



**WRITTEN COMMENTS ON 2023 HEALTH SERVICE AREA I
FIXED PET SCANNER COMPETITIVE REVIEW**

SUBMITTED BY ADVENTHEALTH HENDERSONVILLE

MARCH 31, 2023

Two applicants submitted CON applications in response to the need identified in the 2023 SMFP for one additional fixed PET scanner in Health Service Area (HSA) I. The applicants include:

- CON Project ID# B-012331-23 AdventHealth Hendersonville
- CON Project ID# B-012335-23 Mission Hospital

AdventHealth Hendersonville submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the competing application, including Mission's ability to conform with applicable statutory and regulatory review criteria and a discussion of the prospective comparative analysis of the applicable and most significant issues concerning this competitive batch review. Other non-conformities may exist in Mission's competing application and AdventHealth Hendersonville may develop additional opinions, as appropriate upon further review and analysis.

COMPARATIVE ANALYSIS OF THE COMPETING FIXED PET SCANNER APPLICATIONS

The following factors have been utilized in prior competitive CON reviews regardless of the type of services or equipment proposed:

- Conformity with Statutory & Regulatory Review Criteria
- Competition (Access to a New or Alternate Provider)
- Scope of Services
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Historical Utilization
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Projected Average Net Revenue
- Projected Average Total Operating Cost

The following pages summarize the competing applications relative to the identified comparative factors.

Conformity to CON Review Criteria

Two CON applications have been submitted to develop a fixed PET scanner in Health Service Area I. Based on the 2023 SMFP’s need determination, only one fixed PET scanner can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by AdventHealth Hendersonville demonstrates conformity to all Statutory and Regulatory Review Criteria.

Conformity of Applicants

Applicant	Project I.D.	Conforming with All Applicable Statutory & Regulatory Review Criteria
AdventHealth Hendersonville	B-012331-23	Yes
Mission Hospital	B-012335-23	No

The AdventHealth Hendersonville application is based upon reasonable and supported volume projections and reasonable projections of cost and revenues. As discussed separately in this document, the Mission application contains errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the **AdventHealth Hendersonville** application is the **most effective** alternative regarding conformity with applicable review Criteria.

Scope of Services

Regarding scope of services, the applications submitted by AdventHealth Hendersonville and Mission Hospital are both responsive to the 2023 SMFP need determination in HSA I for one fixed PET scanner. The following table compares the scope of services proposed to be offered by each applicant. Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor.

Scope of Services

Facility	Type of Facility	Proposed Scope of Services		
		Oncological PET	Neurologic PET	Cardiac PET
Mission Hospital – 5 Vanderbilt Park Drive	Hospital Based Outpatient Department	X	X	X
AdventHealth Hendersonville	Hospital Based Outpatient Department	X	X	X

Mission Hospital-5 Vanderbilt Park Drive is an existing hospital-based outpatient department. AdventHealth Hendersonville’s proposed fixed PET scanner will also be developed as a hospital outpatient department. Mission Hospital-5 Vanderbilt Park Drive proposes to offer oncological, neurological, and cardiac PET scans. AdventHealth Hendersonville’s proposed fixed PET scanner will also offer oncological, neurological, and cardiac PET scans. Therefore, with regard to scope of services, the competing applications are equally effective alternatives.

Historical Utilization

In previous competitive reviews, the Agency has attempted to assess historical utilization among the competing applicants. This comparison cannot be performed in this review because AdventHealth Hendersonville does not currently operate a fixed PET scanner and, thus, has no historical fixed PET utilization. Therefore, this comparative factor should not be used in this review.

Geographic Accessibility

The 2023 SMFP identifies the need for one fixed PET scanner in HSA I. The following table summarizes the locations of existing and approved fixed PET scanners in HSA I as reported by the 2023 SMFP and other publicly available information.

Facility Name	Inventory	Location City/County
Mission Hospital	1 existing	Asheville/Buncombe Co.
Catawba Valley Medical Center / Frye Regional Medical Center	1 existing	Hickory/Catawba County
Messino Cancer Center	1 approved	Asheville/Buncombe Co.

As documented in Section C.3 of AdventHealth Hendersonville’s application, residents of western North Carolina do not travel to Catawba County for fixed PET services.

Currently, access to fixed PET scanners in western North Carolina is consolidated in one county, Buncombe County. There are two facilities in Asheville that are approved to offer fixed PET services, Mission Hospital and Messino Cancer Center. The consolidation of fixed PET services within one county creates an inequitable distribution of medical resources, when many patients are travelling long distances to access these services. This can be particularly challenging for patients who live in rural or remote areas, or for those who have limited mobility.

Mission Hospital proposes to develop a fixed PET scanner in Buncombe County, which already hosts two fixed PET scanners. AdventHealth Hendersonville proposes to develop a fixed PET scanner in Henderson County, which does not currently host a fixed PET scanner. Therefore, regarding geographic accessibility, **AdventHealth Hendersonville** creates a new geographic point of access within Health Service Area I and is the **most effective alternative**.

Access By Service Area Residents

The 2023 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 include: 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 the defined 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.

AdventHealth Hendersonville and Mission each propose to provide access to PET services to patients from the 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. This conclusion is consistent with the Agency’s analysis of this comparative factor in the 2021 Health Service Area I Fixed PET Review.

Competition (Patient Access to a New or Alternate Provider)

According to the Federal Trade Commission, competition in health care markets benefits consumers because it helps contain costs, improve quality, and encourage innovation. The introduction of a new provider in the service area would be the most effective alternative because increased patient choice encourages all providers in the service area to improve quality or lower costs in order to compete for patients.

Mission Hospital currently operates one fixed PET scanner in HSA I. AdventHealth Hendersonville does not currently own or operate a fixed PET scanner in HSA I. Therefore, regarding the introduction of a new provider of fixed PET services in the service area, the application submitted by **AdventHealth Hendersonville** is the **most effective alternative**.

AdventHealth Hendersonville’s project will create a new point of access for fixed PET services in western North Carolina providing more choices for patients to receive high-quality health care close to home.

Access By Underserved Groups

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

“Medically underserved groups, such as medically indigent or low-income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”

For access by underserved groups, applications are compared concerning 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.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare, or Medicaid procedures
- Charity care, Medicare, or Medicaid procedures as a percentage of total procedures
- Total charity care, Medicare, or Medicaid dollars
- Charity care, Medicare, or Medicaid dollars as a percentage of total gross or net revenues
- Charity care, Medicare, or Medicaid cases per procedure

The above metrics the Agency uses are determined by whether or not the applications included in the review provide data that can be compared as presented above and whether or not such a comparison would be of value in evaluating the alternative factors.

In this competitive review, both applicants propose to develop fixed PET scanners as part of a hospital outpatient department. Both applicants also propose to offer the same scope of PET scanner services, i.e., oncology, neurology, and cardiac. Therefore, conclusive comparisons can be made for each factor related to access by underserved groups.

Projected Charity Care

The following table compares projected charity care for the applicants in the third full fiscal year following project completion.

