

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 13, 2021

Findings Date: September 13, 2021

Project Analyst: Kim Meymandi

Co-Signer: Gloria C. Hale

### COMPETITIVE REVIEW

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Project ID #: B-12057-21  
Facility: Mission Hospital – 5 Vanderbilt Park Drive  
FID #: 210276  
County: Buncombe  
Applicant(s): MH Mission Hospital, LLLP  
Project: Acquire one fixed PET/CT scanner pursuant to the need determination in the 2021 SMFP

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Project ID #: B-12059-21  
Facility: Messino Cancer Centers  
FID #: 210261  
County: Buncombe  
Applicant(s): American Oncology Partners, P.A.  
Project: Develop a new diagnostic center by acquiring no more than one fixed PET/CT scanner pursuant to the need determination in the 2021 SMFP

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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 all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

## REVIEW CRITERIA

G.S. 131E § 183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

### C-Both Applications

#### **Need Determination**

The 2021 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional positron emission tomography (PET) scanners in North Carolina by service area. Application of the need methodology in the 2021 SMFP identified a need for one additional fixed PET scanner in Health Service Area I (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 scanners. However, pursuant to the need determination, only one additional fixed PET scanner may be approved in this review.

#### **Policies**

There are two policies in Chapter 4 of the 2021 SMFP applicable to the applications received in response to the Buncombe County PET scanner need determination.

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

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

Policy GEN-3 applies to both applications in this review.

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 29 of the 2021 SMFP, states:

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

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

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

Policy GEN-4 applies to both applications in this review.

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

**MH Mission Hospital, LLLP (Mission Hospital)**, the applicant, proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP. Mission Hospital currently owns and operates a PET/CT scanner at Mission Hospital State Employees Credit Union (SECU) Cancer Center located on the main campus of Mission Hospital. Therefore, at the completion of this project, Mission Hospital would have a total of two fixed PET/CT scanners.

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

**Policy GEN-3.** In Section B.2, pages 30-33, the applicant explains why it believes its application is conforming to Policy GEN-3. On pages 30-33, the applicant states:

*“The new PET scanner at Mission Hospital will improve the safety and quality of health services offered to the community by improving access to specialized equipment that will facilitate the diagnosis and treatment planning of cancerous tumors in conjunction with mission hospital’s oncology services.*

....

*Mission Hospital will provide robust financial assistance to individuals with no insurance, high deductible insurance, or coinsurance plans without sacrificing quality of service - just as it has historically done in order to meet the health care needs of low-income individuals.*

....

*The proposed PT will provide maximum health care value for the resources expended because the facility will have the ability to work with HCA's experienced architects and engineers to develop the proposed project."*

**Policy GEN-4.** The proposed capital expenditure is greater than \$2 million but less than \$5 million. In Section B.2, pages 33-34, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant states that efforts to improve energy efficiency and reduce consumption include:

- Working with experienced architects and engineers to ensure the use of energy efficient systems
- Optimizing existing space with interior renovations to limit the disruption of outside areas
- Utilization of new, more efficient equipment, environmentally preferable products, and practices
- Replacement of plumbing fixtures with new fixtures certified to meet low flow criteria of the Environmental Protection Agency (EPA) and comply with NC Energy Conservation Codes

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant does not propose to acquire more fixed PET scanners than are determined to be needed in the service area.

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of PET scanner services;
  - The applicant adequately documents how the project will promote equitable access to PET scanner services; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

American Oncology Partners, P.A. (AOP), the applicant, proposes to acquire one fixed PET scanner to be located at Messino Cancer Centers, creating a new non-hospital licensed diagnostic center to be located at an existing oncology medical office clinic located at 551 Brevard Road, Asheville, Buncombe County pursuant to the need determination in the 2021 SMFP. Messino Cancer Centers, a division of AOP, does not currently offer PET services in North Carolina.

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

**Policy GEN-3.** In Section B.2, pages 28-34, the applicant explains why it believes its application is conforming to Policy GEN-3. On pages 28-34, the applicant states:

*“The project will promote safety and quality in the delivery of PET scans. The proposed PET scanner will be accredited by the American College of Radiology’s (ACR) Nuclear Medicine Accreditation Program. ACR accreditation ensures the quality and safety of patient care in radiology.*

....

*AOP is committed to promoting equitable access in the delivery of PET services. AOP will not deny health care to any patient solely based on age, race, sex, or ability to pay.*

.....

*AOP’s proposed project will maximize healthcare value in two primary ways: (1) through cost-effective design and construction, and (2) by offering a lower-cost PET service than now exists in HSA I.”*

**Policy GEN-4.** The proposed capital expenditure is greater than \$2 million. In Section B.2, page 35, the applicant describes the project's plan to improve energy efficiency and conserve

water. The applicant states that efforts to improve energy efficiency and reduce consumption include:

- Engaging professionals to ensure the space meets all government requirements for energy efficiency and water conservation
- Monitoring utility and water usage
- Utilizing equipment and products consistent with energy efficiency and water conservation

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

### **Conclusion**

The Agency reviewed the:

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

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

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

(2) Repealed effective July 1, 1987.

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

C-Both Applications

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive /  
Acquire one fixed PET/CT scanner**

**Mission Hospital** proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP. The existing PET scanner at Mission Hospital is used for oncology and neurology patients. Upon completion of this project, the applicant would have a total of two fixed PET scanners. The applicant plans to use the proposed PET scanner for oncology and neurology patients as well as for cardiac services.

**Patient Origin**

On page 367, the 2021 SMFP defines the service area for a fixed PET scanner as “*the HSA [Health Service Area] in which it is located (Table 17F-1).*” The applicant proposes to locate the dedicated fixed PET scanner in Buncombe County, which is in HSA I. Thus, the service area for this facility is HSA I. HSA I consists of 26 counties in the western region of the state. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 44, the applicant provides historical patient origin for PET services provided at Mission Hospital for the last full operating year (CY2020), as summarized in the table below.

<b>Mission Hospital PET Services</b>		
<b>County</b>	<b>Last Full FY (1/1/2020 – 12/31/2020)</b>	
	<b># of Patients</b>	<b>% of Total</b>
Buncombe	1,136	43.5%
Henderson	239	9.2%
McDowell	195	7.5%
Haywood	175	6.7%
Transylvania	153	5.9%
Madison	111	4.3%
Yancey	110	4.2%
Macon	95	3.6%
Jackson	78	3.0%
Mitchell	62	2.4%
Burke	48	1.8%
Swain	40	1.5%
Rutherford	38	1.5%
Cherokee	21	0.8%
Polk	21	0.8%
Graham	15	0.6%
Avery	11	0.4%
Clay	9	0.3%
Other NC Counties*	18	0.7%
Out of State	36	1.4%
<b>Total</b>	<b>2,611</b>	<b>100.0%</b>

\*Other NC Counties includes: Clay, Catawba, Cleveland, Wake, Ashe, Gaston, Mecklenburg, and Rowan

The following table illustrates projected patient origin for the proposed PET Scanner at 5 Vanderbilt Park Drive.

<b>Mission Hospital-5 Vanderbilt Park</b>						
<b>County</b>	<b>1<sup>st</sup> Full FY CY2023</b>		<b>2<sup>nd</sup> Full FY CY2024</b>		<b>3<sup>rd</sup> Full FY CY2025</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Buncombe	727	39.9%	790	40.0%	856	40.1%
Henderson	184	10.1%	199	10.1%	214	10.0%
McDowell	60	3.3%	65	3.3%	70	3.3%
Haywood	122	6.7%	132	6.7%	143	6.7%
Transylvania	124	6.8%	135	6.8%	146	6.8%
Madison	100	5.5%	108	5.5%	117	5.5%
Macon	26	1.4%	28	1.4%	30	1.4%
Yancey	49	2.7%	53	2.7%	56	2.6%
Burke	68	3.7%	74	3.7%	80	3.7%
Jackson	69	3.8%	75	3.8%	82	3.8%
Rutherford	64	3.5%	68	3.5%	73	3.4%
Mitchell	27	1.5%	29	1.5%	32	1.5%
Swain	67	3.7%	73	3.7%	79	3.7%
Cherokee	11	0.6%	12	0.6%	12	0.6%
Polk	12	0.6%	13	0.6%	14	0.6%
Avery	22	1.2%	23	1.2%	25	1.2%
Graham	40	2.2%	43	2.2%	47	2.2%
Clay	13	0.7%	14	0.7%	15	0.7%
Other NC Counties*	13	0.7%	14	0.7%	15	0.7%
Out of State	25	1.4%	27	1.4%	29	1.4%
<b>Total</b>	<b>1,822</b>	<b>100.0%</b>	<b>1,975</b>	<b>100.0%</b>	<b>2,136</b>	<b>100.0%</b>

Source: Section C.3, page 45

\*Other NC Counties includes: Clay, Catawba, Cleveland, Wake, Ashe, Gaston, Mecklenburg, and Rowan

Totals may not foot due to rounding

The following table summarizes projected patient origin for the PET scanner at the Mission Hospital Main Campus and the proposed PET scanner at 5 Vanderbilt Park combined for the first three full fiscal years of operation:

<b>Mission Hospital Main Campus and Mission Hospital-5 Vanderbilt Park Combined</b>						
<b>County</b>	<b>1<sup>st</sup> Full FY CY2023</b>		<b>2<sup>nd</sup> Full FY CY2024</b>		<b>3<sup>rd</sup> Full FY CY2025</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Buncombe	1,591	41.8%	1,732	41.8%	1,883	41.9%
Henderson	365	9.6%	397	9.6%	431	9.6%
McDowell	120	3.1%	130	3.1%	141	3.1%
Haywood	255	6.7%	278	6.7%	301	6.7%
Transylvania	272	7.1%	296	7.2%	322	7.2%
Madison	216	5.7%	235	5.7%	255	5.7%
Yancey	42	1.1%	45	1.1%	49	1.1%
Macon	78	2.1%	84	2.0%	91	2.0%
Jackson	141	3.7%	153	3.7%	166	3.7%
Burke	154	4.0%	167	4.0%	182	4.1%
Mitchell	100	2.6%	108	2.6%	116	2.6%
Rutherford	57	1.5%	62	1.5%	68	1.5%
Swain	151	4.0%	164	4.0%	179	4.0%
Cherokee	18	0.5%	19	0.5%	21	0.5%
Polk	23	0.6%	25	0.6%	27	0.6%
Graham	38	1.0%	41	1.0%	44	1.0%
Avery	87	2.3%	94	2.3%	103	2.3%
Clay	22	0.6%	24	0.6%	25	0.6%
Other NC Counties*	26	0.7%	29	0.7%	31	0.7%
Out of State	52	1.4%	57	1.4%	62	1.4%
<b>Total</b>	<b>3,809</b>	<b>100.0%</b>	<b>4,141</b>	<b>100.0%</b>	<b>4,496</b>	<b>100.0%</b>

Source: Section C.3, page 46

\*Other NC Counties includes: Clay, Catawba, Cleveland, Wake, Ashe, Gaston, Mecklenburg, and Rowan

Totals may not foot due to rounding

In Section C, page 45, the applicant provides the assumptions and methodology used to project its patient origin which is based on the patient origin of existing oncology and neurology PET patients at the Mission Hospital main campus and the addition of the projected cardiac PET scans calculated in Section C, page 63.

