Comments on AdventHealth Asheville's, MH Mission Hospital's, and Novant Health's Fixed PET Scanner Certificate of Need Applications, Project IDs #B-012688-25, #B-012685-25, and # B-012684-25

October 1, 2025

Competitive Comments on Health Service Area I
Fixed PET Scanner Applications

submitted by

UNC Health Pardee

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), UNC Health Pardee hereby submits the following comments related to the competing applications filed by AdventHealth Asheville, Inc. (AdventHealth), MH Mission Hospital, LLLP (Mission Hospital), and Novant Health Long Shoals Imaging, LLC (Novant Health) to add a dedicated fixed PET scanner in response to the need identified in the *2025 State Medical Facilities Plan* (*SMFP*) for one dedicated fixed PET scanner for Health Service Area (HSA) I. AdventHealth proposes to acquire an additional fixed PET scanner and locate it at a new acute care hospital campus in Weaverville, in Buncombe County, that has been approved but is under appeal by Mission. Mission Hospital proposes to acquire an additional fixed PET scanner and locate it at an outpatient department of the hospital in Asheville in Buncombe County. Novant Health proposes to acquire a fixed PET scanner and locate it at a freestanding medical office building (MOB) in Arden in Buncombe County. UNC Health Pardee's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*." See N.C. GEN. STAT. § 131E-185(a1)(1)(c).[1] In order to facilitate the Agency's ease in reviewing these comments, UNC Health Pardee has organized its discussion by issue, specifically noting the general Certificate of Need (CON) statutory review criteria and regulations creating the non-conformity of each issue, as they relate to the AdventHealth application (Project ID # B-012688-25), the Mission Hospital application (Project ID # B-012685-25), and the Novant Health application (Project ID # B-012684-25). UNC Health Pardee's comments include issue-specific comments on the AdventHealth, Mission Hospital, and Novant Health applications as well as a comparative analysis related to its own application, Project ID # B-012675-25.

As detailed above, given the number of proposed additional fixed PET scanners, all the applications submitted cannot be approved as proposed. UNC Health Pardee's detailed comments include application-specific comments related to each competing application and a comparative analysis relative to its application. The comments below include substantial issues that UNC Health Pardee believes render most of the competing applications non-conforming with applicable statutory criteria and regulatory review criteria. However, as presented at the end of these comments, even if one or more of these applications is found conforming, the UNC Health Pardee application is comparatively superior to the other applications filed and represents the most effective alternative for expanding access to fixed PET services in HSA I.

[1] UNC Health Pardee is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its application filed on August 15, 2025 (Project ID # B-012675-25).

GENERAL COMMENTS ON ADVENTHEALTH

AdventHealth's proposal to develop a fixed PET at its conditionally approved new acute care hospital in Weaverville in Buncombe County represents a change of scope for that facility as originally outlined in Project ID # B-12233-22 and Project ID # B-12526-24. Accordingly, the proposed PET scanner is contingent on the development and opening of the hospital in 2027, a date that is in question due to Mission's appeal of the Agency's decision to award AdventHealth a total of 93 acute care beds in Buncombe County.[2] With respect to the PET component of the project, this uncertainty surrounding the hospital raises important questions about the viability and timeline of the proposed PET scanner, which is entirely dependent on the completion of a facility that has not yet begun construction and faces ongoing legal challenges. While the fact of a project being under appeal does not in and of itself constitute non-conformity, it is nonetheless true that the associated proceedings have the effect of extending initial timelines, which is of greater relevance when there is an identified need that results in a competitive review.

AdventHealth's proposal is further complicated by its demonstrated failure to develop a project involving the same service component, specifically its previously approved but not yet developed PET scanner at AdventHealth Hendersonville in Henderson County (Project ID B-12331-23). Despite receiving CON approval in July 2023, AdventHealth has made no meaningful progress on this previous project, with zero milestones completed and no capital expenditures made as documented on its March 2025 progress report to the Agency, even in the months before Hurricane Helene made landfall in September 2024 (see Attachment A). This failure to advance an approved project for over 18 months raises serious questions about AdventHealth's reliability and commitment to developing the proposed Buncombe County PET scanner in an efficient, timely way – all the more so given the added complexity of developing the scanner in conjunction with an entirely new hospital facility. Similar to the aforementioned legal challenge against AdventHealth's new Weaverville hospital, the issue of timely development becomes proportionally more relevant in the context of a competitive review.

As detailed in the issue-specific comments in the following section, AdventHealth's application does not conform to all of the Certificate of Need (CON) statutory review criteria and regulations. Most critically, AdventHealth presents projected PET market share assumptions that do not accurately reflect the historically smaller command of market share of its existing acute care hospital in Henderson County. AdventHealth Hendersonville has operated within the service area for many years, yet total market shares range from only 0.6 percent to 13.2 percent across proximate HSA I counties. Ignoring the realities of an already competitive healthcare landscape, AdventHealth projects that the previously approved and proposed PET scanners will capture combined PET market shares of 25 to 90 percent across the counties identified in its 2023 and 2025 applications. This represents market share increases of 40 to 77 percentage points above current performance – projections that defy both logic and established market dynamics. The obvious gap between AdventHealth's actual and projected market share is particularly striking in the clinical specialties that generate the majority of PET referrals—neurology, oncology, and cardiology—where AdventHealth's market presence is minimal in spite of its position as a long-established provider in the service area.

Equally problematic, AdventHealth fails to address the obvious duplication and cannibalization between its approved Henderson and proposed Buncombe County scanners. Instead, it unreasonably assumes that

---

[2] Jones, Andrew R. "North Carolina Supreme Court Grants Mission Hospital's Request for Temporary Stay in Battle for 67 Beds." *North Carolina Health News*. August 2, 2025. North Carolina Supreme Court grants Mission Hospital's request for temporary stay in battle for 67 beds. Accessed September 12, 2025.

the Buncombe County scanner projections are entirely additive to the Henderson projections. The applicant provides no substantive analysis of how patients would be allocated between the two facilities or how the overlapping service areas would be differentiated, despite the two scanners targeting the same counties and patient populations. This methodology flaw significantly undermines the credibility of the utilization projections.

Additionally, AdventHealth's financial projections relative to pharmaceutical and housekeeping costs materially understate operating expenses, thereby artificially inflating the apparent profitability of the project. These unrealistic projections assume declining per-scan costs, particularly for items dependent on procedure volume such as pharmaceutical supplies, which fails to provide a reasonable basis for demonstrating financial feasibility.

When the application's methodology flaws are considered alongside the indeterminate legal status of the underlying hospital project and AdventHealth's unreliability in developing the previously approved PET project, it becomes clear that AdventHealth's proposal rests on a series of miscalculations and is considerably dependent on future contingencies. In light of these qualitative and quantitative shortcomings, AdventHealth's application is not approvable and should be found non-conforming with both applicable statutory review criteria and regulatory requirements.

ISSUE-SPECIFIC COMMENTS ON ADVENTHEALTH

1. AdventHealth's projected PET market share is unreasonable and unsupported.

AdventHealth's utilization projections rest on market share assumptions that are demonstrably false and methodologically indefensible. The methodology assumes PET market shares that bear no relationship to the actual performance of AdventHealth Hendersonville, a facility that the applicant has operated in Henderson County for years. According to SFY 2024 Hospital Inpatient Database (HIDI) data (see Attachment B), AdventHealth Hendersonville's total inpatient market share across key HSA I counties ranges from only 0.6 percent to 13.2 percent, with most counties showing market shares well below 5 percent.

AdventHealth Hendersonville SFY 2024
Actual Total Inpatient Market Share

County	*SFY 2024 Total Inpatient Share*
Buncombe	4.3%
Haywood	0.9%
Henderson	13.2%
Madison	3.7%
McDowell	0.6%
Polk	7.9%
Transylvania	4.2%
Yancey	1.4%

Source: HIDI, SFY 2024.

While inpatient market share does not directly correlate with PET market share, these recent figures still serve to demonstrate AdventHealth's actual competitive standing within the western North Carolina service area. Despite this evidence to the contrary, AdventHealth assumes that its approved but not yet developed scanner in Hendersonville and its proposed Asheville scanner will capture dramatically higher market shares, ranging from 45 percent to as high as 90 percent. These disparities in market share capture rates are highlighted in the table below.

AdventHealth Market Share Comparison: Actual Inpatient vs. Projected PET

County	*SFY 2024 Total Inpatient Share^*	*2028-2031 Combined PET Market Share^^*	*Projected Differential in Market Share*
Buncombe	4.3%	45%	+40.7%
Haywood	0.9%	45%	+44.1%
Henderson	13.2%	90%	+76.8%
Madison	3.7%	60%	+56.3%
McDowell	0.6%	45%	+44.4%
Polk	7.9%	55%	+47.1%
Transylvania	4.2%	50%	+45.8%
Yancey	1.4%	60%	+58.6%

Sources: ^HIDI, SFY 2024;
^^2023 AdventHealth PET Application CON Project ID # B-12331-23, p.120, and 2025 AdventHealth PET Application CON Project ID # B-012688-25, p.131.

The disconnect between actual and projected performance cannot be overstated. AdventHealth's projections assume market share increases ranging from 40.7 to 76.8 percent above its inpatient share – a differential that would require AdventHealth to capture patients from well-established competitors with decades of market presence and comprehensive referral networks.

The difference between similar performance and projected performance – as represented by these double-digit values - is considerable and indicates the extremely low likelihood, if not the impossibility, of the latter rates of market share being achieved. For example, in Henderson County, where AdventHealth has its strongest presence at 13.2 percent of inpatients, it projects capturing 90 percent of PET patients. By comparison, AdventHealth currently captures only 4.3 percent of Buncombe County inpatients but projects capturing 45 percent of PET patients. These unreasonable market share projections become even more problematic when considering the competitive landscape. Whereas AdventHealth competes with only one other hospital provider for inpatients in Buncombe County, there are already two existing PET providers in that county with whom AdventHealth would have to compete to gain almost half the market share it projects, Mission Hospital and Messino Cancer Centers. Additionally, there are the fixed PET services Catawba Valley Medical Center (CVMC) provides in Catawba County as well as the inventory represented by existing mobile PET services at over a dozen sites in HSA I. To assume that a single provider would capture 45 to 90 percent PET market share and exert this level of dominance in a market with three other fixed PET competitors and PET mobile services is simply unreasonable.

Moreover, the application provides no supporting evidence to explain or support such unprecedented market share gains. While AdventHealth has been approved to develop a new hospital in Buncombe County, this does not change the fundamental market dynamics or the outlook for performance of its inpatient facility in neighboring Henderson County. AdventHealth Hendersonville has operated for years with established physician relationships, referral patterns, and market presence, yet achieves only modest market share even in its home county, with one other hospital provider. Therefore, the addition of a new hospital does not provide adequate justification for projecting market share increases that are multiples above current market share.

Closer examination shows that AdventHealth's market share projections are unreasonable even when compared against the capture rate associated with the applicant's best-performing service lines. An analysis of SFY 2024 HIDI data (see Attachment B) illustrates that AdventHealth Hendersonville achieves its highest market share in specific service lines, yet most of these examples of peak market share still fall dramatically short of projected PET market share. The only instance in which AdventHealth achieves a market share above 30 percent is Polk County gynecology at 90.6 percent. However, this represents a specialized service in a county with a small population and further emphasizes that obstetrics and gynecology are areas where AdventHealth performs most strongly out of all its inpatient service lines.

AdventHealth Top Service Line Market Shares, SFY 2024

County/Service Line	*SFY 2024 IP Market Share^*	*2028-2031 Combined PET Market Share^^*
Henderson Co Gynecology	28.3%	90%
Henderson Co Obstetrics	28.6%	90%
Henderson Co Neonatology	25.9%	90%
Transylvania Co Neonatology	18.1%	50%
Transylvania Co Obstetrics	20.4%	50%

Sources: ^HIDI, SFY 2024
^^2023 AdventHealth PET Application CON Project ID # B-12331-23, p.120, and 2025 AdventHealth PET Application CON Project ID # B-012688-25, p.131.

It must also be noted that AdventHealth's market share in the clinical service lines that actually utilize PET imaging demonstrates significantly weaker competitive positioning.