Projected Charity Care – 3rd Full FY

Applicant	Form C.2b	Form F.2b	Charity Care per Procedure	Form F.2b	Charity Care as a % of Net Revenue	Number of Charity Care Procedures as % of Net Revenue
	# of Procedures	Total Projected Charity Care		Net Revenue		
AdventHealth Hendersonville	2,124	\$267,941	\$126	\$4,554,991	5.88%	125
Mission Hospital (5 Vanderbilt Park)	2,137	\$154,059	\$72	\$5,348,658	2.88%	62

Source: CON applications

As shown in the table above, AdventHealth Hendersonville 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 based on the charity care percent of net revenue. Therefore, regarding charity care access, **AdventHealth Hendersonville** is the **most effective alternative**.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for all the applicants in the review.

Projected Medicare Revenue – 3rd Full FY

Applicant	Form F.2b	Form F.2b	Medicare Gross Revenue as a % of Total Gross Revenue
	Gross Revenue Project Year 3	Medicare Gross Revenue Project Year 3	
AdventHealth Hendersonville	\$21,435,252	\$15,090,418	70.4%
Mission Hospital (5 Vanderbilt Park)	\$24,843,027	\$17,381,207	70.0%

Source: CON applications

As shown in the previous table, AdventHealth Hendersonville proposes to provide the highest percentage of Medicare Gross Revenue as a percentage of Total Gross Revenue. Therefore, regarding Medicare access, **AdventHealth Hendersonville** is the **most effective alternative**.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants in the review.

Projected Medicaid Revenue – 3rd Full FY

Applicant	Form F.2b	Form F.2b	Medicaid Gross Revenue as a % of Total Gross Revenue
	Gross Revenue Project Year 3	Medicaid Gross Revenue Project Year 3	
AdventHealth Hendersonville	\$21,435,252	\$664,493	3.1%
Mission Hospital (5 Vanderbilt Park)	\$24,843,027	\$996,719	4.0%

Source: CON applications

Mission projects to serve a higher percentage of Medicaid Gross Revenue as a percentage of Total Gross Revenue. However, Mission’s application does not conform to all statutory and regulatory review criteria and cannot be approved. Therefore, Mission cannot be the most effective alternative.

Projected Average Net Revenue per Patient

The following table shows each applicant's projected average net revenue per patient in the third year of operation, based on the information provided in the applicants’ pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per PET Procedure – 3rd Full FY

Applicant	Form C.2b	Form F.2b	Average Net Revenue per PET Procedure
	Fixed PET Procedures	Net Revenue	
AdventHealth Hendersonville	2,124	\$4,554,991	\$2,145
Mission Hospital (5 Vanderbilt Park)	2,137	\$5,348,658	\$2,503

Source: CON applications

As shown in the table above, **AdventHealth Hendersonville** 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 **AdventHealth Hendersonville** is the **most effective alternative**.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per PET procedure in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense is the more effective alternative concerning this comparative factor to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

Projected Average Operating Expense per PET Procedure – 3rd Full FY

Applicant	Form C.1b	Form F.2b	Average Operating Expense per PET Procedure
	Fixed PET Procedures	Operating Expense	
AdventHealth Hendersonville	2,124	\$2,408,518	\$1,134
Mission Hospital (5 Vanderbilt Park)	2,137	\$3,630,495	\$1,699

Source: CON applications

As shown in the previous table, **AdventHealth Hendersonville** projects the lowest average operating expense per PET scan procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **AdventHealth Hendersonville** is the **most effective alternative**.

Summary

The table below summarizes the comparative factors and states which application is the most effective alternative.

Comparative Factor	AdventHealth Hendersonville	Mission Hospital - 5 Vanderbilt Park
Conformity with Statutory and Regulatory Review Criteria	Most Effective	Least Effective
Scope of Services	Equally Effective	Equally Effective
Access to Lower Cost Services	Equally Effective	Equally Effective
Historical Utilization	Inconclusive	Inconclusive
Geographic Accessibility (Location within the Service Area)	Most Effective	Least Effective
Access by Service Area Residents	Inconclusive	Inconclusive
Access by Charity Care	Most Effective	Least Effective
Access by Medicaid	Least Effective	Most Effective
Access by Medicare	Most Effective	Least Effective
Competition (Access to a New or Alternate Provider)	Most Effective	Least Effective
Projected Average Net Revenue per PET Procedure	Most Effective	Least Effective
Projected Average Operating Expense per PET Procedure	Most Effective	Least Effective

For each of the comparative factors previously discussed, AdventHealth Hendersonville’s application is determined to be the most effective alternative for the following factors:

- Conformity with Review Criteria
- Geographic Accessibility
- Charity Care Access
- Medicare Access
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per PET Procedure
- Projected Average Operating Expense per PET Procedure

Mission’s application fails to conform with all applicable statutory and regulatory review criteria; thus, it cannot be approved. In addition, Mission’s application fails to measure more favorably with respect to the aforementioned comparative factors.

Based on the previous analysis and discussion, the application submitted by AdventHealth Hendersonville is comparatively superior and should be approved in this competitive review.

The following pages provide application-specific comments regarding the Mission application and its respective conformity to applicable statutory and regulatory review criteria.

**COMMENTS SPECIFIC TO MISSION HOSPITAL
PROJECT ID #B-012335-23**

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

The Mission Methodology Results in Overstated PET Projections

Application page 67 states, *“starting in May 2022, Mission implemented PSMA scans, which quickly ramped up, resulting in 237 total scans for calendar year 2022.”* In other words, PSMA scans resulted in 237 incremental PET procedures at Mission during 2022. As shown in the following table, Mission’s PET scan volume experienced an overall increase of 120 PET scans during CY2022 compared to CY2021 (2,946-2,826 = 120). Therefore, excluding PSMA scans, Mission’s PET scanner actually experienced a decrease in PET scan volume. See also the following table recreated from Step 1 of Mission’s methodology.

**Step 1
Mission Baseline Oncology PET/CT Scans**

	CY2018	CY2019	CY2020	CY2021	CY2022	2018- 2022 CAGR
Baseline PET/CT Scans	2,261	2,586	2,611	2,826	2,946	6.8%
PSMA Scans					237	
Baseline PET/CT Scans <u>Excluding</u> PSMA Scans					2,709	4.6%
<i>Net Change from Prior Year Excluding PSMA Scans</i>					-117	

Source: Application page 66

It is important to acknowledge the 2018-2022 CAGR (6.8%) calculated in Step 1 of Mission’s methodology includes PSMA scans. The introduction of PSMA scans starting in May 2022 was a one-time incremental gain to Mission’s PET procedure volume. As the previous table demonstrates, without the PSMA scans, Mission’s 2018-2022 CAGR is 4.6 percent, not 6.8 percent. Therefore, application of a 6.8 percent CAGR to project future oncology PET scans is inflated because Mission is growing baseline oncology PET scans by a rate that is heavily impacted by the introduction of PSMA scans in 2022. Indeed, the non-PSMA PET scans actually decreased from CY2021 to CY2022. The following table recalculates Mission’s CY2023 and CY2024 projections based on the 2018-2022 CAGR of 4.6 percent, i.e., the CAGR that excludes the 2022 PSMA scans.

