Fletcher Hospital, Incorporated d/b/a AdventHealth Hendersonville CON for a New Fixed PET Scanner Project ID B-012331-23 Opposition on Behalf of MH Mission Hospital, LLLP

Introduction:

The 2023 SMFP identifies a need for one additional PET scanner in Health Service Area I (HSA I) that includes Alexander, Alleghany, Ashe, Avery, Buncombe, Burke, Caldwell, Catawba, Cherokee, Clay, Cleveland, Graham, Haywood, Henderson, Jackson, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, Watauga, Wilkes, and Yancey Counties. The need was generated by the high utilization of Mission Hospital, one of three existing and approved providers of fixed PET services in the HSA. Mission is the regional tertiary medical center and, as a result, cares for the entirety of western North Carolina. In response to the demand for its specialized oncologic, cardiac, and neurological services, Mission applied for the addition of a second fixed PET/CT unit to be located within an MOB at 5 Vanderbilt Park to address these specific needs.

One other applicant has applied for a new, fixed PET/CT unit based upon the need determination in the SMFP. AdventHealth Hendersonville ("Advent"), Project ID B-012331-23, has submitted an application to the Department in response to the published need.

Advent's application is based on capturing an unrealistic and significant market share of PET/CT patients without any underlying clinical or referral assumptions. In addition, Advent almost entirely fails to consider or even acknowledge that there is an approved, non-operational PET/CT in the service area at the Messino Cancer Center, which has the potential to dramatically impact Advent's projections. While its application outlines the various clinical uses for PET/CT, it does not clearly define what types of PET/CT scans and procedures that Advent intends to offer, and it fails to quantify its projections by type. Further, the Applicant never describes or identifies its current service lines that will be aided or enhanced with the proposed equipment and never identifies affiliated practices, partners, and Departments of the Applicant which will be referring patients to the equipment.

Advent's application is composed of numerous generalized responses that could be used in an application for any type of project. It fails to describe in detail the proposed PET program, how Advent will ensure quality in the proposed service, how it will enhance existing service lines, or even very basic information like what floor of the proposed Medical Office Building (MOB) on which it will be located and where on that floor.

Most importantly, Advent's application is largely incomplete and rife with inaccuracies and flaws. It appears almost as if Advent applied at the last minute and did not fully develop their project, the narrative, the basis for need or the required financial feasibility documents. As a result, the location for the proposed project cannot be adequately defined; financial projections and total project costs are flawed and incomplete; and projected utilization cannot be relied upon as a basis for need or feasibility. Advent's application should be found to be incomplete and the proposed project should not be approved as it is non-conforming with numerous CON review criteria.

Criterion (1) Advent's Application is Inconsistent with the SMFP and Policy GEN-3

Advent's proposal is inconsistent with the need determination in the State Medical Facilities Plan. First, Advent's proposal demonstrates that it will not reasonably increase access to PET/CT services to HSA I. Advent has provided mobile PET on a part-time basis on the Hendersonville campus through Alliance Healthcare, a contracted provider, for years. Advent's historical utilization shows that it only has a meaningful demand for PET services by patients from four to five counties. Advent's proposal to draw patients from a 16-county service area is not realistic and it has not established a reasonable foundation that demonstrates need or projected utilization.

Advent Does not Conform with the Basic Principles Outlined in Policy GEN-3

Policy GEN-3: Basic Principles states:

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

Advent's proposal is inconsistent with all aspects of Policy GEN-3. The proposed project fails to document how it will promote safety and quality *with respect to the proposed project*. It also fails to maximize healthcare value for the resources expended. Finally, the Applicant does not document how its projected volumes incorporate GEN-3 concepts in meeting the need identified in the 2023 SMFP and the needs of *all residents* in the proposed service area. Like other sections of the Application, these sections demonstrate that the Applicant failed to answer numerous items with respect to the proposed project and instead offers general responses that could apply to any project application.

Promotion of Safety and Quality in the Delivery of Healthcare Services

Advent's application fails to satisfy Policy GEN-3 as it omits any documentation or explanation related to the promotion of safety and quality with respect to the proposed project. In Advent's response to the application items related to Policy GEN-3 on pages 27 and 28 of its application, it outlines several quality accolades for the overall hospital including:

- Recognition as a Leapfrog Safety Grade A Hospital
- CMS Overall Hospital Quality Star Rating
- Accreditation as a Geriatric Emergency Department

- Joint Commission Accreditation
- Existing Quality-Related Policies used by AdventHealth

However, it fails to mention its proposed PET project entirely – <u>it does not even use the acronym</u> "PET" in this section. While the hospital may have previously achieved quality accolades, Advent fails to document that the organization will do anything at all to ensure safety and quality related to the project under review. Advent fails to explain how or if the addition of this service will aid its patients from a quality-of-care standpoint. Based on the information provided and omitted in this section of the application, it can only be assumed that Advent does not intend to seek ACR or another accreditation for the proposed PET scanner. Further, based on the information provided, there are no policies or procedures being developed for the proposed project or safety committees that exist or in development to provide oversight of the proposed project since none of these critical undertakings are identified or explained in the application.

Promotion of Equitable Access

Advent's project fails to promote equitable access and to address the needs of all residents in HSA I. Again, Advent's response to this item (p.28) was minimal at best, referring to financial forms and documentation included later in the application and its general financial policies. Advent omits any discussion of how the addition of a fixed PET unit and the service itself promotes equitable access related to finances, geography, or other limiting factors.

Maximizing Healthcare Value

In addition, the proposed project does not maximize healthcare value for resources expended. Advent proposes to spend \$4,393,902 to develop a fixed PET program for which it has not documented a need. The costly project is an unnecessary addition given the small size and service offerings of Advent's existing oncology and cardiac care programs.

Advent has noted throughout the application that it intends to offer PET/CT services for cancer and cardiology related scans. However, Advent has not stated anywhere in the application how this proposed service will support existing programs nor provided a description of any existing oncology and cardiac care programs. As a result, only publicly available data can be used to assess these service offerings. Based on its 2022 LRA (pp. 9-10), AdventHealth currently offers no specialized cardiac services including cardiac catheterization and open-heart surgery. Further, AdventHealth does not offer radiation therapy services (2022 LRA p.19-20), one of the two primary cancer treatment methods. This is a key component of a complete oncology treatment program. Without robust cardiac care and cancer programs, there is little need for a full-time PET scanner. Advent's application has offered no information or evidence to indicate that it needs a fixed PET/CT scanner to support any existing programs or that it has referral sources that intend to refer patients to the proposed scanner should it be approved.

While details included in the application are vague, it appears that Advent intends to construct a new building to house the proposed unit and related offices. While the acquisition of the proposed unit itself represents poor value, the new construction of a building to house the unit only

compounds the issue. The proposed addition of a fixed PET/CT unit by Advent does not maximize healthcare value.

For the many reasons set forth above, Advent's application does not meet the criteria required in the Policy GEN-3: Basic Principles and cannot be approved. Advent's project should be found non-conforming with Criterion (1).

Criterion (3) Advent Fails to Adequately Document Need for the Project

Advent fails to document the need for the project. First, Advent fails to identify the population to be served by constructing an unreasonable and unsupported service area. Next, Advent entirely fails to document the need that this population has for the proposed service by presenting a utilization methodology that compounds one inflated factor with the next in order to force their model to meet the minimum required utilization threshold. Its assumptions are illogical, its methodology is flawed, and as a result, its utilization projections are grossly overstated.

Advent's Fails to Identify Appropriately the Population to be Served with a Flawed and Overstated Service Area

The 2023 SMFP defines the service area for the project to be HSA I, which is composed of Alexander, Alleghany, Ashe, Avery, Buncombe, Burke, Caldwell, Catawba, Cherokee, Clay, Cleveland, Graham, Haywood, Henderson, Jackson, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, Watauga, Wilkes and Yancey Counties.

Advent has operated a mobile PET scanner through a contract arrangement with Alliance Imaging for more than five years. During this time, it has built a record of historical utilization that is relatively consistent. One would expect this historical utilization to serve as a basis for its proposed service area. Historically, the vast majority of Advent's PET patients originate from the four counties of Henderson, Buncombe, Transylvania, and Polk. By contrast, in its application, Advent defines its primary service area or "Catchment Area" for the project to be the HSA I counties with the exceptions of Alexander, Alleghany, Avery, Ashe, Burke, Caldwell, Catawba, Cleveland, Watauga, and Wilkes Counties - all in the eastern part of HSA I. See **Figure 1** for a map of Advent's proposed service area. In other words, Advent's proposed service area is composed of the sixteen Westernmost counties of the 26-county HSA I, while they primarily serve only four of these counties now.

JENNESSEE HAMBLEN GREENE ANDERSON UNICO AVERY JEFFERSON MITCHELL · Oak Ridge KNOX • Knoxville CALDWELL COCKE SEVIER BURKE LOUDON BLOUNT Asheville MONROE NORTH GAROLINA HENLESON CLEVELAND LEGEND County SOUTH CAROLINA [Map (2)].Area SPARTANBUR! Fixed PET Catchment Are PICKENS RGIA TOWNS .5 Other RABUN 10 OCONEE @2021 CALIPER

Figure 1

AdventHealth Hendersonville Fixed PET Catchment Area

Source: Application for Project ID B-012331-23, p.51

Advent has provided mobile PET on a part-time basis on the Hendersonville campus through a contracted provider for more than five years. Thus, it is reasonable to look to Advent's historical patient origin for the mobile PET service as a basis for a proposed service area. Pages 49 and 50 of Advent's Application provide a graphic of its total mobile PET utilization by county of origin for Fiscal Years 2019-2022. See **Figure 2**. While this map shows that patients from thirteen counties were served by the Advent mobile PET during this time, a deeper dive into its actual volume reveals that it only has meaningful levels of PET utilization in four to five counties including Henderson, Buncombe, Transylvania, Polk, and Rutherford Counties. However, over a four-year period from 2019-2022, Advent served less than 20 patients per year from Transylvania and Polk Counties and less than 10 patients per year from Rutherford County.

