

REQUIRED STATE AGENCY FINDINGS

CORRECTED

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 26, 2023

Findings Date: July 26, 2023

Project Analyst: Tanya M. Saporito

Co-Signer: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: B-12331-23

Facility: AdventHealth Hendersonville

FID #: 943388

County: Henderson

Applicant(s): Fletcher Hospital, Inc.

Project: Develop no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of no more than one fixed PET scanner upon project completion

Project ID #: B-12335-23

Facility: Mission Hospital

FID #: 943349

County: Buncombe

Applicant: MH Mission Hospital, LLLP

Project: Develop no more than one PET/CT scanner pursuant to the need determination in the 2023 SMFP for a total of no more than two fixed PET 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 2023 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 2023 SMFP identified a need for one additional fixed PET/CT scanner in Health Service Area (HSA) I. 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 I. However, pursuant to the need determination, only one fixed PET/CT scanner may be approved in this review.

Policies

Policy GEN-3 in Chapter 4 of the 2023 SMFP applies to both applications received in response to the need determination. Policy GEN-4 in Chapter 4 of the 2023 SMFP applies to the application submitted by MH Mission Hospital, LLLP.

Policy GEN-3

Policy GEN-3 on page 30 of the 2023 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 30 of the 2023 SMFP states:

“Any person proposing a capital expenditure greater than \$4 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."

Project ID #B-12331-23 Fletcher Hospital, Inc. (hereinafter referred to as "the applicant") operates AdventHealth Hendersonville in Hendersonville, an acute care hospital licensed for 62 acute care beds that also provides emergency and imaging services. In 2022, pursuant to Project ID #B-12233-22, the applicant was approved to develop an acute care hospital in Asheville, in Buncombe County. That application is currently under appeal. In this application, the applicant proposes to acquire one fixed PET scanner to be located at AdventHealth Hendersonville. Following project completion, the applicant would be licensed for one fixed PET/CT scanner.

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

Policy GEN-3. In Section B, pages 27-30 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 \$4 million but less than \$5 million. In Section B, page 31, the applicant explains why it believes its application is conforming to Policy GEN-4.

The Agency reviewed the:

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

- Remarks made at the public hearing
- 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 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 I service area;
 - The applicant adequately documents how the project will promote equitable access to PET services in the HSA I 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.

Project ID #B-12335-23 MH Mission Hospital, LLLP (hereinafter referred to as “the applicant” or “Mission Hospital”) proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of two fixed PET scanners. The applicant proposes to develop the PET scanner in renovated space in an existing hospital-based outpatient department in Asheville, Buncombe County, where the applicant currently provides cardiovascular diagnostic services. The applicant states the proposed fixed PET scanner will provide oncologic and cardiac PET imaging services.

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

Policy GEN-3. In Section B, pages 29-34 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 more than \$5 million. In Section B, pages 35-36, the applicant explains why it believes its application is conforming to Policy GEN-4.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

- 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 I service area;
 - The applicant adequately documents how the project will promote equitable access to PET services in the HSA I 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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant proposes to acquire one fixed PET/CT scanner to be located on the AdventHealth Hendersonville campus pursuant to the need determination in the 2023 SMFP. Following project completion, the applicant would be licensed for one fixed PET scanner.

In Section C, pages 32-36, the applicant describes the project. On pages 32-33, the applicant states:

“Established as a health care system in 1973, Adventist Health System Sunbelt Healthcare Corporation (Advent Health) is a faith-based, connected system of care that includes hospitals, outpatient clinics, skilled nursing facilities, home health agencies, and hospice center. A shared vision, common values, focus on whole-person health, and commitment to making communities healthier unify the system's more than 50 hospital campuses and hundreds of care sites in diverse markets throughout almost a dozen states.

...

AdventHealth operates PET scanners at numerous facilities

AdventHealth will leverage its experience and capabilities to develop the proposed fixed PET scanner successfully and efficiently in Henderson County.”

Patient Origin

On page 360, the 2023 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 Henderson County which, according to Appendix A on page 365 of the 2023 SMFP is in HSA I. Thus, the service area for this proposal is HSA I. Facilities may also serve residents of counties not included in their service area.

The applicant does not currently offer fixed PET services at AdventHealth Hendersonville but does contract for mobile PET services at that campus. The following tables illustrate historical patient origin for mobile PET services at AdventHealth Hendersonville and projected patient origin (for the third full project year, calendar year 2028) for fixed PET services, from pages 36 and 38, respectfully:

ADVENTHEALTH HENDERSONVILLE HISTORICAL MOBILE PET SERVICES

COUNTY	OCTOBER 1, 2021 – SEPTEMBER 30, 2022	
	PATIENTS	% OF TOTAL
Henderson	144	59.8%
Buncombe	46	19.1%
Transylvania	20	8.3%
Polk	12	5.0%
Rutherford	6	2.5%
Out of State	6	2.5%
Madison	3	1.2%
Mitchell	2	0.8%
Jackson	1	0.4%
McDowell	1	0.4%
Total	241	100.0%

Source: Application page 36

ADVENTHEALTH HENDERSONVILLE PROJECTED PET SERVICES

COUNTY /ZIP CODE	JANUARY 1, 2028 – DECEMBER 31, 2028	
	PATIENTS	% OF TOTAL
Buncombe	551	25.9%
Cherokee	23	1.1%
Clay	9	0.4%
Graham	12	0.6%
Haywood	123	5.8%
Henderson	606	28.5%
Jackson	10	4.8%
Macon	60	2.8%
Madison	50	2.3%
McDowell	101	4.8%
Mitchell	33	1.6%
Polk	59	2.8%
Rutherford	172	8.1%
Swain	22	1.0%
Transylvania	104	4.9%
Yancey	42	2.0%
Other*	53	2.5%
Total	2,124	100.0%

Source: Application page 38

*The applicant states on page 38 that *other* includes less than 1% patient origin from each of the remaining counties in North Carolina and other states.

In Section C, pages 50-54 and in Section Q, the applicant provides the assumptions and methodology used to project patient origin for the proposed fixed PET scanner.

The applicant’s assumptions are reasonable and adequately supported because they are based on historical patient origin for the applicant’s mobile PET services and the entire AdventHealth Hendersonville hospital patient origin.

Analysis of Need

In Section C.4, pages 40-60, the applicant explains why it believes the population projected to utilize the proposed fixed PET services needs the proposed services, as summarized below:

- There is a need determination in the 2023 SMFP for one additional fixed PET scanner in HSA I, and the applicant proposes to locate the proposed fixed PET scanner at the AdventHealth Hendersonville campus in Henderson County, which is in HSA I. The applicant explains the PET services it proposes to provide and how that satisfies the need determination in the 2023 SMFP (pages 40-46).
- Growing demand for PET services in North Carolina – The applicant states the demand for PET services across the state is increasing and cites data from the North Carolina

Office of State Budget and Management (NCOSBM). The applicant states the use rate per 1,000 has steadily increased since FY 2016, despite the anomalous negative effects of COVID-19 on many medical procedures. (pages 46-47)

- Need for enhanced access to PET services – The applicant states that, despite the availability of mobile PET services in the service area, there is a need for enhanced access to fixed PET services, since availability of the mobile PET scanner totals only approximately 26 days per year, assuming no down time for maintenance, staffing or scheduling conflicts. In addition, the applicant states the mobile PET scanner it currently uses is at AdventHealth Hendersonville on Sundays, which negatively affects the availability of radiopharmaceutical agents necessary for PMSA PET scans (those scans unique to prostate cancer imaging). The applicant states that, in addition to a need for expanded access at AdventHealth Hendersonville, there is a need for expanded access to fixed PET services in the entire service area. The applicant notes that Frye Regional Medical Center operates a fixed PET scanner in Catawba County, which is in HSA I east of Buncombe County, but the only other existing licensed fixed PET scanner in the area is operated by Mission Hospital. The PET scanner approved for Messino Cancer Center is not yet operational. When the fixed PET scanner approved for Messino Cancer Center is operational, both fixed PET will be located in Buncombe County.

The applicant states the development of a fixed PET scanner on its main campus will permit AdventHealth Hendersonville to provide both cardiac and oncology scans, including PMSA PET procedures. Additionally, it will improve access to PET services for its patients by offering increased availability, reliability and improved scheduling (pages 47-50).

- Service area population to be served by the proposed fixed PET scanner – Using its own internal data as discussed in Section C, the applicant the applicant states the mobile PET scanner it currently contracts with provides services to a population originating from counties within HSA I in western North Carolina and other states. The applicant states the location of the proposed fixed PET scanner on the main hospital campus will not only serve its existing patient base but will allow the applicant to expand service to a broader range of patients residing in HSA I who seek fixed PET services. To test the reasonableness of its proposed catchment area, in addition to its own historical patient origin data, the applicant examined the hospital license renewal applications (LRAs) of existing providers of PET services in HSA I. The applicant states its proposed catchment area for fixed PET services is actually conservative when compared to existing fixed PET providers (Mission Hospital and Frye Regional Medical Center), whose PET services draw patients from 20-30 North Carolina counties. Additionally, the applicant consulted the NCOSBM population data that indicate the total population in its proposed catchment area will increase by a compound annual growth rate (CAGR) of 0.7% from 2023-2028, while the over 65 population is projected to increase by a CAGR of 1.7% during the same time. The applicant states the over 65 cohort is more likely to need PET services than younger population groups (pages 50-54).

- Service area disease incidence – Citing data obtained from the North Carolina Central Cancer Registry, the applicant analyzed data that reported the age-adjusted rate of cancer incidence in the state as a whole from 2016-2020. The applicant states the data show that many of the counties in AdventHealth Hendersonville’s fixed PET service area experience higher cancer incidence rates compared to the state as a whole, particularly in the over 65 age group. Similarly, citing data from the North Carolina State Center for Health Statistics, the applicant states the incidence of cardiovascular disease and diabetes (a contributor to cardiovascular disease) in western North Carolina is increasing. Alzheimer’s disease is another disease that is increasingly prevalent in the state as a whole and in western North Carolina. The applicant states the demographics and disease incidence in the catchment area support the demand for the proposed fixed PET scanner at AdventHealth Hendersonville (pages 54-59).

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

- There is a need determination in the 2023 SMFP for one additional PET scanner in HSA I, which includes Henderson County.
- The applicant uses its own internal historical utilization of the mobile PET scanner with which it contracts to illustrate the increasing demand for PET services in the service area.
- The applicant uses reasonable and clearly identified demographic data to make assumptions supporting identification of 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 and clearly identified information to support the need for a fixed PET scanner at AdventHealth Hendersonville based on the existing and projected incidence of diseases for which patients benefit from PET services in the service area, as well as its future plans for expanded diagnostic and treatment utilization of the proposed fixed PET scanner.