**Step 1
 Baseline Oncology PET/CT Scans**

	CY2018	CY2019	CY2020	CY2021	CY2022	2018-2022 CAGR	CY2023	CY2024
Baseline PET/CT Scans	2,261	2,586	2,611	2,826	2,946	4.6%	3,082	3,225

Source: Application page 66, recalculated based on 4.6%

The Mission Methodology Wrongly Reduces the Impact of Messino Cancer Centers PET Scanner on Future PET Volume

In Step 2 of its methodology, Mission subtracts only a portion of Messino Cancer Center’s projected PET referrals from its projected baseline PET procedures.¹ Mission projects Messino Cancer Center’s 2022 PET referrals will increase based on the same 6.8 percent CAGR identified in Step 1; however, Mission subtracts only 65 percent of Messino Cancer Center’s projected referrals during 2023 and 70 percent of projected referrals in 2024. See also the following tables.

**Step 2
 Projected Referrals Lost to Messino PET Unit**

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

Source: Application page 66

Step 4

	Historical	Interim Year	
	2018-2022 CAGR	CY 2023	CY 2024
Step 1: Baseline PET/CT Scans	6.8%	3,148	3,363
Step 2: Shift to Messino PET*		(901)	(1,036)
Adjusted Baseline Scans		2,247	2,326

Source: Application page 70

It is unclear why Mission assumes only 65 and 70 percent of Messino Cancer Center’s projected referrals will shift away from Mission and to the approved Messino PET scanner. Mission application page 66 states, *“In Messino’s application it demonstrated that not all of its patient referrals were to Mission and that not all referrals would be redirected from Mission.”* Emphasis added. However, Mission’s claim is incorrect.

¹ In Project ID #: B-12059-21, Messino Cancer Center is also referred to as AOP

In Project ID B-12059-21, Messino Cancer Center calculated its share of PET referrals based on actual FY2020 data. As shown in the excerpt below from the application, Messino Cancer Center’s total share in HSA I was 16.4% (which is largely based on 1,042 referrals to Mission Hospital).²

AOP Market Share of 2020 Referrals to HSA I PET Scanners

	Total FY 2020 Scans	2020 AOP Referrals	AOP Market Share
Mission Hospital	2,695	1,042	38.7%
Pardee Memorial Hospital	504	3	0.6%
Advent Health Hendersonville	243		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%
Total HSA I	7,022	1,154	16.4%

Sources: 2021 LRAs, internal AOP data

Source: B-12059-21, page 119

Messino Cancer Center projected its share of FY2020 PET referrals to remain constant through its third project year.

Step 4: Determine to Hold AOP Market Share Constant

For purposes of the next steps in its methodology, AOP conservatively projects its market share in future years to remain constant with its 2020 market share percentage. It is conservative for AOP physicians to project a continuation, without increase, of its 16.4% share of scan referrals through CY2025 because the reputation and quality of care offered by the practice is excellent.

Source: B-12059-21, page 119

There was no discussion or assumption regarding the reduction of AOP’s projected PET referrals on the basis that “not all referrals would be redirected from Mission.” To the contrary, Mission held its 16.4% HSA I market share constant through 2025 to project PET scans from Messino Cancer Center physicians. See also Step 6 from Messino Cancer Center’s application below.

As its next step, AOP applies its 16.4% market share to the total scan volumes identified in Step 5 to determine the number of AOP scans expected on the proposed AOP PET scanner for each Project Year.

Projected Scans Referred by AOP Physicians

	2020	2021	2022	YR 1	YR 2	YR 3
				2023	2024	2025
Total HSA I Scans	7,022	7,786	8,632	9,571	10,611	11,765
AOP Mkt Share-Held Constant	16.4%	16.4%	16.4%	16.4%	16.4%	16.4%
AOP Scans	1,154	1,279	1,419	1,573	1,744	1,934

Source: B-12059-21, page 122

² Messino Cancer Center referred 1,042 PET scans to Mission during 2020, which equates to 14.8 percent of Health Service Area I (1,072 ÷ 7,022 = .148).

By holding its 2020 market share (16.4%) constant, Messino Cancer Center projects the same proportion of its referrals to Mission during 2020 will instead be referred to Messino Cancer Center’s PET scanner during 2023-2025. Therefore, Messino Cancer Center’s methodology assumed to keep all of its 2020 market share, i.e., PET referrals, upon completion of its project. The following table demonstrates the Messino Cancer Center physician referrals in Step 9 are the same as the projected Messino Cancer Center scans based on 2020 market share held constant in Step 6 (above).

Step 9: Develop Utilization Projections for Total Scans

In the final step of its methodology, AOP adds the projections for scans to be referred by AOP physicians to the projections for scan referrals from non-AOP physicians (per the assumptions in Step 8) to determine the total utilization projections for the proposed project.

Projected AOP PET Scans			
	YR 1	YR 2	YR 3
	2023	2024	2025
AOP Physician Scans from Step 6	1,573	1,744	1,934
Additional Scan Volume (Non-AOP MDs Per Step 8)	127	190	253
Total AOP PET Volume	1,699	1,934	2,187

Source: B-12059-21, page 125

See also Attachment A for a copy of the assumptions and methodology used to project PET scan volumes for Messino Cancer Center, Project ID B-12059-21.

Using the methodology assumptions from Project ID B-12059-21, the following tables illustrate the Messino referral impact that should have been factored into Mission’s methodology.

- Messino Cancer Center’s 2020 PET referrals to Mission Hospital equate to approximately 14.8 percent of 2020 HSA I PET procedures.

2020 AOP Referrals to Mission	1,042
Total HSA I Scans	7,022
AOP Mission PET Referral Share of HSA I PET Scans	<u>14.8%</u>

Source: Project ID B-12059-21, page 119

- Messino Cancer Center projected its 2020 PET market share to remain constant through its third project year. The following table reflects the share of Messino referrals that were to Mission (14.8%) projected through 2025.

AOP Referrals to Mission Based on 2020 Share of HSA I PET scans (14.8%)

	2020	2021	2022	2023	2024	2025
Total HSA I Scans	7,022	7,786	8,632	9,571	10,611	11,765
AOP Share of HSA I PET Scans Based on Share of Referrals to Mission (14.8%)	1,042	1,155	1,281	<u>1,420</u>	<u>1,575</u>	<u>1,746</u>

Source: Project ID B-12059-21, page 121

As shown in the previous table, the approved Messino Cancer Center application will reduce referrals to Mission’s existing PET scanner by 1,746 PET scans during 2025. However, Mission’s methodology assumes Messino’s approved PET scanner will reduce referrals by 1,036 PET scans, a difference of 710 PET scans. Therefore, Step 2 of Mission’s methodology results in overstated projected PET procedures by failing to appropriately account for the impact of Messino Cancer Center’s approved PET scanner which will become operational during 2023.

Mission’s Methodology for Projecting Cardiac PET Scans Contains Errors & Miscalculations

AdventHealth Hendersonville would note that Mission’s PET projection methodology for its 2023 application projects to perform more than two times the number of cardiac PET scans compared to its 2021 PET scanner application methodology. Please see the following table.