AdventHealth PET-Related Service Line Market Shares, SFY 2024

County/Service Line	*SFY 2024 IP Market Share^*	*2028-2031 Combined PET Market Share^^*
Henderson Co Oncology/Hematology	7.1%	90%
Henderson Co Cardiology	3.9%	90%
Henderson Co Neurology	10.1%	90%
Buncombe Co Oncology/Hematology	4.4%	45%
Buncombe Co Cardiology	1.6%	45%
Buncombe Co Neurology	1.8%	45%

Sources: ^HIDI, SFY 2024
^^2023 AdventHealth PET Application CON Project ID # B-12331-23, p.120, and 2025 AdventHealth PET Application CON Project ID # B-012688-25, p.131.

Even in Henderson County, where AdventHealth has its strongest overall presence and operates its main hospital, its oncology market share represents only 7.1 percent, and cardiology only 3.9 percent. In Buncombe County, AdventHealth's rate of market capture for PET-related specialties is lower still, at 4.4 percent for oncology, 1.8 percent for neurology, and 1.6 percent for cardiology. Since PET volume is heavily dependent on the referrals generated by these clinical specialties, it therefore becomes a serious question of operational viability when AdventHealth captures less

than 10 percent of these referring physicians' patients yet projects capturing 45 to 90 percent of PET patients.

Further compounding these competitive disadvantages, Mission Hospital serves as a tertiary care provider in Buncombe County, typically receiving the more complex cases that require advanced imaging such as PET scans. Despite Mission's corresponding role as a tertiary center for complex cases, AdventHealth projects capturing not only 45 percent of PET imaging volume in Buncombe County but the majority of PET imaging volume in adjacent counties – Henderson, Madison, Polk, and Yancey – without demonstrating how it would overcome established referral patterns.

In short, AdventHealth offers no analysis of why PET patients would show different loyalties or provider preferences than patients requiring oncology, cardiology, or neurology services. This underlying disconnect between the applicant's demonstrated market performance in the clinical specialties that refer for PET imaging and projected PET market performance thus renders the utilization projections unreasonable and inadequately supported.

Based on this analysis, AdventHealth's application has failed to adequately demonstrate need for the proposed fixed PET scanner and is non-conforming with Criteria 3, 4, 5, 6, and 18a as well as the performance standards in 10 NCAC 14C .3703 and should not be approved.

2. AdventHealth fails to address duplication between its approved and proposed scanners.

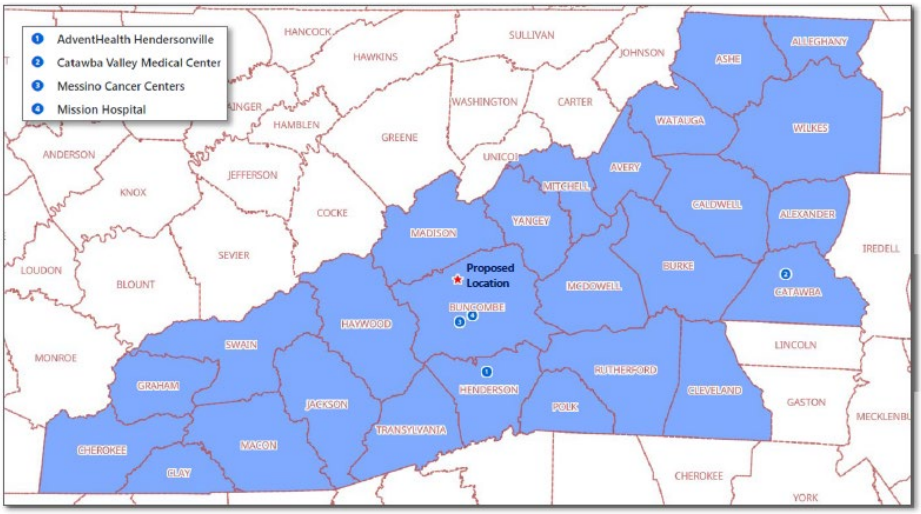
On pages 134 to 135 of its 2025 application, AdventHealth makes no attempt to analyze or address the duplication and cannibalization that would result from the development of its approved Henderson County PET scanner and proposed Buncombe County PET scanner. Yet, AdventHealth simply assumes that all projected utilization for the Buncombe County scanner represents entirely new volume that will not affect Henderson County projections.

On page 70 of its 2025 application, AdventHeath states:

> *"The proposed fixed PET scanner in Weaverville will complement the fixed PET scanner that AdventHealth is currently developing in Hendersonville. While the two service areas may share some overlapping counties, the scanners will serve as discreet, strategically located points of access that improve geographic coverage and scheduling flexibility for residents across western North Carolina."*

However, AdventHealth provides no analysis of how it will differentiate between the two facilities or any rationale for why patients would choose one location over the other. As outlined in its respective applications and indicated by the map reproduced below, the two scanners will serve what is essentially the same geographic region. This is hardly surprising given that Henderson County, the location of the approved scanner, is adjacent to Buncombe County, the location of the proposed scanner.

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



Source: 2025 AdventHealth Application CON Project ID # B-012688-25, p. 61.

A side-by-side comparison of the projected patient origin for the two scanners further highlights the degree of overlap between the projected patient populations. With the sole exception of Avery County, the list of counties included in the projected patient origin for the two scanners is identical. The inclusion of Avery County in the patient origin projections for the Buncombe County scanner should not be understood as a significant difference given that this county is expected to account for no patients in Year 1 and only 1.0 percent of total PET volume in Year 3.

Fixed PET Scanner	AdventHealth Hendersonville *					
	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027		01/01/2028 to 12/31/2028	
County	Patients	% of Total	Patients	% of Total	Patients	% of Total
Buncombe	194	22.6%	414	28.4%	551	25.9%
Cherokee	5	0.6%	11	0.7%	23	1.1%
Clay	2	0.2%	4	0.3%	9	0.4%
Graham	5	0.6%	29	2.0%	12	0.6%
Haywood	22	2.5%	46	3.2%	123	5.8%
Henderson	329	38.3%	438	30.0%	606	28.5%
Jackson	30	3.5%	48	3.3%	102	4.8%
Macon	26	3.1%	56	3.8%	60	2.8%
Madison	15	1.7%	24	1.6%	50	2.3%
McDowell	30	3.5%	48	3.3%	101	4.8%
Mitchell	10	1.2%	16	1.1%	33	1.6%
Polk	27	3.1%	42	2.9%	59	2.8%
Rutherford	66	7.7%	93	6.4%	172	8.1%
Swain	10	1.1%	52	3.6%	22	1.0%
Transylvania	46	5.4%	74	5.1%	104	4.9%
Yancey	19	2.2%	26	1.8%	42	2.0%
Other^	21	2.5%	36	2.5%	53	2.5%
Total	858	100.0%	1,457	100.0%	2,124	100.0%

^Other includes <1 percent patient origin from each of the remaining counties in North Carolina and other states.
* This should match the name provided in Section A, Question 4.

Fixed PET Scanner	AdventHealth Asheville					
	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2029 to 12/31/2029		01/01/2030 to 12/31/2030		01/01/2031 to 12/31/2031	
County	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Avery	0	0.0%	10	0.7%	21	1.0%
Buncombe	307	34.9%	496	34.3%	712	34.0%
Cherokee	16	1.8%	35	2.4%	56	2.7%
Clay	7	0.8%	14	1.0%	23	1.1%
Graham	8	1.0%	13	0.9%	19	0.9%
Haywood	69	7.9%	111	7.7%	159	7.6%
Henderson	202	23.0%	290	20.0%	390	18.7%
Jackson	49	5.5%	78	5.4%	112	5.4%
Macon	21	2.4%	45	3.1%	73	3.5%
Madison	46	5.3%	62	4.3%	80	3.8%
McDowell	23	2.7%	50	3.4%	80	3.8%
Mitchell	15	1.7%	24	1.7%	34	1.6%
Polk	10	1.2%	22	1.5%	35	1.7%
Rutherford	34	3.9%	73	5.1%	117	5.6%
Swain	14	1.6%	23	1.6%	32	1.5%
Transylvania	0	0.0%	19	1.3%	40	1.9%
Yancey	39	4.4%	52	3.6%	67	3.2%
Other*	18	2.0%	29	2.0%	42	2.0%
Total	880	100.0%	1,447	100.0%	2,091	100.0%

*Other includes the remaining counties in HSA I and other states.

Sources: (On left) 2023 AdventHealth PET Application CON Project ID # B-12331-23, p. 38; (On right) 2025 AdventHealth PET Application CON Project ID # B-012688-25, p.72.

On pages 60 to 61 of its 2025 application, AdventHealth makes it a point to emphasize how its proposed Buncombe County scanner will improve access for northern counties, such as Avery,

Madison, Mitchell, and Yancey counties, presenting this as a key justification for the development of a second scanner. However, these same counties were also presented as benefiting from the development of the Hendersonville fixed PET scanner on pages 50 to 51 of AdventHealth's conditionally approved 2023 application. While patient origin projections are marginally higher for these counties in the 2025 application compared to the 2023 application, their respective populations are small and would generate a correspondingly modest volume of procedures – certainly not enough to define a Buncombe County PET service area distinct from a Henderson County PET service area.

The market share projections presented in the methodology exhibit the same faulty assumption, treating volume associated with the Buncombe PET scanner as purely additive. According to the market share projections from AdventHealth's 2023 and 2025 PET applications, reproduced below, AdventHealth assumes that combined market share in Henderson County will achieve a 90 percent rate of capture by Year 3 of the Buncombe County PET project (25.0 percent AdventHealth Asheville PET + 65.0 percent AdventHealth Hendersonville PET = 90.0 percent). Total AdventHealth PET market share in Madison and Yancey counties is expected to reach 60 percent in each county by the same project year, while market share in multiple other counties is no less ambitiously expected to reach anywhere from 45 to 55 percent.

AdventHealth Hendersonville
Projected PET Market Share

County	Partial Year 2025	Project Year 1 2026	Project Year 2 2027	Project Year 3 2028
Buncombe	7.5%	10.0%	20.0%	25.0%
Cherokee	0.0%	2.5%	5.0%	10.0%
Clay	0.0%	2.5%	5.0%	10.0%
Graham	2.5%	10.0%	50.0%	20.0%
Haywood	5.0%	5.0%	10.0%	25.0%
Henderson	22.4%	40.0%	50.0%	65.0%
Jackson	5.0%	10.0%	15.0%	30.0%
Macon	2.5%	10.0%	20.0%	20.0%
Madison	5.0%	10.0%	15.0%	30.0%
McDowell	5.0%	10.0%	15.0%	30.0%
Mitchell	5.0%	10.0%	15.0%	30.0%
Polk	11.2%	20.0%	30.0%	40.0%
Rutherford	5.0%	15.0%	20.0%	35.0%
Swain	2.5%	10.0%	50.0%	20.0%
Transylvania	10.9%	20.0%	30.0%	40.0%
Yancey	5.0%	15.0%	20.0%	30.0%

AdventHealth Asheville
Projected PET Market Share

County	2029	2030	2031
Avery	0.0%	5.0%	10.0%
Buncombe	10.0%	15.0%	20.0%
Cherokee	5.0%	10.0%	15.0%
Clay	5.0%	10.0%	15.0%
Graham	10.0%	15.0%	20.0%
Haywood	10.0%	15.0%	20.0%
Henderson	15.0%	20.0%	25.0%
Jackson	10.0%	15.0%	20.0%
Macon	5.0%	10.0%	15.0%
Madison	20.0%	25.0%	30.0%
McDowell	5.0%	10.0%	15.0%
Mitchell	10.0%	15.0%	20.0%
Polk	5.0%	10.0%	15.0%
Rutherford	5.0%	10.0%	15.0%
Swain	10.0%	15.0%	20.0%
Transylvania	0.0%	5.0%	10.0%
Yancey	20.0%	25.0%	30.0%

Sources: (On left) 2023 AdventHealth PET Application CON Project ID # B-12331-23, p. 120; (On right) 2025 AdventHealth PET Application CON Project ID # B-012688-25, p. 131.

It must also be pointed out that these combined percentages assume minimal market share for existing competitors Mission Hospital and Messino Cancer Center, both of which currently operate PET scanners in the region and collectively serve thousands of patients annually, as well as the mobile PET sites established in the region.

By projecting a substantial market share for AdventHealth Asheville while maintaining a near constant market share for AdventHealth Hendersonville with no adjustment to factor in the impact of a new PET facility that will serve the system's patients, AdventHealth fails to account for overlap in the PET procedures projected to be performed at the two facilities. This represents a fundamental methodological error that no reasonable healthcare planner would make. This error artificially inflates the total projected volume for AdventHealth's PET services and overstates

the demand for the proposed AdventHealth Asheville facility. Particularly given that AdventHealth's current market share of PET services consists of mobile PET service provided one day a week every other week at AdventHealth Hendersonville and according to *SMFP* data resulted in total utilization of only 278 procedures in 2022-2023 and zero procedures in 2023-2024.