AdventHealth Hendersonville Mobile PET Patient Origin, FY2019-FY2022 HANCOCK SULLIVAN ALLEGHANY CLARGENE HAWKINS CAMPBELL Johnson City UNION TENNESSEE HAMBLEN WILKES ANDERSON AVERY CALDWELL - Leno COCKE ALEXANDER REDEL SEVIER NORTH CAROLINA CATAWRA BLOUNT LEGEND County MONROE State [2019-2022 PET Pati GRAHAM 10 to 29 MACON

Figure 2

Source: Application for Project ID B-012331-23, p. 50

TOWNS CALIPER Source: AdventHealth license renewal applications

According to its License Renewal Applications ("LRAs"), Advent has served mobile PET patients originating from fifteen¹ North Carolina counties from 2019-2022. See **Figure 3**. Ten or less patients originated from ten of these counties over a four-year period – Ashe, Haywood, Jackson, Madison, Martin, McDowell, Mitchell, Swain, Watauga, and Yancey. Inexplicably, Advent excludes Ashe and Watauga from its service area but includes four counties – Cherokee, Clay, Graham, and Macon – that have not been served by Advent's mobile PET unit at all in the last four fiscal years.

GREENVILLE

SPARTANBURG SOUTH CAROLINA

¹ Our analysis of 2019-2022 LRAs indicated that Advent's mobile PET served 15 counties in North Carolina as opposed to the thirteen indicated on Advent's map. See Figures 3 and 4.

Figure 3
Historical Patient Origin Volume for AdventHealth Mobile PET 2019-2022

	Total PET Patients					
	2019	2020	2021	2022	Total 2019- 2022	
Ashe	1	0	0	0	1	
Buncombe	39	39	46	43	167	
Haywood	0	2	4	4	10	
Henderson	102	186	157	158	603	
Jackson	0	2	2	2	6	
Madison	0	0	3	2	5	
Martin	0	0	0	1	1	
McDowell	1	0	1	1	3	
Mitchell	1	0	0	1	2	
Polk	6	12	11	8	37	
Rutherford	2	7	7	3	19	
Swain	0	1	0	0	1	
Transylvania	15	6	8	16	45	
Watauga	1	0	0	0	1	
Yancey	2	3	2	1	8	
TOTAL	170	258	241	240	909	

Source: 2019-2022 LRAS for AdventHealth; Application p.38

Advent's historical patient origin does not support its proposed service area and the size of Advent's proposed service area is unreasonably inflated. Only Henderson, Buncombe, Polk, and Transylvania Counties compose any meaningful percentage of the patients currently accessing Advent for mobile PET services. However, Advent incorporates twelve counties it has barely served in the last four years (see **Figure 3**) along with four additional counties that have historically represented the vast majority of its patient utilization to comprise an unreasonable sixteen-county service area for the proposed project. See **Figure 4**.

Figure 4
Comparison of Historical Patient Origin to Proposed Service Area

2019-2022 Mobile PET	Fixed PET Service Area
Counties of Origin	Years 1-3
Henderson	Henderson
Buncombe	Buncombe
Polk	Polk
Transylvania	Transylvania
Rutherford	Rutherford
Haywood	Haywood
Jackson	Jackson
Yancey	Yancey
Madison	Madison
McDowell	McDowell
Mitchell	Mitchell
Swain	Swain
Martin	NOT INCLUDED
Ashe	NOT INCLUDED
Watuga	NOT INCLUDED
	Clay
	Cherokee
	Graham
	Macon
Source: 2010-2022 I PAs: Applie	

Source: 2019-2022 LRAs; Application pp. 38-39, 51

More surprising than the size of the service area, however, is the inconsistent changes in the percent of patients originating from most of these counties compared to historical patient origin. See **Figure 5**. For example, the percentage of patients originating from McDowell County is projected to increase by 4.47% by Project Year 3. Advent's home county of Henderson is projected to drop from 66.3 percent of patient volume to 28.5%. Transylvania County, the third highest volume of historical PET patients for Advent, is also projected to decline as a percent of total patients. By contrast, the percentage of Buncombe County patients, originating from the most populous county in the service area, and home to Mission's existing and Messino's approved but not yet operational fixed PET units, is estimated to grow by over 7.5% by Project Year 3. Jackson, McDowell, and Rutherford Counties are likewise projected to experience unexplained growth in the percent of patient origin. Finally, Clay, Cherokee, Graham, and Macon Counties are included in the service area but no patients are projected for these counties.

Figure 5
Change from Historical to Projected Patient Origin

	Percent of Total PET Patients				
			Projected Change		
			in % Patient		
	2019-2022	Project Year 3	Origin		
Ashe*	0.11%	0.00%	-0.11%		
Buncombe	18.37%	25.90%	7.53%		
Haywood	1.10%	5.80%	4.70%		
Henderson	66.34%	28.50%	-37.84%		
Jackson	0.66%	4.80%	4.14%		
Madison	0.55%	2.30%	1.75%		
Martin*	0.11%	0.00%	-0.11%		
McDowell	0.33%	4.80%	4.47%		
Mitchell	0.22%	1.60%	1.38%		
Polk	4.07%	2.80%	-1.27%		
Rutherford	2.09%	8.10%	6.01%		
Swain	0.11%	1.00%	0.89%		
Transylvania	4.95%	4.90%	-0.05%		
Watauga*	0.11%	0.00%	-0.11%		
Yancey	0.88%	2.00%	1.12%		
TOTAL					

Source: 2019-2022 LRAS for AdventHealth; Application p.38

While some room for expansion in patient origin and utilization is reasonable with a new service, the level of growth in many of the service area counties is not realistically achievable for Advent. Though Advent states throughout the application that its assumptions are made based upon historical provision of its mobile PET services, assumptions related to service area, market share and other factors do not generate the projected volume that Advent proposes to serve. It appears that Advent has projected volumes either arbitrarily or intentionally to generate a need for their proposed project because there is no correlation at all between their historical mobile PET patient origin and utilization and their projected patient origin and utilization.

It is clear that patient origin percentage is shifted to Buncombe County because its significantly higher population results in more patients - even though the methodology utilizes a substantially lower market share for Buncombe County than it does for Henderson County (see **Figure 12**). Henderson County simply can't generate enough patients for Advent to meet the performance standard even with the massive 65% market share (see **Figure 12**) it projects to capture by Year 3 of operation. This illogical foundation renders the utilization projections for this project unreliable and faulty, as will be discussed.

^{*}Not Included in Service Area

In addition, as shown in **Figure 6**, Advent's service area for PET is significantly larger than its service area for the overall existing hospital. It is illogical that the PET service would have a "catchment" area that far exceeds the facility overall. In theory, the patients accessing AdventHealth Hendersonville and its affiliated providers are the same patients that would be referred to PET. However, Advent provides no documentation in its application related to referral sources for the proposed PET service that would justify its projected departure from its historical experience or any meaningful description of related service lines and programs that would be utilizing PET.

Figure 6
Comparison of Historical Mobile PET Patient Origin
Proposed Fixed PET Service Area and Advent's Facility Service Area

2020-2022 Mobile PET	Fixed PET Service Area	Facility Service Area
Counties of Origin	Years 1-3	Years 1-3*
Henderson	Henderson	Henderson
Buncombe	Buncombe	Buncombe
Polk	Polk	Polk
Transylvania	Transylvania	Transylvania
Rutherford	Rutherford	Rutherford
Haywood	Haywood	Haywood
Jackson	Jackson	Jackson
Yancey	Yancey	Yancey
Madison	Madison	Madison
McDowell	McDowell	McDowell
Mitchell	Mitchell	NOT INCLUDED
Swain	Swain	NOT INCLUDED
Martin	NOT INCLUDED	NOT INCLUDED
	Clay	
	Cherokee	
	Graham	
	Macon	

Source: 2020-2022 LRAs; Application pp. 38-39, 51

Advent has clearly failed to document a reasonable and consistent population to be served (service area). As discussed in detail to follow, the flawed service area definition leads to market share projections that are entirely unreasonable and utilization projections that are extremely overstated.

Advent's Projection Methodology is Arbitrary and Results in Inflated Projections

The most compelling flaw in Advent's application relates to its projected utilization. Advent's methodology and assumptions, particularly its application of market share, result in volumes so overstated that they are not reliable.

^{* &}quot;Out of State" is listed and included twice; "Other" is noted to include out of state. Therefore, there are inaccuracies in the total patients, but it does not appear to affect the individual counties listed.

Service Area and Population Projections (Step 1)

Advent begins its utilization projections by calculating the projected population for each of its "catchment area" counties over the project horizon. While the population projections are reasonable, the inflated catchment area is not reasonable as previously explained. With an unsupported service area definition as the starting point (Step 1), all other steps are fundamentally flawed throughout the projection.

PET Use Rate and Projected Demand (Steps 2 and 3)

Next, Advent calculated a statewide PET use rate for FY2016 through FY2021. Years 2016 through 2019 grew by a CAGR of 5.5%. Due to COVID-19, the use rate for 2020 declined notably but returned to just under the 2019 use rate in 2021. See **Figure 7**.

Figure 7

	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	CAGR
Use Rate	4.46	4.72	5.07	5.24	4.83	5.19	3.08%

Source: Application p.117.

