

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 29, 2019

Findings Date: May 6, 2019

Project Analyst: Bernetta Thorne-Williams

Primary Co-Signer: Lisa Pittman, Assistant Chief

Secondary Co-Signer: Martha J. Frisone, Chief

COMPETITIVE REVIEW

Project ID #: F-11627-18

FID #: 180557

Service Area: Statewide

Applicant(s): Mobile Imaging Partners of North Carolina, LLC

Project: Acquire one mobile PET/CT scanner pursuant to the need determination in the 2018 State Medical Facilities Plan

Project ID #: E-11630-18

FID #: 180563

Service Area: Statewide

Applicant(s): InSight Health Corp.

Project: Acquire one mobile PET/CT scanner pursuant to the need determination in the 2018 State Medical Facilities Plan

Project ID #: G-11640-18

Facility: Novant Health Forsyth Medical Center

FID #: 923174

Service Area: Statewide

Applicant(s): Forsyth Memorial Hospital, Inc.

Project: Acquire a second mobile PET/CT scanner pursuant to the need determination in the 2018 State Medical Facilities Plan

Project ID #: G-11647-18

FID #: 180566

Service Area: Statewide

Applicant(s): Perspective PET Imaging, LLC

Project: Acquire one mobile PET/CT scanner pursuant to the need determination in the 2018 State Medical Facilities Plan

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (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.

NC – PPI C – All Other Applications

Need Determination

The 2018 State Medical Facilities Plan (SMFP) includes a need determination for one mobile positron emission tomography (PET) scanner. Four applications were received by the Healthcare Planning and Certificate of Need Section (Agency) proposing to acquire a mobile PET scanner. However, pursuant to the need determination in the 2018 SMFP only one mobile PET scanner can be approved in this review. The Decision follows the Comparative Analysis.

Policies

There is one policy applicable to all four applications in this review.

Policy GEN-3: Basic Principles, on page 33 of the 2018 SMFP, states:

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

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC
Mobile Imaging Partners of North Carolina, LLC (MIPNC) proposes to acquire one mobile PET/CT scanner to serve nine host sites. MIPNC is a joint venture between Alliance HealthCare Services, Inc. (**Alliance**) and UNC Rockingham Health Care, Inc. (**UNC Rockingham**).

Need Determination - The applicant proposes to acquire only one mobile PET scanner.

Policy GEN-3 - In Section B.10, pages 22-26, the applicant adequately explains why it believes the application is consistent with Policy GEN-3.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more mobile PET scanners than are determined to be needed in the state.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.

Project ID #E-11630-18/InSight Health Corp.

InSight Health Corp. (**InSight**) proposes to acquire one mobile PET/CT scanner to serve two host sites.

Need Determination - The applicant proposes to acquire only one mobile PET scanner.

Policy GEN-3 - In Section B.10, pages 22-26, the applicant adequately explains why it believes the application is consistent with Policy GEN-3.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more mobile PET scanners than are determined to be needed in the state.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center (**NHFMC**), proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new). NHFMC is owned by Novant Health, Inc. (**Novant**).

Need Determination - The applicant proposes to acquire only one mobile PET scanner.

Policy GEN-3 - In Section B.10, pages 22-26, the applicant adequately explains why it believes the application is consistent with Policy GEN-3.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more mobile PET scanners than are determined to be needed in the state.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.

Project ID #G-11647-18/Perspective PET Imaging, LLC

Perspective PET Imaging, LLC (**PPI**) proposes to acquire one mobile PET/CT scanner to serve three host sites. PPI is a joint venture between Raleigh Radiology Enterprises, LLC (**Raleigh Radiology**) and Radiology Imaging Partners, LLC (**Radiology Imaging**).

Need Determination - The applicant proposes to acquire only one mobile PET scanner.

Policy GEN-3 - In Section B.10, pages 32-35, the applicant explains why it believes the application is consistent with Policy GEN-3. However, the applicant does not adequately demonstrate that the proposal would maximize healthcare value because the applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Because projected utilization is questionable, the financial feasibility of the proposal, which is based on projected utilization, is also questionable. Consequently, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended in meeting the need for a mobile PET scanner. Thus, the application is not consistent with Policy GEN-3.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

- (2) Repealed effective July 1, 1987.
- (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.

NC - PPI
C – All Other Applications

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC
 MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

MIPNC is a new legal entity and does not own or operate any PET scanners in North Carolina. However, Alliance, one of the members of MIPNC owns and operates two of the three existing mobile PET scanners in North Carolina.

MIPNC will own the proposed mobile PET/CT scanner and Alliance will operate it. The applicant states that the proposed mobile PET/CT scanner will increase services to hospital host sites in rural areas. None of the nine proposed host sites have a fixed PET scanner, however all but one offers PET services on one of Alliance’s mobile PET/CT scanners. The following table lists the host sites for the proposed MIPNC PET/CT scanner and illustrates the proposed number of slots per week at each host site.

Proposed Host Sites	City	County	Proposed # of Slots per Week
UNC Rockingham*	Eden	Rockingham	8 to 10
Northern District Hospital Surry	Mount Airy	Surry	8 to 10
Onslow Memorial Hospital	Jacksonville	Onslow	16 to 18
Wayne UNC Health Care	Goldsboro	Wayne	16 to 18
Wilson Medical Center	Wilson	Wilson	16 to 18
Maria Parham Medical Center	Henderson	Vance	8 to 10
UNC Pardee	Hendersonville	Henderson	8 to 10
CHS Lincoln	Lincolnton	Lincoln	16
Caldwell Memorial Hospital	Lenoir	Caldwell	8 to 10

Source: Section C, page 29

*UNC Rockingham does not currently offer PET services on a mobile scanner.

Patient Origin - On page 134, the 2018 SMFP defines the service area for a mobile PET scanner as, “statewide.”

In Section C, page 38, and Section Q, pages 111-112, the applicant projects PET procedures by host site, as illustrated below.

Proposed Host Site / County	1st Full Fiscal Year (FY) CY2020		2nd Full FY CY2021		3rd Full FY CY2022	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
UNC Rockingham Health Care / Rockingham	208	8.42%	218	8.40%	229	8.41%
Northern District Hospital / Surry	135	5.46%	141	5.44%	148	5.43%
Onslow Memorial Hospital / Onslow	523	21.17%	549	21.16%	576	21.15%
Wayne UNC Health Care / Wayne	401	16.23%	421	16.23%	442	16.23%
Wilson Medical Center / Wilson	417	16.88%	438	16.89%	459	16.85%
Maria Parham Medical Center / Vance	123	4.97%	130	5.01%	136	5.00%
UNC Pardee / Henderson	326	13.19%	343	13.22%	360	13.22%
CHS Lincoln / Lincoln	181	7.32%	190	7.32%	199	7.31%
Caldwell Memorial Hospital / Caldwell	157	6.35%	164	6.32%	173	6.35%
Total	2,470	100.0%	2,594	100.0%	2,724	100.0%

In Section C, page 38, the applicant states that projected procedures by host site is based on historical PET/CT patient origin percentages that were calculated using data reported in the host site's 2018 Hospital License Renewal Application (LRA). The applicant's assumptions are reasonable and adequately supported.

Analysis of Need - In Section C.4, pages 39-51, the applicant describes the factors which it states supports the need for the proposed project, including:

- The need determination in the 2018 SMFP for one mobile PET/CT scanner was triggered by the high utilization of the two existing Alliance mobile PET/CT scanners which serve 31 hospitals throughout North Carolina (see pages 40, and 45-48).
- UNC Rockingham needs to add mobile PET/CT services to provide access to diagnostic procedures and enhance its cancer services. Currently the hospital does offer fixed or mobile PET/CT services (see page 41).
- The need for additional mobile PET/CT services in mostly rural counties with a high percentage of medically underserved patients and a higher cancer incidence. The other eight projected host sites receive mobile PET/CT services ranging from one half-day on alternating weeks to one full-day on alternating weeks. The proposed PET/CT scanner will increase the availability of services in rural areas with limited access and reduce the need for patients to travel outside the county to receive PET/CT services. None of the hospitals proposed as host sites have a fixed PET scanner located within their county. The majority of the counties have an elevated cancer incidence rate which is higher than the North Carolina statewide average of 464.6 (see pages 42-43).
- Advances in radiotracers, expanded diagnostic capabilities, and changes in approved reimbursement for additional types of scans. PET/CT procedures are more precise and useful for oncology, surgical planning, radiation therapy and cancer staging (see page 44).

- Letters of support from the hospital host sites and local physicians who support the project (see Exhibit C.4(b)).

Based on review of the information provided by the applicant in Section C, pages 39-51, Section Q, and referenced exhibits, the comments received during the first 30 days of the review cycle, and the applicant’s response to the comments received at the public hearing, the applicant adequately demonstrates the need to acquire the proposed mobile PET/CT scanner.

Projected Utilization - In Section C, pages 49-50 and Section Q, Form C, the applicant provides projected utilization for the proposed mobile PET/CT scanner. The applicant provides the assumptions and methodology used to project utilization for the proposed mobile PET/CT scanner in Section Q, which are summarized below.

Assumptions for the proposed MIPNC scanner:

- Historical PET/CT utilization is based on actual utilization per host site and the 2018 SMFP.
- The fourth quarter of CY2018 is based on 25% of the previous 12 months actual utilization. Projection of this interim quarter is the result of a shift to projecting utilization on a calendar year basis rather than on a federal fiscal year (FFY) basis.
- UNC Rockingham begins its first full fiscal year at 4 scans per week with 5 percent annual growth.
- The existing host sites listed shift from Alliance to MIPNC and increase procedures at 5 percent annually due to improved scheduling capacity, expanded access and expanded PET reimbursement.

The following table illustrates historical utilization of the Alliance scanners and projected utilization of the proposed MIPNC scanner.

Host Site	Utilization of the Existing Alliance Scanners				Utilization of the Proposed MIPNC Scanner		
	FFY2016 10/1/16- 9/30/17	FFY2017 10/1/17- 9/30/18	4 th Quarter CY2018	CY2019	1st Full FY CY2020	2nd Full FY CY2021	3rd Full FY CY2022
UNC Rockingham	0	0	0	0	208	218	229
Northern District Hosp. Surry	89	122	31	128	135	141	148
Onslow Memorial	503	474	119	498	523	549	576
Wayne Memorial	238	364	91	382	401	421	442
Wilson Medical	407	378	95	397	417	438	459
Maria Parham	75	112	28	118	123	130	136
Pardee Memorial	180	296	74	311	326	343	360
CHS Lincoln	35	164	41	172	181	190	199
Caldwell Memorial	102	142	36	149	157	164	173
Total	1,629	2,052	513	2,155	2,470	2,594	2,724

Totals may not foot due to rounding.

Assumptions for the Existing Alliance Scanners:

- Historical PET/CT utilization is based on actual utilization per host site and the 2018 SMFP.
- The fourth quarter of CY2018 is based on 25 percent of the previous 12 months actual utilization. Projection of this interim quarter is the result of a shift to projecting utilization on a calendar year basis rather than a federal fiscal year (FFY) basis.
- Duke Raleigh Hospital (DRaH) was approved to operate a fixed PET/CT scanner on January 26, 2018. Assumes an increase of 5 percent annually and that the hospital will discontinue use of mobile PET/CT after five months (Oct. 1, 2018 – Feb. 28, 2019). The DRaH fixed PET/CT scanner is projected to begin serving patients on March 1, 2019. (Previous year scan volume times 1.05) times (5 months divided by 12 months) ($1,189 \times 1.05 = 1,248.45 \times 5 = 6,242.25 / 12 = 520.19$).
- Assume existing host sites will increase at 5 percent annually due to increased availability of the scanners and expanded PET reimbursement.

The following tables illustrate historical and projected utilization for the two existing Alliance mobile PET/CT scanners.

Alliance PET/CT I Host Sites	FFY2016 10/1/16- 9/30/17	FFY2017 10/1/17- 9/30/18	4 th Quarter CY2018	CY2019	1st Full FY CY2020	2nd Full FY CY2021	3rd Full FY CY2022
Randolph Memorial	135	126	32	132	139	146	153
CHS Blue Ridge.	280	232	58	244	256	269	282
CHS Cleveland Reg'l	786	696	174	731	767	806	846
CHS Stanly Regional	226	244	61	256	269	282	297
Harris Regional	263	237	59	249	261	274	288
Haywood Regional	39	171	43	180	189	198	208
Park Ridge Health	126	178	45	187	196	206	216
Rutherford Regional	127	181	45	190	200	210	220
Total	1,982	1,939 [2,065]	516	2,168	2,277	2,390	2,510

Alliance PET/CT II Host Sites	FFY2016 10/1/16- 9/30/17	FFY2017 10/1/17- 9/30/18	4 th Quarter CY2018	CY2019	1 st Full FY CY2020	2 nd Full FY CY2021	3 rd Full FY CY2022
CHS Columbia Reg'l	3	117	29	123	129	135	142
DRaH*	1,092	1,189	297	520	0	0	0
Duplin General	0	21	5	22	23	24	26
Johnston Health	195	265	66	278	292	307	322
Lenoir Memorial	126	173	43	182	191	200	210
Sentara Albemarle Hosp.	216	365	91	383	402	423	444
Scotland Memorial	115	124	31	130	137	144	151
Southeastern Regional	281	267	67	280	294	309	325
The Outer Banks Hosp.	159	152	38	160	168	176	185
Vidant Chowan	9	64	16	67	71	74	78
Carteret General Hosp.	249	390	98	410	430	451	474
Total	2,445	3,127	782	2,555	2,137	2,243	2,356

*The DRaH fixed PET/CT scanner is expected to begin services March 1, 2019.

As shown in the tables above, the applicant projects that the proposed PET/CT scanner will perform 2,724 procedures in the 3rd full FY. Collectively, the two existing Alliance PET/CT scanners and the proposed MIPNC PET/CT scanner are projected to perform 7,590 procedures during the 3rd full FY (2,724 + 2,510 + 2,356 = 7,590) or an average of 2,530 procedures per scanner (7,590 / 3 = 2,530), which exceeds the performance standards promulgated in 10A NCAC 14C .3703(a).

Projected utilization of the proposed MIPNC scanner and the existing Alliance scanners is based on reasonable and adequately supported assumptions for the following reasons:

- The 2018 SMFP identified a need for an additional mobile PET scanner.
- Utilization of the two existing Alliance scanners has been consistently increasing for a number of years (see Table 9M(2) in the 2018 SMFP).
- Continued demand for PET services is supported by projected population growth, especially in the 65+ cohort.

Access - In Section C.11, page 56, the applicant states MIPNC, “does not exclude people or treat them differently due to race, color, national origin, religion, age, disability, or sex. The proposed mobile PET/CT scanner is designed and constructed for use by handicapped persons ... [H]ost sites will provide qualified interpreters and information written in other languages for people whose primary language is not English.” In Section C.11, page 56 and Section L.3, page 97, the applicant provides the payor source for the proposed host sites, based on their 2018 LRAs, as illustrated in the table below.

Current Payor Source for Proposed Host Sites

Payor Source	UNC Rockingham	Northern Hosp.	Caldwell Memorial	Onslow Memorial	Wayne UNC	Wilson Med.	Maria Parham	Margaret Pardee	CHS Lincoln
Self-Pay, Indigent, Charity Care	11%	4%	6%	4%	8%	10%	8%	8%	0%
Medicare*	44%	31%	46%	39%	47%	42%	55%	61%	46%
Medicaid*	17%	20%	15%	19%	15%	14%	15%	8%	16%
Private Insurance*	26%	43%	11%	23%	29%	33%	22%	21%	35%
Other	3%	1%	21%	15%	1%	1%	0%	3%	3%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%

*Includes managed care plans

On page 97, the applicant states MIPNC will enter into a service agreement with each host site. The host site bills the patient or third party payor for the PET services. The radiologist bills separately for his or her professional services. The applicant states it projects future payor mix based on its historical experience and the current payor mix of existing host sites. The projected payor mix is reasonable and adequately supported.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this application for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant adequately projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately supports its assumptions.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

The following table identifies the two proposed host sites and illustrates the county of residence of the patients served by each host site.

Proposed Host Sites	
Harris Regional Hospital	Caldwell Memorial Hospital
Jackson	Caldwell
Cherokee	Alexander
Macon	Wilkes
Swain	
Haywood	

Patient Origin - On page 134, the 2018 SMFP defines the service area for a mobile PET scanner as, “statewide.” Thus, the service area for this proposal is statewide.

As a new provider of mobile PET/CT services in North Carolina, InSight has no historical patient origin to report. In Section C.3(a), page 20, and Section Q, the applicant provides the projected patient origin for the first three full fiscal years (October 1 - September 30) for the proposed mobile PET/CT scanner, as illustrated below.

