

**Competitive Comments Submitted by Mobile Imaging Partners of North Carolina
Regarding the
2018 Mobile PET Scanner Certificate of Need Applications**

Four applications were submitted in response to the need determination in the 2018 State Medical Facilities Plan for one additional mobile PET scanner to serve the statewide service area. These include:

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|-------------------|--|
| F-11627-18 | Mobile Imaging Partners of North Carolina, LLC / Acquire a mobile PET/CT scanner pursuant to the need determination in the 2018 SMFP / Statewide |
| E-11630-18 | InSight Health Corp. / Acquire a mobile PET/CT scanner pursuant to the need determination in the 2018 SMFP / Statewide |
| G-11640-18 | Novant Health Forsyth Medical Center / Acquire a mobile PET/CT scanner pursuant to the need determination in the 2018 SMFP / Statewide |
| G-11647-18 | Perspective PET Imaging, LLC / Acquire a mobile PET/CT scanner pursuant to the need determination in the 2018 SMFP / Statewide |

The following comments are submitted in accordance with N.C. Gen. Stat. § 131E-185(a1) (1) and address the representations in the project applications, including a comparative analysis and discussion as to whether the applications comply with the Certificate of Need (“CON”) review criteria. These comments submitted by Mobile Imaging Partners of North Carolina, LLC are not intended to include any additional information that would represent an amendment to its application.

Comparative Analysis

Demonstration of Need and Unnecessary Duplication

Mobile Imaging Partners of North Carolina, LLC (MIPNC) adequately demonstrates the need for the proposed mobile PET/CT scanner to increase days of service at eight existing hospital host sites and to add a new host site at UNC Rockingham Healthcare. Furthermore, MIPNC effectively demonstrates that its proposed scanner will not result in unnecessary duplication of existing or proposed PET scanners in North Carolina. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

InSight Health Corp. (InSight) unrealistically hopes to serve at least two host sites. However, both Harris Regional Hospital and Caldwell Memorial Hospital sites have existing agreements to receive mobile PET service from Alliance Healthcare Services. Furthermore, Caldwell Memorial Hospital’s letter of support for the InSight application has been rescinded as seen in Attachment 1. InSight does not adequately demonstrate the need for the proposed PET scanner because the utilization projections for the host sites are overstated and based on unreliable assumptions. Unsupported market share assumptions and inaccurate patient origins undermine the overall credibility of this proposal. Moreover, InSight fails to demonstrate that its proposed scanner will not result in unnecessary

duplication of existing or proposed PET scanners in North Carolina. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

Novant Health Forsyth Medical Center (Novant) conjectures that additional mobile PET is needed to serve multiple existing Novant host sites plus additional new Novant host sites in Mecklenburg, Stokes and Wilkes County. However, the Novant Health Oncology Specialists office at 1913 West Park Drive, North Wilkesboro has no existing mobile services pad that could accommodate a mobile PET/CT scanner. The application does not include funds to construct a mobile pad. As a result the utilization projection for this proposed new site is not based on reasonable assumptions. Adding more mobile PET capacity to existing sites in Mecklenburg and Forsyth County will divert more patients from Novant's fixed sites which is what actually occurred in 2017 when Novant implemented its existing mobile PET. Consequently, Novant fails to demonstrate that its proposed new scanner will not result in unnecessary duplication of existing or proposed PET scanners in North Carolina. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

Perspective PET Imaging, LLC (Perspective) proposes to provide mobile PET sites at two imaging center locations in Wake County and one imaging center in Guilford County. However, the application fails to demonstrate that the patient origin projections and utilization estimates are based on reasonable assumptions. The PET procedure volumes include grossly overstated numbers of patients from Mecklenburg, Cabarrus, Buncombe and Durham Counties where patients readily have access to fixed PET scanners. The applicant proposes to add mobile host sites in Wake and Guilford Counties where existing fixed PET scanners have available capacity. Wake County has one CON-approved fixed PET scanner pending development at Duke Raleigh plus a need determination for an additional fixed PET scanner in the 2019 State Medical Facilities Plan. Consequently, Perspective fails to demonstrate that its proposed scanner will not result in unnecessary duplication of existing or approved PET scanners in North Carolina. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

Conformity with All Applicable Criteria

The MIPNC application is conforming to all CON review criteria. In contrast, the applications by InSight, Novant and Perspective fail to conform to multiple CON review criteria and are not viable proposals. Please see the Criteria-specific comments regarding each of these applications for additional discussion.

