

WRITTEN COMMENTS ON 2025 HEALTH SERVICE AREA I FIXED PET SCANNER COMPETITIVE REVIEW

SUBMITTED BY ADVENTHEALTH ASHEVILLE

October 1, 2025

Four applicants submitted CON applications in response to the need identified in the 2025 SMFP for one additional fixed PET scanner in Health Service Area (HSA) I. The applicants include:

- CON Project ID B-012688-25: AdventHealth Ashville, Inc.
- CON Project ID B-012684-25: Novant Health Asheville PET
- CON Project ID B-012675-25: UNC Health Pardee
- CON Project ID B-012685-25: Mission Hospital

AdventHealth Asheville (AdventHealth) submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the competing applications, including the applicants' 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 the competing applications and AdventHealth may develop additional opinions, as appropriate upon further review and analysis.

COMPARATIVE ANALYSIS OF THE COMPETING FIXED PET SCANNER APPLICATIONS

The following factors have typically 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: 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

Four CON applications have been submitted to develop a fixed PET scanner in Health Service Area I. Based on the 2024 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 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 Asheville	B-012688-25	Yes
Novant Health Asheville PET	B-012684-25	No
UNC Pardee	B-012675-25	No
Mission Hospital	B-012685-25	No

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

Scope of Services

Regarding scope of services, the competing applications are each responsive to the 2025 SMFP need determination in HSA I for one fixed PET scanner. The following table compares the scope of services 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

	Proposed Scope of Services			
Facility	Oncological PET	Neurologic PET	Cardiac PET	
AdventHealth Asheville	х	Х	Х	
Novant Health Asheville PET	Х	Х	Х	
UNC Pardee	Х	Х	Х	
Mission Hospital	Х		Х	

Source: CON applications

AdventHealth's proposes to develop a hospital-based fixed PET scanner, providing rapid, accurate imaging for oncology, neurology, cardiology, and other specialties critical to the medically underserved populations in the service area. UNC Pardee and Novant Health also propose to offer oncological, neurological, and cardiac PET scans; however, UNC Pardee and Novant Health fail to conform to applicable review criteria and administrative rules. Mission Hospital fails to mention the offering of any neurological

diagnostics. Therefore, the AdventHealth application is a **more effective alternative** regarding scope of services.

Historical Utilization

In previous competitive reviews, the Agency has assessed historical utilization among the competing applicants. Mission Hospital is the only applicant operating an existing PET scanner. Based on the lack of historical utilization rate data for all other applicants, the finding of this competitive factor is inconclusive.

	PET Scanner	FFY2023	
Applicant	Planning Inventory	Procedures	PET Utilization Rate*
AdventHealth	1^	N/A	N/A
Novant Health	0	N/A	N/A
UNC Pardee	0	N/A	N/A
Mission Hospital	1	2,862	95.4%

^{*}Based on a fixed PET scanner capacity of 3,000 procedures per unit

Source: Proposed 2025 SMFP, Table 15F-1: Utilization of Existing Dedicated Fixed PET Scanners

Geographic Accessibility

The 2025 SMFP identifies the need for one fixed PET scanner in HSA I. HSA I is a multi-county service area that includes Avery, Buncombe, Burke, Cherokee, Clay, Graham, Haywood, Henderson, Jackson, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, Yancey. The following table summarizes the locations of existing and approved fixed PET scanners in HSA I as reported by the 2025 SMFP and other publicly available information.

Facility	Planning Inventory	Location
AdventHealth Hendersonville *	1	Weaverville
Catawba Valley Medical Center/		
Frye Regional Medical Center	1	Hickory
Messino Cancer Center	1	Asheville
Mission Hospital	1	Asheville

^{*} Approved but not yet operational. The project is under development (Project ID B-12331-23). Source: Table 15F-1: Utilization of Existing Dedicated Fixed PET Scanners; 2025 SMFP

The current distribution of the existing and approved fixed PET scanners within HSA I is heavily concentrated in the southern and eastern portions of the region, including sites in Asheville, Hendersonville, and Hickory. This distribution creates a geographic gap in access for residents of the more remote northwestern counties where terrain, infrastructure, and distance pose substantial barriers to timely care.

[^]Approved but not yet operational. The project is under development.

HANCOC SULLIVAN AdventHealth Hendersonville JOHNSON HAWKINS Catawba Valley Medical Center Messino Cancer Centers WASHINGTON CARTER Mission Hospital GREENE ANDERSON UNICO **JEFFERSON** MITCHELL KNOX COCKE IREDELL SEVIER **Proposed Location** LOUDON BLOUNT BUNCOMBE 3 LINCOLN MONROE 0 GASTON MECKLENB CHEROKEE

Health Service Area I: Existing & Approved Fixed PET Scanner Locations

The proposed development of AdventHealth's fixed PET scanner in Weaverville will meaningfully enhance geographic access to advanced diagnostic imaging for residents across HSA I, with particular benefit to underserved, mountainous counties such as Madison, Mitchell, and Yancey.

Madison, Mitchell, and Yancey counties are rural, mountainous communities in the northern portion of HSA I. These counties lack local access to fixed PET services and are not in close proximity to any of the existing fixed PET sites. Patients in these areas must travel significant distances, often through challenging mountain terrain and inclement weather, to access PET imaging, posing a barrier to timely diagnosis and care. Such barriers contribute to delayed diagnosis, missed appointments, and disparities in access to time-sensitive imaging for cancer, neurological, and cardiac conditions.

Mission Hospital plans to add a second PET scanner near their existing Asheville site, only two miles away at Vanderbilt Park, this does not significantly expand access to underserved or distant areas. Similarly, UNC Pardee Hospital's proposed scanner in Hendersonville and Novant Health Asheville's location in Arden primarily serve existing access points without substantially expanding coverage to underserved regions.

Therefore, **AdventHealth's** Weaverville location offers a **more effective alternative** regarding geographic accessibility

Access By Service Area Residents

The 2025 SMFP defines the service area for a fixed PET scanner as "the HSA [Health Service Area] in which it is located (Table 15F-1)." Thus, the service area for this review is HSA I. The counties in HSA I include:

Avery, Buncombe, Burke, Cherokee, Clay, Graham, Haywood, Henderson, Jackson, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, 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 or percentage 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 Asheville	Novant Health Asheville PET	UNC Pardee	Mission Hospital
PET Patients from				
HSA I	2,049	2,422	2,531	1,883
Total PET				
Patients	2,091	2,481	2,696	2,120
HSA III % of Total				
Patients	98.0%	97.6%	93.9%	88.8%

Source: CON Applications Section C.3

AdventHealth's application projects to serve the largest percentage of patients from HSA I. Therefore, regarding this comparative factor, **AdventHealth** is a **more effective** alternative.

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 to compete for patients.

Mission Health is the only applicant currently operating a fixed PET scanner in the service area. Novant and UNC Pardee fail to conform to the applicable statutory review criteria and administrative rules; therefore, the applications cannot be approved. AdventHealth Asheville would be a new hospital provider of fixed PET services in the service area. Thus, regarding competition for fixed PET services in the service area, the application submitted by **AdventHealth** is a **more effective** in this review.

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, the applications are compared concerning two underserved groups: Medicare patients, and Medicaid patients.¹ Access by each group is treated as a separate factor.

¹ Due to differences in definitions of charity care among applicants, comparisons of charity care are inconclusive.

In this competitive review, all applicants propose to develop fixed PET scanners Therefore, conclusive comparisons can presumably be made for each factor related to access by underserved groups. The following tables compare projected access by Medicare and Medicaid for the applicants.

Projected Medicare Access

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

Projected Medicare Revenue - 3rd Full FY

			Medicare % of Total
	Medicare Revenue	Total Gross Revenue	Gross Revenue
AdventHealth Asheville	\$39,163,032	\$50,505,156	77.5%
Novant Health Asheville PET	\$21,720,275	\$30,721,747	70.7%
UNC Pardee	\$23,263,226	\$30,167,403	77.1%
Mission Hospital	\$34,064,069	\$48,070,676	70.9%

Source: CON applications

As shown in the table above, AdventHealth projects to provide the highest Medicaid total gross revenue as well as a higher percentage of Medicare Gross Revenue as a percentage of Total Gross Revenue. Therefore, **AdventHealth** is the **most effective alternative** regarding Medicare access.

Projected Medicaid Access

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

Projected Medicaid Revenue - 3rd Full FY

	Medicaid Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
AdventHealth Asheville	\$3,038,924	\$50,505,156	6.0%
Novant Health Asheville PET	\$1,781,861	\$30,721,747	5.8%
UNC Pardee	\$1,441,905	\$30,167,403	4.8%
Mission Hospital	\$2,689,269	\$48,070,676	5.6%

Source: CON applications

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

<u>Projected Average Net Revenue Per Fixed PET Procedure</u>

The following table compares the applicants' projected average net revenue per fixed PET procedure 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

	Form C.2b	Form F.2b	Average Net
	Fixed PET		Revenue
Applicant	Procedures	Net Revenue	per PET Procedure
AdventHealth Asheville	2,091	\$5,808,093	\$2,778
Novant Health Asheville PET	2,481	\$4,081,511	\$1,645
UNC Pardee	2,696	\$7,095,040	\$2,632
Mission Hospital	2,120	\$6,650,032	\$3,137

Source: CON applications

As shown in the previous table, Novant Health and UNC Pardee project a lower average net revenue per PET scan procedure in the third full fiscal year following project completion. However, as described in the application specific comments, their applications fails to demonstrate that its projected utilization, revenues, and expenses are based on reasonable and adequately supported assumptions. Therefore, the applications cannot be the most effective alternatives. **AdventHealth** projects a lower average net revenue per procedure than Mission Hospital making it the **more effective alternative**.

