Novant Health Forsyth Medical Center
Comments in Opposition to
Mobile Imaging Partners of North Carolina, 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 MIPNC 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

MIPNC's Ownership, Management are Entirely Unclear and Poorly Documented

An important part of the evaluation of MIPNC's application is to understand the ownership and operational relationship between this applicant and Alliance HealthCare Services, Inc. ("Alliance"), the owner and operator of two of the three existing mobile PET/CT units in North Carolina. First, MIPNC fails to disclose any meaningful details about the ownership relationship of MIPNC in terms of the percentage owned by Alliance and its joint venture partner, UNC Rockingham Health Care Inc. ("UNC Rockingham"). It is also unclear what role UNC Rockingham will play in the operations of the proposed mobile PET/CT services. The new applicant entity, MIPNC, will own the equipment, but it will be operated by Alliance. Other than the undisclosed ownership percentage by UNC Rockingham Health Care, UNC Rockingham does

not appear to provide any other meaningful benefit to the project and in fact appears to simply be a disguise that this is essentially an Alliance project for a third mobile PET/CT scanner in North Carolina. To the best of NHFMC's knowledge, UNC Rockingham has no experience whatsoever with respect to PET imaging generally or mobile PET imaging specifically. Other than lending its name, UNC Rockingham appears to be a straw man.

The MIPNC application claims the benefits of affiliation with Alliance, yet it fails to provide historical information for Alliance in several parts of the application. For example, the application states that Alliance will provide all of the funding for the project as owner's equity, but the application fails to provide any historical financial information for the affiliate entity that owns MIPNC or for Alliance as a whole.

Purportedly, Alliance will provide management services for MIPNC, but the management relationship is entirely unclear. MIPNC provides a Management Services Agreement (MSA) in Exhibit A.9 that is supposedly between Alliance and MIPNC, as Alliance will be the operator of the mobile PET/CT unit. A closer look at the agreement brings up several issues. First, it is unclear what parties the agreement includes. The very first line of the agreement states, *"This Management Services Agreement is made and entered between _____, a [state] [entity type] ('Facility') and Mobile Imaging Partners of North Carolina, LLC… ('LLC')…"* There is no mention of Alliance anywhere in the MSA.

The agreement goes on to list the "LLC Services and Obligations" in bullet point 4. The document indicates that the LLC (identified as MIPNC) will provide management and administrative services, equipment maintenance, supplies, technical and support personnel, and professional interpretation services. However, throughout the entire application, MIPNC indicates that Alliance will provide the aforementioned services. Further, Page 27 of the MSA states that "…without reliving LLC of any obligations under this Agreement, LLC may subcontract with other persons, corporations, or other entities to perform any particular obligation under this Agreement."

Despite the fact that the project will be fully funded by Alliance, operated by Alliance, and serve existing host sites served by Alliance, the applicant avoids providing historical financial information about the existing Alliance mobile PET/CT units through the use of a newly formed entity, MIPNC.

A lack of clarity, flaws and inconsistencies are found throughout the application. Moreover, MIPNC's application fails to meet numerous review criteria and therefore 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."

The MIPNC application is non-conforming with Criterion (1) because it does not promote quality and safety, promote equitable access, or maximize healthcare value as required by Policy GEN-3: Basic Principles.

Safety and Quality

As described above, the quality of the proposed MIPNC project cannot be separated from the historical experience of Alliance based on both ownership and operations. For many years, Alliance, part owner of the MIPNC joint venture, delivered PET/CT services on scanners that were dated and consistently in need of repair. Recall that prior to approval of Novant Health's existing mobile PET/CT program, Novant Health contracted with Alliance for many years for its mobile PET/CT needs, as Alliance was the only provider of mobile PET/CT services in the entire state. As such, NHFMC has direct experience with the level of care Alliance has provided over the past decade.

Historically, Alliance has used aging PET/CT equipment that is in frequent need of repair. In the past six years, Alliance's scanners have been down and in need of a temporary or permanent replacement at least 15 times. See **Exhibit 1** below. In fact, in 2018, Alliance requested exemption from the State to temporarily replace its PET/CT Unit 110 until repairs could be made five times in the past six months.