Increasing Geographic Access

The MIPNC application proposes to increase mobile PET service to eight existing hospital host sites in rural counties and to implement mobile PET service in Rockingham County at UNC Health Care where no existing fixed or mobile PET service is located. The following table shows the distribution of the proposed mobile host sites by Health Service Area (HSA) for each of the applicants.

	MIPNC Host Sites	InSight Host Sites	Novant Host Sites	Perspective Host Sites
HSA I	2	2	1	0
HSA II	2	0	4	1
HSA III	1	0	4	0
HSA IV	1	0	0	2
HSA V	0	0	0	0
HSA VI	3	0	0	0
Total Host Sites	9	2	9	3

The MIPNC proposal adds mobile PET service to Rockingham County, which currently has no PET services, and increases service to eight existing hospital host sites in rural counties. These nine hospital host sites will enhance access for both inpatients and outpatients over a broad geographic area based on reliable historical patient origin data. Furthermore, the nine host sites are located in five of the six HSAs demonstrating that the MIPNC application is the most effective proposal to fulfill the need determination for the statewide service area.

The InSight application proposes to serve only two hospital host sites in HSA II with no new host sites. Now that the Caldwell Memorial Hospital support for the InSight proposal has been rescinded, only the proposed Harris Regional Hospital site remains. Farfetched patient origin projections are dependent on unachievable market share assumptions. The project is not an effective proposal because it has the fewest host sites of all the applications and would serve sites in only HSA I. The InSight proposal fails to expand geographic access in counties that have no existing fixed or mobile PET. In addition, MIPNC proposes to expand existing mobile PET service to Caldwell Memorial Hospital which is one of the two proposed host sites for InSight.

Novant predicts a total of nine host sites for the proposed mobile PET with most of the locations in urban counties in HSAs II and III where multiple fixed PET scanners are located. Even though its existing mobile PET scanner is underutilized, Novant's hopes to divert market share from competing fixed PET scanners by oversaturating Mecklenburg with mobile PET capacity that is unnecessary. Novant's proposed physician office host site in Wilkes County (HSA I) is not viable due to the lack of a mobile services pad. Consequently the Novant application is not an effective proposal to increase geographic access.

Perspective proposes serving three imaging center host site locations with one in HSA II and two in HSA IV. Guilford County has existing fixed PET locations with available capacity and no unmet need. Wake has multiple existing and approved fixed PET locations with available capacity. Patient origin projections for the Perspective host sites are based on unreasonable market share assumptions for distant counties. The proposed host sites at the three imaging centers would serve only outpatients. The Perspective proposal fails to expand geographic access in counties that have no existing fixed or mobile PET. Therefore, the Perspective proposal is not an effective proposal to increase geographic access.

New Alternative Provider

The MIPNC application provides a new alternative provider that would enhance mobile PET services on a state-wide basis. While Alliance Healthcare Services has partial ownership in MIPNC, the application documents that the proposed mobile PET would provide an alternative service schedule, new fee alternatives, and enhanced competition in terms of host site service and patient satisfaction.

Perspective and InSight are new alternative providers for mobile PET that are not viable proposals due to unreasonable utilization projections. The Novant proposal is the least effective application as a new alternative provider because its proposal is based on overstated utilization and the project would simply increase the inventory of Novant-owned PET scanners to solely serve Novant host site locations.

PET Technologist Staffing Level and Salary for Year 2

MIPNC proposes the most robust level of PET Technologist staffing with 4.6 FTEs and the second highest annual salary for Year 2 at \$84,060. InSight projects the second lowest PET Technologist staffing level with 1.74 FTEs and the lowest annual salary for Year 2 at \$66,300. Novant's staffing indicates 2.6 FTEs for PET Technologist per mobile PET scanner and an annual salary of \$82,188 for Year 2.