Projected Average Operating Expense per PET Procedure

The following table compares 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

	Form C.1b Form F.2b		Average Operating
	Fixed PET		Expense
Applicant	Procedures	Operating Expense	per PET Procedure
AdventHealth Asheville	2,091	\$3,810,974	\$1,823
Novant Health Asheville PET	2,481	\$2,100,619	\$847
UNC Pardee	2,696	\$4,397,223	\$1,631
Mission Hospital	2,120	\$4,889,300	\$2,306

Source: CON applications

As shown in the previous table, Novant Health and UNC Pardee project a lower average operating expense per PET scan procedure in the third full fiscal year following project completion. However, as discussed in the application-specific comments, those applications fail to demonstrate that projected utilization,

revenues, and expenses are based on reasonable and adequately supported assumptions. Therefore, the applications cannot be the most effective alternative.

AdventHealth projects and lower average operating expense per procedure than Mission Hospital making it the **more effective alternative.**

Summary

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

CRITERIA	AdventHealth Asheville	Novant Health Asheville PET	UNC Pardee	Mission Hospital
Conformity with Statutory & Regulatory Review	More Effective	Less effective	Less effective	Less effective
Competition (Access to new/alternative Provider)	More Effective	More Effective*	More Effective*	Less effective
Scope of Services	More Effective	More Effective*	More Effective*	Less effective
Access by Service Area Residents	More Effective	Less effective	Less effective	Less effective
Geographic Accessibility (Location within Service Area)	More Effective	Less effective	Less effective	Less effective
Historical Utilization	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Group: Medicaid	More Effective	Less effective	Less effective	Less effective
Access by Underserved Group: Medicare	More Effective	Less effective	Less effective	Less effective
Projected Average Net Revenue	Less effective	More Effective*	Less effective	Less effective
Projected Average Total Operating Cost	Less effective	More Effective*	Less effective	Less effective

^{*}Not approvable.

For each of the comparative factors previously discussed, Advent Health's application is determined to be the more effective alternative for the following factors:

- Conformity with Review Criteria
- Competition
- Geographic Accessibility
- Access by Service Area Residents
- Access by Medicaid Patients
- Access by Medicare Patients

The other applications fail to conform with all applicable statutory and regulatory review criteria; thus they cannot be approved. In addition, they fail to measure more favorably with respect to the aforementioned comparative factors. Based on the previous analysis and discussion, the application submitted by **AdventHealth** is **comparatively superior** and should be approved in this competitive review.

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

COMMENTS SPECIFIC TO MISSION APPLICATION PROJECT I.D. # B-012685-25

The Mission application fails to conform with the statutory and regulatory review criteria based on the following:

Failure to Demonstrate Reasonable Utilization

On page 146 of its application, Mission states "To establish a baseline projection, Mission applied a conservative compound annual growth rate ("CAGR") of 7% to annualized CY 2025 PET volumes, projecting through CY 2030 (Project Year 3). This baseline project [sic] reflects the total estimated volume of oncologic PET patients to be served during the Interim Years and Project Years 1-3. See Figure 4. The projected growth rate of 7% is conservative given service area growth rate of 10.4% and statewide growth in demand of 15%." However, as demonstrated below, Mission's projected growth rate is anything but conservative and fails to account for the development of additional capacity in the service area.

In stating that its 7% growth rate is conservative, Mission cites historical service area growth of 10.4% annually and a "statewide rate" of 15%, both of which are presented in a prior table on page 146 and excerpted below.

Figure 3
Growth Trends in PET/CT Scans

Mission 2024-2025 Growth Rate	6.0%
Service Area Fixed Scanners (2020-2024)	10.4%
Statewide Rate	15.0%

First, Mission provides no information or data for the statewide growth rate to indicate the time period or source in the table or anywhere else in its application. Thus, the statewide growth rate is unsupported. Second, as shown in Mission's application, the Service Area Fixed Scanners (2020-2024) rate of 10.4% annually is entirely driven by the entrance of a new provider, Messino Cancer Centers, to the market. As shown on the prior page (page 145) of Mission's application, Messino Cancer Center's utilization has increased significantly since it began operation in 2023 while Mission's utilization has declined substantially.

Figure 2
Historical Service Area PET Utilization Trend (FY – SMFP)

SMFP	2022	2023	2024	2025	Draft 2026	2020-2024
Data Year	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	CAGR %
Mission Hospital	2,695	2,808	2,919	2,862	1,893	
Messino		-	-	195	2,111	
Total	2,695	2,808	2,919	3,057	4,004	10.4%
Annual Growth		4.2%	4.0%	4.7%	31.0%	

Source: 2022-Draft 2026 SMFPs

Notably, Mission did not calculate its 2020-2024 CAGR in the table above which is negative 8.5% annually. In fact, prior to the development of the Messino Cancer Center PET unit, Mission's annual utilization grew far less than 7% annually. As shown in the table above, Mission grew only 4.2% from 2022 to 2023 and only 4.0% from 2023 to 2024. These historical annual growth rates do not support Mission's assumption that its baseline oncology PET procedures will grow 7% annually. Further, Mission's 6% growth from 2024-2025 is based on only five months of 2025 data annualized, and it is still below the assumed 7% growth rate.

Moreover, Mission's 7% annual growth rate does not account for the future development of AdventHealth Hendersonville's PET unit. The opening of Messino Cancer Center's PET unit in 2023 led to a 2% decline for Mission from 2022 to 2023 and a 34% decline from 2023 to 2024. Mission understates the impact of Messino Cancer PET scanner in its application stating on page 107 that "In 2023, Messino Cancer Center's fixed PET/CT scanner came online in Buncombe County. As expected, Mission experienced a slight decline in PET volumes following the launch of Messino PET" and on page 132 that "Mission experienced a modest decline in PET volumes following the launch of Messino's unit" (emphasis added). Mission acknowledges the future development of AdventHealth Hendersonville scanner in its application, but fails to account for any impact from that scanner stating in its Form C Assumptions and Methodology, "Mission also recognizes AdventHealth Hendersonville is expected to bring a PET/CT scanner online in CY 2025. Mission does not expect this addition to impact Mission's PET volumes, because AdventHealth does not have medical staff working with or referring PET patients to Mission" (page 145). Given the 34% decline Mission experience as a result of the development of Messino Cancer Center's PET scanner, it is unreasonable for Mission to assume that the AdventHealth Hendersonville scanner will have zero impact on Mission's utilization.

As shown on pages 59-61 of its application, more than 7% of Mission's PET patients historically originated from Henderson County, the location of AdventHealth Hendersonville's new PET unit, and Mission does not project this to change through 2030. Further, Mission projects no change in its patient origin percentages for any county, including Buncombe. However, the AdventHealth Hendersonville's approved PET scanner application projected to provide PET services to an increasing number of Henderson and Buncombe County patients. As the Agency Findings state on page 12: ²

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

The applicant currently provides mobile PET services via a contract with Alliance.
 Developing a fixed PET scanner will allow the applicant to leverage the existing
 PET referral relationships and develop new referral relationships. Additionally, the
 applicant assumes the mobile contract will be terminated when the proposed
 fixed PET scanner is developed, thus providing an opportunity for maximizing
 additional referrals for fixed PET services.

 $\frac{https://info.ncdhhs.gov/dhsr/coneed/decisions/2023/jul/findings/2023\%20HSA\%20I\%20PET\%20Findings\%20CORR}{ECTED.pdf}$

² See:

- The applicant has an existing network of physicians in <u>Henderson</u> and <u>Buncombe</u> counties and has received letters of support from area physicians.
- The development of the proposed fixed PET scanner will increase access to PET services throughout western North Carolina. The applicant states current PET availability will increase from every other Sunday to five days per week, 50 weeks per year, an increase from approximately 26 days currently to 250 days annually.
- The applicant has been approved pursuant to CON Project ID #B-12233-22 to develop a new hospital in Asheville in <u>Buncombe County</u> (currently under appeal), which will likewise positively impact the projected continued growth of AdventHealth's provider and referral network in the area.

Emphasis added

The Agency Findings show the expected impact of AdventHealth Hendersonville's project through its patient origin. As shown below, AdventHealth Hendersonville projected to provide an increased number of PET scans to Henderson and Buncombe County residents.

ADVENTHEALTH HENDERSONVILLE HISTORICAL MOBILE PET SERVICES

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

Source: Application page 36

ADVENTHEALTH HENDERSONVILLE PROJECTED PET SERVICES

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

Source: Application page 38

As shown in the patient origin tables cited by the Agency Findings, AdventHealth Hendersonville expects an increase from 46 Buncombe County patients in FFY 2022 to 551 patients in CY 2028 and an increase from 144 to 606 patients in Henderson County over the same period.

Yet, despite Mission's historical 34% decline in PET utilization following the development of the Messino Cancer Center PET unit and the available evidence from the Agency Findings that the approved AdventHealth Hendersonville PET unit will impact PET services in Buncombe and Henderson counties as well as Mission's status as only one of two PET units in Buncombe County, Mission assumes that AdventHealth Hendersonville's PET unit will have <u>no impact</u> on its projected utilization. This is simply unsupported and unreasonable.

Given the factors discussed above, Mission fails to provide reasonable utilization projections in its application. As such, the Mission application is non-conforming with Criteria (1), (3), (4), (5), (6), (8), and (18(a) as well as 10A NCAC 14C .3703.