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

**Analysis of Need**

In Section C.4, pages 47-64, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- There is a need determination in the 2021 SMFP for one additional fixed PET scanner in HSA I.
- Steady population growth and significant aging in the service area - The applicant cites data from the North Carolina Office of State Budget and Management (NCOSBM) to illustrate that the service area is projected to increase by 4.1% from 2021 to 2026, with the 65 and older population growing at a rate of 11.0%. The applicant states that the elderly population uses health care resources at a higher rate than other groups and oncologic, neurologic, and cardiac conditions are most common in middle aged to elderly age groups, thereby creating a higher demand for PET/CT services (pages 50-51).
- The leading causes of death in North Carolina and Buncombe County are attributable to oncologic, cardiac, and neurological disease which are all clinical indicators for the use of a PET scanner. The applicant provides information from the Centers for Disease Control and Prevention (CDC) which shows that in North Carolina the first and second leading causes of death are cancer and heart disease. The fifth and sixth leading causes are stroke and heart disease. Information from the North Carolina State Center for Health Statistics, 2018 shows the cause of death rankings in Buncombe County are similar to those of the state with cancer and heart disease being ranked one and two and cerebrovascular disease and Alzheimer's disease ranking fifth and sixth (pages 52-54).
- The existing PET scanner at Mission Hospital is experiencing capacity constraints and scheduling delays. The applicant provides 2017-2020 PET/CT volume for the existing PET scanner at the SECU Cancer Center to illustrate a 9% annual growth rate and states that the unit is operating at 87% capacity. The applicant states that in March 2021 the average wait time for a routine PET scan was 10 business days and for more advanced PET scans the wait time is 21 business days (pages 58-59).
- Mission physicians are concerned that the capacity and scheduling constraints will affect patient experience and may, over time also impact quality of care (page 59). In Exhibit C, the applicant provides eight letters of support from area oncologists, cardiologists, and radiologists, which state that an additional PET scanner will help reduce wait time and improve overall quality of care and patient satisfaction.
- There are no providers of cardiac PET/CT in the service area, leaving those patients who could benefit from this service without adequate access to care. The applicant cites the growing use of PET scans in the screening, diagnosis and management of cardiac disease and states that without the provision of cardiac PET in the service area, patient access to quality care will be limited (pages 56-57).
- 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. The applicant states that these new clinical applications allow for the early detection of initial and recurrent prostate cancer and the detection of neuroendocrine tumors (NETs). The applicant also notes the superiority as well as the

ongoing advances being made in utilizing PET imaging to diagnose and treat cardiac and neurological conditions (pages 55-58).

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

- There is a need determination in the 2021 SMFP for one additional PET scanner in HSA I, which includes Buncombe County.
- The applicant uses reasonable and clearly identified historical and demographic data to make assumptions with regard to identifying the population to be served, its projected growth, and the need the identified population has for the proposed services.
- The applicant provides reasonable information to support the need for an additional PET scanner at the Mission Hospital - 5 Vanderbilt Park location based on documented historical utilization and future plans for expanded diagnostic and treatment use of the unit.

Projected Utilization

In Section Q, Form C, the applicant provides historical and projected utilization, as illustrated in the following tables:

**Historical and Interim Utilization**

	LAST FULL FY CY 2020	INTERIM FULL FY CY 2021	INTERIM FULL FY CY 2022
# PET Scanners	1	1	1
# Procedures	2,611	2,846	3,102

**Projected Utilization**

	1 <sup>ST</sup> FULL FY CY 2023	2 <sup>ND</sup> FULL FY CY 2024	3 <sup>RD</sup> FULL FY CY 2025
<b>Mission Hospital 5 Vanderbilt Park</b>			
# PET Scanners	1	1	1
# Procedures	1,822	1,975	2,135
<b>Mission Hospital SECU and 5 Vanderbilt Park</b>			
# PET Scanners	2	2	2
# Procedures	3,809	4,141	4,496

In Section C4, pages 58-64, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins projecting the utilization of oncology/neurology scans by using the historical compound annual growth rate (CAGR) of 9% derived from the historical utilization of PET scans from 2017-2020. The applicant notes that this is a conservative CAGR given that PET scans grew at a 13.3% CAGR from 2017-2019 and increased more than 14% from 2018 to 2019. The historical and projected total oncological and neurological PET scans are show in the table below.

Historical					Interim Years		Project Years		
CY 2017	CY 2018	CY 2019	CY 2020	3 Year CAGR	CY 2021	CY 2022	Year 1 CY 2023	Year 2 CY 2024	Year 3 CY 2025
2,016	2,261	2,586	2,611	9.0%	2,846	3,102	3,382	3,686	4,018

- The applicant states that in 2020 Mission Hospital, on average, saw 148 new patients per month. They are assuming a ramp-up of 20% in Month 1 for the proposed PET unit at Mission Hospital-5 Vanderbilt Park with an additional 5% ramp-up each month thereafter until the balance of new patients between both sites reaches 50%. The applicant projects that between Month 7 and the end of the first 12 months of operation the ramp-up will level off and remain at 50% as shown in the tables below found on page 61.

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
<b>Projected Ramp-Up</b>												
<b>Mission Cancer Center</b>	80%	75%	70%	65%	60%	55%	50%	50%	50%	50%	50%	50%
<b>Mission 5 Vanderbilt Park</b>	20%	25%	30%	35%	40%	45%	50%	50%	50%	50%	50%	50%
<b>Projected Patients per Month</b>												
<b>Mission Cancer Center</b>	225	211	197	183	169	155	141	141	141	141	141	141
<b>Mission 5 Vanderbilt Park</b>	56	70	85	99	113	127	141	141	141	141	141	141

**Year 1 Oncology/Neurology Scans by Location**

Mission Cancer Center	1,987
Mission-5 Vanderbilt Park	1,395
<b>Total Year 1 Oncology/Neurology Scans</b>	<b>3,382</b>
<b>% Scheduled at Mission 5 Vanderbilt Park</b>	<b>41.3%</b>

- The applicant projects cardiac PET scan utilization using 2019 data from two providers of significant cardiac PET volume in the state, Rex Healthcare (Rex) and University of North Carolina Hospitals (UNC) since there are no cardiac PET scan providers in HSA I. The 2019 UNC/Rex use rate for persons 65 and older per 100,000 population is used in Year 1 for Mission’s new PET/CT service and then increased by an assumed rate of 5% for Years 2 and 3. The applicant states these rates are very conservative when compared to the projected use rates for Mission’s 18-county service area according to the Advisory Board. The information used by the applicant in this step is provided on pages 62-63 and shown in the tables below.

**REX and UNC Cardiac PET  
 2019 Cardiac PET Use Rates per 100,000 Population**

<b>Orange and Wake Counties</b>	<b>2019</b>
Age 65+ use rate	144.23
Under age 65 use rate	15.20
<b>Contiguous Counties</b>	
Age 65+ use rate	93.42
Under age 65 use rate	26.01

Source: Hidi Analytics

**Projected Mission Service Area Cardiac PET  
 Use Rates per 100,000 Population**

	<b>2023</b>	<b>2024</b>	<b>2025</b>
<b>Orange and Wake Counties</b>			
Age 65+ use rate	144.23	151.44	159.02
Under age 65 use rate	15.20	15.96	16.76
<b>Contiguous Counties</b>			
Age 65+ use rate	93.42	98.09	102.99
Under age 65 use rate	26.01	27.31	28.67

Source: Hidi Analytics, NCOSBM

**Mission 18-County Service Area Cardiac PET Use Rates According to Advisory Board**

<b>PET Type</b>	<b>Use Rate per 100,000 Population</b>			<b>5-Year Change</b>	<b>10-Year Change</b>
	<b>2019</b>	<b>2024</b>	<b>2029</b>		
Myocardial PET	73	129	170	76.5%	132.3%

Source: Advisory Board

- To calculate the projected cardiac PET volume by county, the applicant applies the UNC/Rex cardiac PET home county use rates to Mission’s home county of Buncombe County and applies the contiguous counties use rates to the remaining counties in the service area as shown in the table below.

**Mission Hospital Total Projected Cardiac PET Volume by County**

	<b>CY 2023</b>	<b>CY 2024</b>	<b>CY 2025</b>
Buncombe	126	135	142
Henderson	56	60	63
Jackson	19	20	21
Haywood	29	31	32
McDowell	20	21	22
Transylvania	18	19	20
Cherokee	15	16	16
Rutherford	29	31	32
Macon	18	19	20
Madison	10	11	11
Burke	38	40	42
Swain	6	6	6
Yancey	8	9	9
Clay	6	6	7
Graham	4	4	4
Polk	11	11	12
Mitchell	7	7	7
Avery	8	8	8
<b>Total</b>	<b>418</b>	<b>446</b>	<b>468</b>

Source: Hidi Analytics; North Carolina Office of State Budget and Management (NCOSBM), 2019

- Based on historical patient origins, and the fact that cardiac PET scans are not currently offered in the service area and are highly specialized, the applicant conservatively assumes an in-migration of 2% for cardiac PET. The following table, as found on page 64 of the application, summarizes the Mission Health System projected PET utilization.