The Perspective Year 2 staffing indicates only 1 FTE for PET Technologist with a projected annual salary of \$93,331. Form H staffing shows 1 FTE for PET Technologist in Years 1, 2 and 3. However, the FTE assumptions and contract hours for PET Technologist FTEs and salary assumption in Section Q are incomplete and unreliable. Therefore the Perspective staffing is not effective.

The MIPNC application is the most effective proposal regarding PET Technologist staffing. The InSight and Perspective applications are the least effective proposals regarding projected PET Technologist staffing and salary.

Average Charge per Scan to Host Sites

The InSight proposal offers the lowest average charge per scan of \$730 to \$763 and is the most effective proposal with regard to this comparative factor. The MIPNC and Perspective applications project average charges per scan of less than \$1,000 per scan and are both effective proposals. The Novant application projects the highest average gross charge per scan of over \$1,700 and represents the least effective proposal.

Average Cost per Scan

The average cost per scan documented in the MIPNC application for Year 2 is \$702; this includes depreciation expense and is based on reasonable utilization projections. InSight's average cost per scan in Year 2 is \$662 and it includes depreciation expense but is not based on reasonable utilization projections. Novant projects an average cost per scan in Year 2 of \$477 that excludes depreciation expense and it is not based on reasonable utilization projections. The Perspective application has \$857 for its average cost per scan in Year 2 and includes depreciation but it is also not based on reasonable utilization projections. InSight, Novant and Perspective did not adequately demonstrate the need to acquire mobile PET scanners and cannot be approved. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application submitted by MIPNC is the most effective alternative with regard to projected average cost per PET scan.

Comparative Data

	MIPNC F-11627-18	Insight E-11630-18	Novant G-11640-18	Perspective G-11647-18
Related Entities	Alliance Healthcare Services UNC Rockingham Health Care	Insight Health Corp	Novant Health Medquest	Greensboro Radiology Raleigh Radiology
New Alternative Provider	Yes	Yes	No	Yes
PET/CT Equipment Manufacturer / Model	GE Discovery IQ	Siemens Biograph	Siemens Biograph	Siemens Biograph
Capital Cost	\$2,020,000	\$1,617,157	\$3,136,822	\$1,966,581
Host Site Facilities <u>New Host Sites</u>	<u>UNC Rockingham Health Care</u> Northern District Hospital of Surry Onslow Memorial Wayne UNC Wilson Medical Center Maria Parham UNC Pardee CHS Lincoln Caldwell Memorial Hospital 9 Hospital sites total	Harris Regional Caldwell Memorial Hospital 2 Hospital sites total	Novant Huntersville Novant Matthews Novant Rowan Novant Thomasville Novant Kernersville <u>NH Wilkes Oncology (Wilkes)</u> <u>NH Mountainview (Stokes)</u> <u>NH University Imaging (Mecklenburg)</u> <u>NH Mint Hill (Mecklenburg)</u> 9 sites total 5 existing + 1 approved Hospital + 3 Clinics	<u>:Raleigh Radiology Blue Ridge Greensboro Radiology Raleigh Radiology Fuquay- Varina</u> Imaging Centers 3 host sites total
Host Site Location Counties	Rockingham Surry Onslow Wayne Wilson Vance Pardee Lincoln Caldwell	Jackson Caldwell	Forsyth Mecklenburg Rowan Davidson Wilkes	Wake Guilford
YR 2 Total FTEs	6.55 FTEs per Mobile	4.30 FTEs per Mobile	3.8 FTEs per Mobile	3.6 FTEs per Mobile
PET Technologist FTEs Annual Salary Year 2	4.6 FTEs \$84,060	1.75 FTE \$66,300	2.6 FTEs per scanner \$82,188	FTE \$93,331