County	1st Full FY FFY2020		2nd Full FY FFY2021		3rd Full FY FFY2022	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alexander	128	8.8%	158	8.9%	191	9.0%
Caldwell	351	24.2%	423	23.9%	501	23.6%
Cherokee	128	8.8%	155	8.8%	185	8.7%
Haywood	210	14.5%	261	14.7%	317	14.9%
Jackson	184	12.7%	223	12.6%	266	12.5%
Macon	150	10.4%	182	10.3%	216	10.2%
Swain	64	4.4%	77	4.3%	91	4.3%
Wilkes	236	16.3%	292	16.5%	354	16.7%
Total	1,452	100.0%	1,771	100.0%	2,123	100.0%

In Section Q, page 108-111, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need - In Section C, pages 21-41, the applicant describes the factors which it states support the need for the proposed project, including:

- *Clinical indications for PET/CT imaging* (see pages 21-25)
 - *2018 SMFP need determination* (see pages 26-28)
- The 2018 SMFP identifies a need determination for one additional mobile PET scanner statewide. The applicant states that during FY2014-FY2017, mobile PET scans increased by 23.8 percent or a compound annual growth rate (CAGR) of 7.4 percent. The applicant states that factors such as an aging population, disease and clinical practice will likely result in a continued increase in use of PET services.

- *Need for access to alternate mobile PET/CT provider* (see pages 28-32)
 The applicant states that North Carolina currently has only two providers of mobile PET services, Alliance and NHFMC. The addition of a new provider in North Carolina would offer competition, which could result in enhanced quality, lower costs and expanded access to PET services.
- *Projected population growth, especially in the 65+ cohort* (see pages 33-34)
 The applicant provides projected population through 2022 and the CAGR for the counties that it projects to serve. The applicant also provides the projected 65+ population for those same counties. The applicant states that projected population growth, particularly in the 65+ cohort, supports the need for the proposed mobile PET scanner.
- *Disease incidence* (see pages 35-40)
 The applicant provides cancer incidence and cardiovascular and Alzheimer’s disease rates for the proposed service area which it states supports a continued “*great need*” for PET services.

The information provided by the applicant in the pages referenced above is reasonable and adequately supported.

Projected Utilization - In Section Q, Form C, the applicant provides projected utilization for the proposed mobile PET/CT scanner, as shown in the table below:

	1st Full FY FFY2020	2nd Full FY FFY2021	3rd Full FY FFY2022
# of mobile PET scanners	1	1	1
Projected # of Procedures	1,452	1,771	2,123

The applicant describes the assumptions and methodology used to project utilization for the proposed mobile PET/CT scanner in Section Q, pages 105-111, which are summarized as follows:

Step 1: Project Population – The applicant obtained projected population data and calculated CAGRs for the counties to be served by each proposed host site through 2022. The CAGRs range from 1.7 percent in Cherokee County to 0.3 percent in Alexander County.

Step 2: Calculate PET Use Rates – The applicant calculated the PET use rate per thousand population from FFY2014-FFY2017, as shown in the following table.

Fiscal Year	State Population	Number of PET Procedures	Use Rate per 1,000 Population
FFY2014	9,945,642	38,251	3.85
FFY2015	10,046,467	41,663	4.15
FFY2016	10,155,942	45,006	4.43
FFY2017	10,272,692	48,066	4.68

Source: Section Q, page 106.

Regarding the PET use rates, InSight states:

- The PET use rate increased by CAGR of 6.8 percent from FFY2014-FFY2017.
- The statewide PET use rate will continue to increase due to an aging population, disease incidence and clinical practice.
- The applicant projects that the PET use rate will increase 5.5 percent annually through the third full fiscal year for the proposed project, which is less than the FFY2015-FFY2017 CAGR of 6.2 percent.

The applicant projects the following use rate from FY2018-FY2022, which is based on historical use rate, as illustrated below.

PET Use Rate per 1,000 Population	Historical	Projected				
	2017	2018	2019	2020	2021	2022
	4.68	4.94	5.21	5.49	5.80	6.12

Totals may not foot due to rounding

Step 3: Project PET Procedure Demand - The applicant projects the PET procedures for each county by dividing the projected population for each county by 1,000 and then multiplying the result by the use rates in Step 2, as illustrated in the table below.

	2018	2019	2020	2021	2022
Harris Regional Hospital					
Jackson	216	230	246	263	280
Cherokee	147	158	170	182	195
Macon	177	188	201	214	228
Swain	75	80	85	90	96
Haywood	310	330	350	373	396
Caldwell Memorial Hospital					
Caldwell	414	441	468	498	528
Alexander	191	202	214	226	239
Wilkes	350	371	393	417	442
Total	1,880	2,000	2,127	2,263	2,404

Example: Jackson County population in 2022 = 45,838 and the use rate = 6.12; $45,838 / 1,000 = 45.838 \times 6.12 = 280.5$ procedures

Step 4: Project Market Share - The applicant assumes its market share will be 60 to 75 percent in the first full fiscal year (FY2020), 70 to 85 percent in the second full fiscal year (FY2021) and 80 to 95 percent in the third full fiscal year (FY2022). The following statements regarding the projected market shares are reasonable and adequately supported:

- Harris Regional Hospital and Caldwell Memorial Hospital currently have limited access to mobile PET services.
- The applicant proposes to leverage existing PET referral relationships and develop additional referral relationships to maximize patient referrals at each host site by:
 - providing marketing support and assisting with awareness of mobile PET/CT imaging;
 - working with each facility to identify and grow the market share;
 - providing clinical education; and
 - providing reports on volumes, provider referral patterns and other market influences.
- The proposed mobile PET scanner would increase access to PET/CT services at the proposed host sites.

InSight would offer an alternative to the two existing providers. Alliance’s existing mobile PET/CT scanners are highly utilized and have been for several years. NHFMC’s existing mobile PET/CT scanner is utilized only at host sites affiliated with Novant. In counties with an existing fixed PET/CT scanner, NHFMC’s existing mobile PET/CT scanner is restricted by the requirements of Policy TE-1 to serve only host sites affiliated with Novant.

Step 5: Projected Mobile PET Procedures – The applicant applies the projected market shares (Step 4) to the projected PET procedure demand (Step 3) to determine how many procedures would be performed on the proposed PET/CT scanner, as shown in the table below.

	1st Full FY FY2020	2nd Full FY FY2021	3rd Full FY FY2022
Harris Regional Hospital			
Jackson	184	223	266
Cherokee	128	155	185
Macon	150	182	216
Swain	64	77	91
Haywood	210	261	317
Subtotal	736	898	1,076
Caldwell Memorial Hospital			
Caldwell	351	423	501
Alexander	128	158	191
Wilkes	236	292	354
Subtotal	716	873	1,046
Total	1,452	1,771	2,123

Totals may not foot due to rounding

The applicant proposes to provide three days of mobile PET/CT imaging services to Harris Regional Hospital and three days of service to Caldwell Memorial Hospital for a total of six days of mobile services during each of the first three full fiscal years. The applicant projects to perform 2,123 mobile PET procedures by the third operating year following completion of the proposed project, which exceeds the performance standards promulgated in 10A NCAC 14C .3703(a). Projected utilization of the proposed InSight mobile PET scanner is based on reasonable and adequately supported assumptions.

During the first 30 days of the review cycle, MIPNC, a competing applicant, submitted written comments about InSight's application. Attached to MIPNC's comments was an undated letter signed by Laura J. Easton, President and CEO of Caldwell UNC Health Care. In her letter, Ms. Easton states she is rescinding her September 10, 2018 letter of support for InSight's proposal and urges the Agency to approve the MIPNC application instead. In addition, three letters from physicians with the McCreary Cancer Center were also attached to MIPNC's comments rescinding their support for InSight's proposal.

In Section C, page 42, InSight indicates that it contacted more than two potential host sites, stating that:

"it received much interest from several additional potential host sites for the proposed mobile PET/CT service. However, InSight has been told by many facilities that serve as host sites for existing mobile PET services that they are wary of unforeseen consequences from the current mobile provider and do not want to risk immediate interruption of their current service."

In its response to MIPNC's comments which were presented to the Agency during the public hearing, InSight states:

"Attachment 1 of Alliance's comments includes a letter from Laura Easton, President and CEO of Caldwell UNC Health Care (Caldwell) stating, '[W]hen I provided the support letter to Insight, I was unaware that Mobile Imaging Partners of North Carolina (MIPNC) would also be pursuing CON approval for a mobile PET/CT that would increase service to our facility.' Based on this language and the fact that Alliance itself provided the letters, it is apparent that Caldwell's letter rescinding its InSight support letter was based on influence from Alliance.

As the Agency is aware, Alliance had a complete monopoly on mobile PET services in the state of North Carolina from 2002 until late 2017, and still has a monopoly except as to facilities owned by Novant Health. Therefore, the vast majority of North Carolina hospitals, physician practices or other host sites that need mobile PET services must still contract with Alliance or go without service.

Alliance's anti-competitive behavior is consistent with the predictions that InSight made in its comments to the State Health Coordinating Council (SHCC) during summer 2017. Specifically, InSight expressed great concern to the SHCC that Alliance's effective monopoly on mobile PET/CT service in North Carolina would limit a new provider's ability to obtain CON support [sic] and that language should have been added to the need determination to protect potential applicants from anti-competitive behavior. A copy of the 2017 comments are attached to this written response for reference.

...

These rescission letters should be disregarded by the Agency for two reasons. First, the submission of these letters by Alliance is an improper attempt by Alliance to amend InSight's CON application, which violates 10A NCAC 14C.0204. InSight cannot amend its own application, and neither can Alliance amend InSight's application by submitting new letters that attempt to change representations in a competing applicant's CON application already under review by the Agency.

The Agency cannot and should not allow Alliance to amend InSight's application in this way, since it would encourage similar tactics in other reviews. ...

*Second, the letters included with Alliance's competitive comments do not undermine the reasonableness of InSight's utilization projections. **It is important to note that the letters are based on the presumption that Alliance will be awarded the CON application** [sic] **to develop an additional mobile PET/CT scanner**, but there is no guarantee that Alliance will be approved in this competitive batch review. Importantly, the rescission letters do not say that Caldwell will not contract with InSight or that McCreary will not refer patients to InSight in the event that InSight is approved. Expressions of support for CON applications are not mutually exclusive, and even if Caldwell/McCreary actually would prefer that Alliance be approved over InSight, there is no reason to doubt they would contract with InSight for the mobile PET/CT service they claim to need if InSight is the approved applicant." (Emphasis in original.)*

Moreover, on July 26, 2017, InSight submitted written comments regarding the need determination for one mobile PET scanner in the Proposed 2018 SMFP, stating:

"InSight is concerned that it may be difficult for new provider applicants to secure letters of support. As the SHCC is likely aware, the CON application process, particularly for mobile services, generally requires applicants to identify the host sites and demonstrate that the host sites are willing to consider using the proposed provider."

In the summer of 2017, InSight expressed concern that it would encounter difficulties in obtaining written commitment of support for a proposal to acquire a mobile PET/CT scanner to meet the need in the SMFP. InSight states in its application as submitted that it did encounter difficulty in obtaining written commitment of support for its proposal to offer mobile PET services.

When InSight submitted its CON application, it did so reasonably believing that it had the support of Caldwell Memorial Hospital. The letters from Ms. Easton and the McCreary's physicians were not sent directly to the Agency but to MIPNC after the review had begun. One of the two owners of MIPNC and the proposed operator, is Alliance, the owner/operator of two of the three existing mobile PET scanners.

Projected utilization is reasonable and adequately supported for the following reasons:

- The 2018 SMFP identified a need for an additional mobile PET scanner.
- InSight would be a new provider of mobile PET services which would foster competition and enhance the availability of mobile PET services.
- Harris Regional Hospital and Caldwell Memorial Hospital expressed a need to increase hours of availability and provided a written commitment of support for InSight’s proposal.
- Two of the three existing mobile PET/CT scanners are highly utilized and have been since FFY2013, as shown in the table below. The third existing mobile PET/CT scanner was only in operation seven months during FFY2017.

FFY	# of Mobile PET/CT Scanners	Total # of Procedures Performed at all Host Sites Combined	Average # of Procedures / Scanner	% of Capacity (2,600 = 100%)
FFY2013	2	5,791	2,896	111.4%
FFY2014	2	5,870	2,935	112.9%
FFY2015	2	6,505	3,253	125.1%
FFY2016	2	7,159	3,580	137.7%
FFY2017*	3	7,265	2,422	93.2%
CAGR		5.8%		

Sources: Table 9M(1) in the 2018 SMFP and Proposed 2019 SMFPs

*The NHFMC mobile PET/CT scanner only operated for only seven months during FFY 2017, performing 830 procedures. The scanner served only host sites affiliated with Novant.

Given the consistently high utilization of the existing mobile PET/CT scanners, it is reasonable to assume that health care facilities will be interested in obtaining mobile PET services from InSight if the application is approved.

Access - In Section L, page 89, the applicant states that it will not bill patients and third party payors; instead it will charge the host sites a flat fee for use of the mobile PET/CT scanner. The applicant projects the following payor mix during the second full fiscal year of operation following completion of the project for the two proposed host sites, as shown below.

Payor Source	Harris Regional Hospital	Caldwell Memorial Hospital
Self-Pay, Charity Care	8.2%	6.2%
Medicare*	43.5%	45.7%
Medicaid*	12.2%	15.3%
Insurance*	33.1%	32.9%
Worker’s Comp	3.1%	0.0%
Total	100.0%	100.0%

*Includes managed care plans

Totals may not foot due to rounding

The applicant states it projected the payor mix based on the historical payor mix for outpatient visits at the proposed host sites. The projected payor mix is reasonable and adequately supported.

Conclusion - The Agency reviewed:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this application for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant adequately projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately supports its assumptions.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

NHFMC proposes to acquire the second mobile PET/CT scanner to serve four new and two existing host sites affiliated with Novant. In Section C, pages 39-40, the applicant states that the existing mobile PET/CT scanner serves five host sites. The applicant proposes to add four additional host sites and provide additional days at two existing host sites, as shown in the table below.

Existing and Proposed Host Sites	Current Mobile Days	County	Proposed Mobile Days
NH Huntersville	1.5 days per week	Mecklenburg	2.5 days per week
NH Matthews	1.5 days per week	Mecklenburg	2 days per week
NH Rowan	1.5 days per week	Rowan	-
NH Thomasville	0.5 days per week	Davidson	-
NH Kernersville	1 day per week	Forsyth County	-
NH Mint Hill	-	Mecklenburg	1 day per week
NH Oncology Specialist	-	Wilkes	1 day per week
NH Mountainview Medical	-	Stokes	1 day per week
NH Imaging University	-	Mecklenburg	1 day per week

Source: pages 40-46 of the application

Patient Origin - On page 134, the 2018 SMFP defines the service area for a mobile PET scanner as, “statewide.”

In Section C, pages 47 and 49, the applicant provides historical and projected patient origin for its fixed and mobile PET/CT services, as shown in the tables below.

County	Historical Patient Origin	
	Number of Patients	Percent of Total
Forsyth	1,427	37.6%
Davidson	337	8.9%
Surry	281	7.4%
Stokes	261	6.9%
Mecklenburg	208	5.5%
Wilkes	207	5.5%
Davie	183	4.8%
Yadkin	149	3.9%
Guilford	89	2.3%
Union	84	2.2%
Iredell	77	2.0%
Ashe	41	1.1%
Rockingham	31	0.8%
Randolph	29	0.8%
Lincoln	25	0.7%
Alleghany	20	0.5%
Cabarrus	14	0.4%
Other NC counties	69	1.8%
Out of state	124	3.3%
Total	3,800	100.0%

County	1st Full FY 4/1/20-3/30/21		2nd Full FY 4/1/21-3/30/22		3rd Full FY 4/1/22-3/30/23	
	Number of Patients	Percent of Total	Number of Patients	Percent of Total	Number of Patients	Percent of Total
Forsyth	1,552	25.9%	1,614	25.2%	1,679	24.6%
Mecklenburg	964	16.1%	1,061	16.6%	1,166	17.1%
Stokes	332	5.5%	352	5.5%	373	5.5%
Davidson	430	7.2%	452	7.1%	474	7.0%
Wilkes	263	4.4%	279	4.4%	296	4.3%
Rowan	401	6.7%	439	6.9%	480	7.0%
Surry	369	6.1%	385	6.0%	402	5.9%
Union	279	4.6%	307	4.8%	337	4.9%
Cabarrus	259	4.3%	286	4.5%	314	4.6%
Davie	208	3.5%	217	3.4%	227	3.3%
Yadkin	191	3.2%	200	3.1%	208	3.1%
Iredell	156	2.6%	169	2.6%	184	2.7%
Guilford	94	1.6%	98	1.5%	102	1.5%
Lincoln	69	1.2%	76	1.2%	84	1.2%
Ashe	43	0.7%	45	0.7%	47	0.7%
Randolph	36	0.6%	37	0.6%	39	0.6%
Rockingham	35	0.6%	37	0.6%	38	0.6%
Gaston	22	0.4%	24	0.4%	26	0.4%
Alleghany	21	0.4%	22	0.3%	23	0.3%
Catawba	17	0.3%	19	0.3%	20	0.3%
Stanly	15	0.3%	17	0.3%	18	0.3%
Guilford	14	0.2%	15	0.2%	16	0.2%
Other NC counties	63	1.1%	68	1.1%	73	1.1%
Out of state	167	2.8%	177	2.8%	188	2.8%
Total	6,001	100.0%	3,394	100.0%	6,814	100.0%

Note: NH Kernersville is on the same license as NHFMC, as such, volumes for both campuses are reported collectively. Totals may not foot due to rounding

In Section C, pages 50-51, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need - In Section C.4, pages 51-74, the applicant describes the factors which it states support the need for the proposed project, including:

- Novant and NHFMC experience - The applicant states that Novant and NHFMC provide fixed PET/CT services and through its partnership with MedQuest it also provides mobile imaging services, including mobile PET/CT services. NHFMC divides its service area into two markets: the Greater Winston-Salem Market and the Greater Charlotte Market (pages 51-56).

