MH Mission Hospital, LLLP
Comments in Opposition to American Oncology Partners, P.A. d/b/a Messino Cancer Centers
Certificate of Need Applications to for a Fixed PET/CT Unit
May 1, 2021 CON Review Cycle

INTRODUCTION

The 2021 State Medical Facilities Plan ("2021 SMFP") recognized a need for one fixed Positron Emission Tomography (PET) unit in HSA I. Two applicants have filed Certificate of Need ("CON") applications for a PET scanner in response to the identified need including Project I.D. B-012057-21 MH Mission Hospital, LLLP ("Mission" or "Mission Hospital") and Project I.D. B-012059-21 American Oncology Partners, P.A. d/b/a Messino Cancer Centers ("Messino").

The identified areas of non-conformity of Messino's application along with the comparative analysis set forth below reveal that Mission Hospital is the most effective applicant in this review and as such, should be approved.

OVERVIEW

American Oncology Partners, P.A. ("AOP") d/b/a Messino Cancer Centers ("Messino") is a group of physicians that owns and operates several oncology physician offices throughout western North Carolina. Messino proposes to offer PET/CT services at its physician practice office located in Asheville, Buncombe County, North Carolina. Among other general claims, Messino cites scheduling delays for PET services, cost for PET services, and lack of geographic access as bases for its proposed project. However, the factors upon which Messino bases its need are either not unique to Messino, unremarkable in general, or completely unfounded. Specifically, Buncombe County already has a fixed PET scanner owned and operated by Mission Hospital. Mission's PET scanner is located on the main campus at Mission's SECU (State Employees Credit Union) Cancer Center ("SECU Cancer Center"), less than 5 miles, or a ten-minute drive, from where Messino proposes to locate its scanner. Messino's project will do nothing to increase geographic access to PET services. Additionally, Messino attempts to equate PET with other diagnostic imaging such as MRI and CT, but PET is different from MRI and CT, as most PET scans are performed in a hospital setting. Comparing the reimbursement and cost structure of MRI and CT to PET is an irrelevant analysis. Further, Mission agrees that scheduling delays currently exist for PET services. However, Messino's project will do little to fix this issue for the service area in general, considering that it is likely Messino will primarily serve its own patients.

Messino cites access for charity care patients, new clinical applications for PET, and growth in PET scans due to the growth and aging of the population in HSA I as additional support for its project. Yet, all providers in HSA I, including Mission, are faced with the same responsibility to address the need for PET services driven by technology advancements and socioeconomic and health factors that impact communities in the service area. Messino's patients have the same socioeconomic and health factors as Mission's patients, since both applicants are located in Buncombe County and both applicants are committed, or purport to commit, to serving the self-pay and charity care population. It should be noted, however, that Messino's projected charity care percentage is not supported by historic provision of charity care for PET and should be deemed unreasonable, as will be described herein.

Importantly, Messino explicitly states in its application that it is ***not*** developing a licensed independent diagnostic treatment facility (IDTF) and proposes to put a PET scanner in its existing physician practice with little to no other support services or diagnostic imaging. Later, Messino concedes that it meets the definition of a diagnostic center under the CON Statute. Messino cannot propose a facility and diagnostic equipment that meets the CON Statute's definition of a diagnostic center (by its own admission) but then claim it is not applying for a diagnostic center CON—that is just not how the law works, but that is what Messino purports to do in its CON application. Relatedly, Messino makes no attempt to address the need for a diagnostic center nor does it follow the CON application instructions specifically directed towards applicants proposing a diagnostic center and complete all of the required CON application forms applicable to a diagnostic center. Essentially, Messino is requesting that the State approve a PET scanner to be operated in a diagnostic center, but expressly says it is not applying for a diagnostic center CON. This approach violates and does not align with the clear language of the CON Statute. This issue is discussed in more detail below.

Lastly, Mission contends that Messino's utilization projections are unreasonable and unsupported. Even if Messino's projections were realistic, Messino's project will have a detrimental impact on Mission's PET volumes – a fact that Mission has experienced with Messino affiliates in other markets for other services as will be discussed below.

Mission will show that Messino's application is riddled with unsupported, erroneous, or misconstrued information that render it non-conforming with the review criteria and performance standards. As such, the Messino application is not approvable.

NON-CONFORMITY WITH REVIEW CRITERIA

Criterion (1) and Policy GEN-3
Messino should be found non-conforming with Criterion (1) because:

- If approved, the proposed project will result in an unnecessary duplication of existing services and two underutilized PET units in the service area which does not maximize healthcare value for resources expended. Specifically, the Messino project as proposed would deflate PET utilization at Mission, and Messino will not meet its projected utilization goals resulting in underutilized PET scanners across the region. More detailed discussion related to the underutilization and duplication of services as a result of Messino's project can be found below in Messino's comments concerning Messino's non-conformity with Criterion (3) and (6). These same factors relate to Messino's failure to meet Criterion (1).

- Messino does not adequately explain how its projected utilization incorporates the concept of maximum value for resources expended. Messino's unsupported utilization projections and unnecessary duplication of services demonstrate that Messino's project does not maximize resources for value. More detailed discussion of each of these factors can be found below in Mission's comments concerning Messino's non-conformity with Criterion (3), Criterion (4), and Criterion (6), respectively. These same factors relate to Messino's failure to meet Criterion (1).

- Messino does not adequately demonstrate need for the proposed project. More detailed discussion regarding failure to establish need can be found below in Mission's comments concerning

Messino's non-conformity with Criterion (3). These same factors relate to Messino's failure to meet Criterion (1).

The proposed project is not conforming to criteria 1, 3, 4 & 6 and thus does not maximize healthcare value for resources expended and is not an efficient use of healthcare resources and thus is not consistent with Policy GEN-3: Basic Principles.

Criterion (3)

Messino fails to demonstrate the need for its proposed project as required by Criterion (3) for several reasons, including unsupported and unrealistic utilization projections and important factors that have been disregarded or misrepresented in its application. These flaws are discussed at length below. For the reasons discussed herein, Messino fails to clearly document the specific need for the proposed project.

Messino has not proven the need for a diagnostic center.