**Summary of Projected PET Utilization for Mission Health System**

	Year 1 CY 2023	Year 2 CY 2024	Year 3 CY 2025
<b>Mission SECU Cancer Center</b>			
Projected Oncology/Neurology PET/CT Scans	3,382	3,686	4,018
% Redirection to Mission 5 Vanderbilt Park	41.3%		
PET/CT Scans Shifted Mission 5 Vanderbilt Park	1,395	1,520	1,657
PET/CT Scans remaining at Mission SECU Cancer Center	1,987	2,166	2,361
<b>Mission 5 Vanderbilt Park</b>			
PET/CT Scans Redirected from SECU Cancer Center	1,395	1,520	1,657
Projected New Cardiac PET/CT Scans	418	446	468
Cardiac PET/CT in-migration (2%)	9	9	10
Total Mission 5 Vanderbilt Park PET/CT Scans	1,822	1,975	2,135
<b>Total Mission Health System PET/CT Scans</b>	<b>3,809</b>	<b>4,141</b>	<b>4,496</b>
Number of Units	2	2	2
Number of Scans per Unit	1,905	2,070	2,248

Numbers may not foot due to rounding

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

- The applicant relies on historical data from utilization of the existing PET scanner currently in use at Mission SECU Cancer Center to project future utilization of PET services for oncology and neurology.
- The applicant relies on utilization rates in Wake and Orange counties for cardiac PET scans and applies those to the population demographics of the service area to project cardiac PET utilization.
- The applicant makes reasonable and conservative assumptions regarding the growth of cardiac PET service in order to project PET utilization of the existing and proposed PET scanner.
- The applicant relies on the demographics and health information for the state and Buncombe County to project overall future PET utilization.
- The projected utilization of the applicant’s existing and proposed PET scanners meets the Performance Standards in 10A NCAC 14C .3703.

**Access to Medically Underserved Groups**

In Section C.6, page 69, the applicant states:

*“The additional PET scanner will provide equitable access to services for patients that are both under insured and not insured. As a leader in the medical fields of oncology and cardiovascular services, and because Mission Hospital is the only provider of*

*advanced services in the region, Mission serves all citizens in the region regardless of their ability to pay.*

.....

*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.”*

The applicant provides the estimated percentage for each medically underserved group, during the third full fiscal year of the project, as shown in the following table from page 70:

<b>Medically Underserved Groups</b>	<b>Percent of Total Patients</b>
Low Income Persons	2.3%*
Racial and ethnic minorities	4.2%
Women	50.5%
Persons with Disabilities**	--
The elderly (persons 65 and older)	65.3%
Medicare beneficiaries	66.5%
Medicaid recipients	4.7%

\*Includes charity and self-pay patients only

\*\*Mission does not track

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

### **Conclusion**

The agency reviewed the:

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

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

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP, creating a new non-hospital licensed diagnostic center in space it currently leases as medical office space at 551 Brevard Road in Asheville, Buncombe County.

**Patient Origin**

On page 367, the 2021 SMFP defines the service area for a fixed PET scanner as “the HSA [Health Service Area] in which it is located (Table 17F-1).” The applicant proposes to locate the dedicated fixed PET scanner in Buncombe County, which is in HSA I. Thus, the service area for this facility is HSA I. Facilities may also serve residents of counties not included in their service area.

The proposed facility has no historical patient origin to report since it does not currently provide the proposed services. In Section C, page 39, the applicant provides projected patient origin for the proposed diagnostic center for the first three full fiscal years of operation:

COUNTY	1 <sup>ST</sup> FULL FY CY 2023		2 <sup>ND</sup> FULL FY CY 2024		3 <sup>RD</sup> FULL FY CY 2025	
	# Pts	% OF TOTAL	# Pts	% OF TOTAL	# Pts	% OF TOTAL
Buncombe	683	40.2%	778	40.2%	879	40.2%
Macon	121	7.1%	138	7.1%	155	7.1%
Henderson	119	7.0%	136	7.0%	154	7.0%
Haywood	118	6.9%	134	6.9%	152	6.9%
McDowell	100	5.9%	114	5.9%	129	5.9%
Jackson	100	5.9%	114	5.9%	129	5.9%
Transylvania	99	5.8%	112	5.8%	127	5.8%
Yancey	79	4.7%	90	4.7%	102	4.7%
Other*	280	16.5%	318	16.5%	360	16.5%
<b>Total</b>	<b>1,699</b>	<b>100.0%</b>	<b>1,934</b>	<b>100.0%</b>	<b>2,187</b>	<b>100.0%</b>

\*Other includes: Madison, Mitchell, Swain, Graham, Burke, Rutherford, Clay, Cherokee, Avery, Polk, Wake, Cleveland, Gaston, Catawba, Rowan & Ashe counties, and specific cities in TN, GA, SC, FL, AL, VA as identified on page 39 of the application.

In Section C, page 38, the applicant provides the assumptions and methodology used to project patient origin. The applicant states projected patient origin is based on the historical patient origin of Messino Cancer Center patients referred out for PET scans. The applicant assumes patient origin from referring physicians in and around the Asheville area will remain generally the same as Messino Cancer Centers’ historical patient origin. The applicant’s assumptions are reasonable and adequately supported, based on the following:

- The applicant bases the projected patient origin on the historical patient origin of Messino Cancer Centers.
- The applicant increases the number of projected future patients based on a reasonable growth rate attributable to the addition of the proposed service.

## **Analysis of Need**

In Section C.4, pages 41-53, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The need determination in the 2021 SMFP for one additional fixed PET scanner in HSA I – The 2021 SMFP has determined there is a need for one additional fixed PET scanner based on a total of two existing fixed PET scanners and 3,722 reported PET scans in 2018-2019 (pages 41-42).
- Rapid growth in HSA I PET scans – The applicant states the total number of PET scans performed by mobile and fixed PET scanners in HSA I grew at a compounded annual growth rate (CAGR) of 10.9% from the year ending September 2017 through September 2020. In addition, the applicant also notes that utilization of PET scans grew in spite of the COVID-19 pandemic and the Governor’s Stay at Home Mandate imposed as a result (pages 42-44).
- Growth of the 65 and over population in HSA I – The applicant cites data from the NCOSBM to illustrate that the over 65 population group in HSA I is expected to grow by 9% between 2021 and 2025. The applicant states that the patient group receiving PET scans is typically older than the general population receiving healthcare services (page 44).
- The need to enhance timely access to PET services – The applicant states that, on average, there is currently a delay of two weeks or more in scheduling PET scans. The applicant states that this delay results in delayed diagnoses and treatment for cancer or another serious disease which in turn serves to heighten patient anxiety. The applicant proposes to expand their operating hours to include evenings and weekends to provide timely access (pages 44-45).
- New clinical applications for PET – The applicant states that PET scans are becoming increasingly important in the diagnosis and treatment of prostate cancer and Alzheimer’s disease and there is great interest in utilizing the proposed PET scanner for these diseases by area physicians (pages 45-47).
- Physician and community access to PET imaging – The applicant states that AOP physicians along with numerous other local physicians and community members support AOP’s proposal to acquire a PET scanner (pages 47-48).
- Need for access to cost-effective PET services and charity care – The applicant states that their proposal will provide patients access to a non-hospital-based PET scanner and will provide cost savings to commercial insurers and their patients. The applicant states they are committed to providing charity scans to Western North Carolina residents (pages 48-49).

- Need to enhance geographic access to PET services – The applicant cites HSA I population data from Esri and utilization data from license renewal applications (LRAs) illustrating the need to locate PET services in Asheville. The applicant states that the proposed AOP location has easier accessibility for patients residing in locations surrounding Buncombe County due to the facility being located near the intersection of major roadway systems that extend through the service area (pages 49-52).

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

- There is a need determination in the 2021 SMFP for one additional fixed PET scanner in HSA I.
- Population growth statistics for the service area demonstrate an increase for the population most likely to use the services being proposed.
- Utilization of mobile and fixed PET scanner services in HSA I have grown at a CAGR of 10.9% for the year ending September 2017 to September 2020.
- The applicant adequately demonstrates the need for a fixed PET scanner in addition to the existing hospital based fixed PET scanners in HSA I.

#### Projected Utilization

In Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table:

	<b>CY 2023</b>	<b>CY 2024</b>	<b>CY 2025</b>
Number of PET Scanners	1	1	1
Total PET Scans	1,699	1,934	2,187

In Section Q, pages 115-125, the applicant provides the assumptions and methodology used to project utilization, which is summarized below:

Step 1: Review HSA I Historical Scan Volumes and Growth – The applicant assumes the PET scanner, if approved, will compete most directly with other PET scanners located in the Western area of HSA I, which the applicant identifies as Buncombe, Henderson, Haywood and Jackson counties. The applicant obtained the most recent data on mobile and fixed PET scan volumes from LRA data for the Fiscal Year Ending September 30<sup>th</sup> for the periods 2017 through 2020. The applicant assigned volumes for scans performed on PET scanners located in-line with, or west of Buncombe County (Buncombe, Henderson, Haywood, and Jackson counties) to the western area and all other counties in the Service Area to the eastern area and calculated CAGRs as illustrated in the following table:

Hospital	County	FYE 2017	FYE 2018	FYE 2019	FYE 2020	CAGR 2017-2020	East or West
Mission Hospital	Buncombe	2040	2203	2507	2695	9.7%	West
Catawba Valley Health	Catawba	1190	1186	1215	1082	-3.1%	East
Atrium Cleveland	Cleveland	783	699	768 [764]	811	1.2%	East
Carolinas HealthCare Blue Ridge	Burke	189	415	421 [253]	483	36.7%	East
Pardee Memorial Hospital	Henderson	180	294	421 [422]	504	40.9%	West
Advent Health Hendersonville	Henderson	129	181	262 [257]	243	23.5%	West
Harris Regional	Jackson	264	236	261 [260]	252	-1.5%	West
Rutherford Regional	Rutherford	127	182	200 [199]	174	11.1%	East
Haywood Regional	Haywood	40	171	163	188	67.5%	West
Watauga Medical Center	Watauga	116	121	164 [165]	195	18.9%	East
Caldwell Memorial Hospital	Caldwell	94	117	158	395	61.4%	East
<b>Total</b>		<b>5,152</b>	<b>5,805</b>	<b>6,540 [6,363]</b>	<b>7,022</b>	<b>10.9%</b>	<b>Total</b>
<b>West</b>		<b>2,653</b>	<b>3,085</b>	<b>3,614</b>	<b>3,882</b>	<b>13.5%</b>	<b>West</b>
<b>East</b>		<b>2,499</b>	<b>2,720</b>	<b>2,926</b>	<b>3,140</b>	<b>7.9%</b>	<b>East</b>

Note: The data in brackets is from the 2021 SMFP and was noted in written comments received from Mission Hospital

The applicant calculated the 2017-2020 CAGR as 10.9% for the entire HSA, 13.5% for western/in-line counties and 7.9% for the eastern counties of the HSA.