- **Increased Utilization of NHFMC’s PET/CT scanners** - The applicant states that prior to providing mobile PET/CT services on its own equipment, Novant contracted with Alliance for mobile PET/CT services. The table on page 57 of the application illustrates the growth at the five existing host sites from FFY2014 to FFY2018 (FFY2018 data is annualized based on 11 months of actual data), as reported on the hospital’s 2015-2018 LRAs. The applicant states that the combined growth rate for those sites was 173.1 percent over the four-year period. The applicant further states that utilization on its fixed PET/CT scanners has grown by 19 percent since 2014. (See Tables 2 and 3 on pages 57-59 of the application).
- **Improved Geographic Access** - The applicant states that the addition of the four proposed new host sites; NH Mint Hill Medical Center, NH Oncology Specialists-Wilkesboro, NH Mountainview Medical and NH Imaging University, would improve geographic access for patients.
- **Service Area Demand for Mobile PET/CT Imaging Services** - The applicant states that several factors are driving the need for additional PET/CT services in the proposed service area including: historical cancer incidence rates, expanding PET scanning capabilities, and an increase in the 65+ population. The applicant reports that HSAs II and III have a higher cancer incidence rate than other parts of North Carolina. The applicant states that of the top 10 counties with high incidence rates, five of those counties are in HSAs II and III. Those counties are Davie, Rockingham, Randolph and Forsyth all of which are located in HSA II and Rowan County which is located in HSA III (See pages 61-64 of the application).
- **Expanding PET Scan Capabilities** - The applicant states that advancements in the field of PET/CT imaging include new radiotracers and applications for non-cancer diagnosis that are expanding the demand for PET/CT services. (See pages 64-68 of the application).
- **Service Area Demographic Trends** - The applicant states that the proposed service area is growing and aging significantly. The applicant provides three tables, which illustrate the population in the service area for 2018 and the projected population of the service area by 2023 as well as the projected CAGR. The overall projected CAGR for the total population in the proposed service area is 1.3 percent. The applicant states that this exceeds the projected statewide CAGR of 1.08 percent. The most significant CAGR is projected in the 65+ cohort (33.6 percent). The 65+ cohort has the highest cancer incidence rates and is more likely to require PET/CT services.

Based on a review of the information provided by the applicant in Section C, pages 51-74, Section Q, page 136 and referenced exhibits; comments received during the first 30 days of the review cycle; and the applicant’s response to the comments received at the public hearing, the applicant adequately documents the need to acquire the proposed mobile PET/CT scanner.

Projected Utilization – In Section C, page 71 and Section Q, Form C, page 136, the applicant provides historical and projected utilization for the existing and proposed PET/CT scanners, as illustrated in the table below.

	CY2017	CY2018 Annualized	CY2019	1st Quarter CY2020	1st Full FY 4/2020- 3/2021	2nd Full FY 4/2021- 3/2022	3rd Full FY 4/2022- 3/2023
NHPMC Fixed PET/CT	1,702	2,183	2,309	611	2,479	2,623	2,776
NHFMC Fixed PET/CT	2,880	2,909	3,011	780	2,455	2,542	2,632
NH Huntersville	385	501	529	139	602	662	728
NH Matthews	372	482	508	134	579	636	699
NH Rowan	260	341	359	95	433	475	523
NH Thomasville	124	167	172	45	187	199	211
NH Kernersville	217	375	388	100	421	447	475
NH Mint Hill			150	75	333	366	402
NH Imaging University					300	333	366
NH Wilkes Oncology					305	324	344
NH Mountainview					385	409	434
Total FMC Mobile	1,358	1,865	2,106	588	3,546	3,852	4,183
Total NHFMC	4,238	4,774	5,117	1,368	6,001	6,394	6,815
NHFMC - Average # of Procedures / Unit	2,119	2,387	2,559	684	2,000	2,131	2,272
Total Novant*	5,940	6,957	7,426	1,979	8,480	9,017	9,591
Novant – Average # of Procedures / Unit	1,980	2,319	2,475	660	2,120	2,254	2,398

Source: Table 12, Section C, page 73

*Totals may not foot due to rounding

As shown in the table above, in the third full fiscal year, utilization is projected to be as follows:

NHPMC Fixed PET/CT Scanner	2,776 Procedures
NHFMC Fixed PET/CT Scanner	2,632 Procedures
NHFMC Mobile PET/CT Scanners	4,183 Procedures
NHFMC Total (3)	6,815 Procedures
Average per Scanner	2,272 Procedures
Novant Total (4)	9,591 Procedures
Average per Scanner	2,398 Procedures

The applicant projects to perform an average of 2,398 PET procedures by the third operating year following completion of the proposed project, which exceeds the performance standards promulgated in 10A NCAC 14C .3703(a).

In Section C, pages 70-74, the applicant provides its methodology and assumptions, which are summarized below:

- The first full fiscal year is projected to start April 1, 2020. Utilization in CY2019 and the first quarter of CY2020 is based on the assumptions found in Table 11 in the application. CY2018 utilization was annualized based on eight months of actual utilization.
- The following table summarizes the applicant’s assumptions from Table 11 in the application.

Location / Host Site	FFY 2014 - FFY 2018	Interim Years	1st Full FY	2 nd Full FY	3 rd Full FY	Assumptions
NHPMC *	5.8%	5.8%	5.8%	5.8%	5.8%	Historical CAGR
NHFMC *	3.5%	3.5%	3.5%	3.5%	3.5%	Historical CAGR
NH Huntersville	11%	5.5%	11.0%	9.9%	9.9%	Interim - ½ of Charlotte Region CAGR, YR 1 historical
NH Matthews	11%	5.5%	11.0%	9.9%	9.9%	CAGR, YR 2-3 90% of historical CAGR
NH Rowan	11%	5.5%	16.0%	9.9%	9.9%	Interim - ½ of Charlotte Region CAGR, YR 1 CAGR + 5% new Cancer Center, YR 2-3 90% of historical
NH Thomasville	6.9%	3.4%	6.9%	6.2%	6.2%	Interim - ½ of Winston-Salem Region CAGR, YR 1 historical
NH Kernersville	6.9%	3.4%	6.9%	6.2%	6.2%	CAGR, YR 2-3 90% of historical CAGR
NH Mint Hill			11.0%	9.9%	9.9%	Interim - Mint Hill budget, YR 1 historic region CAGR, YR 2-3 90% of historical CAGR
NH Imaging University			11.0%	.9%	9.9%	YR 1 budget based on 3 Oncologist, YR 2-3 90% of historic region CAGR
NH Wilkes Oncology		3.5%	6.9%	6.2%	6.2%	County patient origin at FMC + immigration,
NH Mountainview		3.5%	6.9%	6.2%	6.2%	Interim at FMC CAGR. YR 2-3 90% of historic region CAGR

*Fixed PET/CT scanner location

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected growth is based on historical CAGRs for the existing fixed and mobile PET/CT scanners.
- The applicant proposes to add hours of service at existing host sites and to add four new host sites.
- One of the four new sites is located in Wilkes County where PET services are not currently available.
- Projected population growth, particularly the 65+ cohort supports the assumption that utilization will continue to increase.
- Projected cancer incidence rates, particularly in HSAs II and III which are among the highest within the state, supports the assumption that utilization will continue to increase.

Access - In Section C, page 80, the applicant states,

“Existing Novant Health acute care hospitals and the existing NHFMC Mobile PET/CT Program do and will continue to provide services in a manner that is consistent with:

- *Title VI of the Civil Rights Act of 1963...*
- *Section 504 of the Rehabilitation Act of 1973...*
- *The Ge Discrimination Act of 1975...*

Novant Health hospitals fulfilled their Hill-Burton obligation.”

In Section L, page 117, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as shown below.

Payor Source	Entire Facility	Mobile PET/CT Services	NHFMC Fixed PET/CT Services
Self-Pay, Charity Care	7.8%	1.8%	2.5%
Medicare*	46.3%	66.4%	69.8%
Medicaid*	16.0%	2.8%	4.7%
Insurance*	27.8%	25.9%	21.3%
Other **	2.2%	3.0%	1.7%
Total	100.0%	100.0%	100.0%

*Includes managed care plans

**Includes Tricare, Workers Compensations, Behavioral Health, Other Government, and Institutional Accounts

Totals may not foot due to rounding

The applicant states it projected its payor mix for the mobile PET services based on its historical experience as a provider of mobile PET services. The projected payor mix is reasonable and adequately supported.

Conclusion - The Agency reviewed:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served need the services proposed in this application.
- Projected utilization is reasonable and adequately supported.

- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately supports its assumptions.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

PPI is a joint venture between Raleigh Radiology Enterprises, LLC and Radiology Imaging Partners, LLC. The proposed host sites are existing imaging facilities owned and operated by the members of PPI. The following table identifies the sites and shows the proposed schedule.

Proposed Host Site	Location	Proposed Schedule
Raleigh Radiology Blue Ridge	Raleigh, Wake County	3 days per week
Raleigh Radiology Fuquay	Fuquay-Varina, Wake County	1.5 days per week
Greensboro Imaging	Greensboro, Guilford County	1.5 days per week

Source: page 65 of the application

Patient Origin - On page 134, the 2018 SMFP defines the service area for a mobile PET scanner as, “statewide.”

Neither PPI nor its members own or operate a PET/CT scanner. The two members of PPI provide imaging services in Wake and Guilford counties at the locations proposed as the host sites for the proposed PET/CT scanner.¹ On pages 46-48, the applicant provides patient origin for the imaging services provided from September 1, 2017 to August 30, 2018 at Raleigh Radiology and from October 1, 2017 to September 30, 2018 at Greensboro Radiology. The following tables illustrate patient origin for all outpatient sites operated by each member.

**Raleigh Radiology
 Historical Patient Origin at All Sites Combined**

County	Number of Patients	Patients as a Percent of Total
Wake	135,251	87.16%
Johnston	4,739	3.05%
Harnett	2,403	1.55%
Durham	2,340	1.51%
Other NC Counties*	4,391	2.83%
Out of State	6,043	3.89%
Total	155,167	100.0%

*Includes: Alamance, Alleghany, Anson, Ashe, Avery, Beaufort, Bertie, Bladen, Brunswick, Buncombe, Cabarrus, Carteret, Caswell, Catawba, Chowan, Columbus, Craven, Currituck, Dare, Davidson, Davie, Duplin, Edgecombe, Gaston, Gates, Granville, Guilford, Halifax, Haywood, Hertford, Hoke, Hyde, Iredell, Lenoir, McDowell, Mecklenburg, Moore, Nash, New Hanover, Northampton, Onslow, Pamlico, Pasquotank, Pender, Person, Pitt, Robeson, Rutherford, Sampson, Stanley, Stokes, Surry, Swain, Tyrrell, Vance, Watauga, and Yadkin counties

¹ Both members offer imaging services at more than just the three proposed host sites in their respective service areas.

**Greensboro Radiology
 Historical Patient Origin at All Sites Combined**

County	Number of Patients	Patients as a Percent of Total
Alamance	2,038	3.07%
Forsyth	1,558	2.34%
Guilford	51,454	77.40%
Randolph	3,500	5.26%
Rockingham	4,645	6.99%
Other NC Counties*	1,588	2.39%
Out of State	1,694	2.55%
Total	66,477	100.0%

*Includes: Ashe, Brunswick, Cabarrus, Caswell, Catawba, Chatham, Cumberland, Davidson, Davie, Durham, Iredell, Lee, Mecklenburg, Montgomery, Moore, New Hanover, Orange, Person, Rowan, Stanly, Stokes, Surry, Wake, Warren, Watauga, Wayne, Yadkin counties

In Section C, pages 51-55, the applicant provides projected patient origin for the first three full fiscal years following completion of the proposed project for each host site, as illustrated in the three tables below. Counties with 25 or more projected patients in the third fiscal year are highlighted in yellow.

Raleigh Radiology Blue Ridge

County	1st Full FY 4/1/20-3/30/21		2nd Full FY 4/1/21-3/30/22		3rd Full FY 4/1/22-3/30/23	
	Number of Patients	Percent of Total	Number of Patients	Percent of Total	Number of Patients	Percent of Total
Alamance	0	0.00%	0	0.00%	0	0.00%
Beaufort	0	0.00%	0	0.00%	1	0.11%
Brunswick	0	0.00%	4	0.46%	10	0.74%
Buncombe	34	6.72%	54	6.50%	87	6.31%
Cabarrus	16	3.10%	26	3.09%	42	3.07%
Carteret	0	0.00%	0	0.00%	0	0.00%
Caswell	0	0.00%	0	0.00%	0	0.00%
Chatham	0	0.00%	0	0.00%	0	0.00%
Craven	0	0.00%	0	0.00%	0	0.00%
Dare	1	0.11%	2	0.18%	3	0.24%
Davidson	0	0.05%	0	0.06%	1	0.06%
Davie	0	0.00%	0	0.00%	0	0.00%
Duplin	7	1.31%	10	1.23%	16	1.17%
Durham	51	9.93%	78	9.46%	124	9.06%
Edgecombe	0	0.00%	0	0.03%	1	0.06%
Forsyth	0	0.00%	0	0.00%	0	0.00%
Granville	9	1.66%	13	1.59%	21	1.52%
Guilford	0	0.03%	0	0.03%	0	0.03%
Halifax	0	0.00%	0	0.00%	1	0.00%
Harnett	16	3.13%	26	3.09%	42	3.06%
Iredell	1	0.22%	3	0.36%	6	0.46%
Johnston	26	5.14%	43	5.16%	71	5.18%
Lenoir	0	0.00%	0	0.05%	2	0.13%
Mecklenburg	149	29.14%	234	28.22%	377	27.43%
Montgomery	0	0.00%	0	0.00%	0	0.00%
Moore	2	0.30%	5	0.58%	10	0.73%
Nash	1	0.16%	3	0.30%	6	0.42%
New Hanover	19	3.65%	31	3.79%	53	3.88%
Northampton	0	0.00%	0	0.01%	0	0.03%
Onslow	13	2.51%	22	2.67%	38	2.79%
Orange	0	0.00%	0	0.00%	0	0.00%
Pender	4	0.79%	7	0.87%	13	0.94%
Person	1	0.18%	2	0.23%	4	0.27%
Pitt	11	2.10%	18	2.17%	30	2.21%
Randolph	0	0.00%	0	0.00%	0	0.00%
Robeson	12	2.31%	18	2.19%	29	2.09%
Rockingham	0	0.00%	0	0.00%	0	0.00%
Sampson	4	0.85%	7	0.83%	11	0.81%
Stokes	0	0.00%	0	0.00%	0	0.00%
Surry	0	0.00%	0	0.00%	0	0.00%
Vance	6	1.10%	9	1.03%	13	0.97%
Wake	113	22.01%	186	22.43%	313	22.80%
Out of State	17	3.33%	28	3.36%	47	3.40%
Total	513	99.83%	829	99.97%	1,372	99.97%

Source: Table C.4, Projected Patient Origin for Each Service Component, pages 51-52.
 Totals may not foot due to rounding.