Messino states that it will not be a licensed IDTF and briefly gives a nod to diagnostic centers on page 18 of its application, stating that it "meets the definition of a diagnostic center". However, Messino makes no attempt to address the need for a diagnostic center in the service area or to respond to any of the CON form questions related specifically to diagnostic centers, despite conceding that it meets the definition of a diagnostic center in the CON Statute (see Mission's comments related to Criterion 5). Essentially, Messino is asking the State to approve the operation of a CON-approved PET unit in a non-approved, unlicensed diagnostic center. For this reason alone, Messino's project must be denied.

Mission drove the need for an additional PET Scanner in HSA I.

Despite the fact that there are two fixed PET providers in HSA I (Mission and Catawba Valley Medical Center/Frye Regional Medical Center), Mission Hospital's utilization drove the need for an additional PET scanner in HSA I. Messino attempts to discount and take credit for this fact. On page 41 of its application, Messino states, "AOP physicians at Messino Cancer Centers refer patients for PET scans and primarily refer them to the fixed PET scanner operated by Mission Hospital. Thus, the scans AOP refers to the Mission Hospital PET scanner are a driver of the need under the standard methodology". In actuality, Mission receives PET referrals from several of its referral relationships within it 18-county service area. Mission's overall utilization drove the need for an additional scanner in the HSA, not just Messino's referrals.

Messino has not proven that its proposed physician-owned PET is needed.

In its application, Messino emphasizes that "patients do not currently have the option to receive a PET scan on a physician-owned PET scanner in HSA I. This increases costs for patients and their health plan." **In fact, all 24 Fixed PET providers across six different HSAs published in the 2021 SMFP are owned by a hospital provider, either wholly owned or as part of a joint venture**.[1] Moreover, all 37 existing mobile PET host sites are located at hospitals throughout the state. There is not one entirely physician-owned fixed PET provider or host site in North Carolina. This is not a coincidence. PET is a complex diagnostic imaging service and is, in many ways, very different from routine MRI and CT diagnostic imaging. First, consider that PET imaging is most often done in conjunction with CT technology or, more recently, MRI technology. Also, PET is often performed on the sickest populations with chronic and/or terminal illness, namely cancer but also cardiac and neurologic diseases. These patients are often already using hospital services to manage

[1] Wake PET Service/Wake Radiology is a joint venture between Wake Radiology Oncology Services and WakeMed in HSA IV. First Imaging of the Carolinas is an affiliate of FirstHealth of the Carolinas in HSA V.

their chronic conditions. It is important that these patients experience continuity of care. Physician offices are not equipped to offer the ancillary support services or the full continuum of care that is offered by hospital providers. Messino admits to this on page 45 of its application where it states that "AOP does not offer the breadth of services provided at a hospital…". This coupled with Messino's lack of experience offering any advanced diagnostic services is particularly concerning.

Messino discusses that the cost of care to patients or their health plan are increased for hospital-based PET services. It is a widely known fact that hospital services are often more costly than services offered by freestanding facilities. Hospitals offer a more comprehensive service than what is offered by freestanding facilities, hence the higher cost of care. However, as demonstrated by the fact that there is no physician-owned PET provider in North Carolina, a healthcare delivery system can operate efficiently without a freestanding PET provider. However, a comprehensive healthcare delivery system typically does not operate efficiently without a hospital-based PET provider to provide more complex care when medically necessary.

The medical necessity of hospital-based PET services is acknowledged in a policy released by Anthem in August 2020 (Guideline #CG-MED-55)[2]. The policy lists nine different scenarios where it is medically necessary to perform an advanced radiologic imaging procedure including PET at a hospital outpatient site of care. Mission found no such policy for freestanding facilities in its research. Specifically, Anthem's Clinical Utilization Management (UM) Guideline document states that, "Hospital-based advanced radiologic imaging procedures are generally more appropriate for individuals whose health status necessitates the availability of more supportive care for the minimization of the risks associated adverse health events." Accordingly, Messino would only be able to serve a subset of the total demand for PET in the market, as evidenced by payor policies documenting the necessity of hospital-based PET services, particularly for medically fragile patients.

Mission acknowledges that there are certain circumstances where freestanding outpatient services are more cost effective and should thereby be considered as an alternative care setting for certain patients and payors. However, in the context of this project, Messino's claim that it is a better alternative provider of PET as a physician-owned practice than Mission is as a hospital-based provider is unfounded. "Cheaper" is not always better, particularly not at the sacrifice of clinical appropriateness, continuity of care, and quality of care.

Mission contends that, unlike physician-owned PET providers, available capacity at hospital-based PET providers is vital, particularly to accommodate the most fragile patient populations in the community who require coordinated, comprehensive care across the continuum of care. The available capacity for hospital-based PET units is even more important in the context of the rarity of published need for a PET scanner in the SMFP. In fact, there has been a published need for only eight fixed PET units and one mobile unit across the past 10 SMFPs. Four of the eight fixed PET scanners were published in the most recent 2021 SMFP. As it relates to Mission's planning area, HSA I, the need for a fixed scanner in the 2021 SMFP is the first need for PET in HSA I in the past 10 years. Published need is not as commonplace for PET services as it is for CT and MRI services. This fact coupled with Mission's existing capacity constraints and the limited scope and provision of PET services proposed by Messino further supports the need for additional hospital-based capacity.

[2] https://www.anthem.com/dam/medpolicies/abcbs/active/guidelines/gl_pw_c191757.html

Mission has been providing healthcare services to the local community for over 130 years, PET services for 18 years, and cancer care services for several decades. Messino's physicians are well aware of Mission's long history of providing comprehensive care in the community, as all of them were part of the Mission physician network prior to leaving and joining the Messino physician practice. The fact that there is no physician-owned practice providing PET services in the state of North Carolina as proposed by Messino, and that even payors acknowledge that PET services in a hospital setting are medically necessary for some patients, shows that hospital-based PET is not an unnecessary expense for patients and their payors. Messino's project will not only take away a significant number of Mission's patients as will be explained below but also will impact quality of care.

Messino's project will not expand access to care for the area.

As set forth in G.S. 131E-183(a)(3), applicants are required to show the extent to which all residents of the area are likely to have access to the services are proposed. Patients gain access to PET services through referral from their physician. Thus, without established relationships with physician referral sources, a facility's available PET capacity is essentially useless. Further, the CON Section projects need for PET services on a regional basis to ensure access to care addresses the overall need of the planning area. It is the burden of the Applicant to show not only how the project will meet an institutional need, but also how it will meet the needs of the region as a whole.