Comments submitted by Mission Hospital question the projected growth rates calculated by AOP, given that some LRA data reported by AOP in the above table did not match what was reported in the SMFPs. In its response to comments, AOP stated that the SMFP data was not available for FY2020 PET volumes, therefore it used LRA data. The Project Analyst recalculated the CAGRs with the data shown in [ ] and found that the data in brackets did not change the resulting CAGRs.

Step 2: Review Historical AOP Scan Volumes – The applicant cites historical data on the number of PET scans AOP physicians referred out in CY 2020 and annualizes the volume for the first quarter (Q1) of 2021 to arrive at a resulting yearly growth percentage of 15.7%. However, the applicant states they did not factor the percent increase into the need methodology.

Step 3: Determine AOP Market Share – Utilizing LRAs and internal data, the applicant calculates their PET scanner market share for HSA I by determining the number of PET scan referrals made by AOP physicians to HSA I PET sites as a percentage of total PET scans for the site in FY 2020, as shown in the table below.

PET Site	Total Scans FY 2020	AOP Referrals 2020	AOP Market Share
Misson Hospital	2,695	1,042	38.7%
Pardee Memorial Hospital	504	3	0.6%
Advent Health Hendersonville	243	0	0.0%
Harris Regional	252	62	24.6%
Haywood Regional	188	4	2.1%
Total, Western HSA I	3,882	1,111	28.6%
Total, Eastern HSA I	3,140	43	1.4%
<b>Total HSA I</b>	<b>7,022</b>	<b>1,154</b>	<b>16.4%</b>

Step 4: Hold AOP Market Share Constant – The applicant conservatively projects the calculated market share of 16.4% for PET scan referrals will remain constant through CY2025 due to the reputation and quality of care offered by AOP.

Step 5: Determine Total Future Scan Volumes – The applicant uses the CAGR of 10.9% calculated in Step 1 to project total HSA I PET scan volumes for the interim years and each of the three project years.

Step 6: Apply AOP Market Share to Total Scan Volumes – The applicant applies the market share calculated in Step 3 and applies it to the volumes calculated in Step 5. The applicant’s calculations from Steps 5 and 6 for interim years 2020-2022 and each of the three project years 2023-2025 are shown in the following table.

	2020	2021	2022	Year 1 2023	Year 2 2024	Year 3 2025
Total PET Scans in HSA I (Step 5)	7,022	7,786	8,632	9,571	10,611	11,765
AOP Market Share	16.4%	16.4%	16.4%	16.4%	16.4%	16.4%
Total Projected AOP Physician Scans	1,154	1,279	1,419	1,573	1,744	1,934

Step 7: Identify Physician Support from Community Physicians – The applicant states they have received several letters of support from physicians in the community and many provide specific estimates regarding the number of PET scans they expect to refer to AOP when the PET scanner becomes operational, should it be approved. Based on the letters of support found in Exhibit C-6, the applicant estimates the total number of scans referred from non-AOP physicians to be in the range of 253 to 290.

Step 8: Develop Assumptions for Non-AOP Referrals – The applicant conservatively assumes the volume of referrals from non-AOP physicians will be on the low end of the total range stated in Step 7 with a ramp up of 50% in Year 1, 75% in Year 2 and 100% of the low-end in Year 3 as shown in the table below.

	Year 1 2023	Year 2 2024	Year 3 2025
Additional Scan Ramp-Up Assumption	50%	75%	100%
Additional Scan Volume (from Step 7)	253	253	253
Total Annual Non-AOP Physician Referrals	127	190	253

In response to comments submitted to the Agency that stated the referral numbers used were high and were also not in line with historic volume from the physicians providing the letters, the applicant states that unless a physician provided a numerical future referral estimate, AOP assigned no projected volume for that physician despite the expression of support. The applicant also states that the projection of 127 PET scan referrals from non-AOP physicians in Year 1 (CY 2023) is reasonable given that these same physicians referred 121 PET scans to Mission Hospital in CY 2019. In addition, in its response to comments, the applicant states that some of the physicians’ PET volume went to mobile PET sites in HSA I and not all to Mission.

Step 9: Develop Utilization Projections for Total Scans – The applicant adds the scans referred by AOP physicians to the projections for scan referrals from non-AOP physicians to determine the total projected PET scan utilization for the proposed project as illustrated in the table below.

	Year 1 2023	Year 2 2024	Year 3 2025
AOP Physician Scans (Step 6)	1,573	1,744	1,934
Non-AOP Physician Scan Volume	127	190	253
Total Project AOP PET Volume	1,699	1,934	2,187

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

- The applicant utilizes data from the 2021 SMFP to support its projected utilization.
- The applicant relies on historical HSA I market share data to project future market share by keeping it constant and applying it to projected PET volumes.
- The applicant makes reasonable assumptions regarding referral volumes from non-AOP physicians based on actual numerical future referral estimates stated in letters of support from those physicians to project total PET volume and historical percentages remain consistent in future projections.
- The applicant conservatively assumes non-AOP PET referrals to be 50% in Year 1, 75% in Year 2, and 100% of the low-end in Year 3.
- The applicant projects utilization of the proposed PET scanner will exceed the Performance Standards in 10A NCAC 14C .3703 by project year three (2025) since the number of projected PET scans must be equal to at least 2,080 scans.

**Access to Medically Underserved Groups**

In Section C.6, page 58, the applicant states:

*“AOP will promote equitable access in the delivery of PET services. AOP will not deny healthcare to any patient solely based on age, race, sex, or ability to pay. PET services will be available to all persons, including (a) low-income persons, (b) racial and ethnic minorities, (c) women, (d) handicapped [disabled] persons, (e) elderly, (f) Medicare beneficiaries, and (g) Medicaid recipients.”*

The applicant provides the estimated percentage for each medically underserved group it proposes to serve during the third full fiscal year, as shown in the following table:

Medically Underserved Groups	Percent of Total Patients
Low Income Persons	AOP does not track
Racial and ethnic minorities	3.8%
Women	51%
Persons with disabilities	AOP does not track
The elderly	69%
Medicare beneficiaries	69%
Medicaid recipients	6%

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

### **Conclusion**

The agency reviewed the:

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of

the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA – Both Applications

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner** - The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner** - The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

C – Both Applications

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

**Mission Hospital** proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP.

In Section E.2, pages 79-80, 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 that this alternative fails to address the current and growing demand for PET services.
- Placing a new PET scanner within Mission Hospital – The applicant states this is not a cost-effective option due to the constraints of existing building infrastructure, which would require a much larger and more costly renovation. The applicant also notes lack of Medicare reimbursement for PET services in an acute inpatient setting and the challenges associated with patients navigating a large building in comparison to having the PET services in an outpatient setting.
- Placing a new PET scanner at SECU Cancer Center – The applicant states that the SECU Cancer Center does not have the space to offer the stress tests associated with cardiac PET scans and oncological PET scans can be performed in a cardiovascular setting.

On page 80, the applicant states that its proposal is the most effective alternative because Mission Hospital – 5 Vanderbilt Park is adjacent to the main Asheville Cardiology Associates clinic, allowing for convenient access to cardiovascular diagnostic resources. Additionally, the facility at Mission Hospital – 5 Vanderbilt Park is equipped with the necessary staff and space to accommodate a PET scanner with no need for new construction and will minimize renovations.

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

### **Conclusion**

The Agency reviewed the:

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

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

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner** – In Section E.2, pages 69-71, 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 maintaining the status quo is inconsistent with the need determination in the 2021 SMFP, would not rectify existing patient access issues such as scheduling delays resulting from the existing PET scanner located at SECU Cancer Center and would not serve to reduce costs.
- Develop the proposed PET scanner at an alternate location in HSA I – The applicant states that Asheville is the largest and most prominent commercial hub, is located in Buncombe County which hosts a critical mass of patients and referring physicians and allows convenient access for patients living in more rural areas of HSA I.
- Build a new building – The applicant states that building a new building, rather than renovating space in its existing physicians offices, would be more expensive and delay the provision of additional PET services.
- Obtain an alternative PET scanner – The applicant states that the piece of equipment they selected for the proposal, the Siemens Biograph Horizon, is the most appropriate

equipment for promoting safety, delivery of quality services, and maximization of health care value.

- Apply jointly with another applicant – The applicant states that this alternative is difficult to achieve given Federal Health Care laws pertaining to shared-ownership. The applicant also states they have the financial and management ability to be a sole applicant and have not identified a suitable joint applicant.

On pages 70-71, the applicant states that its proposal is the most effective alternative because it will allow AOP to meet the need identified in the 2021 SMFP and they are choosing to increase access by expanding hours of operation, offer lower negotiated rates, commit to the provision of charity care and access to underserved populations.

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

### **Conclusion**

The Agency reviewed the:

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

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

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C – Both Applications

### **Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

Mission Hospital proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP.