Comparison of Cardiac PET Scans in Mission CON Applications, 2021 vs. 2023

	Project Year 1	Project Year 2	Project Year 3
2021 Mission PET Application	427	455	478
2023 Mission PET Application	682	987	1,109

Source: Project ID B-12059-21, page 64; Project ID B-12335-23, page 71

Upon careful review, Advent Health Hendersonville discovered the mathematical calculations provided in Mission’s 2023 application are inconsistent with the methodology described in the application. For example, application page 70 states:

- *“To calculate projected cardiac cases³ for the service area, Mission multiplied the population of the corresponding year by the appropriate Advisory Board rate and divided it by 100,000 (Example for 2025: Cases = 938,011*1.30/100,000).” Emphasis added*

The following table reflects the potential cardiac PET scans projected by Mission on application page 71.

³ Mission methodology’s references to “cases” are confusing as the proposed project involves development of a PET scanner which performs PET scans.

Step 5
Projected Cardiac PET/CT Scans

	2025	2026	2027
Population	938,011	943,914	949,300
Advisory Board Rate	1.30	1.58	1.64
Cases	1,219	1,492	1,558

Source: Project ID B-12335-23, page 71

However, Mission erred when it performed the cardiac PET scan projection calculations reflected in Step 5 of its application (p.71). Mission multiplied the population of the corresponding year by the “Advisory Board rate” and divided it by 1,000 not 100,000 as is described on application page 70. The corrected cardiac PET scan calculations are provided in the following table.

Corrected Cardiac PET Scans Based on Mission Methodology

	2025	2026	2027
Population	938,011	943,914	949,300
Advisory Board Rate per 100,000	1.30	1.58	1.64
Cardiac PET Scans	12	15	16

Source: Corrected based on methodology described in Project ID B-12335-23, page 70
 Example for 2025: Cases = 938,011*1.30/100,000

The corrected cardiac PET scan projections result in a mere fraction of projected cardiac PET scans compared to Mission’s miscalculations.

AdventHealth Hendersonville anticipates that Mission may respond to these comments by stating its methodology includes a typo and may attempt to amend its application. However, Mission failed to provide any supporting documentation regarding the Advisory Board rate for cardiac PET scans in its application as submitted and Mission cannot amend its application to provide any new information. The only reference to an Advisory Board rate for cardiac PET scans is on application page 70. Absent any other substantiating information in Mission’s application as submitted, one cannot draw any conclusion other than mathematical error.

Separate from the mathematical error, Mission did not provide any rationale to explain why it projects the Advisory Board rate for cardiac PET scans will increase during the three project years.

Step 5
Projected Cardiac PET/CT Scans

	2025	2026	2027
Population	938,011	943,914	949,300
Advisory Board Rate	1.30	1.58	1.64
Cases	1,219	1,492	1,558

Source: Project ID B-12335-23, page 71

AdventHealth also believes that Mission’s projected “capture rate” of projected cardiac PET scans is exceedingly high. Mission failed to provide any information to support the assumption that it will capture 70 percent of all cardiac PET scans during the third project year.

In summary, the following table recalculates Mission’s methodology based on 1) application of a 4.6% CAGR (which excludes PSMA growth during 2022), 2) the shift of Messino Cancer Center referrals to the approved PET scanner (based on the approved methodology in B-12059-21), and 3) the corrected cardiac PET scans based on Mission’s stated methodology.

	2018-2022 CAGR	CY2023	CY2024	Year 1 CY2025	Year 2 CY2026	Year 3 CY2027
Step 1: Baseline PET/CT Scans	4.6%	3,082	3,225			
Step 2: Shift to Messino PET		1,420	1,575			
Adjusted Baseline Scans		1,662	1,650			
Step 3: Incremental PSMA Scans		226	267			
Step 4: Projected Oncology Scans		1,888	1,917			
Step 5: Cardiac PET Projections				7	10	11
Total Mission Cancer Center PET Scans		1,888	1,917	2,012	2,108	2,206
Number of Units				2	2	2
Number of Scans per Unit				1,006	1,054	1,103

As shown in the previous table, when the errors in Mission’s methodology are corrected, the proposal fails to reach the minimum performance standard for two fixed PET scanners, i.e., 2,080 PET procedures per fixed PET scanner. Therefore, Mission fails to demonstrate the need it has for two fixed PET scanners.

For the reasons previously stated, the Mission application fails to adequately demonstrate the need it has for the proposed fixed PET scanner and that projected utilization is based on reasonable and supported assumptions. Therefore, the application does not conform to criterion 3.

Impact on Other Review Criteria

Based on the previously described facts for which the Mission application does not conform to criterion 3, the application is also **non-conforming to criteria 1, 4, 5, 6, and 18a and 10A NCAC 14C .3703.**

Criterion 20 “An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.”

There is publicly available data to document Mission’s failure to provide quality care in the past.

Mission Hospital’s Leapfrog Hospital Safety Grade scored a “B” grade during Spring 2021, Spring, 2020, and Spring 2019. Mission Hospital scored as low as a “C” grade during Fall 2019.

**Mission Hospital
Leapfrog Hospital Safety Grades**



Source: <https://www.hospitalsafetygrade.org/>

Since 2012, Leapfrog has released Safety Grades twice per year for nearly 3,000 hospitals across the U.S. To be as transparent as possible, Leapfrog makes past grades available. Examining past grades makes it clear which hospitals consistently achieve high standards of patient safety. According to Leapfrog, past grades can tell a lot about a hospital’s track record in keeping its patients safe from errors, injuries, accidents, and infections.

A small number of hospitals have consistently achieved "A" grades. AdventHealth Hendersonville is proud to have received consecutive “A” grades as demonstrated below.

**AdventHealth Hendersonville
Leapfrog Hospital Safety Grades**



Source: <https://www.hospitalsafetygrade.org/>

Another quality assessment tool is the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey which asks a random sample of recently discharged patients about their hospital care experience like how well nurses and doctors communicated, how responsive hospital staff were to their needs, and the cleanliness and quietness of the hospital environment. HCAHPS is required by CMS

(the Centers for Medicare and Medicaid Services) for all hospitals in the United States. The HCAHPS star ratings summarize patient experience, which is one aspect of hospital quality. **More stars mean better quality care.** Healthcare consumers can use the star ratings along with other quality information when making decisions about choosing a hospital.⁴

Mission scored only two stars (out of five) for the most recent patient survey rating. In comparison, AdventHealth Hendersonville scored four stars. Mission's HCAHPS scores are all well below state and national benchmarks. The following table summarizes Mission's patient survey star ratings and average survey responses.