Raleigh Radiology Fuquay-Varina

County	1st Full FY 4/1/20-3/30/21		2nd Full FY 4/1/21-3/30/22		3rd Full FY 4/1/22-3/30/23	
	Number of Patients	Percent of Total	Number of Patients	Percent of Total	Number of Patients	Percent of Total
Alamance	0	0.00%	0	0.00%	0	0.00%
Beaufort	0	0.00%	0	0.04%	1	0.11%
Brunswick	0	0.09%	2	0.46%	5	0.74%
Buncombe	19	6.72%	29	6.50%	47	6.31%
Cabarrus	9	3.10%	14	3.09%	23	3.07%
Carteret	0	0.00%	0	0.00%	0	0.00%
Caswell	0	0.00%	0	0.00%	0	0.00%
Chatham	0	0.00%	0	0.00%	0	0.00%
Craven	0	0.00%	0	0.00%	0	0.00%
Dare	0	0.11%	1	0.18%	2	0.24%
Davidson	0	0.05%	0	0.06%	0	0.06%
Davie	0	0.00%	0	0.00%	0	0.00%
Duplin	4	1.31%	6	1.23%	9	1.17%
Durham	27	9.93%	42	9.46%	67	9.06%
Edgecombe	0	0.00%	0	0.03%	0	0.06%
Forsyth	0	0.00%	0	0.00%	0	0.00%
Granville	5	1.66%	7	1.59%	11	1.52%
Guilford	0	0.03%	0	0.03%	0	0.03%
Halifax	0	0.00%	0	0.00%	0	0.00%
Harnett	9	3.13%	14	3.09%	23	3.06%
Iredell	1	0.22%	2	0.36%	3	0.46%
Johnston	14	5.14%	23	5.16%	38	5.18%
Lenoir	0	0.00%	0	0.05%	1	0.13%
Mecklenburg	80	29.14%	126	28.22%	203	27.43%
Montgomery	0	0.00%	0	0.00%	0	0.00%
Moore	1	0.37%	3	0.58%	5	0.73%
Nash	0	0.16%	1	0.30%	3	0.42%
New Hanover	10	3.65%	17	3.79%	29	3.88%
Northampton	0	0.00%	0	0.01%	0	0.03%
Onslow	7	2.51%	12	2.67%	21	2.79%
Orange	0	0.00%	0	0.00%	0	0.00%
Pender	2	0.79%	4	0.87%	7	0.94%
Person	0	0.18%	1	0.23%	2	0.27%
Pitt	6	2.10%	10	2.17%	16	2.21%
Randolph	0	0.00%	0	0.00%	0	0.00%
Robeson	6	2.31%	10	2.19%	15	2.09%
Rockingham	0	0.00%	0	0.00%	0	0.00%
Sampson	2	0.85%	4	0.83%	6	0.81%
Stokes	0	0.00%	0	0.00%	0	0.00%
Surry	0	0.00%	0	0.00%	0	0.00%
Vance	3	1.10%	5	1.03%	7	0.97%
Wake	61	22.01%	100	22.43%	169	22.80%
Out of State	9	3.33%	15	3.36%	25	3.40%
Total	275	99.99%	448	100.01%	738	99.97%

Source: Table C.4, Projected Patient Origin for Each Service Component, pages 52-53.
 Totals may not foot due to rounding.

Greensboro Radiology

County	1st Full FY 4/1/20-3/30/21		2nd Full FY 4/1/21-3/30/22		3rd Full FY 4/1/22-3/30/23	
	Number of Patients	Percent of Total	Number of Patients	Percent of Total	Number of Patients	Percent of Total
Alamance	0	0.00%	0	0.00%	0	0.00%
Beaufort	0	0.00%	0	0.00%	0	0.00%
Brunswick	0	0.09%	1	0.40%	3	0.61%
Buncombe	0	0.00%	0	0.00%	0	0.00%
Cabarrus	15	8.65%	24	8.27%	40	7.76%
Carteret	0	0.00%	0	0.00%	0	0.00%
Caswell	0	0.00%	0	0.00%	0	0.00%
Chatham	1	0.71%	5	1.60%	11	2.23%
Craven	0	0.00%	0	0.00%	0	0.00%
Dare	0	0.00%	0	0.00%	0	0.00%
Davidson	12	7.23%	22	7.57%	39	7.57%
Davie	0	0.00%	0	0.00%	0	0.00%
Duplin	0	0.00%	0	0.00%	0	0.00%
Durham	0	0.23%	1	0.21%	1	0.19%
Edgecombe	0	0.00%	0	0.00%	0	0.00%
Forsyth	0	0.00%	0	0.00%	13	2.57%
Granville	0	0.00%	0	0.00%	0	0.00%
Guilford	73	42.5%	118	40.54%	194	37.89%
Halifax	0	0.00%	0	0.00%	0	0.00%
Harnett	0	0.00%	0	0.00%	0	0.00%
Iredell	4	2.33%	10	3.58%	22	4.36%
Johnston	0	0.00%	0	0.00%	0	0.00%
Lenoir	0	0.00%	0	0.00%	0	0.00%
Mecklenburg	34	19.73%	53	18.36%	86	16.83%
Montgomery	1	0.80%	3	0.92%	5	0.97%
Moore	0	0.12%	1	0.18%	1	0.21%
Nash	0	0.00%	0	0.00%	0	0.00%
New Hanover	1	0.84%	2	0.84%	4	0.81%
Northampton	0	0.00%	0	0.00%	0	0.00%
Onslow	0	0.00%	0	0.00%	0	0.00%
Orange	6	3.23%	12	4.27%	25	4.87%
Pender	0	0.00%	0	0.00%	0	0.00%
Person	0	0.04%	0	0.05%	0	0.05%
Pitt	0	0.00%	0	0.00%	0	0.00%
Randolph	16	9.21%	26	9.08%	44	8.70%
Robeson	0	0.00%	0	0.00%	0	0.00%
Rockingham	0	0.00%	0	0.00%	2	0.42%
Sampson	0	0.00%	0	0.00%	0	0.00%
Stokes	0	0.00%	0	0.00%	0	0.00%
Surry	0	0.00%	0	0.00%	0	0.00%
Vance	0	0.00%	0	0.00%	0	0.00%
Wake	0	0.02%	0	0.02%	0	0.02%
Out of State	7	4.26%	12	4.13%	20	3.93%
Total	170	99.99%	290	100.02%	510	99.99%

Source: Table C.4, Projected Patient Origin for Each Service Component, pages 54-55.
 Totals may not foot due to rounding.

In Section Q, Form C, pages 24-29, the applicant provides the assumptions and methodology used to project its patient origin for the proposed PET/CT procedures. See the discussion below regarding the reasonableness of the applicant’s projected patient origin.

Analysis of Need - In Section C, pages 56-63, the applicant describes the factors which it states support the need for the proposed project, as follows:

- North Carolina Cancer Rates - The applicant states the cancer incidence rates in North Carolina exceed the national average (see pages 56-58).
- Population - The applicant states that the North Carolina Office of State Budget & Management (NCOSBM) estimates that the population of the state will increase 1.1% per year from 2018 through 2023 (see pages 58- 60).
- Other Factors Driving the Demand for PET/CT services - The applicant states that increased affordability and minimally invasive technology will continue to drive the need for PET/CT services (see pages 60-62).
- Mobile PET Scanner Availability - The applicant states North Carolina has two mobile PET/CT vendors, Alliance Imaging and Novant Health. The applicant states it is virtually impossible to get time on an Alliance scanner because their utilization is so high. Additionally, the applicant states that Alliance’s cost arrangements make it difficult to provide “a sustainable low-charge service.” (See page 63).

Projected Utilization - In Section Q, Form C, the applicant provides projected utilization for the proposed mobile PET/CT scanner, as illustrated in the table below.

PPI Projected Utilization			
First Three Full Fiscal Years			
	1st Full Fiscal Year 4/1/20-3/31/21	2nd Full Fiscal Year 4/1/21-3/31/22	3rd Full Fiscal Year 4/1/22-3/31/23
Projected Procedures	961	1,567	2,624

Source: Section Q, page 43

In Section Q, the applicant provides its methodology and assumptions, which are summarized below. There are 20 steps.

PPI’s projected “target area” consists of the following 42 counties:

Alamance	Edgecombe	Northampton
Beaufort	Forsyth	Onslow
Brunswick	Granville	Orange
Buncombe	Guilford	Pender
Cabarrus	Halifax	Person
Carteret	Harnett	Pitt
Caswell	Iredell	Randolph
Chatham	Johnston	Robeson
Craven	Lenoir	Rockingham
Dare	Mecklenburg	Sampson
Davidson	Moore	Stokes
Davie	Montgomery	Surry
Duplin	Nash	Vance
Durham	New Hanover	Wake

“Step 1: Obtain North Carolina Population by County by Year, 2015 through 2023.” See Table 2 on pages 3-5 in Section Q.

“Step 2: Obtain PET Procedures Performed in North Carolina, by Patient County Origin, 2015-2017.” See Table 3 on pages 6-7 in Section Q.

“Step 3: Calculate the North Carolina PET Use Rates by County for 2015-2017.” See Table 4 on pages 8-9 in Section Q.

“Step 4: Determine the Historic Pattern of North Carolina PET Procedure Use, 2015-2017 and Select Basis for Forecasting Future Need.” See Table 5 on page 10 and Table 6 on page 11 in Section Q.

“Step 5: Estimate PET Patients by North Carolina County by Year, 2020-2023.” See Table 7 on pages 12-13 in Section Q.

“Step 6: Determine the Projected In-migration of PET patients from other states to North Carolina PET scanners, 2020-2023.” See Figure 1 and Table 8 on page 14 in Section Q.

“Step 7: Estimate the Number of Outpatient PET Patients served in North Carolina, 2020-2023.” See Table 9 on pages 16-17 in Section Q.

“Step 8: Estimate the Unmet Need for PET Patient Scans by County for the years 2020-2023” (emphasis in original). See Table 10 on pages 18-19 in Section Q.

The applicant estimates future unmet need by subtracting the actual number of PET procedures performed in 2017 (Step 2) from the outpatient PET procedures projected to be performed through the third full fiscal year (Step 7).

The applicant assumes that the number of PET procedures performed by the existing providers in 2017 will not increase through 2023. However, the applicant does not adequately demonstrate in the application as submitted that this is a reasonable and adequately supported assumption. In Step 4, the applicant states that it assumes that the use rate per 10,000 population will continue to increase and that the total number of PET procedures will continue to increase. The applicant does not adequately explain why the utilization of the existing providers would remain constant under those circumstances.

“Step 9: Adjust the Projected Unmet Need for Outpatient PET Scans in North Carolina for the Proposed New Duke Raleigh PET Patients Served, 2020-2023.” See Table 11 on page 21 and Table 12 on pages 22-23 in Section Q.

“Step 10: Obtain Patients Origin of Host Site Entities.” See Table 13 on pages 25-26 and Table 14 on pages 27-28 in Section Q.

“Step 11: Determine Target Area Counties.” See Table 15 on pages 29-30 and Table 16 on page 31 in Section Q.

After reviewing historical patient origin for the proposed host sites during the last 12 months, the applicant determined that any county with 25 or more patients showed *“a trend of regular use of host site entities for imaging services.”* The applicant excluded any county where there were 24 or fewer patients in the past 12 months. However, the applicant does not adequately demonstrate in the application as submitted that it is reasonable to assume that 25 patients per year is a *“trend of regular use.”* Particularly, since 25 patients represents only 0.01% of total patients for all imaging facilities combined (221,644). To illustrate how *de minimis* 25 patients is, it would take 2,216 patients ($0.01 \times 221,644 = 2,216$) to equal just 1% of total patients and 4,433 patients to equal just 2% of total patients ($0.02 \times 221,644 = 4,433$).

“Step 12: Determine the Estimated Outpatient PET Patient Need at the Estimated State Use Rate by Target Area County by Year, 2020-2023.” See Table, 17 on pages 32-33 in Section Q

“Step 13: Determine the Estimated Unmet Outpatient PET Patient Need at the 2020 State Use Rate by Target Area County by Year, 2020-2023.” See Table 18 on pages 34-35 in Section Q.

“Step 14: Estimate the Outpatient PET Patient Unmet Need Absorbed by Existing Providers.” See Tables 19-22 on pages 36-38 in Section Q.

The applicant states in Section Q, page 36, that some existing providers of PET services currently serving the 42 target counties have excess capacity. The applicant states it *“allowed for providers that had capacity and whose caseload showed a pattern of growth through 2017 to continue growing.”* See Tables 19, 20, 21 and 22 on pages 36-38 in Section Q.

“Step 15: Estimate Capacity of the New Mobile PET Scanner.” See Table 23 on page 39 and Table 24 on page 40 in Section Q.

“Step 16: Estimate PPI Market Share of the Outpatient PET Scan Patients in the Target Area Counties, First Three Operating Years 2021-2023.” See Table 25 on page 41 in Section Q.

The applicant projects the following market shares:

1 st Full FY	35%
2 nd Full FY	45%
3 rd Full FY	60%

On page 41 in Section Q, the applicant states that its assumptions for the projected market share percentages are based on the following:

- *“The applicant will be a new provider in the market and case volume will build in proportion to need and capacity of the proposed sites.*
- *It is reasonable to assume that utilization of the new scanner will grow over time, because of availability and the proposed value proposition. At this time, PPI proposes to offer the only host sites in the state that will be reimbursed as freestanding radiology imaging centers.*
- *Patients will continue a demonstrated pattern of coming to the host sites, and physicians’ referrals to these host sites will continue.*
- *The applicant therefore proposes to serve a reasonable portion of the unmet need.”*

However, the applicant does not adequately demonstrate in the application as submitted that its assumption that there is a *“demonstrated pattern of coming to host sites”* is reasonable and adequately supported. See discussion below.

In Table 25 on page 41 in Section Q, the applicant projects the total number of PET procedures to be performed on the proposed PPI PET/CT scanner, as shown below.

	FY1 2021	FY2 2022	FY3 2023
Total Remaining Unmet Need in Target Counties (Table 22)	2,649	3,361	4,221
PPI Market Share of Target Counties	35.0%	45.0%	60.0%
Total PPI Scans	927	1,512	2,532

On page 42 in Section Q, the applicant states it based the projected procedures in Table 25 on the following:

- *“Utilization grows gradually over time. Market share is applied to the net unmet need after adjusting for patients that would be served by existing providers. ...*
- *The Step 14 outpatient unmet PET need is reasonable.*
- *The target area reasonably reflects demonstrated patient referral patterns to the two host site providers.*
- *Market share of the conservatively forecast total PET scans in the state for 2023, 4 percent (2,532/63,011), is very reasonable, in light of the proposed locations, the value basis of the proposed equipment and billing arrangements, referring physician and payor interest in*

the proposed project. Some fixed PET scanners in the state consistently operate at low volumes.” (Emphasis in original.)

However, the applicant does not adequately demonstrate in the application as submitted that its assumptions regarding market share are reasonable and adequately supported. See discussion below about the counties included in the applicant’s service area.

“Step 17: Adjust the Total Annual PPI Scans to include Out-of-State Patients 2021-2023.” See Table 26 on page 43 in Section Q.

“Step 18: Estimate the PET Patient Origin from Target Area Counties 2021-2023.” See Table 27 on pages 44-45 in Section Q.

“Step 19: Estimate PET Patient Origin by Target Area County by Host Site 2021-2023.” See Table 28 on pages 46-47 in Section Q.

On page 47, the applicant states the assumptions for the projected patient origin by county, by host site, is based on the following:

- *“That historical patterns reasonably represent future patterns.*
- *That the unmet need will be addressed in proportion to the historical patterns of the two host providers.*
- *With Raleigh Radiology, the days available on a four-week cycle divides one-third to Fuquay-Varina, and two-thirds to Blue Ridge. ...*
- *The proportions would remain constant all three years.”*

“Step 20: Test PET Host Site Capacity to Accommodate Estimated Patients.” See Table 29 on page 49 in Section Q.

However, the applicant does not adequately demonstrate in the application as submitted that projected utilization is based on adequately supported assumptions for all the following reasons:

- The applicant reviewed historical patient origin data for all imaging services provided at all Raleigh Radiology and Greensboro Radiology sites during the past 12 months. After reviewing the data, the applicant determined that any county with 25 or more patients showed *“a trend of regular use of host site entities for imaging services.”* In determining which counties to include in its “target area counties,” the applicant excluded any county where there were 24 or fewer patients in the past 12 months. However, the applicant does not adequately demonstrate in the application as submitted that it is reasonable to assume that 25 patients per year is a *“trend of regular use,”* given that, during the most recent 12 months, a total of 221,644 imaging procedures were performed at these sites. Twenty five (25) patients represents only 0.01% of total patients. It would take 2,216 patients ($0.01 \times 221,644 = 2,216$) to equal 1% of total patients and 4,433 patients to equal 2% of total patients ($0.02 \times 221,644 = 4,433$). The applicant includes Mecklenburg and Buncombe counties in its “target area counties.” However, the 178 Mecklenburg County residents that received services equals only 0.08% ($178 / 221,644 = 0.0008$) of the total. The 39

Buncombe County residents that received services equals only 0.02% of the total (39 / 221,644 = 0.0002).

