Novant Health Forsyth Medical Center
Comments in Opposition to
InSight Health Corp.'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 InSight's application 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

While InSight is an experienced vendor of mobile services, its application is fatally flawed by the lack of support and reasonable number of host sites (only two) to appropriately support a new mobile PET/CT unit. Even the two proposed host sites are questionable in their level of commitment to use InSight's proposed unit. Without adequate host sites and reasonable volume, InSight cannot be found conforming with numerous Review Criteria and as such, cannot be approved as will be described in detail below. It is very clear that InSight's application should not even be considered in a comparative review given its fatal flaws.

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."

InSight Health Corp. ("InSight") should be found non-conforming with Criterion (1) because it does not promote quality and safety and does not maximize healthcare value as required by Policy GEN-3: Basic Principles. InSight proposes to serve only two host sites, Caldwell UNC Health Care ("Caldwell") and Harris Regional Health System ("Harris"), both of which are currently receiving mobile services through Alliance Imaging. These host sites are small community hospitals that have historically provided comparatively low utilization, as will be described below. Ultimately, the two proposed sites do not provide enough volume to support a mobile PET/CT program. In addition, a provider with only two host sites does not maximize healthcare value. The approved application responding to the need in SMFP should maximize value by expanding access to care, by serving a full schedule of sites, and adding new site locations that expand geographic access for residents of North Carolina.

<u>The proposed project does not maximize healthcare value and is not an efficient use of healthcare resources and thus, is not consistent with Policy GEN-3 and is non-conforming with Criterion (1).</u>

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."

InSight fails to demonstrate the need for its proposed project as required by Criterion (3) for several reasons, including unsupported and unrealistic utilization projections. InSight attempts to establish a need for the proposed project by citing several factors that are ultimately nothing more than smoke and mirrors.

<u>InSight Proposes Inadequate Host Sites and Unreasonable Utilization</u>

InSight only proposes to serve two host sites, and these two host sites' commitments are unreliable. As previously mentioned, InSight proposes to provide mobile services to Caldwell and Harris. Both Caldwell and Harris are currently host sites for Alliance Healthcare Services ("Alliance"), which owns two of three mobile PET/CT units in North Carolina. Ironically, Caldwell is also a proposed host site for Mobile Imaging Partners of North Carolina, LLC ("MIPNC") as shown in application F-011627-18. MIPNC is a joint venture affiliate of Alliance. Caldwell wrote a letter of

support for both MIPNC and InSight. Further, neither Caldwell's nor Harris' letter explicitly commits to becoming a host site for InSight if the project were approved. InSight even says on page 42 of its application that each host site has an interest in "potentially contracting" with InSight. The lack of explicit commitment from Harris, as well as Caldwell's ambiguity in commitment to both MIPNC and InSight, calls into question how InSight will achieve its proposed utilization.

In an attempt to mitigate the lack of commitment from host sites, InSight states that many other host sites have expressed interest in its services and that "it will receive additional requests from host sites beyond what is proposed in this application" (page 42). This is completely irrelevant, as InSight cannot speak on what requests it will receive in the future. No such expressions of interest or future commitments are documented in the application. For the purposes of this application, what matters is the current commitment from host sites that are actually contained in the application, which InSight cannot provide.

InSight Fails to Consider Actual Historical Utilization for its Proposed Host Sites

In addition to InSight's lack of committed site locations, its projected utilization is unreasonable and without supportable assumptions. As previously established, the two proposed host sites have existing access to PET/CT services which means that there is publicly available utilization data upon which the basis of projected utilization can be made. However, InSight fails to consider the historical PET/CT utilization of its two site locations in projecting future utilization. Instead, InSight completely ignores this data and undertakes an unreasonable method to project utilization at the proposed host sites; the results of which are completely unrealistic and irrational. Furthermore, InSight's two host sites would have had data available through most, if not all, of another reporting year (October 2017 to September 2018) that InSight should have considered.