When Alliance was the vendor for Novant's PET/CT service, the lack of up-to-date equipment, Alliance's sole presence in the mobile PET/CT market, and the lack of capacity to expand services often caused concerns about image quality and accuracy of test results. Just recently, in 2016 and 2018, Alliance requested exemptions to permanently replace its aging equipment; however, its temporary units that are often brought back online in the event that the permanent units are down are outdated. For instance, Alliance's PET/CT Unit 44 is a 12-year-old unit that was used as the temporary replacement for PET/CT Unit 110 when it was down for repair on multiple occasions this year alone.

Although Alliance has recently updated some of its equipment, the updated scanners are from two different manufacturers: GE and Siemens. Both manufacturers produce high-quality scanners; however, it can be difficult to compare scans completed on two different types of equipment. Many patients have a baseline PET/CT study done and must come back for another scan months later in order to monitor the progression of their cancer. If a repeat patient goes to a different site affiliated with Alliance or perhaps the usual scanner at a host site is down and a temporary replacement that

is not the same model is in use, study results may vary, making it difficult to provide consistent results and ultimately impacting quality of care.

Exhibit 1
Alliance Imaging PET/CT Unit Replacement Log

Date Granted	Type of Equipment	Replacement Equipment	Reason for Replacement	Temporary or Permanent
2/15/12	PET/CT Unit 44	PET/CT Unit 110	PET/CT 44 needs to be repaired and returned in approximately 3-4 days. Unit is worn with holes and tears in the laminate posing safety concerns.	Temporary
2/17/12	PET/CT Unit 45	PET/CT Unit 110	PET/CT 45 needs to be repaired and returned in approximately 3-4 days. Unit is worn with holes and tears in the laminate posing safety concerns.	Temporary
9/18/13	PET/CT Unit 44	PET/CT Unit 63	Unit has not been operational for three days and the date of completion for repairs is uncertain. Replacing unit with PET/ CT unit 63 as temporary replacement.	Temporary
10/16/13	PET/CT Unit 45	PET/CT Unit 110	Unit requires repairs with no known date of completion. Replacing unit with PET/ CT unit 101 as temporary replacement.	Temporary
3/11/14	PET/CT Unit 45	PET/CT Unit 110	Unit requires replacement in the trailer that will take 3-4 days to complete.	Temporary
7/18/14	PET/CT Unit 45	PET/CT Unit 56	Unit requires repairs of approximately 3 weeks to complete. PET/CT unit 56 will serve as temporary replacement.	Temporary
7/21/16	PET/CT Unit 44	PET/CT Unit 53	Unit needs extensive maintenance, repairs, and upgrades. Unknown timeframe for repairs.	Temporary
12/22/16	PET/CT Unit 45	1st Scanner - Siemens Unit PE R 8272 (leased) 2nd Scanner: PET/CT Unit 110	Unit has not been operational for two days. Temporarily replace existing mobile PET/CT scanner with sequential mobile PET/CT scanners. First replacement unit will be leased; usage dates (12/26/2016-12/28/2016). PET/CT Unit 110 to be used after until PET/45 is repaired/permanently replaced.	Temporary
4/12/17	PET/CT Unit 44	PET CT Unit 171	PET/CT 44 has required frequent repairs due to age and condition. Needs permanent replacement.	Permanent
11/9/17	PET/CT Unit 45	Either Siemens PET/CT Biograph mCT S 20-NC Scanner or GE Discovery IQ 4 Ring PET/CT Scanner	PET/CT45 cannot be repaired. Existing PET/CT 110 is nine years old and has required frequent repairs. Require a permanent replacement in area.	Permanent
2/19/18	PET/CT Unit 110	PET/CT Unit 44	Unit has been out of service for two days and repair parts have been ordered.	Temporary
3/22/18	PET/CT Unit 110	PET/CT Unit 44	Unit has been out of service for two days and repair parts have been ordered.	Temporary
6/1/18	PET/CT Unit 110	PET/CT Unit 44	Unit has been out of service for two days and repair parts have been ordered.	Temporary
6/26/18	PET/CT Unit 110	PET/CT Unit 44	Unit has been out of service for two days and repair parts have been ordered.	Temporary
8/10/18	PET/CT Unit 110	PET/CT Unit 44	Unit requires maintenance such as replacement and upgrade of uninterrupted power supply.	Temporary