HCAHPS Patient Survey Ratings

	Mission	AdventHealth Hendersonville	NC Average	National Average
Overall Patient Survey Rating	★ ★	★ ★ ★ ★		
Patients who reported that their nurses "Always" communicated well.	72%	79%	79%	79%
Patients who reported that their doctors "Always" communicated well.	75%	81%	81%	80%
Patients who reported that they "Always" received help as soon as they wanted.	46%	61%	63%	66%
Patients who reported that the staff "Always" explained about medicines before giving it to them.	55%	61%	62%	62%
Patients who reported that their room and bathroom were "Always" clean.	53%	72%	70%	72%
Patients who reported that the area around their room was "Always" quiet at night.	54%	64%	62%	62%
Patients who reported that YES, they were given information about what to do during their recovery at home.	81%	90%	86%	86%
Patients who "Strongly Agree" they understood their care when they left the hospital.	41%	56%	50%	51%
Patients who gave their hospital a rating of 9 or 10 on a scale from 0 (lowest) to 10 (highest).	55%	76%	69%	71%
Patients who reported YES, they would definitely recommend the hospital.	50%	81%	67%	70%
No. of Completed Surveys	403	546		

Source: Centers for Medicare & Medicaid Services (CMS), Hospital Compare, updated 01.06.2023

The N.C. Department of Labor's Occupational Safety and Health Division (OSH) performed three inspections in October and November 2021 at Mission Hospital, resulting in nearly \$30,000 of civil

⁴ <https://www.medicare.gov/care-compare/resources/hospital/patient-survey-rating>

penalties. In addition to failing to fit employees for N95 respirators properly, OSH investigators said the hospital waited to report that one of its workers had been hospitalized with COVID-19 and later died.⁵

According to the NCDOL citation, "the employer did not ensure that the employee(s) using a tight-fitting facepiece respirator were fit tested prior to initial use of the respirator, whenever a different respirator facepiece ... were used." Hannah Drummond, an emergency room nurse at Mission and the chief nurse representative with the local chapter of National Nurses United reported, "the fit-test issues stemmed from a lack of oversight."⁶

One of the citations also indicates the hospital did not report an employee's October 18, 2021 COVID-related hospitalization and subsequent death until nurses filed a complaint on November 22, 2021. Hospital officials are required to report each work-related COVID death to OSH within eight hours. The employee died on November 10, 2021, according to the citation, OSH was not notified until Nov. 22. According to an article published in Cardinal & Pine, the employee was a nurse in a COVID ward.⁷

Mission Hospital staff have been vocal regarding their safety concerns. In June and September 2021 and February 2022, the labor union representing registered nurses at Mission Hospital staged protests to call attention to what it called "patient safety and unsafe working conditions" at Mission Hospital. Among other complaints, the National Nurses Organizing Committee of National Nurses United asserted that HCA Healthcare-owned Mission Hospital scheduled symptomatic, COVID-positive nurses to work at the hospital and failed to provide nurses with adequate masks, gowns, gloves, and other personal protective equipment. "Since HCA purchased our hospital in 2019, the management has cut corners on safe patient care by cutting support staff and violating their own nurse staffing grids," said Shelby Runkles, a cardiovascular Intensive Care Unit RN at Mission. "With each additional patient, nurses are more prone to make mistakes and the risk of serious complications increases."⁸

In August 2022, registered nurses from Mission Hospital held a rally "to protest management's refusal to address chronic short staffing that jeopardizes patient safety."⁹

On January 26, 2023, registered nurses from Mission Hospital rallied again outside the hospital to call for safe staffing levels.

The repeat demonstrations of staff nurses rallying for safe staffing levels is legitimate evidence of Mission's failure to provide quality care.

⁵ <https://www.charlotteobserver.com/news/coronavirus/article259696570.html#storylink=cpy>

⁶ <https://www.citizen-times.com/story/news/2022/03/23/mission-hca-citations-show-ppe-and-covid-death-reporting-failures/7139196001/>

⁷ <https://cardinalpine.com/story/nc-fines-asheville-hospital-30000-after-nurses-complain-of-covid-risks/>

⁸ <https://avlwatcdog.org/barks/nurses-to-picket-mission-hospital-citing-concerns-about-safety/>

⁹ <https://www.asheville.com/news/2022/08/mission-hospital-nurses-to-hold-rally-for-patient-safety-concerns-on-thursday-aug-25th/>

Conclusion

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. The applicants collectively propose to develop two fixed PET scanners in Health Service Area I. Based on the 2023 SMFP's need determination, only one fixed PET scanner can be approved.

AdventHealth Hendersonville is the only application fully conforming to all statutory and regulatory review criteria. Furthermore, AdventHealth Hendersonville is comparatively superior to the Mission proposal. AdventHealth Hendersonville will:

- increase patient access to fixed PET scanner services in the service area,
- enhance geographic access to fixed PET scanner in the service area; and
- offer patients and families enhanced choice for fixed PET scanner services in western North Carolina.

Thus, the application submitted by AdventHealth Hendersonville is the most effective alternative and should be approved as submitted.

Attachment A

**Assumptions & Methodology from Messino Cancer Center Application
Project ID B-12059-21**

**Form C.2b
Utilization – Assumptions and Methodology**

AOP’s Project Timetable calls for the AOP PET scanner to be operational on 1/1/23 following the completion of facility renovations during CY 2022. The initial project years are CY 2023, CY 2024, and CY 2025.

AOP projected the number of PET procedures it will perform in the first three years of operation using the following assumptions, data and calculations:

<i>Step</i>	<i>Description</i>
<i>Step 1</i>	<i>Review Health Service Area I Historical Scan Volumes & Growth</i>
<i>Step 2</i>	<i>Review AOP Historical Scan Volumes</i>
<i>Step 3</i>	<i>Determine AOP Market Share</i>
<i>Step 4</i>	<i>Determine to Hold AOP Market Share Constant</i>
<i>Step 5</i>	<i>Determine Total Future Scan Volumes</i>
<i>Step 6</i>	<i>Apply AOP Market Share to Total Scan Volumes</i>
<i>Step 7</i>	<i>Identify Physician Support from Community Physicians</i>
<i>Step 8</i>	<i>Develop Assumptions for Non-AOP Referrals</i>
<i>Step 9</i>	<i>Develop Utilization Projections for Total Scans</i>

Each step is described in detail below.

Step 1: Review Health Service Area I Historical Scan Volumes & Growth

AOP’s methodology begins with the assumption that the AOP scanner will compete with existing PET scanners in HSA I, but will compete most directly with those in Western HSA I (scanners in Buncombe, Henderson, Haywood and Jackson Counties).

AOP first examined the most current available data on PET scan volumes. Based on 2021 License Renewal Applications, the number of scans at PET scanners in Western HSA I in FYE September 2020 was 3,882. The total number of scans at HSA I PET scanners was 7,022.

AOP next reviewed reported scan volume data for purposes of determining a historical growth rate. AOP relied on 2017-2020 data on PET volumes for scans performed at all sites in Health Service Area I.

AOP acknowledges that the COVID-19 pandemic impacted 2020 healthcare utilization, particularly non-emergency healthcare including diagnostic imaging and cancer screenings. *Time Magazine* reported that

73% of Americans delayed at least one medical service during the pandemic. A recent study analyzed Medicare claims data to assess changes in the utilization of cancer services from March through July 2020. The study found there were decreases and delays in identifying new cancer and receiving cancer treatment during those four months. The authors describe the reduction as “significant short-term disruptions in care delivery” for cancer patients.¹ Similarly, an article in the *Journal of Nuclear Medicine* found that survey respondents reported the number of PET/CT scans in the US and Canada decreased by over 30 percent from pre-COVID levels.² See Exhibit C-4.5 for copies of these articles.