While Messino claims that it will serve patients from referral sources other than its own physicians, it is clear these other referral sources are an afterthought – secondary to Messino's own physicians' needs. At first glance, Messino has several template letters of support from referral sources outside of its own practice that appear to validate its claim that the project will serve patients other than its own. However, a closer look at these template letters reveals a slightly different story.

On page 46 of the application, Messino dedicates a paragraph to "one group that expressed interest in the AOP PET" – Asheville Urological Associates ("AUA"). The implication is that AUA will serve as a large referral source for prostate cancer patients in need of PET services, considering the recent advances in PET technology for prostate cancer patients. However, the only actual evidence for this claimed volume is a form letter and survey with no letterhead signed by one AUA physician, Dr. JG Cargill, with the number "4" listed as the "historical/anticipated volumes of PET scan referrals". No other AUA physician signed Messino's template letter and fully completed a survey despite the fact that a majority of AUA physicians have historically referred their prostate cancer patients in need of PET to Mission, the only existing PET provider in Messino's service area. Note that:

- Dr. Andrew Franklin with AUA signed a form letter but did not complete a survey and has not historically referred any patients to Mission.
- Dr. Michael Burris with AUA signed a form letter but did not complete a survey.
- Dr. H. Brooks Hooper with AUA signed a template letter and intentionally completed only two questions on the survey, specifically opting not to complete the survey question concerning patients expected to be referred.

It appears the remaining AUA physicians did not sign or complete a survey on behalf of Messino at all. Other than its own patients, it is unclear how Messino will enhance the utilization of advanced prostate PET imaging with only the potential 4 patients to be referred by Dr. Cargill.

Next, on page 47 of the application, Messino discusses the advances in PET imaging for Alzheimer's disease patients and identifies a nonprofit charitable organization, MemoryCare, as a potential referral source for Alzheimer patients in need of PET services. Messino states that "MemoryCare's physicians expect to refer twelve to fifteen scans annually to the AOP PET scanner in Asheville". However, MemoryCare physician's referral patterns to Mission, the existing PET scanner in Asheville, is inconsistent with this statement. From 2018 to 2020, MemoryCare physicians referred a total of 5 patients in three years to Mission for PET services – one in 2018 and four in 2020. See **Figure 1** below. This does not align with MemoryCare's survey results which indicate that it historically referred 12 PET patients in 2019. It is unclear how MemoryCare will more than triple its historical referrals.

Figure 1
MemoryCare MDs PET Referrals to Mission

	2018	2019	2020
Della Simon, MD	-	-	1
Amy Cohen, MD	1	-	1
C. David Johnson, MD	-	-	2
Virginia Templeton, MD	-	-	-
Pamela Gutman, MD	-	-	-
Margaret Noel, MD	-	-	-
Margaret Word-Sims, MD	-	-	-
Total	**1**	**0**	**4**

Source: Internal Data

While Messino projects that it will receive referrals from numerous physician groups not currently affiliated with Messino, it only provides letters of support and concrete referral numbers from two such physician groups. There is a significant misalignment between what Messino presents as its projected non-affiliated referral volume and the historical referrals from these referral sources to Mission. This discrepancy calls into question Messino's utilization projections, financial feasibility, and ability to make any meaningful impact on access to PET services for service area patients other than the patients of its network of 15 physicians. Even if one were to accept that Messino's projected non-affiliated volume is realistic, its own data shows that only 11 percent of its patients (253 patients out of 2,187 total patients) will be from referral sources other than Messino-affiliated physicians.

Unlike Messino, Mission is a long-time provider of PET services in the service area and is the regional tertiary and quaternary care center in western North Carolina. As such, Mission works with hundreds of medical oncologists, neurologists, cardiologists, urologists, and other physician specialists throughout the service area (both Mission and non-Mission physicians), has established referral patterns with these physicians, and has historically provided an array of PET studies for a wide range of oncologic and neurologic diseases.

Messino's project will do nothing to enhance access to care for HSA I and will, instead, primarily benefit Messino.

<u>Messino's project will not enhance access to care for charity care patients.</u>
As will be discussed in Mission's comments related to Criterion (13), Messino "commits" its application to dedicating 3 percent of its PET volumes to charity care patients. This commitment is not consistent with

the historical charity care utilization in service area market and, in fact, is overstated. Messino provides no explanation and no basis for its inflated charity care projection. This not only calls into question Messino's representations about its level of service to the medically underserved but also calls into question Messino's knowledge of the HSA I and Buncombe County market, particularly as it relates to the provision of PET services and its ability to achieve its lofty "commitment" to serve underserved populations. Please see Mission's comments related to Criterion (13).

The high utilization at Mission does not support need for Messino's proposed project.

On page 44 of its application, Messino discusses a need to enhance timely access to PET services due to scheduling delays for Mission's existing PET unit. Mission could not agree more. The high utilization of Mission's PET scanner drove the need for an additional PET scanner, and while this alone does not automatically imply that Mission should be approved for an additional PET Scanner, it is an essential part of the demonstration of need for additional capacity at Mission.

Messino's patients are not the only patients experiencing delays when being referred to PET services at Mission. Mission proposes to remedy this for *all* patients in its broad 18-county service area as well as expand access to cardiac PET, a service which is currently not available to service area residents. As evidenced by its own patient origin and questionable volumes from its purported non-Messino-affiliated referral sources, Messino will primarily only expand access to care for its own oncology patients. The need for an additional fixed PET scanner is for the entire HSA, not just Messino's patients.

Messino claims that "although the utilization of the PET scanner at Mission Hospital exceeds the 80% utilization percentage, triggering a Need Determination for HSA I, Mission Hospital does not regularly schedule weekend or evening patient appointments." (Messino Application, page 42) and that "AOP's proposed scanner will met a demonstrated need in HSA I for timely access to PET imaging services by expanding hours of operation" (Messino Application, page 45). As discussed in its application, Mission offers extended hours to patients in need of PET services outside of normal work hours and will continue to extend operating hours for the proposed project as needed. Messino's statement is unfounded.