In general, cannibalization resulting from a single provider operating multiple facilities in overlapping markets undermines standard healthcare planning principles. However, AdventHealth entirely disregards these principles, offering no explanation of how utilization of the Henderson County scanner might be affected by the introduction of the Buncombe County scanner or vice versa. The failure to acknowledge this clear duplication of resources within the proposed service area renders AdventHeath's utilization projections unreasonable and brings the application in conflict with both Criterion 3 and Criterion 6, among other issues of non-conformity.

Accordingly, AdventHealth's application is non-conforming with Criterion 3, 4, 5, 6, and 18a as well as the performance standards in 10 NCAC 14C .3703 and should not be approved.

3. <u>AdventHealth's pharmaceutical cost and housekeeping and laundry cost projections are unreasonable and unsupported.</u>

Analysis of AdventHealth's projected pharmaceutical costs reveals several fundamental errors that result in project expenses understated by hundreds of thousands of dollars annually. These errors, in turn, render the overall financial projections unrealistic and unreasonable.

Form F.3b Projected Operating Costs upon Project Completion

Form F.3 Operating Costs Criterion (5)	1st Full FY CY2029 From: 01/01/2029 To: 12/31/2029	2nd Full FY CY2030 From: 01/01/2030 To: 12/31/2030	3rd Full FY CY2031 From: 01/01/2031 To: 12/31/2031
Salaries (from Form H Staffing)	$287,040	$295,651	$304,521
Taxes and Benefits	$71,760	$73,913	$76,130
Independent Contractors (1)	$2,500	$2,550	$2,601
Medical Supplies	$17,595	$29,514	$43,518
Pharmacy (2)	$1,042,703	$1,714,757	$2,528,402
Housekeeping/Laundry (2)	$10,200	$10,404	$10,612
Equipment Maintenance		$88,500	$88,500
Utilities	$48,960	$49,939	$50,938
Depreciation - Buildings	$72,784	$72,784	$72,784
Depreciation - Equipment	$513,306	$513,306	$513,306
Other (See Assumptions)	$3,500	$3,500	$3,500
Other Expenses (Overhead)	$47,900	$79,561	$116,162
Total Expenses	**$2,118,248**	**$2,934,378**	**$3,810,974**

(1) Include only the cost of independent contractors on this line. Employees should be included in the Salaries line.
(2) Do not include salaries on this line. Salaries should be included in the Salaries line.

Source: 2025 AdventHealth Application CON Project ID # B-012688-25, p. 138

When compared against the number of PET scans projected for Years 1 through 3, annual pharmaceutical costs break down to the following cost-per-scan amounts.

- Year 1 (CY2029): $1,042,703 for 880 scans = $1,185 per scan
- Year 2 (CY2030): $1,714,757 for 1,447 scans = $1,185 per scan
- Year 3 (CY2031): $2,528,402 for 2,091 scans = $1,209 per scan

The per-scan pharmaceutical cost remains exactly $1,185 in both Year 1 and Year 2, indicating no inflation adjustment, which directly contradicts AdventHealth's own assumption, stated on page 142, that "pharmaceutical costs are projected based on historical experience, inflated 2.0 percent annually." The minimal increase to $1,209 per scan in Year 3 represents only a 2.0 percent total increase over three years, which is insufficient to account for the cumulative effect of 2.0 percent annual inflation.

Furthermore, pharmaceutical costs for PET imaging are inherently volume-based, with radiopharmaceuticals representing a primary cost driver that scales directly with scan volume. Each PET scan requires a specific dose of radiotracer, making pharmaceutical costs a direct function of scan volume plus appropriate inflation adjustments. While AdventHealth's assumption, stated on page 142, is ambiguous as to whether inflation applies to total costs or per-unit costs, appropriate costing would indicate that per-scan pharmaceutical costs be inflated annually to reflect rising radiotracer prices. AdventHealth's failure to inflate per-scan costs in Year 2, combined with the ambiguous language used, suggests inadequate consideration of the volume-based nature of PET pharmaceutical costs and contributes to unrealistic financial projections.

Similarly, AdventHealth's housekeeping and laundry cost projections demonstrate an unexplained and unsupported decline in per-scan costs over the three-year projection period.

Form F.3b Projected Operating Costs upon Project Completion

Form F.3 Operating Costs Criterion (5)	1st Full FY CY2029 From: 01/01/2029 To: 12/31/2029	2nd Full FY CY2030 From: 01/01/2030 To: 12/31/2030	3rd Full FY CY2031 From: 01/01/2031 To: 12/31/2031
Salaries (from Form H Staffing)	$287,040	$295,651	$304,521
Taxes and Benefits	$71,760	$73,913	$76,130
Independent Contractors (1)	$2,500	$2,550	$2,601
Medical Supplies	$17,595	$29,514	$43,518
Pharmacy (2)	$1,042,703	$1,714,757	$2,528,402
Housekeeping/Laundry (2)	$10,200	$10,404	$10,612
Equipment Maintenance		$88,500	$88,500
Utilities	$48,960	$49,939	$50,938
Depreciation - Buildings	$72,784	$72,784	$72,784
Depreciation - Equipment	$513,306	$513,306	$513,306
Other (See Assumptions)	$3,500	$3,500	$3,500
Other Expenses (Overhead)	$47,900	$79,561	$116,162
Total Expenses	**$2,118,248**	**$2,934,378**	**$3,810,974**

(1) Include only the cost of independent contractors on this line. Employees should be included in the Salaries line.
(2) Do not include salaries on this line. Salaries should be included in the Salaries line.

Source: 2025 AdventHealth Application CON Project ID # B-012688-25, p. 138

When compared against the number of PET scans projected for Years 1 through 3, annual costs for housekeeping and laundry services break down to the following cost-per-scan amounts.

- Year 1 (CY2029): $10,200 for 880 scans = $11.59 per scan
- Year 2 (CY2030): $10,404 for 1,447 procedures = $7.19 per scan
- Year 3 (CY2031): $10,612 for 2,091 procedures = $5.08 per scan

This projection results in housekeeping and laundry costs declining from $11.59 per scan in Year 1 to $5.08 per scan in Year 3, equating to a 56 percent decrease in per-scan costs. However, laundry costs are variable costs that scale directly with procedure volume, as each PET scan generates patient gowns and linens that must be cleaned. While housekeeping costs may have some fixed components, laundry expenses should remain relatively constant on a per-procedure basis as volume increases. Accordingly, AdventHealth's projection of declining per-scan costs from $11.59 to less than half that dollar amount is particularly unreasonable for the laundry component, which, at minimum, represents a direct variable cost.

Given the lack of clarity regarding pharmaceutical and housekeeping costs projected in AdventHealth's application and described above, AdventHealth has not demonstrated that its operating expenses are based upon reasonable assumptions. Thus, AdventHealth's application is non-conforming with Criteria 4, 5, and 18a.

4. <u>AdventHealth fails to demonstrate that it offers the most effective or least costly means of meeting the identified need.</u>

AdventHealth has demonstrated an inability to develop approved projects in a timely manner. AdventHealth received CON approval on July 26, 2023 to develop a fixed PET at its Hendersonville hospital campus. However, the CON was not issued until March 5, 2024, following an appeal against the project by Mission. Even allowing for adjustments in proposed milestones due to this delay, AdventHealth still had sufficient time – a period of nearly 6 months – to complete preliminary development steps before Hurricane Helene made landfall in western North Carolina on September 24, 2024.

Milestone		Date mm/dd/yyyy
1	Financing Obtained	
2	Drawings Completed	01/01/2024
3	Land Acquired	
4	Construction / Renovation Contract(s) Executed	02/01/2024
5	25% of Construction / Renovation Completed (25% of the cost is in place)	
6	50% of Construction / Renovation Completed	
7	75% of Construction / Renovation Completed	
8	Construction / Renovation Completed	05/28/2025
9	Equipment Ordered	01/01/2025
10	Equipment Installed	06/01/2025
11	Equipment Operational	06/15/2025
12	Building / Space Occupied	06/15/2025
13	Licensure Obtained	
14	**Services Offered** *	07/01/2025
15	Medicare and / or Medicaid Certification Obtained	
16	Facility or Service Accredited	
17	First Annual Report Due * ^	03/01/2027

* Required

Source: 2023 AdventHealth Application CON Project ID # B-12331-23, p. 113.

As evidenced by the project timetable provided in the 2023 application, reproduced above, there were a number of development phases that could have been carried out before the damage caused by Hurricane Helene, including the completion of drawings or the execution of a construction contract. The fact that the project involved renovation at AdventHealth's existing hospital in Hendersonville rather than the construction of a new facility further supports the reasonable expectation for efficiency and minimal delay. More recently, as UNC Health Pardee points out on page 48 of its PET application, AdventHealth's March 18, 2025 progress report (see Attachment A) documents zero milestones completed and no capital expenditures made.

These details are relevant not only because they suggest the applicant's lack of ability to develop projects in a timely manner, but also because AdventHealth points to the hypothetical volumes to be performed on this approved, not yet developed, scanner as support for the claims surrounding the projected performance of its proposed scanner. On page 93 of its 2025 PET application, AdventHealth states: "Importantly, AdventHealth's approved fixed PET scanner in Hendersonville is projected to exceed the CON performance standard of 2,080 procedures by its third operating year, confirming sustained demand for PET services in the region."

Furthermore, as a result of these circumstances, AdventHealth has another alternative for developing needed PET capacity. Instead of locating the approved but not yet developed PET at the Hendersonville campus as described in AdventHealth's 2023 application, there is the option of developing the scanner at the future Weaverville campus according to the plans described in AdventHealth's 2025 application. Despite this representing a reasonable alternative to the acquisition of a second PET, AdventHealth does not address this possibility in its application, thereby failing to demonstrate that it offers the most effective or least costly means of meeting the identified need in HSA I. This is especially meaningful given the highly unreasonable market share projections and assumptions about additive volume discussed above.

For these reasons, AdventHealth's application is non-conforming with Criteria 4 and 12, and should not be approved.

In summary, based on the issues detailed above, the AdventHealth application is non-conforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria 3, 4, 5, 6 and 18a, as well as the performance standards specified in 10A NCAC 14C .3703. The AdventHealth application should not be approved.

GENERAL COMMENTS ON MISSION HOSPITAL

As detailed in the issue-specific comments in the following section, Mission Hospital's application does not conform to all of the CON statutory review criteria and regulations. First, Mission Hospital's current application is considerably undermined by the applicant's own recent and repeated assertions made in two recent petitions to the State Health Coordinating Council (SHCC) that no additional general PET capacity is needed in HSA I. In 2024, Mission submitted a Summer Petition to convert the 2025 HSA I PET need determination to a cardiac-specific PET scanner, arguing that there was "no need for another general PET unit" in HSA I and that existing providers had "adequate capacity" for oncology services with collective utilization at only 39 percent.[3] Mission expressed very similar views in a 2025 Spring Petition for a policy that would allow open-heart surgery providers to obtain cardiac PET scanners outside the standard methodology, again emphasizing that general PET capacity for oncology and neurology procedures was sufficient.[4] Yet Mission's own CON application projects capturing substantial general oncology and neurology volume, directly contradicting its recent and repeated stance that need does not exist for these applications and other providers have adequate capacity to serve the existing demand for oncology and neurology PET in HSA I. Notably, the utilization represented by general PET applications, including oncology and neurology, is over 21 percent of the total volume to be performed by the proposed scanner, the equivalent of one of out every five scans.

Figure 7
Mission Health System Summary of Projected PET Utilization by Location

	Year 1 CY 2028	Year 2 CY 2029	Year 3 CY 2030
Mission Cancer Center			
Projected Oncology/Neurology PET/CT Scans	2,237	2,394	2,562
% Redirection to Mission 5 Vanderbilt Park	17.5%		
PET/CT Scans Shifted Mission 5 Vanderbilt Park	392	419	448
PET/CT Scans Remaining at Mission Cancer Center	1,846	1,975	2,113
Mission 5 Vanderbilt Park			
PET/CT Scans Redirected from Mission Cancer Center	392	419	448
Projected New Cardiac PET/CT Scans	1,322	1,542	1,671
Total Mission 5 Vanderbilt Park PET/CT Scans	1,713	1,961	2,120
Total Mission Health System PET/CT Scans	3,560	3,936	4,233
Number of Units	2	2	2
Number of Scans per Unit	1,780	1,968	2,117

Note: Totals may not foot due to rounding.