Projected Utilization

In Section Q, Form C.2b, the applicant provides projected utilization for the first partial year of services (July 1, 2025-December 31, 2025) and the three full project years (PYs), calendar years (CYs) 2026-2028 for the proposed fixed PET scanner at AdventHealth Hendersonville, as illustrated in the following table:

AdventHealth Hendersonville PET Services Projected Utilization				
NMRMC	PARTIAL PY	FIRST FULL PY	SECOND FULL PY	THIRD FULL PY
	7/1/25-12/31/25	CY 2026	CY 2027	CY 2028
# PET Scanners	1	1	1	1
# Procedures	456	858	1,457	2,124

Source: Application Section Q, Form C2b, page 115

In Section Q, on *Form C.2b Utilization – Assumptions and Methodology*, pages 116-122, the applicant provides the assumptions and methodology used to project utilization as summarized below:

Step 1: Population Projections – Citing population data from the NCOSBM, the applicant identifies the 16 counties that comprise the projected population to be served at AdventHealth Hendersonville, as illustrated in the table on page 117.

Step 2: Calculate a PET procedure use rate – The applicant used data from the NCOSBM and from past SMFPs to calculate the historical statewide PET utilization rate of both fixed and mobile PET scanners in the state from FY 2016-FY 2021, as illustrated in the following table:

North Carolina Statewide PET Use Rate, FY 2016-FY 2021

FISCAL YEAR	STATE POPULATION	# PET PROCEDURES	USE RATE/1,000
FY 2016	10,080,436	45,006	4.46
FY 2017	10,181,491	48,066	4.72
FY 2018	10,284,335	52,167	5.07
FY 2019	10,381,670	54,416	5.24
FY 2020	10,463,226	50,572	4.83
FY 2021	10,556,299	54,837	5.19

Source: application pages 47 & 117

The applicant states PET utilization in FY 2020 decreased due to the Stay at Home order issued by Governor Cooper in response to the COVID-19 pandemic. The applicant states that PET utilization in the state is increasing following the anomalous decrease during the COVID-19 pandemic.

The applicant states the state-wide PET procedure use rate increased by a CAGR of 5.5% from FY 2016-FY 2019. The applicant projects growth in PET procedures in the state as a whole by applying the historical pre-COVID PET procedure use rate, which the applicant states is reasonable, given population aging, disease incidence and increasing clinical indications. The following table, from Section Q page 118 illustrates these projections through 2028, the third PY:

Projected North Carolina PET Use Rate, 2022-2028

	2022	2023	2024	2025	2026	2027	2028
PET Use Rate	5.48	5.78	6.10	6.43	6.79	7.16	7.55

Source: Application Section Q, page 118

Step 3: Projected PET procedure demand based on use rate – To project PET procedure demand from CY 2025-2028, the applicant applied the yearly projected North Carolina PET procedure use rate to the projected population of each of the counties in the proposed service area. See the table that illustrates these projections in Section Q, page 118. The applicant states

the projected procedures are reasonable based on the projected population growth, particularly in the over 65 age group and projected disease incidence rates.

Step 4: AdventHealth Hendersonville PET market share – The applicant states that, despite the limited access to mobile PET services, which are available approximately 26 days per year, AdventHealth Hendersonville has achieved “robust” market shares in three counties: Henderson (the applicant references *Hendersonville County*, but the Project Analyst concludes this is a typographical error and is referring to the town of Hendersonville in Henderson County. This conclusion is supported by the table provided by the applicant in Section Q page 119 that references *Henderson County*), Polk and Transylvania. The applicant bases its market share projections during partial year 2025 on FY 2022 PET market share at AdventHealth Hendersonville.

The applicant states the availability of a full-time fixed PET scanner on the hospital campus will allow AdventHealth Hendersonville to maximize access to needed PET services throughout the catchment area. The applicant projects market share volumes for PET services for each of the counties in its proposed service area for each of the three project years, as illustrated in the table provided in Section Q page 120. The applicant states these market share projections are reasonable based on, but not limited to, the following:

- The applicant currently provides mobile PET services via a contract with Alliance. Developing a fixed PET scanner will allow the applicant to leverage the existing PET referral relationships and develop new referral relationships. Additionally, the applicant assumes the mobile contract will be terminated when the proposed fixed PET scanner is developed, thus providing an opportunity for maximizing additional referrals for fixed PET services.
- The applicant has an existing network of physicians in Henderson and Buncombe counties and has received letters of support from area physicians.
- The development of the proposed fixed PET scanner will increase access to PET services throughout western North Carolina. The applicant states current PET availability will increase from every other Sunday to five days per week, 50 weeks per year, an increase from approximately 26 days currently to 250 days annually.
- The applicant has been approved pursuant to CON Project ID #B-12233-22 to develop a new hospital in Asheville in Buncombe County (currently under appeal), which will likewise positively impact the projected continued growth of AdventHealth’s provider and referral network in the area.

Step 5: Project AdventHealth Hendersonville fixed PET procedures – To project the number of PET procedures to be performed at AdventHealth Hendersonville, the applicant applied the projected market share from *Step 4* to the projected PET demand from *Step 3*. In addition, the applicant states it has historically served approximately 2.5% of patients seeking PET services from other states, which is confirmed by the data in the applicant’s 2022 LRA. Therefore, the

applicant also projects a 2.5% in-migration of patients from other states will seek PET services on the fixed PET scanner at AdventHealth Hendersonville. The following table, from Section Q page 121, summarizes the projections:

AdventHealth Hendersonville Projected Fixed PET Procedures

COUNTY	PARTIAL YEAR 2025 (7/1-12/31)	PROJECT YEAR 1 CY 2026	PROJECT YEAR 2 CY 2027	PROJECT YEAR 3 CY 2028
Buncombe	137	194	414	551
Cherokee	0	5	11	23
Clay	0	2	4	9
Graham	1	5	29	12
Haywood	21	22	46	123
Henderson	173	329	438	606
Jackson	14	30	48	102
Macon	6	26	56	60
Madison	7	15	24	50
McDowell	14	30	48	101
Mitchell	5	10	16	33
Polk	14	27	42	59
Rutherford	21	66	93	172
Swain	2	10	52	22
Transylvania	24	46	74	104
Yancey	6	19	26	42
Total	445	836	1,421	2,069
2.5% in-migration*	11	21	36	52
Total	456	857	1,457	2,121

Source: Application Section Q page 121

*2.5% of total projected patients

Numbers may not sum due to rounding

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

- The applicant relies on historical utilization data on the mobile PET scanner with which it contracts to project future utilization of PET services.
- The applicant makes reasonable and conservative assumptions regarding projected PET utilization based on documented historical patient origin, market share, and population data.
- The projected utilization of the applicant’s proposed fixed PET scanner meets the Performance Standards in 10A NCAC 14C .3703.

Access to Medically Underserved Groups

In Section C.6, page 65, 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 AdventHealth Hendersonville, as clinically appropriate. AdventHealth does not discriminate based on race, ethnicity, age, gender, or disability. ...

The proposed new spaces will be accessible to persons with disabilities, as required by the Americans with Disabilities Act.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from Section C, page 66:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	14.0%
Racial and ethnic minorities	11.0%
Women	51.0%
Persons with Disabilities*	
Persons 65 and older	70.4%
Medicare beneficiaries	70.4%
Medicaid recipients	3.1%

*the applicant states it does not retain data that includes the number of disabled persons it serves and thus does not have a reasonable basis with which to estimate the percentage of disabled persons it proposes to serve.

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 all of AdventHealth Hendersonville services, including PET services, for all residents of the service area, including underserved groups.
- The applicant provides its projected payor mix, which includes underserved groups, based on its historical experience.

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
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP (hereinafter referred to as “the applicant” or “Mission Hospital”) proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP. Upon project completion, the applicant will be licensed for a total of two fixed PET scanners, one at the Mission Hospital SECU Cancer Center on the main hospital campus in Asheville and one at the hospital-based outpatient department approximately two miles from the main hospital campus.

Patient Origin

On page 360, the 2023 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 Buncombe County which, according to Appendix A on page 365 of the 2023 SMFP is in HSA I. Thus, the service area for this proposal is HSA I. Facilities may also serve residents of counties not included in their service area.

In Section C page 47, the applicant provides the following historical patient origin for the Mission SECU Cancer Center, where the current fixed PET scanner is located, for the last full fiscal year, CY 2022:

**Mission SECU Cancer Center
Historical Patient Origin, CY 2022**

COUNTY	# OF SCANS	% OF TOTAL
Buncombe	1,257	42.7%
Haywood	276	9.4%
Henderson	235	8.0%
McDowell	200	6.8%
Transylvania	152	5.2%
Madison	136	4.6%
Macon	117	4.0%
Yancey	101	3.4%
Jackson	82	2.8%
Mitchell	79	2.7%
Burke	60	2.0%
Clay	54	1.8%
Rutherford	51	1.7%
Swain	36	1.2%
Polk	22	0.7%
Cherokee	20	0.7%
Graham	10	0.3%
Avery	8	0.3%
Other NC Counties*	32	1.1%
Out of state	18	0.6%
Total	2,946	100.0%

*The applicant states in Section C page 47 that "other NC Counties" includes Alamance, Alexander, Ashe, Cabarrus, Caldwell, Catawba, Cleveland, Iredell, Lincoln, Mecklenburg, New Hanover and Watauga counties based on its internal data.

In Section C, page 48, the applicant projects patient origin for its proposed PET scanner for the first three project years, CYs 2025-2027, as shown in the table below:

**Mission SECU Cancer Center
 Projected Patient Origin, CY 2025-2027**

COUNTY	1 ST PY (CY 2025)		2 ND PY (CY 2026)		3 RD PY (CY 2027)	
	# OF SCANS	% OF TOTAL	# OF SCANS	% OF TOTAL	# OF SCANS	% OF TOTAL
Buncombe	675	42.7%	832	42.7%	912	42.7%
Haywood	148	9.4%	183	9.4%	200	9.4%
Henderson	126	8.0%	155	8.0%	170	8.0%
McDowell	107	6.8%	132	6.8%	145	6.8%
Transylvania	82	5.2%	101	5.2%	110	5.2%
Madison	73	4.6%	90	4.6%	99	4.6%
Macon	63	4.0%	77	4.0%	85	4.0%
Yancey	54	3.4%	67	3.4%	73	3.4%
Jackson	44	2.8%	54	2.8%	59	2.8%
Mitchell	42	2.7%	52	2.7%	57	2.7%
Burke	32	2.0%	40	2.0%	44	2.0%
Clay	29	1.8%	36	1.8%	39	1.8%
Rutherford	27	1.7%	34	1.7%	37	1.7%
Swain	19	1.2%	24	1.2%	26	1.2%
Polk	12	0.7%	15	0.7%	16	0.7%
Cherokee	11	0.7%	13	0.7%	15	0.7%
Graham	5	0.3%	7	0.3%	7	0.3%
Avery	4	0.3%	5	0.3%	6	0.3%
Other NC Counties*	17	1.1%	21	1.1%	23	1.1%
Out of state	10	0.6%	12	0.6%	13	0.6%
Total	1,583	100.0%	1,949	100.0%	2,137	100.0%

*The applicant states in Section C page 47 that "other NC Counties" includes Alamance, Alexander, Ashe, Cabarrus, Caldwell, Catawba, Cleveland, Iredell, Lincoln, Mecklenburg, New Hanover and Watauga counties based on its internal data.