Despite Messino's baseless assertions, high utilization at Mission that results in scheduling delays does not support a need for Messino's project. Instead, the high utilization evidenced by existing scheduling delays supports a need for an additional scanner operated by Mission, an experienced PET and healthcare services provider in the service area. Mission is proposing to operate an additional PET scanner at its existing hospital outpatient department (HOPD) at 5 Vanderbilt Park Dr. ("Mission 5 Vanderbilt Park") which currently offers several other diagnostic imaging services. Unlike Messino's proposed project, Mission 5 Vanderbilt Park will offer patients ready access to a known provider of PET services and continuity of care for *all* service area patients in need of PET services, not just Messino's oncology patients.

Messino's project will have a significant adverse impact on Mission.

Both the CON Statute at N.C. Gen. Stat. section 131E-175(4) and the current CON application form itself require the CON Section to evaluate the impact of a proposed new service on similar, existing services in the service area. This is commonly referred to as "unnecessary duplication." While the CON Statute is not designed to protect the market share of any existing provider, the CON Law does prohibit the CON Section from approving a CON application that represents unnecessary duplication and a negative impact on existing providers in the absence of a compelling reason for such duplication, such as the offering of a broader array of services than existing providers or the offering of services to currently underserved patients, among others. The Messino project is a prime example of an "unnecessary duplication" of existing

services because it simply seeks to pull PET patients away from Mission (the only existing PET provider in the service area); to serve a much smaller population array than Mission (only serving its own current patients) with a more limited range of PET services than Mission. Messino's project does not offer any distinctive PET services or attributes not already offered that would justify the dilution of Mission's existing PET services.

Messino admits it in its application that a vast majority of its referrals go to Mission for PET services. The table on page 119 of Messino's application shows that over 90 percent (1,042 out of 1,154 PET referrals) of Messino's PET referrals are sent to Mission. The table also shows that Messino's referrals make up over 38 percent of Mission's total PET volume in 2020. **Figure 2** below provides the trend in referrals to Mission from Messino physicians from CY 2018 to CY 2020. Note that referrals from Messino to Mission have continued to grow despite Messino's claim that scheduling delays prevent its patients from receiving adequate PET services.

Figure 2
2018-2020 Messino Referrals to Mission

CY 2018	CY 2019	CY 2020	2 Yr CAGR
803	937	1,012	12.3%

Source: Internal Data

If Messino's project is approved, Mission will inevitably lose all of the volume referred by Messino's physician office as well as the volume from other referral sources that Messino proposes to serve. As the regional tertiary and quaternary care center and the region's safety net hospital, the financial viability of Mission and availability of comprehensive care at Mission is of the utmost importance to meet the needs of the service area. If Messino's project is approved, the potential loss of Messino's referrals will be significant for Mission and could potentially impact its ability to offer comprehensive care to its patients. As it relates to cancer care, continuity of care is vital to the quality of care provided. Many of the patients who receive PET services at Mission also receive other cancer services at Mission. The proposed project will disrupt continuity of care and could, in turn, compromise quality of care.

<u>Messino's project will not enhance geographic access to PET services.</u>
Messino contends that its project will "create a new point of geographic access for PET services in a location accessible to a majority of residents of HSA I". Messino conducts a drive time analysis, including the growth in PET scans based on hospital utilization by proximity to Buncombe County to show that utilization west of Buncombe County is growing at rates that are higher than areas east of Buncombe County. Mission has no issues with the basis of the analysis; however, Messino mistakenly concludes that its location, a mere 10-minute drive in peak traffic from Mission, is evidence of enhanced geographic access. Messino also mentions that "residents of communities surrounding Buncombe County can access the AOP location without navigating into the midst of Asheville and the hospital grounds" (Messino Application, Page 51).

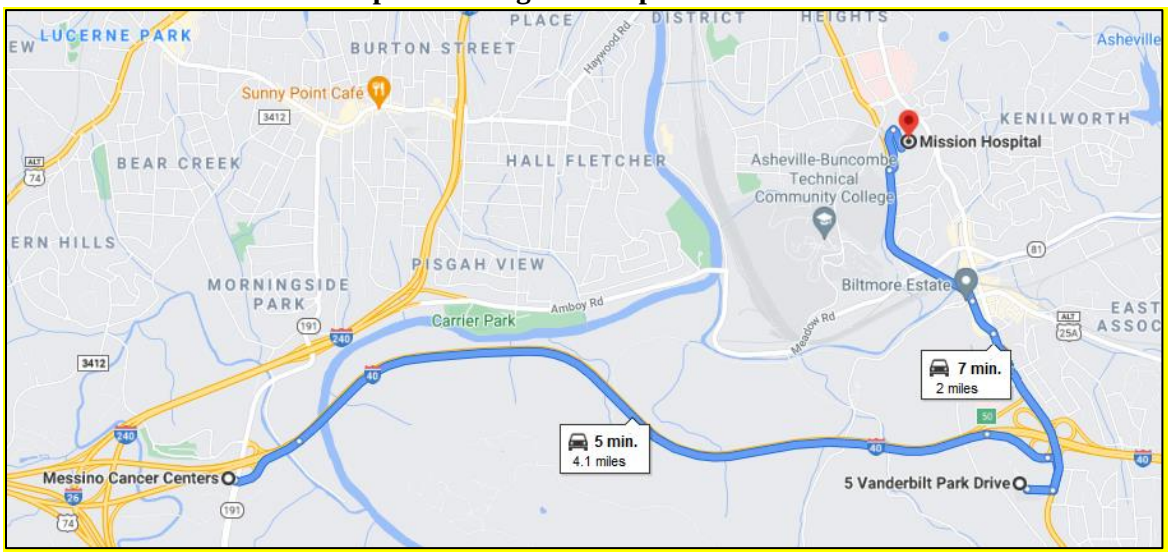
As a comprehensive healthcare provider and the regional tertiary and quaternary care center, Mission's main campus is admittedly large. However, Mission's existing PET scanner is located at Mission Cancer's flagship location – Mission Hospital SECU (State Employees Credit Union) Cancer Center ("SECU Cancer Center") at the front of Mission's main campus on the corner of McDowell Street and Hospital Drive. The building has a parking deck located right beside it for easy parking and does not require the patient to travel deep into the campus' epicenter. It is the most accessible building on Mission's campus.

Figure 3
Mission SECU Cancer Center

Despite Messino's assertions otherwise, the proposed project will not enhance geographic access to care, as Mission is already located in Asheville, less than 5 miles from Messino's proposed location. Traffic patterns do not show evidence of any significant delay in access to existing PET services outside of normal traffic conditions.

