

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: November 23, 2021

Findings Date: December 2, 2021

Project Analyst: Tanya M. Saporito

Co-Signer: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: J-12083-21
Facility: Duke University Hospital
FID #: 943138
County: Durham
Applicant(s): Duke University Health System, Inc.
Project: Acquire 1 fixed PET/CT scanner pursuant to the need determination in the 2021 SMFP for a total of no more than 3 fixed PET/CT scanners upon project completion

Project ID #: J-12089-21
Facility: University of North Carolina Hospitals
FID #: 923517
County: Orange
Applicant(s): University of North Carolina Hospitals at Chapel Hill
Project: Acquire 1 fixed PET/CT scanner pursuant to the need determination in the 2021 SMFP for a total of no more than 3 fixed PET/CT scanners upon project completion

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of both applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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

Need Determination

The 2021 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed PET/CT scanners in North Carolina by service area. Application of the need methodology in the 2021 SMFP identified a need for one additional fixed PET/CT scanner in Health Service Area (HSA) IV. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) proposing to develop a total of two new fixed PET/CT scanners in HSA IV. However, pursuant to the need determination, only one fixed PET/CT scanner may be approved in this review.

Policies

Two policies in Chapter 4 of the 2021 SMFP are applicable to the applications received in response to the need determination.

Policy GEN-3

Policy GEN-3 on page 29 of the 2021 SMFP states:

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

Policy GEN-4

Policy GEN-4 on page 29 of the 2021 SMFP states:

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

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, 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 of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

J-12083-21 Duke University Health System, Inc. (hereinafter referred to as “the applicant” or “DUHS”) operates Duke University Hospital (DUH), an acute care hospital located in Durham. DUHS also operates Duke Regional Hospital in Durham County and Duke Raleigh Hospital in Wake County. In this application, DUHS proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP. Following project completion, DUHS would be licensed for three fixed PET/CT scanners.

Need Determination. The applicant does not propose to develop more fixed PET/CT scanners than are determined to be needed in the HSA IV PET/CT scanner service area.

Policy GEN-3. In Section B, page 25 the applicant explains why it believes its application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 26, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

The Agency reviewed the:

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

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

- The applicant does not propose to acquire more than one fixed PET/CT scanner that is determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of PET/CT services in the HSA IV service area;
 - The applicant adequately documents how the project will promote equitable access to PET/CT services in the HSA IV service area;
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

J-11089-21 University of North Carolina Hospitals at Chapel Hill (hereinafter referred to as "the applicant" or "UNC") operates two existing fixed PET scanners in HSA IV. In this application, UNC proposes to acquire one fixed PET scanner to be located at the NC Cancer Center at the main UNC hospital campus on Manning Drive in Chapel Hill. Following project completion, UNC would be licensed for three fixed PET scanners.

Need Determination. The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA IV PET scanner service area.

Policy GEN-3. In Section B, pages 26-30 the applicant explains why it believes its application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, pages 30-31, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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

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

- The applicant does not propose to acquire more than one fixed PET/CT scanner that is determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of PET services in the HSA IV service area;
 - The applicant adequately documents how the project will promote equitable access to PET services in the HSA IV service area;
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(2) Repealed effective July 1, 1987.

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

C
Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – DUHS proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP. Following project completion, DUHS would be licensed for three fixed PET/CT scanners.

Patient Origin

On page 367, the 2021 SMFP defines the service area for fixed PET scanners as follows: “A fixed PET scanner’s *service area* is the HSA in which it is located (Table 17F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Durham County which, according to Appendix A on page 373 is 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.

The following table illustrates historical and projected patient origin for DUHS’s PET scanner services:

COUNTY	HISTORICAL JULY 1, 2019 – JUNE 30, 2020		3 RD FULL FY JULY 1, 2025 – JUNE 30, 2026	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Alamance	96	2.6%	152	2.6%
Caswell	26	0.7%	41	0.7%
Chatham	29	0.8%	46	0.8%
Cumberland	105	2.8%	166	2.8%
Durham	713	19.3%	1,126	19.3%
Franklin	42	1.1%	66	1.1%
Granville	134	3.6%	212	3.6%
Guilford	84	2.3%	133	2.3%
Harnett	29	0.8%	46	0.8%
Johnston	64	1.7%	101	1.7%
Lee	27	0.7%	43	0.7%
Nash	28	0.8%	44	0.8%
Orange	141	3.8%	223	3.8%
Person	124	3.4%	196	3.4%
Robeson	67	1.8%	106	1.8%
Vance	67	1.8%	106	1.8%
Wake	470	12.7%	742	12.7%
Warren	36	1.0%	57	1.0%
Wilson	20	0.5%	32	0.5%
Other NC Counties	803	21.7%	1,268	21.7%
Virginia	305	8.2%	482	8.2%
Other States	287	7.8%	453	7.8%
Total	3,697	100.0%	5,838	100.0%

Source: Application pages 28 and 30

In Section C, pages 29-30, the applicant provides the assumptions and methodology used to project its patient origin which is based on the applicant’s experience in providing PET services on its existing PET scanners.

The applicant’s assumptions are reasonable and adequately supported because they are based on historical patient origin for the applicant’s other PET scanners located in HSA IV.

Analysis of Need

In Section C.4, pages 32-37, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- There is a need determination in the 2021 SMFP for one additional PET scanner in HSA IV.
- Need for additional PET capacity in HSA IV – the applicant states the utilization of its existing PET scanners at DUH is what generated the need for the PET scanner

identified in the 2021 SMFP for HSA IV. The following table, from page 33 illustrates existing inpatient (IP) and outpatient (OP) PET utilization at DUH from FY 2018-FY 2020:

	FY 2018		FY 2019		FY 2020	
	IP	OP	IP	OP	IP	OP
PET Procedures	446	4,339	408	4,539	402	4,268
Total		4,785		4,947		4,670

The applicant states the COVID-19 pandemic effected a decrease in utilization in FY 2020, from which DUH has already rebounded. In fact, the applicant states current utilization levels create “*significant capacity constraints*” at DUH. As the table above shows, PET utilization at DUH in FY 2018, FY 2019 and FY 2020 was in excess of the 2,080 procedures required by the Performance Standards promulgated at 10A NCAC 14C .3703.

- The applicant states that in the first nine months of 2021, Duke Raleigh Hospital performed a total of 1,048 procedures on its PET scanner which, when annualized, is 1,397 procedures $[(1,048 / 9) \times 12 = 1,397.33]$. The applicant states PET utilization at DUHS facilities has increased by more than 19% over the past three years (pages 33-34).
- DUH service area growth – the applicant states the population of counties served by the applicant within HSA IV is projected to increase by 6.6% from 2021-2026, while the population of the state as a whole is projected to increase by 4.9% during the same time. Additionally, the applicant states the incidence of cancer in the counties the applicant states represent DUH’s “most significant volumes” (Alamance, Durham, Granville, Orange, Person, Vance and Wake) is projected to increase as illustrated in the following table (page 34):

CANCER TYPE	2019-2024 GROWTH RATE	2019-2029 GROWTH RATE
Breast	16.7%	33.3%
GI	22.2%	45.9%
Lung	25.5%	52.4%
Urologic	22.5%	45.2%
All Types	20.5%	41.6%

Source: application page 34

On page 34, the applicant states that cancer diagnosis, monitoring and treatment evaluation are the most common applications of PET imaging services.

- DUHS planned physician recruitment – the applicant states Duke Health continues to invest in its provider network and facilities to meet the healthcare needs of the population it serves. The applicant states it plans to recruit more than 50 additional providers over the next 12 months, including cancer providers who rely on PET imaging services. The applicant states the existing PET scanners “do not have

significant excess capacity” to accommodate the projected growth in PET services (page 35).

- New uses for PET services – the applicant states that while the projected growth in its PET utilization supports the need for an additional scanner, ongoing clinical developments indicate increased need for additional PET capacity, as summarized below (pages 36-37):
 - Breast cancer – earlier this year, the FDA approved PET imaging of estrogen receptors on patients with metastatic breast cancer to guide hormonal therapy, and the applicant states these studies may require two additional PET scans weekly beyond the anticipated volume.
 - Cardiac PET scans – the applicant states DUH now uses PET imaging to assess myocardial perfusion (a nuclear stress test to measure how well blood flows through the heart muscle¹) for patients with heart disease.
 - Prostate cancer – the FDA approved PET imaging for more effective diagnosis and monitoring of prostate cancer; specifically, a tracer for use in imaging of “*prostate-specific membrane antigen (PMSA) positive lesions in men with prostate cancer.*” The applicant cites the FDA’s approval notice and The American Cancer Society and states that prostate cancer is projected to be the most commonly diagnosed cancer in men in 2021. The applicant states the PMSA-PET procedure will have broader clinical indications than previous imaging options, and the proposed PET scanner will enable DUH to provide this service to its patients.

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2021 SMFP for one additional PET scanner in HSA IV, which includes Orange County.
- The applicant uses reasonable and clearly identified historical and demographic data to make assumptions regarding identifying the population to be served, the projected growth of that population, and the need the identified population has for the proposed PET services.
- The applicant provides reasonable information to support the need for an additional PET scanner at the DUH campus in Durham based on documented historical utilization and future plans for expanded diagnostic and treatment use of the unit.