In Section C, page 48, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on historical patient origin for existing PET services at Mission Hospital.

Analysis of Need

In Section C.4, pages 50-51, the applicant introduces its project as follows:

"The proposed project will alleviate existing capacity constraints for Mission oncology scans and patients, allowing for additional capacity to offer cardiac PET and other PET studies that are currently not offered to the service area. The following factors support the need for the project:

- *Mission's PET/CT utilization drove the need for an additional fixed PET scanner as published in the 2023 SMFP;*
- *There is steady population growth and significant aging in the service area;*

- *There is a growing incidence of cancer in the state and the service area;*
- *Oncologic and cardiac disease are top causes of death in North Carolina and Buncombe County, and these diseases are also clinical indicators for PET/CT;*
- *The existing PET/CT unit at Mission is experiencing capacity constraints and scheduling delays;*
- *Physicians report patient experience concerns related to PET/CT capacity constraints and scheduling delays and are concerned that such constraints may impact improvements in quality of care over time;*
- *There are no providers of cardiac PET/CT in the service area, leaving patients in the service area who could benefit from this service without adequate access to care; and*
- *Additional clinical applications of new radioisotopes are expanding the application of PET/CT imaging to additional cancer types, which will increase demand for additional oncology scan volume.”*

In Section C.4, pages 51-63, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services as summarized below:

- Service area definition and population trends – The applicant states Mission Hospital is the primary tertiary hospital in the service area, serving 18 counties. The applicant states the only other existing fixed PET scanner in the area is located in Catawba County, over 70 miles from the hospital. Messino Cancer Center was approved for a fixed PET scanner in 2021 and began offering services May 8, 2023 per Messino Cancer Center’s May 31, 2023 Progress Report. The area is also served by a mobile PET scanner several days per week.

The applicant cites population growth data from the North Carolina Office of State Budget and Management (NCOSBM) for the counties in the proposed service area for 2023-2028, which shows the overall population is projected to increase by 3.1%. Additionally, the applicant states that same data shows the population of the 65+ age group is projected to increase by 8.5% in the service area during the same time. The 65+ age group is more likely to utilize health care resources than other age groups, and is the group more likely to experience cardiac and oncological conditions. See the tables on pages 53 and 54 that illustrate the projected population growth in the service area and the state as a whole (pages 51-55).

- Chronic conditions and diseases that impact demand for PET services – The applicant states PET scanners are utilized to stage and diagnose many types of cancer and is also used to diagnose and image cardiac and brain function to detect abnormalities. The applicant cites data from the North Carolina Central Cancer Registry and the Center for Disease Control and Prevention from January 2022 that shows the age-adjusted incidence of cancer and the mortality rates from cancer in the counties that comprise the proposed service area. The data shows that both the incidence rate and the mortality rate for cancer in eight counties in the service area are higher than the incidence and

mortality rates in the state as a whole, which underscores the need for additional fixed PET services in the area. There is similar data regarding heart disease prevalence in the service area (pages 55-57).

- Advancements in PET technology and Prostate Specific Membrane Antigen (PMSA) PET imaging – The applicant notes that PET technology has advanced to the point of being able to pinpoint prostate cancer in men, including metastatic prostate cancer. PET scans are utilized for PMSA imaging to detect and diagnose prostate cancer in its early stages. Timely access to additional fixed PET services in the service area, given the high incidence of cancer and other diseases for which PET technology is appropriate is critical to diagnosis and treatment for Mission’s existing and projected patients. The applicant states Mission began providing PMSA PET scans in May 2022 and utilization has increased steadily since then (pages 57-60).
- Neuroendocrine and other cancer imaging with PET scanners – The applicant states PET imaging technology for the detection of neuroendocrine tumors (NETs), both benign and malignant is effective when the imaging utilizes a certain type of radiotracer, which Mission began implementing in 2018 and 2020. Since then, the applicant states NET PET volume has increased. The applicant describes the other types of cancers for which PET imaging is an important diagnostic tool, and states Mission can more effectively serve its existing and projected patients with an additional fixed PET scanner (pages 60-63).
- Mission’s PET utilization – The applicant states its existing fixed PET scanner is highly utilized, and in CY 2022, that unit was operating at 98.2% capacity. The applicant states there are long wait times and scheduling delays on the existing PET scanner, which negatively impacts patients. Patients who are diagnosed with cancer experience enough stress, states the applicant, without also having to deal with scheduling delays. The applicant provides support letters from area physicians and oncologists in Exhibit C-4.1 (pages 63-65).

Projected Utilization

In Section Q, Form C.2b, pages 136-137 the applicant provides projected utilization for the first three full FYs of operation, CYs 2025-2027 for its existing and proposed PET scanners, as illustrated in the following tables:

Mission Hospital SECU Cancer Center Projected PET Utilization

	1ST FULL FY (CY 2025)	2ND FULL FY (CY 2026)	3RD FULL FY (CY 2027)
# PET Scanners	1	1	1
Procedures	1,870	1,998	2,135

Source: Section Q, Form C.2b, page 136

Mission Hospital 5 Vanderbilt Drive Projected PET Utilization

	1ST FULL FY (CY 2025)	2ND FULL FY (CY 2026)	3RD FULL FY (CY 2027)
# PET Scanners	1	1	1
Procedures	1,583	1,949	2,137

Source: Section Q, Form C.2b, page 137

In Section C, pages 65-72 the applicant provides the assumptions and methodology used to project utilization, as summarized below:

Step 1: Projected growth in baseline utilization – The applicant analyzed historical PET utilization from 2018-2022, which yielded a 6.8% CAGR. The applicant states PET utilization continued to increase even through the COVID-19 pandemic; PET scans at Mission increased by 14.4% from 2018-2019. To project future growth in PET scans, the applicant applied the 6.8% historical CAGR for the first two interim years, CY 2023-2024 and to PYs 1-3, as shown in the following table from page 66:

	HISTORICAL UTILIZATION						INTERIM YEARS	
	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CAGR	CY 2023	CY 2024
Baseline PET/CT Scans	2,261	2,586	2,611	2,826	2,946	6.8%	3,148	3,363

Step 2: Shift of referral volume from Messino – The applicant states the Messino Cancer Center (Messino) fixed PET scanner was projected to be operational in May 2023. The applicant analyzed internal data to determine the number of referrals from Messino in 2022 and grew those referrals by 6.8% to project the shift of patients to Messino, and thus the volume of patients who would not be available to Mission. See the following table from application page 66:

Projected Referrals Lost to Messino PET

	2022	2023	2024
Messino Referrals	1,297	1,386	1,480
% Shift to New PET		65.0%	70.0%
# Scans Shift to New PET		901	1,036

Step 3: Incremental PSMA scan volume – The applicant began offering PSMA scans in May 2022, and states volume quickly ramped up thereafter. The applicant analyzed prostate cancer incidence by age groups 65 and under and 65+ to project future utilization, according to the following steps:

- The applicant obtained average historical population data from 2015-2019 from the NCOSBM.

- The applicant calculated the actual prostate cancer average annual cases by age group in the service area to determine a raw (non-age adjusted) incidence rate per 100,000 population for the same time period (2015-2019).
- The applicant used the incidence rate calculated as described above to project new cases for 2022-2027, by multiplying the rate by the projected population and dividing by 100,000 for each year and each age group.
- The applicant estimated the percentage of high to moderate risk patients likely to be referred for PSMA through discussions with Mission’s referring uro-oncologists, and compared that estimation with the rates of metastatic, non-local prostate cancer. The applicant used that rate to estimate the number of potential cases that would be at risk for metastatic prostate cancer, for whom PSMA PET scans would be appropriate.

Step 3A: Determine how many PSMA PET scans would be captured by Mission – The applicant states not all of the patients in the service area would be referred for PSMA; therefore, in order to determine the portion that Mission would serve, the applicant calculated a “capture rate” based on projected oncology demand in the service area for PET services versus the actual PET scans performed for all providers in the service area, using data from the 2021 service area population, the 2021 DHSR PET Patient Origin Report and the Advisory Board’s PET use rate per 100,000 population. The applicant divided the number of PET scans performed by the projected demand to calculate a capture rate of 70.6%. See the tables on page 68 that illustrate the calculations.

Step 3B: Determine recurrent cases and in-migration – The applicant differentiates recurrent PSMA scans from new patient scans based on its historical experience and determined that 50% of all cases are recurrent and 50% are new. The applicant states this percentage may be conservative, given that the rate of prostate cancer recurrence is 50% at 20 years post treatment. To project in-migration, the applicant relies on its historical experience on Mission’s existing PET scanner, which shows that in FY 2022, 1.1% of PET volume was from other NC counties, and 0.6% of PET volume was from out of state. See the following table from page 69 that summarizes Step 3B:

NEW CASE PSMA REFERRALS	2022	2023	2024
Age 65+	156	172	188
Under Age 65	52	56	60
Total New Service Area Case Referrals	207	227	248
Recurrent Cases	207	227	248
Total Service Area Cases	415	455	496
Other NC Counties	5	5	5
Out of State	3	3	3
Total Service Area Scans	422	463	504

Step 3C: Incremental PSMA PET scans – To determine the number of incremental PSMA PET scans, the applicant began with the actual number of PET scans performed at Mission in CY

2022 (237 PSMA scans). The applicant subtracted the CY 2022 scans from each of the interim years' projected total scans for each of the two interim years, CYs 2023 and 2024.

Step 4: Total oncology scans – The applicant used the numbers from *Steps 1-3* to project total oncology PET scans through the two interim years, CYs 2023-2024. The applicant projected the oncology scans to grow at the 6.8% growth rate calculated in *Step 1*. The table below, from application page 70, shows the interim years' projections:

	HISTORICAL 2018-2022 CAGR	INTERIM YEARS	
		CY 2023	CY 2024
Step 1: Baseline PET Scans	6.8%	3,148	3,363
Step 2: Shift to Messino PET		(901)	(1,036)
Adjusted Baseline Scans		2,247	2,326
Step 3: Incremental PSMA Scans		226	267
Step 4: Projected Oncology Scans		2,473	2,593

Step 4A: Project ramp up of oncology cases and distribution between Mission SECU Cancer Center and 5 Vanderbilt Drive – The applicant assumes a 20% ramp up at the 5 Vanderbilt Park location in month one of operation, followed by 5% per month thereafter, until volume at 5 Vanderbilt Park reaches 32.5% by the end of the first project year, CY 2025.