Source: Mission Application CON Project ID #B-012685-25, p. 148.

Second, Mission Hospital has experienced a marked decline in overall PET utilization following the development of fixed PET services at Messino Cancer Center, losing 969 procedures or 34 percent of its volume in a single year and resulting in the creation of significant available capacity at Mission. As shown in the table below, Mission's PET volumes fell dramatically from 2,862 procedures as reported in the *2024 SMFP* to 1,893 procedures as reported in the *Proposed 2026 SMFP.* This massive loss of market share to a new competitor demonstrates Mission's vulnerability and inability to maintain volume in a competitive

[3] "Petition to Add a Dedicated Cardiac PET Need Determination in Health Service Area ("HSA") I to the 2025 State Medical Facilities Plan ("SMFP")." July 24, 2024. Accessed at https://info.ncdhhs.gov/dhsr/mfp/pets/2024/summer/T01_MissionHospital_CardiacPET.pdf.

[4] "Petition to State Health Coordinating Council Regarding a Policy for Dedicated Cardiac PET for Open Heart Surgery Providers." March 5, 2025. Accessed at https://info.ncdhhs.gov/dhsr/mfp/pets/2025/spring/T05_P_Mission_PET_Cardiac.pdf.

environment. Conversely, Messino Cancer Center achieved 2,111 procedures during the same period, suggesting a sizeable shift in PET volume that undercuts Mission's stated need for a second PET scanner to relieve previous capacity constraints.

Mission Hospital and Messino Cancer Center Fixed PET Utilization

	2024	*2025*	*2026*
Mission Hospital Historical PET Procedures	2,919	2,862	1,893
Messino Cancer Center Historical PET Procedures	0	192	2,111
Mission Hospital Facility Rate Utilization	97.30%	95.40%	63.10%

Source: *2024 SMFP, 2025 SMFP*, and *Proposed 2026 SMFP*

From a financial perspective, Mission's projections also contain a number of flaws, namely the exclusion of several operating costs essential for PET service delivery, including medical supplies, housekeeping services, space allocation costs, and various administrative expenses, which renders the corresponding financial feasibility projections both unrealistic and unreliable.

ISSUE-SPECIFIC COMMENTS ON MISSION HOSPITAL

1. Mission Hospital's projected PET utilization relies on overly selective data and fails to account for the effects of present and potential competition.

   Mission Hospital's utilization projections employ a flawed methodology that cherry-picks favorable data points while downplaying the significant decline in Mission's actual PET volumes. This approach creates artificially optimistic projections that also fail to account for the competitive realities of the current market landscape, which include Mission's demonstrable loss of market share to Messino Cancer Center.

   On page 109 of the application, Mission references the growth in Buncombe County PET providers' utilization between FY 2023 and FY 2024 as evidence of surging demand in the service area: "PET scan volumes in the service area surged by an impressive 31% between FY 2023 and FY 2024 and are projected to continue rising."

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

Source: Mission Hospital Application CON Project ID #B-012685-25, p. 145.

However, the use of this figure is misleading because it represents combined utilization across both Mission and Messino scanners and masks the fact that Mission's own volumes fell dramatically during this same period. Isolating Mission-specific data shows that the applicant experienced a 37 percent decline in PET procedures, which corresponded to a sharp drop in the facility utilization rate, from 95.4 percent to 63.1 percent. Messino Cancer Center, on the other hand, saw volumes rise from 195 scans in FY 2023 to 2,111 scans in FY 2024, a more than ten-fold increase that also resulted in the facility performing nearly 53 percent of PET scans in Buncombe County.

Mission states, on page 145 of the application, that "Mission Hospital PET volume declined (as predicted) when Messino began providing PET scans to its oncology patients in CY 2023 and CY 2024" but goes on to claim that "Mission Hospital's volume is rebounding with a projected growth in demand to 1,826 scans based on annualized 2025 data." This statement illogically implies that the volume shift to Messino, a specialized provider of oncology care, is only temporary and that large portions of this volume will be recaptured despite providing no evidence to support why patients who have chosen to receive care from Messino would return to Mission for this care.

Figure 1

Mission Cancer Center – Historical PET Scan Volume

	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023*	CY 2024	CY 2025 Annualized
Mission PET CT Scans	2,261	2,586	2,611	2,826	2,946	2,735	1,723	1,826

Source: Mission Internal Data

Note: CY 2025 is annulized based on 5 months of actual data.

**Messino PET scanner came online in 2023.*

Source: Mission Hospital Application CON Project ID #B-012685-25, p. 145.

Mission further compounds these flaws by projecting a 7 percent CAGR for baseline PET growth, which it claims is "conservative" relative to the 10.4 percent service area growth rate. However, a CAGR calculation based solely on Mission's PET utilization during the same period reveals that the facility has been experiencing negative growth at a rate of -8.5 percent, reflecting the significant decline described in the previous sections. The unrealistic nature of Mission's growth projections is highlighted in the table below, which demonstrates that over the past four years, on an annual basis, Mission has failed to attain even 60 percent of the seven percent growth rate projected.

Mission Hospital PET Utilization Trends, *SMFP*

	2022	***2023***	***2024***	***2025***	***2026***	***22-24 CAGR***
Mission Hospital	2,695	2,808	2,919	2,862	1,893	-8.5%*
Annual Growth		4.2%	4.0%	-2.0%	-33.9%	

Sources: *2022 SMFP* to *Proposed 2026 SMFP*; data corresponds to FY 2020 to FY 2024, respectively.

Not only do these projections fail to account for the existing and increasingly competitive impact of Messino Cancer Center, they also do not adequately address the competitive impact of the approved but not yet developed AdventHealth Hendersonville scanner that presumably will eventually come online in neighboring Henderson County. On page 145 of the application, Mission summarily acknowledges AdventHealth's approved scanner but lightly dismisses the possibility of any significant impact by stating: "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." This assumption ignores the reality that AdventHealth has been approved to serve many of the same geographic markets and patient populations that Mission intends to target, as evidenced by the figures in their respective projected patient origin shown in the tables below. Given the experience with Messino, it is unlikely that there will be no impact to Mission as a result of the AdventHealth Hendersonville PET coming online.

Positron Emission Tomography (PET)	<Mission – 5 Vanderbilt Park>*					
	1st Full FY		2nd Full FY		3rd Full FY	
	1/1/2028 to 12/31/2028		1/1/2029 to 12/31/2029		1/1/2030 to 12/31/2030	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Buncombe	679	39.6%	777	39.6%	840	39.6%
Haywood	190	11.1%	217	11.1%	235	11.1%
Henderson	123	7.2%	141	7.2%	153	7.2%
McDowell	96	5.6%	110	5.6%	119	5.6%
Macon	86	5.0%	98	5.0%	106	5.0%
Madison	72	4.2%	82	4.2%	89	4.2%
Transylvania	54	3.1%	61	3.1%	66	3.1%
Jackson	52	3.0%	59	3.0%	64	3.0%
Yancey	42	2.4%	48	2.4%	52	2.4%
Mitchell	36	2.1%	41	2.1%	44	2.1%
Rutherford	24	1.4%	27	1.4%	30	1.4%
Burke	15	0.9%	17	0.9%	18	0.9%
Swain	14	0.8%	16	0.8%	17	0.8%
Polk	12	0.7%	14	0.7%	15	0.7%
Cherokee	9	0.5%	10	0.5%	11	0.5%
Caldwell	8	0.5%	9	0.5%	10	0.5%
Graham	6	0.3%	7	0.3%	7	0.3%
Clay	5	0.3%	6	0.3%	6	0.3%
Other NC Counties	**18**	**1.0%**	**20**	**1.0%**	**22**	**1.0%**
Out of State	**174**	**10.2%**	**199**	**10.2%**	**215**	**10.2%**
Total	**1,713**	**100.0%**	**1,961**	**100.0%**	**2,120**	**100.0%**

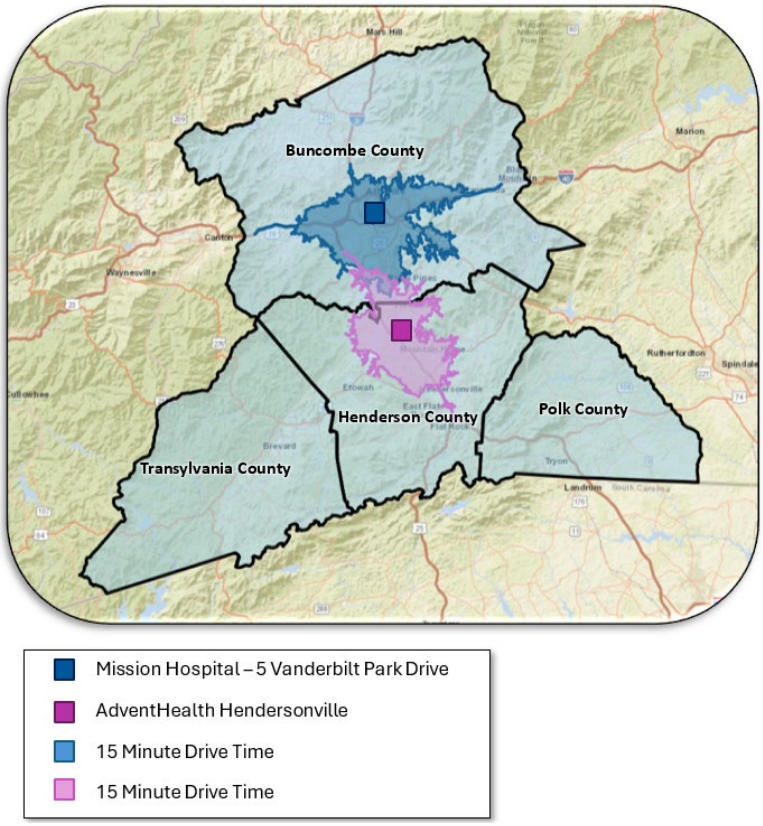
* This should match the name provided in Section A, Question 4, and includes mobile health services
** Home health agencies should report the number of unduplicated clients.

Fixed PET Scanner	AdventHealth Hendersonville *					
	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027		01/01/2028 to 12/31/2028	
County	Patients	% of Total	Patients	% of Total	Patients	% of Total
Buncombe	194	22.6%	414	28.4%	551	25.9%
Cherokee	5	0.6%	11	0.7%	23	1.1%
Clay	2	0.2%	4	0.3%	9	0.4%
Graham	5	0.6%	29	2.0%	12	0.6%
Haywood	22	2.5%	46	3.2%	123	5.8%
Henderson	329	38.3%	438	30.0%	606	28.5%
Jackson	30	3.5%	48	3.3%	102	4.8%
Macon	26	3.1%	56	3.8%	60	2.8%
Madison	15	1.7%	24	1.6%	50	2.3%
McDowell	30	3.5%	48	3.3%	101	4.8%
Mitchell	10	1.2%	16	1.1%	33	1.6%
Polk	27	3.1%	42	2.9%	59	2.8%
Rutherford	66	7.7%	93	6.4%	172	8.1%
Swain	10	1.1%	52	3.6%	22	1.0%
Transylvania	46	5.4%	74	5.1%	104	4.9%
Yancey	19	2.2%	26	1.8%	42	2.0%
Other^	21	2.5%	36	2.5%	53	2.5%
Total	858	100.0%	1,457	100.0%	2,124	100.0%

^Other includes <1 percent patient origin from each of the remaining counties in North Carolina and other states.
* This should match the name provided in Section A, Question 4.

Sources: (On left) Mission Hospital Application CON Project ID #B-012685-25, p. 60; (On right) 2023 AdventHealth Application CON Project ID # B-12331-23, p. 38.

Furthermore, Mission does not account for the possibility that a portion of the patients it currently serves, who reside in Henderson, Polk, and Transylvania counties, may choose to instead receive PET services at the more geographically proximate AdventHealth Hendersonville facility following the development of its approved scanner.



Not only is Mission's proposed site at 5 Vanderbilt Park in Asheville farther from Transylvania, Polk, and Henderson counties, the proposed PET service will not provide a broader scope of clinical applications than AdventHealth's approved but not yet developed PET in Hendersonville. If these incremental PET procedures from Polk, Henderson and Transylvania Counties are removed, Mission's total PET volume at 5 Vanderbilt Park in Asheville in Project Year 3 would be reduced from 2,120 procedures to 1,886 procedures (2,120 – 234 = 1,886). This would ultimately result in Mission being below the per scanner performance threshold of 2,080 procedures. Even if the procedures from Polk, Henderson and Transylvania counties are only reduced by half of Mission's projections, (2,120 – 117 = 2,003) they still would fail to meet the performance standards.