Advent used the 5.5% CAGR from FY 2016 to FY 2019 to grow the use rate through the project horizon ending in FY 2028. See **Figure 8**. This CAGR exceeds the average of the rates from FY2017-2021 as presented in in **Figure 7** (CON page 117). Advent simply chooses to ignore the impact of COVID in its projections.

Figure 8
North Carolina PET Procedure Use Rate (per 1,000 population)

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

Source: Application p. 118.

These clearly inappropriate statewide use rates shown in **Figure 8** above are applied to the annual projected county populations of the overly large service area to calculate the projected total PET procedures for each county.

Advent makes no effort to compare the statewide use rates to what is actually occurring in its service area on a county-by-county basis. An analysis of the actual FY 2021 PET utilization obtained from the 2021 PET Patient Origin Reports published by the Agency show the flaw in applying the statewide use rate as presented in **Figure 9**. This actual historical data reflects anywhere from a declining 0.5% growth rate (Clay County) to a 28.9% CAGR for Cherokee County. Advent applies the same use rate to all counties regardless of their historical experience. Thus, Advent's overall market projections are completely unrelated to actual historical PET utilization in its proposed service area counties.

Figure 9
Growth Rate from Actual 2021 PET Scans to
Advent's Projected 2028 PET Scans

		2028	
	2021 Actual	Projected	
County	PET Scans	Scans	CAGR %
Buncombe	1,362	2,024	5.8%
Cherokee	39	230	28.9%
Clay	95	92	-0.5%
Graham	56	61	1.2%
Haywood	443	493	1.5%
Henderson	828	933	1.7%
Jackson	164	341	11.0%
Macon	220	298	4.4%
Madison	143	166	2.2%
McDowell	300	338	1.7%
Mitchell	89	111	3.2%
Polk	87	148	7.9%
Rutherford	259	493	9.6%
Swain	77	110	5.2%
Transylvania	230	260	1.8%
Yancey	115	139	2.7%
Total	4,507	6,237	4.8%

Sources: FY 2021 PET Patient Origin Report. CON page 118.

Market Share Assumptions are Arbitrary and Inflated (Step 4)

Advent uses Step 4 to estimate its FY 2022 market share for Henderson, Transylvania, and Polk counties based on several factors, including a statewide use rate, for the purpose of demonstrating its "robust PET market share" in these counties. It is not clear why Advent ignores the existence of actual patient origin/market share data compiled by the Agency for FY 2021. When this actual data is used, Advent's market share is actually lower as shown in **Figure 10**.

Figure 10 Advent's Actual 2021 Market Share

	FY2021 Total	Advent	Market
	Market Scans	Health Scans	Share
Henderson	828	158	19.1%
Transylvania	230	16	7.0%
Polk	87	8	9.2%

Sources: 2021 PET Patient Origin Reports. Advent 2022 LRA.

In Step 4, Advent arbitrarily chooses market share percentages for each of its sixteen service area counties for partial year 2025 through Year 3. 2025 market share projections for Henderson, Transylvania, and Polk Counties are equivalent to FY2022 estimated market share calculated in Step 4, which appear to be overstated based on 2021 actual data. The projected PET market share by county is shown in **Figure 11** below. There is absolutely no meaningful or quantitative basis

provided for the projected market share, which increases from 15% to 40% between the partial year and third full year of operation.

Figure 11
AdventHealth Hendersonville
Projected PET Market Share

	Partial Year	Project Year 1	Project Year 2	Project Year 3
County	2025	2026	2027	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%

Source: Application p. 120

By Project Year 3, Advent projects to achieve significant market share in all service area counties, even though patients from many of these counties have not or have barely utilized its mobile PET in the past.

According to the Applicant (p.120), their proposed market shares are supported by the following six statements:

Statement 1

 AdventHealth Hendersonville currently provides mobile PET services via contract with Alliance Imaging (on a limited basis). AdventHealth Hendersonville's proposed fixed PET service will leverage existing PET referral relationships and will also develop additional referral relationships and maximize patient referrals.

Source: Application p.120

Advent uses its mobile PET service over and over again to justify its assumptions, but the historical utilization of the mobile PET actually shows that these assumptions are unfounded. For example, Advent has provided PET services to one total patient from Mitchell County and two patients from McDowell County in the last three years. However, it projects a 30% market share in these

counties in PY 3 supposedly based on its experience with its mobile unit. Likewise, it has not served Graham or Macon Counties at all during this time frame and projects a 20% market share based on its experience and growth in its existing referral relationships. See **Figure 12**. These referral relationships upon which Advent bases its assumptions are not mentioned or identified within the application.

Figure 12 Comparison of Historical and Projected Market Share

	Total FY 2021	Advent FY	FY 2021	Market Share
	PET Scans	2021 Patients	Market Share	by County PY 3
Henderson	828	158	19.1%	65%
Buncombe	1,362	43	3.2%	25%
Polk	87	8	9.2%	40%
Transylvania	230	16	7.0%	40%
Rutherford	259	3	1.2%	35%
Haywood	443	4	0.9%	25%
Jackson	164	2	1.2%	30%
Yancey	115	1	0.9%	30%
Madison	143	2	1.4%	30%
McDowell	300	1	0.3%	30%
Mitchell	89	1	1.1%	30%
Swain	77	1	1.3%	20%
Clay	95	0	0.0%	10%
Cherokee	39	0	0.0%	10%
Graham	56	0	0.0%	20%
Macon	220	0	0.0%	20%
Total Service Area	4,507	240	5.3%	33.2%

Source: 2020-2022 LRAs for AdventHealth; Application p.120

2022 PET/CT Patient Origin Reports, Agency website.

Statement 2

 AdventHealth Hendersonville's growing network of physicians in Henderson and Buncombe counties. With more than 140 employed providers and more than 250 providers on staff, AdventHealth Hendersonville maintains a critical mass of local clinical professionals.

Source: Application p.120

Advent also supports its market share assumptions by relying on its alleged growing network of physicians in Henderson and Buncombe counites. However, in this statement, Advent equates <u>all</u> physicians as referral sources and users of the proposed PET unit. In reality, PET is a highly specialized diagnostic modality with uses specific to cardiology, oncology, and neurology. A typical family physician, OB/GYN, orthopedic surgeon, or dermatologist, for example, will have little to no use for PET for its patients. Advent fails to describe or quantify the physicians within its network that have an actual use for this modality. The affiliated oncology and cardiology

practices or hospital departments who will use the proposed scanner are not clearly identified in the application because they do not exist in reality.

As described previously, Advent does not currently offer radiation therapy services, cardiac catheterization, or open-heart surgery. Without full-service oncology and cardiology programs, Advent will have a difficult time generating enough utilization for this project to be feasible. This further indicates that these figures are inflated and are not rooted in reality.

Statement 3

• Letters of support from referring providers and members of the community in Exhibit I.2.

Source: Application p.120

This statement is simply not factual. The letters of support included in Advent's application do not provide any indication that its robust market share projections are reasonable. The application includes:

- Three community letters of support;
- Three letters from healthcare providers unrelated to AdventHealth and who would not be potential referral sources;
- Twenty-four identical form letters signed by AdventHealth providers who support the project but will not be referring to the PET scanner due to their field of practice; and
- <u>One letter</u> of support from an Advent-affiliated Hematologist-Oncologist who intends to refer patients to the proposed PET/CT

The strongest indicator that the Applicant does not have the referral base to support the market share assumptions and projected utilization may be the fact that it can only provide one letter of support from a potential referral source in combination with the fact that their LRA demonstrates that they do not provide the needed service lines that support PET utilization.

Statement 4

 The projected market shares assume the current Alliance Imaging contract would be replaced with the proposed fixed PET scanner.

Source: Application p.120

It is unclear why this statement would bring credence to Advent's market share assumptions. On page 119, Advent has demonstrated that it has strong market share in three counties based on its services through Alliance Imaging. However, it also assumes robust market share in thirteen counties that it has never served or has served minimally. While sunsetting use of the mobile PET scanner will stabilize and transfer the PET utilization for three existing counties with "robust" market share over to the fixed unit, it does not demonstrate how Advent will remotely achieve its projected market share and utilization projections for the other 13 counties.

Statement 5

 The proposed project will greatly increase access to PET services for residents throughout western North Carolina. The current Alliance Imaging service is available to AdventHealth Hendersonville on

a limited basis, i.e., every other Sunday. AdventHealth Hendersonville intends to operate the fixed PET scanner at least five days per week, 50 weeks per year. Therefore, AdventHealth Hendersonville will increase access to PET services from the current 26 days annually to 250 days annually. AdventHealth Hendersonville will be able to offer much greater access to PET services for their patients, thus, affording the opportunity to maximize market share for patients needing PET procedures.

Source: Application pp.120-121

While the availability of PET services at Advent would unquestionably increase capacity to provide PET service, Advent has failed to demonstrate anywhere in the application that it has the PET volume to support it. There is no description of the programs and or practices that need enhanced access to PET/CT at AdventHealth and there is only one letter of support from a physician who intends to refer to the new unit. Advent's focus seems to be on claiming overstated levels of market share throughout the western counties instead of assessing and enhancing access to the service.

Statement 6

 AdventHealth is conditionally approved to develop a new acute care hospital with 67-acute care beds in Buncombe County. The addition of a new AdventHealth hospital in Buncombe County is expected to have a positive impact on the continued growth of AdventHealth's provider and referral network.

Source: Application p.121

Again, the hospital proposed by AdventHealth for Buncombe County is a small community hospital virtually identical to the size and scope of Advent Hendersonville with a limited scope oncology and cardiology services. Referral relationships from these two services and their affiliated providers sources are the foundation for providing PET/CT scans and Advent simply does not have these service lines to any significant extent. Advent has provided no narrative and no documentation to indicate that they are developing these programs or relationships in Buncombe County, or in Henderson County for that matter. Without referral relationships in these two specialties, there is no need for developing a full-time PET program.