Projected Utilization

In Section Q, Form C, the applicant provides historical and projected utilization for the last full fiscal year (FY) and the interim and projected FYs, as illustrated in the following tables:

¹ See <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/myocardial-perfusion-scan-resting>

DUH Historical and Interim PET Utilization

	LAST FULL FY (7/1/19-6/30/20)	INTERIM FULL FY (7/1/20-6/30/21)	INTERIM FULL FY (7/1/21-6/30/22)
# PET Scanners	2	2	2
# Procedures - PET	4,670	5,255	6,165
# Procedures – CT	2,456	2,280	2,302
Total Procedures	7,126	7,535	8,467

Source: Section Q, Form C.2a, page 1

DUH Projected PET Utilization

	PARTIAL FY (7/1/22-6/30/23)	1ST FULL FY (7/1/23-6/30/24)	2ND FULL FY (7/1/24-6/30/25)	3RD FULL FY (7/1/25-6/30/26)
# PET Scanners	3	3	3	3
# Procedures - PET	6,965	7,267	7,320	7,375
# Procedures – CT	2,325	2,348	2,371	2,396
Total Procedures	9,290	9,615	9,692	9,771

Source: Section Q, Form C.2a, page 1

In Section Q, pages 88-91, the applicant provides the assumptions and methodology used to project utilization. The applicant states it projected PET volumes in three categories: traditional non-cardiac imaging, which comprises the majority of DUH’s historical PET utilization; cardiac PET imaging and PSMA-PET imaging, the new FDA-approved imaging for prostate cancer. The assumptions and methodology are summarized below:

- Traditional non-cardiac imaging – the applicant evaluated DUH’s non-cardiac PET scanner volumes since FY 2018, and annualized FY 2021 based on nine months of data. The applicant calculated a three year compound annual growth rate (CAGR) of 3.15% for 2018-2021 (annualized). The applicant states the growth rate across all DUH PET scanners was 9.7% during that time, which included a 19.4% PET scanner volume increase at Duke Raleigh Hospital (DRH). Based on the historical increase in PET utilization at DUH facilities, the projected population increase and the projected increase in cancer diagnoses in the service area, the applicant projects non-cardiac utilization of its existing and proposed PET scanners will increase by 3.0% per year. The applicant projects that 25% of the projected utilization will be at DUH and the remainder will be at DRH, based on the following factors:
 - DUH is already operating at “*well above the capacity of procedures assumed by the state performance standards.*” The applicant states that even with the additional scanner, the projected incremental cardiac and PSMA procedures at DUH may limit available capacity.
 - The applicant states approximately 72% of the projected population growth in HSA IV will occur in Wake, Johnston and Franklin counties, which are more proximate to DRH.

- The applicant states PET utilization for non-cardiac procedures at DRH increased at a faster rate than utilization for non-cardiac procedures at DUH. The applicant calculated a 3.0% CAGR as shown in the following table from page 89:

Non-cardiac PET Imaging Growth, FY 2018-FY 2026

LOCATION	FY 2018	FY 2019	FY 2020	FY 2021*	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
DUH	4,765	4,907	4,625	5,116	5,165	5,215	5,267	5,320	5,375
DRH	1,170	1,255	1,259	1,397	1,544	1,695	1,850	2,010	2,175
DUHS System	5,935	6,162	5,884	6,513	6,709	6,910	7,117	7,331	7,551
System Growth					3%	3%	3%	3%	3%

*annualized

Because of the projected population growth in Wake, Johnston and Franklin counties and the proximity of those counties to DRH, and because of the faster growth of non-cardiac PET procedures at DRH, the applicant projects that 25% of the incremental growth in the number of procedures to be performed will be performed at DUH and the remainder will be performed at DRH.

- Cardiac imaging – the applicant states it has performed increasing numbers of cardiac PET/CT procedures in recent years. These images help in the assessment of myocardial perfusion for patients with heart disease. The applicant states PET/CT images take less time to perform, provide superior images and are more accurate than conventional cardiac imaging procedures, particularly in larger patients. Additionally, the applicant states the hospital is acquiring software for use on its existing PET scanners that will allow physicians to quantitatively calculate coronary blood flow from cardiac PET scans – a capability unique to PET imaging and better positioned to serve cardiac patients. The following table illustrates historical and projected cardiac imaging procedures at DUH:

Cardiac PET Procedures, Duke University Hospital FY 2018 – FY 2026

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
DUH	20	40	45	139	500	750	750	750	750

Source: Application page 89

The applicant states it has already increased the number of slots available for cardiac PET imaging at the hospital to 3 slots per day or 15 per week, stating that one slot accommodates one patient. In Exhibit C.4(a), the applicant provides letters of support from DUH cardiologists that confirm the number of referrals and the need for the additional PET capacity. The applicant states it held the 15 slots per week constant in all project years to be conservative.

- PSMA – the applicant states that in May 2021, the FDA approved a drug for use in PET imaging of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer. The drug is administered intravenously to aid in PET imaging that will assist urologic oncologists in assessing patients and optimizing treatments. The

applicant states it has five oncologists who specialize in advanced prostate cancer and who treated over 2,000 patients in FY 2020. The applicant states that from 2019-2021 it has treated over 5,700 patients diagnosed with prostate cancer. The applicant states the additional PET scanner will add incremental volume to current PET volume for prostate and other types of cancers in patients. In Exhibit C.4(a) the applicant provides a letter from the Director of Genitourinary Oncology confirming the projected PET volume. See the following table, form page 90, to illustrate projected PSMA procedures following the addition of the proposed PET scanner:

Projected PSMA-PET Procedures, FY 2022 – FY 2026

	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
DUH	500	1,000	1,250	1,250	1,250

Source: Application page 90

On page 91, the applicant summarized projected PET-CT scanner volume, as illustrated in the following table:

PET Volume, Duke University Hospital FY 2018 – FY 2026

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
DUH (non-cardiac)	4,765	4,907	4,625	5,116	5,165	5,215	5,267	5,320	5,375
DUH (cardiac)	20	40	45	139	500	750	750	750	750
DUH (PSMA)					500	1,000	1,250	1,250	1,250
Total (3 scanners)	4,785	4,947	4,670	5,255	6,165	6,965	7,267	7,320	7,375
Procedures/Scanner	2,392.5	2,473.5	2,335	2,627.5	3,082.5	2,321.7	2,422.4	2,440.2	2,458

Source: Application page 91

- CT volume – The applicant also addresses CT volume on the proposed PET-CT scanner, and applied a ratio of 1,710/3,837 to the projected number of non-cardiac, non-PSMA procedures annually to determine CT volume, based on historical experience.
- PET volume at DRH – the applicant also projected volume at DRH, although pursuant to N. C. Gen. Stat. §131E-183(b), the applicant is not required to document utilization at other facilities. The applicant states it provides the projected utilization to show the existing and proposed PET scanners are and will be well utilized. See the following table from page 92:

DRH PET Procedures FY 2018 – FY 2026

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
DRH	1,170	1,255	1,259	1,397	1,544	1,695	1,850	2,010	2,175

Source: Application page 92

Projected utilization at DUH is reasonable and adequately supported based on the following:

- The applicant relies on historical data from utilization of the existing PET-CT scanners within the DUH system to project future utilization of PET services for oncology and cardiology.
- The applicant makes reasonable and conservative assumptions regarding growth of cardiac and PSMA PET services in order to project PET utilization of the existing and proposed PET scanners.
- The projected utilization of the applicant’s existing and proposed PET scanners meets the Performance Standards in 10A NCAC 14C .3703.

Access to Medically Underserved Groups

In Section C.6, page 41, the applicant states:

“All individuals, including low income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients and other underserved groups, will have access to DUH, as clinically appropriate and consistent with DUHS financial assistance policies. DUH does not discriminate on the basis of race, ethnicity, age, gender, or disability. ... A significant proportion of DUH’s proposed services will be provided to Medicare, Medicaid, and uninsured persons.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	20.0%*
Racial and ethnic minorities	40.6%
Women	52.6%
Persons with Disabilities	DUH does not retain this data
Persons 65 and older	39.0%
Medicare beneficiaries	39.7%
Medicaid recipients	11.2%

*the applicant states the term “low income person” is not defined; the percentage estimate is based on projected Medicare and Medicaid beneficiaries and charity/reduced care recipients from Application Section L.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents historical and projected access to DUH services to all residents of the service area, including underserved groups.
- The applicant provides its projected payor mix, which includes underserved groups, and assumes it will remain constant for the first three years of operation.

Conclusion

The agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written comments
- Response to Comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – UNC proposes to acquire one fixed PET scanner to be located at the UNC Cancer Center on Manning Drive in Chapel Hill pursuant to the need determination in the 2021 SMFP. Following project completion, UNC would be licensed for three fixed PET scanners.

Patient Origin

On page 367, the 2021 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s service area is the HSA in which it is located (Table 17F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Orange County which, according to Appendix A on page 373 is 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.