Completely ignoring the actual PET/CT utilization experience of Caldwell and Harris, InSight uses a statewide use rate analysis to project total potential PET demand from the purported service area for each host site. The result in unrealistic overall utilization and unsupported patient origin projections. InSight claims to have and should have reviewed the Licensure Renewal Applications (LRA) for each site, to project more reasonable patient origin. Two pages of Harris' and Caldwell's LRA are included in Exhibit 9 to show financial accessibility; however, patient origin information is not included and disregarded. No LRA data on patient origin is included for either site, despite InSight's claims to consider such data.

While InSight may have chosen service area counties for each site from the LRA, the resultant projection of PET/CT patient origin, based on statewide use rates and unrealistic market share, is completely disconnected from historical patient origin and completely unrealistic. For example, Caldwell has historically received over 90 percent of its inpatient volume and imaging volume

from Caldwell County; however, InSight projects just 48 percent of PET/CT volume to come from Caldwell County and unrealistically high 52 percentage of patients to come from other surrounding counties.

InSight's projections also assumes completely unreasonable and unsupported levels of growth between historical PET/CT utilization for Caldwell and Harris and projected utilization. See **Exhibit 1** for a comparison of the proposed host sites' historical utilization in comparison to InSight's projected utilization. **Exhibit 2** provides the corresponding growth rates for each projection year.

Exhibit 1
InSight Host Sites' Historical and Projected Utilization

	Historical Utilization for YE 9/30				Projection for YE 12/30		
Site:	**2013-2014**	**2014-2015**	**2015-2016**	**2016-2017**	**2020**	**2021**	**2022**
Caldwell Memorial Hospital	96	79	70	102	736	898	1,076
Harris Regional Hospital	296	305	283	263	716	873	1,046
Total	**392**	**384**	**353**	**365**	**1,452**	**1,771**	**2,122**

Source: SMFPs 2015-2019, Insight CON page 110.

Exhibit 2
Comparison of InSight's Projected Growth Rates for Host Sites

	Growth Rates				
Site:	**4-Year CAGR FY 2013-FY2017**	**CAGR FY2017 to Year 1**	**% Increase Year 1 to Year 2**	**% Increase Year 2 to Year 3**	**Total CAGR for Projection Period**
Caldwell Memorial Hospital	2.04%	83.69%	22.0%	19.8%	56.6%
Harris Regional Hospital	-3.86%	36.09%	21.9%	19.8%	30.1%
Total	**-2.35%**	**52.94%**	**22.0%**	**19.8%**	**39.8%**

Source: SMFPs 2015-2019, Insight CON page 110.

InSight's proposed host sites collectively performed 365 scans from 2016 to 2017, yet InSight projects the two host sites will perform 2,122 total scans by the third year of operation. Historically, the two sites collectively experienced a decline in utilization. Caldwell experienced a slight compounded annual growth rate (CAGR) of 2.04 percent over the last 4 years, while Harris declined by 3.86 percent during the same time period. InSight projects a collective 52.9 percent annual growth rate, between the most recently reported year and the first year of operation, completely ignoring the historical utilization levels and trends. Over the projection period from year end 9/30/2017 to the third year of operation (2022), InSight projects a 954 percent growth for Caldwell and 297 percent increase for Harris for a total growth in utilization of 481 percent. The

few physician letters InSight provides alone do not support any meaningful increase in utilization. Again, these projections are complete unreasonable, unrealistic and unsupported.

In addition to ignoring historical data, InSight also projects unreasonable market shares ranging from 60 percent to 95 percent. For instance, InSight projects 80 percent market share in Haywood County in Year 3; however, there is nothing unique about InSight's service that would suggest such high market share, which clearly Harris Regional is not capturing today. Haywood County already has access to a mobile provider at Haywood Regional Medical Center as well as access to a fixed PET/CT unit and comprehensive cancer services at Mission Hospital in neighboring Buncombe County. With access to established mobile and fixed services, it is unreasonable to expect 80 percent market share within the Haywood County market. Caldwell and Harris are two, small community hospitals with 110 and 86 beds respectively. Neither site offers comprehensive oncology services that would suggest such high levels of market share. For example, Caldwell reports serving just 85 cancer patients with its linear accelerator for the year end 9/30/2017. Such a small cancer program cannot begin to support over 1,000 PET scans as projected by InSight. As such, patients in these counties are likely to travel to hospitals that offer specialized cancer treatment.