	MIPNC F-11627-18	Insight E-11630-18	Novant G-11640-18	Perspective G-11647-18
Annual Utilization				
YR 1	2,470	1,452	1,818	961
YR 2	2,594	1,771	1,950	1,567
YR 3	2,724	2,123	2,091	2,624
Methodology Outline	Historical Data Modest Growth Rate Conservative volume for new hospital host site	Population Use Rate Market share for multiple counties beyond Jackson and Caldwell plus market share for adjoining counties	Historical data for existing fixed and mobile sites combined. Growth from more days of service and shift to new sites plus market share for adjoining counties	Population Use Rate Market share for numerous counties beyond Guilford and Wake
Access for Inpatients and Outpatients	Yes	Yes	Yes at hospital sites	No - Only Outpatients
Charge per Scan				
YR 1	\$952	\$730	\$1767	\$800 + \$120 = \$920
YR 2	\$952	\$746	\$1723	\$760 + \$122 = \$882
YR 3	\$952	\$763	\$1720	\$700 + \$125 = \$825
	Includes radiotracer	Includes radiotracer	Includes radiotracer	Scan + radiotracer
Average Cost per Scan				
YR 1	Cost per scan mobile \$658	Cost per scan mobile \$695	Cost per scan mobile \$483	Cost per scan mobile \$1052
YR 2	\$702	\$662	\$477	\$857
YR 3	\$679	\$578	\$474	\$605
	Includes depreciation	Includes depreciation	Depreciation PET scanners omitted	Includes depreciation
Expands Geographic Access in Counties that have no fixed or mobile PET	YES - Rockingham Adds capacity to eight existing hospital sites	NO Only adds capacity to existing sites	Only Novant office in Kings Stokes has a pad. Existing and new sites in Mecklenburg and Forsyth	NO New sites in Wake and Guilford

**Comments Specific to InSight Health Corp. (InSight)
CON Project ID # E-11630-18**

The InSight project application is not conforming to the CON Review Criteria due to multiple deficiencies as follows:

Criterion (1) *The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.*

InSight does not adequately demonstrate the need for the proposed project based on reasonable utilization projections. Therefore, the applicant fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2018 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3. The InSight application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

Criterion (3) *“The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”*

InSight was unable to obtain letters of support from a sufficient number of potential host sites to develop a viable proposal for a mobile PET/CT scanner. Caldwell Memorial Hospital’s letter of support as a potential host site has been rescinded as seen in Attachment 1. Laura Easton, President and CEO of Caldwell UNC Health Care fully supports the approval of the MIPNC CON application. As seen in Attachment 2, the letters of support for the InSight application have been rescinded by:

James Hathorn, MD with McCreary Cancer Center
Roger Holland, MD with McCreary Cancer Center
Tim Roten, Director of Cancer Services at McCreary Cancer Center.

Caldwell Memorial Hospital is no longer a potential host site for the proposed InSight mobile PET/CT. Consequently the InSight application cannot be approved with only one host site.

Scan volume projections are overstated with huge numbers of patients from adjoining counties outside of Jackson and Caldwell Counties, which is entirely inconsistent with the historical patient origin data for Harris Regional Hospital and Caldwell Memorial Hospital. Both facilities serve a majority of patients from their home counties and smaller percentages from other adjacent counties. InSight omits this historical patient origin data from the application. Instead, the applicant unreasonably projects the vast majority of patients to originate from outside of Caldwell and Jackson Counties where the two proposed host sites are located.

The InSight proposal is premised on overstated utilization projections for its two proposed host sites based on unsupported market share projections. Furthermore, the applicant’s projections for the two mobile host sites are unreliable because these volumes also exceed many of the full-time fixed PET scanners that are located in counties with larger populations and more referring physicians such as Alamance, Iredell and Cumberland Counties.

**InSight Imaging
Mobile PET/CT Scanner
Patient Origin, FY2020-FY2022**

County	FY2020		FY2021		FY2022	
	Patients	% of Total	Patients	% of Total	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%

Totals may not foot due to rounding.

For Year 2 in the above table, only 23.9 percent of patients are projected to originate from Caldwell County and 12.6 percent of patients from Jackson County. It is unreasonable for InSight to assume that 65.5 percent of patients will originate from other counties in western NC due to travel distances and the lack of physician referral relationships.

InSight’s market share assumptions and projected utilization are simply not reasonable or adequately supported:

- Neither of the proposed host sites verifies their willingness to utilize the proposed mobile PET/CT scanner for service three days per week.
- No documentation is provided regarding referral relationships with physician practices at hospitals in Alexander, Cherokee, Haywood, Macon, Swain and Wilkes Counties.
- No examples are provided to demonstrate that InSight has any mobile PET scanners anywhere in the United States that are performing more than 1700 PET scans while serving only two host sites.