The following table illustrates historical patient origin during fiscal year (FY) 2020 for UNC’s PET scanner services:

UNC Historical PET Services FY 2020		
COUNTY	FY 2020	
	JULY 1, 2019-JUNE 30, 2020	
	# Pts.	% OF TOTAL
Orange	553	13.9%
Wake	514	12.9%
Alamance	262	6.6%
Cumberland	246	6.2%
Chatham	237	5.9%
Durham	229	5.7%
Lee	149	3.7%
Other*	1,801	45.1%
Total	3,991	100.0%

*The applicant states UNC Hospitals regularly provides services to patients in all 100 NC counties and other states.
 Source: Application page 43

The following table illustrates historical patient origin during fiscal year (FY) 2020 for the entire UNC hospital facility:

UNC Medical Center Patient Origin FY 2020

COUNTY	FY 2020	
	JULY 1, 2019-JUNE 30, 2020	
	# PTS.	% OF TOTAL
Orange	182,418	22.72%
Wake	112,063	13.95%
Durham	82,124	10.23%
Alamance	72,241	9.00%
Chatham	55,314	6.89%
Cumberland	30,669	3.82%
Lee	27,285	3.40%
Moore	16,120	2.01%
Guilford	13,797	1.72%
Johnston	13,611	1.69%
Harnett	12,089	1.51%
Granville	10,061	1.25%
Robeson	9,520	1.19%
Randolph	9,187	1.14%
Other*	156,556	19.50%
Total	803,055	100.0%

*The applicant states UNC Hospitals regularly provides services to patients in all 100 NC counties and other states.
 Source: Application page 44

The following table illustrates projected patient origin during the first three FYs of the project for UNC's PET scanner services:

UNC Projected PET Services FY 2024-FY 2026

COUNTY	1 ST FULL FY		2 ND FULL FY		3 RD FULL FY	
	JULY 1, 2023-JUNE 30, 2024		JULY 1, 2024-JUNE 30, 2025		JULY 1, 2025-JUNE 30, 2026	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Orange	755	13.9%	815	13.9%	880	13.9%
Wake	701	12.9%	757	12.9%	818	12.9%
Alamance	358	6.6%	386	6.6%	417	6.6%
Cumberland	336	6.2%	362	6.2%	391	6.2%
Chatham	323	5.9%	349	5.9%	377	5.9%
Durham	312	5.7%	337	5.7%	364	5.7%
Lee	203	3.7%	220	3.7%	237	3.7%
Other*	2,458	45.1%	2,654	45.1%	2,865	45.1%
Total	5,446	100.0%	5,880	100.0%	6,349	100.0%

*The applicant states UNC Hospitals regularly provides services to patients in all 100 NC counties and other states.
 Source: Application page 46

The following table illustrates projected patient origin during the first three FYs of the project for the entire UNC hospital facility:

UNC Entire Facility Projected Patient Origin FY 2024-FY 2026

COUNTY	1 ST FULL FY		2 ND FULL FY		3 RD FULL FY	
	JULY 1, 2023-JUNE 30, 2024		JULY 1, 2024-JUNE 30, 2025		JULY 1, 2025-JUNE 30, 2026	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Orange	189,306	22.72%	191,068	22.72%	192,847	22.72%
Wake	116,294	13.95%	117,377	13.95%	118,470	13.95%
Durham	85,225	10.23%	86,018	10.23%	86,819	10.23%
Alamance	74,969	9.00%	75,667	9.00%	76,371	9.00%
Chatham	57,403	6.89%	57,937	6.89%	58,476	6.89%
Cumberland	31,827	3.82%	32,123	3.82%	32,422	3.82%
Lee	28,315	3.40%	28,579	3.40%	28,845	3.40%
Moore	16,729	2.01%	16,884	2.01%	17,042	2.01%
Guilford	14,318	1.72%	14,451	1.72%	14,586	1.72%
Johnston	14,125	1.69%	14,256	1.69%	14,389	1.69%
Harnett	12,545	1.51%	12,662	1.51%	12,780	1.51%
Granville	10,441	1.25%	10,538	1.25%	10,636	1.25%
Robeson	9,879	1.19%	9,971	1.19%	10,064	1.19%
Randolph	9,543	1.14%	9,623	1.14%	9,712	1.14%
Other*	162,467	19.50%	163,980	19.50%	165,506	19.50%
Total	833,378	100.0%	841,136	100.0%	848,966	100.0%

*The applicant states UNC Hospitals regularly provides services to patients in all 100 NC counties and other states.

Source: Application page 47

In Section C, page 45, the applicant provides the assumptions and methodology used to project its patient origin which is based on the applicant’s experience in providing PET services on its existing PET scanners.

The applicant’s assumptions are reasonable and adequately supported because they are based on actual historical patient origin for the applicant’s other PET scanner located in HSA IV.

Analysis of Need

In Section C.4, pages 48-55, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- There is a need determination in the 2021 SMFP for one additional PET scanner in HSA IV.
- HSA IV population growth – the applicant states that, according to the North Carolina Office of State Budget and Management (OSBM), HSA IV is the fastest growing HSA in the state, projected to increase by a compound annual growth rate (CAGR) of 1.6% from 2021-2026. See the following table from page 49:

HSA	2021 POPULATION	2026 POPULATION	CAGR
IV	2,187,106	2,367,530	1.6%
III	2,307,082	2,490,800	1.5%
I	1,440,462	1,494,473	0.7%
II	1,727,193	1,787,169	0.7%
V	1,499,534	1,555,597	0.7%
VI	1,497,340	1,527,026	0.4%
State Total	10,658,717	11,222,595	1.0%

- Need for additional fixed PET capacity at UNC Hospitals – the applicant states there are several indicators of need for additional PET capacity at UNC specifically:
 - Designated comprehensive cancer centers – the applicant states that two of the 11 counties that comprise HSA IV, Orange and Durham, are home to two designated comprehensive cancer centers: UNC Hospitals and Duke University Hospital, each of which is part of a larger healthcare system and each of which delivers critical cancer treatments to its patients. The applicant explains what comprises a designation as a National Cancer Institute-Designated Cancer Center (NCI-Designated Cancer Center) and the critical role it serves in cancer research, diagnosis and treatment (pages 49-51).
 - Linear accelerator utilization – the applicant states it is important to analyze linear accelerator utilization in the context of PET scanner utilization in the service area, because PET scanners are frequently used for diagnosis and staging of cancers and linear accelerators are used for cancer treatment. The applicant states linear accelerator utilization provides helpful information regarding the most effective location for an additional PET scanner in the service area, because of the interrelationship between the two units of equipment. The applicant referred to the 2019 SMFP data to show that UNC hospitals’ linear accelerators were more highly utilized than others in the service area in 2019, as shown in the table below (page 51):

Linear Accelerator Utilization, 2019

PROVIDER	2019 ESTVs
UNC Hospitals	40,917
Duke University Hospital	40,578

Source: Application page 51

- Cancer Mortality – the applicant states cancer mortality rates in the proposed service area are a cogent indicator of the need for PET services. The applicant researched the State Center for Health Statistics to determine the incidence of cancer deaths in populations aged 65 and older in Orange and Durham Counties, as shown in the following table (page 52):

Cancer Death in Durham and Orange Counties

COUNTY	% OF DEATHS
Orange	22.1%
Durham	21.7%
North Carolina	20.5%

Source: Application page 52

- Projected PET growth at UNC Medical Center – the applicant states existing PET capacity is limited, according to UNC physicians; yet, both nationally and in the state and the service area, PET utilization is expected to increase between 2019-2024. Additionally, the applicant states the proposed PET scanner is designed for various forms of imaging, including oncological, cardiac and neurological, including PET procedures to monitor a new FDA-approved drug therapy for Alzheimer’s disease. The applicant also states increased uses of PET scans, physician recruitment at UNC and continued expansion of UNC affiliates and physician referrals substantiate the need for additional PET capacity at the hospital. The applicant states that, according to 2021 Hospital License Renewal Applications (LRAs), UNC Hospitals served more NC residents on its existing PET scanners than other providers, as shown in the following table:

COUNTY	FACILITY	# PET SCANNERS	# NC RESIDENTS AS Pts.
Orange	UNC Hospitals	2	4,560
Wake	UNC REX Hospital	2	3,292
Durham	Duke University Hospital	2	3,105
Wake	Duke Raleigh Hospital	1	1,002
Wake	Wake PET Services	1	622

The applicant states its designation as a state-owned Academic Medical Center Teaching Hospital and the only public NCI-Designated Cancer Center attracts residents from across the state to utilize its PET scanners.

Projected Utilization

In Section Q, Form C, the applicant provides historical and projected utilization for the last full fiscal year (FY) and the interim and projected FYs, as illustrated in the following tables:

UNC Historical and Interim PET Utilization

	LAST FULL FY (7/1/19-6/30/20)	INTERIM FULL FY (7/1/20-6/30/21)	INTERIM FULL FY (7/1/21-6/30/22)	INTERIM FULL FY (7/1/22-6/30/23)
# PET Scanners	2	2	2	2
Procedures	3,991	4,327	4,672	5,044

Source: Section Q, Form C.2a, page 1

UNC Projected PET Utilization

	1ST FULL FY (7/1/23-6/30/24)	2ND FULL FY (7/1/24-6/30/25)	3RD FULL FY (7/1/25-6/30/26)
# PET Scanners	3	3	3
Procedures	5,446	5,880	6,349

Source: Section Q, Form C.2a, page 1

In Section Q, *Form C Utilization – Assumptions and Methodology*, pages 1-4, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

- Current and historical PET utilization – The applicant states it currently operates two fixed PET scanners, one of which was acquired pursuant to Policy AC-3². Additionally, the second PET scanner is used as described by the applicant “to offer to clinical patients who can benefit from this advanced imaging, but do not ‘qualify’ for a specific research study, the ability to utilize [the PET/MR technology] as part of the identification and treatment of their diseases.” The following table illustrates UNC Hospitals historical PET utilization, from UNC internal data:

CLINICAL AREA	FY 2019	FY 2020¹	FY 2021²
Oncology	2,731	2,738	2,660
Cardiac	847	853	864
Other*	834	727	757
Neurology	38	39	47
Total	4,450	4,357	4,327

¹ Applicant states 2020 data was normalized excluding March – May when utilization was most impacted by COVID-19 and then adjusted for those months based on proportional utilization data from 2019.

² Applicant states 2021 data was seasonalized utilizing July 2020 through April 2021 data as a percent of total procedures based on 2020 internal UNC data.

*Applicant states “other” includes PET procedures that are not oncological, neurological or cardiac in nature.