- The applicant projects that residents of 42 counties (“target area counties”) would utilize the proposed mobile PET/CT scanner at one of three host sites located in either Guilford or Wake counties. However, the applicant does not adequately demonstrate in the application as submitted that it is reasonable to assume that residents of all the 42 counties included in the applicant’s “target area counties” would travel from where they live to one of the proposed host sites. The primary reason for making technology mobile is for the technology to travel to sites that do not have it or are unable to generate enough volume to support fixed technology of their own.
 - *Mecklenburg County.* In the 3rd Full FY, the applicant assumes that 580 residents of Mecklenburg County will drive to Wake County for a mobile PET/CT procedure. There are three existing fixed PET/CT scanners located in Mecklenburg County: two at Carolinas Medical Center (CMC); and one at Novant Health Presbyterian Medical Center (PMC). During FFY 2017, the utilization rate for the two PET/CT scanners at CMC was 68.9% and the one PET/CT scanner at PMC was 57.03%. In contrast, the applicant assumes that only 482 Wake County residents will utilize the mobile PET/CT scanner at one of the two host sites located in Wake County, which is 98 fewer Wake County patients than Mecklenburg County patients.
 - *Buncombe County.* In the 3rd Full FY, the applicant assumes that 134 residents of Buncombe County will drive to Wake County for a mobile PET/CT procedure. There is one existing fixed PET/CT scanner located in Buncombe County. During FFY 2017, the utilization rate for the Buncombe County PET/CT scanner was 68%. Residents of Buncombe County would have to drive more than 200 miles² to the Wake County host sites. Assuming these residents take I-40, they would have to drive past 11 fixed PET/CT scanners in six counties³ along I-40 that have capacity. Moreover, the patients would have to drive past the applicant’s proposed host site in Greensboro.
- The applicant assumes that the number of PET procedures performed by the existing providers in 2017 will not increase through 2023. However, the applicant does not adequately demonstrate in the application as submitted that this is a reasonable and adequately supported assumption. In Step 4, the applicant states that it assumes that the use rate per 10,000 population will continue to increase and that the total number of PET procedures will continue to increase. The applicant does not adequately explain why the utilization of the existing providers would remain constant under those circumstances.

² According to the 2013-2014 Official State Transportation Map of North Carolina, the distance between Asheville and Raleigh is 241 miles.

³ The counties include: Catawba (1), Forsyth (3), Guilford (2), Alamance (1), Orange (2), and Durham (2).

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

Based on that review, the Agency concluded that the application is not conforming to this criterion for the following reasons:

- The applicant did not adequately identify the population to be served.
- The applicant does not adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is not reasonable and is not adequately supported.

Access - In Section C.11, page 70, the applicant states,

“All procedures will be performed at physician offices initially ... Therefore, all existing policies pertaining to financial and nondiscrimination policies that address facility access for low-income, uninsured, underinsured, racial, and ethnic minorities, women, elderly, and persons with disabilities pertain to PET scanner patients served by the applicant’s equipment. The applicant will only provide services to sites with non-discriminating policies”

In Section L, page 121, the applicant projects the following payor mix during the second full fiscal year (FY) of operation following completion of the project for its mobile PET/CT services, as shown below.

Payor Category	Raleigh Radiology	Greensboro Radiology	Proposed Mobile PET/CT Services
Self-Pay	3.6%	1.2%	2.4%
Charity Care	0.1%	0.5%	0.4%
Medicare*	30.1%	41.3%	58.0%
Medicaid*	3.7%	4.2%	3.9%
Insurance*	60.3%	51.0%	34.0%
TRICARE	1.3%	0.5%	0.9%
Workers Comp	0.5%	0.8%	0.4%
Total	100.0%	100.0%	100.0%

*Includes managed care plans

The applicant states it projected payor mix for the proposed mobile PET/CT scanner based on its historical experience providing imaging services and the current payor mix of existing host sites. The projected payor mix is reasonable and adequately supported.

Conclusion - The Agency reviewed:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is nonconforming to this application for the following reasons:

- The applicant does not adequately identify the population to be served.
 - The applicant does not adequately explain why the population to be served needs the services proposed in this application.
 - Projected utilization is not based on reasonable and adequately supported assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA - All Applications

None of the applicants propose to reduce or eliminate, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to any applications in this review.

- (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.

**NC – PPI
C – All Other Applications**

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC
MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

In Section E, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- **Maintain the Status Quo** - The applicant states that maintaining the status quo is not the most effective alternative because of the current limited capacity for new mobile PET host sites. Additionally, the 2018 SMFP identified a need for an additional mobile PET scanner. Therefore, maintaining the status quo is not the least costly or most effective alternative.

- Only serve a few high volume host sites that average 400+ annual scans. The applicant states this alternative would fail to adequately improve geographic access statewide. Therefore, this alternative was not considered to be the most effective alternative.

After considering the above alternatives, the applicant determined the proposed project is the most effective alternative to meet the need identified in the 2018 SMFP.

Conclusion - The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- There is a need determination in the 2018 SMFP for an additional mobile PET scanner.
- The application is conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative.

The Agency reviewed:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all of the reasons stated above.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

In Section E, pages 58-60, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- **Maintain the Status Quo** - The applicant states that maintaining the status quo is not the most effective alternative because the number of PET scans in North Carolina has consistently increased. During FY2014-FY2017, the number of mobile PET scans increased at a CAGR of 7.4 percent. Additionally, the 2018 SMFP identified a need for an additional mobile PET scanner. Therefore, maintaining the status quo is not the least costly or most effective alternative.
- **Locate the mobile PET/CT scanner at other host sites** - The applicant states several medical facilities expressed an interest in adding to or changing their existing mobile PET services contract. The applicant, however, does not have documentation from those providers. The applicant states, *“InSight is confident that if awarded the CON to develop a mobile PET/CT service in North Carolina, it will receive additional requests from host sites beyond what are proposed in this application.”*

After considering the above alternatives, the applicant determined the proposed project, to acquire one mobile PET/CT scanner pursuant to the need determination in the 2018 SMFP, is the most effective alternative to meet the identified need.

Conclusion - The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- There is a need determination in the 2018 SMFP for an additional mobile PET scanner.
- The application is conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative.

The Agency reviewed:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all of the reasons stated above.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

In Section E, pages 93-94, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo - The applicant states that maintaining the status quo is not the most effective alternative because doing nothing would not improve access. Additionally, the 2018 SMFP identifies a need for an additional mobile PET scanner. Therefore, maintaining the status quo is not the least costly or most effective alternative.
- Convert the existing fixed PET/CT scanner to mobile - The applicant states this is not a feasible alternative because the existing fixed PET/CT scanner is highly utilized. Additionally, converting the fixed PET/CT scanner to a mobile unit would not address the need for additional PET services across the state.

After considering the above alternatives, the applicant determined the proposed project is the most effective alternative to meet the need identified in the 2018 SMFP.

Conclusion - The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- There is a need determination in the 2018 SMFP for an additional mobile PET scanner.
- The application is conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative.

The Agency reviewed:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all of the reasons stated above.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

In Section E, pages 81-84, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- **Maintain the Status Quo** - The applicant states that maintaining the status quo is not the most effective alternative because to do nothing would not improve access to mobile PET services statewide. Additionally, the 2018 SMFP identified a need for an additional mobile PET scanner. Therefore, maintaining the status quo is not the least costly or most effective alternative.
- **Choose Different Equipment or Isotope Vendors** – Adding the CT component to the PET scanner provides essential anatomic location data to associate with the nuclear metabolic data from the PET. The applicant could have selected less expensive, refurbished equipment, but opted on new equipment that would provide high quality image resolution. Selecting refurbished equipment lacking the CT component is not the least costly or most effective alternative.
- **Apply for a fixed PET/CT scanner in the 2019 SMFP** - The 2019 SMFP identified a need for one fixed PET scanner in HSA IV. However, a fixed PET scanner does not move, whereas, the proposed mobile PET/CT scanner has the potential to reach residents of 72 percent of North Carolina counties based on the historical experience at the three proposed host sites. Therefore, this alternative was not considered to be the least costly or most effective alternative to address the need for additional PET/CT capacity statewide.
- **Choose Different Locations for Service** – On page 82, the applicant explains why it believes that “*the “alternative of taking the mobile scanner to multiple remote sites [sic] less effective, at least initially.”*” The applicant states that one factor that makes this alternative more costly is the cost of transporting the trailer. Limiting the distance travelled by the trailer reduces operating expenses and increases the frequency of availability to the three proposed host sites. The applicant believes that patients will travel to the proposed host sites based on the historical experience of “*reaching 72 percent of the counties in the state.*” Therefore, the applicant concluded that the “*multiple site approach*” is not the least costly or most effective alternative.

After considering the above alternatives, the applicant determined the proposed project as represented in the application to acquire one mobile PET/CT scanner, pursuant to the need determination in the 2018 SMFP, is the most effective alternative to meet the identified need.

Conclusion - The applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The applicant states it considered other locations for service but determined that, at least initially, that alternative was not the least costly or most effective alternative. However, the primary reason for making technology mobile is for the technology to travel to sites that do not have it or are unable to generate enough volume to support fixed technology of their own. Moreover, the applicant does not adequately demonstrate that its assumption that residents of the 42 counties included in its “target area counties” would travel to either Greensboro, Raleigh or Fuquay-Varina for mobile PET services.
 - Buncombe County: In the 3rd Full FY, the applicant assumes that 134 residents of Buncombe County will drive to Wake County for a mobile PET/CT procedure. There is one existing fixed PET/CT scanner located in Buncombe County. During FFY 2017, the utilization rate for the Buncombe County PET/CT scanner was 68%. The applicant projects that residents of Buncombe County would drive more than 200 miles⁴ to host sites in Wake County to access the proposed mobile PET/CT scanner. Assuming these residents take I-40, they would have to drive past 11 fixed PET/CT scanners in six counties⁵ along I-40 that have capacity. Moreover, the patients would have to drive past the applicant’s proposed host site in Greensboro.
 - Mecklenburg County: In the 3rd Full FY, the applicant assumes that 580 residents of Mecklenburg County will drive to Wake County for a mobile PET/CT procedure. There are three existing fixed PET/CT scanners located in Mecklenburg County: two at Carolinas Medical Center (CMC); and one at Novant Health Presbyterian Medical Center (PMC). During FFY 2017, the utilization rate for the two PET/CT scanners at CMC was 68.9% and the one PET/CT scanner at PMC was 57.03%. In contrast, the applicant assumes that only 482 Wake County residents will utilize the mobile PET/CT scanner at one of the two host sites located in Wake County, which is 98 fewer Wake County patients than Mecklenburg County patients.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

⁴ According to the 2013-2014 Official State Transportation Map of North Carolina, the distance between Asheville and Raleigh is 241 miles.

⁵ The counties include: Catawba (1), Forsyth (3), Guilford (2), Alamance (1), Orange (2), and Durham (2).

- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for all of the reasons stated above.

- (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.

NC - PPI
C - All Other Applications

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC

MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

Capital and Working Capital Costs - In Section Q, Form F.1a, the applicant provides the total capital cost for the proposed project, as follows:

Medical Equipment	\$1,737,512
Other (Taxes & Miscellaneous)	\$122,488
Total Capital Cost	\$1,860,000

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 74, the applicant states there will be no start-up expenses associated with the proposed project. However, the applicant projects initial operating expenses of \$200,000 for a total working capital of \$200,000.

Availability of Funds - In Section F, page 72, the applicant states the capital costs for the proposed project will be funded as shown in the table below.

Sources of Capital Cost Financing	Amount
Loans	
Accumulated reserves or Owner's Equity	\$1,860,000
Bonds	
Other (Specify)	
Total	\$1,860,000

In Section F, page 75, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital	Amount
Loans	
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$200,000
Lines of credit	
Bonds	
Total	\$200,000

As shown in the tables above, in Section F, the applicant states that the capital and working capital needs of the project will be funded with cash or cash equivalents or accumulated reserves. However, in Section F, the applicant does not identify who will be providing the cash and cash equivalents or accumulated reserves. The applicant includes a letter in Exhibit F.3 from the Vice President of Finance for Alliance Healthcare Services, Inc. committing up to \$1,860,000 in accumulated reserves for the capital costs of the proposed project and an additional \$200,000 for the working capital needs. Based on documents in Exhibit F.3, Alliance, one of the members of MIPNC, will be borrowing the money that it proposes to use to finance the capital and working capital needs of the project.

Financial Feasibility - The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years, as shown in the table below.

	1 st Full FY CY2020	2 nd Full FY CY2021	3 rd Full FY CY2022
Total Procedures	2,470	2,574	2,724
Total Gross Revenues (Charges)	\$2,351,440	\$2,450,448	\$2,593,248
Total Net Revenue	\$2,322,047	\$2,419,817	\$2,560,832
Average Net Revenue per Procedure	\$940	\$940	\$940
Total Operating Expenses (Costs)	\$1,626,136	\$1,806,803	\$1,848,757
Average Operating Expense per Procedure	\$658	\$702	\$679
Net Income	\$695,911	\$613,014	\$712,075

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion - The Agency reviewed the:

- Application
- Exhibits in the application
- Written comments

- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposed project.
- The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

Capital and Working Capital Costs - In Section Q, Form F.1a, the applicant provides the total capital cost for the proposed project, as follows:

Medical Equipment	\$1,542,157
Consultant Fees	\$55,000
Other (contingency)	\$20,000
Total Capital Cost	\$1,617,157

In Section F, page 61, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 63-64, the applicant states there will be start-up expenses of \$10,000 and initial operating expenses of \$45,000 for a total working capital of \$55,000.

Availability of Funds - In Section F, page 62, the applicant states the capital costs for the proposed project will be funded as shown in the table below.

Sources of Capital Cost Financing	Total
Loans	\$1,617,157
Accumulated reserves or Owner's Equity	
Bonds	
Other (Specify)	
Total	\$1,617,157

In Section F, page 64, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital	Amount
Loans	\$55,000
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	
Lines of credit	
Bonds	
Total	\$55,000

Exhibit F.10 contains a letter dated October 31, 2018 from the Regional Finance Manager for Siemens Financial Services, Inc., agreeing to provide financing up to \$2,000,000 for the capital and working capital costs of the proposed project. The financing term is projected to be 5 years. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital costs of the proposed project.

Financial Feasibility - The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years, as shown in the table below.

	1 st Full FY FY2020	2 nd Full FY FY2021	3 rd Full FY FY2022
Total Procedures	1,452	1,771	2,123
Total Gross Revenues (Charges)	\$1,059,869	\$1,321,635	\$1,620,232
Total Net Revenue	\$1,046,620	\$1,305,115	\$1,599,979
Average Net Revenue per Procedure	\$721	\$737	\$754
Total Operating Expenses (Costs)	\$1,008,634	\$1,173,417	\$1,229,187
Average Operating Expense per Procedure	\$695	\$663	\$579
Net Income	\$37,986	\$131,698	\$370,793

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion - The Agency reviewed the:

- Application
- Exhibits in the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposed project.
- The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

Capital and Working Capital Costs - In Section Q, Form F.1a, the applicant provides the total capital cost for the proposed project, as follows:

Medical Equipment	\$3,086,822
Consultant Fees	\$45,000
Other (DHSR Fees and License)	\$5,000
Total Capital Cost	\$3,136,822

In Section Q, page 137 and Exhibit F-1, the applicant provides the assumptions used to project the capital cost.

In Section F, page 97, the applicant states there will be start-up expenses of \$35,184 and initial operating expenses of \$122,259 for a total working capital of \$157,443.

Availability of Funds - In Section F.2, page 95, the applicant states the capital costs for the proposed project will be funded as shown in the table below.

Sources of Capital Cost Financing	Amount
Loans	
Accumulated reserves or Owner's Equity	\$3,136,822
Bonds	
Other (Specify)	
Total	\$ 3,136,822

In Section F, page 98, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital	Amount
Loans	
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$157,443
Lines of credit	
Bonds	
Total	\$157,443

Exhibit F.2.1 contains a letter dated November 15, 2018 from the Senior Vice President of Novant committing accumulated reserves in the amount of \$3,136,822 for the capital cost and up to \$200,000 for the working capital cost of the proposed project. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital costs of the proposed project.

Financial Feasibility - The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4, the applicant projects that revenues will exceed operating expenses in the first three fiscal years for the proposed mobile services, as shown in the table below.

