Novant Health Forsyth Medical Center
Comments in Opposition to
Perspective PET Imaging, LLC's Application to Acquire a Mobile PET/CT Unit
Pursuant to the 2018 Need Determination
December 1, 2018 CON Review Cycle

INTRODUCTION

In accordance with N.C. Gen. Stat. § 131E-185(a)(1), Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center (NHFMC) submits the following comments related to competing applications to acquire a mobile PET/CT unit pursuant to the need determination as published in the 2018 State Medical Facilities Plan (SMFP). To facilitate the Agency's review of these comments, NHFMC has organized its discussion by issue, citing the general CON statutory review criteria and specific regulatory criteria and standards that create non-conformity relative to each issue by applicant. NHFMC also provides a comparative analysis of all applications.

Four applicants have filed Certificate of Need ("CON") applications in response to the identified need including Project ID G-011640-18 – Forsyth Memorial Hospital. The other three applicants are:

- E-011630-18 InSight Health Corp. ("InSight")
- G-011647-18 Perspective PET Imaging, LLC ("PPI")
- F-011627-18 Mobile Imaging Partners of North Carolina, LLC ("MIPNC")

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

OVERVIEW

PPI presents an unusual project proposing to provide mobile PET/CT services at two existing, freestanding diagnostic imaging centers in Wake and Guilford Counties. The freestanding imaging center sites are owned and operated by two radiology groups, Raleigh Radiology and Greensboro Radiology, affiliates of the applicant. Essentially, these two groups would benefit from revenue associated with both the PET/Vendor services fee for use of the mobile, and the global imaging fee paid to the host sites. This application is simply an effort for these radiology practices to benefit from as many revenue streams as possible for imaging services.

Most importantly, the proposed project with three hosts sites (two in Wake County and one in Guilford County) completely duplicate existing services in these areas, many of which are underutilized. As shown in the letters of support, the volume that would be referred to these facilities would come from local hospitals, many of which have excess PET/CT capacity. Finally,

PPI's projected utilization is unreasonable and unrealistically assumes patients would travel extensive distances to PPI's affiliated host sites bypassing numerous existing mobile and fixed PET/CT services. As a result of these flaws, PPI's application is non-conforming with numerous Review Criteria and cannot be approved.

NON-CONFORMITY WITH REVIEW CRITERIA

Criterion (1)

"The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved."

PPI should be found non-conforming with Criterion (1) because it does not improve safety and quality of care, promote equitable access, or maximize healthcare value as required by Policy GEN-3. First, PPI is made up of existing radiology imaging centers and physicians' offices with no experience providing mobile or PET/CT services, raising questions about its ability to provide quality care. As previously established, PPI is made up of existing radiology imaging centers or physicians' offices with no experience providing mobile services. As such, PPI proposes to obtain contracts for essentially every component of the mobile PET/CT service, including transportation services, all staff, including technologists and management, billing and scheduling, digital imaging transmission, and equipment maintenance.

PPI passes along the responsibility of staffing and managing the mobile unit to the host site, which affects PPI's ability to control quality of care delivered. One may argue that PPI is serving its own radiology centers as host sites and as such, can control quality of care; however, PPI never explicitly states that it intends to only serve affiliated sites. In fact, PPI states in its application that it plans to serve other radiology imaging centers in the future. Regardless, the host sites identified in the PPI application have no experience with staffing and managing fixed or mobile PET imaging.

PPI states that it will "provide functions, such as management, imaging equipment quality control, regulatory compliance, and staff quality that are in its areas of expertise" (PPI Application, Section C, page 42); however, according to Form H, both management and staffing will be contracted, and maintenance of equipment will be contracted (PPI Application, Section C, page 40). Essentially, it appears that PPI itself is only proposing to provide a mobile PET/CT unit, leaving the operation, management, and quality control procedures to the host sites and the companies with which PPI contracts its services. Contracting a majority of the components of the PET/CT service, especially staffing to host sites with no PET experience, most certainly brings into question PPI's ability to control the quality of care provided.

Without experience offering mobile PET/CT services as either a vendor or through the proposed affiliated fixed site, quality is questionable particularly when management and support services are not already established when mobile services are provided to a hospital host site. This is not to say that a freestanding site is inappropriate for mobile PET/CT services; however, without more documentation of the qualifications, experience, and management expertise, the quality of care at PPI's affiliate host sites has not been documented.

Second, PPI does not expand equitable access as PPI proposes to serve sites in Guilford and Wake Counties located in HSA II and IV respectively. The counties in which the proposed sites are located already have ample access to PET/CT services including fixed hospital PET/CT units with excess unused capacity. Not one of PPI's proposed host sites is actually expanding geographic access to care or alleviating capacity constraints. Certainly, the proposed access does not maximize healthcare value by serving sites that already have adequate access to PET/CT services.

Based on these issues, PPI's application is not consistent with Policy GEN-3 and should be found non-conforming with Criterion (1).

Criterion (3)

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

PPI should be found non-conforming with Criterion (3) based on an inappropriately defined service area and population to be served, unreasonable and unrealistic utilization projections and failure to expand accessibility to the population it proposes to serve.