- The applicant notes that the PET scanner that was approved pursuant to Policy AC-3 performs clinical CT procedures as well as PET procedures; however, the applicant cautions that the PET procedures used in this methodology are PET procedures alone, exclusive of PET-CT procedures that are also performed at the hospital.
- The applicant thus examined historical PET utilization at UNC Medical Center from FFY 2016-FFY 2019 and calculated an overall CAGR of 10.6% for all the counties that comprise HSA IV, as shown in the following table:

² Policy AC-3 exempts from need determinations certain projects submitted by Academic Medical Center Teaching Hospitals. See Project ID #J-10016-12.

COUNTY	FFY 2016	FFY 2017	FFY 2018	FFY 2019	CAGR
Chatham	252	362	359	388	15.5%
Durham	767	938	947	908	5.8%
Franklin	223	271	287	329	13.8%
Granville	175	198	209	353	26.54%
Johnston	655	674	771	772	5.6%
Lee	346	216	312	380	3.23%
Orange	487	705	596	793	17.6%
Person	176	192	202	196	3.7%
Vance	159	148	212	220	11.4%
Wake	3,376	3,784	4,485	4,615	11.0%
Warren	43	76	72	62	13.0%
Total	6,659	7,564	8,452	9,016	10.6%

- The applicant states the 10.6% CAGR increase in PET procedures in all HSA IV counties was lower than the 17.6% CAGR increase in PET procedures in Orange County from FFY 2016-FFY 2019. The applicant states that, notwithstanding the recent anomalous decrease in PET utilization as a result of COVID-19, UNC’s historical PET utilization is the most reliable and accurate predictor of future PET utilization, and projects growth based on a portion of the historical utilization. The applicant projects future utilization based on 75% of the overall HSA IV PET utilization growth, or an increase of 8% annually [$10.6\% \times 0.75 = 8.0\%$]. The applicant notes this is lower than Orange County’s PET utilization historical CAGR of 17.6%. See the following table, from page 3 Section Q, Tab “Form C Method”:

	SFY* 2022	SFY 2023	SFY 2024	SFY 2025	SFY 2026	RATE**
PET Procedures	4,672	5,044	5,446	5,880	6,349	8.0%

*SFY = State Fiscal Year, July 1-June 30.

**The applicant labels this column as “CAGR”; however, the growth rate is an annual rate of 8% as noted by the applicant, not a compound annual growth rate.

The applicant states the projected number of PET scans in the third project year exceeds the minimum required by the Performance Standard at 10A NCAC 14C .3703(a)(1) of 2,080 PET procedures by the third project year [$6,349 / 3 \text{ scanners} = 2,116 \text{ scans per PET scanner}$].

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2021 SMFP for one additional PET scanner in HSA IV, which includes Orange County.
- The applicant uses reasonable and clearly identified historical and demographic data to make assumptions regarding identifying the population to be served, the projected growth of that population, and the need the identified population has for the proposed PET services.

- The applicant provides reasonable information to support the need for an additional PET scanner at the UNC campus in Chapel Hill based on documented historical utilization and future plans for expanded diagnostic and treatment use of the unit.

Access to Medically Underserved Groups

In Section C.6, page 62, the applicant states:

“As North Carolina’s only state-owned, comprehensive, full-service hospital system, UNC Health, including UNC Hospitals, has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance.”

On page 63, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	UNC does not retain this data
Racial and ethnic minorities	39.4%
Women	41.7%
Persons with Disabilities	UNC does not retain this data
Persons 65 and older	29.2%
Medicare beneficiaries	34.1%
Medicaid recipients	14.7%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents historical and projected access to UNC services to all residents of the service area, including underserved groups.
- The applicant provides its projected payor mix, which includes underserved groups, and assumes it will remain constant for the first three years of operation.

Conclusion

The agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written comments
- Response to Comments

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

- (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, ... persons [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

J-11089-21 University of North Carolina Hospitals at Chapel Hill – Acquire one fixed PET/CT scanner – The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

C – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – In Section E.2, page 51, the applicant describes the one alternative it considered and explains why that alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternative considered was:

- Alternate location for the PET scanner – The applicant states this is not a cost-effective option because DRH has a new PET scanner and is expected to be able to accommodate projected patient volume at the hospital. In addition, DUH's existing PET scanners are highly utilized. Adding an additional scanner at DUH will best address patient needs with minimal construction so that the proposed scanner can be operational much faster than at other locations and thus serve patients more quickly.

On page 51, the applicant states that this proposal is the most effective alternative because it would allow DUH to accommodate projected growth in cardiac and PSMA PET procedures and meet patient demand in the Duke system.

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

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – Acquire one fixed PET/CT scanner – In Section E.2, pages 74-75, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states this is not a cost-effective option because without the additional PET scanner capacity, UNC would not have adequate capacity to meet future demand for PET services. The applicant states existing PET scanners are currently near capacity, and with projected growth, the existing scanners will not meet the need. Thus, this is not an effective alternative to meet increasing demand for PET services in HSA IV.
- Locate the proposed PET scanner at another location – the applicant states this is an unreasonable alternative because it would be more costly to complete necessary renovation and construction elsewhere when the proposed scanner can be developed in existing space in the UNC Cancer Center. In addition, the applicant states this alternative fails to optimize the standard of care and operational efficiencies at UNC and its physicians and oncologists at the medical center. Thus, this is not an effective alternative.

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

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

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

- (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

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – DUH proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP.

Capital and Working Capital Costs

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

Site Costs	NA
Construction / Renovation Costs*	\$749,007
Miscellaneous Costs	\$3,857,993
Total	\$4,606,000

*Includes architect/engineering fees and contingency

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant bases its costs on similar projects it has undertaken in the past.
- The applicant provides a June 9, 2021 architect letter in Exhibit F.1(a) that confirms the projected construction/renovation cost.
- The applicant provides an equipment quote in Exhibit F.1(b) that confirms the equipment cost.

Availability of Funds

In Section F.2, page 52, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

TYPE	DUKE UNIVERSITY HEALTH SYSTEM, INC.	TOTAL
Loans	\$0	\$0
Accumulated reserves, OE*, Cash/Cash Equivalents	\$4,606,000	\$4,606,000
Bonds	\$0	\$0
Other (internal revenue and/or credit)	\$	\$
Total Financing	\$4,606,000	\$4,606,000

*OE = Owner's Equity

In Exhibit F.2(a), the applicant provides a June 2, 2021 letter from the Senior Vice President, Chief Financial Officer and Treasurer for Duke University Health System documenting the availability of sufficient funds to finance the proposed project. Exhibit F.2(b) contains DUH's Consolidated Financial Statements for years ending December 31, 2020 and 2019 that show cash and cash equivalents as of December 31, 2020 in the amount of \$157,803,000.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F.2(a) contains a letter from the Senior Vice President, Chief Financial Officer and Treasurer for Duke University Health System documenting the availability of sufficient funds to finance the proposed project.
- The letter in Exhibit F.2(b) states the applicant has sufficient cash reserves to fund the project without negatively impacting regular operations or other pending projects and confirms the balance sheets indicate sufficient cash and cash equivalents as of December 31, 2020.
- Exhibit F.2(b) contains a copy of DUH's balance sheet as of December 31, 2020, showing adequate funds and revenue necessary to cover the capital costs 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 Form F.2, the applicant projects that revenues will exceed operating expenses in all three full fiscal years following completion of the project, as shown in the table below.

DUH PROJECTED REVENUE AND EXPENSES

	1 ST FFY FY 2024	2 ND FFY FY 2025	3 RD FFY FY 2026
Total PET scans	9,615	9,692	9,771
Total Gross Revenues (Charges)	\$15,130,938	\$15,679,428	\$16,251,897
Total Net Revenue	\$4,732,541	\$4,889,757	\$5,053,564
Average Net Revenue per PET scan	\$492	\$505	\$517
Total Operating Expenses (Costs)	\$4,497,218	\$4,647,150	\$4,801,525
Average Operating Expense per PET scan	\$468	\$479	\$491
Net Income	\$235,323	\$242,607	\$252,039

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant bases its projections on the DUH system and the DUH PET/CT historical experience.
- The applicant accounts and explains the basis for projected operating expenses, such as salaries, equipment maintenance and administrative support, consistent with projections elsewhere in the application.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

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

- The applicant bases its projections on DUH's historical experience.
- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

J-11089-21 University of North Carolina Hospitals at Chapel Hill – UNC proposes to acquire one fixed PET scanner to be located at the UNC Cancer Center on Manning Drive in Chapel Hill pursuant to the need determination in the 2021 SMFP. Following project completion, UNC would be licensed for three fixed PET scanners.

Capital and Working Capital Costs

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

Site Costs	NA
Construction / Renovation Costs	\$607,200
Miscellaneous Costs	\$3,596,660
Total	\$4,203,860

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant bases its project costs on similar projects it has undertaken in the past.
- The applicant provides an architectural certified cost estimate in Exhibit F.1(a) that confirms the projected construction/renovation cost.
- The applicant bases its equipment costs on vendor estimates and UNC’s experience with other similar projects.