From top to bottom, Advent's market shares are unfounded, inflated, and not based in reality. As a result, its forthcoming utilization projections are significantly overstated.

Projected Utilization (Step 5)

Step 5 involves applying the projected market share to the projected total county demand for PET to determine the projected utilization for the proposed PET scanner. Based on an inflated service area, unreasonable service use rates/growth rates, and wildly overestimated market shares, the total projected utilization is not realistic and is highly overstated.

Advent's overstated projections are demonstrated by a comparison of the AdventHealth Hendersonville total facility patient projections by county for PY3 with the PET service line patient projections for the same time period.² See **Figure 13**. For example, Advent projects 102 total PET patients to originate from Jackson County in PY 3. For this same time period, the entire AdventHealth facility projects 153 patients from Jackson County for all services it provided to patients from that county. PET patients represent 68.0% of total facility patients originating from Jackson County in PY 3. This example also applies to Haywood, McDowell, Rutherford, and Yancey Counties as highlighted in yellow in **Figure 13** below.

Figure 13

Comparison of Projected Patients by County for Project Year 3

	•				PET Patients as a
		% of PET	Total Facility	% of Total	% of Total
County	PET Patients	Patients	Patients	Facility Patients	Facility Patients
Buncombe	551	25.97%	15,609	34.29%	3.53%
Cherokee	23	1.08%	*	<1%	*
Clay	9	0.42%	*	<1%	*
Graham	12	0.57%	*	<1%	*
Haywood	123	5.80%	556	1.22%	22.12%
Henderson	606	28.56%	23,284	51.14%	2.60%
Jackson	102	4.81%	150	0.33%	68.00%
Macon	60	2.83%	*	<1%	*
Madison	50	2.36%	816	1.79%	6.13%
McDowell	101	4.76%	283	0.62%	35.69%
Mitchell	33	1.56%	*	<1%	*
Polk	59	2.78%	869	1.91%	6.79%
Rutherford	172	8.11%	431	0.95%	39.91%
Swain	22	1.04%	*	<1%	*
Transylvania	104	4.90%	1,145	2.52%	9.08%
Yancey	42	1.98%	195	0.43%	21.54%
Other**	53	2.50%	2,188	4.81%	2.42%
Total	2,122	100.00%	45,526	100.00%	

^{*}These counties represent <1% patient origin by county for the facility overall and are not included in the service area for AdventHealth Hendersonville, though they are included in the service area for the PET project.

There are no assumptions provided for total facility patients and no definition of what type of patients are included in these figures.

Source: Application pp. 38-39

Advent's inflated PET projections are further demonstrated by the six counties that are not included in the total facility column and are marked with an asterisk. These counties are included in the service area for the PET project (p.38) but are not included in the service area for the hospital itself (p.39). According to the application, the patient origin for each of these six counties compose less than one percent of the total patient origin for the overall facility. However, in many cases, they compose a more significant percentage of total PET patient origin. This anomaly is not limited to these counties. The cells highlighted in green in **Figure 13** show the counties which have significantly different PET patient origin percentages than the facility overall. While some variation is natural and expected between the two, these levels suggest that counties were added and/or inflated to achieve appropriate utilization levels.

^{**&}quot;Other" for the Total Facility includes two "Out of State" line items and the "Other" line item included on page 39.

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² It should be noted that there are no assumptions for the total facility utilization and it is completely unclear what these total patients even represent. It is possible this is the sum of the patient origin for inpatients, emergency patients, inpatient surgery patients, ambulatory surgery patients, MRI patients, and PET patients from the various patient origin tables on the 2023 LRA, although a sum of these patients would undoubtedly include duplicates such as an inpatient who gets and MRI or an emergency patient who gets outpatient surgery.

In summary, Advent's service area, PET use rates, and market share are overstated, resulting in a highly inflated and overestimated projected utilization that is not realistically achievable based on the information and documentation presented in the application.

Other Considerations Related to Need and Projected Utilization

There are several additional factors that impact Advent's need argument. These include:

- Clinical uses for PET are not clearly identified.
- Utilization cannot be determined by specialty.
- Market share projections and the need methodology does not consider Messino Cancer Center.
- Additional anomalies exist within market share projections.

The consideration of these factors further deteriorates the reliability of Advent's need analysis.

Clinical Uses for PET are not Clearly Identified and Utilization Cannot be Determined by Specialty

In Section C, Pages 41-46 of the Application, Advent presents a general overview of PET and its clinical indications to include additional information related to Oncology, Prostate Cancer, Neurology, and Cardiology. All of the information presented on these pages is general to PET services and is not specific to Advent. Pages 47-49 expand somewhat on Advent's need for a fixed PET scanner, but mainly focus on the need to expand upon its current mobile service and an alternative to traveling to Buncombe County for those in the western part of the service area. It should be noted that Advent has not demonstrated that its patient demand for PET services exceeds its mobile capacity or that its location will be more accessible than existing providers for residents of western North Carolina.

Advent does not identify its current clinical PET offerings or specifically identify and address the scans it intends to offer as part of this project. Advent vaguely mentions the difficulty in offering PSMA PET on page 47 due to its current scheduling constraints, but never specifically states that it will offer PSMA PET or other radiopharmaceutical scans and theranostics as part of this project. The application generally mentions using the proposed project for cancer and cardiac indications in several places but does not expand beyond these general statements. The most specific statement offered by the Applicant regarding its service offerings is located on page 128 in the Form 2.b Revenue and Net Income Assumptions. Under Gross Revenues, the Applicant states "The average gross charge reflects a weighted average blend of PET procedures for oncology, cardiology, and PSMA prostate patients." However, no additional information is provided regarding the weighting of these procedures, so it is impossible to assess the percentages and total procedures that can be assigned to each. Moreover, there are no letters of support from cardiologists, urologists, or neurologists that would indicate referrals for these specific types of PET services and only one letter of support from an oncologist.

Without the data described above and without information regarding related hospital departments, practices, and referral sources, it is impossible to assess the reasonability of Advent's projected utilization assumptions and methodology.

Messino Cancer Center is not Considered in the Market Share Assumptions

Messino Cancer Center was approved to develop a fixed PET unit in Asheville, Buncombe County under the 2021 SMFP. Advent discusses Messino Cancer Center one time in its application. On page 50 it states,

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

While Mission is currently the only provider of PET procedures on a fixed scanner in Buncombe County and the surrounding counties, Messino Cancer Center projects to open its approved PET scanner in May 2023. Advent did not consider Messino's approval and pending operation in any of their projections or discussion of need for their project. The operation of an additional PET scanner in the service area does not appear to be taken into consideration, especially with market shares projected to reach as high as 65% when the Messino unit is not yet operational. This statement also ignores the fact that numerous mobile PET units are offered throughout Advent's service area.

Additional Anomalies Exist Within Market Share Projections

As described above, Advent's market share projections are unreliable and overestimated. However, within the market share growth lies additional anomalies. Both Graham and Swain counties are projected to have a ten percent market share in PY1, an incredible jump to a 50 percent market share in PY2 and then a drastic decline to 20 percent market share in PY3. No PET patients have originated to Advent from Graham County in the last three years and only one patient has originated from Swain County in this time period. To assume a 50 percent market share for these counties in Project Year 2 is illogical as is the total three-year projected pattern of growth and decline. See **Figure 14**.

Figure 14

AdventHealth Hendersonville Projected PET Market Share

	Partial Year	Project Year 1	Project Year 2	Project Year 3
County	2025	2026	2027	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%

Source: Application p.117

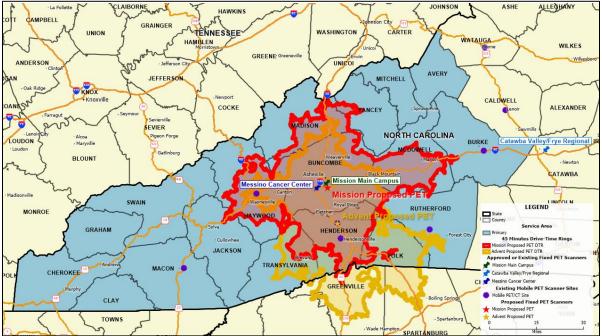
Advent Will Not Meaningfully Increase Access to Care

As described in detail previously, Advent does not have the clinical infrastructure, referral resources, and programs to support a full-time PET unit. In addition, its location does not meaningfully increase geographic access to the service. According to GoogleMaps, the proposed location is less than fifteen miles from Mission Hospital and Messino Cancer Center. Advent's proposed location (AdventHealth Hendersonville campus) is directly south of both existing facilities and is one of the southernmost counties in the HSA. A 45-minute drive time map shows that most of Advent's drive time area is subsumed within the drive time area for Mission/Messino's locations.³ A 45-minute drive time was used due to the fact that PET/CT services area non-urgent/non-emergent scheduled outpatient services. See **Figure 15**. As a result, the only service area counties receiving some benefit from Advent's proposed location are Henderson, Polk, and Transylvania. Much of Polk County is closer to a mobile unit in Rutherford County. In the grand scheme of Advent's sixteen-county service area, the addition of Advent's proposed Hendersonville location is not meaningful given that two other providers of fixed PET/CT are located just fifteen miles north.

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³ Mission and Messino drive time contours are virtually the same.

Figure 15
45-Minute Drive Time Analysis



Source: Maptitude

If mobile PET services are considered, Advent's claim to increase access to western North Carolina can be further refuted. Existing mobile units near Waynesville (Haywood County) and in Macon County provide options that are far more proximal than Hendersonville to western North Carolina counties.

Advent's project fails to expand geographic access to PET/CT services. In fact, its patient origin projections demonstrate an expansive area which already has comparable, if not more favorable, access to PET/CT services than that proposed by Advent.