Source: NC DHSR Website

Although Alliance has made recent strides toward improving the quality of its equipment, it took Alliance many years to do so. Furthermore, it is clear that there are still some unresolved issues, as described above, that most certainly impact quality of care. For years, Alliance was the only mobile PET/CT provider in North Carolina with no competition. Its track record of providing outdated equipment demonstrates the difference between a provider offering PET/CT services and a vendor-only operator.

In addition, as described above, the entire Management Services Agreement is completely unclear and contradictory concerning who is responsible for the operation of the proposed project. Further, the potential to subcontract services to a third-party as described within the MSA certainly presents quality concerns.

Equitable Access

MIPNC proposes that it will promote equitable access in the delivery of healthcare services because the proposed services will be provided at hospital host sites that are committed to serve Medicare, Medicaid, and low-income patients. However, all but the UNC Rockingham proposed host site are existing Alliance host sites. Thus, eight of the nine host sites already have access to mobile PET/CT services. The proposed project simply shifts host sites from existing Alliance mobile units to the proposed MIPNC/Alliance mobile unit without expanding access, other than the UNC Rockingham site.

As will be established, MIPNC's proposed service area is completely inefficient with respect to travel distances for one mobile unit. A vast majority of MIPNC's proposed host sites are small, community hospitals in rural counties spread across the state from east to west in four of the five different HSAs. It is clear that MIPNC has cherry picked its sites from Alliance's existing routes to suggest a comparative advantage of serving rural communities instead of addressing capacity constraints, supporting growth, or promoting efficient travel routes.

Maximum Healthcare Value

MIPNC proposes a widespread, non-contiguous, and, most importantly, inefficient service area for one mobile PET/CT unit. MIPNC appears to have "engineered" a descriptively rural route without considering historical utilization trends for these providers and where capacity constraints exist. MIPNC's project does not maximize healthcare value.

Based on these issues, MIPNC'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

MIPNC fails to demonstrate the need for its proposed project as required by Criterion (3) for numerous reasons, including unsupported and unrealistic utilization projections, an inefficient and unjustified route, questionable documentation from at least one host site, and the unclear relationship between MIPNC and Alliance

MIPNC's Proposed Sites and Route Are Inefficient and Unsupported

As Alliance is one of the owners of MIPNC and all but one of the proposed host sites are currently served by an existing Alliance mobile unit, Novant Health examined the route of Alliance's current units in comparison to MIPNC's proposed route.

Exhibit 2 provides the map of Alliance's existing mobile units' routes. It is clear that each unit's route mainly covers specific regions of the state – Alliance I covers the western region and Alliance II covers the eastern region. These routes are efficient and, in general, make geographic sense.