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

Mission's PET projection methodology for projected cardiac PET scans overstates utilization by 100 times and projects significantly more utilization than its cardiac PET projections in Mission's 2023 and 2021 applications. As shown in the table below, Mission's 2024 application projects to perform 50 to 93% more cardiac PET scans than its 2023 PET scanner application methodology and more than three times the number of scans projected in its 2021 application.

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

Comparison of Cardiac PET Scans in Mission CON Applications, 2021, 2023, and 2024

	Project Year 1	Project Year 2	Project Year 3
2021 Mission PET Application	427	455	478
2023 Mission PET Application	682	987	1,109
2024 Mission PET Application	1,322	1,542	1,671
Increase from 2023 to 2024 Applications	93.8%	56.2%	50.7%

Source: Mission application, pages 146 and 152

Upon careful review, Advent Health Hendersonville discovered the mathematical calculations provided in Mission's 2024 application are inconsistent with the methodology described in the application. Specifically, application page 147 states:

• To calculate projected cardiac cases 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 2028: Cases = 966,017*1.74/100,000 = 1,676 scans.) Emphasis added

The following table reflects the potential cardiac PET scans projected by Mission on page 147.

Figure 5
Projected Cardiac PET/CT Scans

	Partial Year	First Full Project Year	Project Year	
	7/1-12/31/27	CY 2028	CY 2029	CY 2030
Population	959,657	966,017	972,251	978,449
Advisory Board Rate	0.88	1.74	1.76	1.78
Cases	844	1,676	1,711	1,746
Capture Rate*	35.0%	70.0%	80.0%	85.0%
Mission Cases	296	1,174	1,369	1,484
Other NC	3	14	16	17
Out of State	34	134	157	170
Total Service Area	333	1,322	1,542	1,671

^{*}Capture rate for 2027 reflects ramp up and a partial year of operation

However, Mission erred when it performed the cardiac PET scan projection calculations reflected in Step 3 of its application (page 147). 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 per Mission Methodology

	Partial Year	First Full Project Year	Second Full Project Year	Third Full Project Year
	Turtiur reur	icai	icai	icai
Population	959,657	966,017	972,251	978,449
Advisory Board Rate	0.88	1.74	1.76	1.78
Cases	8	17	17	17
Capture Rate	35%	70%	80%	85%
Mission Cases	3	12	14	15
Other NC	0	0	0	0
Out of State	0	1	2	2
Total Service Area	3	13	15	17

Source: Mission application pages 146 and 152

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 147. 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.

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 85 percent of all cardiac PET scans during the third project year.

As noted in the Comments above, Mission's baseline oncology PET scans growth rate is unsupported and fails to account for the development of the AdventHealth Hendersonville PET scanner. Notwithstanding those erroneous assumptions, the table below recalculates Mission's methodology based on corrected cardiac PET scans and demonstrates that Mission's stated methodology fails to demonstrate the need for its proposed additional fixed PET scanner.

Corrected PET Scans per Mission Methodology

	Partial Year	First Full Project Year	Second Full Project Year	Third Full Project Year
Baseline Scans (Oncology &	raitiai ieai	Teal	Teal	Teal
Neuro) from page 148	1,090	2,237	2,394	2,562
Corrected Cardiac PET Scans	3	13	15	17
Total Scans	1,093	2,250	2,409	2,579
Performance Standard				4,160

Source: Mission application pages 147-148

Given the factors discussed above, Mission fails to provide reasonable utilization projections in its application. As such, the Mission application is non-conforming with Criteria (1), (3), (4), (5), (6), (8), and (18(a) as well as 10A NCAC 14C .3703.

Failure to Demonstrate Quality

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

In February 2024, the Center for Medicare and Medicaid Services (CMS) informed Mission that it was not in compliance with the Medicare Conditions of Participation and that the noncompliance posed immediate jeopardy to patients' health and safety.³ The notification came 44 days after inspectors from the North Carolina Department of Health and Human Services, on behalf of CMS, recommended the hospital be placed in immediate jeopardy, citing nine deficiencies related to incidents occurring over 19 months. Although CMS later accepted a corrective action plan, the citation is representative of a pattern of substandard care which resulted in patient harm and death.

In mid-2025, the Dogwood Health Trust's independent-monitor report and related coverage indicated potential non-compliance with the 2019 purchase agreement for a second consecutive year, spotlighting ongoing issues in emergency and oncology services notwithstanding HCA statements about subsequent surveys.⁴

The North Carolina Attorney General's office (now AG Jeff Jackson) continues litigation related to HCA's compliance at Mission and publicly aligned with findings of possible continuing problems; meanwhile,

³ https://avlwatchdog.org/wp-content/uploads/2024/02/Memorial-Mission-and-Asheville-Surgery-Center-CCN-34-0002-Hospital-CoP Ongoing-IJ-02.01.24.pdf

⁴ Carolina Public Press. (2025, May 28). HCA potentially not in compliance with purchase deal for NC hospital group. Carolina Public Press. https://carolinapublicpress.org/71974/hca-potentially-not-in-compliance-with-purchase-deal-for-nc-hospital-group/

multiple local-government antitrust suits against HCA/Mission were settled in August 2025 after a 2024 federal ruling let claims proceed.^{5,6}

Wake Forest University's Health Law & Policy Program documented substantial post-acquisition staffing reductions at Mission relative to NC peers and linked those cuts to quality-of-care and access concerns, findings echoed by independent reporting. ⁷

Further, Mission Hospital's Leapfrog Hospital Safety Grade was a "B" in both Fall and Spring of 2024.

Mission Hospital Leapfrog Hospital Safety Grades



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

In past years, Mission's Hospital Safety Grade was as low as a "C".

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

⁵ Bonner, L. (2025, August 16). HCA settles antitrust lawsuit with Western NC local governments. North Carolina Health News. https://www.northcarolinahealthnews.org/2025/08/16/hca-settles-antitrust-lawsuit-with-western-nc-local-governments/

⁶ Miller, C. (2025, August 19). Attorney General Jackson: NC's HCA Mission Health in 'noncompliance'. Carolina Public Press. https://carolinapublicpress.org/72325/attorney-general-jackson-nc-hca-mission-health-noncompliance/

⁷ Hall, M. A. (2025, April). HCA/Mission: Changes in patient care following HCA's purchase. Wake Forest University, Health Law and Policy Program. Retrieved from https://prod.wp.cdn.aws.wfu.edu/sites/499/2025/04/HCA-Mission-Changes-in-Patient-Care-Following-HCAs-Purchase-working-draft-WFU.pdf

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.



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 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. Mission scored only one star (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

⁸ See https://www.medicare.gov/care-compare/

HCAHPS Patient Survey Ratings

	Mission	AdventHealth Hendersonville	NC Average	US Average
Overall Patient Survey Rating	*	* * * *	NA	NA
Patients who reported that their nurses "Always" communicated well	71%	83%	80%	80%
Patients who reported that their doctors "Always" communicated well.	72%	83%	81%	80%
Patients who reported that they "Always" received help as soon as they wanted.	46%	63%	64%	66%
Patients who reported that the staff "Always" explained about medicines before giving it to them.	50%	63%	62%	62%
Patients who reported that their room and bathroom were "Always" clean.	48%	82%	71%	74%
Patients who reported that the area around their room was "Always" quiet at night.	56%	67%	62%	62%
Patients who reported that YES, they were given information about what to do during their recovery at home	81%	89%	86%	86%
Patients who "Strongly Agree" they understood their care when they left the hospital.	38%	59%	52%	52%
Patients who gave their hospital a rating of 9 or 10 on a scale from 0 (lowest) to 10 (highest).	53%	83%	71%	72%
Patients who reported YES, they would definitely recommend the hospital.	49%	86%	69%	70%
No. of Completed Surveys	465	734		

Source: Mission application, pages 146 and 152

Given the factors discussed above, Mission fails to demonstrate that quality care has been provided in the past in its application. As such, the Mission application is **non-conforming with Criterion (20).**

Failure to Demonstrate Financial Feasibility

Mission's projected financial statements contain numerous errors and fail to account for all costs incurred by its proposed project. Thus, Mission fails to demonstrate the financial feasibility of the proposed project.

On page 152 of its application, Mission provides its assumptions for the Mission Cancer Center Form F.2a which show that Mission assumed much higher PET utilization than demonstrated in Form C Assumptions and Methodology. As shown in the excerpt below, Mission Cancer Center Form F.2a assumptions project 2,473 PET procedures in CY 2025, 2,593 PET procedures in CY 2026, and 2,594 PET procedures in CY 2027.

Form F.2a Historic and Interim Revenues and Net Income Assumptions:

Mission Hospital PET/CT (Mission Cancer Center)

Assumptions

Total #PET Procedures Average PET Charge per Procedure¹ Total PET Gross Revenue²

Last Full FY	Interim Full FY	Interim Full FY	Interim Partial FY
F: 01/01/2024	F: 01/01/2025	F: 01/01/2026	F: 01/01/2027
T: 12/31/2024	T: 12/31/2025	T: 12/31/2026	T: 12/31/2027
1,723	2,473	2,593	2,594
\$14,289	\$15,432	\$16,667	\$18,000
\$24,619,947	\$38,163,633	\$43,216,726	\$46,692,064

Source: Mission application, page 152

By contrast, Mission's Form C Assumptions and Methodology project far lower utilization in those years, as shown in the excerpted Figure 4 below from page 146.

Figure 4
Mission Baseline Projected PET/CT Scans (Oncology and Neurology)

							Projected
	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030	CAGR
Mission Baseline PET CT Scans							
(Oncology and Neurology)	1,826	1,954	2,091	2,237	2,394	2,562	7.0%

The table below demonstrates that the volumes assumed in Mission's Form F.2a are overstated by 503 to 647 PET procedures annually or **by 24 to 35 percent**.