The application provides no documentation that physicians with practices in Haywood County will provide PET referrals to the Harris host site in Jackson County. Since Haywood residents already have access to existing mobile PET service at Haywood Regional Medical Center and access to fixed PET at

Mission Hospital, in adjacent Buncombe County, it is unreasonable for InSight to project a 60 to 80 percent market share from Haywood County. Furthermore, it is irrational to expect that more patients will originate from Haywood County than the number of patients from Jackson County.

InSight unreasonably predicts huge market share gains, expecting hundreds of patients originating from Wilkes and Alexander Counties to travel to the Caldwell host site. The application provides no documentation from physicians practicing in Wilkes and Alexander Counties that they are willing to refer patients to the InSight host site in Caldwell County. Since Wilkes Regional Medical Center is now affiliated with Wake Forest Baptist Hospital, it is most likely that Wilkes patients will continue to utilize PET scanners in Forsyth County. Alexander patients have favorable access to the existing fixed PET in Catawba County that has available capacity.

InSight's proposal fails to demonstrate that the project is viable. Caldwell Memorial Hospital's letter of support as a potential InSight host site has been rescinded as seen in Attachment 1. Physician support letters have been rescinded as seen in Attachment 2. Consequently the InSight application cannot be approved with only one site because a mobile PET scanner is required to serve two or more host sites.

The InSight application fails to conform to Criteria 3 because the patient origin projections are not credible and the utilization projections are overstated and unreasonable.

Criterion (4) *“Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.”*

InSight does not adequately demonstrate that the alternative proposed in its application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the InSight application is not conforming to Criteria (4).

Criterion (5) *“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”*

InSight's financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments. Consequently the financial projections are unreliable causing the application to not conform to Criterion 5.

Neither Harris Regional Hospital nor Caldwell Memorial Hospital verifies their willingness or genuine need to utilize InSight's proposed mobile PET scanner three days per week. In fact, Caldwell Memorial Hospital's letter of support as a potential host site has been rescinded.

The projected annual utilization and costs for the mobile PET/CT service to these two hospitals is summarized in the table below:

	YR 1	YR 2	YR 3
Harris Regional Hospital	736	898	1076
Caldwell Memorial Hospital	716	873	1046
Average Net Rev (Fee) per Scan	730	746	763
Harris Regional Hospital Annual Fees	\$532,302	\$663,437	\$812,698
Caldwell Memorial Hospital Annual Fees	\$516,968	\$644,982	\$791,332
Total Expenses to Hospitals	\$1,049,270	\$1,308,419	\$1,604,030

InSight’s salary projection of \$65,000 for Year 1 for the NucMed/PET Technologist position is understated by 15 to 20 percent. Consequently the financial projections are not based on reasonable expense assumptions.

InSight erroneously calculates working capital costs because most of its cash expenses, such as salaries and supplies, would be paid out on a bi-weekly or monthly basis and not on a quarterly basis. Furthermore, InSight’s net revenue projections are overstated due to unreliable volume projections. Therefore the total working capital amount is incorrect and understated because net revenues will be far less than projected and cash expenses substantially greater.