Step 5: Project cardiac PET scans – The applicant projects to provide cardiac PET scans in addition to the oncology scans on its proposed fixed PET scanner. To project the number of cardiac PET scans to be performed, the applicant analyzed population data from the NCOSBM for years 2025-2027 and applied the same capture rate calculated in *Step 3A*. To project in-migration for cardiac PET volume, the applicant applied the same percentages for “other NC counties” and “out of state” as it did with the PSMA PET volume, 1.1% and 0.6%, respectively. See the following table, from application page 71:

	2025	2026	2027
Population	938,011	943,914	949,300
Advisory Board Rate	1.30	1.58	1.64
Cases	1,219	1,492	1,558
Capture Rate	55.0%	65.0%	70.0%
Mission Cases	671	970	1,091
Other NC Counties	7	11	12
Out of State	4	6	7
Total Service Area Cardiac Scans	682	987	1,109

Step 6: Summary of total PET utilization by location – The applicant combined the projections from *Steps 4* and *5* to project total PET utilization at each of the two locations: the SECU Cancer Center and 5 Vanderbilt Drive, as shown in the following table:

Total Projected PET Utilization

	PY 1 CY 2025	PY 2 CY 2026	PY 3 CY 2027
Projected Oncology Scans	2,771	2,960	3,163
Projected Cardiac PET Scans	682	987	1,109
Total Mission PET/CT Scans	3,453	3,947	4,272

Step 6A: Projected PET utilization by location – Relying on the previously detailed steps, the applicant provided the following table to illustrate projected PET utilization by location for each of the three project years, CYs 2025-2027. See the following table, from application page 72:

Mission Health System Projected PET Utilization by Location

	PY 1 CY 2025	PY 2 CY 2026	PY 3 CY 2027
Mission SECU Cancer Center			
Projected Oncology/Neurology PET/CT Scans	2,771	2,960	3,163
% Redirected to Mission 5 Vanderbilt Park	32.5%		
# Scans Shifting to 5 Vanderbilt Park	901	962	1,028
PET/CT Scans Remaining at Mission SECU Cancer Center	1,870	1,998	2,135
Mission 5 Vanderbilt Park			
PET/CT Scans Redirected from Mission SECU Cancer Center	901	962	1,028
Projected New Cardiac PET/CT Scans	682	987	1,109
Total Mission 5 Vanderbilt Park PET/CT Scans	1,583	1,949	2,137
Total Mission Health System PET/CT Scans	3,453	3,948	4,272
Number of PET Units	2	2	2
Number of PET Scans / Unit	1,727	1,974	2,136

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

- The applicant relies on its own historical utilization data from its existing fixed PET scanner at Mission SECU Cancer Center to project future utilization of fixed PET services for oncology, cardiology and neurology.
- The applicant relies on utilization rates in the service area counties for cardiac PET scans and applies those to the population demographics of the service area to project cardiac PET utilization.
- The applicant relies on its own historical utilization data regarding prostate cancer imaging, particularly PSMA scans, combined with data from the NCOSBM to project future PSMA PET scans.
- The applicant makes reasonable and conservative assumptions regarding the growth of PET services in order to project PET utilization of its existing and proposed fixed PET scanner.

- The applicant relies on the demographics and health information for the state and the service area to project overall future PET utilization.
- The projected utilization of the applicant's existing and proposed fixed PET scanners meets the Performance Standards in 10A NCAC 14C .3703.

Access to Medically Underserved Groups

In Section C.6, page 78, the applicant states:

“The facility already demonstrates its service to all patients, regardless of gender, race, or ability to pay, by being one of the leading providers of indigent and charity care to patients seeking services in the region. The approval of this project will allow Mission to continue serving all patient populations.”

On page 78, 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*	6.3%
Racial and ethnic minorities	4.1%
Women	49.9%
Persons with Disabilities^	N/A
Persons 65 and older	68.0%
Medicare beneficiaries	70.4%
Medicaid recipients	4.7%

*The applicant states on Application page 78 that “low income persons” is a general category that often includes Medicaid recipients.

**The applicant states on Application page 78 that it does not track persons with disabilities as a category in any dataset.

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 projected access to the proposed PET services for all residents of the service area, including underserved groups, based on its internal historical data.
- The applicant provides its projected payor mix, which includes underserved groups.

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
- Remarks made at the public hearing

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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET 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.

B-12335-23 MH Mission Hospital, LLLP – 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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant proposes to acquire one fixed PET/CT scanner to be located on the AdventHealth Hendersonville campus pursuant to the need determination in the 2023 SMFP. Following project completion, the applicant would be licensed for one fixed PET scanner.

In Section E.2, pages 75-76, 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 it determined that maintaining status quo is not an effective alternative, because it would ignore the need identified in the 2023 SMFP for an additional fixed PET scanner in the service area and would deprive service

area residents of expanded access to acute care services. Therefore, the applicant states this is not an option.

- Develop the proposed fixed PET scanner at a different location – The applicant considered locating the proposed fixed PET scanner at the previously approved acute care hospital in Asheville, but since that project is currently under appeal it is on hold pending the outcome of the appeal and would further delay access to PET services for area residents. Additionally, the applicant states there is one fixed PET scanner at Mission Hospital in Asheville and one approved fixed PET scanner under development at Messina Cancer Center in Asheville. Thus, adding a third fixed PET scanner in Buncombe County would not enhance geographic access to PET services in HSA I and thus is not a reasonable alternative.
- Pursue a joint venture – The applicant states this is not an effective alternative because it did not have an opportunity for a joint venture to develop the proposed fixed PET scanner. Additionally, the applicant states AdventHealth possesses the experience and financial capability to develop the proposed fixed PET scanner in an efficient and cost-effective manner. Thus, a joint venture was determined to be a less 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 to meet the need for an additional fixed PET scanner in HSA I.
- 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
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of two fixed PET scanners.

In Section E.2, pages 88-89, the applicant describes the alternatives it considered and explains why those alternatives are either more costly or less effective than the alternative proposed in this application to meet the need for fixed PET services. The alternatives considered were:

- Maintain the status quo – the applicant states this is not a reasonable alternative because the current fixed PET scanner, at the SECU Cancer Center, experiences scheduling and capacity difficulties. The applicant states in CY 2022 the existing fixed PET scanner operated at 98.2% of capacity, and wait times were up to three weeks. The applicant states maintaining the status quo would not adequately address the current and projected demand for PET services in the service area; thus, this is not an effective alternative.
- Locating the proposed PET scanner at the main hospital campus – The applicant states locating the proposed PET scanner at the hospital is not a cost effective alternative because it would require more costly renovations to the existing building. Additionally, since Medicare does not reimburse PET services as inpatient services; therefore, the applicant states there is no patient care-related reason to locate the proposed fixed PET scanner in an acute inpatient setting.
- Locating the proposed PET scanner at the SECU Cancer Center – The applicant states it considered locating the proposed PET scanner at the Cancer Center but doing so would limit the proposed scanner's availability to serve increasing demand for cardiac PET scans. Cardiac PET scans require simultaneous use of stress testing, and the cancer center does not have adequate space to accommodate the necessary equipment. The applicant states cancer-related PET scans are able to be performed in a cardiovascular setting. Thus, locating the proposed fixed PET scanner in the existing SECU Cancer Center is not an effective alternative.

In Section C, page 89 the applicant states its proposal is the most cost effective alternative to meet the need because the proposed location is adjacent to the main Asheville Cardiology Associates clinic, thereby providing easy access to PET services. Additionally, the proposed location is an existing diagnostic center and has ample space to accommodate the proposed fixed PET scanner.

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 to meet the need for an additional fixed PET scanner in HSA I.
- 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
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant proposes to acquire one fixed PET/CT scanner to be located on the AdventHealth Hendersonville campus pursuant to the need determination in the 2023 SMFP. Following project completion, the applicant would be licensed for one fixed PET scanner.

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	\$1,086,675
Miscellaneous Costs	\$3,307,227
Total	\$4,393,902

In Section F.3, page 79, the applicant states there are no start-up costs or initial operating expenses associated with the project because the PET scanner will be developed as part of AdventHealth Hendersonville's existing hospital radiology department.

In Section Q, page 128 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 provides a letter signed by an architect in Exhibit K.3 that confirms the projected construction/renovation cost for the project.

- The applicant provides an equipment quote in Exhibit F-1 that confirms the equipment cost for the project.

Availability of Funds

In Section F.2, page 77, the applicant states that the capital cost will be funded as shown in the table below:

TYPE	FLETCHER HOSPITAL, INC.	TOTAL
Loans	\$0	\$0
Accumulated reserves, OE*, Cash/Cash Equivalents	\$4,393,902	\$4,393,902
Bonds	\$0	\$0
Other (internal revenue and/or credit)	\$0	\$0
Total Financing	\$4,393,902	\$4,393,902

*OE = Owner's Equity

In Exhibit F-2, the applicant provides a February 15, 2023 letter from the President and Chief Executive Officer of AdventHealth Hendersonville that documents the availability of sufficient funds to finance the capital cost and any initial operating expenses that may be incurred for proposed project. Exhibit F-2 also contains AdventHealth Hendersonville balance sheet as of December 31, 2022 that shows cash and cash equivalents in the amount of \$137,356,685 and total net assets of \$191,028,770.

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

- Exhibit F-2 contains a letter signed by the President and Chief Executive Officer of AdventHealth Hendersonville that documents the availability of sufficient funds to cover the capital cost and any associated costs for the proposed project. That letter also commits to use those funds to finance the proposed project.
- Exhibit F-2 contains a copy of AdventHealth Hendersonville's December 31, 2022 balance sheet that documents adequate available funds 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:

ADVENTHEALTH HENDERSONVILLE PET REVENUE AND EXPENSES

	1ST FY CY 2026	2ND FY CY 2027	3RD FY CY 2028
Total PET scans	858	1,457	2,124
Total Gross Revenues (Charges)	\$8,661,130	\$14,708,870	\$21,435,252
Total Net Revenue	\$1,840,490	\$3,125,635	\$4,554,991
Average Net Revenue per PET scan	\$2,145	\$2,145	\$2,146
Total Operating Expenses (Costs)	\$1,517,408	\$1,975,004	\$2,408,518
Average Operating Expense per PET scan	\$1,769	\$1,356	\$1,134
Net Income	\$323,082	\$1,150,631	\$2,146,473

Comments submitted by Mission Hospital, LLLP state that the Form F.2b for AdventHealth Hendersonville PET scanner services submitted with Fletcher Hospital, Inc.'s application appears to omit a line item in the spreadsheet for patient revenue from insurance. The same comments suggest that it could be a spacing error since the sum of total patient services gross revenue is consistent with the total gross revenue on the form. The Project Analyst reviewed the forms F.2b and F.3 and determined that the apparent error was an omission, since the gross revenue and patient services gross revenue are consistent.

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 AdventHealth Hendersonville's FY 2022 mobile PET services historical experience.
- The applicant bases projections for gross revenue on a weighted average of PET procedures for oncology, cardiology and PMSA prostate patients.
- 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
- Remarks made at the public hearing

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 AdventHealth Hendersonville’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.