For all of these reasons, InSight's projected utilization is clearly unreasonable and unsupported. The proposed host sites cannot and will not meet the 2,080 minimum number of scans by Year 3 as required by 10A NCAC14C.3703(a)(1) Performance Standards. This fact alone should result in a finding of non-conformity with Criterion (3) and, as a result, InSight's proposed project should be denied.

Other Factors Suggesting Need are Incorrect or Meaningless

To suggest the need for its project, InSight emphasizes that the service area 65+ population is aging faster than the general population; however, the annual growth rate from 2018-2023 is not growing faster than the state average for the 65+ population. See **Exhibit 3** below.

Exhibit 3
InSight Service Area Population

Counties	2018	2019	2020	2021	2022	4-Year CAGR
Jackson	8,420	8,659	8,897	9,154	9,386	*2.75%*
Cherokee	8,669	9,008	9,325	9,608	9,890	*3.35%*
Macon	10,218	10,419	10,625	10,791	10,942	*1.73%*
Swain	2,960	3,027	3,097	3,150	3,215	*2.09%*
Haywood	15,802	16,161	16,481	16,789	17,135	*2.05%*
Caldwell	16,081	16,573	17,026	17,485	17,883	*2.69%*
Alexander	7,649	7,854	8,072	8,313	8,495	*2.66%*

Wilkes	14,986	15,386	15,779	16,156	16,526	*2.48%*
State of North Carolina	**3,345,664**	**3,461,294**	**3,579,450**	**3,697,506**	**3,815,702**	***3.34%***

Source: InSight CON page 34, NC State Office of State Budget & Management

Note that in all service area counties except for one, the 65+ population is growing at a rate significantly lower than the state average. Cherokee County is the only county where the 65+ population is growing at the same rate as the state average. But Cherokee County has less than 10,000 in population age 65+ today, and it will have less than 10,000 in population age 65+ in 2022. Essentially, the growth of the 65+ population within InSight's identified service area is not remarkable in comparison to the growth of the state overall. Thus, the population growth in InSight's service area does not support the projected demand for PET services needed to increase from 365 scans in 2016-2017 to 2,122 total scans in projected Year 3 as shown previously **Exhibit 1.**

InSight goes on to highlight the cancer incidences in the service area counties, which again, are not remarkable in comparison to other areas in the state. Further, InSight made an error in its presentation of the cancer incidence rate in Alexander County as presented on page 35 of its application. See the correct cancer incidence rates for the proposed service area in **Exhibit 4** below.

Exhibit 4
InSight Service Area Cancer Incidence Rates

County	**2012-2016**
Alexander	*418.4*
Caldwell	473.5
Cherokee	439.1
Haywood	483.6
Jackson	396.4
Macon	447.3
Swain	551
Wilkes	409.9
North Carolina	**464.6**

Source: InSight CON p. 35, NC State Center for Health Statistics, NC Cancer Registry

As shown above, only three of the eight-county service area's cancer incidence rates, in other words less than half, exceed the state's cancer incidence rate. It is clear that, overall, neither the growth and aging population, nor the cancer incidence rates in the service area counties support the demand for mobile PET services in the proposed service area. Demographic trends and incidence rates do not support the need for the proposed project.

Based on these issues, InSight's application should be found non-conforming with Criterion (3) and 10A NCAC14C.3703.

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 stated, the proposed host sites already have access to PET/CT services through an existing contract with Alliance Imaging. Although Caldwell's PET/CT volume has grown slightly over time, the actual volume is comparatively low. Contrarily, Harris has more volume, but the growth rate has decreased over the past few years by three percent annually. See **Exhibit 2** above.