	1 st Full FY FY2020	2 nd Full FY FY2021	3 rd Full FY FY2022
Total Procedures	3,546	3,852	4,183
Total Gross Revenues (Charges)	\$6,264,088	\$6,635,310	\$7,196,201
Total Net Revenue	\$6,264,088	\$6,635,310	\$7,196,201
Average Net Revenue per Procedure	\$1,767	\$1,723	\$1,720
Total Operating Expenses (Costs)	\$1,708,386	\$1,838,752	\$1,981,476
Average Operating Expense per Procedure	\$482	\$477	\$474
Net Income	\$4,555,701	\$4,796,558	\$5,214,725

Additionally, Form F.3, the applicant projects that revenues will exceed operating expenses in the first three operating years for the NHFMC.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion - The Agency reviewed the:

- Application
- Exhibits in the application
- Written comments
- Remarks made at the public hearing

- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposed project.
- The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

Capital and Working Capital Costs - In Section Q, Form F.1a, the applicant provides the total capital cost for the proposed project, as follows:

Medical Equipment	\$1,822,935
Consultant Fees	\$50,000
Other (10% Contingency) [5%]*	\$93,647
Total Capital Cost	\$1,966,581

In Section Q, Assumptions, it states that the contingency is 5%, not 10%

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 88, the applicant projects start-up expenses of \$34,065 and initial operating expenses of \$104,529 for a total working capital of \$138,594.

Availability of Funds - In Section F, page 86, the applicant states the capital costs for the proposed project will be funded as shown in the table below.

Sources of Capital Cost Financing	Total
Loans	\$1,966,581
Accumulated reserves or Owner's Equity	
Bonds	
Other (Specify)	
Total	\$1,966,581

In Section F, page 89, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital	Amount
Loans	\$138,594
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	
Lines of credit	
Bonds	
Total	\$138,594

Exhibit F.2 contains a letter dated November 14, 2018 from the Vice President of Wells Fargo, committing to finance acquisition of the proposed mobile PET/CT scanner in an amount not to exceed \$3,000,000. Exhibit F.2 also contains a letter dated November 15, 2018 from the Managing Member of PPI committing to use the funds from Wells Fargo for the proposed project. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital costs of the proposed project.

Financial Feasibility - The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4, the applicant projects that revenues will exceed operating expenses in the second and third full fiscal years for the proposed mobile service, as shown in the table below.

	1 st Full FY FY2020	2 nd Full FY FY2021	3 rd Full FY FY2022
Total Procedures	961	1,567	2,624
Total Gross Revenues (Charges)	\$883,860	\$1,382,988	\$2,164,598
Total Net Revenue	\$883,860	\$1,382,988	\$2,164,598
Average Net Revenue per Procedure	\$920	\$883	\$825
Total Operating Expenses (Costs)	\$1,010,986	\$1,343,528	\$1,587,932
Average Operating Expense per Procedure	\$1,052	\$857	\$605
Net Income	(\$127,126)	\$39,460	\$576,667

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable or adequately supported because projected utilization is questionable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since the projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are also questionable.

Conclusion - The Agency reviewed the:

- Application
- Exhibits in the application
- Written comments
- Remarks made at the public hearing

- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

NC - PPI
C – All Other Applications

The 2018 SMFP includes a need determination for one dedicated mobile PET scanner statewide. On page 134, the 2018 SMFP defines the service area for a mobile PET scanner as, “A mobile PET scanner has a statewide service area.”

The first table below identifies the existing mobile PET scanners as reported in Table 9M(1), on page 138 of the 2018 SMFP. The second table identifies the existing mobile PET scanner as reported in Table 9M(1) in the Proposed 2019 SMFP.

Table 9M(1) 2018 SMFP

Mobile Provider	Procedures	Utilization Rate	
		Year 2015-2016 Procedures, 2600 as Capacity	
Alliance Imaging I	3,508		135%
Alliance Imaging II	3,651		140%
Total	7,159		

Table 9M(1) Proposed 2019 SMFP

Mobile Provider	Procedures	Utilization Rate	
		Year 2016-2017 Procedures, 2600 as Capacity	
Alliance Imaging I	2,767		106%
Alliance Imaging II	3,668		141%
Novant Health Forsyth Medical Center (NHFMCC) *	830		32%
Total	7,265		

*Service begin 2/27/2017. Reporting period 2/27/2017 - 9/30/2017

The following table identifies the host sites for the existing mobile PET/CT scanners as reported in Table 9M(2), page 138 of the 2018 SMFP.

Mobile Site	Provider	County	Procedures			
			2012-2013	2013-2014	2014-2015	2015-2016
Carolinas HealthCare - Blue Ridge	Alliance I	Burke	113	228	241	257
Valdese Hospital (Closed 12/2012)*	Alliance I	Burke	119	0	0	0
Caldwell Memorial Hospital	Alliance I	Caldwell	139	96	79	70
Carteret General Hospital	Alliance II	Carteret	226	248	230	342
Carolinas HealthCare - Cleveland	Alliance I	Cleveland	501	575	685	753
The Outer Banks Hospital	Alliance II	Dare	114	116	117	141
Novant Health Thomasville	Alliance I	Davie	97	85	68	87
Maria Parham Medical Center	Alliance II	Granville	0	56	160	88
Cone Health	Alliance I	Guilford	61	29	0	0
Margaret R Pardee Memorial Center	Alliance I	Henderson	166	164	172	191
Park Ridge Health	Alliance I	Henderson	126	143	124	133
Lake Norman Regional Medical	Alliance I	Iredell	198	198	167	198
Harris Regional Hospital	Alliance I	Jackson	292	296	305	283
Johnston Health	Alliance II	Johnston	197	180	203	200
Lenoir Memorial Hospital	Alliance II	Lenoir	170	154	169	148
Novant Health Huntersville	Alliance I	Mecklenburg	197	218	232	297
Novant Health Matthews	Alliance I	Mecklenburg	134	119	119	145
Onslow Memorial Center	Alliance II	Onslow	240	293	363	467
Sentara Albemarle Medical Center	Alliance II	Pasquotank	239	186	158	157
Randolph Hospital	Alliance I	Randolph	120	146	179	151
Southeastern Regional Medical	Alliance II	Robeson	257	273	271	264
Novant Health Rowan	Alliance I	Rowan	216	239	232	236
Rutherford Regional Medical Center	Alliance I	Rutherford	127	122	134	134
Scotland Memorial Hospital	Alliance II	Scotland	149	164	163	101
Carolinas HealthCare - Stanly	Alliance I	Stanly	144	119	173	230
Northern Hospital Surry County	Alliance I	Surry	87	96	117	117
Duke Raleigh Hospital	Alliance II	Wake	545	493	675	951
Watauga Medical Center	Alliance I	Watauga	96	160	210	226
Wayne Memorial Hospital	Alliance II	Wayne	332	303	329	348
Wilson Medical Center	Alliance II	Wilson	389	371	430	444
Total			5,791	5,870	6,505	7,159

*Procedure totals are included with Carolina HealthCare Blue Ridge

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC
 MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

MIPNC explains why it believes its proposal would not result in the unnecessary duplication of existing or approved mobile PET/CT scanner services in Section G of the application. The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved mobile PET/CT scanner services statewide based on the following analysis:

- There is a need determination in the 2018 SMFP for a mobile PET scanner.
- The nine proposed host sites are located in counties where there is no fixed PET scanner and access to mobile PET/CT services is limited.
- The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Because projected utilization in the application as submitted is reasonable, the applicant adequately demonstrates that its proposed mobile PET/CT scanner is needed in addition to the existing mobile PET/CT scanners. Therefore, the applicant adequately demonstrates that its proposal would not result in an unnecessary duplication of the existing mobile PET/CT scanners.

Conclusion - The Agency reviewed the:

- Application
- Exhibits in the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, The Agency concludes that the application is conforming to this criterion for all of the reasons stated above.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

InSight explains why it believes its proposal would not result in the unnecessary duplication of existing or approved mobile PET/CT scanner services in Section G of the application.

The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved mobile PET/CT scanner services statewide based on the following analysis:

- There is a need determination in the 2018 SMFP for a mobile PET scanner.
- The two host sites are located in counties where there is no fixed PET scanner and access to mobile PET/CT services is limited.
- The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Because projected utilization in the application as submitted is reasonable, the applicant adequately demonstrates that its proposed mobile PET/CT scanner is needed in addition to the existing mobile PET/CT scanners. Therefore, the applicant adequately demonstrates that its proposal would not result in an unnecessary duplication of the existing mobile PET/CT scanners.

Conclusion - The Agency reviewed the:

- Application
- Exhibits in the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, The Agency concludes that the application is conforming to this criterion for all of the reasons stated above.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

NHFMC explains why it believes its proposal would not result in the unnecessary duplication of existing or approved mobile PET/CT scanner services in Section G of the application.

The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved mobile PET/CT scanner services statewide based on the following analysis:

- There is a need determination in the 2018 SMFP for a mobile PET scanner.
- The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Because projected utilization in the application as submitted is reasonable, the applicant adequately demonstrates that its proposed mobile PET/CT scanner is needed in addition to the existing mobile PET/CT scanners. Therefore, the applicant adequately demonstrates that its proposal would not result in an unnecessary duplication of the existing mobile PET/CT scanners.

Conclusion - The Agency reviewed the:

- Application
- Exhibits in the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, The Agency concludes that the application is conforming to this criterion for all of the reasons stated above.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

PPI explains why it believes its proposal would not result in the unnecessary duplication of existing or approved mobile PET/CT scanner services in Section G of the application.

However, the applicant did not adequately demonstrate projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Because PPI’s projected utilization is questionable, the applicant does not adequately demonstrate that its proposed mobile PET/CT scanner is needed in addition to the existing mobile PET/CT scanners. Therefore, PPI does not adequately demonstrate that its proposal would not result in an unnecessary duplication of the existing mobile PET/CT scanners.

Conclusion - The Agency reviewed the:

- Application
- Exhibits in the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is nonconforming to this criterion for all of the reasons stated above.

- (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.

C - All Applications

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC

MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

The applicant provides the proposed staffing for the first three full fiscal years in Section Q, Form H, as illustrated below.

Position	Projected Staff in Full-Time Equivalents (FTEs)		
	1 st Full FY CY2020	2 nd Full FY CY2021	3 rd Full FY CY2022
PET Technologists	4.60	4.60	4.60
PET/CT Supervisor	1.00	1.00	1.00
Manager of Operations	0.20	0.20	0.20
Truck Driver	0.75	0.75	0.75
TOTAL	6.55	6.55	6.55

The applicant provides its assumptions for Form H in Section Q, page 124. In Section H, page 83, the applicant describes its process for recruiting staff. In Section H, page 84, the applicant states there will be at least two radiologists available in place at each host site to interpret the PET/CT scans. On page 84, the applicant states that each proposed hospital host site has an existing medical director.

Conclusion - The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of adequate health manpower and management personnel for the provision of the proposed services.
- The applicant adequately documents methods of staff recruitment and training.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

The applicant provides the proposed staffing for the first three full fiscal years in Section Q, Form H, as illustrated below.

Position	Projected Staff in FTEs		
	1 st Full FY FY2020	2 nd Full FY FY2021	3 rd Full FY FY2022
Medical Director	0.10	0.10	0.10
PET Technologists	1.50	1.75	2.00
PET/CT Tech Assistant	1.00	1.00	1.00
Area Manager	0.10	0.10	0.10
Operations Manager	0.10	0.10	0.10
Truck Driver	1.00	1.00	1.00
TOTAL	3.80	4.05	4.30

The applicant provides its assumptions for staffing in Section H, page 72 and Section Q. In Section H, page 73, the applicant describes its process for recruiting staff. On page 75, the applicant states any physician providing patient care at the proposed host sites will have access to the PET/CT scanner. On page 75, the applicant identifies Dr. Robert Y. Kanterman as the current Medical Director for InSight Imaging’s existing mobile PET/CT services. The

applicant also states on page 75 that Dr. Kanterman will serve as the Medical Director for the proposed mobile PET/CT scanner services.

Conclusion - The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of adequate health manpower and management personnel for the provision of the proposed services.
- The applicant adequately documents methods of staff recruitment and training.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

The applicant provides the current and proposed staffing for the first three full fiscal years in Section Q, Form H, as illustrated below.

Position	Current Staff in FTEs CY2018	Projected Staff in FTEs		
		1st Full FY FY2020	2nd Full FY FY2021	3rd Full FY FY2022
PET Technologists	2.60	5.20	5.20	5.20
Director	0.10	0.10	0.10	0.10
Manager	0.10	0.10	0.10	0.10
Operations Assistant	1.00	2.00	2.00	2.00
Safety Officer	0.10	0.10	0.10	0.10
Equipment Manager	0.10	0.10	0.10	0.10
Truck Driver	1.00	2.00	2.00	2.00
TOTAL	5.00	9.60	9.60	9.60

The applicant provides its assumptions for staffing in Section Q. In Section H, pages 104-105, the applicant describes its process for recruiting staff. On page 106, the applicant states NHFMC is an existing hospital with physicians and surgeons. The proposed host sites are also existing hospitals with established medical staff. The Novant physician network includes over 1,600 physicians that will have access to the PET/CT scanner. On page 106, the applicant

identifies Dr. Liston Orr as the current Medical Director for NHFMC. The applicant also identifies Dr. Robert Quarles as the Medical Director at the host sites operated in the Greater Charlotte market.

Conclusion - The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of adequate health manpower and management personnel for the provision of the proposed services.
- The applicant adequately documents methods of staff recruitment and training.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

The applicant provides the proposed staffing for the first three full fiscal years in Section Q, Form H, as illustrated below.

Position *	Projected Staff in FTEs		
	1st Full FY FY2020	2nd Full FY FY2021	3rd Full FY FY2022
PET Technologists	1.00	1.00	1.00
Clerical	0.20	0.20	0.20
Assistant Technologists	1.00	1.00	1.00
Clean up Technologists	0.10	0.10	0.10
Manager	0.10	0.10	0.10
Additional Clerical	0.20	0.20	0.20
Marketing	1.00	1.00	1.00
TOTAL	3.60	3.60	3.60

*All positions are contract positions

The applicant provides its assumptions for staffing in Section Q. In Section H, page 100, the applicant describes its process for recruiting staff. On page 101, the applicant identifies Dr. Andrew Moran and Dr. Stewart Edmunds, as the Co-Medical Directors for the proposed project. On page 102, the applicant identifies 18 physicians currently associated with Raleigh Radiology and Greensboro Radiology who are qualified to interpret PET/CT scans.

Conclusion - The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of adequate health manpower and management personnel for the provision of the proposed services.
- The applicant adequately documents methods of staff recruitment and training.

This determination is based on a review of the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C – All Applications

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC
MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

In Section I, pages 86-88, the applicant states that each host site will provide the necessary ancillary and support services. The applicant states the proposed PET/CT scanner will be operated by Alliance and Alliance will provide the truck driver. The applicant adequately demonstrates how the necessary ancillary and support services will be made available.

In Section I, pages 86-88, the applicant describes its relationships with other local health care and social service providers and provides supporting documentation in an Exhibit. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

In Section I, pages 77-78, the applicant lists the ancillary and support services that InSight will provide. The applicant adequately demonstrates how the necessary ancillary and support services will be made available.

In Section I, pages 77-78, the applicant describes its relationships with other local health care and social service providers and provides supporting documentation in an Exhibit. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

In Section I, pages 108-110, the lists the ancillary and support services that will be provided by NHFMC staff and by consultants. On page 109, applicant states that NHFMC will provide the PET technologists and a licensed driver. The applicant states each PET/CT host site has qualified radiologists to interpret the PET images. The applicant further states that it has contracted with the existing NHFMC Radiation Safety Office to provide the necessary radiation safety oversight. The applicant adequately demonstrates how the necessary ancillary and support services will be made available.

In Section I, pages 108-110, the applicant describes its relationships with other local health care and social service providers and provides supporting documentation in an Exhibit. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

In Section I, page 104-107, the applicant lists the ancillary and support services that will be provided by PPI and by a contract vendor. Greensboro Radiology has a license to handle radiopharmaceutical materials and Raleigh Radiology is in the process of obtaining a license to handle those materials. The applicant states each PET/CT host site has qualified radiologists to interpret the PET images. Each host site currently offers a full range of ancillary services necessary to support their operations, including patient scheduling, medical record maintenance and billing. The applicant adequately demonstrates how the necessary ancillary and support services will be made available.

In Section I, pages 104-107, the applicant describes its relationships with other local health care and social service providers and provides supporting documentation in an Exhibit. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA - All Applications

Each of the applicants propose to acquire one mobile PET/CT scanner pursuant to the need determination in the 2018 State Medical Facilities Plan. None of the applicants project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicants do not project to provide the proposed services to a substantial number of persons in other states that are not adjacent to the North Carolina counties in which the services will be offered. Therefore, this criterion is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO.