PPI will not Increase Access to Care

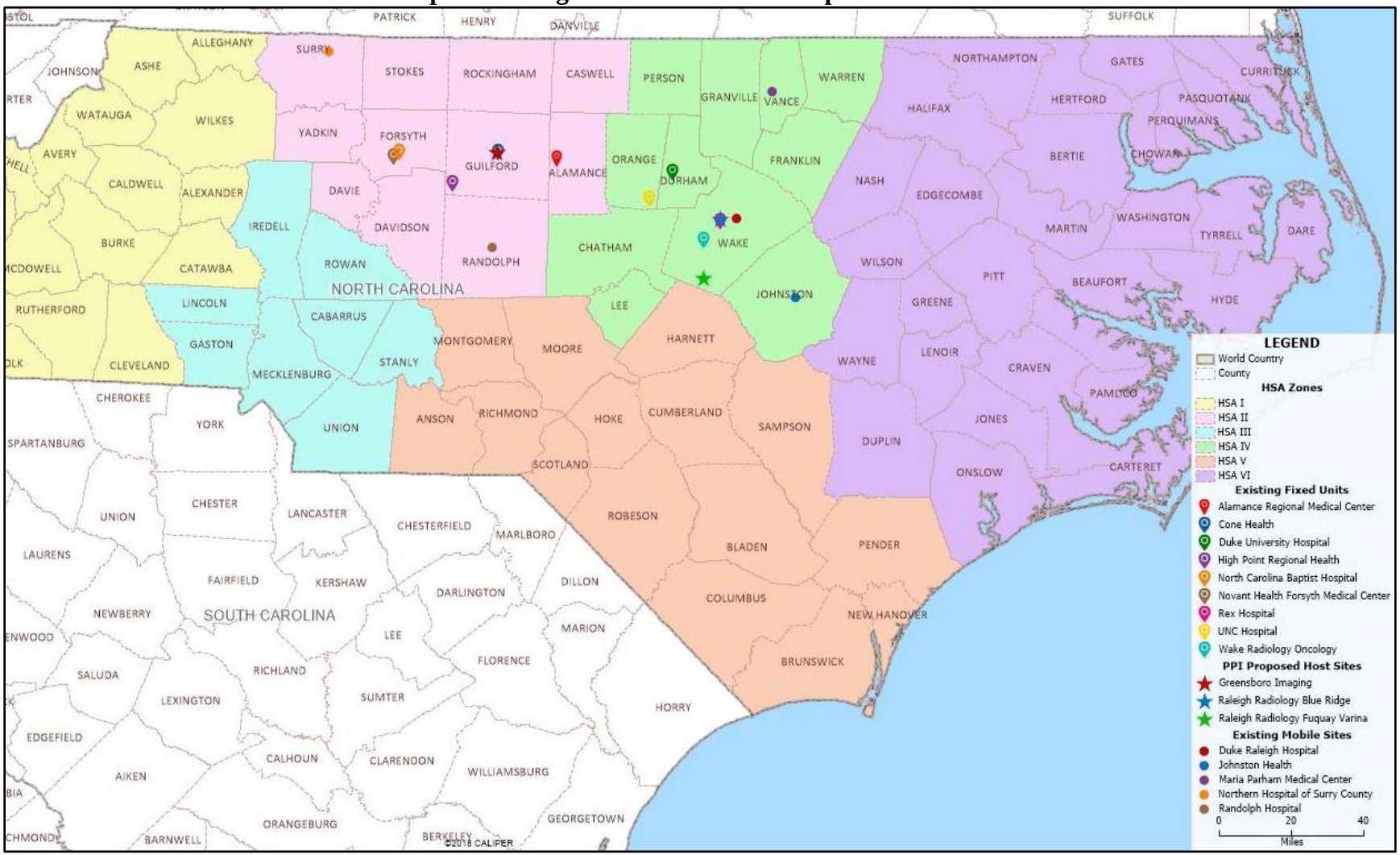
PPI proposes to serve two host sites in Wake County and one host site in Guilford County. **Exhibit 1** below provides a map of the existing fixed and mobile units in Health Service Areas II and IV where PPI's proposed host sites will be located.

PPI's host site in Guilford County is less than one mile away from Cone Health, which has an existing fixed unit with ample capacity as will be shown below. More importantly, HSA IV and Wake County, where two of PPI's proposed sites are located, have the most access to PET/CT services out of all HSAs with four fixed units, three mobile sites, one additional approved fixed unit at Duke Raleigh Hospital, and published need in the 2019 SMFP for a sixth fixed unit. Note

that PPI's proposed "home host site," Raleigh Radiology Blue Ridge, is also less than a mile from Rex Hospital which has two fixed units on site.

It is clear that PPI will not enhance geographic access to PET/CT services and will in fact duplicate existing capacity at immediately adjacent hospital PET/CT locations.

Exhibit 1
Map of Existing Providers and PPI Proposed Host Sites



PPI's Service Area is Unreasonably Defined and Inappropriate

PPI's projected utilization is unreasonable. First, PPI provides the historical patient origin for all outpatient sites of the members. Raleigh Radiology has six locations; however, only one of these existing locations is a proposed PPI host site: Raleigh Radiology Blue Ridge (Raleigh Radiology Fuquay Varina opens in January 2019). PPI uses the historical patient origin for all six locations as a basis for its projected utilization at the Raleigh Radiology host sites. This is inappropriate. It would have been more appropriate to present patient origin by site. Nonetheless, this historical imaging patient origin is more reasonable than the projected patient origin for PET/CT services, which appears to have no meaningful relationship to the location of the proposed host sites, reasonable travel access for PET/CT services, or the referral sources from which PPI will purportedly gain its projected utilization.

The irrationality of PPI's service area and projected patient origin stands in direct contrast to the historical imaging services patient origin for PPI's affiliated host sites as shown in **Exhibit 2.** Each practice has essentially a single county primary service area – Wake County for Raleigh Radiology and Guilford County for Greensboro Radiology – and at most three other counties as a secondary service area comprising well over 95 percent of each practice's patient origin.

Exhibit 2
Historical Patient Origin and Service Area Definition for PPI Host Sites

County	Raleigh Radiology %
Wake	87.16%
Johnston	3.05%
Harnett	1.55%
Durham	1.51%
Other NC Counties	2.84%
Out of State	3.89%
Total	100.00%

County	Greensboro Radiology %
Guilford	77.40%
Rockingham	6.99%
Randolph	5.26%
Alamance	3.07%
Other NC Counties	4.73%
Out of State	2.55%
Total	100.00%

Source: PPI CON Pages 46-48.