### **Capital and Working Capital Costs**

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

Site Costs	NA
Construction / Renovation Costs	\$1,893,000.00
Miscellaneous Costs	\$3,104,702.49
<b>Total</b>	<b>\$4,997,702.49</b>

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

- In Exhibit F-1.1, the applicant provides documentation from an architect projecting capital costs which are included in the projected capital cost.
- In Exhibit F-1.2, the applicant provides documentation to support prices for all the items associated with the delivery and installation of the proposed equipment and these costs are included in the projected capital cost.
- In Section F, page 84, the applicant states that there will be no start-up or initial operating costs associated with this project.

**Availability of Funds**

In Section F.2, page 81, 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 or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Funding from parent company)	\$4,997,702.49	\$4,997,702.49
<b>Total Financing</b>	<b>\$4,997,702.49</b>	<b>\$4,997,702.49</b>

\*OE = Owner's Equity

In Exhibit F-2.1, the applicant provides a letter dated April 7, 2021, from the Chief Financial Officer for the North Carolina Division of HCA Healthcare, Inc. (HCA) documenting its intention to provide intercompany funding to finance the proposed project. HCA Healthcare, Inc. is the ultimate parent company of the applicant. Exhibit F-2.2, contains the Consolidated Financial Statements for HCA Healthcare, Inc. for the years ending December 31, 2020, 2019 and 2018.

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

- Exhibit F-2.1 contains a letter from the Chief Financial Officer for the North Carolina Division of HCA Healthcare, Inc. documenting that HCA intends to fund the total projected cost of the project through internally generated and/or borrowed funds.

- The letter from the Chief Financial Officer in Exhibit F-2.1 states that for the 12 months ending December 31, 2019, HCA generated \$7.602 billion of cash flow and has revolving credit totaling \$5.75 billion.
- Exhibit F-2.1 contains a copy of HCA Healthcare, Inc.’s consolidated balance sheet as of December 31, 2020, showing cash and cash equivalents of \$1.793 billion.

**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.2b, 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.

<b>MISSION HOSPITAL – 5 VANDERBILT PARK</b>			
	<b>1<sup>ST</sup> FFY CY 2023</b>	<b>2<sup>ND</sup> FFY CY 2024</b>	<b>3<sup>RD</sup> FFY CY 2025</b>
Total PET scans	1,822	1,975	2,135
Total Gross Revenues (Charges)	\$17,436,602	\$18,894,596	\$20,427,625
Total Net Revenue	\$4,156,135	\$4,507,894	\$4,871,580
Average Net Revenue per PET scan	\$2,281	\$2,282	\$2,282
Total Operating Expenses (Costs)	\$1,827,001	\$2,034,471	\$2,109,789
Average Operating Expense per PET scan	\$1,003	\$1,030	\$988
Net Income	\$2,329,134	\$2,473,423	\$2,761,791

AOP States in comments submitted that Mission Hospital does not account for the radiopharmaceutical, Rubidium, nor the equipment needed to generate it, in its operating costs. In its response to comments Mission Hospital states that it anticipates the vast majority of its cardiac scans will be nonperfusion FDG-18 studies which will not require Rubidium and its associated equipment. The Project Analyst notes that pharmaceutical costs were included in Mission Hospital’s operating costs and has determined that the applicant’s operating costs are reasonable. In addition, AOP stated in its comments that Mission Hospital did not include staffing costs for cardiac nurses or administrative staff. Mission Hospital stated in its response to comments that cardiac nurses and administrative staff were already on staff at 5 Vanderbilt Park. The Project Analyst determined that Mission Hospital accounted for appropriate costs given the operation of an existing outpatient medical facility.

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 Mission Hospital SECU’s historical experience and adequately accounts for projected operating expenses, such as salaries, equipment maintenance and administrative support, consistent with projections elsewhere in the application.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

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

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

- The applicant bases its projections on 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.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP creating a new non-hospital licensed diagnostic center in space it currently leases as medical office space at 551 Brevard Road in Asheville, Buncombe County.

**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	\$564,071
Miscellaneous Costs	\$1,541,960
<b>Total</b>	<b>\$2,106,031</b>

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

- The applicant provides documentation of equipment costs in Exhibit E-2.1.
- In Exhibit K-3, the applicant provides documentation from a construction company projecting construction plans and costs which are included in the projected capital cost.

- The applicant bases non-medical miscellaneous costs on its experience and review of vendor quotes.

In Section F.3, pages 74-75, the applicant projects that start-up costs will be \$136,330 and initial operating expenses will be \$337,700 for a total working capital of \$471,030 [\$474,030]. On pages 75-76, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant identifies the initial operating period needed before revenues will exceed expenses.
- The applicant identifies the costs included in the estimated start-up costs and bases its projections on its experience operating PET scanners in other states and the leadership of AOP.

**Availability of Funds**

In Section F.2, page 73, the applicant states that the capital cost will be funded by the applicant as shown in the table below.

SOURCES OF CAPITAL COST FINANCING	
TYPE	AMOUNT
Loans	\$0
Accumulated reserves or OE *	\$2,106,031
Bonds	\$0
Other (Line of credit)	\$0
<b>Total Financing</b>	<b>\$2,106,031</b>

\*OE = Owner's Equity

In Section F.3, page 78, the applicant states that the working capital needs of the project will be funded as shown in the table below.

SOURCES OF FINANCING FOR WORKING CAPITAL	AMOUNT
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or OE	\$471,030
Lines of credit	\$0
Bonds	\$0
<b>Total</b>	<b>\$471,030</b>

Exhibit F-2 contains a letter dated April 12, 2021 from Vipul M. Patel, MD, President of AOP documenting the applicant's intention to fund the project's capital and working capital costs with accumulated reserves of the applicant. Exhibit F-2 also contains a bank statement for AOP from SunTrust Bank indicating the applicant had \$8.8 million in cash as of March 31, 2021.

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

- The applicant provides a letter from the President of AOP documenting that AOP intends to fund the total projected capital and working capital needs of the project with accumulated reserves.
- The applicant provides a bank statement from AOP documenting cash reserves in excess of the amount of the proposed capital and working capital needs of the project.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In 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.

<b>AOP</b>			
	<b>1<sup>ST</sup> FFY CY 2023</b>	<b>2<sup>ND</sup> FFY CY 2024</b>	<b>3<sup>RD</sup> FFY CY 2025</b>
Total PET scans	1,699	1,934	2,187
Total Gross Revenues (Charges)	\$7,101,820	\$8,084,120	\$9,141,660
Total Net Revenue	\$2,816,599	\$3,205,080	\$3,624,939
Average Net Revenue per PET scan	\$1,658	\$1,657	\$1,657
Total Operating Expenses (Costs)	\$1,369,561	\$1,608,517	\$1,735,095
Average Operating Expense per PET scan	\$806	\$832	\$793
Net Income	\$1,447,038	\$1,596,563	\$1,889,844

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 revenues and operating expense projections on its HSA I market share and a reasonable estimate of outside referrals with no projected increase through the project years.
- Procedure charges are based on AOP historical experience of providing PET scans in other states.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Response to comments

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

- The applicant adequately demonstrates that the capital and working 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 and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (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 Applicants

On page 367, the 2021 SMFP defines the service area for a fixed dedicated PET scanner as “the HSA [Health Service Area] in which it is located (Table 17F-1).” Both applicants propose to locate a dedicated 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	Number of PET Scanners	Total Scans in 2018-2019	County
Fixed	Catawba Valley/Frye Regional Medical Center	1	1,215	Catawba
Fixed	Mission Hospital	1	2,507	Buncombe

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

Mission Hospital proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP.

In Section G, page 91, 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, including the need identified in the 2021 SMFP. The applicant states:

*“There is only one other 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. As such, there is minimal overlap in markets served by both providers.”*

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

- There is a need determination in the 2021 SMFP for the proposed fixed PET scanner in HSA I.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing 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

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

### **Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP creating a new non-hospital licensed diagnostic center in space it currently leases as medical office space at 551 Brevard Road in Asheville, Buncombe County.

In Section G, page 83, 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, including the need identified in the 2021 SMFP. The applicant states:

*“The 2021 SMFP shows a need for an additional fixed PET scanner in HSA I. The scanner proposed by AOP will not represent ‘unnecessary duplication’ because there is a need for additional fixed PET scanner capacity in HSA I. Further, the proposed scanner is not unnecessary duplication because it introduces a new provider to the area that will deliver services at a lower cost than the hospital based fixed and mobile scanners.*

*The proposed project will not result in an unnecessary duplication of the existing fixed PET scanners in HSA I. As of the date of this application, there are no approved but not yet developed fixed PET scanners in HSA I.”*

On page 86, the applicant states:

*“The scanner proposed by AOP will not duplicate the scanner at Catawba Valley, as Catawba Valley’s scanner is not reasonably accessible or, for whatever reason, has not provided a PET service historically used by a significant portion of HSA I residents.”*

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

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

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

### **Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

**Mission Hospital** proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP.

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

**Mission Hospital – 5 Vanderbilt Park Current and Projected Staffing**

Position	Current and Projected FTE Positions			
	Current FTE as of 3/18/21	1 <sup>st</sup> Full FY (CY 2023)	2 <sup>nd</sup> Full FY (CY 2024)	3 <sup>rd</sup> Full FY (CY 2025)
Radiology Technologist*	2.0	4.0	4.0	4.0
<b>Total</b>	<b>2.0</b>	<b>4.0</b>	<b>4.0</b>	<b>4.0</b>

\*The Project Analyst notes that the applicant refers to this position as Nuclear Medicine Technologist on pages 92-93 and in Exhibit H-1.1. Therefore, the Project Analyst assumes the applicant used a general term in Section Q, Form H.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is in Section Q. Given the applicant is operating an existing outpatient medical facility, the Project Analyst has determined it is reasonable to assume that existing staff, such as cardiac nurses and administrative staff, could be utilized for the proposed project as needed. In Section H.2 and H.3, pages 92-93, 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 another outpatient facility and providing PET services.

**Conclusion**

The Agency reviewed the:

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

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

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP creating a new non-hospital licensed diagnostic center in space it currently leases as medical office space at 551 Brevard Road in Asheville, Buncombe County.