Conclusion to Criterion (3)

In summary, Advent's proposed project fails to demonstrate need and enhanced accessibility for fixed PET services. The service area is not logically based on historical utilization; its projected utilization volume is inflated, unreasonable, and erroneous; and the proposed project clearly fails to enhance accessibility to PET services, especially once the overstatement of volumes is taken into account. Because of the numerous factors described above, Advent's proposed project should be found non-conforming with Criterion (3).

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

Advent fails to demonstrate that its project is either the least costly or the most effective alternative. From a cost standpoint, construction of a new facility and acquisition of new equipment for a full-

time PET program is not cost effective because Advent has not demonstrated that it has the volume to support a full-time program. As discussed in detail with regard to Criterion (3), Advent's utilization projections are highly overstated. The expansion of its mobile PET program would be far more cost-effective. Operating costs associated with a free-standing, full-time diagnostic suite will also be far higher than those associated with the expansion of the mobile PET service.

Interestingly, Advent provides three alternative methods that it deemed to be ineffective: 1) maintain the status quo, 2) develop a fixed scanner in another geographic location, and 3) pursue a joint venture (pp. 75-76). It entirely fails to consider expanding its limited mobile PET service as an alternative. Had this alternative been considered, it would have been impossible to dismiss.

Approving a project with large capital and operating costs when a much less costly alternative is available is inconsistent with this review criterion. For these reasons and the associated discussions regarding Criteria (1), (3), (5), (12), and (20), Advent cannot be found conforming with Criterion (4).

Criterion (5) Financial Feasibility

Projected Utilization

As discussed in detail in Criterion (3), Advent's projected utilization is unreasonable, unsupported, and based on a flawed methodology that compounds inflated factors upon other inflated factors. As a result, Advent's financial projections are unreasonable, undocumented, and acutely overstated. There is no way to verify that the proposed project is financially feasible based on Advent's projected utilization as it undoubtedly results in far overstated revenues.

Capital Costs

While construction costs are included in the capital costs listing and are documented by an architect, the level of detail regarding the proposed facility is so vague, it is impossible to assess the reasonableness of the estimate. The line drawings included with the application do not indicate the floor on which the PET suite will be located, associated square footage of individual interior walls or the overall sizes of the spaces shown on the line drawings, or any additional detail to assess what specifically is estimated with regard to cost. In addition, the letter of documentation from the architect is not on letterhead, does not contain a raised seal, does not include a certification number for the architect, and misspells the name of the architectural firm. Moreover, as this building does not yet exist, the cost for both the allocated shell and core and the buildout of the PET suite are completely unknown and unclear. As a result, this estimate is unreliable.

Expenses

There are several expense categories that are not clear in terms of inclusion or reasonability in Form F.3b (p.125) and related Exhibits. There is an expense pool related to pharmaceutical costs in Form F.3b. Due to the radiopharmaceuticals needed for many of the procedures performed on the PET CT, this is expected. However, sufficient information is omitted from the application that

would allow an analysis of reasonableness and feasibility related to these figures. Based on Mission's experience, it appears that Advent's radiopharmaceutical costs are low.

Staffing/salary figures are also questionable. Advent projects 4.25 FTEs for the project in Form H (the total of positions listed is actual 3.25 FTEs). In reality, Advent may need additional staffing resources since all proposed staffing shown in Form H is clinical and given its location in a standalone suite outside the hospital, the PET service will likely require administrative staff as well for check in, registration, and billing functions. There is no information about any other services that may be in that building that may or may not support the proposed PET service.

Revenues

There are numerous issues with Advent's revenues outlined in Form F.2b (p.124). First, it appears as if there is a formatting issue with the spreadsheet. At first glance, revenues from patients with insurance appear to be omitted completely. More likely, a spacing issue occurred. Adding all figures through Total Patient Services Gross Revenue sums to the correct Total Gross Revenue. Nevertheless, this error results in speculation regarding the figures included in the Patient Services Gross Revenue section.

The other significant issue with revenues results from the vague identification of procedures that will be performed on the proposed PET/CT. Section C identifies numerous uses for the proposed unit, including a detailed description of uses in neurology. Advent presents Alzheimer's Disease death rates for the proposed service area on page 59 of the application as part of its need description. However, the assumptions for gross revenue on page 128 state that "the average gross charges reflect a weighted average blend of PET procedures for oncology, cardiology, and PSMA prostate patients." No neurology scans are mentioned in these assumptions. This presents a number of questions:

- Does Advent intend or project to perform neurology-related scans as suggested in its need section?
- What are the various weights/assumptions used for each procedure type?
- PSMA prostate procedures ARE oncological studies. Does Advent intend to perform other types of procedures using radiopharmaceuticals or do they separate these procedures because radiopharmaceutical scans will be limited to PSMA prostate scans?

All of these issues highlight the questionability of the revenues presented in the application. They are undoubtedly overstated due to inflated utilization projections and are likely further flawed due to the related issues described above.

Payor Mix

Advent states on page 128 that its "payor mix is based on AdventHealth Hendersonville's FY 2022 payor mix for mobile PET services." This assumption will result in an inaccurate projected payor mix given the drastic change in service area proposed for this project. As discussed in detail related to Criterion (3) above, Advent mainly served Henderson, Polk, and Transylvania Counties with its mobile PET unit. Advent now proposes to serve a large, sixteen-county service area that is largely

rural. As a result, the payor mix for the proposed service area would not logically mirror the payor mix for the historical mobile PET service.

In summary, there are flaws and questionable information throughout all areas of Advent's financial projections. For these reasons, Advent should be found non-conforming with Criterion (5).

Criterion (6) Unnecessary Duplication

Advent's proposed project represents an unnecessary duplication of services – both its own and other fixed services in the HSA. As described in detail previously, Advent's proposed location in Hendersonville does not increase geographic access to most of its proposed service area. It provides a marginally closer location to parts of Henderson, Polk, and Transylvania counties, but does not increase access to the vast majority of its 16-county service area.

On page 87, Advent states, "The proposed project will also offer a convenient, accessible alternative to Mission's enormous tertiary care hospital located on a congested campus." This statement is inaccurate. While Mission's existing PET unit is located on the hospital campus, it is NOT located in the hospital. Mission's existing PET unit is located in the SECU Cancer Center at 21 Hospital Drive in a standalone medical office facility dedicated to cancer care, **just like the one Advent is proposing to construct in its application**. Mission's Cancer Center has convenient parking right outside of the center and it is separate from the parking area for the hospital. Advent's characterization of Mission's current PET location is completely false.

In addition, Advent once again completely ignores Messino Cancer Center. It is anticipated that Messino's PET unit will come online in May 2023, likely before the review of this project is complete. Messino already offers an alternative to a hospital campus-based PET unit for HSA I, so Advent's alternative is not unique (though Advent *is* proposing a hospital campus-based unit).

For these reasons and those referenced in the associated discussions of Criteria (1), (3), (4), and (18a), Advent should be found non-conforming with Criterion (6).

Criterion (7) Staffing

As described previously, there are a number of conflicting statements regarding staffing in Advent's Application. These include the following:

- The total FTEs on Form H do not match the sum of the identified FTEs by position. It is unclear if a position is missing.
- All staff included on Form H (p.126) are clinical (PET Technologist and RN). Necessary administrative staff for check-in and other related functions are omitted and are not described in the application, except to acknowledge that these functions will be necessary in Section I, Ancillary and Support Services (p.90). As noted, it is completely unclear what else will be in the MOB and what resources may be there.

- Section I, p.90 of Advent's application, which is related to Ancillary and Support Services states, "Expenses for all necessary ancillary and support services are included in Form H Staffing or Form F.3b Operating Costs." As described in the bullet immediately above, no ancillary or support services staff included in Form H.
- However, Form F.3b Expense Assumptions (p.129) further contradicts this, saying, "Total salary expense based on projected staffing and salaries in Form H." Form H includes no ancillary or support staff.
- Advent does not allocate any central office or administrative costs on Form F.3b. It is simply unclear how the proposed service will be supported.

In summary, Advent provides a number of conflicting statements and very little information about staffing. Its project description and its response to staffing items provide no narrative response related to staffing requirements and needs for the proposed project. It is impossible to understand the scope of staffing related to the full patient experience in obtaining the proposed fixed PET services from Advent. Review of the line drawing for this project discussed under Criterion (12) below adds even further confusion to this topic as the suite includes no space for any ancillary functions. For these reasons, Advent's application should be found non-conforming with Criterion (7).

Criterion (8) Support Services

In Section I.1a (p.90), Advent acknowledges that it would need to provide or contract the following ancillary and support services to be able to offer the health services proposed in the application:

- Administration/management
- Billing/finance
- Marketing
- Human Resource/Staff Recruitment and Retention
- Staff Training
- Information Technology
- Building Maintenance/Groundskeeping
- Equipment Maintenance
- Purchasing/Materials Maintenance/Central Sterile Supply
- Housekeeping/Linen
- Medical Records

With the exception of housekeeping and equipment maintenance, none of these functions are accounted for in Form H or Form F.3b. Further, no description is provided of how the service will operate, how these functions tie in, where they will take place, and who will be performing them. See response to Criterion (7) above.

In response to Question I.2a to describe its coordination with existing and proposed relationships with other local healthcare and social service providers, Advent states, "As documented in Exhibit I.2, the letters of support from a diverse array of service area representatives are evidence that the proposed service is needed and will be embraced and well-utilized by referring physicians and patients within the service area." This statement is not factual. Advent provides three letters of

community support and three letters of support from healthcare providers outside of the Advent system. All other letters are form letters from Advent-employed or -affiliated physicians and only one of these letters is from an actual referral source. With the exception of the <u>one letter</u>, all other provider letters are from providers which practice in areas that would not refer patients for PET scans.