By contrast, PPI claims a service area encompassing patients in 42 different counties across the state based on the host sites. PPI says as much in Section Q Page 24 of its application: *"The applicant assumes that the current patient origin patterns are a reasonable proxy for PET imaging patient patterns at the proposed host sites"*; however, PPI's projected patient origin bears no resemblance to the historical patient origin of Raleigh Radiology or Greensboro Radiology as shown in **Exhibit 3.**

Exhibit 3

Projected Patient Origin and Service Area Definition for PPI Host Sites

County	Raleigh Radiology Blue Ridge %	County	Raleigh Radiology Fuquay Variana %	County	Greensboro Radiology %
Wake	22.80%	Wake	22.80%	Guilford	37.89%
Johnston	5.18%	Johnston	5.18%	Rockingham	0.42%
Harnett	3.06%	Harnett	3.06%	Randolph	8.70%
Durham	9.06%	Durham	9.06%	Alamance	0.00%
Mecklenburg	**27.43%**	**Mecklenburg**	**27.43%**	**Mecklenburg**	**16.82%**
Buncombe	**6.31%**	**Buncombe**	**6.31%**	**Cabarrus**	**7.76%**
New Hanover	**3.88%**	**New Hanover**	**3.88%**	**Orange**	**4.87%**
Cabarrus	**3.07%**	**Cabarrus**	**3.07%**	**Iredell**	**4.36%**
Onslow	**2.79%**	**Onslow**	**2.79%**	**Forsyth**	**2.57%**
Pitt	**2.21%**	**Pitt**	**2.21%**	**Chatham**	**2.23%**
Robeson	**2.09%**	**Robeson**	**2.09%**	**Montgomery**	**0.97%**
Other NC Counties	**8.72%**	**Other NC Counties**	**8.72%**	**Other NC Counties**	**9.48%**
Out of State	3.40%	Out of State	3.40%	Out of State	3.93%
Total	100.00%	Total	100.00%	Total	100.00%
% From Historic Service Area	40.10%	% From Historic Service Area	40.10%	% From Historic Service Area	47.01%
% From Total Outside Historic Area	**59.90%**	**% From Total Outside Historic Area**	**59.90%**	**% From Total Outside Historic Area**	**52.99%**

Source: PPI CON Pages 51-55.

Again, it is unreasonable to assume that a material number of patients from all over the state will travel past existing host sites to a new PET/CT vendor that is not affiliated with any existing oncology specialty program for PET/CT services and that has no experience offering mobile PET/CT services. For instance, PPI includes Buncombe County in its target counties for PET/CT services (PPI Application, Section Q, page 31), but no host site in Buncombe County is included in the PPI application. Buncombe County has access to comprehensive oncology services at Mission Hospital and is a minimum of 240 miles or 3.5 hours away from Raleigh Radiology Blue Ridge, where PPI proposes these patients will be served. On the far east side of the state, PPI proposes to draw patients from New Hanover and Onslow Counties. This implies that patients will endure more than a two-hour drive, approximately 136 - 145 miles across the state, when there are existing closer options at New Hanover Regional Medical Center and Onslow Medical Center for PET/CT services.

Most notably, PPI projects more patients to drive from Mecklenburg County to the two Raleigh Radiology locations, than from Wake County. Both Raleigh Radiology host sites project that 27.43 percent of its patients will come from Mecklenburg County, and 22.8 percent of its patients will come from Wake County. However, historically, 0.1 percent of its patients have been from Mecklenburg County, and 87.16 percent of its patients have originated from Wake County (PPI Application pages 45-47). The Greensboro host site is expected to capture over 16 percent of its patients from Mecklenburg County, when historically 0.3 percent of Greensboro Radiology patients have come from Mecklenburg County (PPI Application page 48). The projected patient origin does not align with historical experience and referral patterns for the same physicians supporting the project, and it does not make geographical sense. Also, Mecklenburg County has

three fixed PET scanners and two mobile host sites. Patients from Mecklenburg County are not going to drive to Greensboro or Raleigh for a PET scan.

Similar issues can be found in the Greensboro Radiology projected patient origin. In its home county of Guilford, PPI only projects 37.89 percent for patient origin. Historically, over 77 percent of patients have originated from Guilford (PPI Application pages 54-55). Likewise, PPI projects 16.8 percent of its patients will originate from Mecklenburg County when, historically, only 0.03 percent have originated from Mecklenburg County (PPI Application, Section C, Page 48). For the Greensboro location, PPI projects no patients from Alamance County and less than 1 percent of its patients from Rockingham County despite the fact that 10.72 percent of patients have come from these two counties historically (PPI Application pages 48, 54-55). There are many other examples of other counties from which PPI proposes to serve a significant number of patients that are well over 100 miles away from the host sites.

PPI provides a list of existing providers and the number of PET patients by county of origin in Exhibit E.1 as further proof that patients in need of PET/CT services will travel for care. Contrarily, this exhibit only reiterates the point that for most mobile sites the vast majority of patients come from the home county or neighboring counties. Several hospitals with fixed units draw patients from a larger population base due to their status as a provider of comprehensive healthcare services and/or their existing oncology programs. PPI is a proposed mobile vendor with no experience operating a mobile PET/CT program and independent of any hospital affiliation. It certainly cannot be compared to existing hospitals that offer comprehensive cancer care and draw patients from a broader base. Furthermore, the physicians supporting the project are based on Guilford and Wake Counties and do not provide any information to suggest they would refer patients from distance locations including Buncombe, Mecklenburg, and New Hanover Counties for example.

It is clear that PPI's projected patient origin is highly flawed and unreasonable and as a result its projected service area is unrealistic. PPI fails to appropriately document the population it proposes to serve.

PPI's Utilization Projections are Completely Flawed

PPI indulges in a 19-step, multi-faceted exercise to arrive at its projected utilization. However, a detailed analysis of PPI's project utilization reveals major flaws that deem the projected utilization unreasonable and unsupported. The patient origin discussion above reveals that the results of the 19-step projection model are impracticable and unsound. The most important flaws are detailed below.