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

<b>AOP Projected Staffing</b>			
<b>Position</b>	<b>Projected FTE Positions</b>		
	<b>1<sup>st</sup> Full FY (CY 2023)</b>	<b>2<sup>nd</sup> Full FY (CY 2024)</b>	<b>3<sup>rd</sup> Full FY (CY 2025)</b>
PET/CT Technologist	2.25	2.5	2.75
Front Desk Rep.	1.75	2	2.25
Business Office	0.25	0.375	0.5
<b>Total</b>	<b>4.25</b>	<b>4.88</b>	<b>5.5</b>

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

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

**Conclusion**

The Agency reviewed the:

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

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

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

C – Both Applications

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

**Mission Hospital** proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP.

### **Ancillary and Support Services**

In Section I, page 95 the applicant identifies the necessary ancillary and support services for the proposed services. On pages 95-96, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the existing providers of existing ancillary and support services and states the same providers will be available for the proposed PET services.
- In Exhibit I.1, the applicant provides supporting documentation that the existing ancillary and support services will be expanded to meet the needs of the proposed additional PET services.

### **Coordination**

In Section I, page 97 the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently provides diagnostic imaging services in Asheville and Buncombe County and has established relationships with local healthcare and social services providers, which will be in place in the proposed program as well.
- The applicant demonstrates physician support for the project in Exhibit C-4.6.

### **Conclusion**

The Agency reviewed the:

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

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

### **Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP creating a new non-hospital licensed diagnostic center.

### **Ancillary and Support Services**

In Section I, pages 90-91 the applicant identifies the necessary ancillary and support services for the proposed service and explains how each ancillary and support service is or will be made available. The applicant 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 lists existing ancillary and support services and states these same services will be available for the proposed PET services.
- The applicant documents the availability of radiological services for the proposed project in Exhibit I-1.

### **Coordination**

In Section I, pages 91-92 the applicant states it is an existing oncological specialty practice with existing relationships with area healthcare providers. The applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits C-6, I-1 and I-2. 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 oncological services in Asheville and Buncombe County and has established relationships with local healthcare and social services providers, which will be in place for the proposed PET services.
- The applicant demonstrates physician support for the project and the availability of radiologists to interpret the PET scans in Exhibit I-1.
- The applicant provides letters from community healthcare providers expressing support for the proposed project in Exhibits C-6 and I-2.

### **Conclusion**

The Agency reviewed the:

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

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA – Both Applicants

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner** Mission Hospital proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP.

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 I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP creating a new non-hospital licensed diagnostic center in space it currently leases as medical office space at 551 Brevard Road in Asheville, Buncombe County.

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 Applicants

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

Mission Hospital proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP.

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP creating a new non-hospital licensed diagnostic center in space it currently leases as medical office space at 551 Brevard Road in Asheville, Buncombe County.

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

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

Mission Hospital proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP.

In Section K, page 100 the applicant states that the project involves renovating 3,232 square feet of existing space. Line drawings are provided in Exhibit K-2.1.

On page 101, 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 that the facility renovation plan was compared with other potential plans in order to minimize renovation square footage.
- The applicant states that the facility renovation will be planned by an experienced architect.
- The applicant states interior renovations are significantly less expensive than the construction of exterior additions.

On page 101, 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 they will obtain the best market price for renovation by placing the construction contract out for bid.
- The applicant states that renovating leased space avoids costs involved with acquiring property and developing land.

On page 101, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

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

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

### **Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP creating a new non-hospital licensed diagnostic center in space it currently leases as medical office space at 551 Brevard Road in Asheville, Buncombe County.

In Section K, page 95 the applicant states that the project involves renovating 1,830 square feet of existing space. Line drawings are provided in Exhibits K-2.1 and K-2.2.

On pages 95-96, 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 proposal to renovate existing space is more efficient because it is less expensive and less time consuming than constructing a new building.
- The applicant states they will rely on professionals to plan and design the space so that it complies with all applicable building codes and standards.
- The applicant states that having the space adjacent to physician offices allows for shared space among ancillary and support services, which reduces costs.

On page 96, 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 will negotiate the rates of PET services, which are expected to result in significant cost savings to area residents.

- The applicant states that the choice of renovating space will not increase charges to the public following the addition of the proposed PET services as it will be more efficient.
- The applicant states that they will offer 3% of annual scans to patients without cost.

On page 96, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

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

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA

Messino Cancer Centers AOP

C

Mission Hospital – 5 Vanderbilt Park Drive

### **Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

In Section L, page 104, the applicant provides the historical payor mix during CY 2020 for its SECU Cancer Center PET Services, as shown in the table below.

Payor Category	PET Services as a % of Total
Self-Pay	0.9%
Charity Care	1.4%
Medicare*	66.5%
Medicaid*	4.7%
Insurance*	23.2%
Workers Compensation	0.0%
TRICARE	0.1%
Other (specify)	3.1%
<b>Total</b>	<b>100.0%</b>

\*Includes managed care plans

In Section L, page 105, the applicant provides the following comparison:

**SECU Cancer Center PET Services**

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY, CY2020	Percentage of the Population of the Service Area
Female	50.54%	51.31%
Male	49.46%	48.69%
Unknown	0.00%	0.00%
64 and Younger	34.71%	76.72%
65 and Older	65.29%	23.28%
American Indian	0.89%	1.33%
Asian	0.48%	1.26%
Black or African-American	2.78%	4.40%
Native Hawaiian or Pacific Islander	0.00%	0.12%
White or Caucasian	94.44%	87.59%
Other Race	0.00%	5.31%
Declined / Unavailable	1.41%	0.00%

The Agency reviewed the:

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

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

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

Neither the applicant nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13) is not applicable.

- (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

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / 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 106, the applicant states it has no such obligation to provide uncompensated care. In regard to community service or access by minorities and persons with disabilities, on page 107 the applicant states that as an HCA-affiliated hospital they must comply with ADA public access provisions and may not discriminate on the basis of disability or national origin.

In Section L, page 108, the applicant states that during the last 18 months 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

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

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring 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 101, the applicant states it has no such obligation.

In Section L, page 101, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against any affiliated entity of AOP.

The Agency reviewed the:

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

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

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

C – Both Applications

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive /  
Acquire one fixed PET/CT scanner**

In Section L, pages 108 and 109, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below:

**Mission – 5 Vanderbilt Park  
Payor Mix, CY 2025**

PAYOR SOURCE	% OF TOTAL
Self-Pay	0.9%
Charity Care	1.4%
Medicare*	66.5%
Medicaid*	4.7%
Insurance*	23.2%
Workers Compensation	0.0%
TRICARE	0.1%
Other (VA and other state or local funding sources)	3.1%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that for the proposed PET service site 0.9% of total services will be provided to self-pay patients, 1.4% to charity care patients, 66.5% to Medicare patients and 4.7% to Medicaid patients.

On page 109, 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 2020 PET payor mix at the SECU Cancer Center.

The Agency reviewed the:

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

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

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

In Section L, page 102, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below:

**AOP Payor Mix, CY 2025**

PAYOR SOURCE	% OF TOTAL
Self-Pay	1%
Charity Care	3%
Medicare*	69%
Medicaid*	6%
Insurance*	21%
Workers Compensation	0%
TRICARE	0%
Other	0%
<b>Total</b>	<b>100%</b>

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1% of total services will be provided to self-pay patients, 3% to charity care patients, 69% to Medicare patients and 6% to Medicaid patients.

On pages 102 and 103, 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 based on the following:

- The applicant projects payor mix based on the payor mix of PET scans referred out by Messino Cancer Centers' physicians in 2020, excluding those PET scans that were cancelled, denied, or not done.
- The projected payor mix was adjusted to account for the 3% charity care scans committed by AOP physicians.

The Agency reviewed the:

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

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

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

C – Both Applicants

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

In Section L, page 110, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

In Section L, pages 103 and 104, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

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

C – Both Applications

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

Mission Hospital proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive for a total of no more than two PET/CT scanners pursuant to the need determination in the 2021 SMFP.

In Section M, page 111, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purpose. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant states it maintains an affiliation with the Mountain Area Health Education Center (MAHEC) to support their residency programs.
- The applicant states the additional proposed PET at the 5 Vanderbilt Park Drive location will provide greater access to additional clinical training opportunities.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP creating a new non-hospital licensed diagnostic center in space it currently leases as medical office space at 551 Brevard Road in Asheville, Buncombe County.

In Section M, page 105, the applicant describes the extent to which health professional training programs in the area will 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:

- The applicant states it currently maintains a training program with MAHEC to provide experience for students in the residency program.
- The applicant states it has a history of educational training programs with local schools, including Western Carolina University, UNC-Wilmington, and Eastern Tennessee State University and if the PET proposal is approved, will extend the relationship to include education on PET scans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

(15) Repealed effective July 1, 1987.

(16) Repealed effective July 1, 1987.

(17) Repealed effective July 1, 1987.

(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

### C – Both Applicants

On page 367, the 2021 SMFP defines the service area for a fixed dedicated PET scanner as “the HSA [Health Service Area] in which it is located (Table 17F-1).” Both applicants propose to locate a dedicated 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	Number of PET Scanners	Total Scans in 2018-2019	County
Fixed	Catawba Valley/Frye Regional Medical Center	1	1,215	Catawba
Fixed	Mission Hospital	1	2,507	Buncombe

**Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

**Mission Hospital** proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 113, the applicant states:

*“The proposed project should have no effect on competition in the service area. Mission is the only provider of PET procedures on a fixed scanner, thus it was Mission Hospital’s volume that generated the current need. Mission Hospital is also projecting very reasonable growth in utilization in line with population growth and aging in the service area and plans to serve the same service area as it services for existing diagnostic services at Mission Hospital.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 113-114, the applicant states:

*“The proposed project will foster cost containment and improve quality of care through efficient design and implementation....*

....