Exhibit 2
Alliance Existing Mobile PET/CT Routes

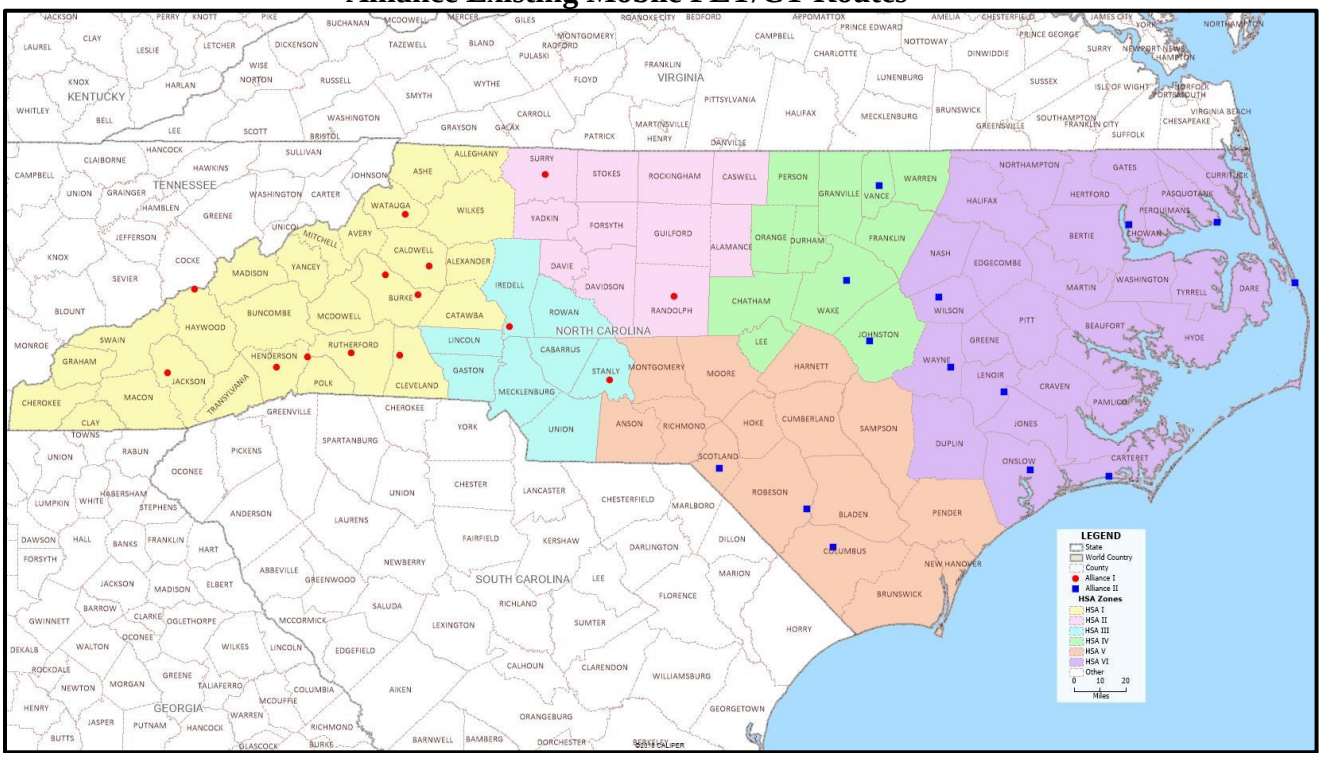
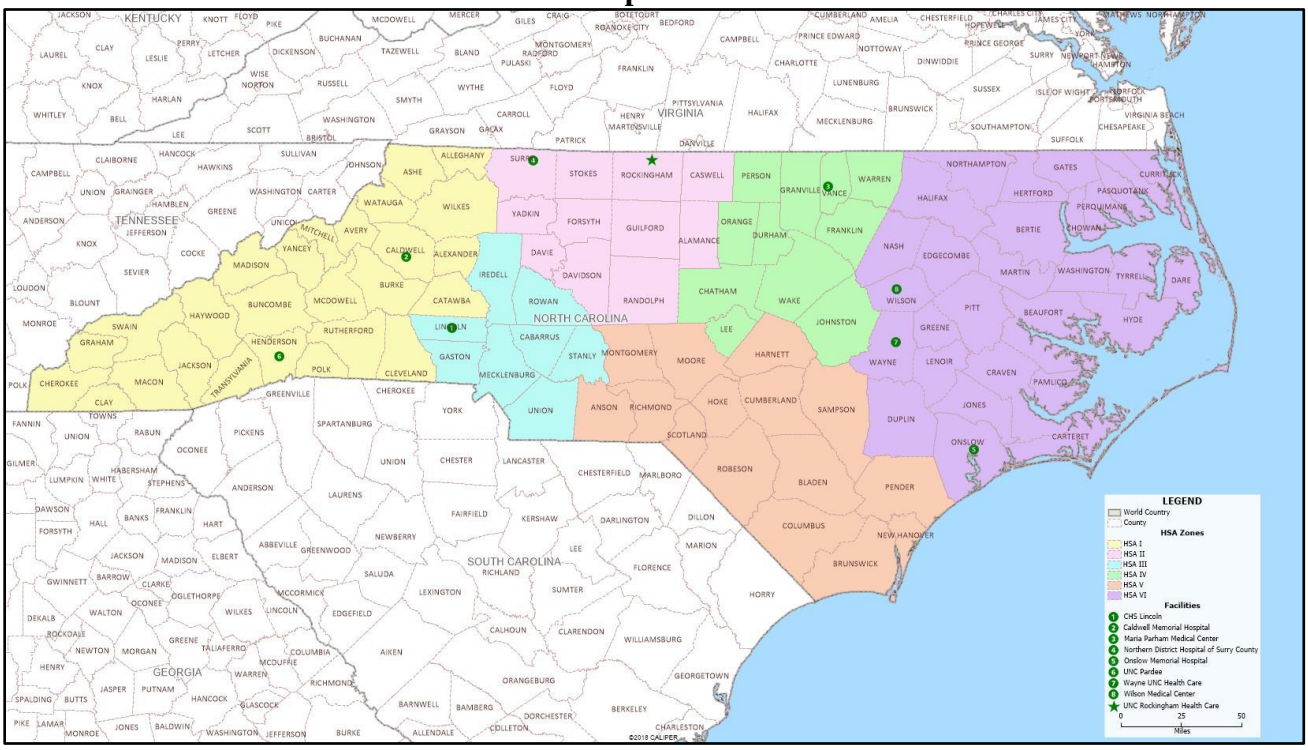