First, PPI uses statewide use rates and applies these rates to the estimated county population to determine the number of patients by county by year. This assumption implies that the use rate for

the entire state is indicative of the use rates in each county, which is simply not true as shown in PPI's own Table 4, Section Q. The assumption that demand will be equal across all counties and that need can be calculated as such is unrealistic (Table 7, Section Q) This assumption and calculation of unmet need by county may point out where patients have less access to PET/CT services, but there is a complete disconnect between this calculation and any assumption that PPI will serve these patients, increasing PET/CT use rates uniformly to the statewide average (Table 10, Section Q).

In Step 14, Table 22 of its projected utilization, PPI does not account for the need published in the 2019 SMFP for a fixed unit in HSA IV, which will most certainly affect the identified unmet need.

In Step 16 of its projected utilization, PPI assumes a 35 percent, 45 percent, and 60 percent market share of unmet need in Year 1, 2, and 3 respectively. However, this market share is extremely aggressive considering that PPI is a new provider with no experience in PET/CT services in an area already saturated with existing providers. Furthermore, it is completely unsound to assume the same level of market share across its unreasonably large 42-county service area, regardless of the distance of these counties from the proposed host sites. The irrationality of this assumption is what results in the completely nonsensical patient origin that bears no resemblance to the historical patient origin for the proposed host site services.

In Step 19, PPI projects its utilization by site. See **Exhibit 4** below. Note that a certain level of ramp up is reasonable to assume from Year 1 to Year 2 for a new service. More concerning, however, is that this aggressive growth rate never tapers off from Year 2 to Year 3. In fact, the growth rate is even higher than the ramp up from Year 1 to Year 2. Such a high growth rate is unreasonable, particularly in a market with several existing providers, another anticipated fixed unit (Duke Raleigh Hospital) to come online in 2019, and a need published for another fixed scanner in the 2019 SMFP.

Exhibit 4
Projected Utilization and Growth Rates

Location	**Year 1 2021**	**Year 2 2022**	**Year 3 2023**	**CAGR**	**Growth Rate Y1 -Y2**	**Growth Rate Y2 -Y3**
All Three Host Sites	961	1,567	2,624	*65.2%*	*63.1%*	*67.5%*
Raleigh Radiology-Blue Ridge	512	830	1,373	*63.8%*	*62.1%*	*65.4%*
Raleigh Radiology-Fuquay Varina	276	447	740	*63.7%*	*62.0%*	*65.5%*
Greensboro Radiology	173	291	511	*71.9%*	*68.2%*	*75.6%*

PPI's Physician Referral Letters Demonstrate Duplication of Services

To further support its projected utilization, PPI states that it projects at least 2,500 annual referrals for all three of its host sites combined (PPI Application Section H, Page 101). At face value, this number seems to support PPI's projected utilization of 2,624 by Year 3; however, in reviewing the letters written by the referring physicians, several concerns arise.

For example, a range of 96 (low) to 129 (high) monthly referrals were projected by physicians at Cone Health Cancer Center at Alamance Regional and Cone Health Cancer Center Wesley Long. However, Cone Health and Alamance Regional Medical Center (ARMC), owned by Cone Health, have fixed units with ample capacity. Further, 4 (low) to 8 (high) projected monthly referrals came from physicians who are affiliated with WakeMed. Wake Radiology Oncology has a fixed unit that has a capacity of 15.63 percent. See **Exhibit 5** below

Exhibit 5

Utilization of Existing Fixed Units in HSA II and IV

Site	2013-2014	2014-2015	2015-2016	2016-2017	HSA	Units	2017 Procedure/ 3000 as Capacity
Alamance Regional Medical Center	780	631	695	791	II	1	26.37%
High Point Regional Health	592	639	649	815	II	1	27.17%
Cone Health	1,463	1,693	1,744	1,726	II	1	57.53%
North Carolina Baptist Hospital	1,967	2,017	2,384	2,610	II	2	43.50%
Duke University Hospital	4,084	4,220	4,643	4,774	IV	2	79.57%
Rex Hospital	1,918	2,085	2,231	2,556	IV	1	85.20%
UNC Hospital	2,142	2,775	2,968	4,152	IV	2	69.20%
Wake PET Services, Wake Radiology Oncology, Wake Radiology	544	465	518	469	IV	1	15.63%

Source: 2015-2018 SMFPs, 2019 Draft SMFP

This would mean that although Cone Health Cancer Center at Alamance Regional, for example, is less than half a mile from the fixed PET/CT unit at ARMC, and the fixed unit at ARMC is only using 26.73 percent of its capacity, referring physicians at the cancer center would refer patients away from their community to travel over 20 miles east to Greensboro Radiology for a PET scan. This is not reasonable.

While PPI's projected referral patterns and volumes appear to be unrealistic, if the projected referrals from Cone Health and WakeMed affiliated practices were to actually materialize, Cone Health/Alamance Regional Medical Center would be severely impacted by seeing a reduction of as many as 1,548 scans annually (129 scans/month X 12 months). WakeMed could see a loss of approximately 100 scans annually. It is clear that this level of referrals from facilities with existing

access to PET/CT services is either unreasonable and will not actually occur, meaning the projected utilization is unsupported, or it will occur as projected causing a huge adverse impact on existing providers.

PPI's Argument Regarding Global Billing is Irrelevant

Throughout its application, PPI presents its global billing approach as an advantage over all other applicants. Global billing is a bundling of physician and technical fees into one bill for Medicare reimbursement. Global billing is only available to independent physician offices, radiology imaging centers, etc. PPI indicates that the proposed project will involve global billing; however, in actuality, the host sites, not PPI, will be providing global billing to the patient. There is no evidence that the patient or payor will experience any lower cost of care. PPI will bill the host site a standard fee per scan just like all other proposed projects. To circumvent this issue, PPI proposes to serve only radiology imaging centers that participate in global billing which limits PPI's ability to serve areas based on need for services. The proposed host sites are in urban areas. The project does not have the ability to serve less urban/metropolitan areas that do not have access to certified nuclear medicine technologists to staff the mobile unit as proposed by PPI.