In sum, Mission strategically selects favorable data to support its growth assumptions while minimizing discussion of recent declining trends, at least partially driven by the introduction of new providers of PET services. The application points out figures such as the service area CAGR from FY 2020 to FY 2024 (10.4 percent) while downplaying Mission's actual performance during the same period, which conversely shows a large decrease in overall volume. These misrepresentations of data result in overstated utilization projections that fail to provide a reasonable basis for determining actual need.

Given the competitive landscape for PET services in HSA I, Mission's application contains unreasonable assumptions for utilization from Polk, Transylvania, and Henderson counties as well as unreasonable assumptions related to overall growth. Accordingly, the application is non-conforming with Criteria 3, 4, 5, 6, and 18a as well as the performance standards in 10 NCAC 14C .3703 and should not be approved.

2. Mission Hospital's unreasonable cardiac PET capture rate projections result in overstated utilization.

Mission's cardiac PET utilization projections are significantly overstated due to the application of an unreasonable 85 percent capture rate that dramatically exceeds Mission's actual cardiac market share performance within its own service area.

Figure 5
Projected Cardiac PET/CT Scans

	Partial Year	First Full Project Year	Second Full Project Year	Third Full 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*

Source: Mission Hospital Application CON Project ID #B-012685-25, p. 147

As shown in the methodology table reproduced above, Mission projects an 85 percent cardiac PET capture rate for HSA I in Project Year 3 (CY 2030), applying this rate to its 18-county service area population of 978,499 to calculate 1,746 total cardiac PET scans. However, Mission's actual cardiac services market share provides evidence that such capture rates are unrealistic and methodologically unsound. According to SFY 2024 HIDI data (see Attachment C), Mission's actual cardiac services market share within the most proximate HSA I counties varies significantly, with several counties showing performance well below the 85 percent projected cardiac PET capture rate.

Mission Hospital Cardiac Services Market Share by County, SFY 2024

County	*Market Share^*	*PET Market Share^^*
Buncombe	91.7%	85%
Haywood	64.2%	85%
Henderson	51.5%	85%
Madison	92.7%	85%
McDowell	64.4%	85%
Polk	45.4%	85%
Transylvania	63.8%	85%
Yancey	76.5%	85%

Source: ^HIDI, SFY 2024
^^2025 Mission PET Application CON Project ID #B-012685-25, p.147.

In Henderson County, Mission currently captures only 51.5 percent of cardiac services yet projects an 85 percent cardiac PET capture rate – a difference of 33.5 percent. This projection is made even more unlikely given that AdventHealth Hendersonville has been approved for a PET scanner in this same county. Similarly, in Polk County, Mission captures just 45.4 percent of cardiac

services, a difference of 39.6 percent compared to the projected rate of market share. Even in counties where Mission performs better, such as Haywood County (64.2 percent) and McDowell County (64.4 percent), the projected 85 percent capture rate still exceeds current performance by over 20 percent.

Crucially, Mission provides no methodology or supporting evidence to explain why cardiac PET capture rates would exceed current cardiac services market share by such dramatic margins. The absence of any justification for these projected market share increases represents a critical flaw in the methodology. To address this issue, Mission would have to demonstrate how it expects to achieve dominance in cardiac PET market share in counties where it currently captures less than half of market share for relevant services, particularly without any predicted changes in referral patterns or provider networks.

On page 147 of its application, Mission justifies its high capture rate by asserting it "is the only provider of tertiary cardiac services in western North Carolina thus serving the vast majority of cardiac-related patients in the region." However, PET services are currently provided by a number of facilities throughout HSA I and the *SMFP* explicitly states that "Any person can apply for a CON to meet [a] need" such that facilities characterized by a different scope of services have the same opportunity to apply to develop cardiac PET services. As shown, county-specific market data further undercut the meaningfulness of this claim. In Henderson and Polk counties, Mission notably captures less than 52 percent of cardiac services, demonstrating that significant portions of cardiac patients in Mission's own service area seek care from other providers. Mission's claim of serving the "vast majority" of cardiac patients is inconsistent with market share data that show Mission serves a much smaller portion of cardiac patients across multiple counties within its proposed service area.

Ultimately, the uniform application of an 85 percent capture rate across all counties ignores documented variations in Mission's actual market performance and fails to account for established referral patterns and competitive dynamics within the service area. On page 108 of the application, Mission even offers the brief acknowledgment that certain providers serve "distinct patient populations." Since existing patient-provider service patterns are heavily influenced by geographic factors and county-specific conditions, there is very little logical basis to infer that cardiac PET services would achieve such uniform capture rates.

By extension, these unreasonable capture rate assumptions create significant risk that Mission will fail to meet the performance standards required under 10A NCAC 14C .3703. Mission projects 4,233 total PET scans in Year 3, providing only a 73-scan surplus above the 4,160 procedures required for two scanners (assuming 2,080 procedures per scanner). Given that Mission's cardiac PET projections represent 1,671 of these total scans, even a modest reduction in cardiac capture rate would result in volumes that fall short of performance standards.

To illustrate the significance of such a narrow margin, Mission would need to maintain at least 1,598 cardiac PET scans to meet the minimum performance standard (4,160 total scans – 2,562 non-cardiac scans). Without making any adjustments to Mission's projected procedure mix or inmigration, this requires approximately 1,411 cardiac scans (1,598 cardiac scans – 187 cardiac scans performed on out-of-state patients and patients from non-HSA I counties), representing a capture rate of 80.8 percent. Therefore, if Mission's projected 85 percent cardiac PET capture rate declines by just 4.2 percent, the facility would fail to meet the performance standard. In

itself, this hypothetical 80.8 percent capture rate substantially exceeds Mission's actual cardiac services market share in multiple counties and is not reasonably attainable across such a wide geography. As such, it is extremely likely that actual cardiac PET capture rates would fall well below this 80.8 percent figure, rendering the application non-conforming with performance standards.

Based on this analysis, Mission Hospital's projected utilization is flawed and the application is therefore non-conforming with Criteria 3, 4, 5, 6, and 18a as well as the performance standards in 10 NCAC 14C .3703, and should not be approved.

3. Mission Hospital's incremental cost pro forma results in unreasonable financial projections.

Mission Hospital presents financial projections for its proposed PET scanner that inappropriately exclude numerous expense categories typically associated with the service, resulting in an incremental cost proforma that fails to demonstrate the true financial impact of the project. This brings the application in conflict with Criterion 5, which states that "financial and operational projections for the project shall demonstrate" … "the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service," and renders the financial feasibility analysis unreasonable and inadequately supported.

As shown in the response to Form F.3b, Mission's financial projections for the proposed scanner include only five expense categories: salaries, taxes and benefits, pharmacy, equipment maintenance, and depreciation and lease costs. The total projected expenses of $1,488,170 in the first full fiscal year exclude numerous operating costs that would reasonably be incurred by providing PET services at the new location.

Form F.3b Projected Operating Costs upon Project Completion	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	F: 07/01/2027	F: 01/01/2028	F: 01/01/2029	F: 01/01/2030
Mission Hospital PET/CT (5 Vanderbilt Park)	T: 12/31/2027	T: 12/31/2028	T: 12/31/2029	T: 12/31/2030
Salaries (from Form H Staffing)	$104,590	$213,364	$217,632	$221,984
Taxes and Benefits	$28,093	$57,310	$58,456	$59,625
Independent Contractors (Consultants) (1)				
Travel Reimbursement (2)				
Training (2)	$50,000			
Medical Supplies				
Other Supplies				
Pharmacy (2)	$816,119	$2,721,320	$3,177,606	$3,503,955
Social Services (2)				
Activities (2)				
Dietary (2)				
Housekeeping / Laundry (2)				
Transportation (2)				
Equipment Maintenance (2)	$0	$62,500	$125,000	$125,000
Building & Grounds Maintenance (2)				
Marketing / Public Relations (2)				
Medicaid Assessment Fee				
Central Office Overhead				
Professional Fees				
Management Fees				
Other Fees (specify)				
Utilities				
Insurance				
Interest Expense				
Rental Expense				
Property and Other Taxes (except Income)				
Depreciation - Buildings				
Depreciation - Equipment	$462,368	$924,736	$924,736	$924,736
Other Expenses (Lease of Rubidium Generator)	$27,000	$54,000	$54,000	$54,000
Total Expenses	$1,488,170	$4,033,230	$4,557,430	$4,889,300

Source: Mission Hospital Application CON Project ID #B-012685-25, p. 163

As such, Mission's projections fail to include basic expenses that are essential for PET service operations. Most notably, Mission projects zero costs for medical supplies, despite PET services requiring materials and other supplies beyond radiopharmaceuticals. Similarly, Mission projects zero costs for housekeeping and laundry services, which are necessary for maintaining clean conditions and patient care standards required for PET imaging services.

On page 164, Mission states that "No incremental space or rental expense will be utilized or incurred in relation to this project," which is contradicted by the fact that Mission will be occupying space at 5 Vanderbilt Park for PET scanner operations. If space is being used for the proposed service, the associated rental or occupancy costs must be included in the financial projections regardless of whether that space is currently being rented. The exclusion of these costs further understates the true financial expenditure involved in the project.

Furthermore, the projections assume zero costs for critical expense categories including billing and collection services, insurance, human resources support, information technology, utilities, building maintenance, marketing, professional fees, and general administrative overhead. Mission provides no explanation for why these services would not be required for the proposed PET service or why no portion of these facility-wide expenses should be allocated to the new service.

In this context, the Agency has established clear precedent regarding incremental cost proformas in its 2001 review of Lake Norman Regional Medical Center's cardiac catheterization application (Project ID # F-6380-01). Specifically, the Agency found that application non-conforming with Criterion 5 because the applicant failed to include reasonable allocations for facility costs, stating "It is not reasonable to assume there will be zero costs for all of the line items listed above, particularly Administrative/Other Personnel, Plant Operation/Maintenance and Other Supplies" (p. 11). The Agency also emphasized that existing administrative and support personnel would continue to provide support to the new service, requiring that "some portion of their salaries, personnel taxes and benefits should be allocated" to the proposed service.

Mission's application exhibits the same fundamental flaw identified in the Lake Norman precedent. The incremental cost approach creates an unrealistic financial scenario that artificially inflates the apparent profitability of the proposed project by excluding costs that would reasonably be required to provide the proposed service. This methodology prevents proper evaluation of whether the project can generate sufficient revenue to cover all costs reasonably attributable to the service and fails to provide an adequate basis for determining financial feasibility.

Mission Hospital's financial projections are therefore non-conforming with Criteria 5 and 18a, as they fail to demonstrate the financial feasibility of the proposal based on reasonable projections of costs and do not adequately support the conclusion that this represents the most effective alternative when significant operating costs are excluded from the analysis.

In summary, based on the issues detailed above, the Mission application is non-conforming with the review criteria established under N.C. GEN. STAT. § 131E-183, specifically Criteria 3, 4, 5, 6, and 18a, as well as the performance standards specified in 10A NCAC 14C .3703. The Mission application should not be approved.

GENERAL COMMENTS ON NOVANT HEALTH

As detailed in the issue-specific comments in the following section, Novant Health's application does not conform to all of the CON statutory review criteria and regulations. Novant Health's application suffers from fundamental methodological flaws that render its utilization projections entirely unreliable. For example, Novant Health's utilization methodology applies a number of inaccurate assumptions that result in overstated projections, specifically the inappropriate use of general imaging market share data to project PET scanner utilization volumes. This approach is fundamentally unsound because PET scanning has inherently different physician referral patterns compared to general imaging services such as CT and MRI, with PET imaging decisions primarily controlled by specialist physicians rather than primary care providers who commonly order general imaging services.

ISSUE-SPECIFIC COMMENTS ON NOVANT HEALTH

1. <u>Novant's market share projections are unreasonable due to its inappropriate application of general imaging market share to PET procedure projections.</u>

   On pages 125 to 126 of the application, Novant Health makes several references to the diagnostic services provided by a related entity, Open MRI & Imaging of Asheville, stating that "it is reasonable that the proposed PET/CT scanner will achieve 75% of the FY2020-FY2024 Fixed MRI scan market share Open MRI & Imaging of Asheville achieved, by its third full year of operation." With this approach, Novant Health inappropriately applies general imaging market share data to project PET scanner utilization volumes.