In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA - All Applications

None of the applicants are HMOs. Therefore, this criterion is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA - All Applications

Each applicant proposes to provide mobile PET/CT services to various host sites. None of the applicants propose to construct any new space or renovate existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C – NHFMC

NA – All Other Applications

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC

MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites. MIPNC is a new legal entity and does not own or operate any PET scanners in North Carolina. Therefore, Criterion (13a) is not applicable to this review.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites. InSight does not own or operate any PET scanners in North Carolina. Therefore, Criterion (13a) is not applicable to this review.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

In Section L, page 117, the applicant provides the historical payor mix during CY2017 for its existing PET services, as shown in the table below.

Payor Category	NHFMC Fixed PET/CT Scanner	NHFMC Mobile PET/CT Scanner	NHPMC Fixed PET/CT Scanner
Self-Pay, Charity Care	7.8%	1.8%	2.5%
Medicare*	46.3%	66.4%	69.8%
Medicaid*	16.0%	2.8%	4.7%
Insurance*	27.8%	25.9%	21.3%
Other**	2.2%	3.0%	1.7%
Total	100.0%	100.0%	100.0%

*Includes managed care plans

**Includes Tricare, Workers Compensation, Behavioral Health, Other Government and Institutional Accounts

In Section L, page 116, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during CY 2017	Percentage of the Population of the Service Area
Female	58.3%	51.7%
Male	41.7%	48.3%
Unknown	0.0%	0.0%
64 and Younger	57.8%	85.6%
65 and Older	42.2%	14.4%
American Indian	0.2%	0.5%
Asian	0.7%	3.9%
Black or African-American	18.5%	24.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	76.1%	62.9%
Other Race	3.7%	8.3%
Declined / Unavailable	0.8%	0.0%

Conclusion - The Agency reviewed the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites. PPI is a new legal entity and does not own or operate any PET scanners in North Carolina. Therefore, Criterion (13a) is not applicable to this review.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C – NHFMC
NA – All Other Applications

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC

MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites. MIPNC is a new legal entity and does not own or operate any PET scanners in North Carolina

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites. Neither the applicant nor any related entities owns, operates or manages an existing PET/CT scanner in the state. Therefore, Criterion (13b) is not applicable to this review.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

In Section L, page 117, the applicant states Novant hospitals have no obligations to provide uncompensated care, community service or access to care by medically underserved, minorities or handicapped persons. On page 118, the applicant states that during the last five years no patient civil rights access complaints have been filed against any facilities owned by the applicant or a related entity located in North Carolina.

Conclusion - The Agency reviewed the:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites. Neither the applicant nor any related entities owns, operates or manages an existing PET/CT scanner in the state. Therefore, Criterion (13b) is not applicable to this review.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C - All Applications

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC

MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

The following table illustrates the projected payor mix during the second full fiscal year for each host site.

Payor Category	UNC Rockingham	Northern Hosp.	Caldwell Memorial	Onslow Memorial	Wayne UNC	Wilson Med.	Maria Parham	Margaret Pardee	CHS Lincoln
Self-Pay, Indigent, Charity Care	11%	4%	6%	4%	8%	10%	8%	8%	0%
Medicare*	44%	31%	46%	39%	47%	42%	55%	61%	46%
Medicaid*	17%	20%	15%	19%	15%	14%	15%	8%	16%
Private Insurance*	26%	43%	11%	23%	29%	33%	22%	21%	35%
Other	3%	1%	21%	15%	1%	1%	0%	3%	3%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%

*Includes managed care plans

On page 98, the applicant states that it intends to implement a charity care policy. See Exhibit B.10(b). In Section L, page 97, the applicant assumes that the payor mix for each host site will be the same as the payor mix for that hospital host site based on hospital LRAs. The projected payor mix is reasonable and adequately supported because the applicant relies on historical data for each proposed host site.

Conclusion - The applicant adequately demonstrates the extent to which the elderly and medically underserved groups will have access to the proposed PET/CT services based on the Agency's review of:

- Application
- Exhibits in the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Therefore, the application is conforming to this criterion.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

The following table illustrates the projected payor mix during the second full fiscal year for each host site.

Payor Category	Harris Regional Hospital	Caldwell Memorial Hospital
Self-Pay, Charity Care	8.2%	6.2%
Medicare*	43.5%	45.7%
Medicaid*	12.2%	15.3%
Insurance*	33.1%	32.9%
Other (Workers Comp) *	3.1%	0.0%
Total	100.0%	100.0%

*Includes managed care plans

The applicant provides its assumptions and methodology used to project payor mix on page 90. The projected payor mix is reasonable and adequately supported because the applicant relies on historical data for each proposed host site.

Conclusion - The applicant adequately demonstrates the extent to which the elderly and medically underserved groups will have access to the proposed PET/CT services based on the Agency's review of:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments

Therefore, the application is conforming to this criterion.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

The following table illustrates the projected payor mix during the second full fiscal year for each PET/CT scanner.

Payor Category	NHFMC Fixed PET/CT Scanner	NHFMC Mobile PET/CT Scanner	NHPMC Fixed PET/CT Scanner
Self-Pay, Charity Care	7.8%	1.8%	2.6%
Medicare*	46.3%	65.7%	70.0%
Medicaid*	16.0%	3.1%	4.8%
Insurance*	27.8%	26.8%	20.9%
Other**	2.2%	2.7%	1.6%
Total	100.0%	100.0%	100.0%

*Includes managed care plans

**Includes Tricare, Workers Compensation, Behavioral

The applicant provides its assumptions and methodology used to project the payor mix on page 119. The projected payor mix is reasonable and adequately supported because it is based on historical data for the existing fixed and mobile PET/CT scanners.

Conclusion - The applicant adequately demonstrates the extent to which the elderly and medically underserved groups will have access to the proposed PET/CT services based on the Agency’s review of:

- Information in the application, including any exhibits
- Written comments
- Remarks made at the public hearing
- Responses to comments

Therefore, the application is conforming to this criterion.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

The following table illustrates the projected payor mix during the second full fiscal year for Raleigh Radiology, Greensboro Imaging and the proposed mobile PET/CT scanner.

Payor Category	Raleigh Radiology	Greensboro Radiology	Proposed Mobile PET/CT Scanner
Self-Pay	3.6%	1.2%	2.4%
Charity Care	0.1%	0.5%	0.4%
Medicare*	30.1%	41.3%	58.0%
Medicaid*	3.7%	4.2%	3.9%
Insurance*	60.3%	51.0%	34.0%
Worker’s Compensation	Included in other	0.5%	Included in other
TRICARE	1.3%	0.5%	0.9%
Other	0.5%	0.8%	0.4%
Total	100.0%	100.0%	100.0%

*Includes managed care plans

The applicant provides its assumptions and methodology used to project payor mix on pages 122-124. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant relies upon historical data for other imaging services provided at the proposed host sites in Wake and Guilford counties.
- The applicant relies upon historical data for PET services provided by facilities located in Wake and Guilford counties.

Conclusion - The applicant adequately demonstrates the extent to which the elderly and medically underserved groups will have access to the proposed PET/CT services based on the Agency’s review of:

- Information in the application, including any exhibits
- Written comments

- Remarks made at the public hearing
- Responses to comments

Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C – All Applications

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC

MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

In Section L, page 98, the applicant adequately describes the range of means by which patients will have access to the proposed mobile PET/CT services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

In Section L, page 91, the applicant adequately describes the range of means by which patients will have access to the proposed mobile PET/CT services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

In Section L, page 122, the applicant adequately describes the range of means by which patients will have access to the proposed mobile PET/CT services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

In Section L, page 124, the applicant adequately describes the range of means by which patients will have access to the proposed mobile PET/CT services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C - All Applications

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC
MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

In Section M, page 99, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

In Section M, page 92, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit 8.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

In Section M, page 124, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit 8.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

In Section M, page 125, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (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.

The 2018 SMFP includes a need determination for one dedicated mobile PET scanner statewide. On page 134, the 2018 SMFP defines the service area for a mobile PET scanner as, “A mobile PET scanner has a statewide service area.”

The first table below identifies the existing mobile PET scanners as reported in Table 9M(1), on page 138 of the 2018 SMFP. The second table identifies the existing mobile PET scanner as reported in Table 9M(1) in the Proposed 2019 SMFP.

Table 9M(1) 2018 SMFP

Mobile Provider	Procedures	Utilization Rate
		Year 2015-2016 Procedures, 2600 as Capacity
Alliance Imaging I	3,508	135%
Alliance Imaging II	3,651	140%
Total	7,159	

Table 9M(1) Proposed 2019 SMFP

Mobile Provider	Procedures	Utilization Rate
		Year 2016-2017 Procedures, 2600 as Capacity
Alliance Imaging I	2,767	106%
Alliance Imaging II	3,668	141%
Novant Health Forsyth Medical Center (NHFMC) *	830	32%
Total	7,265	

*Service begin 2/27/2017. Reporting period 2/27/2017 - 9/30/2017

The following table identifies the host sites for the existing mobile PET/CT scanners as reported in Table 9M(2), page 138 of the 2018 SMFP.

Mobile Site	Provider	County	Procedures			
			2012-2013	2013-2014	2014-2015	2015-2016
Carolinas HealthCare - Blue Ridge	Alliance I	Burke	113	228	241	257
Valdese Hospital (Closed 12/2012)*	Alliance I	Burke	119	0	0	0
Caldwell Memorial Hospital	Alliance I	Caldwell	139	96	79	70
Carteret General Hospital	Alliance II	Carteret	226	248	230	342
Carolinas HealthCare - Cleveland	Alliance I	Cleveland	501	575	685	753
The Outer Banks Hospital	Alliance II	Dare	114	116	117	141
Novant Health Thomasville	Alliance I	Davie	97	85	68	87
Maria Parham Medical Center	Alliance II	Granville	0	56	160	88
Cone Health	Alliance I	Guilford	61	29	0	0
Margaret R Pardee Memorial Center	Alliance I	Henderson	166	164	172	191
Park Ridge Health	Alliance I	Henderson	126	143	124	133
Lake Norman Regional Medical	Alliance I	Iredell	198	198	167	198
Harris Regional Hospital	Alliance I	Jackson	292	296	305	283
Johnston Health	Alliance II	Johnston	197	180	203	200
Lenoir Memorial Hospital	Alliance II	Lenoir	170	154	169	148
Novant Health Huntersville	Alliance I	Mecklenburg	197	218	232	297
Novant Health Matthews	Alliance I	Mecklenburg	134	119	119	145
Onslow Memorial Center	Alliance II	Onslow	240	293	363	467
Sentara Albemarle Medical Center	Alliance II	Pasquotank	239	186	158	157
Randolph Hospital	Alliance I	Randolph	120	146	179	151
Southeastern Regional Medical	Alliance II	Robeson	257	273	271	264
Novant Health Rowan	Alliance I	Rowan	216	239	232	236
Rutherford Regional Medical Center	Alliance I	Rutherford	127	122	134	134
Scotland Memorial Hospital	Alliance II	Scotland	149	164	163	101
Carolinas HealthCare - Stanly	Alliance I	Stanly	144	119	173	230
Northern Hospital Surry County	Alliance I	Surry	87	96	117	117
Duke Raleigh Hospital	Alliance II	Wake	545	493	675	951
Watauga Medical Center	Alliance I	Watauga	96	160	210	226
Wayne Memorial Hospital	Alliance II	Wayne	332	303	329	348
Wilson Medical Center	Alliance II	Wilson	389	371	430	444
Total			5,791	5,870	6,505	7,159

*Procedure totals are included with Carolina HealthCare Blue Ridge

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC
 MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

In Section N of the application, pages 100-102, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. In Section N, pages 100-101, the applicant states:

“The proposed project will enhance access to mobile PET/CT scans for all of the hospitals that contract with MIPNC and Alliance throughout the state because the new PET/CT route will add 84 hours per week of service. Schedules and routes for the two Alliance current mobile PET/CT scanners will be adjusted to increase the available PET/CT timeslots at existing host sites. In this way the PET/CT hospital host sites will

offer expanded services to patients and be more competitive with fixed PET/CT sites. The ... teams will work diligently to contain operating costs through quality improvement, management of staffing expenses, purchasing contracts for supplies and radiopharmaceuticals, and enhancing maintenance and transportation cost. ... The proposed project will improve cost-effectiveness by utilizing existing Alliance resources to take advantage of greater economies of scale to maximize healthcare values. ... [W]ill also promote equitable access by expanding availability of mobile PET/CT service to hospitals in rural counties where the overall percentages of Medicare, Medicaid and low-income persons are higher as compared to the urban counties.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F, and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all of the reasons stated above.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

In Section N of the application, pages 93-98, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. In Section N, pages 93-98, the applicant states:

“As a new provider of mobile PET/CT services, InSight will have a positive effect on competition in North Carolina. The proposed project will promote cost effective, high quality medical diagnostic imaging services that will be accessible by local residents ...InSight assumes no adverse effect on the two current providers of mobile PET/CT diagnostic imaging services because additional mobile PET/CT capacity is needed in North Carolina. ... The proposed PET/CT system ... use will enable a high volume of scans per day, thus containing the cost per scan. Because the proposed equipment is

mobile and will be hosted by existing medical facilities, operational infrastructure costs are nil, and the InSight Imaging corporate support structure already exists. ... Staff for the mobile PER/CT will be efficient. ... InSight's proposed project will improve access to PET/CT imaging services to underserved groups."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F, and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all of the reasons stated above.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

In Section N of the application, pages 126-127, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. In Section N, pages 126-127, the applicant states:

"The proposed project will promote cost-effective approaches, expand health care services to the medically underserved, and encourage quality health care services by improving access to mobile PET/CT scanner diagnostic imaging to the patient population served by the proposed expanded mobile PET/CT program and the existing fixed PET/CT unit at NHFMC. ... Currently, there are only three mobile PET/CT units serving the entire state of North Carolina. All three scanners are highly utilized. ... Alliance Imaging is the vendor for two of the three mobile PET/CT units. ... Alliance Imaging was the sole vendor of mobile PET/CT services and provided services to many Novant Health facilities. For more than a decade, healthcare providers ... had no choice in vendor selection ...NHFMC brings a unique option to the local mobile PET/CT market. As a vendor and a provider, NHFMC not only delivers PET/CT services but also promotes coordination, high quality, financially accessible care for

its patients. Thus, approval of the proposed project will have a positive impact on competition. ... Accessibility will increase on a local level and thereby reduce unnecessary travel burdens and costs for patients.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F, and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all of the reasons stated above.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

In Section N of the application, pages 127-128, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. In Section N, pages 127-128, the applicant states:

“The project will offer the state a new mobile PET scanner competitor, representing a 33 percent increase in mobile PET scanner competitors. ... The cost per scan for host sites will be highly competitive ... The low price per scan for the mobile unit and the absence of a minimum required number of scans per day will make it possible for host sites to offer patients and payors competitive pricing. ... The services will be available six days per week. Both host site practices have non-discrimination policies with regard to age, sex, religion, ethnicity, and disability, and have adhered to those policies.”

However, the applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Furthermore, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of costs and charges. The discussion regarding projected utilization found in Criterion (5) is incorporated herein by reference. Therefore, the applicant does not

adequately demonstrate that the proposal is cost-effective. Consequently, the applicant does not adequately demonstrate that any enhanced competition would have a positive impact on the cost effectiveness of the proposed PET services.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C – All Applications

Project ID # F-11627-18/Mobile Imaging Partners of North Carolina, LLC
MIPNC proposes to acquire one mobile PET/CT scanner to serve nine host sites.

In Section O, page 105, the applicant identifies two mobile PET scanners operated by Alliance Healthcare Services located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant states that Alliance HealthCare Services has “*maintained compliance with licensure requirements, accreditation standards...*” Additionally, the applicant states that UNC Rockingham Health Care was found to be out of compliance with the CMS rules of participation as of September 5, but subsequently back in compliance as of October 30, 2018. After reviewing and considering information provided by the applicant considering the quality of care provided on the Alliance PET scanners, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID #E-11630-18/InSight Health Corp.

InSight proposes to acquire one mobile PET/CT scanner to serve two host sites.

In Section O, page 101-102, the applicant states InSight does not offer any PET/CT services in North Carolina. However, the applicant does offer mobile MRI services in North Carolina.

In Section O, pages 101-102, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred on any of its diagnostic equipment. After reviewing and considering information provided by the applicant and considering the quality of care provided on the InSight mobile MRI scanners,

the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID #G-11640-18/Forsyth Memorial Hospital, Inc.

NHFMC proposes to acquire a second mobile PET/CT scanner to serve six host sites (two existing and four new).