Further, Mission proposes a new location for its second PET scanner at an existing HOPD – Mission 5 Vanderbilt Park, a stand-alone building with a dedicated parking lot just off of Interstate-40 and Hendersonville Road. This location is approximately 2 miles from Mission's main campus. See **Figure 4** below with a map of Messino's location, Mission's proposed location, and Mission Hospital's main campus.

Figure 4
Map of Existing and Proposed Locations



Source: Google Maps

Messino's claims of enhance geographic access are baseless and misleading.

Messino's projected utilization is unsupported.

Messino projects its utilization based on historical referrals to Mission and volumes projected by surveys completed by area physicians. However, there are several fatal flaws in Messino's projections.

The projected growth in PET Scans at HSA I facilities utilized by Messino in its CON application is inconsistent with volumes reported in the SMFP. For instance, Messino indicated in the chart on page 117 of its application that Carolinas Healthcare Blue Ridge performed 421 PET scans in FY 2019; however, the 2021 SMFP states that Carolinas Healthcare Blue Ridge performed 253 PET scans in FY 2019. Messino also indicated that Advent Health Hendersonville performed 262 PET Scans in FY 2019; however, the SMFP says that Advent Health Hendersonville performed 257 PET Scans in the same period. These and the other discrepancies between the numbers presented in the chart on page 117 of the Messino application and the numbers presented in the 2021 SMFP call into question the validity of Messino's growth rate assumptions for HSA I PET volume.

Messino relies on surveys from referral sources outside of Messino in an attempt to show that they will expand access to care for referral sources outside of its own practice. However, these numbers are unreliable. Mission compared the referrals to its existing PET unit by the aforementioned referral sources. This comparison is appropriate given that:

- Mission is the only existing provider of PET services in Buncombe County.
- The referring providers listed in the table below indicate that they will refer patients to Messino's proposed PET unit in Buncombe County.
- Messino's template letters and surveys signed by the referring physicians indicate that a vast majority of the referring physicians have practices in Buncombe County.

Note that in 2020, the referrals from the referring physicians in **Figure 5** below total 105 scans. This does not align with the volumes projected to be referred to Messino in its application. **Essentially, Messino projects referral volumes that are 150 percent of historical referral volumes for these physicians.** This is unrealistic, and Messino has not provided any reasonable basis for the significant growth in referrals from these physicians. Messino projects it will capture no new market share other than the additional unrealistic projected volume from outside referral sources.

Figure 5
Historical Referrals vs. Projected Referrals – Non-AOP MDs

	Historical Referrals to Mission			Projected Referrals (to Messino)	
	2018	**2019**	**2020**	**Minimum**	**Maximum**
Paul Ahearne, MD	44	61	44	30	50
Lauren Bernstein, MD	2	1	1	10	10
Colin Bird, MD	10	15	16	50	50
John Cargill, MD	2	6	3	4	4
MemoryCare*				10	15
Elizabeth Cohen, MD	1	0	1		
C. David Johnson, MD			2		
Della Simon, MD			1		
Pamela Gutman, MD					
Virginia Templeton, MD					
Margaret Noel, MD					
Margaret Word-Sims, MD					
Brian Cumbie, MD	3	1	1	10	10
Benjamin Deschner, MD			2	25	25
Richard Dodd, MD			0	10	10
Ronald Lane, MD.	4	4	1	12	24
Victor Marlar, MD			1	10	10
Frank Melvin, MD	33	23	24	50	50
Thomas C. Mitchell, MD			1	10	10
Theodore Rheney, MD	8	10	7	10	12
Hilary Thomas, MD			0	10	10
Total	**107**	**121**	**105**	**251**	**290**
Shortfall (Historical 2019 vs. Projected)				(130)	(169)
Shortfall (Historical 2020 vs. Projected)				(146)	(185)

Source: Internal Data

*Note Messino mistakenly stated that Memory Care's minimum is 12; however, the letter explicitly states the minimum projected volume is 10.

Importantly, the difference between what Messino projects its referral volume to be from outside referral sources and the actual historical referral patterns for these physicians is a shortfall of anywhere between 130 and 185 scans. When Messino's projected utilization is updated to account for this discrepancy, Messino's projected utilization would be as shown in **Figure 6** below.

Figure 6
AOP PET Volumes based on Mission Referrals

	Year 1 2023	Year 2 2024	Year 3 2025
Scenario 1: AOP PET Volume based on 2020 Referrals to Mission			
AOP Physician Scans	1,573	1,744	1,934
Additional Scan Volume (Non-AOP MDs) based on 2020 Referrals	53	79	105
Total AOP PET Volume	**1,626**	**1,823**	**2,039**
Scenario 2: AOP PET Volume based on 2019 Referrals to Mission			
AOP Physician Scans	1,573	1,744	1,934
Additional Scan Volume (Non-AOP MDs) based on 2019 Referrals	61	91	121
Total AOP PET Volume	**1,634**	**1,835**	**2,055**

Source: Internal Data; Messino CON Application

Whether using the 2019 referral volumes for "non-AOP MDs" (pre-COVID) or the 2020 referral volumes for "non-AOPMDs", Messino will fall short of the performance standards requirement of at least 2,080 procedures. In the analysis above, Mission assumed that:

- The volumes upon which Messino relies for the growth in PET scans in the HSA I market are accurate, despite apparent inconsistencies with the 2021 SMFP (Messino Application, page 117); and
- Messino's assumption that it will serve all of the patients it historically referred to Mission is correct, despite the fact that it is medically necessary for high-risk patients to be treated in a hospital-based setting, not a physician's office as proposed by Messino.

Thus, it is likely that Messino's projections fall even further below the performance standards established in 10A NCAC 14C.3703 for PET Services.

Messino fails to demonstrate the need for its proposed project as required by Criterion (3) for several reasons, including unsupported and unrealistic utilization projections as detailed herein. Thus, its project should be denied.

Criterion (4)
Messino has not shown that its project is the most effective alternative. If Messino's projections were to materialize as proposed, the project would result in an unnecessary duplication of existing resources, causing the two PET units in the service area to be underutilized as will be shown in Mission's comments related to Criterion (6). Further, Messino does not effectively establish that the alternative proposed in this application is the most effective alternative to meet the identified need because the application does not adequately document its projected utilization, financial feasibility, or financial accessibility as documented in other sections of this document.