*As an affiliate of HCA, Mission Hospital now has access to a broad resource base of administrative, financial, and technical expertise and hospital operations as well as centralized purchasing, distribution, payroll, billing, collections, employee benefit, regulatory compliance, quality resources, and IT support. HCA also has a Design, Construction, and Equipment Planning Department that has significant resources to streamline the architectural planning, construction building, and project management processes. These shared services result in real and ongoing economies of operations for all of the hospitals in the system, including Mission.*

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

Regarding the impact of the proposal on quality, in Section N, page 114, 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.*

....

*...PET/ CT is increasingly recognized as an innovative method of diagnosing coronary artery disease for patients who may not have previously been candidates due to body size and shape. It also improves quality and safety because it is minimally invasive and exposes patients to less radiation overtime when they are required to have repeated scans to monitor ongoing heart disease. “*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 114 the applicant states:

*“...as demonstrated in the tables in Section L.4a and L.4b, Mission hospital proposes to serve both Charity Care patients and patients who need services at reduced cost.”*

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

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

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

### **Conclusion**

The Agency reviewed the:

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

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

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP creating a new non-hospital licensed diagnostic center in space it currently leases as medical office space at 551 Brevard Road in Asheville, Buncombe County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 106, the applicant states:

*“The proposed project is expected to enhance competition in the service area by promoting cost-effectiveness, quality, and access to fixed PET services.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 106, the applicant states:

*“...commercially insured patients will receive PET scans at AOP at a significantly lower cost to the patient and the health plan as compared to HSA I’s hospital-based scanners. ... By developing the project in renovated space, AOP will offer a new service cost-effectively.”*

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

Regarding the impact of the proposal on quality, in Section N, page 106, the applicant states:

*“The proposed PET scanner will receive ACR accreditation, which is a key indicator for the delivery of safety and quality. The proposed PET scanner services will be offered in accord with policies and procedures designed to facilitate the delivery of safe, quality care.”*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 106-107 the applicant states:

*“AOP physicians are committed to giving back to Western North Carolina residents with a commitment and plan to offer charity (free) scans to the Western North Carolina region on its proposed PET scanner.”*

...

*AOP will not deny healthcare to any patient solely based on age, race, sex, or ability to pay.”*

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

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

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

### **Conclusion**

The Agency reviewed the:

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

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

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

C – Both Applications

### **Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

**Mission Hospital** proposes to acquire one fixed PET/CT scanner to be located at the existing hospital-based outpatient department (HOPD) at 5 Vanderbilt Park Drive pursuant to the need determination in the 2021 SMFP.

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

In Section O, pages 117-118, the applicant states that, during the 18 months immediately preceding the submittal of the application, one incident related to quality of care that resulted in an immediate jeopardy violation occurred in this facility. However, the facility is now back in compliance after submitting a Plan of Correction. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, two incidents related to quality of care have occurred in this facility, both of which have been resolved resulting in a return to compliance. 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 this facility, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

AOP proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP creating a new non-hospital licensed diagnostic center in space it currently leases as medical office space at 551 Brevard Road in Asheville, Buncombe County.

In Section O, the applicant states neither they nor any related entity owns, operates, or manages existing PET scanners in North Carolina.

In Section O, page 108, the applicant states:

*“The executive management team American Oncology brings over three decades of oncology practice management experience, enabling physicians to focus on what matters most: providing the highest quality care for patients. AOP policies and procedures comply with all state and federal regulations and will minimize patient and personnel risks and maximize the quality of the diagnostic information obtained through the scanning process.*

...

*AOP will obtain American College of Radiology (ACR) accreditation, which incorporates rigorous evaluation of policy's for safety and quality, personnel qualifications, and study results.”*

After reviewing and considering information provided by the applicant, 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 dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that:*
- (1) *the proposed dedicated PET scanner, including a proposed mobile dedicated PET scanner, shall be utilized at an annual rate of at least 2,080 PET procedures by the end of the third year following completion of the project;*
    - C- **Mission Hospital.** In Section C, page 64 and Section Q, the applicant projects that the proposed PET scanner will perform more than 2,080 procedures by the end of the third year of operation. Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.
    - C- **AOP.** In Section Q, page 125, the applicant projects that the proposed PET scanner will perform more than 2,080 procedures by the end of the third year of operation. Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.
  - (2) *if an applicant operates an existing dedicated PET scanner, its existing dedicated PET scanners, excluding those used exclusively for research, performed an average of at least 2,080 PET procedures per PET scanner in the last year; and*

- C- **Mission Hospital.** In Section C, page 61 and Form C.2a, the applicant states the PET scanner owned by Mission Hospital and located at the SECU Cancer Center performed 2,611 procedures in CY 2020. The application is conforming to this Rule.
  - NA- **AOP** does not currently own or operate an existing PET scanner in North Carolina.
- (3) *its existing and approved dedicated PET scanners shall perform an average of at least 2,080 PET procedures per PET scanner during the third year following completion of the project.*
- C- **Mission Hospital.** In Section C, page 64, the applicant projects that the existing PET scanner owned by Mission Hospital and located at the SECU Cancer Center will perform a total of 2,361 procedures in the third year following completion of the project. The application is conforming to this rule.
  - NA- **AOP** does not currently own or operate an existing PET scanner in North Carolina.
- (b) *The applicant shall describe the assumptions and provide data to support and document the assumptions and methodology used for each projection required in this Rule.*
- C- **Mission Hospital.** The applicant provides its assumptions and methodology in Section C and Section Q, Form C. The applicant adequately demonstrates that its assumptions and methodology are reasonable and adequately supported. See the discussion found in Criterion (3) regarding projected utilization which is incorporated herein by reference. The application is conforming to this Rule.
  - C- **AOP.** The applicant provides its assumptions and methodology in Section C and Section Q, Form C. The applicant adequately demonstrates that its assumptions and methodology are reasonable and adequately supported. See the discussion found in Criterion (3) regarding projected utilization which is incorporated herein by reference. The application is conforming to this Rule.

### COMPARATIVE ANALYSIS

Pursuant to G.S. § 131E-183(a)(1) and the 2021 SMFP, no more than one PET Scanner can be approved for HSA I in this review. Because the two applications in this review collectively propose to develop two additional PET scanners, all the applications cannot be approved. 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 should be approved.

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

- Project ID# B-12057-21/ **Mission Hospital – 5 Vanderbilt Park Drive** / Acquire one fixed PET/CT scanner
- Project I.D. #B – 12059-21 / **Messino Cancer Centers** / Develop a new diagnostic center by acquiring one fixed PET/CT scanner

**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**

With regard to scope of services, applications submitted by **Mission Hospital and AOP** are both in response to the 2021 State Medical Facilities Plan (SMFP) need determination in HSA I for one fixed PET scanner. The following table compares the scope of services proposed to be offered. Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor.

Facility	Type of Facility	Proposed Scope of Services		
		Oncological PET	Neurologic PET	Cardiac PET
<b>Mission Hospital – 5 Vanderbilt Park Drive</b>	Hospital Based Outpatient Department	X	X	X
<b>Messino Cancer Centers</b>	Freestanding Diagnostic Center	X	X	

**Mission Hospital - 5 Vanderbilt Park Drive** is an existing hospital-based outpatient department located in a medical office building which provides outpatient services including hospital-based cardiac rehabilitation, a sleep lab and cardiovascular diagnostic services. **AOP’s** facility, **Messino Cancer Centers**, is a physician’s practice office that only provides outpatient oncology services. **Mission Hospital-5 Vanderbilt Park Drive** proposes to offer oncological, neurological and cardiac PET scans. **AOP** proposes to primarily offer oncological PET scans with the potential to receive a small number of neurological PET scan referrals. Therefore, with regard to scope of services, **Mission Hospital** is the more effective alternative.

**Patient Access to Lower Cost PET Procedures**

There are currently two existing dedicated fixed PET scanners in HSA I and both are located in a hospital setting. Dedicated fixed PET scanners can be located either in a free-standing diagnostic center or a hospital. The 2021 SMFP shows that statewide, there are a total of 25 fixed PET providers across six different HSAs. Two of the 25 fixed PET providers are free-standing diagnostic centers; Wake PET Services, Wake Radiology Oncology, Wake Radiology located in HSA IV and First Imaging of the

Carolinas located in HSA V. Currently, there are no free-standing diagnostic centers with a fixed PET scanner in HSA I. Based on the applications, written comments and response to comments, many, but not all PET scans can be appropriately performed either in a licensed hospital setting or non-hospital licensed diagnostic center; however, the cost for that same service will often be much higher in a hospital licensed facility or, conversely, much less expensive if received in a non-hospital licensed facility at a free-standing diagnostic center.

**Fixed PET Scanners in HSA I**

Facility	# of Fixed PET Scanners	Hospital Based or Freestanding	Location
Catawba Valley Medical Center/Frye Regional Medical Center	1	Hospital Based	Hickory/Catawba County
Mission Hospital	1	Hospital Based	Asheville/Buncombe County

Source: 2021 SMFP and LRAs

Therefore, with respect to this comparative factor, the application submitted by **AOP** is the more effective proposal and the **Mission Hospital - 5 Vanderbilt Park Drive** application is less effective.

**Historical Utilization**

The following table illustrates utilization of the existing fixed PET scanners located in HSA I as provided in Table 17F-1 of the **2021 SMFP** representing FY 2019 reported utilization.

**Fixed PET Scanners in HSA I**

Facility	# of Fixed PET Scanners	Total Procedures	Utilization Rate
Catawba Valley Medical Center/Frye Regional Medical Center	1	1,215	40.50%
Mission Hospital	1	2,507	83.57%

Source: 2021 SMFP, page 369

**AOP** does not currently provide PET services at a facility and thus has no historical utilization to report. Thus, the result of this analysis is inconclusive.

**Geographical Accessibility (Location within the Service Area)**

The 2021 SMFP identifies the need for one fixed PET scanner in HSA I. The following table identifies the location of the existing and approved fixed PET scanners in HSA I as reported by the 2021 SMFP and other publicly available information.