In summary, it has been established that the projected utilization and patient origin are highly flawed and senseless. It has also been established that the referrals that are projected by PPI are either unrealistic or will be detrimental to existing providers. With no sound basis for its projections, PPI has not demonstrated the need for its project.

Based on these issues, PPI's application 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."

As previously established, HSA IV, where two of the three proposed host sites are located, is clearly not in need of expanded access to PET/CT services. With four existing fixed units, three existing mobile sites, one approved fixed unit at Duke Raleigh Hospital to be implemented in 2019, and published need for one additional fixed unit in the 2019 SMFP, HSA IV is clearly well-served. More specifically, Wake County has two of the four existing fixed units in HSA IV and will have a third fixed unit when the Duke Raleigh Hospital unit comes online. Providing PET/CT services in an area already well-served by existing and impending units is not cost effective or an efficient allocation of PET/CT resources. There are clearly areas within the state in need of increased access to services—HSA IV is not one of those areas. PPI's project is not the least costly or most effective alternative when there are numerous existing providers, including a not-yet-implemented fixed unit in Wake County, highly proximate to two of PPI's proposed sites.

Based on this issue, PPI's application should be found non-conforming with Criterion (4).

Criterion (5)

"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."

PPI projects to fund all $1.97 million in capital costs through a loan. The loan is documented through a letter from Wells Fargo to Raleigh Radiology. A letter from Raleigh Radiology claims to have the authority to provide the funding to PPI. No other financial documentation is provided by either Raleigh Radiology or Greensboro Radiology. As a new entity, PPI does not provide financial statements or any information on the financial viability of its affiliates. No financial resources are demonstrated other than the potential for a loan.

PPI relies on contract arrangements with existing host sites to provide most of the operational support for the mobile PET/CT scanner, yet no information about the resources of these host sites is provided.

The absence of any financial information on PPI as an existing entity coupled with the fact that PPI proposes to finance 100 percent of the capital costs brings into question the applicant's ability to follow through with the terms of the proposed funding source in the long term. PPI projects a loss during the start-up period of $34,065 in the Interim Fiscal Year and $127,126 in the first full year of operation. The funding sources do not show adequate cash flow to cover the first-year loss from operations. At this point, PPI's financial ability to cover this loss and remain solvent is unclear, as the applicant has not provided the required financial documentation.

Most important, PPI's utilization projections are completely flawed and do not support the financial projections provided in the application. If PPI fails to capture the unrealistically large patient volume from Mecklenburg County, for example, and the other disperse counties throughout the state as projected, the project will most certainly not be feasible based on the pro forma projections and assumptions projected.

As noted in detail below, PPI does not include sufficient staffing in its pro forma to align with its stated intent to provide two technologists at all times. Inclusion of additional staffing would most certainly result in more expenses and impact the bottom line of the pro forma projections.

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

Criterion (6)
"The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."

PPI's proposed project is clearly a duplication of existing services as outlined above. The proposed host sites are located in areas that are already well-served by existing providers with available capacity.

Based on this issue, PPI should be found non-conforming with Criterion (6).

Criterion (7)
"The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided."

In Section B, Page 32 of PPI's application, PPI states that, "Two techs will be on the trailer at all times during patient care for tech and patient safety." PPI also indicates that one of the techs will be a senior nuclear medicine technologist. However, on Form H, PPI only projects one FTE for a nuclear medicine technologist across all three years and does not indicate a pay variance that would be expected to differentiate a senior tech from a regular nuclear medicine technologist.

Further, with no clear basis, the annual salary per FTE for a nuclear medicine technologist increases by almost $40,000 from Year 1 to Year 2 and $60,000 from Year 1 to Year 2. For assistant technologist, PPI projects a $16,000 pay increase from Year 1 to Year 2 and a $25,000 pay increase from Year 2 to Year 3. Each increase is the equivalent of 68 percent. The total salary expense projected on Form H matches the total salary expense on Form F.4 under direct expenses. Such a high increase in pay per year is not reasonable.

One nuclear medicine technologist cannot provide the appropriate level of care necessary for the volume of patients PPI proposes to serve. Moreover, at 10 hours per day, six days per week, one technologist cannot work the 60 hours per week required to cover all shifts.

Based on these issues, PPI should be found non-conforming with Criterion (7).

Criterion (18a)
"The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact."

As previously discussed, PPI's projected utilization is unsupported and unreasonable. The volume or referrals PPI projects is either unreasonable or will duplicate existing PET/CT services and take volume away from existing providers, including underutilized fixed-based PET/CT units at local hospitals. The proposed project, if approved, will most certainly have a negative impact on competition. The project is not cost effective, does not improve quality, and does not enhance access to care as the proposed host sites are located in areas that already have adequate access to PET/CT services.

Based on these issues, PPI should be found non-conforming with Criterion 18(a).

FAILURE TO MEET PERFORMANCE STANDARDS

10A NCAC 14C .3700 sets the criteria and standards for a Positron Emission Tomography Scanner. As such, 10A NCAC 14C .3703(a)(1) states that:

> *"An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that 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 described herein, PPI's application consists of several unreasonable and unsupported projected utilization assumptions that make its projections unrealistic. This brings into question PPI's ability to meet the minimum 2,080 PET procedures by the end of the third year following completion of the project as required. Accordingly, PPI's proposed project should be denied.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2018 SMFP, there is a need for one additional mobile PET scanner statewide; thus, although there are four identified applicants, only one can be approved in this review. NHMFC acknowledges that each review is different and, therefore, that the comparative review factors employed by the Project Analyst in any given review may be different depending upon the relevant factors at issue.

NHFMC has provided a detailed assessment of each application and its conformity with the CON Review Criteria and the Performance Standards for PET/CT set forth in 10A NCAC 14C .3703 in which it is clear that the MIPNC, InSight, and PPI applications all contain major flaws, particularly with respect to Criterion (3) – Need and Criterion (5) – Financial Feasibility that should result in denial of each application. Therefore, there should be no need for a comparative review.