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of two fixed PET scanners.

Capital and Working Capital Costs

In Form F.1a, Section Q, page 139 the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction / Renovation Costs	\$2,267,248
Miscellaneous Costs	\$3,412,846
Total	\$5,680,094

In Section Q, page 139 and referenced exhibits the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 92, the applicant states there are no start-up costs or initial operating expenses associated with the project because the PET scanner will be placed in an existing hospital outpatient department that is staffed and operational.

The applicant adequately demonstrates that the projected capital costs are based on reasonable and adequately supported assumptions based on the following:

- The applicant provides an architectural certified cost estimate in Exhibit F.1.1 that confirms the construction/renovation cost.
- The applicant bases its equipment costs on vendor estimates included in Exhibit F.1.2.

Availability of Funds

In Section F.2, page 90, the applicant states that the capital cost will be funded as shown in the table below:

TYPE	MH MISSION HOSPITAL, LLLP	TOTAL
Loans	\$0	\$0
Accumulated reserves, OE*, Cash/Cash Equivalents	\$5,680,094	\$0
Bonds	\$0	\$0
Other	\$0	\$0
Total Financing	\$5,680,094	\$5,680,094

*OE = Owner's Equity

Numbers have been rounded by the Project Analyst

In Exhibit F.2.1, the applicant provides February 8, 2023 letter from the Chief Financial Officer of HCA Healthcare, ultimate parent company to MH Mission Hospital, LLLP that documents HCA's commitment to providing funds through intercompany funding necessary for the project development and confirms the availability of sufficient funds for the project. Exhibit F.2.2 provides HCA's consolidated balance sheets for years ending December 31, 2020 and December 31, 2021 that confirms cash and cash equivalents in the amount of \$1.4 billion.

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

- Exhibit F.2.1 contains a letter from the Chief Financial Officer of HCA that documents sufficient funds and commits those funds to the project.
- The letter in Exhibit F.2.1 indicates HCA has revolving credit facilities in its network totaling \$3.64 billion and generated \$8.98 billion in cash flow from operations during the year ending December 31, 2021.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion for the proposed fixed PET scanner and for the two fixed PET scanners that will be operational (one at the SECU Cancer Center and one at 5 Vanderbilt Park). In Form F.2b, page 144 the applicant projects that revenues will exceed operating expenses in all three project years (CYs 2025-2027) at 5 Vanderbilt Park following project completion, as shown in the table below:

MISSION HOSPITAL PROPOSED PET SERVICES PROJECTED REVENUE AND EXPENSES, 5 VANDERBILT PARK

	1ST PY CY 2025	2ND PY CY 2026	3RD PY CY 2027
Total PET Procedures	1,583	1,949	2,137
Total Gross Revenues (Charges)	\$18,413,075	\$22,669,992	\$24,843,027
Total Net Revenue	\$3,975,477	\$4,882,155	\$5,348,658
Average Net Revenue per PET scan	\$2,511	\$2,505	\$2,503
Total Operating Expenses (Costs)	\$2,848,532	\$3,384,431	\$3,630,495
Average Operating Expense per PET scan	\$1,799	\$1,736	\$1,699
Net Income	\$1,126,945	\$1,497,724	\$1,718,163

Source: Forms C.2.b and F.2b, Section Q, pages 137 and 144 respectively
 Numbers may not sum due to rounding

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 of charges on historical PET gross revenue for CY 2022 and multiplying by projected volumes in Form C.2.b.
- The applicant bases projections for gross revenue on historical internal financial information from CY 2022.
- 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
- Remarks made at the public hearing

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 Mission Hospital'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 360, the 2023 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).” AdventHealth Hendersonville (Project ID #B-12331-23) proposes to locate the proposed fixed PET scanner in Henderson County, which is in HSA I. MH Mission Hospital, LLLP, (Project ID #B-12335-23) proposes to locate the proposed fixed PET scanner in Buncombe County, which is in HSA I. Thus, the service area for both proposals is HSA I. 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 I, 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 I			
TYPE	SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2020-2021
Fixed	Catawba Valley Medical Center/Frye Regional Medical Center	1	1,140
Fixed	Mission Hospital	1	2,808
Fixed	Messino Cancer Center*	1	0
Total HSA I fixed PET scanners		3	

*CON issued pursuant to Project ID #B-12059-21, effective February 2, 2022

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant proposes to acquire one fixed PET/CT scanner to be located on the AdventHealth Hendersonville campus pursuant to the need determination in the 2023 SMFP. Following project completion, the applicant would be licensed for one fixed PET scanner.

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 I, in addition to the need identified in the 2023 SMFP. The applicant states:

“AdventHealth Hendersonville will not unnecessarily duplicate any other facility in the service area. AdventHealth Hendersonville will offer patients a geographic

alternative to the existing and approved PET services in Buncombe County. As its historical patient origin indicates, patients currently travel from throughout western North Carolina to obtain PET procedures on AdventHealth's mobile PET scanner, which is available every other Sunday. With the proposed project, AdventHealth Hendersonville will offer a full-time access to fixed PET services, thus, facilitating timely access for a greater number of patients needing PET procedures. The proposed project also will offer a convenient, accessible alternative to Mission's enormous tertiary care hospital located on a congested campus. AdventHealth Hendersonville will be more convenient to patients in terms of traffic and ease of access compared to Mission's existing PET services."

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 2023 SMFP for the proposed fixed PET scanner in HSA I.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing or approved fixed PET scanners in HSA I.

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
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of two fixed PET scanners.

In Section G, pages 99-101, 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 I. In Section G, page 100 the applicant states:

"There is only one other existing provider of fixed PET services in HSA I, which is the Catawba Valley Medical Center/Frye Regional PET in Hickory, North Carolina. This location is over 70 miles from the Mission Hospital PET scanner, with a drive time of

more than one hour and fifteen minutes, and is not located in Mission's proposed service area. ... Mission Hospital PET volume from Catawba Valley/Frye Regional's Primary Service Area (PSA) for PET is 2.2% of Mission's total volume. Catawba Valley/Frye Regional PET volume from Mission Hospital's PSA is 9.3% of its total PET volume.

While Mission is currently the only provider of PET procedures on a fixed scanner in Buncombe County and the surrounding counties, Messino Cancer Center projects to open its approved PET scanner in May 2023. That said, with the continued projected population growth and the use of PET in the diagnosis and treatment of cancer patients, along with the anticipated explosive growth of PET in serving cardiovascular patients, Mission Hospital believes capacity constraints of PET services at Mission Hospital will continue to be significant."

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 2023 SMFP for the proposed fixed PET scanner in HSA I.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing or approved fixed PET scanners in HSA I.

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
- Remarks made at the public hearing

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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant proposes to acquire one fixed PET/CT scanner to be located on the AdventHealth

Hendersonville campus pursuant to the need determination in the 2023 SMFP. Following project completion, the applicant would be licensed for one fixed PET scanner.

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

POSITION	1ST FULL FY (CY 2026)	2ND FULL FY (CY 2027)	3RD FULL FY (CY 2028)
Registered Nurse	1.00	1.00	1.00
PET Technologist	2.25	2.25	2.25
Total	4.25	4.25	4.25

The assumptions and methodology used to project staffing are provided in Section Q, page 129. 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 Sections 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 hospital staffing and providing PET services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of two fixed PET scanners.

In Section Q, Form H, page 156 the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

Projected Staffing

POSITION	CURRENT (AS OF 1/31/22)	1 ST FULL FY	2 ND FULL FY	3 RD FULL FY
Radiology Technologist	2	4	4	4
RN	0	1	1	1
Total*	2	5	5	5

*In the staffing chart I Form H, Section Q, the applicant totaled the three project year FTEs to 4; the Project Analyst checked the "Form H Staffing Assumptions" and concluded that the insertion of the number 4 was a typographical error, because the calculations in the Staffing Assumptions are consistent with a total of 5: four radiology technicians and one RN.

The assumptions and methodology used to project staffing are provided in Section Q, page 156. 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 Sections H.2 and H.3, pages 102-105, 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 the existing hospital and existing fixed PET services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant proposes to acquire one fixed PET/CT scanner to be located on the AdventHealth

Hendersonville campus pursuant to the need determination in the 2023 SMFP. Following project completion, the applicant would be licensed for one fixed PET scanner.

Ancillary and Support Services

In Section I, page 90 the applicant identifies the necessary ancillary and support services for the proposed fixed 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 currently utilized by AdventHealth Hendersonville and states the same providers will be available for the proposed fixed PET services.
- The applicant provides a letter in Exhibit I.1 from Hendersonville Radiological Consultants, PA which confirms an existing relationship with AdventHealth Hendersonville for radiological services and an intent to expand those services to PET/CT services.

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 PET services on a mobile PET scanner in the service area and has established relationships with local healthcare and social services providers, which will be in place in the proposed fixed PET scanner 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
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of two fixed PET scanners.

Ancillary and Support Services

In Section I, page 106 the applicant identifies the necessary ancillary and support services for the proposed PET services. On pages 106-107, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.1. 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 for existing PET services and states the same providers will be available for the proposed additional fixed PET services.

Coordination

In Section I, page 108 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 fixed PET 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
- Remarks made at the public hearing

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

B-12331-23 Fletcher Hospital, 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.

Project ID #B-12335-23 MH Mission Hospital, LLLP - 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.

- (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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT 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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant proposes to acquire one fixed PET/CT scanner to be located on the AdventHealth Hendersonville campus pursuant to the need determination in the 2023 SMFP. Following project completion, the applicant would be licensed for one fixed PET scanner.

In Section K, page 93 the applicant states that the project involves constructing 2,966 square feet of new space and renovation of existing space in which the proposed fixed PET scanner will be located, which the applicant states will be co-located with existing oncology services. Line drawings are provided in Exhibit K-1.

In Section K, page 93 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 architect based the design and construction cost on a review of the project and costs of similar projects, published construction cost data, and the architect's experience with similar projects.
- The applicant states that the proposed co-location of the PET scanner with existing oncology services will help ensure the most reasonable design and cost alternative to ensure access to its patients.

In Section K, page 94 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 it relies on its experience developing and operating PET services to ensure that the size and scope of the proposed project are consistent with the need the population has for the proposed fixed PET scanner.
- The applicant states the project will not increase charges or projected reimbursement for the proposed services, which are established by Medicare, Medicaid and/or existing private payor contracts.

In Section K, page 94 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
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of two fixed PET scanners.

In Section K, page 111 the applicant states that the project involves renovating 3,536 square feet of existing space in its existing HOPD on Vanderbilt Drive. Line drawings are provided in Exhibit K-2.1.

On page 111, 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 requires only interior renovation to existing space which is more cost effective than new construction.
- The applicant states the space to be renovated was vetted against other existing space to minimize the square footage of renovation that would be needed to accommodate the proposed fixed PET scanner.