Availability of Funds

In Section F.2, page 76, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

TYPE	UNC HOSPITALS	TOTAL
Loans	\$0	\$0
Accumulated reserves, OE*, Cash/Cash Equivalents	\$4,203,860	\$4,203,860
Bonds	\$0	\$0
Other (internal revenue and/or credit)	\$	\$
Total Financing	\$4,203,860	\$4,203,860

*OE = Owner’s Equity

In Exhibit F.2(1), the applicant provides a June 15, 2021 letter from the Chief Financial Officer for UNC Health documenting the availability of sufficient funds to finance the proposed project. Exhibit F.2(2) contains UNC’s Consolidated Financial Statements for years ending June 30, 2020 that show cash and cash equivalents as of June 30, 2020 in the amount of \$431,681,827.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F.2(1) contains a letter from the Chief Financial Officer for UNC Health documenting the availability of sufficient funds to finance the proposed project.
- The letter in Exhibit F.2(1) states the applicant has sufficient cash reserves to fund the project without negatively impacting regular operations or other pending projects and confirms the balance sheets indicate sufficient cash and cash equivalents as of June 30, 2020.
- Exhibit F.2(2) contains a copy of UNC’s balance sheet as of June 30, 2020, showing adequate funds and revenue necessary to cover the capital costs 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 Form F.2, the applicant projects that revenues will exceed operating expenses in all three full fiscal years following completion of the project, as shown in the table below.

	1ST FFY FY 2024	2ND FFY FY 2025	3RD FFY FY 2026
Total PET scans	5,446	5,880	6,349
Total Gross Revenues (Charges)	\$40,237,676	\$44,748,628	\$49,765,293
Total Net Revenue	\$12,005,901	\$13,351,854	\$14,848,700
Average Net Revenue per PET scan	\$2,204	\$2,270	\$2,338
Total Operating Expenses (Costs)	\$11,107,005	\$12,616,061	\$13,667,807
Average Operating Expense per PET scan	\$2,039	\$2,145	\$2,152
Net Income	\$898,896	\$735,793	\$1,180,893

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant bases its projections on UNC's FY 2020 historical experience.
- The applicant accounts for and explains the basis for projected operating expenses such as salaries, supplies, equipment maintenance and administrative support, consistent with projections elsewhere in the application.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

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

- The applicant bases its projections on UNC's historical experience.
- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.

- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- (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

On page 367, the 2021 SMFP defines the service area for a fixed dedicated PET scanner as “the HSA [Health Service Area] in which it is located (Table 17F-1).” DUH proposes to locate the fixed PET scanner in Durham County, and UNC proposes to locate the fixed PET scanner in Orange County. Both Durham and Orange counties are in HSA IV. Each applicant proposes to locate a fixed PET scanner in HSA IV. Thus, the service area for both proposals is HSA IV. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing dedicated fixed PET scanners in HSA IV, and the number of procedures for each PET scanner in 2018-2019 as found in Table 17F-1 on page 369 of the 2021 SMFP:

Fixed PET Scanners HSA IV			
TYPE	SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2018-2019
Fixed	Duke Raleigh Hospital*	1	0
Fixed	Duke University Hospital	2	4,947
Fixed	Rex Hospital	2	3,282
Fixed	UNC Hospitals	2	4,019
Fixed	Wake PET Services, Wake Radiology Oncology, Wake Radiology	1	550

*CON issued pursuant to Project ID #N-11866-20, effective June 27, 2020

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – DUH proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP.

In Section G, pages 60-61, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanner services in HSA IV, including the need identified in the 2021 SMFP. The applicant states:

“...the need for additional PET capacity in the 2021 SMFP was driven by the demand for DUH’s highly specialized services. The PET methodology generates need based on utilization at an individual provider, not based on the service area inventory as a whole. ... This reflects the integral nature of PET scanning services to cancer care. The proposed equipment is specifically needed at DUH to expand access to the hospital’s

well-utilized imaging services, specifically those supporting Duke's comprehensive cancer center, which do not duplicate the services provided by any other facility. ... Co-locating the services with other essential cancer services is more convenient for patients and provides better coordination of care by providers. Moreover, much of the need for additional capacity is based on anticipated radiopharmaceutical PSMA-PET studies that will not necessarily be performed at other locations."

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

- There is a need determination in the 2021 SMFP for the proposed fixed PET scanner in HSA IV.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing or approved fixed and mobile PET scanners in HSA IV.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written Comments
- Responses to comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – UNC proposes to acquire one fixed PET scanner to be located at the UNC Cancer Center on Manning Drive in Chapel Hill pursuant to the need determination in the 2021 SMFP. Following project completion, UNC would be licensed for three fixed PET scanners.

In Section G, pages 86-87, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanner services in HSA IV, including the need identified in the 2021 SMFP. The applicant states:

"...UNC Medical Center is the only State-owned teaching hospital in North Carolina as well as the only public [National Cancer Institute]-Designated Comprehensive Cancer Center in North Carolina. ... the proposed project will not result in unnecessary duplication, but rather, will enhance competition by expanding the capacity of PET services at UNC Hospitals. Further, the proposed project will assist UNC Hospitals in meeting its four-fold mission of patient care, teaching, research, and community service."

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

- There is a need determination in the 2021 SMFP for the proposed fixed PET scanner in HSA IV.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing or approved fixed and mobile PET scanners in HSA IV.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written Comments
- Responses to comments

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

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

C – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – DUH proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP.

In Section Q, Form H the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

Duke University Hospital Current and Projected Staffing				
POSITION	CURRENT FTE AS OF 5/31/21	1ST FULL FY (7/1/23-6/30/24)	2ND FULL FY (7/1/24-6/30/25)	3RD FULL FY (7/1/25-6/30/26)
Nuclear Medicine Technologist	7.36	11.09	11.18	11.27
Radiology Supervisor	1.15	1.06	1.06	1.06
Patient Service Associate	2.15	3.00	3.00	3.00
Physician’s Assistant	0.55	1.00	1.00	1.00
Total	11.21	16.15	16.24	16.33

The assumptions and methodology used to project staffing are provided in Section Q, page 103. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is in Section Q. In Section H.2 and

H.3, pages 62-63, the applicant describes the methods used to recruit or fill new positions and its existing and proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services because it is based on the applicant’s experience in staffing and operating other diagnostic centers and providing PET services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – UNC proposes to acquire one fixed PET scanner to be located at the UNC Cancer Center on Manning Drive in Chapel Hill pursuant to the need determination in the 2021 SMFP. Following project completion, UNC would be licensed for three fixed PET scanners.

In Section Q, Form H the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

UNC Hospital Current and Projected Staffing

POSITION	CURRENT FTE AS OF 6/30/21	1 ST FULL FY (7/1/23- 6/30/24)	2 ND FULL FY (7/1/24- 6/30/25)	3 RD FULL FY (7/1/25- 6/30/26)
Molecular Imaging Technologist	4.0	6.0	6.0	6.0
Clinical Nurse II	1.0	2.0	2.0	2.0
Radiation Physicist	0.3	0.3	0.3	0.3
Radio-Pharmacist	0.4	0.4	0.4	0.4
Total	5.7	8.7	8.7	8.7

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is in Section Q. In Section H.2 and H.3, pages 88-89, the applicant describes the methods used to recruit or fill new positions and its existing and proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services because it is based on the applicant’s experience in staffing and operating other diagnostic centers and providing PET services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

C – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – DUH proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP.

Ancillary and Support Services

In Section I, page 64 the applicant identifies the necessary ancillary and support services for the proposed services. On pages 64-65, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the existing providers of existing ancillary and support services and states the same providers will be available for the proposed PET services.
- The applicant explains how the Duke University Health System currently provides similar ancillary and support services on its existing PET scanners and describes how those same relationships will be in place to provide ancillary and support services on the new proposed PET scanner.

Coordination

In Section I, page 65 the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently provides diagnostic imaging services in the service area and has established relationships with local healthcare and social services providers, which will be in place in the proposed program as well.
- The applicant demonstrates physician support for the project in Exhibit C.4(a).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – UNC proposes to acquire one fixed PET scanner to be located at the UNC Cancer Center on Manning Drive in Chapel Hill pursuant to the need determination in the 2021 SMFP. Following project completion, UNC would be licensed for three fixed PET scanners.

Ancillary and Support Services

In Section I, page 90 the applicant identifies the necessary ancillary and support services for the proposed PET services. On page 90, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the existing providers of existing ancillary and support services and states the same providers will be available for the proposed PET services.
- The applicant explains how the UNC Health System currently provides similar ancillary and support services on its existing PET scanners and describes how those same relationships will be in place to provide ancillary and support services on the new proposed PET scanner.

Coordination

In Section I, page 91 the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently provides diagnostic imaging services in the service area and has established relationships with local healthcare and social services providers, which will be in place in the proposed program as well.
- The applicant demonstrates physician support for the project in Exhibit I.2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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 – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

J-11089-21 University of North Carolina Hospitals at Chapel Hill – Acquire one fixed PET scanner – The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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 – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner –
The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

J-11089-21 University of North Carolina Hospitals at Chapel Hill – Acquire one fixed PET scanner –
The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner –
DUH proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP.

In Section K, page 68 the applicant states that the project involves renovating 640 square feet of existing space. Line drawings are provided in Exhibit K.2.

On pages 68-69, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the project will be developed in existing space in the Duke Cancer Center, adjacent to the hospital's existing PET scanners.
- The applicant states that the facility renovation will be in existing space currently used for storage and will not require relocation of any clinical services.

On page 69, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the project will not increase charges or reimbursement for the proposed services, which are established by Medicare, Medicaid and/or existing private payor contracts regardless of the number of PET scanners operated at the cancer center.
- The applicant states that the project does not require major construction or capital investment beyond the cost of the equipment, thus minimizing capital expenditure.

On page 69, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – Acquire one fixed PET scanner – UNC proposes to acquire one fixed PET scanner to be located at the UNC Cancer Center on Manning Drive in Chapel Hill pursuant to the need determination in the 2021 SMFP. Following project completion, UNC would be licensed for three fixed PET scanners.