Advent's application is not conforming with any part of Criterion (8) and should not be approved.

Criterion (12) Cost and Design

Site and Location

Based on the limited information presented in the application, it appears that the proposed PET suite will be located in a medical office building to be constructed on the campus of AdventHealth Hendersonville. There is no information included in Advent's application to determine the exact location of the proposed project. Though the application form instructs the applicant "to be as specific as possible," Advent lists the site address as 100 Hospital Drive. This is the general campus address for AdventHealth Hendersonville, which does not indicate where the site is or where the medical office building housing the proposed project will be located. Responses to questions 4c and 4e state that the scanner will be located on the AdventHealth Hendersonville campus, but no detailed information regarding the site location is included in response to Section K. Questions K.1 and K.2 indicate that the project involves new construction and renovation of existing space. Question K.4.b says that the applicant owns the site but does not indicate anything about who will own the yet to be built MOB. No documentation of ownership is provided. It is unclear if Advent will be building this MOB or another party. No rent is included. Verification/documentation of utilities, and zoning is not included and cannot be confirmed since an exact site is not provided.

Construction Details

There are few construction details included in the application. Section K states that the PET scanner will be co-located with AdventHealth Hendersonville's oncology services, but there are no additional details beyond this statement. Advent states that it "believes the cost, design, and means of construction represents the most reasonable alternative for the proposed project." However, there is no narrative explanation of any of these factors. Construction costs are only provided in the architect's letter as one lump sum estimate and there is no mechanism for determining if construction costs are complete and are reasonably estimated. For example, do the costs include an allocation of shell and core costs for the not yet built MOB or does the cost only include the buildout of the PET suite?

Without knowing the location, it is impossible to estimate or verify any additional, related costs that should be allocated to the suite including site work, grading, hardscaping, parking, etc. have been included in the construction estimate. The lack of detail associated with the site, architectural, and construction information makes it impossible to assess the reasonability of the chosen alternative.

Line Drawings

The line drawing included in Exhibit K.1 includes a partial representation of an unlabeled floor of the proposed building. There are stairs and elevators labeled on the line drawing, which indicates the building is not single-story, but the location of the PET suite within the building cannot be determined based on the information available on the drawing or in the application. In addition, the PET suite has no check-in/registration area or other areas for administrative functions. There is no explanation for the lack of this space or explanation of how and where these functions are performed in the application. The line drawings provided do not indicate square footage, though a total of 2,996 s.f. is listed on page 93 of the application. The drawing does not indicate the location for the proposed medical office building and lists the address as 100 Hospital Drive, the general address for the campus.

It should also be noted that the letter of documentation from the architect is not on letterhead, does not contain a raised seal, does not include a certification number for the architect, and misspells the name of the architectural firm. As a result, the letter itself is unreliable.

For all of the reasons described above, the application should be found non-conforming with Criterion (12).

Criterion (13) Medically Underserved Population

Advent's commitment to serve the medically underserved is unreliable based on the information presented in its application. Advent does not provide any payor mix information for their existing mobile PET/CT unit. It is unclear what the projected payor mix is based on; however, **Figure 16** below shows a comparison of its overall facility payor mix with its projected fixed PET payor mix for the same time period.

Figure 16

	Percentage of Total Patients Served AdventHealth Hendersonville				
	Hospital-Wide	Hospital-Wide	Fixed PET		
	1/01/2022 to 12/31/2022	1/01/2028 to 12/31/2028	1/01/2028 to 12/31/2028		
Self-Pay	3.7%	3.7%	0.8%		
Charity Care	Included in Self-Pay	Included in Self-Pay	Included in Self-Pay		
Medicare	54.9%	54.9%	70.4%		
Medicaid	9.1%	9.1%	3.1%		
Insurance	29.3%	29.3%	23.8%		
Other	3.0%	3.0%	3.0%		

Source: Application pp. 97 and 100

Most notable in the figure above is Advent's charity care estimate for the fixed PET. While Advent doesn't break out charity care individually, it does include charity care in its self-pay estimate. Advent's entire self-pay percentage for fixed PET in project year 3 represents only 0.8% of PET patients. This suggests that less than 0.8% of Advent's Fixed PET patients will receive charity care. Meanwhile, the facility overall appears to have a much higher percentage of patients receiving charity care as self-pay is estimated to be - and has been historically - 3.7% of total patients.

As a result, Advent's application cannot be found conforming with Criterion (13).

Criterion (18a) Advent's Project will Not be Cost Effective, Offer Quality Care, Increase Access, or Improve Competition

Advent's responses to items in Application Section N essentially regurgitate the language from Criterion 18(a) and the SMFP and fail to offer any detailed or specific responses about Advent's specific, proposed project. Responses to questions 2(a - c) once again provide generalized responses that would apply to any Advent project and are not specific to the project under review.

As discussed in detail above regarding Criteria (1), (3), (4), (5), (6), (7), (8), (12), and (13), , it is clear that Advent does not propose a cost-effective project. The proposed fixed PET does not represent the most cost-effective option from a capital or operating cost standpoint, which would be for Advent to expand its mobile PET service. That option is not even mentioned by Advent. Moreover, Advent has failed to adequately document its capital or operating costs, with both likely underestimated.

Regarding the quality-of-care aspect of this criterion, Advent provides absolutely no information and provides no discussion about quality of care guarantees or initiatives specific to the proposed PET project. While Advent documents historical quality accolades for AdventHealth Hendersonville, it does not begin to address quality initiatives related to the PET service or any associated clinical programs such as oncology and cardiology. As detailed in response to Criteria (1), Advent fails to outline any quality measures it will take to ensure that the PET program meets the quality standards it touts for the hospital and various other programs.

As discussed previously, Advent's project will not create meaningful competition and will not increase access in the vast majority of its sixteen service area counties. Only Henderson, Polk, and Transylvania counties will experience minor improvements to geographic access. Further, Advent proposes to serve an expansive set of counties that it has never historically reached with its existing mobile PET services. There is no reason to believe that the proposed fixed service will inexplicably result in a new, expanded service area when nothing else is changing.

Advent should be found non-conforming with Criterion (18a)

Criteria and Standards – Advent's Project Does Not Address or Conform to the Performance Standards for PET

As explained in detail related to Criteria (1) and (3), Advent will not realistically meet the performance standards for PET as its projected utilization is highly overstated. Numerous flaws, inaccuracies, and illogical assumptions related to its methodology render its calculations unreliable.

Specifically, Advent will not meet the performance standard of the required 2,080 scans by the third year of operation. Advent's proposed volume of 2,122 leaves little room for inaccuracy. The

number of overstated factors being used by Advent to project volume will undoubtedly result in volumes that realistically fall well below 2,080.

Figure 17 below shows a replication of Advent's projected volumes for its first three years of operation. It does not meet the minimum performance standard until its third full year. As shown previously, Advent's mobile PET has had no patients originating from Cherokee, Clay, Graham, or Macon Counties in the last four years. If these four counties are removed from the proposed service area Advent's projected volume in Project Year 3 is 2,018, well below the minimum performance standard of 2,080. If Macon County alone is removed from the service area, the projected volume of 2,062 would prevent the project from meeting the minimum performance standard. Patients from these four counties have not utilized Advent's existing mobile PET service at all in the last four years. The volumes calculated for these counties are significant in size, highly overestimated, and determinant of Advent's conformance to the performance standards. However, all of the service area counties were subject to the same inflated assumptions and methodologies as these four counties, which indicates there is no way Advent will come close to meeting is projected utilization and thereby meet the minimum performance standards. In addition, it is simply unreasonable that 551 patients would come from Buncombe County when this county has an existing fixed PET provider (Mission) and an approved provider (Messino Cancer Center).

Figure 17 AdventHealth Hendersonville Fixed PET Projections

	Partial Year	Project Year 1	Project Year 2	Project Year 3
County	2025	2026	2027	2028
Buncombe	137	194	414	551
Cherokee	-	5	11	23
Clay	-	2	4	9
Graham	1	5	29	12
Haywood	21	22	46	123
Henderson	173	329	438	606
Jackson	14	30	48	102
Macon	6	26	56	60
Madison	7	15	24	50
McDowell	14	30	48	101
Mitchell	5	10	16	33
Polk	14	27	42	59
Rutherford	21	66	93	172
Swain	2	10	52	22
Transylvaniua	24	46	74	104
Yancey	6	19	26	42
In-Migration	11	21	36	53
Total*	456	857	1,457	2,122

^{*} It is assumed that the Project Year 1 Total and Project Year 3 Total varies from the chart presented in the application (p.122) due to rounding.

As a result of these factors, Advent does not meet the performance standards outlined in Section (a) and cannot be approved. The Standards outlined in section (b) do not apply to Advent's project.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2023 State Medical Facilities Plan ("SMFP"), no more than one additional PET unit may be approved for unit in Health Service Area ("HSA") I in this review. Because the applicants in this review collectively propose to develop two additional PET units in HSA I, all applicants cannot be approved for the total number of PET units proposed. Therefore, after considering all review criteria, Mission conducted a comparative analysis of each proposal to demonstrate why Mission is the best applicant and should be approved.

Below is a brief description of the projects included in the PET Comparative Analysis.

- Project ID B-012331-23/ **Fletcher Hospital Incorporated d/b/a AdventHealth Hendersonville ("Advent")**/ Develop no more than one fixed PET Scanner in Hendersonville pursuant to the 2023 SMFP Need Determination.
- Project ID B-012335-23/ **Mission Hospital, LLLP ("Mission")**/ Develop no more than one fixed PET Scanner in Buncombe pursuant to the 2023 SMFP Need Determination.