Exhibit 3 is the route for MIPNC's mobile unit. The travel route has no clear pattern, spanning over 1,000 miles on a weekly basis. The counties are widespread with only two contiguous counties included in the route. Seemingly random host sites from both of Alliance's two existing routes were gathered to form the new route.

Exhibit 3

MIPNC Proposed Route



Sites appear to have been chosen based on rural communities, to tout the "rural access" of its project; however, it is clear that there is nothing new to be offered that is not already available through existing Alliance service. While each site will be provided with more time slots, it is not clear that each host needs more capacity as will be discussed below.

MIPNC boasts its route as an advantage; however, such a large service area most certainly increases transportation costs and wear and tear on the equipment. In order to cover this area, Alliance must operate 12 hours a day/7 days a week, serving more than one site a day and traveling late at night across the state. Patients would have to fast for hours to accommodate a late evening scan. Further, any unforeseen circumstance that may arise could easily disrupt such a distant and complicated schedule, for instance, inclement weather or an accident on a major highway. A more reasonable service area would allow for flexibility to adjust when such uncontrollable issues occur. The aggressive travel route for the proposed scanner makes it more likely that the scanner and the

coach will be down for repairs on a frequent basis. The same quality issues that impacted Alliance before are likely to resurface.

Although MIPNC suggests otherwise, its project does not extend geographic access. MIPNC proposes to serve only one new site that could have easily been incorporated into Alliance's existing route. This is especially true given that Duke Raleigh, Alliance's most highly utilized site, is getting its own fixed unit in 2019. According to Alliance's Section Q form, Duke Raleigh provided 38 percent of PET/CT volume for the Alliance I mobile unit. This capacity will be available to expand capacity at existing Alliance sites and could allow Alliance to accommodate UNC Rockingham; however, there is no evidence that any of these host sites need additional capacity or are not sufficiently well served.

MIPNC has adopted an unreasonable approach in order to promote its agenda to only serve rural communities. However, a closer look at the proposed travel route reveals the major inefficiencies that will ultimately impact not only the value of healthcare but also the quality of care provided.

MIPNC's Projected Utilization is Unreasonable

In projecting its utilization by host site, MIPNC uses a consistent 5 percent annual growth rate. This rate is unsupported and wholly inconsistent with the historical trend experienced by the existing sites served by Alliance. **Exhibit 4** shows the trend in historical utilization for each existing host site as reported on Alliance's Medical Equipment Registration surveys as well as the internal data provided by MIPNC for the year end 9/30/2018. Several of MIPNC's host sites have experienced growth rates far in excess of 5 percent annual growth while others have actually experienced a decline in utilization. It is unreasonable for MIPNC to project a static 5 percent annual growth rate across all sites and then plan a route around such volumes. For example, declining sites such as Wayne Memorial Hospital and Northern Hospital of Surry County should not be projected to increase at 5 percent annually.