On page 112, 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 renovation costs will be controlled by competitively bidding the construction contract to obtain the best market price.
- The applicant states project development costs will be lessened by renovating existing space rather than incurring costs of property acquisition and land development.

In Section K, page 112 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
- Remarks made at the public hearing

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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – In Section L, page 97, the applicant provides the historical payor mix for CY 2022 for the entire AdventHealth Hendersonville campus, as shown in the following table:

AdventHealth Hendersonville Historical Payor Mix, CY 2022

PAYOR SOURCE	% OF TOTAL
Self-Pay	3.7%
Charity Care*	-
Medicare**	54.9%
Medicaid**	9.1%
Insurance**	29.3%
Other^	3.0%
Total	100.0%

Numbers may not sum due to rounding

*The applicant states "charity care" is included in self-pay

**Includes managed care plans

^The applicant states "other" includes VA, Tricare, Workers Compensation and other government payors.

In Section L, page 98, 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	62.9%	51.7%
Male	37.1%	48.3%
Unknown	0.0%	0.0%
64 and Younger	53.4%	73.4%
65 and Older	46.6%	26.6%
American Indian	0.1%	0.7%
Asian	0.4%	1.3%
Black or African American	2.6%	3.4%
Native Hawaiian or Pacific Islander	0.1%	0.3%
White or Caucasian	56.2%	82.5%
Other Race	36.9%	12.8%
Declined / Unavailable	3.7%	-

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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.

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – In Section L, page 115, the applicant provides the historical payor mix for Mission SECU Cancer Center for CY 2022, as shown in the following table:

Mission SECU Cancer Center Historical Payor Mix, CY 2022

PAYOR SOURCE	% OF TOTAL
Self-Pay	0.8%
Charity Care	0.8%
Medicare*	70.4%
Medicaid*	4.7%
Insurance*	20.1%
TRICARE	0.3%
Other^	3.0%
Total	100.0%

Numbers may not sum due to rounding

*Includes managed care plans

^The applicant states on page 115 that "other" includes "Other Fed, Non-M'aid State"

In Section L, page 116, 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	49.9%	51.8%
Male	50.1%	48.2%
Unknown	0.0%	0.0%
64 and Younger	32.0%	79.0%
65 and Older	68.0%	21.0%
American Indian	0.4%	0.6%
Asian	0.4%	1.5%
Black or African American	3.1%	6.2%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	95.9%	82.9%
Other Race	0.0%	2.3%
Declined / Unavailable	0.2%	-

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

B-12331-23 Fletcher Hospital, 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 99, the applicant states it has no such obligation to provide uncompensated care.

In Section L, page 99, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina..

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP - 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 117, the applicant states it has no such obligation to provide uncompensated care.

In Section L, page 119, the applicant provides the following information:

“In September of 2021, a surgeon affiliated with Asheville Surgery Center, a department of Mission Hospital, cancelled a scheduled procedure because the patient was exhibiting aggressive behavior. The patient subsequently filed a complaint with The U.S. Department of Justice, alleging a violation of the Americans With Disabilities Act, claiming to suffer from PTSD and anxiety. A State investigation followed in March of 2022 with no substantiated deficiencies cited. In June of 2022, the matter was referred by the DOJ to Key

Bridge Foundation with a request that Mission participate in a mediation to achieve resolution of the matter. Mission willingly agreed to do so and provided to Keybridge all requested information. The matter is currently pending, awaiting the mediation.

In February of 2022, the mother of a 7-year-old patient who was transported to the Mission Hospital Emergency Department complained to the Joint Commission that when her son arrived at the Mission ED, there was no in-person interpreter for her hearing-impaired son, as she reportedly had requested in advance. Instead, Mission utilized a VRI method of interpreting and the device apparently functioned intermittently with some interruptions. The patient's mother alleged that the incident was a violation of the Americans With Disabilities Act. In response, Mission implemented a multi-layered Systems Improvement Plan that included an investigation of the incident; further education of appropriate staff; upgrading of applicable educational modules; staff meetings and training on technology called Culturalink as a stopgap measure when in-person interpreters are not immediately available; updating of all available interpreter information; and IT improvements; among other measures. Effective April 22, 2022, the Joint Commission notified Mission that based upon its response to the complaint and its Systems Improvement Plan, the matter had been closed without further action by The Joint Commission."

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – In Section L, page 100, 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 AdventHealth Hendersonville campus and the proposed fixed PET scanner as shown in the tables below:

**AdventHealth Hendersonville Campus
 Projected Payor Mix CY 2028**

PAYOR SOURCE	% OF TOTAL
Self-Pay	3.7%
Charity Care*	-
Medicare**	54.9%
Medicaid**	9.1%
Insurance**	29.3%
Other^	3.0%
Total	100.0%

Numbers may not sum due to rounding

*The applicant states "charity care" is included in self-pay

**Includes managed care plans

^The applicant states "other" includes VA, Tricare, Workers Compensation and other government payors.

**AdventHealth Hendersonville Fixed PET Services
 Projected Payor Mix CY 2028**

PAYOR SOURCE	% OF TOTAL
Self-Pay	0.8%
Charity Care*	-
Medicare**	70.4%
Medicaid**	3.1%
Insurance**	23.8%
Other^	2.0%
Total	100.0%

Numbers may not sum due to rounding

*The applicant states "charity care" is included in self-pay

**Includes managed care plans

^The applicant states "other" includes VA, Tricare, Workers Compensation and other government payors.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.7% of total services at AdventHealth Hendersonville will be provided to self-pay patients, 54.9% to Medicare patients and 3.0% to Medicaid patients. Additionally, the applicant projects that during the third full fiscal year of operation, 0.8% of total fixed PET services at AdventHealth Hendersonville will be provided to self-pay patients, 70.4% to Medicare patients and 3.1% to Medicaid patients.

In Section L, page 100, 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 2022 payor mix at AdventHealth Hendersonville.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – In Section L, page 120, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project for PET services at both the SECU Cancer Center and 5 Vanderbilt Drive, as shown in the tables below:

5 Vanderbilt Drive Projected Payor Mix, CY 2027

PAYOR SOURCE	% OF TOTAL
Self-Pay	0.8%
Charity Care	0.8%
Medicare*	70.4%
Medicaid*	4.7%
Insurance*	20.1%
TRICARE	0.3%
Other^	3.0%
Total	100.0%

Numbers may not sum due to rounding

*Includes managed care plans

^The applicant states on page 115 that “other” includes “Other Fed, Non-M’aid State”

SECU Cancer Center Projected Payor Mix, CY 2027

PAYOR SOURCE	% OF TOTAL
Self-Pay	0.8%
Charity Care	0.8%
Medicare*	70.4%
Medicaid*	4.7%
Insurance*	20.1%
TRICARE	0.3%
Other^	3.0%
Total	100.0%

Numbers may not sum due to rounding

*Includes managed care plans

^The applicant states on page 115 that “other” includes “Other Fed, Non-M’aid State”

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.8% of total PET services will be provided to self-pay patients, 70.4% to Medicare patients and 4.7% to Medicaid patients.

On page 120, 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 CY 2022 payor mix for PET services at Mission 5 Vanderbilt Drive.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – In Section L, page 102, 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
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner –In Section L, page 122, 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
- Remarks made at the public hearing

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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant proposes to acquire one fixed PET/CT scanner to be located on the AdventHealth Hendersonville campus pursuant to the need determination in the 2023 SMFP. Following project completion, the applicant would be licensed for one fixed PET scanner.

In Section M, pages 103-104, the applicant describes the extent to which health professional training programs in the area currently have access to AdventHealth Hendersonville and will continue to have access to the facility for training purposes, including for the proposed fixed PET services. 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:

- AdventHealth Hendersonville is an existing hospital and has existing relationships and established agreements with numerous professional training programs, listed on pages 103-104. The applicant states those relationships and agreements will continue to operate after the addition of the proposed fixed PET scanner.
- Exhibit M-1 contains an example of one of the existing clinical education agreements currently in place AdventHealth Hendersonville, which will be applicable to the proposed additional fixed PET scanner services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to written comments
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of two fixed PET scanners.

In Section M, pages 123-125, the applicant describes the extent to which health professional training programs in the area currently have and will continue to have access to the facility for training purposes. 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:

- Mission Hospital has a history of supporting health professional training programs in the community.
- The applicant states it will continue to offer those same programs after the addition of the proposed fixed PET scanner.
- The applicant provides a copy of an existing clinical education agreement in Exhibit M-1.1

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to written comments
- Remarks made at the public hearing

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 360, the 2023 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 Henderson County which, according to Appendix A on page 365 of the 2023 SMFP is in HSA I. Thus, the service area for this proposal is HSA I. 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 I, and the number of procedures for each PET scanner in 2020-2021 as found in Table 17F-1 on page 362 of the 2023 SMFP:

Fixed PET Scanners HSA I			
TYPE	SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2018-2019
Fixed	Catawba Valley Medical Center/Frye Regional Medical Center	1	1,140
Fixed	Mission Hospital	1	2,808
Fixed	Messino Cancer Center*	1	0
Total		3	3,948

*CON issued pursuant to Project ID #B-10259-21, effective February 2, 2022

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant proposes to acquire one fixed PET/CT scanner to be located on the AdventHealth Hendersonville campus pursuant to the need determination in the 2023 SMFP. Following project completion, the applicant would be licensed for one fixed PET scanner.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 105, the applicant states:

“The proposed project will have a positive effect on competition in the service area because it will promote cost-effectiveness, quality, and access to services for residents. Furthermore, the proposed project will allow AdventHealth to create a new point of access for fixed PET services in western North Carolina providing more choices for patients to receive high-quality health care close to home.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 105, the applicant states:

“The Value Basic Principle governing the 2023 State Medical Facilities Plan states long-term enhancement of health care value will result from a State Medical Facilities

Plan that promotes a balance of competition and collaboration and encourages innovation in healthcare delivery. The need determination for one additional fixed PET scanner in Health Service Area I presents an opportunity to promote enhanced competition, collaboration, and encourage innovation.

AdventHealth's goal is to provide the highest-quality care while containing costs for patients. AdventHealth utilizes several strategies to meet this objective."

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

Regarding the impact of the proposal on quality, in Section N, pages 105-106, the applicant states:

"To deliver high-quality at a lower cost, AdventHealth has developed an ambulatory care management model to address the needs of high- and rising-risk patients. This model is a whole-person approach to managing chronic illness, eliminating gaps in care, reducing fragmentation, and improving communication while focusing on the needs of the patient and working collaboratively with physicians. Highly trained nurse health coaches support AdventHealth physicians by reinforcing treatment plans for population patients with high- and rising-risk patients."

...

AdventHealth also participates in value-based payment models. AdventHealth has recently partnered with Cedar Gate Technologies, a leading value-based care performance management company, to assess commercial bundled payment program opportunities for multiple specialty service lines. Bundled payments provide a clear path to value by bringing payers, providers, and employers to the table to agree on a reimbursement model that alleviates financial pressures and incentivizes [sic] based on patient outcomes.