In the following analysis, Mission describes the relative comparability of each competing applicant regarding those comparative criteria typically used by the CON Section and further indicates which factors cannot be effectively compared in this review because of the differences between the two competing applicants.

Conformity with Applicable Statutory and Regulatory Review Criteria

As previously stated, the Advent application does not conform with all applicable statutory and regulatory review criteria for reasons discussed throughout Mission's Comments in Opposition. Therefore, the application submitted by Advent is not an effective alternative even standing on its own and is comparatively inferior to the Mission application. Despite this fact, Mission has prepared the following comparative analysis.

Mission is conforming with all applicable statutory and regulatory review criteria. Therefore, the application submitted by Mission is the most effective alternative with respect to conformity with statutory and regulatory review criteria.

Scope of Services

Generally speaking, projects that provide access to a broader scope of services will improve access to care more than a provider that offers a more limited scope of services. There are three general types of PET studies: oncologic, neurologic, and cardiac PET. The table below compares the types of PET studies proposed to be offered by each applicant. Advent describes neurologic applications for PET but does not say they will provide them. Advent provides no concrete documentation that it will provide cardiac PET and has no support from any cardiologist. It is important to note that Advent does not even have a cardiac cath lab, which is a basic component of any cardiology program.

	Mission	Advent
Oncologic PET	X	X
Cardiac PET	X	Unclear

Mission is an existing provider of oncology and neurology related PET/CT scans. In its application, Mission very clearly describes adding cardiac PET/CT services projecting specific cardiac PET volume. While Advent describes all three uses for PET in its application, it only proposes to offer oncologic and cardiac PET scans. No specific information is provided regarding the volume of each type of scan. It is unclear if Advent has the clinical knowledge and capability to provide cardiac PET scans given their lack of a basic cardiology program. No meaningful information is provided about neurologic scans and Advent does not include them in its financial assumptions.

As it relates to the scope of PET services, Mission is the more effective applicant.

Geographic Accessibility (Location within HSA I)

The 2023 SMFP identifies a need for one fixed PET in HSA I. The table below identifies the locations of the existing, approved, and proposed fixed PETs within HSA I. The existing provider Catawba Valley Medical Center/Frye Regional Medical Center ("Catawba Valley/Frye Regional") is located on the eastern portion of HSA I in Catawba County. The existing Mission PET located at Mission Main Campus, the approved Messino Cancer Center ("Messino"), and the Mission proposed PET are located in the middle of HSA I in Buncombe County. Advent's proposed PET is located in the middle southern portion of HSA I in Henderson County, in the same location where the Advent Mobile site is located. There are seven other mobile sites dispersed throughout HSA I.

	# of Fixed	Hospital- Based		
	PET	or		
Facility	Scanners	Freestanding	Locations	
Existing PET Scanners	S			
Catawba Valley/Frye	1	Hognital Daged	Highany/Catawha County	
Regional	1	Hospital Based	Hickory/Catawba County	
Mission	1	Hospital Based	Ashville/Buncombe County	
Approved PET Scanner				
Messino	1	Freestanding	Ashville/Buncombe County	
Proposed PET Scanners				
Mission	1	Hospital Based	Ashville/Buncombe County	
Advent	1	Hospital Based	Hendersonville /Henderson County	

Concerning geographic accessibility, both applicants have proposed adding a fixed PET scanner in an outpatient setting. The map below shows the 60-minute drive-time rings ("DTR") around each applicant's proposed location. Mission's 60-minute DTR (in Red) consists predominantly of counties included in HSA I, which needs a fixed PET scanner. Mission's 60-minute DTR (in Red)

includes large portions of 12 counties (Madison, Yancey, McDowell, Burke, Buncombe, Haywood, Rutherford, Polk, Henderson Transylvania, and Jackson Counties) included in HSA I, which 6 of the counties (Madison, Yancey, McDowell, Polk, Transylvania, and Jackson Counties) do not have a fixed or mobile PET scanner.

In contrast, Advent's 60-minute DTR (in Yellow) includes fewer HSA I counties than Mission and a large portion of counties in South Carolina. Advent's 60-minute DTR (in Yellow) includes large portions of 8 counties (Madison, Haywood, Buncombe, McDowell, Rutherford, Transylvania, Henderson, and Polk Counties) includes in HSA I, which 4 of the counties (Madison, McDowell, Transylvania, and Polk Counties) do not have a fixed or mobile PET. Additionally, other mobile units are located within an hour of Advent's proposed PET. Pardee Hospital in Hendersonville (mobile) is further south than Advent, providing access to areas in South Carolina. Advent's location essentially increases access for South Carolina patients. There are multiple fixed PET services in Greenville, SC. Thus, the geographic location of Mission is more effective in meeting the demands of HSA I. See map below.

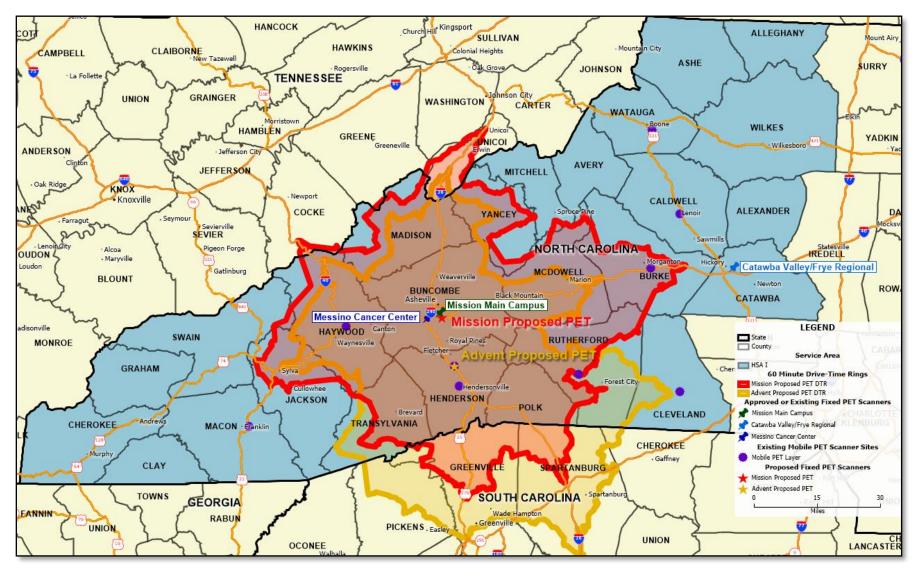
Service to the HSA I Counties (Access by Services Residents)

The service area for this review of a fixed PET/CT scanner is HSA I. Facilities may also serve residents of counties not included in the service area. Generally, the application projected to be the most accessible to HSA I residents is the most effective alternative with regard to this comparative factor. The table below shows the projected patient origin by county for the two applicants.

Projected HSA I Patient Origin (3rd Full Year)

County	Miss	sion	Advent	
Avery County	6	0.3%	N/A	N/A
Buncombe County	912	42.7%	551	26.0%
Burke County	44	2.1%	N/A	N/A
Cherokee County	15	0.7%	23	1.1%
Clay County	39	1.8%	9	0.4%
Graham County	7	0.3%	12	0.6%
Haywood County	200	9.4%	123	5.8%
Henderson County	170	8.0%	606	28.6%
Jackson County	59	2.8%	102	4.8%
Macon County	85	4.0%	60	2.8%
Madison County	99	4.6%	50	2.4%
McDowell County	145	6.8%	101	4.8%
Mitchell County	57	2.7%	33	1.6%
Polk County	16	0.7%	59	2.8%
Rutherford County	37	1.7%	172	8.1%
Swain County	26	1.2%	22	1.0%
Transylvania County	110	5.1%	104	4.9%
Yancey County	73	3.4%	42	2.0%
Total HSA I*	2,100	98.3%	2,069	97.5%
Total Projected Patients	2,136		2,122	

^{*}Includes HSA I counties individually identified by each applicant.



Source: Maptitude

The table above shows that Mission is projected to serve a higher percentage and more patients from the HSA I counties. Of the 18 counties listed in the table, Mission serves a higher percentage and more patients in 12 counties (66.7%). Furthermore, Mission lists in its "Other NC Counties" that it also serves some patients from Alexander, Ashe, Caldwell, Catawba, Cleveland, and Watauga Counties, which are included in HSA I. Advent does not specify the individual counties for HSA I that are included in its "Other" section.

As discussed under Criterion (3) above, Advent's basis for its projected utilization and patient origin are unclear and unsupported by reasonable documentation. Thus, Advent's patient origin is not reasonable.

Regarding this comparative factor, Mission is the most effective alternative in serving HSA I.

Access by Underserved Groups

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

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

For access by underserved groups, the applications in this review are compared with respect to three underserved groups: charity care patients (i.e., medically indigent, or low-income persons), Medicare patients, and Medicaid patients. Access by each group is treated as a separate factor.

Projected Charity Care

The table below compares projected charity care during the third full year following the completion of the project for each facility. In general, the application proposing the most charity care (either the higher percentage or number of charity care procedures) is the more effective alternative concerning this comparative factor. However, Advent's percentage of charity care patients is not broken out and includes self-pay patients. Therefore, for the two applicants' projected charity care to be comparable, self-pay patients must be included for both applicants. As shown below, Mission projects more charity care/self-pay patients per unit and a higher percentage of charity care/self-pay in comparison to Advent. Therefore, the application submitted by Mission is the most effective alternative regarding projected access by charity care recipients.