Exhibit 4

Comparison of Historical and Projected Utilization for MIPNC's Proposed Host Sites							
Mobile Site	**Mobile Unit**	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**CAGR% (FY 14-17)**	**Projected Growth Rate**
UNC Rockingham							5.0%
CHS Lincoln*	**?**				**NR***		5.0%
Caldwell Memorial Hospital	Alliance I	96	79	70	102	2.0%	5.0%
Margaret R. Pardee Memorial Hospital	Alliance I	164	172	191	180	3.2%	5.0%
Maria Parham Medical Center	Alliance II	56	160	88	75	10.2%	5.0%
Northern Hospital of Surry County	Alliance I	96	117	117	89	-2.5%	5.0%
Onslow Memorial Hospital	Alliance II	293	363	467	503	19.7%	5.0%
Wayne Memorial Hospital	Alliance II	303	329	348	238	-7.7%	5.0%
Wilson Medical Center	Alliance II	371	430	444	407	3.1%	5.0%
Total		1,379	1,650	1,725	1,594	4.9%	5.0%
Source: 2015-2019 SMFPs, Alliance Equipment Registration 2018.							
**Alliance does not report CHS Lincoln on its Medical Equipment Registration documents for 10/1/2016 to 9/30/2018*							

Regardless of historical experience, MIPNC projects the same rate of growth across all sites and also projects to add capacity across all sites. This is unreasonable, inefficient, and not cost effective. For example, Wayne Memorial's volume has declined by an average of 7.7 percent annually between FY2014 and FY2017, yet MIPNC is projecting to increase capacity and frequency of service to this site. MIPNC has not provided any documentation to support this assumption. MIPNC provides internal data for Alliance units for year end 9/20/2018, which has not yet been reported. (See MIPNC Application page 54.) Both Onslow Memorial Hospital and Wilson Medical Center experienced declining utilization between 2017 and 2018, yet MIPNC projects continued 5 percent annual growth.

Further calling into question the reliability of MIPNC's projections is the fact that Caldwell Memorial Hospital submitted a host site letter for another competing applicant, Insight Health Corp. As will be discussed, this letter complains about the lack of competition for mobile services with Alliance dominating access to care.

MIPNC's Projections for Alliance are Unreasonable

Like its projections for MIPNC, the projections for Alliance I and II mobile units following the implementation of the proposed MIPNC are flawed. Note in Section Q, MIPNC does not show a percent change in volume for any of the host sites served by Alliance. (See p. 110.) The same 5 percent annual growth rate is applied across all sites regardless of actual historical trend. Sites such as CHS – Blue Ridge, Harris Regional Medical Center, Randolph Hospital, and Watauga Medical Center, served by Alliance I, have all experienced declining utilization. Sites such as Scotland Memorial Hospital and Southeastern Regional Medical Center, served by Alliance II, have also experienced declining utilization. No documentation supporting the reasonableness of

a 5 percent annual growth rate at these sites was provided. Most of the growth associated with Alliance II is associated with Duke Raleigh Hospital, which will be converted to a fixed PET/CT unit in 2019. Without Duke Raleigh, Alliance II utilization increased by just 0.8 percent between FY2014 and FY 2017.

MIPNC Does not Offer an Alternative to Alliance or Provide for Competition

On page 32 of its application, MIPNC states: "[a]s a new legal entity, MIPNC offers hospitals a new choice of mobile PET/CT provider as an alternative to both Alliance Healthcare Services and Novant Health Forsyth Medical Center." This is simply not true. MIPNC reveals little to no information about the actual ownership structure of the organization. But what is provided in the application shows that MIPNC is Alliance in disguise. UNC Rockingham gave its name to the project, but it has no meaningful role in the project.