As such, the 2020 PET referrals were likely lower due to the COVID-19 pandemic and the Stay-at-Home mandate (Executive Order No. 121) of North Carolina’s Governor. Because PET referrals in 2020 were impacted by COVID-19, data for the 2020 period may not be representative of future years. AOP does not anticipate the COVID-19 pandemic will have a negative impact on the future need for PET services at AOP nor the need for those services in Health Service Area I. The underlying health issues requiring PET imaging have not changed and thus, AOP assumes the incidence of conditions requiring PET services will ultimately continue. As discussed elsewhere, the health conditions in the Service Area population will continue to support a great need for PET services.

While volumes for 2020 were likely lower based on the COVID-19 pandemic and the Governor’s Stay at Home mandate, AOP determined it reasonable and conservative to rely on an examination of historical utilization from 2017-2020 to derive a compound annual growth rate (CAGR).

To determine a CAGR for the western and eastern areas of Health Service Area I, AOP identified all PET volumes (mobile and fixed) as reported on the License Renewal Applications for the Fiscal Year Ending September (9/30) for the periods 2017 through 2020.

AOP assigned volumes for PET scans performed on PET scanners located in-line with, or west of Buncombe County (*i.e.*, those performed in Buncombe, Henderson, Haywood, and Jackson Counties) to the “western” area and all others in the Service Area to the “eastern” area.

As shown in the following table, for 2017 – 2020, the compound annual growth rate for PET scans on PET scanners in Western HSA I was 13.5 percent. For the entire Health Service Area, the CAGR was 10.9 percent.

¹ Debra Patt et al., “Impact of COVID-10 on Cancer Care: How the Pandemic is Delaying Cancer Diagnosis and Treatment for American Seniors,” *JCO Clinical Cancer Informatics* 4 (Nov. 2020): 1059–1071.

² Lutz Freudenbuerg et al., “Global Impact of COVID-19 on Nuclear Medicine Departments: An International Survey in April 2020,” *The Journal of Nuclear Medicine* (Sept. 2020), <https://jnm.snmjournals.org/content/jnumed/61/9/1278.full.pdf>.

Growth in PET Scans at HSA I Facilities

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

The data on the growth of PET scan volumes for Health Service Area I shows scan volumes are growing most rapidly in the western areas of HSA I. Specifically, the number of PET scans performed on HSA I scanners located in-line with, or west of Buncombe County (*i.e.*, those performed in Buncombe, Henderson, Haywood, and Jackson counties) grew at a CAGR of 13.5% from 2017-2020, versus a CAGR of 7.9% for scans performed at sites in the eastern portion of the HSA.

As noted above, these CAGR values may be lower than they would have otherwise been absent the impacts of the COVID-19 pandemic. As such, the CAGR values are likely a conservative indicator of the future growth of PET volumes in the region.

This data suggests that a significant (and fast-growing) number of patients found it sufficiently convenient to access a PET scan at one of the existing sites in the counties in or to the west of Buncombe County. All these western sites are within a reasonable drive time from the proposed AOP PET site, indicating this large and expanding volume of residents are likely to find the proposed AOP PET site to be a reasonably proximate choice at which to receive PET imaging services.

Step 2: Review AOP Historical Scan Volumes

A critical assumption in the AOP Need Methodology is the assumption that the number of scans historically “referred out” by AOP physicians to PET scanners in Health Service Area 1 will, after

implementation of the proposed project, translate directly into PET scans “performed on” the AOP PET scanner.

For many years, Messino Cancer Centers physicians have relied on PET scans to diagnose and treat their patients. The projected utilization for the AOP PET scanner is reasonably based, in part, on the existing PET referral patterns of the Messino Cancer Centers’ physicians (as well as referrals from non-Messino physicians as discussed as a later step in the Methodology).

Because the AOP physicians are championing this application’s proposal to add a PET scanner within AOP’s offices at Messino Cancer Centers and are pledging their support to the project, it is reasonable to assume, consistent with their physician letters, that the volumes these physicians formerly referred out to other existing PET locations in Service Area I will, in the future, be performed on the AOP PET scanner proposed in this application.

AOP does not have access to the PET referral volumes for the Messino Cancer Centers’ physicians for years prior to 2020. The Messino doctors split from Mission Hospital in January of 2020 and later that year entered the existing arrangement with AOP. AOP does have access to 2020 and First Quarter 2021 data on the PET referrals of AOP physicians.

Based on internal data, AOP physicians referred out 1,154 of the PET scans on HSA I PET scanners in CY 2020.³ For this application, AOP assumed the number of scans AOP physicians referred in CY2020 would be the same as the number referred in the year ending September 31, 2020. This is a conservative assumption because calendar year 2020 included two additional months during which COVID-19 was affecting scheduled medical care.

For point of reference, AOP also accessed internal data to determine that AOP physicians referred out 334 scans in the First Quarter of 2021. By annualizing Q1 2021 data, AOP estimated the AOP physicians would refer 1,336 PET procedures in CY 2021. This volume of referrals, annualized, would equate to an estimate of 1,336 AOP referrals in CY 2021 reflecting a growth of approximately 15.7% over AOP physicians’ CY 2020 referrals.

Period / % Increase	AOP PET Referrals
CY 2020	1,154
Q1 2021	334
Annualized CY 2021	1,336
% Increase CY 2020 to CY 2021	15.7%

While AOP examined annualized 2021 data and the resulting year-over-year growth, the percentage growth between 2020 and 2021 is not factored into future steps in the AOP need methodology.

Step 3: Determine AOP Market Share

As a next step, AOP examined its “market share” or the share of total scans performed on Service Area scanners which were represented by the scans referred by AOP physicians.

³ Note: PET scans that were ordered but cancelled, denied, or not done were excluded from this analysis.

To be clear, AOP is not now and has not historically been a PET scanner site in Health Service Area I. Yet, because all PET scans require a physician referral, it is possible to determine the percentage of total scans performed **on the referral of an AOP physician** and thus, to define the extent of the AOP “market share” of scans as a percentage of total scans performed on PET scanners within the Service Area.

AOP examined its market share of total scans performed at all sites in Health Service Area I as well as its market share of scans performed in Western HSA I. AOP used 2020 data as reported in 2021 License Renewal Application and its own data.

As shown in the table below, AOP physicians accounted for 16.4% of PET scans at HSA I in 2020. Although AOP’s market share of scans limited to Western HSA I is larger (28.6%), the Applicant based its projections on its market share for all of HSA I, to be conservative.

AOP Market Share of 2020 Referrals to HSA I PET Scanners

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

Sources: 2021 LRAs, internal AOP data

Step 4: Determine to Hold AOP Market Share Constant

For purposes of the next steps in its methodology, AOP conservatively projects its market share in future years to remain constant with its 2020 market share percentage. It is conservative for AOP physicians to project a continuation, without increase, of its 16.4% share of scan referrals through CY2025 because the reputation and quality of care offered by the practice is excellent.