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

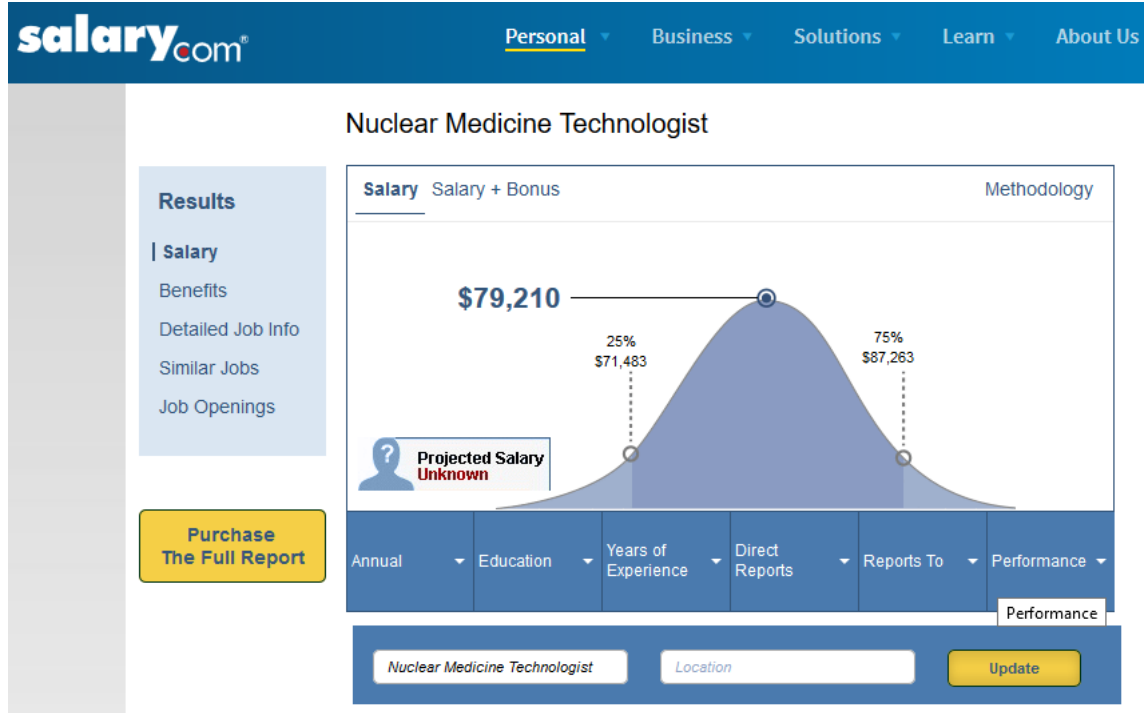
InSight fails to demonstrate that its proposal would not result in unnecessary duplication of mobile PET service because the utilization projections are unreliable. The application is not conforming to Criterion (6).

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

The application is not conforming to Criterion (7) because InSight’s projected annual salaries for the NucMed/PET Technologist of \$65,000 in Year 1, \$66,300 in Year 2 and \$67,626 are inaccurate and less than current median salaries. According to the US Department of Labor, Bureau of Labor Statistics, the 2017 median pay for a nuclear medicine technologist is \$75,660.¹ Furthermore, the InSight application states that the salary projections were based on “salary information on the website salary.com”.

¹ www.bls.gov/ooh/healthcare/nuclear-medicine-technologists.htm

The following is salary information from the salary.com website.²



Therefore, InSight has projected substandard salaries for its NucMed/PET Technologist position and will not be able to recruit and retain adequate personnel.

Criteria (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.”*

InSight’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate it will promote the cost effective services. The applicant’s projected utilization is not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

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:

² www.salary.com

- (1) The proposed dedicated PET scanner, including a proposed mobile dedicated PET scanner, shall be utilized at an annual rate of at least 2080 PET procedures by the end of the third year following completion of the project:
 - (2) if an applicant operates an existing dedicated PET, its existing dedicated PET scanners, excluding those used for research, shall perform an average of 2080 PET procedures per PET scanner in the last year, and
 - (3) its existing and approved dedicated PET scanners shall perform an average of at least 2080 PET procedures per PET scanner during the third year following completion of the project.
- (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.

The InSight application does not conform to the performance standards. Its proposal fails to adequately demonstrate that it will serve at least two host sites. Utilization projections for the proposed InSight mobile PET are not based on reasonable assumptions and methodology. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

**Comments Specific to Novant Health Forsyth Medical Center (Novant)
CON Project ID # G-11640-18**

The Novant project application is not conforming to the CON Review Criteria due to multiple deficiencies as follows:

Criterion (1) *The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.*

Novant Health does not adequately demonstrate the need for the proposed project based on reasonable utilization projections. Therefore, the applicant fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2018 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3. The Novant Health application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

Criterion (3) *“The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”*

Novant proposes to acquire an additional mobile PET scanner but the application lacks adequate justification and would provide excess PET capacity in Mecklenburg and Forsyth Counties where the existing PET scanners are underutilized. The application fails to demonstrate the need for additional PET capacity in Mecklenburg County because there is both available fixed PET and mobile PET capacity. The Presbyterian fixed PET scanner in Mecklenburg remains underutilized. Novant fails to provide documentation that patients are experiencing delays in obtaining access to PET in Forsyth County. No PET capacity constraints exist for Novant facilities in Mecklenburg County.