Open MRI & Imaging of Asheville's Fixed MRI Market, FY 2020-2024

	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 20-24 Total
Asheville Open MRI Fixed MRI Scans	10,264	11,114	12,625	13,511	14,254	61,768
Total Buncombe County Fixed MRI Scans	29,027	33,954	38,191	39,890	39,228	180,290
Asheville Open MRI Market Share	35.36%	32.73%	33.06%	33.87%	36.34%	34.26%

Source: 2022-Draft 2026 SMFP, Chapter 15

Source: Novant Health Application CON Project ID # B-012684-25, p. 125.

> Open MRI & Imaging of Asheville's market share ranged from 32.7% to 36.3% of fixed MRI scans across the five years. Open MRI & Imaging of Asheville will provide its local reputation, expertise, and referral network to this project and will help NH Asheville PET develop its own referral network. As part of the Novant Health system, Open MRI & Imaging of Asheville has proven its ability to attract patients in Western North Carolina who need imaging services. The applicants believe it is reasonable that the proposed PET/CT scanner will achieve 75% of the FY2020-FY2024 Fixed MRI Scan market share Open MRI & Imaging of Asheville achieved, by its third full year of operation.[1] This equates to a 25.70% market share for NH Asheville PET in Year 3 (.75*34.26=25.70). This is reasonable, given that both are part of the Novant Health system and will share a referral network. It is also a lower market share

Sources: Novant Health Application, p. 126.

This methodological flaw directly contradicts established Agency precedent. The Agency regularly evaluates the impact and location of existing facilities' utilization on proposed projects—both for facilities operated by the same applicant and by competitors—and expects reasonable projections of volume shifts between related facilities. Notably, in the 2024 Wake Acute Care Bed findings, the Agency found Novant non-conforming with Criterion 3 due to the applicant not providing a reasonable basis for assessing market share capture rates and thereby overstating utilization projections. In that instance, the Agency offered the following evaluation of the Novant proposal (Project ID # J-012534-24):

> *"Proposing that a brand-new small community hospital, unsupported by an existing hospital system within the Wake County acute care bed service area and competing with three long established hospitals systems within the service area would reasonably command a 20%/10% market shift within a designated group of patients within its first three years of operation is not reasonable or supported by the application, exhibits to the application, comments, response to comments, remarks at the public hearing, or information publicly available during the review."* – p. 38

Similarly, Novant's current application fails to provide a reasonable basis for its market share assumptions by inappropriately extrapolating general imaging performance to specialized PET services.

Although Novant Health presents Open MRI & Imaging as a facility that has "proven its ability to attract patients in Western North Carolina who need imaging services," it provides no additional basis for assuming its proposed PET facility would perform similarly to a MRI/imaging provider, apart from describing the two providers as "part of the Novant Health system" and sharing a referral network. More problematically, this approach ignores the inherently different physician referral patterns associated with PET compared to general imaging services such as MRI.

Current U.S. medical practice demonstrates that primary care physicians function as gatekeepers who refer patients to oncology specialists rather than directly ordering advanced imaging. A 2023 article from Lindberg Cancer Center identifies scenarios where "primary care physicians may refer the patient to an oncologist" for issues such as "abnormal test results" and "suspicious symptoms," noting that "[a] referral to an oncologist is crucial since it allows for specialized testing and expertise."[5]

Additionally, major U.S. insurance providers such as Aetna maintain strict medical necessity criteria for PET scans, limiting authorization to very specific, often oncologic, indications. Language published in an Aetna bulletin notes that "[u]pon individual case review, FDG-PET scanning may be considered medically necessary for other oncologic indications that are not listed as medically necessary above, when the conventional imaging that is indicated for that oncological indication is equivocal."[6] These case-by-case determinations for equivocal conventional imaging findings require sophisticated clinical judgment regarding oncologic conditions, an undertaking that typically falls well outside the purview of a primary care physician.

Critically, this same document notes that "[i]n general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis."[7] This staging function represents a notable portion of PET utilization and is placed exclusively within the domain of oncology specialists who manage cancer treatment planning rather than primary care physicians who handle initial symptom evaluation.

Accordingly, the referral pattern is therefore quite distinct from general imaging services. While X-ray, CT, and MRI are ordered by a wide variety of medical specialties including primary care, orthopedics, and numerous other disciplines, PET imaging is predominantly ordered by the specialty treating the specific medical condition – primarily oncology for cancer patients, with cardiology and neurology generally accounting for a smaller proportion. The typical referral pathway for PET can thus be outlined as Primary Care → Specialty Physician → PET scan, not the direct ordering pattern common with general imaging services.

---

5 Lindenberg Cancer & Hematology Center. "5 Reasons a Patient Might Be Referred to an Oncologist." Lindenbergcancer.com, July 26, 2023. https://lindenbergcancer.com/blog/5-reasons-a-patient-might-be-referred-to-an-oncologist/ (accessed September 15, 2025)

6 Aetna. "Positron Emission Tomography (PET) - Medical Clinical Policy Bulletins." Aetna.com. https://www.aetna.com/cpb/medical/data/1_99/0071.html (accessed September 15, 2025)

7 Ibid.

Given this broader context, the application provides no analytical justification for why market share achieved in general imaging services would translate to PET services. While Open MRI & Imaging has the ability to demonstrate a broad referral base of specialties that can refer for general imaging, this does not translate to the concentrated specialist-driven referral pattern that defines PET imaging.

Open MRI & Imaging of Asheville Referral Specialties (2024)

Allergy & Immunology	Hand Surgery	Optometrist	Psychiatry
Anesthesiology	Hematology	Orthopedic Care	Pulmonary Care
Cancer Care	Hospitalist	Otolaryngology	Radiation Oncology
Cardiovascular Disease	Internal Medicine	Pain Management	Rheumatology
Chiropractor	Medical Oncology	Pain Medicine	Sports Medicine
Dermatology	Nephrology	Pediatrics	Surgery
Emergency Medicine	Neurology & Neurosurgery	Pediatric Endocrinology	Thoracic Surgery
Endocrinology	Obstetrics & Gynecology	Physical Med & Rehabilitation	Urgent Care
Family Medicine	Occupational Medicine	Plastic Surgery	Urology
Gastroenterology	Ophthalmology	Podiatrist	Women's Health

Source: Open MRI & Imaging of Asheville Internal Data.

Source: Novant Health Application CON Project ID #B-12684-25, p. 56

Furthermore, the application fails to demonstrate that the Novant Health PET would have access to a sufficient base of disease-specific specialists to support its projected utilization volumes. Although the application lists several Novant Health-affiliated physician practices in HSA I, the majority of these practices do not represent the oncology specialties that generate the predominant share of PET referrals, nor any cardiology or neurology specialties.

Novant Health-Aligned Providers

As discussed in response to Section I, Question 2a, Novant Health has several affiliated physician practices in HSA I: Asheville Endocrinology, Novant Health Plastic & Reconstructive Surgery, Novant Health Surgical Partners-Biltmore and Novant Health Women's Specialty. Novant Health also has affiliated urgent care centers through Novant Health GoHealth Urgent Care. Many Novant Health-aligned physicians have written letters of support for this application, which are found in Exhibit C-4.1.

Source: Novant Health Application CON Project ID #B-12684-25, p. 55.

Of these, only portions of the surgical specialties could reasonably be expected to generate PET referrals, and none represent dedicated medical oncology practices. Despite the limited scope of a referral network for its proposed PET, Novant Health projects achieving 25.70 percent market share by Year 3, representing 2,481 procedures annually. Given that PET referrals are concentrated among disease-specific specialists, Novant Health would need a substantial base of oncology, neurology, or cardiology practices to support this volume, which the Novant application fails to demonstrate exist within HSA I.

	YR 1	YR 3	YR 3
	2029	2030	2031
Fixed PET Scans in HSA I (Step 4)	8,278	8,939	9,652
Year 3 Market Share	25.70%	25.70%	25.70%
Percent of Year 3 Market Share	50%	75%	100%
NH Asheville PET Market Share	12.9%	19.3%	25.7%
NH Asheville PET Scans	1,064	1,723	2,481

Sources: Step 4, 2022-Draft 2026 SMFP, Chapter 15

Source: Novant Health Application CON Project ID #B-12684-25, p. 126.

Based on the analysis detailed above, Novant has failed to adequately demonstrate need for the proposed project and is non-conforming with Criteria 3, 4, 5, 6, and 18a as well as the performance standards in 10 NCAC 14C .3703 and should not be approved.

COMPARATIVE ANALYSIS

AdventHealth (Project ID # B-012688-25), Mission Hospital (Project ID # B-012685-25), Novant Health (Project ID # B-012684-25), and UNC Health Pardee (Project ID # B-012675-25) each propose to develop a fixed PET scanner in response to the *2025 SMFP* need determination in HSA I. Given that four applicants propose to meet the need for the fixed PET scanner in HSA I, only one can be approved as proposed. To determine the comparative factors that are applicable in this review, UNC Health Pardee examined recent Agency findings for competitive fixed PET scanner reviews. Based on that examination and the facts and circumstances of the competing applications in this review, UNC Health Pardee considered the following comparative factors:

- Conformity with Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility
- Access by Service Area Residents
- Competition – Access to a New Provider
- Access by Underserved Groups
    - Projected Medicare and
    - Projected Medicaid
- Average Net Revenue per Procedure
- Average Operating Expense per Procedure

UNC Health Pardee believes that the factors presented above and discussed in turn below should be used by the Agency in reviewing the competing applications.

Conformity with Applicable Statutory and Regulatory Review Criteria

The UNC Health Pardee application adequately demonstrates that its fixed PET scanner proposal is conforming to all applicable statutory and regulatory review criteria. In contrast, neither the AdventHealth application nor the Mission Hospital application nor the Novant Health application adequately demonstrates that its proposal is conforming to all applicable statutory review criteria as discussed previously. Specifically, the AdventHealth application is non-conforming with Criteria 3, 4, 5, 6, and 18a and fails to meet the performance standards specified in 10A NCAC 14C .3703, while the Mission Hospital application is non-conforming with Criteria 3, 4, 5, 6, and 18a, and fails to meet the performance standards specified in 10A NCAC 14C .3703, and the Novant Health application is non-conforming with Criteria 3, 4, 5, 6, and 18a and fails to meet the performance standards specified in 10A NCAC 14C .3703. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, with regard to conformity, the UNC Health Pardee application is more effective than the Novant, Mission and Advent applications.

Scope of Services

Generally, the application that proposes to provide the broadest scope of services with the proposed equipment is the more effective alternative regarding this comparative factor.

The following table compares the scope of services proposed by each applicant:

Proposed Scope of Service

	Oncology	*Cardiac*	*Neurology*
UNC Health Pardee	X	X	X
AdventHealth Asheville	X	X	X
Mission Hospital	X	X	X
Novant Health Long Shoals	X	X	X

As shown above, all four applicants propose to provide PET services for oncology, cardiac, and neurology applications as described in their respective applications. However, significant differences exist in the comprehensiveness and integration of services each facility can deliver. UNC Health Pardee proposes locating its PET scanner on its main hospital campus with established networks of cardiac, neurology, and oncology providers already in place to support comprehensive service delivery across all three primary PET applications. This integrated campus location ensures immediate coordination with multiple specialties and seamless patient care pathways. In contrast, Mission Hospital proposes locating its PET scanner in a medical office building approximately 2 miles from the main hospital campus, with a primary focus on cardiac PET patients. While Mission states it will shift a percentage of neurology and oncology patients to the new location, the application combines these volumes into a single undifferentiated category, failing to provide specific projections for neurology versus oncology procedures and appearing predominantly oriented toward cardiac services. AdventHealth's proposed scanner would eventually operate under its planned hospital license on the hospital campus in Weaverville, though the facility remains under appeal and has not yet been constructed, creating uncertainty about timeline and initial service integration. Novant Health proposes a freestanding imaging facility that would serve a balanced mix of oncology, cardiac, and neurology patients but would lack the integrated specialty networks and immediate care coordination available at a hospital campus. Given these configurations, UNC Health Pardee presents the most effective alternative regarding scope of services with its established provider networks across all service lines and integrated campus setting that facilitates comprehensive, coordinated care.

Historical Utilization

Generally, regarding this comparative factor, an existing provider with higher historical utilization rates is the more effective alternative based on an assumption that that provider has a greater need for the proposed fixed PET scanner in order to serve its projected patients.