Nonetheless, NHFMC has provided the following comparative review among the four applications. This analysis further confirms that not only is NHFMC the only approvable applicant based on the review criteria and performance standard but also that NHFMC is the comparatively superior application.

In order to determine the most effective alternative to meet the identified need for a mobile PET scanner in the state of North Carolina, NHFMC has reviewed and compared the following factors in each application:

- Conformity with Review Criteria
- Geographic Accessibility
- Proposed PET/CT Equipment
- Access by Underserved Groups
- Projected Average Operating Expense per PET Procedure
- Staffing
- Physician/Clinician Support

Conformity with Review Criteria

As discussed above, only the NHFMC application is conforming to all applicable review criteria and rules. Therefore, the NHFMC application is the most effective alternative with respect to this factor.

Geographic Accessibility

Due to the unique nature of mobile services, there are several factors that must be considered when analyzing geographic accessibility, including total number of sites, number of proposed new sites, number of existing and approved providers in the service area, efficiency of providing services to the proposed service area, and need for expanded accessibility within the service area. The table below compares the number of new and existing proposed sites for each applicant.

Applicant	New Sites	Existing Sites	Total Sites
InSight	0	2	2
Mobile Imaging Partners	1	8	9
Perspective PET Imaging	3	0	3
NHFMC	4	5	9

InSight Health Corp

InSight proposes to serve the least number of sites—two small community hospitals in HSA I. Service area counties include Jackson, Cherokee, Macon, Swain, Haywood, Caldwell, Alexander,

and Wilkes. The proposed host sites are existing Alliance Imaging host sites. One host site also commits to being a host site for MIPNC, which brings into question how InSight's project is viable without clear commitment from either host site.

Regardless, the proposed project does not bring any expanded access to PET/CT services for the proposed service area counties.

Mobile Imaging Partners of North Carolina

MIPNC host sites are located in Rockingham, Surry, Onslow, Wayne, Wilson, Vance, Henderson, Lincoln, and Caldwell Counties. MIPNC proposes to serve the aforementioned counties and 35 other North Carolina counties across the entire state. MIPNC's expansive service area is unreasonable and inefficient.

MIPNC ties with NHFMC for the most proposed host sites; however, MIPNC's service area is scattered throughout multiple HSAs, and MIPNC only proposes to serve one new site: UNC Rockingham. The UNC Rockingham site is limited in its ability to expand access to care for North Carolina residents. According to UNC Rockingham's projected patient origin, 20 percent of the patients served will be from Virginia, meaning that only 80 percent of the patients to be served at UNC Rockingham reside in North Carolina. This population is limited primarily to Rockingham County with less than 4 percent of patients coming from neighboring Caswell County and the remaining 77 percent coming from Rockingham County.

It is clear that the proposed project does not significantly expand geographic access to care. Other than UNC Rockingham's narrow service area, all service area counties will continue to receive the accessibility that they currently have.

Perspective PET Imaging

PPI proposes to serve three new sites in Wake County (HSA IV) and Guilford County (HSA II). Wake County, in particular, has the most access to PET/CT services of any other county in the state. PPI proposes that two of its host sites will be located in Wake County. It is clear that with the existing mobile and fixed units in HSA IV and the approved units to be approved and implemented according to the 2017 SMFP and 2019 SMFP need determinations, HSA IV is not in need of expanded access to mobile PET/CT services. PPI's location in Guilford County is less than a mile away from an existing fixed unit at Cone Health with ample available capacity.

Further, PPI proposes an illogical 42-county service area (also called "target area counties"). PPI proposes that a material number of patients will come from as far west as Buncombe County and as far east as Dare County. This vast service area is completely unreasonable and is unlikely to

occur considering the number of existing providers that patients would have to pass by to reach PPI, a freestanding radiology imaging services provider with no experience offering mobile or fixed PET/CT services.

It is clear that the proposed project does not expand geographic access to care, as Wake and Guilford Counties are already well-served by existing providers. It is also clear that PPI's service area is unreasonable, and thus, does not expand access to care as proposed.

Novant Health Forsyth Medical Center

NHFMC ties with MIPNC for the most sites overall, but NFHMC proposes to serve the most number of new sites. NHFMC's proposed host sites are reasonably distributed in HSAs II and III so that proposed unit can efficiently serve patients and not spend excessive amounts of time crisscrossing North Carolina. The proposed project will expand access to care for HSA II and III, the areas that most need expanded access. All service area counties are contiguous, making the mobile unit travel route efficient.

With regard to geographic accessibility, NFHMC is clearly the most effective applicant and should be approved.

Proposed Equipment

As previously discussed, NHFMC proposes to acquire a PET/CT scanner that is identical to the current mobile scanner and the fixed PET/CT scanners at Forsyth Medical Center and Presbyterian Medical Center. This particular scanner was selected by the radiologists from Mecklenburg Radiology Associates and Triad Radiology Associates, the professional groups that support Novant Health. By purchasing the same scanner, patients will be afforded the same high-quality standard of care, regardless of where the exam is completed. The table below presents the proposed PET/CT unit for each applicant.

Summary of Proposed PET/CT Units

Applicant	NHFMC	InSight	MIPNC	Perspective PET Imaging
PET/CT Unit	Siemens Biograph mCT 40	Siemens Biograph Horizon	GE Discovery IQ	Siemens Biograph Horizon

Below is a summary of the advantages of the Siemens mCT 40 PET/CT scanner as described by the manufacturer:

- Fastest scan times (10-16 minutes) with the best spatial resolution
- Highest number of crystals, resulting in better spatial resolution, more counts, and faster scan times
- The shortest coincidence window which allows for best reduction of randoms/scatter
- Superior resolution and small lesion detectability
- Time of Flight technology
- Largest field of view (FOV), hence faster scan times and more counts

In addition, the mCT 40 includes FlowMotion technology that moves the patient smoothly through the system's gantry, while continuously acquiring PET data. This technology eliminates overlapping bed acquisitions and maintains uniform noise sensitivity across the entire scan range. It also enables anatomy-based imaging protocols. Furthermore, the continuous sense of progress throughout the scan provides the patient with a more comfortable exam experience. Combined with the 78 cm large bore, FlowMotion potentially improves patient satisfaction.