**Fixed PET Scanners in HSA I**

Facility	# of Fixed PET Scanners	Hospital Based or Freestanding	Location
Catawba Valley Medical Center/Frye Regional Medical Center	1	Hospital Based	Hickory/Catawba County
Mission Hospital	1	Hospital Based	Asheville/Buncombe County

Source: 2021 SMFP and LRAs

Both Mission Hospital and AOP propose to locate the fixed PET scanner in Asheville, Buncombe County, which is in HSA I and both locations offer services in an outpatient setting. Therefore, regarding geographical accessibility, both applications are equally effective alternatives.

**Access by Service Area Residents**

The 2021 SMFP defines the service area for a fixed PET scanner as “*the HSA [Health Service Area] in which it is located (Table 17F-1).*” Thus, the service area for this review is HSA I. The counties in HSA I are: Alexander, Alleghany, Ashe, Avery, Buncombe, Burke, Caldwell, Catawba, Cherokee, Clay, Cleveland, Graham, Haywood, Henderson, Jackson, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, Watauga, Wilkes and Yancey. Facilities may also serve residents of counties not included in their service 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 scanners in the service area where they live.

Both applicants propose to provide access to PET services in 21 of 28 counties in HSA I. Both applicants provide a percentage for the “other” category in their projected patient origin tables. However, because both applicants include counties in the “other” category that are not in HSA I, it is not possible to quantify the number of patients projected to be served solely in HSA I counties. Therefore, the result of this analysis is inconclusive.

**Access by Underserved Groups**

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

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

***Projected Charity Care***

The following table compares projected charity care in the third full fiscal year following project completion for each facility using the following metrics. Generally, the application proposing to provide the most charity care is the more effective alternative with regard to this comparative factor.

Charity Care OY 3						
Applicant	# of Procedures	Total Projected Charity Care	Charity Care per Procedure	Net Revenue	Charity Care as a % of Net Revenue	Number of Charity Care Procedures as % of Net Revenue
Mission Hospital (5 Vanderbilt Park)	2,135	\$189,305	\$89	\$4,871,580	3.89%	83
AOP	2,187	\$275,880	\$126	\$3,624,939	7.61%	166

Source: Section Q Forms C.2b and F.2b

As shown in the table above, AOP proposes to provide the most charity care in dollars, the most charity care dollars per procedure, the highest percentage of charity care as a percentage of net revenue, and the highest number of charity care procedures as a percent of its net revenue. However, differences in the types of facilities and the types of PET procedures proposed by each of the facilities may impact the average shown in the table above. Thus, the result of this analysis is inconclusive.

***Projected Medicare and Medicaid***

The following table compares access by Medicaid and Medicare patients in the third full fiscal year following project completion for each facility using the following metrics: Medicare and Medicaid procedures as a percent of total procedures projected to be served by the proposed PET scanner. Generally, the application proposing to provide a higher percentage of gross revenue to Medicaid or Medicare patients is the more effective alternative with regard to this comparative factor.

APPLICANT	GROSS REVENUE PROJECT YEAR 3	MEDICARE GROSS REVENUE PROJECT YEAR 3	MEDICARE PROCEDURES AS % OF GROSS REVENUE	NUMBER OF MEDICARE PROCEDURES PER PET SCANNER	MEDICAID PROCEDURES AS % OF GROSS REVENUE	MEDICAID GROSS REVENUE PROJECT YEAR 3	NUMBER OF MEDICAID PROCEDURES PER PET SCANNER
Mission Hospital (5 Vanderbilt Park)	\$20,427,625	\$13,439,745	66.5%	1,420	4.7%	\$849,669	100
AOP	\$9,141,660	\$6,307,620	69.0%	1,509	6.0%	\$547,580	91

Source: Section Q Form F.2b

**Mission Hospital** proposes to provide 66.5% of gross revenue to Medicare patients, which represents 1,420 procedures. **AOP** proposes to provide 69.0% of gross revenue to Medicare patients, which represents 1,509 procedures. As shown in the table above, when taking into consideration the number of patients served per PET scanner, **AOP** projects to serve a greater percentage of Medicare patients

and a greater number of Medicare patients in the third full fiscal year following project completion than **Mission Hospital**. Therefore, for this comparative factor, **AOP** is the more effective alternative. However, differences in the types of facilities and the types of PET procedures proposed by each of the facilities may impact the averages shown in the table above, thus, the result of this analysis is inconclusive.

**Mission** proposes to provide 4.7% of gross revenue to Medicaid patients, which represents 100 procedures. **AOP** proposes to provide 6.0% of gross revenue to Medicaid patients, which represents 91 procedures. Therefore, **Mission Hospital** projects to serve a greater number of Medicaid patients in the third full fiscal year following project completion than **AOP**. Therefore, for this comparative factor, the application submitted by **Mission Hospital** is a more effective alternative. However, differences in the types of facilities and the types of PET procedures proposed by each of the facilities may impact the averages shown in the table above, thus, the result of this analysis is inconclusive.

**Competition (Access to a New or Alternate Provider)**

The following table illustrates the existing and approved providers located in the service area. Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer fixed PET scanners than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

**Fixed PET Scanners in HSA I**

Facility	# of Fixed PET Scanners	Hospital Based or Freestanding	Location
Catawba Valley Medical Center/Frye Regional Medical Center	1	Hospital Based	Hickory/Catawba County
Mission Hospital	1	Hospital Based	Asheville/Buncombe County

**Mission Hospital** currently operates one fixed PET scanner in HSA I. **AOP** does not currently own or operate a fixed PET scanner in HSA I. Therefore, with regard to the introduction of a new provider of fixed PET services in the service area, the application submitted by **AOP** is a more effective alternative.

**Projected Average Net Revenue per PET Procedure**

The following table compares projected average net revenue per PET procedure in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average net revenue per PET procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

AVERAGE NET REVENUE PER PATIENT PET PROCEDURE 3 <sup>RD</sup> FULL FY			
APPLICANT	TOTAL # OF PET PROCEDURES	NET REVENUE	AVERAGE NET REVENUE PER PET PROCEDURE
Mission Hospital (5 Vanderbilt Park)	2,135	\$4,871,580	\$2,282
AOP	2,187	\$3,624,939	\$1,657

Source: Applications Forms C Utilization and Form F.2b

As shown in the table above, **AOP** projects the lowest average net revenue per PET scan procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **AOP** is a more effective alternative. However, differences in the types of facilities and the types of PET procedures proposed by each of the facilities may impact the averages shown in the table above, thus, the result of this analysis is inconclusive.

**Projected Average Operating Expense per PET Procedure**

The following table compares projected average operating expense per PET procedure in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average operating expense per patient day, surgical case or procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

AVERAGE OPERATING EXPENSE PER PATIENT PET PROCEDURE 3 <sup>RD</sup> FULL FY			
APPLICANT	TOTAL # OF PET SCAN PROCEDURES	OPERATING EXPENSE	AVERAGE OPERATING EXPENSE PER WEIGHTED PET PROCEDURE
Mission Hospital (5 Vanderbilt Park)	2,135	\$2,109,789	\$988
AOP	2,187	\$1,735,095	\$793

Source: Applications Forms C Utilization and Form F.2b

As shown in the table above, **AOP** projects the lowest average operating expense per PET procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **AOP** is a more effective alternative. However, differences in the types of facilities and the types of PET procedures proposed by each of the facilities may impact the averages shown in the table above, thus, the result of this analysis is inconclusive.

**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	MISSION HOSPITAL-5 VANDERBILT PARK	AOP
Conformity with Statutory and Regulatory Review Criteria	Equally Effective	Equally Effective
Scope of Services	More Effective	Less Effective
Access to Lower Cost Services	Less Effective	More Effective
Historical Utilization	Inconclusive	Inconclusive
Geographic Accessibility (Location within the Service Area)	Equally Effective	Equally Effective
Access by Service Area Residents	Inconclusive	Inconclusive
Access by Charity Care	Inconclusive	Inconclusive
Access by Medicaid	Inconclusive	Inconclusive
Access by Medicare	Inconclusive	Inconclusive
Competition (Access to a New or Alternate Provider)	Less Effective	More Effective
Projected Average Net Revenue per PET Procedure	Inconclusive	Inconclusive
Projected Average Operating Expense per PET Procedure	Inconclusive	Inconclusive

Both applications are conforming to all applicable statutory and regulatory review criteria, and thus both applications are approvable standing alone. However, collectively they propose a total of two fixed PET scanners in HSA I, but the need determination is for only one fixed PET scanner. Therefore, only one application for one PET scanner can be approved.

As shown in the table above, **Mission Hospital** was determined to be a more effective alternative for the following factor:

- Scope of services

As shown in the table above, **AOP** was determined to be a more effective alternative for the following two factors:

- Access to lower cost services
- Competition (access to a new or alternate provider)

### DECISION

Each application is individually conforming to the need determination in the 2021 SMFP for one additional dedicated fixed PET scanner in HSA I as well as individually conforming to all statutory and regulatory review criteria. However, G.S. § 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed PET scanners that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the following application is approved as submitted:

- **Project I.D. #B – 12059-21 / Messino Cancer Centers / Develop a new diagnostic center by acquiring one fixed PET/CT scanner**

And the following application is denied:

- **Project ID# B-12057-21/ Mission Hospital – 5 Vanderbilt Park Drive / Acquire one fixed PET/CT scanner**

**Project ID# B-12059-21** is approved subject to the following conditions.

1. **American Oncology Partners, P.A. (herein after “the 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 dedicated PET scanner pursuant to the need determination in the 2021 SMFP to develop a new diagnostic center.**
3. **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.**
4. **Progress Reports:**
  - a. **Pursuant to G.S. § 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. **The certificate holder shall complete all sections of the Progress Report form.**
  - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. **Progress reports shall be due on the first day of every third month. The first progress report shall be due on February 1, 2022. The second progress report shall be due on May 1, 2022 and so forth.**
5. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
  - a. **Payor mix for the services authorized in this certificate of need.**
  - b. **Utilization of the services authorized in this certificate of need.**
  - c. **Revenues and operating costs for the services authorized in this certificate of need.**
  - d. **Average gross revenue per unit of service.**
  - e. **Average net revenue per unit of service.**
  - f. **Average operating cost per unit of service.**
6. **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.**