with regard to this comparative factor. The applications are listed in the table below in decreasing order of effectiveness based on the number of Medicaid procedures projected to be served.

Applicant	# of Fixed PET Scanners	Total Number of Procedures Per Machine	Projected Number of Medicaid Procedures Per Machine	Medicaid Procedures as a Percentage of Total Procedures
DRaH	1	2,134	70	3.3%
UNC Rex*	2	2,109	138	3.3%

Source: Section Q of the applications.

*Procedures per machine (4,218 / 2 = 2,109), Medicare procedure per machine (138 / 2 = 69)

As shown in the table above, DRaH and UNC Rex project to serve the same percentage of total Medicaid procedures in Project Year 2. Moreover, the projected number of Medicaid procedures is virtually the same (70 vs 69). Therefore, the application submitted by DRaH and UNC Rex are comparable with regard to projected access by Medicaid recipients.

Projected Average Net Revenue per PET Procedure

The following table shows the projected net revenue per procedure in Project Year 2 for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form F.4). Generally, the application proposing the lowest average net revenue per procedure is the more effective alternative with regard to this comparative factor.

OY2	DRaH	UNC Rex
Net Revenue	\$4,032,670	\$7,933,455
Procedures	2,134	4,218
Net Revenue per Procedure	\$1,889	\$1,881

Source: Form F.4 of pro formas of each application.

As shown in the table above, DRaH and UNC Rex project virtually the same net revenue per procedure in Project Year 2. DRaH’s and UNC Rex’s projected total procedures are based on reasonable and adequately supported assumptions. The discussion found in Criterion (3) regarding DRaH’s and UNC Rex’s projected utilization is incorporated herein by reference. Therefore, the applications submitted by DRaH and UNC Rex comparable alternative with regard to the projected average net revenue per procedure in Project Year 2.

Projected Average Operating Expense per PET Procedure

The following table shows the projected average operating expense per procedure in Project Year 2 for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form F.4). Generally, the application proposing the lowest average operating expense per procedure is the more effective alternative with regard to this comparative factor.

OY2	DRaH	UNC Rex
Total Operating Expenses	\$1,875,386	\$4,835,997
Procedures	2,134	4,218
Operating Expenses per Procedure	\$879	\$1,147

Source: Form F.4 of pro formas of each application.

As shown in the table above, DRaH projects the lowest average operating expense per procedure in Project Year 2. DRaH's projected total procedures are based on reasonable and adequately supported assumptions. The discussion found in Criterion (3) regarding DRaH's projected utilization is incorporated herein by reference. Therefore, the application submitted by DRaH is the most effective alternative with regard to average operating expense per procedure in Project Year 2.

SUMMARY

Both applications were determined to be conforming with all applicable statutory and regulatory review criteria.

For each of the comparative factors listed below, both applications were determined to be equally effective:

- Conformity with applicable Statutory and Regulatory Review Criteria
- Geographic Accessibility
- Projected Access by Medicaid Recipients
- Projected Average Net Revenue per Procedure

For each of the comparative factors listed below Duke Raleigh Hospital was determined to be the most effective:

- Patient Access to Alternative Providers of fixed PET scanner services.
- Projected Average Operating Expense

For each of the comparative factors listed below UNC Rex Hospital was determined to be the most effective:

- Projected Access by Medicare Patients

CONCLUSION

Both of the applications are individually conforming to the need determination in the 2017 SMFP for one fixed Positron Emission Tomography (PET) Scanner in HSA IV. However, N.C. Gen. Stat. § 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed PET scanners that can be approved by the Healthcare Planning and Certificate of Need Section (Agency). The Agency determined that the application submitted by Duke Raleigh Hospital is the most effective alternative proposed in this review for the development of one additional fixed PET scanner in HSA IV. The approval of the UNC Rex Hospital application would result in the

approval of fixed PET scanners in excess of the need determination in HSA IV, and therefore, the UNC Rex application is denied.

The applicant submitted by Duke Raleigh Hospital is approved subject to the following conditions:

1. Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application.
2. Duke University Health System, Inc. shall acquire no more than one fixed Positron Emission Tomography scanner to be located at Duke Raleigh Hospital in HSA IV, Wake County.
3. Duke University Health System, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.
4. Duke University Health System, Inc. shall 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.
5. 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, Duke University Health System, 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.
6. Duke University Health System shall acknowledge acceptance and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.