The applicant provides articles of incorporation for each member of the joint venture, but does not provide any governing documents for the joint venture itself. It is a complete mystery as to what UNC Rockingham is actually contributing to the joint venture, as Alliance is fully funding the project, providing all resources for the project, and operating the mobile unit. As previously mentioned, all but one site is an existing Alliance host site. All policies and documents (charity, host site agreements, etc.) belong to Alliance. It is not clear how this joint venture will bring anything new to the market. In fact, it is not clear what UNC Rockingham is bringing to the project at all since it has no experience whatsoever with PET imaging. It does not even serve as a host site for any existing mobile PET program. See Table 9M(2) of the 2018 SMFP, p. 138.

Essentially, MIPNC is Alliance's misleading attempt to appear to inject competition into the market as a new provider. Even MIPNC acknowledges this, making an ironic Freudian slip on page 82 of its application: *"Both existing Alliance PET/CT scanners have been replaced with new units within the past two years, so that all existing sites and the sites to be served by the proposed new **Alliance** scanner will have access to the advanced technology, faster imaging acquisition and the availability of multiple radioisotopes"*. (emphasis added).

Ironically, Caldwell Memorial Hospital, one of the proposed host sites for MIPNC and a current host site for Alliance, submitted a letter of interest to Insight Imaging, one of the competing applicants. Harris Regional Hospital, another one of Alliance's existing host sites, also submitted a letter of support as a host site for Insight. In their letters of support for Insight, Caldwell and Harris refer to Alliance as *"one provider that has been operating two mobile scanners for 15 years essentially without competition, and dominates the state."* The letters go on to state that they are seeking timely access to quality PET/CT services which would indicate that currently they do not have access to such care. Insight's application also states that other existing host sites are unhappy with their provider and are interested in Insight's services but were hesitant to provide support due

to fear of repercussions from Alliance. NHFMC has also had Alliance host sites share their concerns about the quality of services provided by Alliance and their interest in finding a new provider. Not only does this bring into question Alliance host sites' satisfaction with the quality of care provided, but it also brings into question how MIPNC will meet its projected utilization if, at minimum, two of its proposed sites are clearly looking for another mobile provider.

There is a clear need for mobile PET/CT services; however, MIPNC does not meet this need. MIPNC is *not* a new alternative provider and only perpetuates the market dominance Alliance has on the mobile PET/CT market in North Carolina. It does not expand geographic access to PET/CT services, as all but one site already has access to services. Its broad geographic service area is very inefficient, and its utilization projections are unrealistic. Lastly, the host site overlap between MIPNC, Alliance, and Insight calls into question MIPNC/Alliance host sites' satisfaction with the quality of services currently provided and MIPNC's ability to reach projected utilization. For these reasons, MIPNC 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."

MIPNC dismisses the most cost-effective alternative. As previously established, MIPNC proposes to serve only one new host site. The remaining eight host sites are existing Alliance host sites. With the additional capacity Alliance will gain when Duke Raleigh's fixed PET/CT unit becomes operational, Alliance would certainly be able to expand capacity at existing sites and provide mobile PET/CT services to UNC Rockingham. This is certainly a more cost-effective option than adding a mobile unit that travels well over 1,000 miles from site to site every week.

Based on this issue, MIPNC 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."

MIPNC's utilization projections are not based on reasonable assumptions and include a host site (Caldwell) that has expressed concern about Alliance's dominant market position in another application. These facts call into question the reasonableness of MIPNC's utilization projections, which in turn raises concerns about the reasonability of MIPNC's financial projections.

As will be described below, it appears that MIPNC has also understated the FTE associated with the truck driver position given the number of sites and distant locations for which MIPNC has planned service. As a result, staffing expense is understated.

As previously established, Alliance is providing 100 percent of the funding for MIPNC's proposed project. However, if MIPNC is a new entity, it should be clear exactly how Alliance will be providing the equipment and resources to this new entity. On page 27 of the MIPNC application, the applicant states that it will acquire the PET/CT scanner and a mobile coach; however, Exhibit C-1 says otherwise. Both the quote for the trailer and the quote from GE for the PET/CT equipment are addressed directly to Alliance, not MIPNC. Nowhere in the MSA does it indicate that Alliance will provide the equipment to MIPNC. In fact, Alliance is never even mentioned in the MSA. This point reiterates the complete ambiguity regarding the separation between Alliance and MIPNC.