Mission Overstated of Volumes in Financials

	CY25	CY26	CY27
PET Procedures			
Assumed in Financials	2,473	2,593	2,594
PET Procedures			
Projected in Form C	1,826	1,954	2,091
Overstated PET Procedures	647	639	503
% Overstatement	35.4%	32.7%	24.1%

Source: Mission application pages 146 and 152

Given that Mission's Financial statements rely on projected volume that far exceeds its assumed volume, Mission has clearly failed to demonstrate the financial feasibility of its project. As many of Mission's financial assumptions rely on trending/inflating results from year to year or are based on CY 2025 results in specific instances, it is unknown what impact the unsupported financial results in the years identified above have on the financial results in other projected years of Mission's project.

Over and above the unsupported utilization demonstrate above, Mission overstates its gross revenue in CY 2027 by over \$46 million or 100% on Form F.2a. As shown on the excerpt above from page 152,

Mission's assumptions for Form F.2a indicate it will provide 2,594 PET procedures with an average charge of \$18,000 for total gross revenue of \$46,692,064. However, as shown below on Form F.2a, Mission projects total gross revenue in that year for more than \$93 million. That total includes more than \$47 million in gross revenue from the Other payor class, which is more than the total gross revenue provided on the Assumptions excerpted above and more than the total gross revenue for all payors projected in prior years. This gross revenue amount is clearly unsupported.

Form F.2a Historical and Interim Revenues	Last Full FY	Interim Full FY	Interim Full FY	Interim Full FY
and Net Income	F: 01/01/2024	F: 01/01/2025	F: 01/01/2026	F: 01/01/2027
Mission Hospital PET/CT (Mission Cancer Center)	T: 12/31/2024	T: 12/31/2025	T: 12/31/2026	T: 12/31/2027
Patient Services Gross Revenue				
Self Pay	\$401,724	\$622,717	\$705,168	\$761,875
Insurance *	\$4,791,994	\$7,428,120	\$8,411,647	\$9,088,082
Medicare *	\$17,446,303	\$27,043,693	\$30,624,440	\$33,087,150
Medicaid *	\$1,377,340	\$2,135,028	\$2,417,719	\$2,612,143
Other (Specify)	\$602,586	\$934,075	\$1,057,752	\$47,834,877
Total Patient Services Gross Revenue	\$24,619,947	\$38,163,633	\$43,216,726	\$93,384,128
Other Revenue (1)	\$0	\$0	\$0	\$0
Total Gross Revenue (2)	\$24,619,947	\$38,163,633	\$43,216,726	\$93,384,128
Adjustments to Revenue				
Charity Care	\$228,983	\$359,385	\$412,057	\$450,758
Bad Debt	\$152,655	\$239,590	\$274,705	\$300,506
Contractual Adjustments	\$19,423,015	\$30,484,162	\$34,951,954	\$77,103,627
Total Adjustments to Revenue	\$19,804,653	\$31,083,138	\$35,638,716	\$77,854,891
Total Net Revenue (3)	\$4,815,294	\$7,080,495	\$7,578,011	\$15,529,238
Total Operating Costs (from Form F.3.a)	\$2,713,474	\$3,077,107	\$3,303,510	\$1,735,415
Net Income (4)	\$2,101,821	\$4,003,388	\$4,274,501	\$13,793,823

Source: Mission application, page 151

As shown in the table below, Mission projects \$46 million more in revenue than is supported or a 100% overstatement.

Mission Overstated Revenue in Financials

	CY27
Gross Revenue	
Assumed in Financials	\$93,384,128
Gross Revenue in Assumptions	\$46,692,064
Overstatement in \$s	\$46,692,064
% Overstatement	100.0%

Source: Mission application, pages 146 and 152

Further, this overstatement of gross revenue results in an overstatement of net revenue. As shown in the excerpted Form F.2a for Mission Cancer Center above from page 151 of the Mission application, Mission projects over \$15.5 million in net revenue in CY 2027 or more than double its net revenue in CY 2026 and its highest net revenue amount in its entire projection period through CY 2030 (as shown on Form F.2b on page 153).

In addition to these errors, Mission's projects its average PET charge per procedure to increase 8% annually without supporting or even stating that assumption in its Financials. As shown in its Form F.2a assumptions, excerpted again below, Mission's average PET charge per Procedure is included for each year.

Form F.2a Historic and Interim Revenues and Net Income Assumptions:

Mission Hospital PET/CT (Mission Cancer Center)

Assumptions

Total # PET Procedures Average PET Charge per Procedure¹ Total PET Gross Revenue²

Last Full FY	Interim Full FY	Interim Full FY	Interim Partial FY	
F: 01/01/2024	F: 01/01/2025	F: 01/01/2026	F: 01/01/2027	
T: 12/31/2024	T: 12/31/2024 T: 12/31/2025		T: 12/31/2027	
1,723	2,473	2,593	2,594	
\$14,289	\$15,432	\$16,667	\$18,000	
\$24,619,947 \$38,163,63		\$43,216,726	\$46,692,064	

See Mission application, page 152

The assumptions for Mission's average charge and gross revenue included on page 152, excerpted below, fail to support their calculations and are illogical.

Mission states that "Average PET Charge per Procedure calculated by taking historic PET gross revenue for CY2024 from internal financials and <u>multiplying</u> by volumes in Form C.2b (Mission Cancer Center)" (emphasis added). As Average Charge would be determined by <u>dividing</u> gross revenue by volume, it is clear that Mission has misstated this assumption. Further, Mission fails to provide the basis by which it determined <u>projected</u> Average PET Charge per Procedure. As the table below shows, Mission projects that its Average PET Charge per Procedure will increase 8% annually, which is unstated in the assumptions and unsupported. Please note that the Average PET Charge per Procedure assumptions stated below are included in the financial statements for both Mission Cancer Center and Mission 5 Vanderbilt Park.

¹ Average PET Charge per Procedure calculated by taking historic PET gross revenue for CY2024 from internal financials and multiplying by volumes in Form C.2b (Mission Cancer Center)

² Total PET gross revenue from financials for CY2024.

³ Patients Services Payor Mix as % Gross Revenue from internal financials for CY2024 and assumed to be held constant in Interim Years

Mission Inflation of Average PET Charge per Procedure

	CY24	CY25	CY26	CY27	CY28	CY29	CY30
Average PET Charge per Procedure	\$14,289	\$15,432	\$16,667	\$18,000	\$19,440	\$20,995	\$22,675
Inflation	NA	8%	8%	8%	8%	8%	8%

Source: Mission application pages 152-158.

Mission's inflation of 8% for its projected Average PET Charge per Procedure is well above its assumed inflation for salaries and other expenses. As stated on its Form F.3a and F.3b Assumptions for both Mission Cancer Center and 5 Vanderbilt Park (pages 160, 162, 164, and 166), Mission assumes 2% inflation in salaries and 2% inflation in Pharmacy expense per scan. Mission has failed to provide reasonable support for its assumed inflation of its Average PET Charge per Procedure and thus has failed to demonstrate the financial feasibility of the project.

Finally, Mission's projected financial statements fail to appropriately account for all expenses that will be incurred as part of the proposed project. None of Mission's financial statements show operating costs that include administrative costs (such as overhead, billing, medical records, scheduling, etc.), utilities, insurance, or rental expense. As Mission states on page 48, the location for the proposed project, "Mission 5 Vanderbilt Park is a 3-story medical office building with approximately 75,000 square feet of space. Mission Hospital rents 42,000 square feet of the building and provides hospital-based cardiac rehabilitation, a sleep lab, and cardiovascular diagnostic services in this location" (emphasis added). Mission's proposed PET service at 5 Vanderbilt Park will require administrative services to schedule, bill, and complete medical records for patients. The service will incur utilities and insurance expense as part of Mission's services at that facility. And clearly, Mission will pay rental expenses for its 5 Vanderbilt location which will include the proposed PET service. Yet, none of these expenses are reflected on Mission's financial statements. As such, Mission has failed to demonstrate the financial feasibility of its project.

Based on the discussion above, Mission has failed to provide reasonable and supported financial assumptions. As such, Mission has not demonstrated the financial feasibility of the proposed project and is non-conforming with Criterion (5).

COMMENTS SPECIFIC TO NOVANT APPLICATION PROJECT I.D. # B-012684-25

The Novant application fails to conform with the statutory and regulatory review criteria based on the following:

Failure to Identify Population to be Served

In its application (p. 37), Novant Health states that it relied exclusively on HIDI data as the "best available data source" for projecting patient origin, noting that Messino Cancer Center's PET/CT data is not included in the HIDI database. Novant further claims that Mission Hospital's PET/CT patient origin is therefore the most reasonable basis for projecting demand.

This assertion is misleading and incomplete. While it is true that HIDI does not capture utilization from freestanding fixed PET providers, there are publicly available data sources that do. Specifically, every freestanding fixed PET provider in North Carolina is required to submit an annual Registration and Inventory of Medical Equipment Report to the Healthcare Planning and Certificate of Need Section. Likewise, every hospital-based fixed PET provider must submit a Hospital License Renewal Application each year. Both of these filings include patient origin by county for the most recent fiscal year.

Therefore, patient origin data for Messino Cancer Center's fixed PET/CT scanner in Buncombe County is publicly available, has already been reported to the State, and should have been considered by Novant in projecting patient origin. The 2025 Registration and Inventory Report is included in Attachment 1. By excluding Messino Cancer Center, Novant's analysis understates the competitive landscape, misrepresents the actual distribution of PET/CT patients in HSA I, and biases its projections toward Mission's service area utilization.