Projected Access for Charity Care Patients (3rd Full Year)

				Charity Care and Self
			Projected number of	Pay Procedures as a
	# of Fixed	Total Number	Charity Care and Self	Percentage of Total
Applicant	PET Scanners	of Procedures	Pay	Procedures
Total Mission PET Charity/Self-Pay*	2	4,272	58	1.3%
Advent Charity/Self-Pay	1	2,124	17	0.8%

^{*}Avg. PET procedure per machine: 58/2 = 29

Projected Medicare

The table below compares projected Medicare during the third full year following the completion of the project for each facility. In general, the application proposing the most Medicare (either the higher percentage or number of Medicare procedures) is the more effective alternative concerning this comparative factor.

Projected Access for Medicare Patients (3rd Full Year)

			Projected number of	Medicare Procedures as a
	# of Fixed PET	Total Number of	Medicare Procedures Per	Percentage of Total
Applicant	Scanners	Procedures	Machine	Procedures
Total Mission PET*	2	4,272	2,986	69.9%
Advent	1	2,124	1,495	70.4%

^{*} Avg. PET procedure per machine: 2,986/2 = 1,493

The difference between the applicants' Medicare percentage of patients is not meaningful. Mission provides far more Medicare patients in total. Even on a per unit basis, there is no meaningful difference between the number of Medicare patients (1,495 vs. 1,493, respectively). Therefore, the comparison of the provision of PET services to patients with Medicare is equally effective.

Projected Medicaid

The table below compares projected Medicaid provision during the third full year following the completion of the project for each facility. In general, the application proposing the most Medicaid (either the higher percentage or number of Medicaid procedures) is the more effective alternative concerning this comparative factor.

Projected Access for Medicaid Patients (3rd Full Year)

Trojected Access for victical and adents (Sturial Tear)				
			Projected number of	Medicaid Procedures as a
	# of Fixed PET	Total Number of	Medicaid Procedures Per	Percentage of Total
Applicant	Scanners	Procedures	Machine	Procedures
Total Mission PET*	2	4,272	171	4.0%
Advent	1	2,124	66	3.1%

^{*} Avg. PET procedure per machine: 171/2 = 85

Mission projects a higher Medicaid percentage and number of Medicaid patients per unit than Advent (85 vs. 66 respectively). Therefore, the application submitted by Mission is the most effective alternative regarding projected access by Medicaid Recipients.

Competition (Access to a New or Alternative Provider)

The following table illustrates the existing and approved providers located in the service area. Additionally, eight mobile PET sites are located in HSA I, one of which is operated by Advent. Thus, numerous providers are providing PET services in HSA I. As shown in the table below, Messino was recently approved to add a fixed unit in a freestanding location which added to the competition in HSA I.

Facility	# of Fixed PET Scanners	Hospital Based or Freestanding	Locations
Catawba Valley/Frye	1	Hospital Based	Hickory/Catawba County
Regional		-	
Mission	1	Hospital Based	Ashville/Buncombe
		_	County
Messino	1	Freestanding	Ashville/Buncombe
			County

To be clear, Advent's proposal does not represent the entry of a new provider or competitor into the market. Advent is an existing provider of PET/CT services. Both applicants already serve HSA I and propose to offer PET services in an outpatient setting. Therefore, regarding competition, both applicants are equally effective alternatives.

Projected Average Net Revenue per PET Procedure

The table below compares projected net revenue per PET procedure during the third full year following the completion of the project for each facility, based on the information provided by the Applicants' Form F.2b. In general, the application proposing the lowest net revenue per procedure is considered to be the most cost-effective alternative.

Projected Average Net Revenue per PET Procedure (3rd Full Year)

	Mission (Total)	Advent
Net Revenue	\$10,695,680	\$4,554,991
Procedures	4,272	2,124
Net Revenue per Procedure	\$2,504	\$2,145

Although Advent projects a lower net revenue per procedure than Mission projects, both applicants vary significantly in the scope of PET services proposed, which inevitably impacts net revenue. It is unclear how Advent has factored in cardiac PET services, which vary in reimbursement from oncology scans. **Attachment A** shows that many of the PET scans for cardiac diagnosis are reimbursed at much higher rates based on data from medicare.gov. Thus, due to significant differences in the number and scope of PET services offered by both facilities, it is impossible to make conclusive comparisons concerning net revenue per case. Differences in the types of PET procedures proposed by each of the facilities may impact the averages shown in the table above, thus, the result of this analysis is inconclusive.

Projected Average Operating Expense per PET Procedure

The table below compares projected operating expense per PET procedure during the third full year following the completion of the project for each facility, based on the information provided by the Applicants' Form F.3b. In general, the application proposing the lowest operating expense per procedure is considered to be the most cost-effective alternative.

Projected Average Operating Expense per PET Procedure (3rd Full Year)

	Mission (Total)	Advent
Total Operating Expense	\$6,482,748	\$2,408,518
Procedures	4,272	2,124
Operating Expenses per Procedure	\$1,517	\$1,134

Although Advent projects a lower operating expense per procedure than Mission projects, both applicants vary significantly in the scope of PET services proposed, which inevitably impacts operating expenses. For example, the costs associated with more complex and newer radioisotopes may be much more expensive. Mission's project is most effective because the scope of services and cost associated with such are clearly documented. However, differences in the types of PET procedures proposed by each of the facilities may impact the averages shown in the table above, thus, the result of this analysis is inconclusive.

Staffing Comparison

Staffing and salary levels are also relevant to the provision of PET/CT services. While the staffing and salary levels for both applicants appear to be similar with both RN and PET/CT or Radiology Tech's, Advent's staff total is 4.25 FTEs while the number of identified positions only sums to 3.25 FTEs. Moreover, Mission has explained that its PET will operate as part of an existing imaging center at 5 Vanderbilt Park Place and thus, administrative and support staff are already in place at this location to support the proposed PET/CT (See CON page 156.). Advent's project location and coordination with other services is unclear as discussed under Criterion (7). Therefore, the availability of administrative and support staff for this new service is not clearly identified or documented.

Mission's project is the most effective alternative for staffing.

Summary

The following is a summary of the comparative analysis performed on the proposed projects, ranking the proposals based on effectiveness for each comparative factor provided herein. As discussed at length throughout the written comments in opposition, Mission contends that Advent is not conforming with all applicable statutory and regulatory review criteria. Thus, technically, the comparative factors do not apply to Advent, and Mission is the most effective alternative. Nonetheless, Mission has provided the summary of the comparative factors on the next page:

Comparative Factor	Mission	Advent
Conformity with Review Criteria	Yes	No
Scope of Services	Most Effective	Least Effective
Geographic Accessibility (Location within the		
HSA I)	Most Effective	Least Effective
Service to the HSA I Counties (Access by Service		
Area Residents)	Most Effective	Least Effective
Access by Underserved Groups:		
Charity Care/Self-Pay	Most Effective	Least Effective
Access by Underserved Groups: Medicare	Equally Effective	Equally Effective
Access by Underserved Groups: Medicaid	Most Effective	Least Effective
Competition (Access to a New or Alternative		
Provider)	Equally Effective	Equally Effective
Projected Average Net Revenue per Case	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive
Staffing	Most Effective	Least Effective

Even if Advent were conforming with all applicable statutory and regulatory review criteria, Mission is still the most effective alternative as shown in the summary table above.

CONCLUSION

Advent's application is not approvable, as it does not conform to Criteria (1), (3), (4), (5), (6), (7), (8), (12), (13), and (18a), and the Performance Standards for PET services. Mission's application meets all applicable criteria and standards for PET services. Also, as shown in the comparative analysis above, Mission is the superior applicant. Accordingly, Mission should be approved.

Attachment A Medicare Payment Comparison

Medicare.gov Comparison of Payment for PET/CT Procedures

	iviedicare.gov Comparison of Payment for PE		1edicare		Patient		
СРТ	Description	'*		'			Total
CPT	Description		Pays		Pays		TOLAI
77608	Brain imaging, positron emission tomography (pet); metabolic evaluation	\$	1,264	\$	315	\$	1,579
77812	Positron emission tomography (pet) imaging; skull base to mid- thigh	\$	1,282	\$	320	\$	1,602
77813	Positron emission tomography (pet) imaging; whole body	\$	1,282	\$	320	\$	1,602
77814	Positron emission tomography (pet) with concurrently acquired computed tomography (ct) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)	\$	1,292	\$	322	\$	1,614
77015	Positron emission tomography (pet) with concurrently acquired computed tomography (ct) for attenuation correction and anatomical localization imaging; skull base to mid-thigh	,	1 201	٠	225	خ	1 626
77815		\$	1,301	\$	325	\$	1,626
77816	Positron emission tomography (pet) with concurrently acquired computed tomography (ct) for attenuation correction and anatomical localization imaging; whole body	\$	1,302	\$	325	\$	1,627
70.420	Myocardial imaging, positron emission tomography (pet), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan	,	1 272	ć	240	.	1 501
78429		\$	1,273	\$	318	\$	1,591
	Myocardial imaging, positron emission tomography (pet), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired						
78430	computed tomography transmission scan	\$	1,270	\$	317	\$	1,587
	Myocardial imaging, positron emission tomography (pet), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired						
78431	computed tomography transmission scan	\$	1,871	\$	467	\$	2,338
78432	Myocardial imaging, positron emission tomography (pet), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	\$	2,276	\$	569	\$	2,845
70422	Myocardial imaging, positron emission tomography (pet), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	,	2 202	.	F.70	.	2.052
78433		\$	2,283	\$	570	\$	2,853
78491	Myocardial imaging, positron emission tomography (pet), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)	\$	1,266	\$	316	\$	1,582
78492	Myocardial imaging, positron emission tomography (pet), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)	\$	1,277	\$	319	\$	1,596
78811	Positron emission tomography (pet) imaging; limited area (eg, chest, head/neck)	\$	1,124	\$	280	\$	1,404

https://www.medicare.gov/procedure-price-lookup/