AOP’s projection for a constant market share is a particularly conservative assumption considering:

- **AOP’s plans to increase the number of physicians in its practice.**

Messino Cancer Centers has a long history of physician growth. In coming years, the number of oncologists in the practice will grow, even allowing for retirement of existing physicians. AOP has in place a firm commitment from an oncologist to join the practice in 2021 and active recruitment on-going for 2022 and 2023 hires. Although one of these new hires will offset a planned retirement, AOP expects two net new physicians to join over this period. AOP plans to recruit new oncologists in 2024 and 2025 for a net addition of one oncologist in each year.

- **Enhanced efficiencies and ability to schedule scans without delays**

The projection of a constant market share is conservative in that it is reasonable for AOP to generally expect its physicians to refer more PET scans after implementation of the AOP PET because the AOP PET scanner will operate more efficiently to allow scans to be promptly performed without scheduling delays. With ready access to an on-site PET scanner, AOP physicians can rely more heavily on their in-house PET scanner to inform clinical judgments with invaluable imaging studies. Those imaging services can be more efficiently ordered, performed, and reported to the physicians who will have increased control over patient in-take and scheduling, equipment maintenance scheduling, and other dynamics which impact the efficiencies of a PET program.

- **Advances in clinical applications for PET and the importance of PET studies in clinical trials.**

The projection of a constant market share is conservative considering physicians from AOP and doctors in other medical specialties can be reasonably expected to refer more scans as advances in medicine and technology reveal new uses for PET studies in diagnosis and treatment of patients. Over time, “new” PET uses can be expected to become the standard of care. Patients participating in clinical trials are expected to rely on the AOP PET based on its ability to quickly schedule and report scan results to allow prompt monitoring of conditions within a study.

- **The potential for Health Plans to steer PET utilization to the most Cost-effective Option.**

AOP’s projection for a constant market share is conservative given the reasonable expectation that commercial health plans will increasingly encourage patients to obtain diagnostic services in lower-cost, non-hospital locations. Anthem, a BlueCross plan with 43 million medical members in 2020,⁴ does not pay for MRIs or CT scans delivered in hospitals, unless the service is only available in a hospital or a review finds it medically necessary to perform the scan in a hospital. In 2019, UnitedHealthcare began limiting the hospital-based MRIs and CT scans it would cover and developed medical necessity criteria that must be met for providers in certain states. In 2020, Cigna stopped covering MRIs and CT scans in hospitals that do not meet medical necessity requirements.⁵ AOP expects where a non-hospital PET scanner is available commercial health plans and Medicare Advantage plans will adopt similar policies for PET scans.

- **Outpatient Imaging Services as Increasingly “Shoppable” Services**

AOP’s projection of a constant market share is conservative given that outpatient imaging services are becoming “shoppable” services, meaning that patients’ ability to compare pricing can be reasonably expected to increase, making competition an even more important factor in healthcare decision-making. CMS increased “price transparency” by requiring hospitals to post their negotiated rates for services on their web sites beginning January 1, 2021. As more hospitals comply with the Federal law’s requirements, more information will become available to patients, employers, and physicians.

⁴ Anthem, Inc. Form 10-K for the Fiscal Year Ended December 31, 2020, page 3. Available at: <https://ir.antheminc.com/static-files/42a5e02c-6196-4246-8f50-cf466940800c>

⁵ Haefner, Morgan. October 19, 2020. What Anthem, Cigna, UnitedHealth’s hospital-based imaging policies entail. Becker’s Hospital Review. Available at: <https://www.beckershospitalreview.com/payer-issues/what-anthem-cigna-unitedhealth-s-hospital-based-imaging-policies-entail.html>

- **North Carolina’s Clear Pricing Project**

AOP’s projection of a constant market share is conservative considering enhanced attention devoted to cost-effective service delivery. At the State level, North Carolina’s State Employee Health Plan implemented its own *Clear Pricing Project* to promote cost containment.⁶ North Carolina has adopted incentives for its insureds to make cost-effective health care decisions. With these and other initiatives, it is reasonable for AOP to expect increased attention to cost considerations and it is further reasonable for AOP to anticipate its own ability to deliver on a promise to be the region’s lower-cost choice for patients requiring PET services. These factors would reasonably support increased market share capture by AOP as a cost-effective choice for PET services in the Area.

- **AOP’s charity care commitment**

AOP’s projection for a constant market share is conservative in light of AOP’s charity care commitment. By allowing for 3% of its scans to be performed as charity (free) scans in each of the first three project years, AOP expects to increase the scans performed from referrals by AOP and non-AOP physicians and to improve regional access to a critical diagnostic tool.

- **Proposed changes in North Carolina’s Medicaid program**

AOP’s projections are conservative given its plans for significant service to residents whose care is reimbursed by Medicaid. North Carolina’s Medicaid Transformation effort is a result of legislation passed in 2015 with patient enrollment beginning in 2021. Under the new system, Prepaid Health Plans will administer the services to Medicaid recipients. These plans will call for enrolled patients to receive care from defined provider networks. AOP will be out front in joining these provider networks allowing AOP’s PET scanner to be a first choice of the Health Plans who will serve North Carolina’s Medicaid recipients.

Step 5: Determine Total Future Scan Volumes

AOP next applied the CAGR determined in Step 1 to identify total projected scan volumes for the Service Area in the interim year and each of the three Project Years.

Projected Scan Volumes – Health Service Area I

				YR 1	YR 2	YR 3
	2020	2021	2022	2023	2024	2025
Total HSA I Scans	7,022	7,786	8,632	9,571	10,611	11,765

Expressed as a CAGR, total scan volumes across Health Service Area I have grown at a rate of nearly 11%. The AOP scanner will be located in the western area of the Service Area which has grown at an even higher annual rate than the growth rate for the Service Area as a whole and at a rate much greater than growth in scans performed in the eastern areas of the Service Area. These data points and the resulting CAGRs show that it is reasonable and conservative for AOP to project growth in PET volumes year over year using the 10.9% service-wide CAGR identified in Step 1.

⁶ “State Health Plan Clear Pricing Project,” North Carolina State Health Plan for Teachers and State Employees, <https://www.shpnc.org/state-health-plan-clear-pricing-project>, accessed April 7, 2021.

Step 6: Apply AOP Market Share to Total Scan Volumes

As noted in Step 3, AOP referrals in 2020 represented 16.4% of the total scan referrals in Service Area I. AOP has plans to add one new physician per year to its group. Based on the per-physician average PET referrals shown in its internal data, each new oncologist can be reasonably expected to refer 95 additional patients for scans each year. Notwithstanding its plans for growth in its group and reasonable expectations for increased market share, to be conservative, AOP projects to hold its 16.4% market share percentage constant over the interim year and all three Project Years.

As its next step, AOP applies its 16.4% market share to the total scan volumes identified in Step 5 to determine the number of AOP scans expected on the proposed AOP PET scanner for each Project Year.