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 107-108 the applicant states:

*"In total, AdventHealth invested **\$1.31 Billion** (emphasis in original) in community investments during 2021..."*

...

*In North Carolina, AdventHealth Hendersonville's 2020 Community Benefit totaled **\$45.57 Million** (emphasis in original). ...*

...

AdventHealth Hendersonville will continue 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 patient as underserved. AdventHealth's financial assistance policy will apply to the proposed services."

See also Sections B, C and L 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
- Remarks made at the public hearing

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

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of two fixed PET scanners.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 126, the applicant states:

“Overall, the proposed project will enhance competition as it relates to Mission Hospital’s provision of advanced and specialized services in western North Carolina. As the major tertiary referral hospital in the region, Mission Hospital competes with other tertiary systems both inside and outside of North Carolina. While the proposed PET unit at Mission’s Cardiovascular Diagnostic Center will largely serve to expand access to an existing base of patients, it will also serve to enhance competition in the broader region by providing a needed service, the closest of which is now 2-6 hours away.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 127, the applicant states:

“The project is cost effective for cancer patients who will, upon approval and implementation of this project, be able to receive a PET scan in a timely fashion, thereby avoiding potential treatment delays and possible negative outcomes that can add to the cost of care. Another potential cost savings is associated with the improved diagnostic capabilities of PET/CT scans for patients with several types of cardiovascular conditions. ...

...

The proposed project will foster cost containment and improve quality of care through efficient design and implementation. As discussed throughout this application, the additional PET scanner will be placed in the existing location at 5 Vanderbilt Park Drive, which provides diagnostic services as a department of Mission Hospital. As outlined in Section E, placing the PET scanner at this location is the most cost-effective option for the project as it is an existing ambulatory facility with available space.”

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

Regarding the impact of the proposal on quality, in Section N, page 128, the applicant states:

“The addition of a new PET scanner at 5 Vanderbilt Park Drive will improve the quality of health services offered to the community by improved access to specialized equipment that will facilitate the diagnosis and treatment planning of cancerous tumors in conjunction with Mission Hospital’s oncology services.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 128 states:

“The additional PET scanner will provide Mission Hospital the flexibility to meet current and future demands for comprehensive cancer services and cardiovascular services in the region. It will also ensure that residents of the health service area have timely access to high quality, affordable diagnostic imaging.”

See also Sections 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
- Remarks made at the public hearing

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

B-12331-23 Fletcher Hospital, Inc. – Acquire one fixed PET/CT scanner – The applicant proposes to acquire one fixed PET/CT scanner to be located on the AdventHealth Hendersonville campus pursuant to the need determination in the 2023 SMFP. Following project completion, the applicant would be licensed for one fixed PET scanner.

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 one existing licensed facility located in North Carolina. In addition, the applicant was conditionally approved pursuant to Project ID #B-12233-22 to develop a new 67-bed hospital pursuant to the need determination in the 2022 SMFP with one dedicated C-section OR and five procedure rooms. That project is currently under appeal.

In Section O, page 111 the applicant states that it is not aware of any deficiencies in quality of care that occurred at AdventHealth Hendersonville during the 18 months immediately preceding the submittal of the application. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred at AdventHealth Hendersonville. 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 AdventHealth Hendersonville, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID #B-12335-23 MH Mission Hospital, LLLP - Acquire one fixed PET/CT scanner – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for a total of two 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 six hospitals located in North Carolina.

In Section O, page 131 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 six 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.

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 fixed PET scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

(1) *identify the existing fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed fixed PET scanner service area;*

-NA- AdventHealth Hendersonville. Neither the applicant nor any related entity owns or operates any existing fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.

-C- MH Mission Hospital, LLLP. The applicant responded to a prior version of these Rules, and thus did not provide a response to this subsection. However, in Section C, page 37, the applicant states it has one existing fixed PET scanner located at its Mission SECU Cancer Center on the main Mission Hospital campus in Asheville, in Buncombe County.

(2) *identify the approved fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed fixed PET scanner service area;*

-NA- AdventHealth Hendersonville. Neither the applicant nor any related entity has been approved to own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.

-NA- MH Mission Hospital, LLLP. The applicant responded to a prior version of these Rules, and thus did not provide a response to this subsection. However, in Section C, page 37 the applicant describes its existing fixed PET scanner and the fixed PET scanner proposed in this application. The Project Analyst concludes, based on the information in the application and in the 2023 SMFP, that neither the applicant nor any related entity has been approved to own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.

(3) *identify the existing mobile PET scanners owned or operated by the applicant or a related entity that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period;*

-NA- AdventHealth Hendersonville. Neither the applicant nor any related entity owns or operates any mobile PET scanners that provided services at host sites located in the proposed fixed PET

scanner service area during the 12 months before the application deadline for the review period. The applicant contracts with Alliance Imaging for mobile PET services, and the mobile PET scanner that provides PET services is operated by Alliance Imaging.

-NA- MH Mission Hospital, LLLP. The applicant responded to a prior version of these Rules, and thus did not provide a response to this subsection. However, in Section C, page 37 the applicant describes its existing fixed PET scanner and the fixed PET scanner proposed in this application. The Project Analyst concludes, based on the information in the application and in the 2023 SMFP, that neither the applicant nor any related entity owns or operates any mobile PET scanners that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period.

(4) identify the approved mobile PET scanners owned or operated by the applicant or a related entity that will provide services at host sites located in the proposed fixed PET scanner service area;

-NA- AdventHealth Hendersonville. Neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that will provide services at host sites located in the proposed fixed PET scanner service area.

-NA- MH Mission Hospital, LLLP. The applicant responded to a prior version of these Rules, and thus did not provide a response to this subsection. However, in Section C, page 37 the applicant describes its existing fixed PET scanner and the fixed PET scanner proposed in this application. The Project Analyst concludes, based on the information in the application and in the 2023 SMFP, that neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period.

(5) provide projected utilization of the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner during each of the first three full fiscal years of operation following completion of the project;

-NA- AdventHealth Hendersonville. Neither the applicant nor any related entity owns or operates or has been approved to own or operate any fixed or mobile PET scanners in the proposed fixed PET scanner service area or in North Carolina.

-C- MH Mission Hospital, LLLP. The applicant responded to a prior version of these Rules, and thus did not provide a response to this subsection. However, in Section Q, Form C.2b, the applicant provides projected utilization for its existing fixed PET scanner and the fixed PET scanner proposed in this application.

(6) provide assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph; and

- NA- **AdventHealth Hendersonville.** Neither the applicant nor any related entity owns or operates or has been approved to own or operate any fixed or mobile PET scanners in the proposed fixed PET scanner service area or in North Carolina.

- C- **MH Mission Hospital, LLLP.** The applicant responded to a prior version of these Rules, and thus did not provide a response to this subsection. However, in Section C, pages 65-72 the applicant provides assumptions and methodology used to project utilization of the existing and proposed fixed PET scanners.
 - (7) *project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.*

- C- **AdventHealth Hendersonville.** In Section Q, Form C.2b, page 115 the applicant projects that the proposed fixed PET scanner will perform 2,124 procedures on the proposed fixed PET scanner during the third full fiscal year of operation following project completion.

- C- **MH Mission Hospital, LLLP.** The applicant responded to a prior version of these Rules, and thus did not provide a response to this subsection. However, in Section C, page 80 and in Section Q, Form C.2b, the applicant projects that the existing fixed PET scanner shall perform 2,135 procedures during the third full fiscal year of operation, and the proposed fixed PET scanner shall perform 2,137 procedures during the third full fiscal year of operation following project completion.

- (b) *An applicant proposing to acquire a mobile PET scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*
 - (1) *identify the existing mobile PET scanners owned or operated by the applicant or a related entity that provided services at host sites located in the proposed mobile PET scanner service area during the 12 months before the application deadline for the review period;*
 - (2) *identify the approved mobile PET scanners owned or operated by the applicant or a related entity that will provide services at host sites located in the proposed mobile PET scanner service area during the first three full fiscal years following completion of the project;*
 - (3) *identify the existing fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed mobile PET scanner service area;*
 - (4) *identify the approved fixed PET scanners owned and operated by the applicant or a related entity and located in the proposed mobile PET scanner service area;*
 - (5) *identify the existing and proposed host sites for each mobile PET scanner identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile PET scanner;*
 - (6) *provide projected utilization of the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile PET scanner during each of the first three full fiscal years of operation following completion of the project;*

- (7) *provide the assumptions and methodology used to project the utilization required by Subparagraph (6) of this Paragraph; and*
- (8) *project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.*

-NA- AdventHealth Hendersonville. The applicant does not propose to acquire a mobile PET scanner.

-NA- MH Mission Hospital, LLLP. The applicant does not propose to acquire a mobile PET scanner.

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 I 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 I, 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 #B-12331-23 Fletcher Hospital, Inc.** – Acquire one fixed PET scanner to be located at AdventHealth Hendersonville pursuant to the need determination in the 2023 SMFP. Following project completion, AdventHealth Hendersonville would be licensed for one fixed PET scanner.
- **Project ID #B-12335-23 / MH Mission Hospital, LLLP** – Acquire 1 fixed PET/CT scanner pursuant to the need determination in the 2023 SMFP for a total of no more than two fixed PET/CT scanners upon project completion.

Conformity with 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

Regarding scope of services, both applications were submitted in response to the need determination for one fixed PET scanner in HSA I in the 2023 State Medical Facilities Plan (SMFP). Generally, the application proposing to provide the broadest scope of services with the proposed equipment is the more effective alternative regarding this comparative factor.

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
Fletcher Hospital, LLC	X	X	X
MH Mission Hospital, LLLP	X	X	X

Both applicants propose to provide PET services to oncology, cardiac and neurologic patients. Therefore, regarding scope of services, both applications are equally effective.

Historical Utilization

The following table illustrates historical utilization of the existing fixed PET scanners in HSA I as provided in the 2023 SMFP representing FY 2021 reported utilization:

Fixed PET Scanners in HSA I

FACILITY	# OF FIXED PET SCANNERS	2021 PET PROCEDURES PER SCANNER
Catawba Valley Medical Center/Frye Regional MC	1	1,140
Mission Hospital	1	2,808
Messino Cancer Center*	1	0

Source: 2023 SMFP

*Not yet operational. Approved pursuant to CON Project ID# B-12059-21, February 2, 2022.