Based on these issues, Messino should be found non-conforming with Criterion (4).

Criterion (5)
As previously discussed, Messino's utilization projections are not supported, and the assumptions are not reasonably documented. This calls into question the reasonableness of Messino's utilization projections which, in turn, raises concerns about the reasonability of Messino's financial projections. Further, as will

be discussed in the written comments related to Criterion (13), Messino provides no basis for its 3 percent charity care projection, and this projection does not align with the historical payor mix for PET services.

On page 18 of the application, Messino indicates that it meets the definition of a diagnostic center. The CON Statute defines a "diagnostic center" as "a freestanding facility, program, or provider, including but not limited to physicians' offices, … in which the total cost of all medical diagnostic equipment utilized by the facility which cost ten thousand dollars ($10,000) or more exceeds five hundred thousand dollars ($500,000). Any facility which meets this definition is, by law, a diagnostic center and is also a "new institutional health service" meaning that the facility must apply for and obtain a CON as a diagnostic center. See N.C. Gen. Stat. sections 131E-176(7a); (16) and 131E-178(a). A facility, specifically including a physician's office, either is or is not a diagnostic center and, if it qualifies as such, it must apply for and obtain a CON to be a diagnostic center. No CON applicant can admit to being a diagnostic center (as Messino does), but then decide for themselves not to go through the appropriate steps to become a diagnostic center, as acknowledged in the statement "we are not applying for a CON to be a diagnostic center even though we meet the statutory definition" and also fail to complete the CON application form questions that relate to diagnostic centers. That is precisely what Messino attempts to do in its application in this review and that alone should disqualify the application from approval.

Messino fails to acknowledge the diagnostic center-related question in the CON form and does not report any other diagnostic equipment, so it is unclear exactly what type of facility Messino proposes. For instance, in Section F of the CON Application Form, Question 4b requires diagnostic centers to complete the revenues and operating costs forms for each service component **and** the entire facility. In Section Q of its application, Messino only completes the revenues and operating costs for PET services and fails to complete the revenues and operating costs for the entire facility.

Finally, the architect estimate found in Exhibit K-3 is not signed by a certified architect and does not appear to include architectural and engineering (A&E) fees. Thus, there is no way to ensure that the construction cost estimate is accurate, reasonable, or reliable.

Based on these issues, Messino should be found non-conforming with Criterion (5).

Criterion (6)

As described above, the proposed project will inevitably result in unnecessary duplication of PET services. Essentially all of the volume Messino projects to serve will come from referrals currently served by Mission. Not only will the project result in a significant adverse impact on Mission, but also it will result in a duplication of services causing the two existing units in Buncombe County to be significantly underutilized. **Figure 7** below shows the utilization of both the existing Mission unit and the proposed Messino unit in the first year of operation (CY 2023) if Messino's project were approved. **Figure 7** considers the utilization of both units in three different scenarios:

- Scenario 1: Mission PET Volume Lost to Messino based on the compound annual growth rate of Messino's referrals to Mission (see **Figure 2** above) and the 2020 referrals to Mission from the non-Messino physicians who completed a Messino survey.
- Scenario 2: Mission PET Volume Lost to Messino based on Messino's Year 1 projections.
- Scenario 3: Mission PET Volume Lost to Messino based on Messino's projections for Messino-affiliated physicians and 2020 referrals to Mission from the non-Messino physicians who completed a Messino survey or signed a template letter of support.

Figure 7
Year 1 (CY 2023) Buncombe County PET Units
Projected Utilization if Messino is Approved

	Scenario 1	Scenario 2	Scenario 3
Mission PET Volume	3,382	3,382	3,382
Volume Lost to Messino			
Messino/AOP MDs	1,432	1,573	1,573
Non-Messino/AOP MDs	105	127	346
Total Messino Volume	**1,537**	**1,700**	**1,919**
Remaining Mission PET Volume	**1,845**	**1,682**	**1,463**
% Capacity - Mission	**61.5%**	**56.1%**	**48.8%**
% Capacity - Messino	**51.2%**	**56.7%**	**64.0%**

Source: Internal Data; Messino CON Application

In all of the three possible scenarios, both proposed PET units will be significantly underutilized which is not an efficient use of healthcare resources and results in unnecessary duplication of services.

On pages 84 and 85 of its application, Messino quotes an article that discusses the closure of several of Mission's medical oncology locations in Franklin, Brevard, Marion, and Spruce Pine. Messino states that "unlike Mission, AOP continues to operate Messino Cancer Centers' patient care service locations throughout the area in Asheville… and at a range of rural area locations, including Brevard (Pisgah Forest, NC), Franklin, Marion, Spruce Pine, and Sylva". Messino conveniently leaves out important context which reveals the *full* story.

Beginning in 2011, Messino's physicians were affiliated with Mission Health System or Hospital as Cancer Care of Western North Carolina ("CCWNC") through a professional services agreement. The physician group primarily provided medical oncology services at Mission's more rural locations, such as Franklin (at an Angel Medical Center OP facility–owned by Mission), Sylva (at a Mission-owned OP facility), Brevard (at Transylvania Regional Hospital–owned by Mission), Marion (at Mission Hospital McDowell-owned by Mission), and Spruce Pine (at Blue Ridge Regional Hospital-owned by Mission). For years prior to Messino's affiliation with Mission in 2011, CCWNC served as the main medical oncology group in most of these markets, providing medical oncology oversight and utilizing the hospital-based infusion centers in these hospitals.

In 2019, Messino physicians decided to end their partnership with Mission and partnered with American Oncology Network ("AON"), a national oncology network out of Florida. Subsequently, AON and Messino built six new Messino Cancer Center facilities offering medical oncology and lucrative infusion therapy services in the exact same markets that they had historically served as Mission-affiliated physicians. The new Messino-AON facilities offered infusion services duplicative to those already provided by the Mission Health facilities in those markets. Unfortunately, Mission could not sustain those specific services without a medical oncology group to oversee and refer to the services and had to discontinue its infusion services in these locations. It is disingenuous for Messino to characterize the chain of events that occurred as Mission abandoning its rural medical oncology locations. In fact, Mission Health continues to be committed to these communities and continues to operate these rural hospitals, most of which are critical access hospitals, despite the loss of medical oncology providers and related services.