Importantly, Novant attributes the lower PET use rate in HSA I to outmigration of patients (pp. 43–44). However, its analysis is limited to HIDI data, which excludes PET procedures performed in non-hospital-based facilities such as Messino Cancer Center. As a result, Novant disregards patient origin data from the single highest-volume PET provider in HSA I. This omission skews its conclusions and masks the actual distribution of PET utilization across the region. In reality, outreach efforts by existing providers—such as AdventHealth—are already expanding access, strengthening referral networks, and driving higher utilization of PET imaging. These initiatives, coupled with improved geographic access for rural counties, provide a far more reasonable explanation for growth in PET use than Novant's claim of patient outmigration.

Novant proposes to develop a freestanding diagnostic center, not a hospital-based PET service. Patients who use hospital-based PET scanners, such as at Mission, often have different referral patterns, payer mixes, and clinical pathways than patients who use independent diagnostic centers. By failing to account for Messino's utilization, the only existing freestanding fixed PET provider in HSA I, Novant has modeled its patient origin on a hospital-based service that does not reflect the type of provider it seeks to develop.

In short, Novant's reliance on Mission alone is selective and incomplete. At minimum, Novant should have supplemented its HIDI-based analysis with the publicly reported patient origin data for Messino Cancer Center to provide a full and accurate picture of PET/CT utilization in Buncombe County. Its failure to do so undermines the credibility of its projections and disadvantages other providers who comply with State reporting requirements.

Given the factors discussed above, Novant fails to demonstrate the population it proposes to serve is based on reasonable and adequately supported assumptions. As such, the Novant application is non-conforming with Criteria (1), (3), (4), (5), (6), (8), and (18(a)).

Misrepresentation of Messino Cancer Centers' Letter of Support

On page 55 of its application, Novant Health asserts that:

"Messino Cancer Centers ... [demonstrated] their willingness to refer their patients to NH Asheville PET's proposed scanner, [which] shows the need for the proposed project and NH Asheville PET's ability to reach its projected scan volume."

However, the actual letter of support from Messino Cancer Centers, included as Exhibit C-4.1, states only:

"The physicians of Messino Cancer Centers believe Novant Health's plan to provide an additional option for patients requiring PET services will improve access to high-quality, patient-centered cancer care."

and

"It is reasonable to expect the number of area residents requiring PET scans will increase over the next several years, and the proposed PET scanner will give patients faster and more convenient access to essential treatment."

At no point does Messino's letter reference referrals or express any intent to direct patients to Novant's proposed scanner. Novant's statement that Messino demonstrated "a willingness to refer their patients" is therefore factually incorrect and misleading.

This mischaracterization is compounded by Novant's selective treatment of data. Although the application relies exclusively on Mission Hospital's hospital-based PET patient origin to project demand, Messino is in fact the largest provider of fixed PET services in HSA I, with 2,211 scans in FY2024 compared to Mission's 1,893. Messino's publicly reported patient origin data show a broader geographic distribution, with stronger penetration into surrounding rural counties such as Jackson (8.1%), Yancey (7.7%), and Transylvania (5.5%). Novant's projection, by contrast, simply replicates Mission's hospital-centric distribution and ignores Messino's actual service area.

If Novant is going to cite Messino's name and characterize its support, then Messino's actual patient origin data, not Mission's, should have been the foundation for Novant's projection. Instead, Novant has both overstated the level of support Messino provided and excluded Messino's real-world data from its analysis. Taken together, these flaws undermine the credibility of the application and overstate the likelihood that Novant can achieve its projected scan volumes.

Open MRI & Imaging of Asheville

Novant's reliance on Open MRI & Imaging of Asheville as a platform for projecting PET/CT referrals represents a significant leap in logic. Open MRI is not a co-applicant in this application, does not provide PET/CT services, and explicitly acknowledges that it lacks the physical space to add such equipment. Nonetheless, Novant claims that because it is the majority owner of Open MRI, and because Open MRI

provides other diagnostic imaging services, Open MRI will somehow become a major referral channel for the proposed PET/CT scanner to be located at a separate facility in Arden.

This is problematic for several reasons:

- 1. Open MRI's existing portfolio consists of MRI, CT, x-ray, and arthrograms. These modalities serve a very different clinical role than PET, which is primarily used for oncologic staging and treatment planning. There is no established basis to assume that high utilization of conventional imaging automatically translates into PET referrals.
- Novant's proposed PET scanner will not be located at Open MRI's site. The application offers no
 evidence that patients or referring providers would naturally shift from Open MRI to a separate
 freestanding PET center simply because Novant is a majority owner of both entities.
- 3. Novant points to the 648 unique referring providers who sent patients to Open MRI in 2024 as if that number can be converted into PET demand. This is a tenuous connection. Referrals for MRI or CT do not predict referrals for PET, which follow distinct oncology-driven clinical pathways and payer approvals.
- 4. Novant leans heavily on Open MRI's promise to "educate area providers" and "have patient education materials" about PET services. This is marketing activity, not proof of need, utilization, or referral intent.

In short, Novant takes the ordinary fact of its ownership interest in Open MRI and stretches it into an assumption that hundreds of Open MRI's referring providers will generate PET referrals for an unrelated site. This is not a reasonable or evidence-based projection; it is a speculative leap that overstates the likely referral base and inflates projected utilization of the proposed fixed PET scanner.

Access by Medically Underserved

On page 63 of its application, Novant Health states:

"Mission's experience is a reasonable basis for projecting future payor mix, as it is a fixed PET/CT provider located in Buncombe County."

Novant asserts that Mission's experience is a reasonable basis for projecting payor mix because it is a fixed PET provider located in Buncombe County. Novant further claims that Messino Cancer Center's PET/CT data cannot be used since it is not included in the HIDI database.

While it is true that Messino's annual Registration and Inventory Report does not include payor mix, Novant's assertion that Mission's experience is the only available basis for projecting payor mix is misleading. Other publicly available Medicare Part B data sources provide information on PET utilization and payments across provider types. These datasets, published annually by CMS, show that freestanding diagnostic facilities and independent physician practices often have a different payor distribution than hospital outpatient departments.

This distinction is critical because Novant proposes to develop a freestanding diagnostic center, not a hospital-based PET service. Hospital outpatient departments such as Mission typically show higher Medicare and Medicaid shares due to hospital-based billing structures and referral pathways.

Independent diagnostic treatment facilities (IDTFs), by contrast, often have a different balance of commercial and government payors.

Because Novant proposes a freestanding diagnostic center rather than a hospital outpatient department, its exclusive reliance on Mission's hospital-based payer mix is unreasonable. In addition, if Novant truly had Messino's support, as it asserts, it could have requested and presented Messino's historical data. The failure to provide that information does not demonstrate support for the application, rather it undermines it.

In short, just as Novant selectively relied on Mission's hospital-based patient origin to the exclusion of Messino's broader service area, it has again relied solely on Mission's hospital-based payor mix to project utilization for a freestanding diagnostic center. Both assumptions fail to provide a reasonable, adequately supported basis for demonstrating conformity to Criterion (3).

Assumptions & Methodology for Projecting Fixed PET Procedures

Novant's methodology for projecting PET utilization is highly speculative and based on arbitrary assumptions.

First, the foundation of Novant's projections is a compound annual growth rate (CAGR) drawn from the 2020–2024 period. The 2020 baseline includes extraordinary COVID-related distortions in diagnostic and treatment activity, when patients experienced significant delays in accessing scans. By using 2020 as the starting point, Novant artificially inflates the appearance of rapid growth in PET utilization. Rather than account for this anomaly, Novant applies a "75 percent of CAGR" adjustment to generate a 7.98 percent growth rate. This assumption serves only as an arbitrary multiplier that gives the appearance of conservatism while still producing aggressive growth assumptions.

Second, Novant's most significant assumption is that its proposed PET scanner will achieve 75 percent of the market share that its affiliated Open MRI & Imaging of Asheville holds for fixed MRI services. This comparison is deeply flawed. MRI and PET are fundamentally different markets. MRI is a broad-based diagnostic tool used across many specialties, while PET is a specialized service, overwhelmingly driven by oncology referrals. Referral patterns for PET are highly concentrated among oncologists, and Novant does not have an existing oncology base in Buncombe County comparable to the one Messino Cancer Centers relied upon when it rapidly grew its PET volumes. The claim that a PET scanner will reach 25.7 percent market share within three years based on Open MRI's MRI performance is not credible.

Relatedly, Novant assumes a rapid ramp-up of referrals, projecting it will achieve half of its targeted market share in year one, 75 percent in year two, and 100 percent in year three. This linear build-up ignores the reality that referral patterns in PET take time to develop and are influenced by longstanding affiliations, payer networks, and established provider relationships. In a competitive environment where multiple providers already provide PET services, it is unrealistic to expect Novant to quickly divert such a large share of patients.

Taken together, Novant's methodology is not an objective forecast of demand, but rather a set of assumptions designed to ensure that its projected volume just clears the 2,080-scan performance standard in the third project year. The Agency should view these projections as speculative and engineered, rather than credible or adequately supported.

Given the factors discussed above, Novant fails to demonstrate projected utilization is reasonable and adequately supported. As such, the Novant application is non-conforming with Criteria (1), (3), (4), (5), (6), (8), and (18(a)) and 10A NCAC 14C .3703.

Errors in Projected Financial Statements

Novant's projected financial statements contain errors and fail to account for all costs incurred by its proposed project. Thus, Novant fails to demonstrate the financial feasibility of the proposed project.