As stated previously, MIPNC, despite its close connection to Alliance, fails to provide any financial information associated with Alliance's historical financial performance in North Carolina, which is to verify its availability of funding and operational financial performance. Forming MIPNC as a new applicant entity appears to be a thinly-veiled attempt to shield the historical financial performance of Alliance from any analysis or scrutiny. It cannot be determined whether MIPNC's host site charges or operating expenses are reasonable by comparison to Alliance's historical experience.

The funding documentation for MIPNC is so inextricably tied to Alliance that without more information the availability of funding and associated terms cannot be determined. The funding letter from Bank of America is to Alliance Healthcare Service, Inc. The letter specifically states the funding would be subject to the *"requirements of the existing Master Note & Security Agreement No. 18843-7000 dated March 15, 2018 (the "Loan), between Alliance Healthcare Services, Inc. and Banc of America Leasing and Capital, LLC."* It is unclear what this agreement reflects and how it may limit the use of the funds for investment in a joint venture for MIPNC. It does not appear that Bank of America was made aware that the funds are to be provided to a different entity for the proposed PET/CT scanner. Further, MIPNC does not include interest expense in its projections although it is clear that Alliance will have to pay interest on the funds received from Bank of America.

Based on these issues, MIPNC's application 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."

If MIPNC is a new entity separate from Alliance, then the proposed project is clearly a duplication of existing services. In fact, MIPNC proposes to work in tandem with existing Alliance units. As previously stated, eight of the nine proposed sites are already being served by Alliance and the proposed new site could be incorporated into Alliance's existing travel route. As discussed previously, MIPNC's projected utilization is unsupported particularly for host sites that have previously experienced little growth or even a decline in utilization. To add more capacity to these rural sites, as proposed by MIPNC, is unnecessary and duplicative, and it has not been shown that many of these sites need more capacity.

It is clear that MIPNC's project is a duplication of existing services and 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."

MIPNC proposes a very widespread service area that will require significant coordination to execute on a weekly basis. Yet 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. Both NHFMC and Insight proposed 1.0 FTE for a truck driver with much more sensible travel routes.

Based on the aforementioned issue, MIPNC 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 set forth above, using MIPNC as the applicant is merely a façade to create the impression of new competition, when in fact the exact the opposite is true. For many years, Alliance had a 100 percent monopoly on mobile PET/CT services in North Carolina, and it fought vigorously to keep its monopoly. For example, when Novant's CON application for a mobile PET/CT scanner was approved, Alliance appealed. No one should be misled into believing MIPNC is a "new" provider; every component of the proposed project is clearly controlled by Alliance. UNC Rockingham's contribution to the "joint venture" is only referred to once in the entire application on page 102: "The involvement of UNC Rockingham Health Care will provide valuable insight into the needs

of rural communities and the best way to care for their residents." This is doubtful since UNC Rockingham has no experience whatsoever with PET imaging. Moreover, the proposed host sites are located in rural communities that Alliance has served for several years. Thus, one would think that Alliance would already have insight on the best way to care for the residents they currently serve.

Alliance's documented quality issues are driven by its approach of quantity over quality – serving as many sites as possible as quickly as possible. The patients who require PET/CT services require and deserve access to coordinated care not fragmented services. MIPNC's proposed project is not cost-effective, does not improve quality, and does not improve access to the services proposed, and most certainly will not have a positive impact on competition in the mobile PET/CT market.

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

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, MIPNC's application consists of several unreasonable and unsupported project utilization assumptions that deem its projections unrealistic. Further, UNC Rockingham, part owner of the MIPNC joint venture, is affiliated with UNC Hospital as well as other UNC affiliates. While MIPNC presented a projection for all of the sites served by affiliate Alliance, it did not present a projection for all UNC affiliated sites with respect to utilization and capacity.

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*