In essence, the Messino physicians left Mission without medical oncology coverage in its more rural areas, and now claims that Mission is failing to serve those areas. Messino physicians' decision to leave Mission was done for the sole benefit of the Messino physicians. Now, they seek to do the same thing to Mission's PET services and patients, and their desire procure a PET scanner has more to do with bolstering their own practice and revenues than it has to do with servicing the broader HSA I service area in its entirety as Mission is currently doing. Messino's proposed project will be located just minutes away from Mission, relies heavily on Mission's current patients for utilization projections, and proposes primarily to serve Messino's own existing patients in its own facility.

It is clear that Messino's project is a duplication of existing services and should be found non-conforming with Criterion (6).

Criterion (7)

Messino's Form F.3b assumptions states that the medical director will be contracted; however, Messino does not provide any information on how this contract will be secured and with whom it will contract for medical direction. It is not clear that viable options for medical direction have been established. Further, as discussed in Mission's comments related to Criterion (5), Messino states that it will have a management service agreement with American Oncology Management but provides no information on the terms of this agreement to ensure adequate management services will be provided.

For these reasons, Messino should be found non-conforming with Criterion (7).

Criterion (8)

As previously established, Messino claims it will be managed through a management services agreement by American Oncology Management; however, Messino does not provide any information related to this agreement. Accordingly, it cannot be verified that adequate management services are available. This is especially important considering that Messino and its affiliates do not currently offer and never have offered PET services anywhere in North Carolina. While Mission is not calling into question Messino's experience providing medical oncology, Messino has no experience providing advanced diagnostic services. Further, Messino's project is not designed to coordinate with the existing health care system. Instead, the project is designed to take volume from the existing provider and to serve Messino's own patients.

For these reasons, Messino should be found non-conforming with Criterion (8).

Criterion (13)

On page 49 of the Messino application, Messino states that it "has committed to providing 3 percent of its annual PET scan volume as charity care". As previously discussed, the projection is not consistent with historical experience for PET scan charity care in the service area and Messino provides no explanation for this variance or no justification for this projection.

Further, Mission has a very generous charity care policy and has been offering PET services in the service area for many years. In FY 2020, 2.3 percent of Mission's PET patients were charity care and self-pay patients combined. As presented by Messino on page 102 of its application, 2 percent of its referrals (a majority of which were made to Mission) were self-pay patients. Messino's projected 3 percent charity care projection does not align with the historical trend Mission has experienced for charity care/self-pay PET patients over time.

The number of eligible charity care patients in the service area is, in part, driven by the socioeconomic status of Buncombe County, where a majority of Mission's and Messino's patients in need of PET reside. According to the U.S. Census Bureau statistics on Buncombe County:

- Over 20 percent of the population is over 65 (the majority of which are covered by Medicare) compared to 16.7 percent for the state of North Carolina.
- 12.5 percent of persons under 65 years old do not have health insurance compared to 13.4 of persons under 65 years old for North Carolina.
- 91.1 percent of the population has a high school degree or higher and 40 percent have a bachelor's degree or higher compared to 87.8 percent and 31.3 percent for North Carolina, respectively.
- The per capita income is $32,426 compared to $30,783 for North Carolina.
- 12.2 of persons are living in poverty compared to 13.6 percent for North Carolina.[3]

In summary, Buncombe County residents are largely elderly, educated, insured, and are employed with steady income; hence, the relatively "low" percent of charity care/self-pay PET patients at Mission. Messino's promise to dedicate 3 percent of its PET scans to charity care patients means nothing if there are not enough patients eligible for charity care in need of PET services. Moreover, considering the limited scope of services Messino will offer, the reasonableness of Messino's payor mix is questionable at best. Messino's proposed charity care percentage is not based in any logic or historical performance and is inconsistent with Mission's experience as the only existing provider of PET services in the service area. Accordingly, Messino should be found non-conforming with Criterion (13).

Criterion (18a)
Messino's CON application will not enhance competition in the service area, nor will it have a positive impact upon cost-effectiveness, quality, and access. If approved, Messino's project will take patients away from Mission, causing a significant adverse impact on the hospital and resulting in two underutilized PET units which represents a duplication of existing services without enhancing access to care. Messino's project is designed to serve its own patients, and with form letters of support and inconsistent surveys from other referral sources, it is unclear how Messino's project will enhance access to the service area patients who are not patients of Messino-affiliated physicians.

Based on these issues, Messino's application should be found non-conforming with Criterion (18a).

FAILURE TO MEET PERFORMANCE STANDARDS
10A NCAC 14C .3703(a)(1) states that:

> *(1) An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that: (1) the proposed dedicated PET scanner, including a proposed mobile dedicated PET scanner, shall be utilized at an annual rate of at least 2,080 PET procedures by the end of the third year following completion of the project.*

As previously discussed, Messino's flawed projections result in a failure to meet the 10A NCAC 14C .3703 Performance Standards that apply to PET services. These flaws include:

[3] https://www.census.gov/quickfacts/fact/table/NC,buncombecountynorthcarolina/PST045219

- Apparent inconsistencies between the PET volumes for HSA I as presented by Messino and as presented in the SMFP.
- Lack of support for referral volume from non-Messino-affiliated referral sources.

When the appropriate adjustments are made to the projected referral volume from non-Messino physicians alone, it is clear that Messino will *not* meet the performance standard as required and should therefore be denied.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2021 SMFP, there is a need for one additional PET unit in HSA. Thus, although there are two identified applicants, only one can be approved in this review. It is clear that the application of American Oncology Partners, P.A. d/b/a Messino Cancer Centers contains major flaws, particularly with respect to Criterion (3), that should result in denial of the application. Therefore, there should be no need for a comparative review. Nonetheless, Mission has provided the following comparative review between the two applicants.

Conformity with Applicable Statutory and Regulatory Review Criteria

As previously stated, the Messino application is not conforming with all applicable statutory and regulatory review criteria for reasons discussed throughout Mission's Comments in Opposition. Therefore, the application submitted by Messino 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 applications 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 provides a comparison of the types of PET studies proposed to be offered by each applicant.