On application page 133, Novant states that "Medical and other supplies are estimated based on CY2024 NH Forsyth Fixed PET expenses, which will scale with volumes and are additionally expected to inflate by 3.0% annually." However, the "other supplies" expense per PET procedure is projected to <u>decrease</u> during Year 2 and Year 3.

	1st Full FY	2nd Full FY	3rd Full FY
	F: 1/1/2029	F: 1/1/2030	F: 1/1/2031
	T: 12/31/2029	T: 12/31/2030	T: 12/31/2031
Total PET Procedures	1,064	1,723	2,481
Other Supplies	\$6,858	\$10,082	\$13,959
Average Expense Per Procedure	\$6.45	\$5.85	\$5.63
Annual Change	N/A	-9.2%	-3.8%

Source: Novant application, Form C, Form F.3

<u>Inconsistent Expense Projections Across Novant Applications</u>

Novant's financial projections for its Buncombe County PET scanner are not only internally inconsistent, but also inconsistent with its own recently filed application in Durham County. In February 2025, Novant Health, Novant Health–Norfolk, LLC, and Durham Diagnostic Imaging jointly filed a CON application to develop a fixed PET scanner in Durham County (J-012593-25). In its Buncombe County application (B-012684-25), Novant specifically identifies Durham Diagnostic Imaging in Form O as a related entity.

Despite this common ownership and corporate affiliation, Novant's projections for average operating expenses per PET procedure differ dramatically between the two applications. In Year 3, Novant projects average expenses of just \$847 per procedure in Asheville, compared with \$1,461 per procedure in Durham. This represents a 72 percent higher expense level in Durham County for nearly the same procedure volume (2,481 vs. 2,875).

	NH Asheville	Durham Diagnostic Imaging
PET Procedures, Year 3	2,481	2,875
Total Expenses, Year 3	\$2,100,619	\$4,199,934
Average Expense Per PET Procedure	\$847	\$1,461

Source: Novant application (B-012684-25), Form C, Form F.3; DDI application (J-012593-25), Form C, Form F.3

Notably, both applications use similar expense assumptions, yet produce vastly different results. For example, NH Asheville explains:

Medical and other supplies are estimated based on CY2024 NH Forsyth Fixed PET expenses, which will scale with volumes and are additionally expected to inflate by 3.0% annually.⁹

By contrast, the Durham Diagnostic Imaging application states:

Medical and other supply expenses are estimated based on Novant's experience providing fixed PET services in North Carolina on a per scan basis for PET/CT service. These expenses increase based on the cost multiplied by the total estimated scan volume per projected year as allotted to PET/CT service. ¹⁰

The effect of these differing assumptions is stark:

	NH Asheville	Durham Diagnostic Imaging
PET Procedures, Year 3	2,481	2,875
"Medical and Other" Expenses, Year 3	\$99,643	\$467,878
Average Expense Per PET Procedure	\$40	\$163

Such wide disparities cannot be explained by market differences or economies of scale, since both applications involve fixed PET services in urban North Carolina counties and are ostensibly based on the same corporate expense models. Instead, the inconsistencies demonstrate that Novant's financials are either arbitrary or erroneous, and therefore cannot be relied upon to demonstrate financial feasibility.

When an applicant's expense assumptions shift so drastically from one project to the next, despite common ownership and nearly identical service offerings, it undermines confidence in the reliability of its projections. As a result, Novant's Buncombe County application cannot be considered the most effective alternative with respect to financial feasibility, reasonableness of assumptions, or overall conformity with the statutory review criteria.

Given the factors discussed above, Novant fails to demonstrate projected costs and revenues are reasonable and adequately supported. As such, the Novant application is **non-conforming with Criterion** (5).

⁹ B-012684-25, page 133

¹⁰ J-012593-25, page 171

COMMENTS SPECIFIC TO PARDEE APPLICATION PROJECT I.D. # B-012675-25

The Pardee application fails to conform with the statutory and regulatory review criteria based on the following:

Management Agreement with UNC Health

In Section A.4.3, Pardee identifies itself as a Henderson County—owned hospital but fails to disclose that it is operated by UNC Health pursuant to a management agreement. This is a material omission.

Public records reflect that in June 2011, Pardee Hospital's Board approved an affiliation or management agreement under which UNC Health is to manage all operations of Pardee, in return for an annual payment and the CEO's salary. The agreement was later extended from 10 to 25 years, with provisions enabling UNC to invest in Pardee's facilities, and to exercise operational oversight over hospital functions. In addition, the NC Auditor's annual UNC Health report explicitly refers to a management service agreement between UNC Health and Pardee (Henderson County Hospital Corporation d/b/a Margaret R. Pardee Memorial Hospital).

At a minimum, Pardee should have included the management agreement, and any related agreements between Pardee and UNC Health, as part of its application. Without this disclosure, the Agency cannot fully evaluate who is actually responsible for developing, financing, and operating the proposed project.

Because Pardee is operated under a management agreement with UNC Health, any project advanced by Pardee is in fact a UNC Health project. The Agency should therefore evaluate this application in the broader context of UNC Health's systemwide strategy, not as an isolated county hospital initiative.

This lack of transparency, combined with the fact that UNC Health is ultimately responsible for Pardee's operations and strategic initiatives, raises serious concerns about the completeness of the application and undermines the Agency's ability to assess conformity with the statutory review criteria. At a minimum, the omission relates to Criteria (5) and (8).

Failure to Demonstrate Need for Project

In its response to Section C.4, under the "Need for Additional PET Capacity in HSA I" heading, Pardee asserts that Henderson County is "the most effective location to develop additional PET capacity at this time" and predicates that need on the population size and the lack of operational fixed PET scanner, stating on page 47, "Therefore, despite Henderson County being the third-largest county in the HSA, it still lacks an operational fixed PET scanner to meet demand for these services." Pardee notes that "AdventHealth was approved to develop a fixed PET scanner under CON Project ID # B-12331-23" and cites to AdventHealth Hendersonville's progress report discussing a delay related to Hurricane Helene's impact. As a healthcare provider in an area significantly impacted by Hurricane Helene, Pardee is aware of the disruption caused by that event. In fact, Pardee notes the "significant disruption" in its operations caused by Hurricane Helene (see application page 51). Yet, Pardee's application assumes that delay caused by Hurricane Helene to AdventHealth Hendersonville's PET project should be treated as indefinite and not temporary. On page 47, Pardee concludes that "As such, placement of the proposed fixed PET scanner in a county without any operational equipment addresses geographic and population-based inequities and avoids the development of resources in areas where available capacity still exists."

However, as noted in the AdventHealth application, development of the AdventHealth Hendersonville PET scanner will occur as proposed in 2026. Notably, Pardee's proposed project is assumed to begin operation on March 1, 2027, or after the development of the AdventHealth Hendersonville PET scanner. Yet, Pardee's application fails to acknowledge or account for the impact the development of the AdventHealth Hendersonville PET scanner in its demonstration of the need for the services proposed. Please see the following comment for more discussion of Pardee's failure to account for the AdventHealth Hendersonville PET scanner in Pardee's projected oncology and cardiac PET utilization.

Given the factors discussed above, Pardee fails to demonstrate the need that its identified population has for the services proposed. As such, the Pardee application is **non-conforming with Criteria (1), (3), (4), (5), (6), (8), and (18(a)).**

Failure to Demonstrate Reasonable Oncology PET Utilization

On page 113 of its application, Pardee states "Given that the majority of historical PET procedures on the mobile PET are oncology-related, UNC Health Pardee reasonably assumes that oncology PET procedures on the proposed fixed PET scanner will grow at the overall CAGR of 16.2 percent . . . UNC Health Pardee believes this growth rate is reasonable in light of several factors." In arguing for the reasonableness of this projected growth rate, Pardee cites its historical annual growth of 32.4%, a statewide growth rate of 13.0%, and an HSA I growth rate of 16.0%. However, Pardee fails to demonstrate that these growth rates provide reasonable support for its assumption.

First, Pardee does not provide any information or reasoning to support its assumption that any factors that drove its unusual historical growth, which far exceeds historical statewide growth in PET demand, such as additional days of mobile PET service or physician recruitment, will continue through its projection period.

Second, the statewide growth rate and HSA I growth rate cited by Pardee include growth in non-oncology PET procedures, particularly cardiac PET procedures. As Pardee notes on page 44 of its application, "As PET scanners have become more widely available, their use for cardiac patients has expanded greatly." As such, a substantial portion of total PET utilization across North Carolina is a result of growth in cardiac PET procedures, and less so for oncology PET procedures. However, Pardee erroneously suggests that these growth rates for total PET procedures including cardiac PET procedures are supportive of its assumed 16.2 percent annual growth rate for oncology-only PET procedures.

Additionally, Pardee's utilization projections entirely fail to account for any impact from the AdventHealth Hendersonville PET scanner under development in the same county as Pardee proposes to develop its PET scanner. Further, AdventHealth Hendersonville's approved PET scanner application projected to provide PET services to an increasing number of Henderson, Buncombe, and Transylvania County patients, which Pardee also proposes to primarily serve according to its Patient Origin projections. As the Agency Findings state on page 12: 11

The applicant states the availability of a full-time fixed PET scanner on the hospital campus will allow AdventHealth Hendersonville to maximize access to needed PET services

 $\frac{https://info.ncdhhs.gov/dhsr/coneed/decisions/2023/jul/findings/2023\%20HSA\%20I\%20PET\%20Findings\%20CORR}{ECTED.pdf}$

¹¹ See:

throughout the catchment area. The applicant projects <u>market share</u> volumes for PET services for each of the counties in its proposed service area for each of the three project years, as illustrated in the table provided in Section Q page 120. The applicant states these market share projections are reasonable based on, but not limited to, the following:

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

Emphasis added

The Agency Findings show the expected impact of AdventHealth Hendersonville's project through its patient origin. As shown below, AdventHealth Hendersonville projected to provide an increased number of PET scans to Henderson, Buncombe, and Transylvania County residents.