NHFMC is the only applicant who proposes to acquire the Medrad® Intego PET Infusion System. This advanced infusion system allows NHFMC to personalize doses for patients, reduce unnecessary radiation exposure for technologists, and improve operational efficiency. Utilizing a fully shielded mobile design, the system infuses accurate, repeatable, patient-specific doses from multi-dose vials, all managed through a simple touch screen. These accurate, repeatable, weight-based dosages are critical to high quality patient care as oncology patients typically undergo multiple PET studies throughout their course of care, from detection and staging to assessment of patient response to therapy.

With respect to quality of proposed PET/CT equipment, NHFMC is the superior applicant and should be approved.

Access by Underserved Groups

Payor Mix

Comparison of access to underserved groups is difficult for any mobile service because the applicant is a vendor and not the direct provider of the service and therefore does not bill the patient or insurance carrier for the scans. For this reason, payor mix for mobile PET providers cannot be compared the same way that fixed PET and other imaging modalities can. For this reason, it should not be assumed that any mobile vendor/applicant has the direct ability to fully control payor mix. However, this is particularly true for vendor-only entities like InSight and MIPNC. By contrast, PPI and NHFMC are affiliated with the billing entity; as such, both entities have access to more information about the patient payor mix for the provider affiliate and the policies and procedures in place to ensure access to care.

In terms of projected payor mix, MIPNC and InSight provide the payor mix for all existing outpatient services at their respective host sites as a basis for demonstrating access to underserved groups. These data include a tremendous range of services well beyond imaging services that are not appropriate indicators of the payor mix for PET/CT services. Regardless of access to patient data and policies/procedures, it should be noted that PPI has no experience providing mobile or fixed PET/CT services and did not provide any clear basis for its projected payor mix adjustments for PET services. This makes it impossible to make a fair comparison of payor mix for all applicants. Only NHFMC is both a vendor and a provider of mobile PET/CT services and can provide definitive payor mix data to demonstrate accessibility to care. Further, only NHFMC can provide and ensure that consistent financial access policies are provided across its proposed host sites.

Comparison of Projected Payor Mix Information for Mobile PET/CT Service

Applicant	Projects for Mobile PET/CT Service Specifically	Source for Payor Mix Information
NHFMC	Yes	Actual Mobile Operations for Host Sites
InSight	No	Provide hospital-wide, all outpatient payor mix for host sites. Not valid or meaningful for PET/CT
Mobile Imaging Partners	No	Provide hospital-wide, all outpatient payor mix for host sites. Not valid or meaningful for PET/CT
Perspective PET Imaging	Yes	Modifies payor mix from other diagnostic imaging services of affiliates

Source: Section L for each applicant.

Charity Care

Each applicant uses a different method of determining the amount charity care provided. Both MIPNC and InSight write off an allotted percentage/number of scans each year for the host sites to contribute towards charity care. As both a vendor and provider, PPI and NHFMC have direct knowledge of the charity care provided by the host site and are able to demonstrate historical and projected write-offs for the actual charity care provided by each host site.

Again, it should be noted that all host sites served by NHFMC provide services under the same charity care policies. This allows NHFMC to ensure that indigent populations have access to charity care. The following table shows the projection of charity care for each applicant and the source/method for presenting this information in each application.

Comparison of Charity Care Projection by Mobile PET/CT Vendor

Applicant	Percent Charity Care	Source
NHFMC	1.8%	Section L
InSight	1.0%	Schedule F.3
Mobile Imaging Partners	0.2%	Schedule F.3
Perspective PET Imaging	0.4%	Section L

NHFMC projects the highest percentage of charity care at 1.8 percent. MIPNC projects the lowest percentage of charity care at 0.2 percent.

Although it is not possible to compare payor mix for all providers, it is clear that as a vendor and provider, both PPI and NHFMC have the benefit of a direct affiliation with each host site. Of the two entities, only NHFMC has experience providing mobile PET/CT services and provides a clear basis for its projected payor mix. NHFMC proposes to serve by far the highest percentage of charity care. As such, NHFMC is the superior applicant in regard to accessibility and should be approved.

Projected Average Charge to Host Site per PET Procedure

Again, as mobile vendors, the applicants are not charging patients directly, and therefore, an analysis of patient gross and net revenue is not relevant. The vendor charge has no relationship to the ultimate charge to the patient/insurance carrier nor does the vendor charge have any impact on the payment by the patient/insurance carrier.

As it pertains to projected revenue or, more specifically, charges to host sites, each applicant includes a variety of services in its fee structure and the converse relies to varying extents on the host sites to provide support to the mobile unit. For example, PPI relies heavily on the host site for contracted services. These factors are built into vendor charges.

Another factor influencing vendor charges is the cost of radiopharmaceuticals, as will be discussed in more detail below. Typically, this cost is passed along to the host site in the vendor charge. It is clear that InSight has understated its costs for FDG and as such its vendor charge to host sites is not reasonable as discussed in relation to specific review criteria.

With so many variables in what is included in the vendor charge and how this value is determined, it is difficult to compare and determine the superior applicant based on projected average charge to host site per PET procedure. Ultimately the hosts sites will determine whether the value of the mobile PET/CT service is commensurate with the proposed charge. The level of commitment from both existing and proposed host sites is the best measure of the value of the service offering.

Projected Average Operating Expense per PET Procedure

MIPNC projects the highest total expense per procedure, and NHFMC project the lowest total expense per procedure.