Page 58 of the Novant application shows that Novant Health Forsyth Medical Center performed 3,834 annual PET procedures during the year that ended 9/30/2017. Therefore these two PET scanners averaged only 1917 annual procedures. Performance Standard 10A NCAC 14C.3703 does not allow for the applicant to substitute 11 months’ annualized data in order to demonstrate conformity to the rules.

Novant’s application fails to demonstrate the need for additional PET capacity in Forsyth County because there is available fixed PET and mobile PET capacity. Its current mobile PET scanner has not achieved its projected utilization as was represented in the 2015 CON application. Novant fails to provide documentation that patients are experiencing delays in obtaining access to PET in Forsyth County. For these reasons, no capacity constraints exist in Forsyth County. The current Novant mobile PET scanner is still underutilized and performed less than 2080 annual scans during the previous 12 months. Furthermore, the existing Novant mobile PET scanner failed to implement mobile PET service

at Morehead Hospital (now UNC Rockingham Health Care) in accordance with the representations in their 2015 CON application.

The utilization projections for the proposed mobile PET scanner are based on unreasonable assumptions regarding the growth in utilization at the existing and proposed Novant PET host sites. The utilization projections for Novant’s existing and proposed mobile PET/CT scanners are summarized in the following table.

	CY 2018 Annualized	2019 Interim	YR 1	YR 2	YR 3
Mobile PET Units	1	1	2	2	2
Scan Projections	1,865	2,106	3,546	3,852	4,183
Volume Increases		241	1440	306	331
Percentage Increases		12.92%	68.38%	8.63%	8.59%

The Novant mobile PET projections are unreasonable to assume the huge increase in Year 1 because:

- The Novant Health Oncology host site in North Wilkesboro has no mobile services pad or capital budget to construct a mobile pad to support mobile PET/CT scans at that location.
- There is no unmet need for additional PET service in Mecklenburg and Forsyth County because both of the existing Novant fixed PET scanners has available capacity.
- Novant’s existing mobile PET scanner is underutilized with a CY utilization projected at 1,865 scans.

For example, Novant’s fixed PET scanner in Forsyth County has experienced a decline in utilization because patients have been diverted to the Novant mobile PET site in Kernersville.

	2017 LRA	2018 LRA	Annualized 2018	% Change
Novant Kernersville Mobile PET		174	343	97.1%
Novant Forsyth Fixed PET	3025	2969	2894	-4.3%

If Novant were to add a mobile host site at Mountainview (Stokes County) it would divert even more patients from the Novant Forsyth fixed PET/CT scanner.

Novant Health Oncology in North Wilkesboro has no existing mobile pad and the application includes no documentation regarding the feasibility or the capital cost to construct a mobile pad. Therefore the utilization projections for this host site cannot be achieved.

Criterion (4) *“Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.”*

Novant does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Criterion (5) *“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”*

Novant’s financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments. There are multiple reasons why the Novant financial projections are unreliable, causing the application to not conform to Criterion (5). The project capital cost is incorrect because Novant omits the cost to develop a mobile services pad for its proposed host site at the Novant Health Oncology Specialists office at 1913 West Park Drive, North Wilkesboro.

Forms F.5 and F.6 document the applicant’s projected gross revenue and net revenue per scan at over \$1,700 per scan, which far exceeds the \$957 rates per scan that were included in the previous Novant CON application # G-11051-15 as seen in the following table. The application fails to explain why the existing Novant mobile PET/CT and the proposed additional mobile PET/CT will be charging the host sites such an exorbitant fee. Clearly the proposed project is not cost effective.