ADVENTHEALTH HENDERSONVILLE HISTORICAL MOBILE PET SERVICES

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

Source: Application page 36

ADVENTHEALTH HENDERSONVILLE PROJECTED PET SERVICES

COUNTY /ZIP CODE	JANUARY 1, 2028 – DECEMBER 3 2028			
	PATIENTS	% OF TOTAL		
Buncombe	551	25.9%		
Cherokee	23	1.1%		
Clay	9	0.4%		
Graham	12	0.6%		
Haywood	123	5.8%		
Henderson	606	28.5%		
Jackson	10	4.8%		
Macon	60	2.8%		
Madison	50	2.3%		
McDowell	101	4.8%		
Mitchell	33	1.6%		
Polk	59	2.8%		
Rutherford	172	8.1%		
Swain	22	1.0%		
Transylvania	104	4.9%		
Yancey	42	2.0%		
Other*	53	2.5%		
Total	2,124	100.0%		

Source: Application page 38

As shown in the patient origin tables cited by the Agency Findings, AdventHealth Hendersonville expects an increase from 46 Buncombe County patients in 2022 to 551 patients in 2028, an increase from 144 to 606 patients in Henderson County over the same period, and an increase from 20 to 104 Transylvania County patients.

Yet, despite the available evidence from the Agency Findings that the approved AdventHealth Hendersonville PET unit will impact PET services in Buncombe, Henderson, and Transylvania counties as well as the Pardee's historical and projected patient origin and proposed Henderson County location, Pardee assumes that AdventHealth Hendersonville's PET unit will have <u>no impact</u> on its projected utilization. This is simply unsupported and unreasonable.

Finally, Pardee's assumed 16.2% annual oncology PET growth rate results in entirely unreasonable projections. As shown on page 113, Pardee projects to provide 1,945 oncology PET procedures in 2030. According to its Patient Origin projections on page 38, 68.4% of Pardee's PET procedures are projected to originate from Henderson County. Accordingly, Pardee estimates that it will provide 1,330 oncology PET procedures to Henderson County residents (1,330 = 1,945 total x 68.4% from Henderson County). As stated on page 47 of its application, Henderson County's total projected population in 2030 is 130,564. Therefore, Pardee projects that its <u>facility alone</u> for <u>oncology procedures only</u> will have a PET use rate of 10.2 procedures per 1,000 population. By comparison, the current statewide PET rate which includes <u>all</u> providers and <u>all</u> types of PET procedures is 7.6 procedures per 1,000 people, as shown on page 123 of AdventHealth's application. Of note, AdventHealth projects that this use rate will grow to 11.10 procedures per 1,000 people in 2030. Assuming that Henderson County achieves an 11.10 per 1,000 PET

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

procedure use rate, Pardee's projections would assume that of the 11.10 total PET procedures per 1,000 for Henderson County, that Pardee will provide 92% or 10.2 of them, and that they will be oncology procedures. This is unreasonable and unsupported as Pardee would be one of two fixed PET providers in the county and its own PET scanner utilization assumes that oncology procedures will comprise only 72% of its 2030 totals (see page 116).

Given the factors discussed above, Pardee fails to provide reasonable utilization projections in its application. As such, the Pardee application is non-conforming with Criteria (1), (3), (4), (5), (6), (8), and (18(a) as well as 10A NCAC 14C .3703.

Failure to Demonstrate Reasonable Cardiac PET Utilization

On pages 114-115, Pardee provides its utilization methodology for cardiac PET procedures. After projecting total cardiac PET procedures for HSA I, Pardee states that "there is currently limited availability of cardiac PET services in HSA I. Moreover, UNC Health Pardee operates an established, robust, and growing cardiology program and has an extensive presence throughout Henderson, Buncombe, and Transylvania counties. As such, UNC Health Pardee conservatively assumes that it will perform one-third of these projected cardiac PET procedures upon approval of the proposed project." However, Pardee's statements fail to demonstrate that its assumed 33.3% share of all cardiac PET procedures that it projects across the 26 counties in HSA is reasonable. In fact, Pardee's projected patient origin for PET procedures makes it clear that Pardee does not project to serve all or even a majority of the 26 HSA I counties. As shown below, Pardee's projected PET patient origin identifies five of the 26 HSA I counties: Henderson, Transylvania, Buncombe, Polk, and Rutherford.

	<unc health="" pardee=""> *</unc>								
<fixed pet=""></fixed>	1 st Fu	ıll FY	2 nd Fo	ull FY	3 rd Full FY				
	07/01/2027 to	06/30/2028	07/01/2028 t	o 06/30/2029	07/01/2029 t	o 06/30/2030			
County or other geographic area such as ZIP code	Number of Patients **	nber of % of Total Number of		% of Total	Number of Patients **	% of Total			
Henderson	1,453	68.4%	1,636	68.4%	1,845	68.4%			
Transylvania	209	9.8%	235	9.8%	265	9.8%			
Buncombe	172	8.1%	193	8.1%	218	8.1%			
Polk	102	4.8%	115	4.8%	4.8% 129	4.8%			
Rutherford	58	2.7%	65	2.7%	74	2.7%			
Other *	130	6.1%	146	6.1%	165	6.1%			
Total	2,123	100.0%	2,391	100.0%	2,696	100.0%			

This should match the name provided in Section A, Question 4, and includes mobile health services

Based on its projected patient origin, Pardee's provision of cardiac PET services will be limited to five HSA I counties, not all 26 as defined by the PET methodology. According to page 48 of Pardee's application, the five HSA I counties it projects to serve will have an Age 65+ population of 144,219 in 2030, as shown below.

^{**} Home health agencies should report the number of unduplicated clients.

^{*} Other includes Greenville, SC, Haywood, McDowell, Jackson, Madison, Spartanburg, SC, Macon, Park, CO, Brunswick, Mecklenburg, Other NC counties, and Other States.

Age 65+ Population for HSA I Counties to Be Served by Pardee

	2030
Handanan	20,000
Henderson	38,999
Transylvania	12,022
Buncombe	71,447
Polk	6,637
Rutherford	15,114
Total	144,219

Source: Pardee application, page 48

In 2030, Pardee assumes that the HSA I 65+ Population will have a Cardiac PET Use Rate per 1,000 of 4.11 (per Table 7 of page 115 of the Pardee application). Thus, the total cardiac PET patient demand for the 65+ residents of the five HSA I counties Pardee projects to serve will be 593 patients (593 = 4.11 x (144,219 / 1,000)). In 2030, Pardee projects to serve 532 cardiac PET procedures for 65+ patients per Table 7 on page 115. Thus, Pardee's projected share of cardiac PET in 2030 is 90% (90% = 532 projected patients / 593 total patients), not one-third as Pardee suggests. This is unreasonable and unsupported as Pardee would be one of two fixed PET providers offering cardiac PET services in Henderson County, the other being AdventHealth Hendersonville. As noted above, Pardee fails to account in any way for the AdventHealth Hendersonville's PET scanner, including in its cardiac PET methodology. As the Agency Findings state on page 8, "The applicant states the development of a fixed PET scanner on its main campus will permit AdventHealth Hendersonville to provide both cardiac and oncology scans, including PMSA PET procedures" (emphasis added). 12 Further, as shown in the excerpts from the Agency Findings above, AdventHealth Hendersonville proposes an increased number of PET scans to residents of each of the five HSA I counties proposed to be served by Pardee. Yet, Pardee assumes that AdventHealth Hendersonville's PET unit will have no impact on its projected cardiac PET utilization and that it will serve 90% of cardiac PET patients from these counties. This is simply unsupported and unreasonable.

Given the factors discussed above, Pardee fails to provide reasonable utilization projections in its application. As such, the Pardee application is non-conforming with Criteria (1), (3), (4), (5), (6), (8), and (18(a) as well as 10A NCAC 14C .3703.

<u>Failure to Demonstrate Financial Feasibility</u>

Pardee's projected financial statements contain numerous errors and fail to account for all costs incurred by its proposed project. Thus, Pardee fails to demonstrate the financial feasibility of the proposed project.

¹² See:

 $[\]frac{https://info.ncdhhs.gov/dhsr/coneed/decisions/2023/jul/findings/2023\%20HSA\%20I\%20PET\%20Findings\%20CORR}{ECTED.pdf}$

On page 123 of its application, Pardee provides Form F.3b which includes Equipment Maintenance expense. Notably, Pardee fails to provide an assumption in its F.3 Assumptions on pages 124-125 describing how it derived its projected Equipment Maintenance expense. Pardee's Section P Schedule states that the proposed project will begin 3/1/2027. Typically, equipment maintenance expense is provided by the equipment vendor for the first 12 months of operation after the purchase of new equipment. Assuming this is the case for Pardee, equipment maintenance expense would begin occurring on 3/1/2028, or during the 4th quarter of Pardee's State Fiscal Year (SFY) 2028, which ends on June 30, 2028. As shown in the excerpt from Pardee Form F.3b below, Pardee projects \$74,648 for equipment maintenance expense in SFY 2028.