Comparison of Direct and Indirect Expense per Scan (Year 3)

	NHFMC	InSight	Mobile Imaging Partners	Perspective PET Imaging
Direct Expense	$1,853,477	$455,385	$1,221,335	$699,161
Indirect Expense	$127,999	$773,802	$627,426	$888,770
Total Expenses	$1,981,476	$1,229,187	$1,848,761	$1,587,931
Procedures	4,183	2,123	2,724	2,624
Direct Expense per Procedure	$443.10	$214.50	$448.36	$266.45
Indirect Expense per Procedure	$30.60	$364.49	$230.33	$338.71
Total Expense per Procedure	$473.70	$578.99	$678.69	$605.16

Form F.4; Year 3

NHFMC projects more costs for direct expenses such as staffing than any other applicant. All other applicants project more costs towards indirect expenses such as interest and management fees.

It is clear that NHFMC is devoted to ensuring that resources are directed toward expenses that impact the patient experience and quality of care. NHFMC is the most cost effective in regard to operating expenses and should be approved.

Staffing

The level of clinical staff presented by each applicant has a direct impact in terms of quality of care. In this regard, PPI does not appear to provide for sufficient clinical FTEs to support its project. It should also be noted that PPI did not include FTEs for a truck driver, as this service is contracted through a separate entity. Further, MIPNC proposes only 0.75 FTE for a truck driver to

drive a 1,110-mile travel route 7 days per week with more than one stop per day, including set-up time. 0.75 FTE is completely unreasonable for the proposed route.

Comparison of Staffing and Salary Expense

	NHFMC	InSight	Mobile Imaging Partners	Perspective PET Imaging
Nuc Med Tech	5.2	2	4.6	1.0
Salary	$ 444,474	$ 135,252	$ 396,296	$ 156,270
Tech Assistant	-	1	0	1.0
Salary	-	$ 27,267	$ -	$ 64,111
Other Clinical Support Staff	0.3	0.1	1	0
Salary	$ 35,857	$ 2,747	$ 103,382	$ -
Other Administrative Support	2.1	0.2	0.2	1.4
Salary	$ 70,192	$ 17,063	$ 22,399	$ 139,170
Truck Driver	2.00	1.00	0.75	-
Salary	$ 116,986	$ 43,281	$ 59,098	$ -
Total Salary	$ 667,509	$ 225,610	$ 581,175	$ 359,551
FTEs (without Truck Driver)	7.60	3.30	5.80	3.40
Staffing Hours per Scan	3.78	3.23	4.43	2.70

For "Other Administrative Support", PPI includes 1 FTE for a full-time marketing position at $89,959 per year and only 0.4 for administrative, and support staff. Thus, PPI is the only applicant that projects almost as much expense for administrative support as it does for clinical support. Most of PPI's administrative support expense goes towards marketing its program instead of ensuring quality of care.

PPI appears to understate its clinical FTEs. In addition, it should be noted that InSight uses Nuclear Medicine Technologist (Nuc Med Tech) Assistant for 1.0 FTE, whereas all other applicants project fully certified Nuc Med Techs.

Comparison of FTEs per Unit

	NHFMC	InSight	Mobile Imaging Partners	Perspective PET Imaging
Clinical FTEs	2.75	3.10	5.60	2.00
Non-Clinical FTEs	2.05	1.20	0.95	1.40
Total	4.8	4.3	6.6	3.4
Average Salary per Nuc Med Tech	$85,476	$67,626	$86,151	$156,270

Source: Form H, year 3

With respect to salary, InSight projects an inappropriately low annual salary per FTE, and PPI projects an inappropriately high salary per FTE. NHFMC and MIPNC project appropriate salary expense per FTE for Nuc Med Tech.

Both NHFMC and MIPNC present reasonable staffing and appropriate salaries. NHFMC projects the second highest staffing hours per scan. InSight and PPI provide either staffing and/or salary levels that are too low or inappropriate. PPI's Nuc Med Tech salary appears to be grossly overstated and unrealistic.

Physician/Clinician Support

While each applicant provides letters of support from physicians and other healthcare providers, the amount of physician/clinician support that can drive the success of the project varies among applications, as shown in the table below:

Applicant	Physician/Clinician Letters of Support	Non-Clinician Letters of Support	Total Letters of Support
NHFMC	53	0	53
InSight	4	2	6
Mobile Imaging Partners	10	2	12
Perspective PET Imaging	38	2	40

Source: PPI Application Exhibit H.4; MIPNC Application Exhibit C.4(b); InSight Application Exhibit 12; NHFMC Application Exhibit H-4.2

Note that letters of support from the host sites committing to provide the site for PET/CT services were not included in the table above in order to compare sources of referral only. All 12 of MIPNC's letters of support come from the host site organizations; no letters are provided by outside referral sources.

Based on the letters of support provided in the applications that serve as referral sources, NHFMC is clearly the more effective alternative with regard to documentation of physician support.

CONCLUSION

As the statements within this document and the summary table below establish, only NHFMC clearly meets all CON Review Criteria and the PET performance standards presenting clear and reasonable documentation through its application. Further, NHFMC is dedicated to prioritizing superior quality PET/CT services. Even if the other applicants met the CON Review Criteria and PET performance standards, which they do not, NHFMC is the best applicant on a comparative basis to ensure access to care and provide the highest level of clinical quality to its proposed host sites and ultimately to patients. NHFMC should be approved.

SUMMARY

Comparative Factor	NHFMC/Ranking		InSight/Ranking		Mobile Imaging Partners/Ranking		Perspective PET Imaging/Ranking	
Expand Geographic Accessibility	Yes	1	No	2	No	2	No	2
Equipment Quality	Siemens Biograph mCT 40	1	GE Discovery IQ	3	Siemens Biograph Horizon	2	Siemens Biograph Horizon	2
Access by Underserved Groups: *Charity Care*	1.8%	1	1.0%	2	0.2%	4	0.4%	3
Projected Average Operating Expense per PET Procedure(1)	$473.70	1	$578.99	2	$678.69	4	$605.16	3
Staffing:								
*Total FTEs**	7.60	2	3.30	3	5.80	1	3.40	4
Staff Hours per Scan	3.78		3.23		4.43		2.70	
Physician/Clinician Support	53	1	6	4	12	3	40	2

(1) *InSight does not appear to have appropriately reflected the cost of FDG in its expense and charges to host site*