Providing PET/CT services to the proposed two sites alone is not a cost-effective option and does not meet the performance standards as outlined in 10A NCAC14C.3703. If approved, the mobile unit will be severely underutilized, as can be shown when using realistic and reasonable utilization projections. Further, neither of the two proposed host sites ever explicitly commit to becoming host sites for InSight's proposed services. There are many other sites and service areas that have a greater need for new or expanded PET/CT services, but InSight submitted an application with ambiguously-worded letters from just two host sites. Thus, the proposed project is not the most effective or least costly alternative.

Based on this issue, InSight 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."

As described in detail above, InSight's utilization projections are highly overstated and unreasonable. As a result, its financial projections that rely on such utilization projections are unreliable and cannot be found to adequately demonstrate financial feasibility of the project.

InSight also understates its staffing expense both in terms of inadequate FTEs and below market salary levels as described in detail in regard to Criterion (7).

InSight projects to fund all of its capital costs through a loan with Siemens Financial Services. The funding letter that InSight provides in Exhibit 10 states that the loan will be for two million dollars; however, the amortization schedule indicates that the loan is for approximately 1.6 million dollars

in capital cost. Regardless of this discrepancy, InSight does not include any financing costs on Form F.1a, although it is clear that financing costs will occur due to the terms of the loan.

Moreover, InSight does not provide any revenue and expense information on Form F.3 for the entire company or parent organization. InSight does not provide financial statements or any information on the financial viability of the company as a whole to offset the lack of information on Form F.3. Although financial statements are not required, it is required to provide the revenue and expenses of the parent organization on Form F.3. InSight is clearly a provider of imaging services in North Carolina, and as such, its historical and projected financial performance should have been provided on Form F.3 for the "Entire Facility or Campus". The absence of any financial information on InSight, as an existing entity, coupled with the fact that InSight proposes to finance 100 percent of the capital costs, brings into question the applicant's ability the follow through with the terms of the proposed funding source in the long-term. InSight's financial feasibility is unclear, as the applicant has not provided the required documentation.

Based on these issues, InSight 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."

The proposed project is clearly an unnecessary duplication of existing PET/CT services. As previously established, the two proposed host sites already have access to PET/CT services through a contract with Alliance Imaging. Neither site is highly utilized—both are small hospitals with a comparatively low PET/CT volume and cannot support the need for a mobile unit. Without any meaningful evidence of the demand for more PET/CT services at the proposed host sites, providing half of a full-time mobile unit to each of the two sites would be completely unnecessary and duplicative of other mobile and fixed PET/CT services within or adjacent to the proposed service area.

Based on this issue, InSight 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."

InSight proposes a staff of 1.5 nuclear medicine technologists and 1 nuclear medicine technologist assistant in Year 1. Considering that InSight proposes to operate six days per week, 1.5 nuclear medicine technologists in Year 1 does not provide enough coverage to meet the safety and quality of care standards.

At $65,000 in Year 1, InSight's projected annual salary for a nuclear medicine technologist is considerably lower than the market average. The average Nuclear Medicine Technician salary in North Carolina is $72,070. More specifically, the average salary in Lenoir, NC, where Caldwell Memorial is located, is $72,424 and Sylva, NC, where Harris Regional is located, is $69,775[1].

It is clear that InSight does not project enough nuclear medicine technology staffing nor does it project an acceptable annual salary for nuclear medicine technologists. As such, InSight 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."

Given that InSight fails to identify sufficient host sites and does not reasonably or realistically project sufficient utilization to support a new mobile PET/CT unit, the proposed project will not enhance competition and will not have a positive impact on cost effectiveness, quality, and access. A poorly utilized mobile PET/CT unit serving only two sites cannot operate cost effectively and serving two sites that already have access to mobile PET/CT services will not enhance access to care.

Based on these issues, InSight'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, InSight's application consists of several unreasonable and unsupported project utilization assumptions that deem its projections infeasible. Most importantly, InSight

[1] https://www1.salary.com/NC/nuclear-medicine-technician-salary.html

proposes to "potentially contract" with two small community hospitals in HSA I that already have access to PET services through Alliance and have historically low PET volume. It is clear that InSight's proposed mobile scanner will not 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 required. Accordingly, InSight'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*