In Section K, page 94 the applicant states that the project involves renovating 792 square feet of existing space in the UNC Cancer Center. Line drawings are provided in Exhibit C.1-1.

On pages 94-95, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the project will be developed in existing space in the UNC Cancer Center that had previously been upfitted with the necessary features to accommodate the proposed PET scanner.

On page 95, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the project will not incur a large capital cost because it will be developed in existing space in the cancer center and will be co-located near the hospital's existing linear accelerators, thereby saving on construction and upfit costs.
- The applicant states that since UNC is part of a large health care system, it benefits from significant cost saving measures by consolidating multiple services and large economies of scale.

In Exhibit B.21, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

(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 persons with disabilities, 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

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – In Section L, page 71, the applicant provides the historical payor mix during FY 2020 (July 1, 2019-June 30, 2020) for the proposed services, as shown in the table below:

PAYOR CATEGORY	PET SERVICES AS A % OF TOTAL
Self-Pay	0.8%
Charity Care	4.3%
Medicare*	38.1%
Medicaid*	11.3%
Insurance*	41.8%
Workers Compensation	0.3%
TRICARE	1.5%
Other	1.8%
Total	100.0%

*Includes managed care plans

In Section L, page 72, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	58.6%	52.3%
Male	41.4%	<i>Not Reported</i>
Unknown	--	--
64 and Younger	65.5%	<i>Not Reported</i>
65 and Older	34.5%	13.6%
American Indian	0.5%	0.9%
Asian	2.8%	5.5%
Black or African-American	26.4%	36.9%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	61.4%	54.0%
Other Race	2.3%	2.6%
Declined / Unavailable	6.5%	--

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – Acquire one fixed PET scanner – In Section L, page 98, the applicant provides the historical payor mix during FY 2020 (July 1, 2019-June 30, 2020) for UNC Medical Center, as shown in the table below:

PAYOR CATEGORY	SERVICES AS A % OF TOTAL
Self-Pay	8.8%
Charity Care**	UNC does not track
Medicare*	34.1%
Medicaid*	14.7%
Insurance*	37.7%
Workers Compensation	Included in "other"
TRICARE	
Other	4.7%
Total	100.0%

*Includes managed care plans

**The applicant states UNC does not include "Charity Care" as a payor source for patients, but patients in any payor category can and do receive charity care.

In Section L, page 99, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	41.7%	52.3%
Male	58.3%	47.7
Unknown	0.0%	0.0%
64 and Younger	70.8%	85.4%
65 and Older	29.2%	14.6%
American Indian	0.8%	0.6%
Asian	2.1%	8.1%
Black or African-American	22.5%	11.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	60.6%	76.9%
Other Race	9.8%	2.5%
Declined / Unavailable	4.1%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's

existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 73, the applicant states it has no such obligation to provide uncompensated care.

In Section L, page 74, the applicant states that during the 18 months immediately preceding the application deadline, one patient civil rights access complaint was filed against the facility. The applicant states:

“DUHS received a letter from US Attorney Office dated February 28, 2020 that notified DUHS that DOJ, Civil Rights Division, Disability Rights, is investigating DUHS concerning 2 ADA complaints. One related to services in July 2015 that was previously closed and one concerning inpatient admission to Duke University Hospital in September 2019. Both complaints allege lack of accessibility of interpreter. ... DUHS has responded detailing the interpreter services that were provided to each patient and providing information regarding its robust accessibility program. DUHS has received no further requests for information.”

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – Acquire one fixed PET scanner – Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 100, the applicant states it has no such obligation to provide uncompensated care.

In Section L, page 100, the applicant states that during the 18 months immediately preceding the application deadline, it has not been notified of any patient civil rights equal access complaints filed against the hospital.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

C – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – In Section L, page 75, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project for the entire Duke University Hospital and for PET-CT procedures, as shown in the tables below:

DUH Entire Facility Projected Payor Mix, FY 2026

PAYOR SOURCE	% OF TOTAL
Self-Pay	1.1%
Charity Care	4.4%
Medicare*	39.7%
Medicaid*	11.2%
Insurance*	40.4%
Workers Compensation	0.2%
TRICARE	1.4%
Other	1.5%
Total	100.0%

DUH PET-CT Projected Payor Mix, FY 2026

PAYOR SOURCE	% OF TOTAL
Self-Pay	1.31%
Charity Care	0.00%
Medicare*	59.90%
Medicaid*	3.98%
Insurance*	28.72%
Workers Compensation	0.07%
TRICARE	2.19%
Other	3.84%
Total	100.0%

As shown in the table above, during the third full fiscal year of operation, the applicant projects that for the total DUH hospital 1.1% of total services will be provided to self-pay patients, 4.4% to charity care patients, 39.7% to Medicare patients and 11.2% to Medicaid patients. For the proposed PET services, the applicant projects that 1.31% of total services will be provided to self-pay patients, 59.9% to Medicare patients and 3.98% to Medicaid patients.

On page 75, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the FY 2021 PET payor mix at the at DUH and for existing PET-CT services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – Acquire one fixed PET scanner – In Section L, page 101, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project for the entire UNC Medical Center and for PET services, as shown in the tables below:

UNC Medical Center Projected Payor Mix, FY 2026

PAYOR SOURCE	% OF TOTAL
Self-Pay	8.8%
Charity Care**	UNC does not track
Medicare*	34.1%
Medicaid*	14.7%
Insurance*	37.7%
Workers Compensation	Included in "other"
TRICARE	
Other	4.7%
Total	100.0%

*Includes managed care plans

**The applicant states UNC does not include "Charity Care" as a payor source for patients, but patients in any payor category can and do receive charity care.

UNC PET Projected Payor Mix, FY 2026

PAYOR SOURCE	% OF TOTAL
Self-Pay	6.5%
Charity Care**	UNC does not track
Medicare*	49.3%
Medicaid*	8.1%
Insurance*	30.9%
Workers Compensation	Included in "other"
TRICARE	
Other	5.1%
Total	100.0%

*Includes managed care plans

**The applicant states UNC does not include "Charity Care" as a payor source for patients, but patients in any payor category can and do receive charity care.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that for the total UNC Medical Center 8.8% of total services will be provided to self-pay patients, 34.1% to Medicare patients and 14.7% to Medicaid patients. For the proposed PET services, the applicant projects that 6.5% of total services will be provided to self-pay patients, 49.3% to Medicare patients and 8.1% to Medicaid patients.

On page 101, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the FY 2021 PET payor mix at the at UNC Medical Center and for existing PET-CT services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

C – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner –

In Section L, page 77, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – Acquire one fixed PET scanner –

In Section L, page 103, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

C – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – DUH proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP.

In Section M, pages 78-79, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purpose. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- DUH is an Academic Medical Center Teaching Hospital that serves as a primary teaching site for Duke University School of Medicine students, residents, fellows, nurses and other health care professionals in its schools of Medicine, Nursing and Medical and Health Professions.
- The applicant states DUH also offers an Imaging Physics Residency for all imaging modalities which requires a Radiology rotation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – UNC proposes to acquire one fixed PET scanner to be located at the UNC Cancer Center on Manning Drive in Chapel Hill pursuant to the need determination in the 2021 SMFP. Following project completion, UNC would be licensed for three fixed PET scanners.

In Section M, pages 104-105, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purpose. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- UNC Medical Center is an Academic Medical Center Teaching Hospital and as such, clinical training is a primary component of its mission. Additionally, the applicant

states UNC Hospitals has a long history of supporting health professional training programs in the community.

- The applicant states UNC offers many fellowship training opportunities through various divisions of the clinical departments.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(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 Applications

On page 367, the 2021 SMFP defines the service area for a fixed dedicated PET scanner as “the HSA [Health Service Area] in which it is located (Table 17F-1).” DUH proposes to locate the fixed PET scanner in Durham County, and UNC proposes to locate the fixed PET scanner in Orange County. Both Durham and Orange counties are in HSA IV. Each applicant proposes to locate a fixed PET scanner in HSA IV. Thus, the service area for both proposals is HSA IV. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing dedicated fixed PET scanners in HSA IV, and the number of procedures for each PET scanner in 2018-2019 as found in Table 17F-1 on page 369 of the 2021 SMFP:

Fixed PET Scanners HSA IV

TYPE	SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2018-2019
Fixed	Duke Raleigh Hospital*	1	0
Fixed	Duke University Hospital	2	4,947
Fixed	Rex Hospital	2	3,282
Fixed	UNC Hospitals	2	4,019
Fixed	Wake PET Services, Wake Radiology Oncology, Wake Radiology	1	550

*CON issued pursuant to Project ID #N-11866-20, effective June 27, 2020

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – DUH proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 80, the applicant states:

“DUH’s service area includes Durham County, the Triangle, and surrounding counties, and the hospital attracts patients from across the state and nation. Current capacity constraints are leading to scheduling delays for procedures. By ensuring sufficient capacity to meet demand for DUH’s specialized services, this project will increase patient choice for patients throughout this region, and benefit cost-effectiveness, quality, and access to services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 80, the applicant states:

“This project will not affect the cost to patients or payors for the services provided by DUH because reimbursement rates are set by the federal government and commercial insurers. ...

...DUHS will continue to participate in initiatives aimed at promoting cost effectiveness and optimizing quality healthcare. ...”

See also Sections C, F, K and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 80-81, the applicant states:

“DUH has existing quality-related policies and procedures, and its quality management programs emphasize a customer-oriented perspective that is used to determine the needs of patients, physicians, and others who utilize hospital services.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 81 the applicant states:

“...DUHS will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a person as underserved. By expanding capacity, DUH hopes to reduce procedure wait times and therefore increase access to all patients needing its services.”