Form F.3b Projected Operating Costs upon Project	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
Completion	F: 07/01/2026	F: 07/01/2027	F: 07/01/2028	F: 07/01/2029
UNC Health Pardee Fixed PET	T: 06/30/2027	T: 06/30/2028	T: 06/30/2029	T: 06/30/2030
Salaries (from Form H Staffing) ^a	\$113,370	\$350,313	\$432,920	\$445,907
Taxes and Benefits ^b	\$22,674	\$70,063	\$86,584	\$89,181
Independent Contractors (Consultants) (1) ^c	\$977,738	\$0	\$0	\$0
Medical Supplies incl. in Pharmacy	\$0	\$0	\$0	\$0
Other Supplies incl. in Pharmacy	\$0	\$0	\$0	\$0
Pharmacy (2) ^d	\$1,417,711	\$2,128,364	\$2,467,948	\$2,866,601
Dietary (2) incl. in Central Office Overhead	\$0	\$0	\$0	\$0
Housekeeping / Laundry (2) incl. in Central Office Overhead	\$0	\$0	\$0	\$0
Equipment Maintenance (2)	\$0	\$74,648	\$223,943	\$230,661
1	1	ı	ı	

Given that this amount represents the expense that occurs in one quarter of the year, it can be assumed that one full year of equipment maintenance expense in SFY 2028 would be \$233,944 (\$233,944 = \$74648 x 4). However, as shown in the excerpt above, Pardee assumes that its equipment maintenance expense, one year later, in SFY 2029, will be \$223,943. This demonstrates that Pardee failed to inflate its equipment maintenance expense from SFY 2028 to 2029. As Pardee states in its Financial assumptions on page 124, "The projected financial statements assume 3.0 percent annual inflation based on expected annual inflation." Thus, Pardee's equipment maintenance expense is understated in SFY 2029 and 2030.

As shown in the excerpt above, Pardee provides its projected Pharmacy expense and cites to Footnote "d" which states "Pharmacy expense is based on FY 2024 experience for the service, converted to a per procedure expense adjusted to reflect more expensive tracers for cardiac procedures, inflated 3.0 percent annually, and multiplied by projected volume. Pharmacy expenses includes tracers, medical supplies, and other supplies." However, Pardee's projected pharmacy expense fails to include any adjustment "to reflect more expensive tracers for cardiac procedures" as shown below.

The table below calculates Pardee's projected Pharmacy expense per procedure based on total Pharmacy expense from Forms F.3a and F.3b and procedures from Forms C.2a and C.2b. As shown, Pardee's Pharmacy expense increases exactly 3.0 percent annually, consistent with its annual inflation assumption.

Pardee Understated Pharmacy Expense

	SFY24	SFY25	SFY26	SFY27	SFY28	SFY29	SFY30
Pharmacy Expense	\$823,751	\$842,960	\$1,008,728	\$1,417,711	\$2,128,364	\$2,467,948	\$2,866,601
PET Procedures	925	919	1068	1457	2123	2391	2696
Pharmacy Expense per Procedure	\$890.54	\$917.26	\$944.50	\$973.03	\$1,002.53	\$1,032.18	\$1,063.28
Annual % Increase		3.0%	3.0%	3.0%	3.0%	3.0%	3.0%

Source: Pardee application, Forms C.2a, C.2b, F.3a, and F.3b

As shown, Pardee's pharmacy expense per procedure increases exactly 3.0% annually consistent with its annual inflation assumption and does <u>not</u> include any adjustment for more expensive tracers for cardiac procedures as stated in its assumptions. Thus, Pardee's financial expenses are understated.

Based on the discussion above, Pardee has failed to provide reasonable and supported financial assumptions. As such, Pardee has not demonstrated the financial feasibility of the proposed project and is non-conforming with Criterion (5).

ATTACHMENT 1: REGISTRATION & INVENTORY REPORT MESSINO CANCER CENTER FIXED PET SCANNER



Registration and Inventory of Medical Equipment

Fixed Positron Emission Tomography Scanners January 2025

Instructions

This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for fixed positron emission tomography scanners. Please complete all sections of this form and return to Healthcare Planning by Friday, January 24, 2025.

- 1. Submit one completed Registration and Inventory form per fixed PET scanner
- 2. Complete and sign the form
- 3. Return the form by one of two methods:
 - a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.
 - b. Mail the form to Andrea Emanuel, Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Andrea Emanuel in Healthcare Planning at (919) 855-3954 or email <u>DHSR.SMFP.Registration-Inventory@dhhs.nc.gov</u>.

Note: Fixed equipment operated in a facility licensed under a hospital should be reported on that hospital's license renewal application, and not duplicated on this form.

C ~	ation 1. Contact Information						
	ction 1: Contact Information Full legal name of corporation, particular equipment by purchase, donation, lease AMERICAN ONCOLOGYPARTNERS PA d/b/m MESSI	e, transfe	r, or co	mparable ar			acquired the
	(Legal Name)						
2.	Address of the corporation, partnership 551 BREVARD RD	, individ	ual, or o	ther legal e	ntity that ac	quired the	e equipment:
	(Street and Number) ASHEVILLE	NC	28806		828-212-7021		
	(City)	(State)	(Zip)		(Phone	Number)	
3.	Chief Executive Officer or approved of form: GUY MESSER	lesignee	who is o		ne informati		
	(Name)				(Title)		
	Same as above						
	(Street and Number)		(City)		(State)	(Zip)	
		uy.messer	@aoncol				
	(Phone Number)	BOB.W	EIR	(Email)			
4,	Information compiled or prepared by:			(Na	ame)		
	(_828)212-7021	BOB.W	EIR@A	ONCOLOGY	.COM		
	(Phone Number)			(Fmail)			



Section 2	:: E	quipmen	t and	Procedures	Information
~				x I o o o u u i o o	**************************************

Reporting Period: x 10/01/2023 – 9/30/2024	☐ Other time period:
--	----------------------

Do not make extra copies of this page if the entity has multiple PET scanners at the same site or in the same county. Submit a complete, separate R&I form for each scanner.

For DHSR Planning Use Only:			
	PET Sca	nner Information	
Manufacturer	SIEMENS		
Model number	10856834		
Serial or I.D. number	16679		
Date of purchase	05/05/2023		
Purchase price	1025046		
Certificate of Need Project ID			
Service Site Information:	Service Site_MESSINO CANCER CENTERAddress _551 BREVARD RD		
	City, State, ZipASHEVILLE NC 28806 CountyBUNCOMBE		
Total number of procedures*:	Inpatient Procedures*	Outpatient Procedures*	

^{*} PET scan means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET procedure means a single discrete study of one patient involving one or more PET scans.

Name of entity that acquired the equipment (from page 1)



Section 3: Patient Origin Data

Please provide the county of residence for each patient who received PET scanner services during the time period of this report. This data should only reflect the number of patients, not number of scans, and should not include other radiopharmaceutical or supply charge codes. Count each patient only once. The number of patients in this table should match the number of PET procedures reported on page 2 of this report.

County in which service was provided:

Patient	Number of	Patient	Number of	Patient	Number of
County	Patients	County	Patients	County	Patients
1. Alamance		37. Gates		73. Person	
Alexander		38. Graham	8	74. Pitt	
Alleghany		39. Granville		75. Polk	4
4. Anson		40. Greene		76. Randolph	
5. Ashe	1	41. Guilford		77. Richmond	
6. Avery	11	42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	183	80. Rowan	
9. Bladen		45. Henderson		81. Rutherford	26
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	1061	47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
4. Caldwell	1	50. Jackson	179	86. Surry	
5. Camden		51. Johnston		87. Swain	32
6. Carteret		52. Jones		88. Transylvania	122
7. Caswell		53. Lee	1	89. Tyrrell	
8. Catawba	3	54. Lenoir		90. Union	
9. Chatham		55. Lincoln	1	91. Vance	
20. Cherokee	21	56. Macon	68	92. Wake	
1. Chowan		57. Madison	105	93. Warren	
2. Clay	4	58. Martin		94. Washington	
23. Cleveland	3	59. McDowell	120	95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
5. Craven		61. Mitchell	35	97. Wilkes	
6. Cumberland	1	62. Montgomery		98. Wilson	
7. Currituck		63. Moore		99. Yadkin	
.8. Dare		64. Nash		100. Yancey	171
9. Davidson		65. New Hanover			
0. Davie		66. Northampton		101. Georgia	5
1. Duplin		67. Onslow		102. South Carolina	10
2. Durham		68. Orange		103. Tennessee	16
3. Edgecombe		69. Pamlico		104. Virginia	1
4. Forsyth		70. Pasquotank		105. Other (specify)	WA 1,MD1,FLA 16
35. Franklin		71. Pender			
6. Gaston		72. Perquimans		Total Number of Patients	2111

Name of entity that acquired the equipment (from page 1)	
--	--



Section 4: Certification and Signature

The undersigned contained on all p	Chief Executive Of pages of this form.	ficer or approved designee certifies the accuracy of the information
Signature		Top Ch Messer
Print Name	Guy Messer	
Date signed	01-24-2025	
Please complete	all sections of this	form and return to Healthcare Dlanning by Evidey, January 24

Please complete all sections of this form and return to Healthcare Planning by Friday, January 24, 2025.

- 1. Complete and sign the form
- 2. Return the form by one of two methods:
 - a. Email a scanned copy to <u>DHSR.SMFP.Registration-Inventory@dhhs.nc.gov</u>.
 - b. Mail the form to Andrea Emanuel in Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Andrea Emanuel in Healthcare Planning at (919) 855-3954 or email <u>DHSR.SMFP.Registration-Inventory@dhhs.nc.gov</u>.

Name of entity that acquired the equipment (from page 1)	
--	--