Not all applicants for the *2025 SMFP* need determination for one fixed PET scanner in HSA I currently provide fixed PET services. Specifically, UNC Health Pardee, AdventHealth, and Novant Health do not currently have any existing fixed PET scanners. While AdventHealth was approved to develop a fixed PET scanner at its Hendersonville campus, the most recent Progress Report dated March 18, 2025 shows that none of the project milestones have been completed and no capital expenditures have been made. Furthermore, although AdventHealth reports mobile PET services at its Hendersonville campus one day a week every other week, the *Proposed 2026 SMFP* does not reflect any utilization of a mobile PET at this site. Of the four applicants, only Mission Hospital currently operates a fixed PET scanner.

The table below represents fixed and mobile PET utilization from Table 15F-1 and Table 15F-2 in the *Proposed 2026 SMFP.*

Utilization of Existing Fixed and Mobile PET Scanners HSA I

	Planning Inventory	*Proposed 2026 SMFP*	*Facility Utilization Rate*
UNC Health Pardee	1^	918	168.00%*
Mission Hospital	1	1,9893	63.10%
Messino Cancer Centers	1	2,111	70.37%
AdventHealth Hendersonville	1^^	0	0.00%

Source: *Proposed 2026 SMFP.*
^UNC Health Pardee operates a mobile PET scanner owned by Alliance every Sunday and two half Fridays each month.
^^AdventHealth Hendersonville has an approved but not yet developed fixed PET scanner.
*Calculated based on mobile days available through vendor.

The historical utilization patterns shown above reveal critical capacity constraints and competitive dynamics in HSA I. Notably, UNC Health Pardee's ability to generate 918 mobile PET procedures despite extremely limited availability - operating only on Sundays and two half-days per month through Alliance's mobile unit - demonstrates exceptional demand and operational efficiency. The mobile service provided at UNC Health Pardee represents approximately 64 days of mobile service annually, suggesting Pardee performs approximately 14 scans per mobile day, indicating high demand, suggestive of unmet demand that cannot be accommodated with such restricted mobile availability. The high mobile volume despite the inherent limitations of mobile service (limited scheduling, weather dependencies, equipment availability) suggests significant pent-up demand that could be better served with a fixed scanner.

Mission Hospital's volume declined to 1,893 procedures in FY 2024, falling below the 2,080 performance threshold. This decline directly correlates with Messino Cancer Centers' market entry and capture of 2,111 procedures, demonstrating Mission's vulnerability to competition. This competitive vulnerability raises concerns about Mission's market position and its ability to maintain or grow volume with additional competition.

AdventHealth Hendersonville's limited mobile PET volume, despite having mobile services available, indicates weak referral patterns and limited market penetration. This low utilization suggests AdventHealth has not yet established the physician relationships or operational processes necessary to generate substantial PET volume, raising questions about its readiness to operate a second fixed scanner effectively.

UNC Health Pardee is the most effective alternative regarding historical utilization. The facility's generation of 918 procedures with only 64 days of annual mobile availability demonstrates extraordinary efficiency and overwhelming unmet demand. This volume, achieved despite severe access constraints, provides compelling evidence that Pardee could substantially increase PET services with a fixed scanner. In stark contrast, AdventHealth's inability to generate any reportable volume despite having mobile services available 26 days annually reveals a lack of operational readiness and market acceptance. Mission Hospital's declining volume and demonstrated vulnerability to competition, raises concerns about effective capacity utilization. Therefore, Pardee's proven ability to maximize limited mobile resources

while AdventHealth fails to utilize available mobile capacity establishes Pardee as the superior alternative for historical utilization.

Geographic Accessibility

The *2025 SMFP* identifies a need for one fixed PET scanner in HSA I. HSA I comprises twenty-six counties, not all of which currently have a PET scanner in-county, and not all of which have the same number of existing PET scanners. As such, UNC Health Pardee believes the applicant that proposes to develop a PET scanner in the county least served by the number of fixed PET scanners is the most effective alternative regarding this comparative factor.

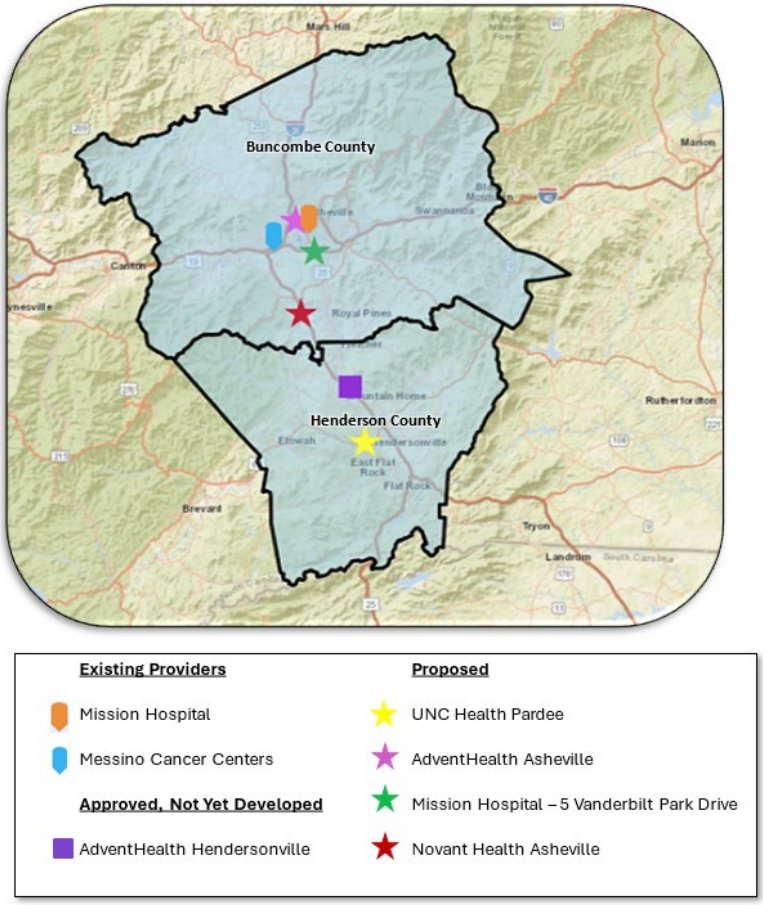
The four applicants propose to develop PET scanners in Buncombe and Henderson counties. Specifically, these two counties have the following number of PET scanners, as listed in the *2025 SMFP*:

Existing fixed PET Scanners in HSA I by County

County	*Number of Existing PET Scanners*
Buncombe	2
Henderson	1^

Source: *2025 SMFP*.
^Approved but not yet developed Advent Health fixed PET CON Project ID #B-12331-23

The geographic distribution of existing, approved but not yet developed, and proposed PET scanners is shown on the map below:



Given that UNC Health Pardee's application proposes to develop a fixed PET scanner in the county with relatively fewer assets than any of the other applications, it follows that the UNC Health Pardee application is the more effective alternative regarding this comparative factor, and all other applicants are least effective.

Access by Service Area Residents

In the most recent previous PET Findings, the Agency has found this comparative factor to be inconclusive. For the 2023 HSA I and HSA II reviews as well as the 2024 HSA III and the 2025 HSA IV fixed PET reviews, the analyst concluded that the Access by Service Area Residents factor was inconclusive because the applicants included an "Other" category in patient origin projections that made it impossible to calculate the total number of patients from within the service area. Consistent with these findings, the Agency should find this comparative factor to be inconclusive for this competitive review. Both AdventHealth, Mission and Novant Health all include an "Other" category in patient origin projections that includes undefined numbers of patients from counties in HSA I, preventing the calculation of accurate totals.[8] Given this, the Access by Service Area Residents comparative factor is inconclusive.

[8] See the responses to C.3 in the respective applications.

Competition – Access to a New or Alternate Provider

Generally, the Agency has taken the position that the introduction of a new provider in the service area is the most effective alternative for this comparative factor. For example, in the 2021 HSA I fixed PET review the Agency found that Messino was the more effective alternative due to Messino not owning or operating a fixed PET scanner in HSA I. This was based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. Based on this analysis, UNC Health Pardee would be a more effective alternative. Although Novant Health would also be a new provider of fixed PET services in HSA I, its application is not conforming to all applicable statutory and regulatory review criteria and cannot be approved.

Access by Underserved Groups

Projected Medicare

In the 2024 HSA III and the 2025 HSA IV Review, the Agency conducted its analysis of Medicare and Medicaid factors using similar measures. For Medicare patients, the Agency compared the total number of Medicare patients as a percentage of total patients in the third full fiscal year of operations. Generally, the application proposing the highest number of Medicare patients as a percentage of total patients is the more effective alternative with regard to this comparative factor. The Agency performed the same analysis for Medicaid. The following table shows each applicant's projected total of fixed PET Medicare patients in the third project year.

Projected Medicare Patients for PET Services – PY3

	UNC Health Pardee	*Mission Hospital*	*AdventHealth*	*Novant Health*
Total PET Patients	2,696	2,120	2,124	2,481
% of Medicare Patients	77.1%	65.5%	70.4%	70.7%
Medicare Patients	2,078	1,389	1,495	1,754

Source: Section L.3 for each application

As shown in the table above, UNC Health Pardee is projected to serve the highest number of Medicare patients, with this payor class accounting for 77.1 percent of the total. UNC Health Pardee is therefore the most effective applicant using this measure.

Projected Medicare as a Percent of Gross Revenue

Additionally, a comparison of raw Medicare charges is inappropriate for this competitive review when looking at access for Medicare patients as this method would arbitrarily and inequitably benefit the applicant with more PET scanners or a higher charge structure. Disconcertingly, AdventHealth, Mission Hospital, and Novant Health would all benefit from the respective higher charge structures which is counter to the goal of reducing healthcare costs. As shown below, AdventHealth projects to charge Medicare PET patients in excess of 100 percent more than UNC Health Pardee. Simply charging more does not translate to better access for the underserved. Despite UNC Health Pardee serving proportionally more Medicare patients, Mission Hospital, AdventHealth and Novant Health all have higher charge structures.

While the table below shows UNC Health Pardee and AdventHealth with the highest Medicare revenue percentages, this metric is distorted by charge structures rather than actual patient access. AdventHealth achieves its revenue percentage by charging Medicare patients more than double UNC Health Pardee's rates ($18,720 vs. $8,629 per procedure)—an approach that increases healthcare costs without improving access. UNC Health Pardee proposes to serve more Medicare patients and a higher percentage of Medicare patients (77.1% vs. 70.4%) than AdventHealth while maintaining reasonable charges. Additionally, as discussed above, the AdventHealth application is non-conforming with multiple review criteria and cannot be approved. Therefore, UNC Health Pardee is most effective.

Medicare Percentage of Gross Revenue – PY3

Applicant	*Medicare Revenue*	*Medicare Procedures*	*Medicare % of Gross Revenue*	*Medicare Gross Charge Per Procedure*
UNC Health Pardee	$23,263,226	2,696	77.1%	$8,629
Novant Health	$21,720,275	2,481	70.7%	$8,755
Mission Hospital	$34,064,069	2,119	70.9%	$16,076
AdventHealth	$39,163,032	2,092	77.5%	$18,720

Source: Section L.3 for each application.

Projected Medicaid

The following table illustrates each applicant's percentage of fixed PET utilization to be provided to Medicaid patients as stated in Section L.3 of the respective applications. Generally, the application proposing the highest number of Medicaid patients as a percentage of total patients is the more effective alternative with regard to this comparative factor.

Projected Medicaid Patients for PET Services – PY3

	UNC Health Pardee	*Mission Hospital*	*AdventHealth*	*Novant Health*
Total PET Patients	2,696	2,119	2,092	2,481
% of Medicaid Patients	4.8%	5.2%	6.0%	5.8%
Medicaid Patients	129	110	126	144

Source: Section L.3 for each application

As shown in the table above, UNC Health Pardee projects 4.8% Medicaid patients, marginally lower than all other applicants. However, this small difference reflects demographic realities rather than access limitations. UNC Health Pardee is the only applicant proposing a PET scanner in Henderson County, where 29.9% of residents are 65 or older compared to just 24.0% in Buncombe County where Mission, AdventHealth and Novant Health propose to locate the PET. This older population drives UNC Health Pardee's Medicare percentage to 77.1%—7 to 12 points higher than other applicants—mathematically requiring lower percentages in other payor categories. Despite serving a substantially higher Medicare population, Pardee's Medicaid percentage differs by less than 1.5 points. When considering both Medicare and Medicaid access combined, UNC Health Pardee serves more underserved patients overall. Furthermore, the Mission Hospital, Novant Health and AdventHealth applications are non-conforming with multiple review criteria and cannot be approved. Therefore, UNC Health Pardee is the most effective alternative for underserved groups.