	Mission Hospital	**Messino Cancer Center**
Oncologic PET	X	X
Neurologic PET	X	X
Cardiac PET	X	

As a physician-owned medical oncology group with no experience offering PET, it is questionable whether Messino has the resources and capability to offer neurologic PET studies in particular. However, even assuming that Messino will offer neurologic PET, Mission proposes to provide a broader scope of PET services than Messino. Thus, as it relates to scope of PET services, Mission is the more effective applicant.

Geographic Accessibility

The 2021 SMFP identifies the need for one fixed PET scanner in HSA I. Both applicants propose to locate the fixed PET scanner in Buncombe County. Therefore, with regard to geographic accessibility both proposed projects are comparable.

Access by Underserved Groups

Projected Charity Care

Based on historical payor mix, Mission projects charity care at 1.4 percent of PET volume. In addition to oncologic and neurologic PET studies, Mission will offer cardiac PET services which are currently not offered by Mission. The charity care percentage for cardiac patients is higher than the overall historical charity care for PET services at Mission; thus, Mission's projected charity care is conservative. While Messino projects a higher percentage of charity care than Mission, Messino provides no basis for its projected charity care. It is also inconsistent with historical experience. Thus, the application submitted by Mission is the most effective alternative with regard to projected access by charity care patients.

Projected Access by Medicare Recipients

The table below compares Project Year 2 projections for the total number of procedures and the number of Medicare patients as a percentage of total PET patients. In general, the application proposing either the higher percentage or number of Medicare procedures is the more effective alternative with regard to this comparative factor.

Projected Access for Medicare Patients (2nd Full Year)

Applicant	# of Fixed PET Scanners	Total Number of Procedures Per Machine	Projected number of Medicare Procedures Per Machine	Medicare Procedures as a Percentage of Total Procedures
Total Mission PET*	2	4,141	2,755	66.5%
Messino Cancer Center	1	1,934	1,334	69.0%

*Avg. PET procedures per machine: 2,755/2 = 1,378

Messino projects a slightly higher Medicare percentage but, on average, fewer Medicare patients per unit in comparison to Mission (1,334 vs. 1,378, respectively). Therefore, the application submitted by Mission is the most effective alternative with regard to projected access by Medicare recipients.

Projected Access by Medicaid Recipients

The table below compares Project Year 2 projections for the total number of procedures and the number of Medicaid patients as a percentage of total PET patients. In general, the application proposing either the higher percentage or number of Medicaid procedures is the more effective alternative with regard to this comparative factor.

Projected Access for Medicaid Patients (2nd Full Year)

Applicant	# of Fixed PET Scanners	Total Number of Procedures Per Machine	Projected number of Medicaid Procedures Per Machine	Medicaid Procedures as a Percentage of Total Procedures
Total Mission PET*	2	4,141	195	4.7%
Messino Cancer Center	1	1,934	116	6.0%

*Avg. PET procedures per machine: 195/2 = 98

Messino projects a slightly higher Medicaid percentage and, on average, slightly more Medicaid patients per machine in comparison to Mission (116 vs. 98, respectively). While this difference is relatively immaterial, as described in Criterion (3), Messino's projected total procedures are based on unreasonable and unsupported assumptions. For these reasons, the application submitted by Mission is the most effective alternative with regard to projected access by Medicaid recipients.

Projected Average Net Revenue per PET Procedure

The table below compares the projected net revenue per PET procedure in Project Year 2 based on the information provided on the Applicants' Form F.2b. In general, the applicant with the lowest net revenue per procedure is considered to be the most cost-effective alternative.

Projected Average Net Revenue per PET Procedure (2nd Full Year)

	Mission (Total)	Messino Cancer Center
Net Revenue	$9,452,047	$3,205,080
Procedures	4,141	1,934
Net Revenue per Procedure	$2,283	$1,657

Messino projects a lower net revenue per procedure than Mission projects. However, Messino's projected total procedures are based on unreasonable and unsupported assumptions as described herein. Further, both applicants vary significantly in the scope of PET services proposed which inevitably impacts net revenue. Lastly, because Messino proposes a physician-owned facility, it cannot accurately be compared against Mission, which is a medical center serving higher acuity cases. Thus, due to significant differences in facility types and the number and scope of PET services proposed by both facilities, it is not possible to make conclusive comparisons with regard to net revenue per case.

Projected Average Operating Expense per PET Procedure

The table below compares the projected net revenue per PET procedure in Project Year 2 based on the information provided on the Applicants' Form F.3b. In general, the applicant with the lowest operating expense per procedure is considered to be the most cost-effective alternative.

Projected Average Operating Expense per PET Procedure (2nd Full Year)

	Mission (Total)	Messino Cancer Center
Total Operating Expenses	$3,792,854	$1,608,517
Procedures	4,141	1,934
Operating Expenses per Procedure	$916	$832

Despite major differences in the cost structure of a hospital-based facility versus the cost structure of a physician-owned diagnostic center, Messino and Mission project similar operating expense per procedure, with only an $84 per procedure difference between the two projects. Regardless, Messino's projected total procedures are based on unreasonable and unsupported assumptions as described herein. Further, both applicants vary significantly in the scope of PET services proposed which inevitably impacts operating expense. Lastly, because Messino proposes a physician-owned diagnostic center, it cannot accurately be compared against Mission, which is a medical center serving higher acuity cases. Thus, due to significant differences in facility types and the number and scope of PET services proposed by both facilities, it is not possible to make conclusive comparisons with regard to operating expense per case.

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 Messino is not conforming with all applicable statutory and regulatory review criteria. Thus, technically, the aforementioned comparative factors do not apply to Messino, and Mission is the most effective alternative. Nonetheless, Mission has provided the summary of the comparative factors below:

Comparative Factor	**Mission Hospital**	**Messino Cancer Center**
Conformity with Review Criteria	Yes	No
Scope of Services	Most Effective	Least Effective
Geographic Accessibility	Equally Effective	Equally Effective
Access by Underserved Groups: Charity Care	Most Effective	Least Effective
Access by Underserved Groups: Medicare	Most Effective	Least Effective
Access by Underserved Groups: Medicaid	Most Effective	Least Effective
Projected Average Net Revenue per Case	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive

Even if Messino 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

Messino's application is not approvable, as it does not conform to Criteria (1), (3), (4), (5), (6), (7), (8) (13), (18a), and the Performance Standards for PET services. Additionally, Messino did not complete the financial pro forma forms as directed for a diagnostic center. 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.