Projected Scans Referred by AOP Physicians

				YR 1	YR 2	YR 3
	2020	2021	2022	2023	2024	2025
Total HSA I Scans	7,022	7,786	8,632	9,571	10,611	11,765
AOP Mkt Share-Held Constant	16.4%	16.4%	16.4%	16.4%	16.4%	16.4%
AOP Scans	1,154	1,279	1,419	1,573	1,744	1,934

Step 7: Identify Physician Support from Community Physicians

AOP’s utilization projections are supported by AOP’s plans to make its proposed PET scanner available to physicians in the community who practice as part of groups other than AOP. In addition to the scans to be referred by AOP’s physicians, AOP has received significant expressions of support from community physicians, many of whom have provided specific estimates of their intent to refer scans to the AOP PET scanner once it becomes operational. Letters of support from non-AOP physicians show they expect to refer 253 to 290 patients to AOP for PET scans. These volumes are summarized in the table below, and Exhibit C-6 includes the physicians’ letters. These PET scans will be scans referred by physicians outside the AOP group, in addition to those referred by AOP physicians.

Estimated PET Scan Volumes from Physician Letters of Support

Physician Name	Physician Specialty	Low Estimated Volume	High Estimated Volume
Frank Melvin	Oto-HNS	50	50
Colin Bird	Colon & Rectal Surgery	50	50
Paul Ahearne	Surgical Oncology	30	50
Benjamin Deschner	Surgical Oncology	25	25
Memory Care Physicians: Virginia Templeton; Amy Cohen; David Johnson; Della Simon; Pamela Gutman; Margaret Noel; Margaret Word-Sims	Internal Medicine, Family Practice, Geriatrics, Hospice/Palliative Medicine	12	15
Ronald Lane	Otolaryngology	12	24
Lauren Bernstein	Endocrinology	10	10
Brian Cumbie	Endocrinology	10	10
Victor Marlar	Endocrinology	10	10
Thomas Mitchell	Endocrinology	10	10
Richard Dodd	Endocrinology	10	10
Theodore Rheney Jr.	Otolaryngology	10	12
Hilary Thomas	Endocrinology	10	10
J.G. Cargill	Urology	4	4
Total Reported Estimated Volumes		253	290

The table below shows there are at least an additional eight independent oncologists, three urologists, and three independent otolaryngologists (ear, nose and throat) in HSA I who are expected to refer patients to the scanner. However, at this time they have not estimated a number of PET scans annually so the Applicant has not assumed any PET scans from these physicians.

Independent Oncologists and Urologists who May Refer Patients for PET Scans

Physician	Specialty	Practice Location(s)
Andrew Franklin	Urology	Asheville
Raymond Thertulien	Oncology-Hematology	Asheville
Robert Moore	Ear, Nose and Throat	Asheville
Don Jackson	Medical Oncologist	Asheville, Weaverville
Charles Wendling	Medical Oncologist	Asheville
Daniel Baseman	Radiation Oncologist	Brevard, Hendersonville
Jeffrey Roberts	Radiation Oncologist	Forest City (Rutherford County)
Jason Roberts	Ear, Nose and Throat	Asheville
Stephen Sean	Ear, Nose and Throat	Asheville
Quinten Black	Radiation Oncologist	Asheville, Hendersonville, Marion, Weaverville
Michael Burris	Urology	Asheville
Hal Hooper	Urology	Asheville
Iaonna Mazotas	Surgical Oncologist	Asheville
Melissa Zoumboros	Surgical Oncologist	Asheville

The AOP physicians have longstanding ties with the medical community in Western North Carolina and will continue to reach out to referring physicians about its plans for a new PET scanner in Asheville. AOP has planned and budgeted funds for marketing and outreach efforts in the days leading up to its projected date for initial operation of its scanner. Besides the oncologists and urologists listed above, other specialties including pulmonologists, surgeons and primary care physicians are regular sources of PET scan referrals. It is reasonable to assume some of these physicians will refer patients to AOP for PET scans. Other physician groups not affiliated with or employed by a hospital system have no constraints on where they can refer patients to receive diagnostic imaging. Other physicians who have alignments with Mission Hospital may send their patients to be scanned at AOP based on physician or patient preference.

It is reasonable to assume that many community physicians will refer patients to AOP because of its lower cost of care (especially for privately insured patients), AOP's expanded operating hours, and patients' interest in diagnostic scanning on the newest available equipment in the region in a physician-office location not situated within a hospital environment or billed by a hospital system.

AOP will implement processes and protocols to streamline and enhance the referral and scan process for the referring physician and the patient. AOP will strive to conveniently schedule scans, to provide scans in a timely manner, and to ensure results are available quickly. Physicians in Western North Carolina have expressed frustration with waits for PET scans. AOP will attract referrals by reducing or eliminating that frustration.

The new PET scanner will attract referrals from outside physicians because of its quality. The AOP PET scanner will be a brand-new PET scanner and will be ACR accredited at the earliest opportunity. AOP physicians are trusted doctors connected throughout the region by their office locations from Franklin west to Marion and Spruce Pine. Mission opted to reduce its presence in many of these rural areas. Referring physicians will have a new option to refer patients for PET scans to AOP.

Step 8: Develop Assumptions for Non-AOP Referrals

As its next step, AOP identified assumptions for incorporating the volume of referrals expected from community physicians practicing in other groups. AOP conservatively relied on the “low” estimates included in instances in which supporting physicians provided a projected range of scans expected to be referred to the AOP scanner.

Also, to take into account time for area physicians to become acquainted with and accustomed to referring patients to the new AOP PET scanner, AOP conservatively assumed a “ramp-up” period which adds new physician referrals to the utilization projections incrementally over the initial Project Years.

The projected PET scans anticipated to be served on the AOP PET scanner as a result of referrals from community physicians (outside the AOP group) are reflected in the table below using the low estimates from the non-AOP physicians, and a ramp up of 50% in Year 1, 75% in Year 2 and 100% of the low-end in Year 3.

Projected PET Scan Referrals from Non-AOP Physicians

	YR 1	YR 2	YR 3
	2023	2024	2025
Additional Scan Ramp-Up Assumption	50%	75%	100%
Additional Scan Volume (Low #s from Step 7)	253	253	253
Annual Non-AOP Physician Referral Volumes	127	190	253

Step 9: Develop Utilization Projections for Total Scans

In the final step of its methodology, AOP adds the projections for scans to be referred by AOP physicians to the projections for scan referrals from non-AOP physicians (per the assumptions in Step 8) to determine the total utilization projections for the proposed project.

Projected AOP PET Scans

	YR 1	YR 2	YR 3
	2023	2024	2025
AOP Physician Scans from Step 6	1,573	1,744	1,934
Additional Scan Volume (Non-AOP MDs Per Step 8)	127	190	253
Total AOP PET Volume	1,699	1,934	2,187

As shown above, AOP’s utilization will exceed the Performance Standard found at 10A NCAC 14C .3703 in its third operating year, stating the proposed dedicated PET scanner “shall be utilized at an annual rate of at least 2,080 procedures by the end of the third year following completion of the project.”