Projected Medicaid as a Percent of Gross Revenue

Similar to what was previously discussed regarding Medicare, a comparison of raw Medicaid charges is also inappropriate for this competitive review when looking at access for Medicaid patients as this method would arbitrarily and inequitably benefit the applicant with more PET scanners or a higher charge structure. Disconcertingly, AdventHealth, Mission Hospital, and Novant Health would all benefit from the respective higher charge structures which is counter to the goal of reducing healthcare costs. As shown below, AdventHealth and Mission Health both project to charge Medicaid PET patients in excess of 100 percent more than UNC Health Pardee. Simply charging more does not translate to better access for the underserved. Despite Novant Health serving proportionally more Medicaid patients, Mission Hospital, AdventHealth and Novant Health all have higher charge structures.

As shown in the table below, Novant Health, Mission Hospital and AdventHealth project the highest percentage of Medicaid revenue. However, as discussed above the Novant Health, Mission Hospital and AdventHealth applications are non-conforming with multiple statutory and regulatory review criteria and cannot be approved.

Medicaid Percentage of Gross Revenue – PY3

Applicant	*Medicaid Revenue*	*Medicaid Procedures*	*Medicaid % of Gross Revenue*	*Medicaid Gross Charge Per Procedure*
UNC Health Pardee	$1,441,905	129	4.8%	$11,178
Novant Health	$1,781,861	144	5.8%	$12,374
Mission Hospital	$2,689,269	110	5.6%	$24,448
AdventHealth	$3,038,924	126	6.0%	$24,118

Source: Section L.3 for each application.

Average Net Revenue per Procedure

The following table shows average net revenue per PET procedure in the third full fiscal year of operation.

Average Net Revenue per PET Procedure – PY3

Applicant	*Total Net Revenue*	*# of Procedures*	*Average Net Revenue per Procedure*
UNC Health Pardee	$7,095,040	2,696	$2,632
Novant Health	$4,081,511	2,481	$1,645
Mission Hospital	$6,650,033	2,119	$3,138
AdventHealth	$5,808,094	2,092	$2,776

Source: Forms C.2b and F.2b for each application.

As shown in the table above, Novant Health has the lowest average net revenue per PET procedure in the third full fiscal year following project completion, while AdventHealth has the highest. Therefore, the application submitted by Novant Health would be more effective regarding this comparative factor. However, as discussed earlier, Novant Health's volume and financial projections are non-conforming with multiple review criteria and cannot be approved. Therefore, UNC Health Pardee with the second lowest average net revenue per PET procedure, is the more effective applicant.

Average Operating Expense per Procedure

The following table calculates average operating expense per PET procedure in the third full fiscal year of operation.

Average Operating Expense per PET Procedure – PY3

Applicant	*Total Operating Expenses*	*# of Procedures*	*Average Operating Expense per Procedure*
UNC Health Pardee	$4,397,223	2,696	$1,631
Novant Health	$2,100,619	2,481	$847
Mission Hospital	$4,889,300	2,119	$2,307
AdventHealth	$3,810,974	2,092	$1,822

Source: Forms C.2b and F.2b for each application.

As shown in the table above, Novant Health projects the lowest average operating cost per PET procedure in the third full fiscal year following project completion. The application submitted by Novant Health would be the more effective alternative regarding this comparative factor. However, as discussed earlier, Novant Health's volume and financial projections are non-conforming with multiple review criteria and cannot be approved. Therefore, UNC Health Pardee with the second lowest average operating expense per procedure, is the more effective applicant.

SUMMARY

In summary, the Mission Hospital, AdventHealth and Novant Health applications are not conforming to all applicable statutory review criteria, nor do they demonstrate they meet the performance standards in Project Year 3. The Mission Hospital, AdventHealth and Novant Health applications are therefore not approvable. Even if these applications were approvable, UNC Health Pardee believes that its application is the most effective alternative for the fixed PET scanner need determination in HSA I. The UNC Health Pardee fixed PET application is fully conforming with all applicable statutory and regulatory review criteria and is comparatively superior on the most relevant factors in this review. As such, the application submitted by Cone Health should be approved.

Please note that in no way does UNC Health Pardee intend for these comments to change or amend its application filed on August 15, 2025. If the Agency considers any of these comments to be amending the UNC Health Pardee application, those responses should not be considered.

Certificate of Need
Progress Report Form

Attachment A

County: Henderson
Facility: AdventHealth Hendersonville
Project ID #: B-12331-23

Date of Progress Report: March 18, 2025
Facility ID #: 943388
Effective Date of Certificate: March 5, 2024

Project Description: Develop one fixed PET scanner in Henderson County pursuant to the need determination in the 2023 SMFP

A. Status of the Project

1. Describe in **detail** the **steps taken** to complete the project since the CON was issued or since the last progress report was submitted. **Inadequate responses to this question will result in the certificate holder being asked to redo the progress report.**

Consistent with the approved Certificate of Need application submitted by Fletcher Hospital, Inc. d/b/a AdventHealth Hendersonville to develop a fixed PET scanner in Henderson County, AdventHealth Hendersonville intends to develop the project as previously approved by the Agency.

2. Identify all changes to this project approved after the issuance of the certificate, including:

   a. Cost Overruns and/or Changes of Scope (Include the Project ID #s);
   b. Material Compliance determinations; and
   c. Declaratory Rulings

Not applicable.

3. If the project is not going to be developed exactly as approved (including the previously approved changes identified in #2 above), describe all differences between the project as approved and the project as currently proposed. Such changes include, but are not limited to, changes in the:

   a. Site;
   b. Design of the facility;
   c. Number or type of beds to be developed;
   d. Medical equipment to be acquired;
   e. Proposed charges; and
   f. Capital cost of the project.

There are no changes to the approved project at this time.

4. Pursuant to N.C. Gen. Stat. § 131E-181(d), the Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) cannot determine that a project is complete until "*the health service or the health service facility for which the certificate of need was issued is licensed and certified and is in material compliance with the representations made in the certificate of need application.*" To document that new or replacement facilities, new or additional beds or dialysis stations, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate sections within the Agency and the Centers for Medicare and Medicaid Services (CMS).

Not applicable. The project is not complete.

B. Timetable

1. Complete **the following table.** The first column **must** include the timetable dates found on the certificate of need. If the Agency has previously authorized an extension of the timetable in writing, you may substitute the dates from that letter in the first column.

2. **Are you requesting a timetable extension?** ☐ Yes ☒ No If the answer is **yes**, enter your proposed completion dates in the third column of the table below. **Proposed completion dates are contingent upon Agency approval.**

3. Explain **the reason(s) for the delay in development:**

Development of the approved fixed PET scanner has been temporarily delayed as AdventHealth Hendersonville continues to recover from the impact of Hurricane Helene.

Project Milestones	Projected Completion Date *	Actual Completion Date	Proposed Completion Date **
	mm/dd/yyyy	mm/dd/yyyy	mm/dd/yyyy
Financing Obtained			
Drawings Completed	01/01/2025		
Land Acquired			
Construction / Renovation Contract(s) Executed	02/01/2025		
25% of Construction / Renovation Completed (25% of the cost is in place)			
50% of Construction / Renovation Completed			
75% of Construction / Renovation Completed			
Construction / Renovation Completed	05/28/2026		
Equipment Ordered	01/01/2026		
Equipment Installed	06/01/2026		
Equipment Operational	06/15/2026		
Building / Space Occupied	06/15/2026		
Licensure Obtained			
Services Offered (Required)	07/01/2026		
Medicare and / or Medicaid Certification Obtained			
Facility or Service Accredited			
First Annual Report Due			

*Provide the dates from the timetable on the certificate or the last **approved** extension of the timetable, whichever is later.
Dates are only proposed, Agency approval is **required for extension of proposed completion dates.

C. Medical Equipment Projects

– If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in N.C. Gen. Stat. § 131E-176(14o); 2) the specific equipment listed in G.S. 131-176(16); or 3) equipment that creates a diagnostic center as defined in N.C. Gen. Stat. § 131E-176(7a), provide the following information for each piece or unit of equipment:

1) Manufacturer
2) Model
3) Date Acquired

The medical equipment has not yet been purchased. AdventHealth Hendersonville will provide the relevant information upon acquisition of the fixed PET scanner.

D. Capital Expenditure

1. What is the total approved capital cost of the project indicated on the certificate of need? **$4,925,188**

2. Complete the table below and provide supporting documentation, which may include:

   a. Copies of executed purchase orders for major medical equipment (as defined in N.C. Gen. Stat. 131E-176(14o)), MRIs, PET scanners, Cath equipment, linacs or simulators, etc. If you previously provided them, you do not need to provide another copy.

   b. If applicable, copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Purchase Price of Land		
Closing Costs		
Site Preparation		
Construction/Renovation Contract(s)		
Landscaping		
Architect / Engineering Fees		
Medical Equipment		
Non-Medical Equipment		
Furniture		
Consultant Fees (specify)		
Financing Costs		
Interest during Construction		
Other (specify)		
Total Capital Cost		

3. What is the projected remaining capital expenditure required to complete the project? **$4,925,188**

4. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference.

At this time, AdventHealth Hendersonville does not anticipate the total actual capital cost of the project will exceed 115% of the approved capital expenditure.

E. Certification – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief. In addition, I acknowledge that incomplete progress report forms **will not** be accepted and **must** be resubmitted upon notification from the Agency Project Analyst.

Signature: _____

Name and Title DeLaina Lewkowicz Director, Community Benefit and Community Health

Telephone Number 828-606-5110

Email address delaina.lewkowicz@adventhealth.com

Fiscal Year **SFY 2024**
Hospital **AdventHealth Hendersonville**

Service Line	Buncombe	Haywood	Henderson	Madison	McDowell	Polk	Transylvania	Yancey
Cardiac Services	1.6%	0.0%	3.9%	1.1%	0.1%	2.2%	0.6%	0.0%
ENT	5.1%	2.1%	5.7%	0.0%	0.0%	0.0%	1.8%	2.0%
General Medicine	7.0%	0.7%	18.7%	5.8%	0.6%	4.2%	3.5%	0.6%
General Surgery	5.0%	1.1%	10.0%	3.7%	0.2%	10.0%	1.2%	1.6%
Gynecology	6.7%	7.4%	28.3%	0.0%	0.0%	90.6%	6.3%	0.0%
N/A	1.1%	0.0%	2.0%	1.3%	0.0%	0.0%	0.6%	0.0%
Neonatology	4.8%	1.2%	25.9%	7.6%	1.0%	22.3%	18.1%	4.3%
Neurology	1.8%	0.4%	10.1%	0.9%	0.2%	2.4%	0.3%	0.9%
Neurosurgery	0.0%	0.0%	0.4%	0.0%	0.0%	0.0%	0.0%	0.0%
Obstetrics	5.0%	1.5%	28.6%	5.9%	1.3%	23.9%	20.4%	4.2%
Oncology/Hematology (Medical)	4.4%	0.0%	7.1%	4.1%	0.6%	2.7%	2.8%	0.0%
Ophthalmology	0.0%	0.0%	14.3%	0.0%	0.0%	0.0%	0.0%	0.0%
Orthopedics	2.9%	0.8%	7.4%	1.5%	1.6%	2.5%	0.5%	2.1%
Other Trauma	1.4%	0.0%	1.6%	0.0%	0.0%	0.0%	0.0%	0.0%
Spine	2.3%	1.1%	3.2%	3.7%	1.4%	0.0%	2.4%	1.3%
Thoracic Surgery	1.9%	3.5%	5.6%	0.0%	0.0%	0.0%	0.0%	0.0%
Urology	6.6%	6.1%	19.8%	11.5%	0.9%	8.3%	6.5%	4.1%
Vascular Services	0.6%	0.0%	0.6%	0.0%	0.0%	2.2%	0.0%	0.8%
TOTAL	4.3%	0.9%	13.2%	3.7%	0.6%	7.9%	4.2%	1.4%

Source: HIDI, SFY 2024

Fiscal Year **SFY 2024**
Hospital **Mission**

Service Line	Buncombe	Haywood	Henderson	Madison	McDowell	Polk	Transylvania	Yancey
Cardiac Services	91.7%	64.2%	51.5%	92.7%	64.4%	45.4%	63.8%	76.5%

Source: HIDI, SFY 2024