In Section O, page 132, the applicant identifies 14 acute care hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. In Section O, page 132, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute Care Licensure and Certification Section and considering the quality of care provided at all 14 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID #G-11647-18/Perspective PET Imaging, LLC

PPI proposes to acquire one mobile PET/CT scanner to serve three host sites.

In Section O, pages 130-132, the applicant identifies the two operational offices, Raleigh Radiology and Greensboro Imaging, operated by the applicant or a related entity as being in good standing with the American College of Radiology (ARC) and the North Carolina Department of Radiation Safety. The applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred at any of its office and that each location remains in good standing with the North Carolina Department of Radiation Safety. After reviewing and considering information provided by the applicant considering and the quality of care provided at each location, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NC – PPI
C – All Other Applications

SECTION .3700 CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER

10A NCAC 14C .3703 PERFORMANCE STANDARDS

(a) *An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that:*

(1) *the proposed dedicated PET scanner, including a proposed mobile dedicated PET scanner, shall be utilized at an annual rate of at least 2,080 PET procedures by the end of the third year following completion of the project;*

-C- MIPNC. In Section C, page 59 and Section Q, the applicant projects that the proposed mobile PET/CT scanner will perform more than 2,080 procedures by the end of the third year of operation. Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.

-C- InSight. In Section C, page 20 and Section Q, the applicant projects that the proposed mobile PET/CT scanner will perform more than 2,080 procedures by the end of the third year of operation. Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.

-C- NHFMC. In Section C, page 84 and Section Q, the applicant projects that the proposed mobile PET/CT scanner will perform more than 2,080 procedures by the end of the third year of operation. Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.

-NC- PPI. In Section C, page 73 and Section Q, projects that the proposed mobile PET/CT scanner will perform more than 2,080 procedures by the end of the third year of operation. However, projected utilization is not based on

reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.

- (2) *if an applicant operates an existing dedicated PET scanner, its existing dedicated PET scanners, excluding those used exclusively for research, performed an average of at least 2,080 PET procedures per PET scanner in the last year; and*
- C- MIPNC.** In Section C, page 60 and Form C, Methodology and Assumptions, the applicant states the two existing mobile PET scanners operated by Alliance performed 3,508 procedures (Alliance I) and 3,651 procedures (Alliance II) for a total of 7,159 procedures in FY2016, as reported on Table 9M(1), of the 2018 SMFP. The application is conforming to this Rule.
- NA- InSight** does not currently own or operate an existing PET scanner in North Carolina.
- C- NHFMC.** In Section C, page 85 and Form C, Methodology and Assumptions, the applicant states its existing fixed scanner performed 2,886 procedures and the mobile performed 1,420 procedures in the last year (9/1/17-8/31/19) which is an average of 2,153 procedures per scanner. The application is conforming to this Rule.
- NA- PPI** does not currently own or operate an existing PET scanner in North Carolina.
- (3) *its existing and approved dedicated PET scanners shall perform an average of at least 2,080 PET procedures per PET scanner during the third year following completion of the project.*
- C- MIPNC.** In Section C, page 62, the applicant projects that the two existing mobile PET/CT scanners owned and operated by Alliance will perform a total of 4,866 procedures in the third year which is an average of 2,433 procedures per scanner. The application is conforming to this Rule.
- NA- InSight** does not currently own or operate an existing PET scanner in North Carolina.
- C- NHFMC.** In Section C, page 86 and Section Q, Form C, the applicant projects that the existing mobile PET/CT scanner will perform a total of 2,092 procedures while the existing fixed PET/CT scanner will perform a total of 2,632 procedures during the third year which is an average of 2,362 procedures per scanner. The application is conforming to this Rule.

-NA- PPI. The applicant does not currently operate an existing PET scanner in North Carolina.

(b) The applicant shall describe the assumptions and provide data to support and document the assumptions and methodology used for each projection required in this Rule.

-C- MIPNC. The applicant provides its assumptions and methodology in Section C and Section Q, Form C. The applicant adequately demonstrates that its assumptions are reasonable and adequately supported. See the discussion found in Criterion (3) regarding projected utilization which is incorporated herein by reference. The application is conforming to this Rule.

-C- InSight. The applicant provides its assumptions and methodology in Section C and Section Q, Form C. The applicant adequately demonstrates that its assumptions are reasonable and adequately supported. See the discussion found in Criterion (3) regarding projected utilization which is incorporated herein by reference. The application is conforming to this Rule.

-C- NHFMC. The applicant provides its assumptions and methodology in Section C and Section Q, Form C. The applicant adequately demonstrates that its assumptions are reasonable and adequately supported. See the discussion found in Criterion (3) regarding projected utilization which is incorporated herein by reference. The application is conforming to this Rule.

-NC- PPI. The applicant provides its assumptions and methodology following Form C in Section Q. However, the applicant does not adequately demonstrate that its assumptions are reasonable and adequately supported. See the discussion found in Criterion (3) regarding projected utilization which is incorporated herein by reference. Therefore, the application is not conforming to this Rule.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2018 SMFP, no more than one mobile PET Scanner can be approved statewide in this review. Because each applicant proposes to acquire one mobile PET scanner for a total of four PET/CT scanners, only one of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals.

Conformity with Review Criteria

MIPNC, InSight and **NHFMC** adequately demonstrated that their applications are conforming to all applicable statutory and regulatory review criteria. **PPI** did not adequately demonstrate that its application is conforming to all applicable statutory and regulatory review criteria. Therefore, the applications submitted by **MIPNC, InSight** and **NHFMC** are all equally effective alternatives with regard to conformity with review criteria and the application submitted by **PPI** is not an effective alternative with regard to conformity with review criteria.

Geographic Accessibility

The service area for mobile PET scanners is statewide.

The following table identifies the host sites for the existing mobile PET/CT scanners as reported in Table 9M(2), on page 138 of the 2018 SMFP.

Mobile Site	Provider	County	Procedures			
			2012-2013	2013-2014	2014-2015	2015-2016
Carolinas HealthCare - Blue Ridge	Alliance I	Burke	113	228	241	257
Valdese Hospital (Closed 12/2012)*	Alliance I	Burke	119	0	0	0
Caldwell Memorial Hospital	Alliance I	Caldwell	139	96	79	70
Carteret General Hospital	Alliance II	Carteret	226	248	230	342
Carolinas HealthCare - Cleveland	Alliance I	Cleveland	501	575	685	753
The Outer Banks Hospital	Alliance II	Dare	114	116	117	141
Novant Health Thomasville	Alliance I	Davie	97	85	68	87
Maria Parham Medical Center	Alliance II	Granville	0	56	160	88
Cone Health	Alliance I	Guilford	61	29	0	0
Margaret R Pardee Memorial Center	Alliance I	Henderson	166	164	172	191
Park Ridge Health	Alliance I	Henderson	126	143	124	133
Lake Norman Regional Medical	Alliance I	Iredell	198	198	167	198
Harris Regional Hospital	Alliance I	Jackson	292	296	305	283
Johnston Health	Alliance II	Johnston	197	180	203	200
Lenoir Memorial Hospital	Alliance II	Lenoir	170	154	169	148
Novant Health Huntersville	Alliance I	Mecklenburg	197	218	232	297
Novant Health Matthews	Alliance I	Mecklenburg	134	119	119	145
Onslow Memorial Center	Alliance II	Onslow	240	293	363	467
Sentara Albemarle Medical Center	Alliance II	Pasquotank	239	186	158	157
Randolph Hospital	Alliance I	Randolph	120	146	179	151
Southeastern Regional Medical	Alliance II	Robeson	257	273	271	264
Novant Health Rowan	Alliance I	Rowan	216	239	232	236
Rutherford Regional Medical Center	Alliance I	Rutherford	127	122	134	134
Scotland Memorial Hospital	Alliance II	Scotland	149	164	163	101
Carolinas HealthCare - Stanly	Alliance I	Stanly	144	119	173	230
Northern Hospital Surry County	Alliance I	Surry	87	96	117	117
Duke Raleigh Hospital	Alliance II	Wake	545	493	675	951
Watauga Medical Center	Alliance I	Watauga	96	160	210	226
Wayne Memorial Hospital	Alliance II	Wayne	332	303	329	348
Wilson Medical Center	Alliance II	Wilson	389	371	430	444
Total			5,791	5,870	6,505	7,159

*Procedure totals are included with Carolina HealthCare Blue Ridge

As shown in the table above, at the time the 2018 SMFP was published, there were 30 existing host sites in 27 counties.

The following tables compare the host sites proposed in each application in this review. For NHFMC, only the host sites to be served by the proposed mobile PET/CT scanner are included.

Applicant	Proposed Host Site	County
MIPNC	UNC Rockingham Health Care* Northern District Hospital Onslow Memorial Hospital Wayne UNC Health Care Wilson Medical Center Maria Parham Medical Center UNC Pardee CHS Lincoln Caldwell Memorial Hospital	Rockingham Surry Onslow Wayne Wilson Vance Henderson Lincoln Caldwell
InSight	Harris Regional Caldwell Memorial Hospital	Jackson Caldwell
NHFMC **	NH Huntersville NH Matthews NH Mint Hill* NH Oncology Specialist* NH Mountainview Medical* NH Imaging University*	Mecklenburg Mecklenburg Mecklenburg Wilkes Stokes Mecklenburg
PPI	Raleigh Radiology Blue Ridge* Raleigh Radiology Fuquay* Greensboro Imaging*	Wake Wake Guilford

*New host sites

** Includes only host sites for the proposed mobile PET/CT scanner.

	MIPNC	InSight	NHFMC **	PPI
Total # Sites	9	2	6	3
# New Sites	1	0	4	3
# of Counties	9	2	3	2

* Includes only host sites for the proposed mobile PET/CT scanner.

As shown in the two tables above,

- MIPNC proposes the most host sites (9) and the most counties (9).
- NHFMC proposes the most new sites (4) but two of the new host sites are located in Mecklenburg County which has three fixed PET/CT scanners and two mobile host sites. Moreover, all of the host sites are affiliated with Novant.
- InSight proposes the fewest host sites (2) and none are new.

With regard to geographic accessibility, the application submitted by **MIPNC** is the most effective alternative and the application submitted by **InSight** is the least effective alternative.

Patient Access to Alternative Provider

The 2018 SMFP includes a need determination for a mobile PET scanner. On page 134, the 2018 SMFP states, “A mobile PET scanner has a statewide service area.”

The table below identifies the existing mobile PET scanners as reported in Table 9M(1), on page 138 of the 2018 SMFP.

Table 9M(1) 2018 SMFP

Mobile Provider	Procedures	Utilization Rate	
		Year 2015-2016 Procedures, 2600 as Capacity	
Alliance Imaging I	3,508		135%
Alliance Imaging II	3,651		140%
Total	7,159		

The table below identifies the existing mobile PET scanners as reported in Table 9M(1) in the Proposed 2019 SMFP, which was published on or about July 1, 2018.

Table 9M(1) Proposed 2019 SMFP

Mobile Provider	Procedures	Utilization Rate	
		Year 2016-2017 Procedures, 2600 as Capacity	
Alliance Imaging I	2,767		106%
Alliance Imaging II	3,668		141%
Novant Health Forsyth Medical Center (NHFMC) *	830		32%
Total	7,265		

*Service begin 2/27/2017. Reporting period 2/27/2017 - 9/30/2017

As shown in the tables above, two of the three existing mobile PET/CT scanners are owned and operated by Alliance, one of the members of MIPNC. The third existing mobile PET/CT scanner is owned and operated by NHFMC, which also owns a fixed PET/CT scanner, and a related entity, Novant, owns a second fixed PET/CT scanner. Neither InSight nor PPI own or operate a PET scanner, fixed or mobile. The proposals submitted by **InSight** and **PPI** would provide patients with access to an alternative provider. However, PPI’s application is not approvable. Therefore, the proposal submitted by **InSight** is the most effective alternative with respect to this comparative factor and the proposals submitted by **MIPNC** and **NHFMC** are the least effective alternatives with respect to this comparative factor.

Access by Underserved Groups

All of the applicants propose to execute a service agreement with each host site. The host site will pay a flat fee to the applicant for the service and the host site will bill the patient or third party payor. Access to medically underserved groups would be the responsibility of each host site and not the applicants. Therefore, the Agency did not compare the applications with respect to projected access to underserved groups in this review.

Projected Average Net Revenue per PET Procedure

The following table shows the projected average net revenue per procedure in the third full fiscal year. Generally, the application proposing the lowest average net revenue per procedure is the more effective alternative with regard to this comparative factor to the extent the average could ultimately result in a lower cost to the patient or third party payor.

3rd Full FY	MIPNC	InSight	NHFMC	PPI
Net Revenue	\$2,560,832	\$1,599,979	\$7,196,201	\$2,164,599
Procedures	2,724	2,123	4,813	2,624
Average Net Revenue per Procedure	\$940	\$734	\$1,495	\$825

Source: Section Q, Form F.4.

As shown in the table above, **InSight** projects the lowest average net revenue per procedure in the third full fiscal year and **NHFMC** projects the highest. Therefore, the application submitted by **InSight** is the most effective application with respect to this comparative factor and the one submitted by **NHFMC** is the least effective alternative.

Projected Average Operating Expense per PET Procedure

The following table shows the projected average operating expense per procedure in the third full fiscal year. Generally, the application proposing the lowest average operating expense per procedure is the more effective alternative with regard to this comparative factor to the extent it reflects a more cost effective service which could also result in lower costs to the patient or third party payor.

3rd Full FY	MIPNC	InSight	NHFMC	PPI
Total Operating Expenses	\$1,848,757	\$1,229,187	\$1,981,476	\$1,587,932
Procedures	2,724	2,123	4,813	2,624
Operating Expense per Procedure	\$679	\$579	\$412	\$605

Source: Section Q, Form F.4.

As shown in the table above, **NHFMC** projects the lowest average operating expense per procedure in the third full fiscal year and **MIPNC** projects the highest. Therefore, the application submitted by **NHFMC** is the most effective alternative with regard to this comparative factor and the application submitted by **MIPNC** is the least effective alternative.

SUMMARY

The following table lists the comparative factors and identifies which applicant is the most effective, less effective or least effective alternative with regard to each comparative factor except conformity with review criteria. For that comparative factor, an application is either conforming to the all criteria or it is not. One application cannot be more conforming than another application. Moreover, the comparative factors are listed in the same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance.

Comparative Factor	MIPNC	InSight	NHFMC	PPI
Conformity with Review Criteria	Equally Effective	Equally Effective	Equally Effective	Least Effective
Geographic Accessibility	Most Effective	Least Effective	Less Effective	Less Effective
Patient Access to Alternative Provider	Least Effective	Most Effective	Less Effective	Less Effective
Access by Underserved	Not Compared	Not Compared	Not Compared	Not Compared
Projected Average Net Revenue per Procedure	Less Effective	Most Effective	Least Effective	Less Effective
Projected Average Operating Expense per Procedure	Least Effective	Less Effective	Most Effective	Less Effective

As shown in the table above:

InSight was determined to be the most effective alternative with regard to:

- Patient Access to Alternative Provider
- Projected Average Net Revenue per Procedure

MIPNC was determined to be the most effective alternative with regard to geographic accessibility.

NHFMC was determined to be the most effective alternative with regard to projected average operating expense per procedure

PPI was not determined to be the most effective alternative with regard to any comparative factor.

DECISION

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **InSight** is the most effective alternative proposed in this review for the development of one additional mobile PET scanner.

The application submitted by **PPI** is not approvable standing alone and is **denied**. While the other two applications, **MIPNC** and **NHFMC**, are approvable standing alone, the approval of either of them would result in the approval of more mobile PET scanners than are determined to be needed, and therefore, the applications submitted by **MIPNC** and **NHFMC** are **denied**.

Project ID #E-11630-18, InSight Health Corp., Acquire one mobile PET/CT scanner pursuant to the need determination in the 2018 SMFP, is approved subject to the following conditions:

1. InSight Health Corp. shall materially comply with all representations made in the certificate of need application.
2. InSight Health Corp. shall acquire no more than one mobile Positron Emission Tomography scanner to serve counties statewide. The mobile PET scanner shall be moved twice weekly to provide mobile PET services to at least two host sites and shall not, at any time, serve less than two host sites each week.
3. InSight Health Corp. shall not change or add host sites unless it first obtains a determination from the Healthcare Planning and Certificate of Need Section authorizing the change in host sites.
4. The mobile PET scanner shall not be converted to a fixed PET scanner without InSight Health Corp. first obtaining a new certificate of need for a fixed scanner.
5. The acquisition of the mobile PET scanner shall constitute development of a mobile diagnostic program and shall not result in the creation of a diagnostic center located at any of the host sites.
6. InSight Health Corp. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.
7. InSight Health Corp. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.