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

J-11089-21 University of North Carolina Hospitals at Chapel Hill – UNC proposes to acquire one fixed PET scanner to be located at the UNC Cancer Center on Manning Drive in Chapel Hill pursuant to the need determination in the 2021 SMFP. Following project completion, UNC would be licensed for three fixed PET scanners.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 107, the applicant states:

“... the proposed project will foster competition in the proposed service area. In particular, UNC Hospitals has a unique mission to serve patients from across the state, and regularly cares for patients from all 100 counties. As such, the proposed project will enhance competition by expanding the capacity of PET services at UNC Hospitals, which will improve its ability to compete with other providers. The proposed project will enhance the provision of timely, quality patient care and will assist UNC Hospitals in meeting its four-fold mission of patient care, teaching, research, and community service.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 107, the applicant references Application Section B.20(c). The Project Analyst notes there is no Section B.20; the reference is to Section B.2(c), page 29 which states in part:

“The proposed project will provide additional PET capacity to meet the continued need at UNC Medical Center.... ... UNC has reduced expenses by utilizing existing space and avoiding new construction and thus has proposed the most value-conscious alternative for the installation of the proposed equipment.”

See also Sections B, C, F, K and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 107, the applicant references Application Section B.20(a). The Project Analyst notes there is no Section B.20; the reference is to Section B.2(a), which provides information regarding the impact of the proposed PET scanner on the quality of services provided by UNC. The applicant provides additional information in Exhibits B.20-1 through B.20-4.

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 108 the applicant references Application Section B.20(b). The Project Analyst notes there is no Section B.20; the reference is to Section B.2(b), which provides information regarding access to proposed PET services provided by UNC. The applicant provides additional information in Exhibits B.20-5 and B.20-6.

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

- Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

C – Both Applications

J-12083-21 Duke University Health System, Inc. – Acquire one fixed PET/CT scanner – DUH proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP.

In Section Q, Form O the applicant identifies the facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three of this type of facility located in North Carolina.

In Section O, page 84 the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in any of these facilities. 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 DUH facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-11089-21 University of North Carolina Hospitals at Chapel Hill – UNC proposes to acquire one fixed PET scanner to be located at the UNC Cancer Center on Manning Drive in

Chapel Hill pursuant to the need determination in the 2021 SMFP. Following project completion, UNC would be licensed for three fixed PET scanners.

In Section Q, Form O the applicant identifies the facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 12 of this type of facility located in North Carolina.

In Section O, page 110 the applicant states that, during the 18 months immediately preceding the submittal of the application, two incidents related to quality of care occurred in two related entities, Onslow Memorial Hospital and UNC Rex Hospital. The applicant states on page 110 that each incident has been resolved, and that there were no incidents resulting in immediate jeopardy at any UNC facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in any of these facilities. 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 UNC facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA – Duke University Health System, Inc.
C – Both Applications

The Criteria and Standards for Positron Emission Tomography Scanners, promulgated in 10A NCAC 14C .3700, are applicable to this review.

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- **DUH.** In Section Q, Form C, the applicant projects that the proposed PET scanner will perform 3,257 procedures, which is more than 2,080 procedures by the end of the third year of operation. Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.
 - C- **UNC.** In Section C, page 65 and Section Q, Form C, the applicant projects that the proposed PET scanner will perform 2,116 procedures, which is more than 2,080 procedures by the end of the third year of operation. Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.
- (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- **DUH.** In Section Q, Form C, the applicant states that the two existing fixed PET scanners at Duke University Hospital performed 7,535 total procedures, or 3,767 procedures per PET scanner, which is more than 2,080 procedures in the last full federal fiscal year. The applicant states the two existing fixed PET scanners performed 5,255 PET-only procedures during the same time, or 2,627 procedures per scanner.
 - C- **UNC.** In Section C, page 66 and Section Q, the applicant states that the two existing fixed PET scanners at UNC Medical Center performed 4,357 total procedures, or 2,178 procedures per PET scanner, which is more than 2,080 procedures in the last full federal fiscal year.
- (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- **DUH.** In Section Q, Form C, the applicant states that the three existing and proposed fixed PET scanners at Duke University Hospital will perform a total of 9,771 procedures, or 3,257 procedures per PET scanner, which is more than 2,080 procedures in the third full federal fiscal year of operation following project completion. The applicant states the three existing and proposed fixed PET scanners will perform a total of 7,375 PT-only procedures, or 2,458 procedures per scanner, which is more than 2,080 procedures in the third full federal fiscal year of operation following project completion.

-C- **UNC.** In Section C, page 66 and Section Q, the applicant states that the three existing and proposed fixed PET scanners at UNC Medical Center will perform 6,349 total procedures, or 2,116 procedures per PET scanner, which is more than 2,080 procedures in the third full federal fiscal year of operation following project completion.

(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- **DUH.** The applicant provides its assumptions and methodology in Section C and Section Q. The applicant adequately demonstrates that its assumptions are reasonable and adequately supported. See the discussion found in Criterion (3) regarding projected utilization which is incorporated herein by reference. The application is conforming to this Rule.

-C- **UNC.** The applicant provides its assumptions and methodology in Section C and Section Q. The applicant adequately demonstrates that its assumptions are reasonable and adequately supported. See the discussion found in Criterion (3) regarding projected utilization which is incorporated herein by reference. The application is conforming to this Rule.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2021 State Medical Facilities Plan, no more than one fixed PET scanner may be approved for Health Service Area IV in this review. Because the two applications in this review collectively propose to develop two additional fixed PET scanners to be located in Health Service Area IV, both applications cannot be approved for the total number of fixed PET scanners proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal could be approved.

Below is a brief description of each project included in this review.

- **Project ID #J-12083-21 / Duke University Health System, Inc.** – Acquire 1 fixed PET/CT scanner pursuant to the need determination in the 2021 SMFP for a total of no more than 3 fixed PET/CT scanners upon project completion.
- **Project ID #J-12089-21 / University of North Carolina Hospitals at Chapel Hill** – Acquire 1 fixed PET/CT scanner pursuant to the need determination in the 2021 SMFP for a total of no more than 3 fixed PET/CT scanners upon project completion.

Conformity with Statutory and Regulatory Review Criteria

The applications submitted by **Duke University Health System, Inc. and University of North Carolina Hospitals at Chapel Hill** are each individually conforming to all applicable statutory and regulatory review criteria.

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

Scope of Services

Generally, the application proposing to provide the broadest scope of services is the more effective alternative regarding this comparative factor. Regarding scope of services, both applications were submitted in response to the need determination for one fixed PET scanner in HSA IV in the 2021 State Medical Facilities Plan (SMFP). Both applications propose to acquire and operate a fixed PET/CT scanner at a hospital location.

The following table compares the scope of services proposed to be offered by each applicant on the proposed fixed PET/CT scanner:

FACILITY	PROPOSED SCOPE OF PET SERVICES		
	ONCOLOGICAL PET	CARDIAC PET	NEUROLOGIC PET
Duke University Medical Center	X	X	
University of North Carolina Hospitals at Chapel Hill	X	X	X

DUH proposes to provide PET services to oncology and cardiac patients. **UNC** proposes to provide PET services to oncology, cardiac and neurologic patients. Therefore, with regard to scope of services, **UNC** is the more effective alternative, because it proposes to offer a broader scope of PET/CT services.

Historical Utilization

The following table illustrates historical utilization of each applicant as provided in the 2021 SMFP representing FY 2019 reported utilization.

Fixed PET Scanners in HSA IV

FACILITY	# OF FIXED PET SCANNERS	FY 2019 TOTAL	2019 PET PROCEDURES PER SCANNER	FY 2020 TOTAL	2020 PET PROCEDURES PER SCANNER
Duke Raleigh Hospital*	1	0	0		0
Duke University Hospital	2	4,947	2,474	4,670	2,335
Rex Hospital	2	3,282	1,641	3,317	1,686
UNC Hospitals	2	4,019	2,010	3,712	1,856
Wake PET Services, Wake Radiology Oncology, Wake Radiology	1	550	550	626	626

*Duke Raleigh Hospital was awarded a CON for a new fixed PET scanner effective June 27, 2020 pursuant to Project ID# N-11866-20.

Source: 2021 SMFP, proposed 2022 SMFP

DUH performed the highest number of procedures per fixed PET scanner in FY 2019 and FY 2020. Therefore, **DUH** is the more effective alternative for this comparative factor.

Geographic Accessibility (Location within the Service Area)

The 2021 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. Following is a table that illustrates the location of the existing and approved fixed MRI scanners in HSA IV:

Fixed PET Scanners in HSA IV

FACILITY	CITY	COUNTY
Duke Raleigh Hospital	Raleigh	Wake
Duke University Hospital	Durham	Durham
Rex Hospital	Raleigh	Wake
UNC Hospitals	Chapel Hill	Orange
Wake PET Services, Wake Radiology Oncology, Wake Radiology	Cary	Wake

All the existing and approved fixed PET scanners in HSA IV are located or proposed to be located in either Wake, Durham or Orange counties. Wake County is situated in the southern portion of HSA IV, and Durham and Orange counties are north and west of Wake County. Durham County is located in between Wake and Orange counties. The three counties form a cluster that is located approximately in the center area of HSA IV, with the other eight HSA IV counties surrounding the cluster to the north, east and west. Each applicant proposes to locate the fixed PET scanner more or less in the central portion of HSA IV. Additionally, facilities may serve residents not included in their service area. Thus, regarding this comparative factor, the proposals are equally effective.