The following table illustrates historical utilization of the existing fixed PET scanners in HSA I as provided in the 2022 SMFP representing FY 2020 reported utilization:

Fixed PET Scanners in HSA I

FACILITY	# OF FIXED PET SCANNERS	2020 PET PROCEDURES PER SCANNER
Catawba Valley Medical Center/Frye Regional MC	1	0
Mission Hospital	1	2,695

Source: 2022 SMFP

MH Mission Hospital, LLLP is the only applicant who is also a current and historical provider of fixed PET services in HSA I in this review and thus performed the highest number of procedures per fixed PET scanner in FY 2021 and FY 2020. It is Mission Hospital's reported utilization in FY 2021 that triggered a need in the 2023 SMFP for an additional fixed PET scanner in HSA I. Therefore, regarding historical utilization, the application submitted by **MH Mission Hospital, LLLP** is the more effective alternative.

Geographic Accessibility (Location within the Service Area)

The 2023 SMFP identifies the need for one fixed PET scanner in HSA I, which includes 26 counties. Following is a table that illustrates the location of the existing and approved fixed PET scanners in HSA I:

Fixed PET Scanners in HSA I

FACILITY	CITY	COUNTY
Catawba Valley Medical Center/Frye Regional Medical Center	Hickory	Catawba
Mission Hospital	Asheville	Buncombe
Messino Cancer Center*	Asheville	Buncombe

*Messino Cancer Center was awarded a Certificate of Need for one fixed PET scanner on February 2, 2022 pursuant to Project ID #B-12059-21.

Two of the three existing or approved fixed PET scanners in HSA I are located or will be located in Asheville in Buncombe County. The other existing fixed PET scanner is located in Hickory, in Catawba County, approximately 77 miles and 1.25 hours driving time¹ from Asheville.

MH Mission Hospital, LLLP proposes to locate its PET scanner in Asheville at its 5 Vanderbilt Drive location, less than two miles from the existing fixed PET scanner located at the main hospital on Biltmore Avenue in Asheville. Additionally, Messino Cancer Center has been approved to locate a fixed PET scanner less than six miles from the existing fixed PET scanner at Mission Hospital in Asheville. **Fletcher Hospital, Inc.** proposes to locate its PET scanner in the radiology department at the main hospital located in Hendersonville in Henderson County, to the south of Asheville and Buncombe County. It is reasonable to conclude that the PET scanner proposed by **Fletcher Hospital, Inc.** would provide more access to patients who live outside of Asheville and/or Buncombe County, in other counties that comprise HSA I. The other fixed PET scanner in HSA I, at Catawba Valley Medical Center, is located in Catawba County, east of Buncombe County. Henderson County is south of Buncombe County. **Fletcher Hospital, Inc.** proposes to provide fixed PET services at a location that is not currently served by any fixed PET scanners and would thus offer fixed PET services to a larger portion of patients residing in HSA I who reside outside of Buncombe County, where there are two fixed PET scanners available. Therefore, regarding this comparative factor, the proposal submitted by **Fletcher Hospital, Inc.** is the more effective alternative, since it proposes to locate the proposed PET scanner in an area that would serve more patients in the southern portion of HSA I not currently served by a fixed PET scanner. The application submitted by **MH Mission Hospital, LLLP** would be less effective, because it proposes to locate the fixed PET scanner in Asheville, less than two miles from an existing fixed PET scanner and less than six miles from an approved fixed PET scanner.

Access by Service Area Residents

On page 360, the 2023 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.” According to Appendix A, HSA I is comprised of 26 counties, including Buncombe, Catawba and Henderson. **Fletcher Hospital, Inc.** proposes to locate the fixed PET scanner in Hendersonville, in Henderson County. **MH Mission Hospital, LLLP** proposes to locate its fixed PET scanner in Asheville, in Buncombe County. Thus, the service area for each proposal is HSA I. Facilities may also serve residents of counties not included in their service

¹

https://www.google.com/search?q=distance+from+hickory+nc+to+asheville+nc&rlz=1C1GCEA_enUS895US895&oq=distance+from+hickory+nc+to+asheville+nc&aqs=chrome.0.0i512j0i390i650.8718j0j7&sourceid=chrome&ie=UTF-8

area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional fixed PET services in or in close proximity to the service area in which they live. Each applicant proposes to serve counties located within HSA I and outside of HSA I. This analysis will focus on service to residents of counties within HSA I, the service area in which a need determination exists.

On page 38 of its application, **Fletcher Hospital, Inc.** states it proposes to offer PET services in 16 of the 26 HSA I counties. The other NC counties and out of state areas comprising its proposed service area are not being considered for this comparative factor.

On page 48 of its application, **MH Mission Hospital, LLLP** states it proposes to offer PET services in 18 of the 26 HSA I counties. The other NC counties and out of state areas comprising its proposed service area are not being considered for this comparative factor.

Each applicant provides the projected number of service area patients to be served in each of the fiscal years following project completion. The Project Analyst prepared the following table to illustrate the projected number of service area patients to be served by each applicant in each applicant's three project years following project completion:

Projected HSA I Service Area Patients by Provider

HSA I COUNTY	FLETCHER HOSPITAL, INC.			MH MISSION HOSPITAL, LLLP		
	PY 1 CY 2026	PY 2 CY 2027	PY 3 CY 2028	PY 1 CY 2025	PY 2 CY 2026	PY 3 CY 2027
Avery	0	0	0	4	5	6
Buncombe	194	414	551	675	832	912
Burke	0	0	0	32	40	44
Cherokee	5	11	23	11	13	15
Clay	2	4	9	29	36	39
Graham	5	29	12	5	7	7
Haywood	22	46	123	148	183	200
Henderson	329	438	606	126	155	170
Jackson	30	48	102	44	54	59
Macon	26	56	60	63	77	85
Madison	15	24	50	73	90	99
McDowell	30	48	101	107	132	145
Mitchell	10	16	33	42	52	57
Polk	27	42	59	12	15	16
Rutherford	66	93	172	27	34	37
Swain	10	52	22	19	24	26
Transylvania	46	74	104	82	101	110
Yancey	19	26	42	54	67	73
Total SA Patients	836	1,421	2,069	1,556	1,916	2,100

Source: B-12331-23: Application page 38; B-12335-23: Application page 48

Fletcher Hospital, Inc. projects to serve fewer residents from counties in the service area than **MH Mission Hospital, LLLP**. However, each of the applicants identifies a category (“*other*”) that includes residents from other counties and other states. The Project Analyst is unable to discern, from the information provided by each applicant, which counties are included in “*other*” that may be part of the defined service area. Therefore, regarding this comparative factor, the results are 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 two underserved groups: Medicare patients and Medicaid patients. Access by each group is evaluated as a separate factor.

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, since the provision of Medicaid can indicate an applicant’s provision of care to medically underserved groups.

PROJECTED MEDICAID			
PROJECT YEAR 3, PET SERVICES			
	Medicaid Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
Fletcher Hospital, Inc.	\$664,493	\$21,435,252	3.1%
MH Mission Hospital, LLLP	\$996,719	\$24,843,027	4.0%

Source: Section Q, Forms F.2.b for each application.

As shown in the table above, **MH Mission Hospital, LLLP** 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, the application submitted by **MH Mission Hospital, LLLP** 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 since the provision of Medicare can indicate an applicant’s provision of care to medically underserved groups.

PROJECTED MEDICARE PROJECT YEAR 3, PET SERVICES			
	Medicare Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
Fletcher Hospital, Inc.	\$15,090,418	\$21,435,252	70.4%
MH Mission Hospital, LLLP	\$17,381,207	\$24,843,027	70.0%

Source: Section Q, Forms F.2.b for each application.

As shown in the table above, **Fletcher Hospital, Inc.** projects the highest percentage of gross revenue for PET services that will be provided to Medicare patients in the third year of operation. However, **MH Mission Hospital, LLLP** projects the highest dollar amount of service to Medicare patients. Therefore, regarding this comparative factor, both applications are equally effective.

Competition (Access to a New or Alternate Provider)

Generally, the application proposing to increase competition in the service area is the more effective alternative regarding this comparative factor. The introduction of a new provider in the service area would be the more 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. **Fletcher Hospital, Inc.** represents a new provider of fixed PET services in HSA I. Furthermore, the application submitted by **MH Mission Hospital, LLLP** proposes to develop its fixed PET scanner in Asheville, which is currently served by one existing fixed PET scanner and will be served by an approved fixed PET scanner. Therefore, regarding this comparative factor, the application submitted by **Fletcher Hospital, Inc.** is the more effective alternative because it introduces a new provider of fixed PET services in the service area; specifically in a town and a county within the service area not currently served by fixed PET services.

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 project, 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
Fletcher Hospital, Inc.	2,124	\$4,554,991	\$2,145
MH Mission Hospital, LLLP	2,137	\$5,348,658	\$2,503

Source: Section Q, Forms F.2.b for each application.

As shown in the table above, **Fletcher Hospital, Inc.** projects the lowest average net revenue per PET procedure in the third full fiscal year following project completion. Therefore, the application submitted by **Fletcher Hospital, Inc.** 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
Fletcher Hospital, Inc.	2,124	\$2,408,518	\$1,134
MH Mission Hospital, LLLP	2,137	\$3,630,495	\$1,699

Source: Section Q, Forms F.2.b for each application.

As shown in the table above, **Fletcher Hospital, Inc.** projects the lowest average operating cost per PET procedure in the third full fiscal year following project completion. Therefore, the application submitted by **Fletcher Hospital, Inc.** 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	FLETCHER HOSPITAL, INC.	MH MISSION HOSPITAL, LLLP
Conformity with Statutory and Regulatory Review Criteria	Yes	Yes
Scope of Services	Equally Effective	Equally Effective
Historical Utilization	Less Effective	More Effective
Geographic Accessibility (Location within the Service Area)	More Effective	Less Effective
Access by Service Area Residents	Inconclusive	Inconclusive
Access by Medicaid Patients	Less Effective	More Effective
Access by Medicare Patients	Equally Effective	Equally Effective
Competition (Access to a New or Alternate Provider)	More Effective	Less Effective
Projected Average Net Revenue per PET Procedure, 3 rd PY	More Effective	Less Effective
Projected Average Operating Cost per PET Procedure, 3 rd PY	More Effective	Less Effective

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

- Geographic Accessibility (Location within the Service Area)
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per PET Procedure in the third project year
- Projected Average Operating Cost per PET Procedure in the third project year

The application submitted by **MH Mission Hospital, LLLP** was determined to be a more effective alternative regarding the following factors:

- Historical Utilization
- Access by Medicaid Patients

DECISION

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **Fletcher Hospital, Inc.** is the more effective alternative proposed in this review for the development of one additional fixed PET scanner in HSA I pursuant to the need determination in the 2023 SMFP.

Fletcher Hospital, Inc. proposes to acquire one fixed PET/CT scanner pursuant to the need determination in the 2023 SMFP. The application submitted by **Fletcher Hospital, Inc.** is approved subject to the following conditions:

1. **Fletcher Hospital, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP, to be located at the main hospital campus at 100 Hospital Drive in Henderson, for a total of no more than one fixed PET scanner.**

3. 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. The first progress report shall be due on December 1, 2023.
4. 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.
 5. 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.

The application submitted by **MH Mission Hospital, LLLP** is denied.