Access by Service Area Residents

On page 367, the 2021 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s service area is the HSA in which it is located (Table 17F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” Each applicant proposes to locate the fixed PET scanner in a county which, according to Appendix A on page 373 is in HSA IV. Thus, the service area for each proposal is HSA IV. Facilities may also serve residents of counties not included in their service area.

On page 34 of its application, **DUH** states:

“Duke typically identifies its primary service area for acute services as Alamance, Durham, Granville, Orange, Person, Vance, and Wake counties....”

On 44 of its application, **UNC** states:

“UNC Hospitals, including UNC Medical Center, regularly provide services to all 100 counties, and while the exact number and counties may change from year to year, UNC Hospitals serves the entire state, by mission.”

DUH provides the projected number of patients to be served by county on page 31 of its application; thus, it is possible to separate the counties it identifies as its “*primary service area for acute services*”. The following table, from page 31, shows the counties that comprise HSA IV and the number of patients DUH projects to serve from those counties. The counties included in this table are not all of the counties included in the applicant’s table, but are extracted to show HSA IV patients:

HSA IV COUNTIES	1 ST FULL FY (FY 2024)	2 ND FULL FY (FY 2025)	3 RD FULL FY (FY 2026)
	# PTs.	# PTs.	# PTs.
Chatham	12,755	13,030	13,291
Durham	496,645	506,578	516,709
Franklin	14,681	14,974	15,274
Granville	43,522	44,393	45,281
Johnston	12,979	13,238	13,503
Lee	6,995	7,135	7,278
Orange	101,309	103,335	105,402
Person	40,434	41,243	42,068
Vance	20,848	21,265	21,691
Wake	223,000	227,460	232,009
Warren	6,327	6,453	6,583
Total	979,495	999,104	1,019,089

UNC provides the projected number of patients to be served by county on page 46 of its application. However, UNC states its service area is the entire state, “*by mission*”. Therefore, a comparison of the applications regarding this comparative factor is inconclusive.

Access by Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

“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 access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is evaluated as a separate factor.

Projected Charity Care

Generally, the application proposing to provide the most charity care is the more effective alternative with regard to this comparative factor.

In Section L, page 76, **DUH** states:

“DUHS estimated the number of charity care (100% financial discount) patients to be served by the entire hospital (including inpatient admissions, surgeries, and emergency department and outpatient encounters) based on average actual encounter experience during FY20 and [FY 2021 annualized based on six months], which constituted 4.37% of total encounters. It applied that percentage to total projected patient volumes across service lines.”

In Section L, page 102, **UNC** states:

“The percent of charity care patients of total patients at UNC Medical Center in FY 2020 was 2.0 percent. ... The proportion of charity care patients to total patients is assumed to be constant through the project years, or 2.0 percent of total patients.”

Each applicant, in response to Section L.4a and in the assumptions to Forms F.2 and F.3 in Section Q, describes the provision of charity care as a system, so it is a factor that can be compared as stated. Each applicant states it bases projected charity care on FY 2020 internal data. **DUH** projects that 4.37% of total patient encounters will be provided as charity care, and a total of \$651,629,000 will be charity care adjustments to revenue for DUHS in the third project year. **UNC** projects that 2.0% of total patients served will be charity care, and a total of \$3,127,322 will be charity care adjustments to revenue for UNC PET services. Assuming that one **DUH** patient encounter is the same as one **UNC** patient, then **DUH** projects to serve a greater percentage of charity care. Regarding dollar amounts provided as charity care, an accurate comparison is not possible, because **DUH** provides information regarding the entire Duke University Hospital System, and **UNC** provides information regarding the PET services to be offered at **UNC**. Therefore, regarding the provision of charity care, the application submitted by **DUH** is more effective regarding the percent of charity care to be provided.

Projected Medicaid

The following table shows each applicant’s percentage of gross revenue and dollar amount projected to be provided to Medicaid patients for PET services in each applicant’s third full year of operation following completion of the project, based on the information provided in each applicant’s pro forma financial statements in Section Q for total facility services. Generally, the application proposing to provide a higher percentage and/or dollar amount of gross revenue to Medicaid patients is the more effective alternative regarding this comparative factor.

PROJECTED MEDICAID PROJECT YEAR 3, PET SERVICES			
	Medicaid Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
Duke University Hospital	\$3,874,579	\$94,538,169	4.1%
UNC Hospital	\$4,040,079	\$49,765,293	8.1%

As shown in the table above, **UNC** projects the highest percentage and dollar amount of Medicaid dollars for PET services as a percent of gross revenue in the third project year. Therefore, **UNC** is the more effective alternative regarding this comparative factor.

Projected Medicare

The following table shows each applicant’s percentage and dollar amount of gross revenue projected to be provided to Medicare patients for PET services in the applicant’s third full year of operation following completion of their project, based on the information provided in the applicant’s pro forma financial statements in Section Q for total facility. Generally, the application proposing to provide a higher

percentage and/or dollar amount of gross revenue to Medicare patients is the more effective alternative regarding this comparative factor.

PROJECTED MEDICARE PROJECT YEAR 3, PET SERVICES			
	Medicare Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
Duke University Hospital	\$55,708,652	\$94,538,169	58.9%
UNC Hospital	\$24,552,208	\$49,765,293	49.3%

As shown in the table above, **DUH** projects the highest percentage and highest dollar amount of gross revenue for PET services will be provided to Medicare patients. Therefore, **DUH** is the more effective alternative regarding this comparative factor.

Competition (Access to a New or Alternate Provider)

Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. The introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, each of the applicants in this review currently provide PET services in HSA IV. Therefore, neither of the applicants would qualify as a new or alternative provider in the service area. Thus, regarding this comparative factor, the proposals are equally effective.

Projected Average Net Revenue per PET Scan

The following table compares projected average net revenue per PET procedure in the third full fiscal year following project completion for each facility, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, the application proposing the lowest average net revenue per procedure is the more effective alternative regarding this comparative factor, assuming the average net revenue per procedure could ultimately result in a lower cost to the patient or third-party payor.

AVERAGE NET REVENUE PER PET PROCEDURE PROJECT YEAR 3			
	TOTAL # OF PROCEDURES	Total Net Revenue	Average Net Revenue / PET Procedure
Duke University Hospital	7,375	\$21,882,814	\$2,967
UNC Hospital	6,349	\$14,848,700	\$2,339

As shown in the table above, **UNC** projects the lowest average net revenue per PET procedure in the third full fiscal year following project completion. Therefore, **UNC** is the most effective alternative regarding this comparative factor.

Projected Average Operating Expense per PET Scan

The following table compares projected average operating expense per PET procedure in the third full fiscal year following project completion for each facility, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, regarding this factor, the application proposing the lowest average operating expense per procedure is the more effective since a lower average operating cost per procedure may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

AVERAGE OPERATING COST PER PET PROCEDURE			
PROJECT YEAR 3			
	TOTAL # OF PROCEDURES	Total Operating Cost	Average Operating Cost / PET Procedure
Duke University Health System, Inc.	7,375	\$13,328,890	\$1,807
UNC Hospital	6,349	\$13,667,807	\$2,153

As shown in the table above, **DUH** projects the lowest average operating cost per PET procedure in the third full fiscal year following project completion. Therefore, **DUH** is the most effective alternative regarding this comparative factor.

SUMMARY

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

COMPARATIVE FACTOR	DUKE UNIVERSITY HOSPITAL	UNC HOSPITAL AT CHAPEL HILL
Conformity with Statutory and Regulatory Review Criteria	Equal	Equal
Scope of Services	Less Effective	More Effective
Historical Utilization	More Effective	Less Effective
Geographic Accessibility (Location within the Service Area)	Equal	Equal
Access by Service Area Residents	Inconclusive	Inconclusive
Provision of Charity Care	More Effective	Less Effective
Access by Medicaid Patients	Less Effective	More Effective
Access by Medicare Patients	More Effective	Less Effective
Competition (Access to a New or Alternate Provider)	Equal	Equal
Projected Average Net Revenue per PET Procedure, 3 rd PY	Less Effective	More Effective
Projected Average Operating Cost per PET Procedure, 3 rd PY	More Effective	Less Effective

Both applications are conforming to all applicable statutory and regulatory review criteria, and thus both applications are approvable standing alone. However, collectively they propose a total of two fixed PET scanners. The need determination in the 2021 SMFP is for only one fixed PET scanner; therefore, only one fixed MRI scanner can be approved.

As shown in the table above, the application submitted by **Duke University Health System, Inc.** was determined to be a more effective alternative regarding the following factors:

- Historical Utilization
- Provision of Charity Care
- Access by Medicare Patients
- Projected Average Operating Cost per PET Procedure in the third project year

DECISION

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **Duke University Health System, Inc.** is the more effective alternative proposed in this review for the development of one additional fixed PET scanner in HSA IV pursuant to the need determination in the 2021 SMFP.

While the application submitted by **University of North Carolina Hospitals at Chapel Hill** is approvable standing alone, the approval of that application would result in the approval of more fixed PET scanners than are determined to be needed, and therefore, the application submitted by **University of North Carolina Hospitals at Chapel Hill** is denied.

Duke University Health System, Inc. proposes to acquire one fixed PET/CT scanner to be located at the Duke University Hospital on Erwin Road in Durham pursuant to the need determination in the 2021 SMFP. The application submitted by **Duke University Health System, Inc.** is approved subject to the following conditions:

1. **Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP, to be located at Duke University Hospital, for a total of three fixed PET scanners.**
3. **Upon completion of the project, Duke University Health System, Inc. shall be licensed for no more than three fixed PET scanners.**
4. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on March 1, 2022. The second progress report shall be due on July 1, 2022 and so forth.**

- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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.**
- 7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**