Novant Forsyth Medical Center CON Project ID # G-11051-15

Mobile PET/CT Service	Project Year 1	Project Year 2	Project Year 3
Projected # of Scans	1,938	2,210	2,472
Projected Average Charge (Patient Revenue / Projected # of Scans)	\$ 957	\$ 957	\$ 957
Patient Revenue	\$ 1,854,666	\$ 2,114,970	\$ 2,365,704
Total Expenses	\$ 1,339,448	\$ 1,522,832	\$ 1,585,924
Net Income	\$ 515,218	\$ 592,138	\$ 779,780

Form F.4 Revenue and Expenses for the Mobile PET scanners is not based on reasonable assumptions because the volume projections are overstated and the projected average fee per scan is excessively high as compared to Novant’s current mobile PET scanner with a \$957 average charge per scan.

Expense projections for the proposed project are unreliable due to the omission of a depreciation expense for the existing mobile PET and proposed mobile PET.

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

Novant fails to demonstrate that its proposal would not result in unnecessary duplication of mobile PET service because the utilization projections are unreliable. Novant’s existing mobile PET has not reached the utilization projections that were represented in application # G-11051-15. Novant has available capacity at its existing fixed PET scanners in both Forsyth and Mecklenburg Counties. Furthermore, utilization at Novant’s fixed PET in Forsyth County shows a decline over the three previous years. Consequently, the application does not conform to Criterion (6).

Criterion (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”

The Novant application fails to include the construction cost to develop a mobile services pad at the proposed host site at the Novant office location in North Wilkesboro. The Novant Health Oncology Specialists office at 1913 West Park Drive, North Wilkesboro was inspected on December 16, 2018 to verify that it has no existing mobile services pad that could accommodate a mobile PET/CT scanner. As seen in the first image below the office is located in a building that faces the parking lot with no mobile services pad visible. The parking lot has traffic islands directly in front of the office making it impractical to develop a mobile pad without extensive and costly reconfiguration of parking and rerouting of traffic. No mobile services pad was found at the back of the building. Neither side of the medical office building has a mobile services pad.

Front View



Furthermore, the narrow width of the road at the rear of the building as seen in the Google Earth view would make it difficult to maneuver the tractor and PET/CT coach.

Google Earth View



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

Novant fails to adequately demonstrate how the proposal will promote the cost effectiveness of the proposed services because the applicant’s projected utilization is not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

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 2080 PET procedures by the end of the third year following completion of the project:

(2) if an applicant operates an existing dedicated PET, its existing dedicated PET scanners, excluding those used for research, shall perform an average of 2080 PET procedures per PET scanner in the last year, and

(3) its existing and approved dedicated PET scanners shall perform an average of at least 2080 PET procedures per PET scanner during the third year following completion of the project.

(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.

The Novant application fails to demonstrate that the projected utilization for its existing and proposed PET scanners are based on reasonable assumptions. Page 58 of the Novant application shows that Novant Health Forsyth Medical Center performed 3,834 annual PET procedures during the year that ended 9/30/2017. Therefore these two PET scanners (1 fixed and 1 mobile) averaged only 1917 annual procedures. Performance Standards included in 10A NCAC 14C.3703 do not allow for the applicant to substitute 11 months' annualized data (10/1/2017 to 8/31/2018) in order to demonstrate conformity to the rules. Furthermore, utilization projections for the proposed PET and the existing PET scanners are not based on reasonable assumptions and methodology. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

**Comments Specific to Perspective PET Imaging, LLC (Perspective)
CON Project ID # G-11647-18**

The Perspective project application is not conforming with the CON Review Criteria due to multiple deficiencies as follows:

***Criterion (1)** The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.*

The Perspective application does not adequately demonstrate the need for the proposed project based on reasonable utilization projections. Therefore, the applicant fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2018 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3. The Perspective application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

***Criterion (3)** “The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”*

Perspective fails to adequately identify the patient origin for its project because the utilization projections are based on unreasonable market share assumptions for the host site counties and the 42 “target area counties”. The application lacks letters of support from referring physicians and hospitals from most of these counties; this omission causes the volume projections for these counties to be entirely speculative and unsupported.

Guilford and Wake Counties are the host site locations and numerous other counties are included in Perspective’s “target area counties.” Guilford and Wake have existing fixed PET scanners that are underutilized. Duke Raleigh Hospital has CON approval to add a dedicated fixed PET in Raleigh that will pre-empt a large portion of the total unmet need in Wake and nearby counties. The 2019 need determination for an additional fixed PET scanner in Wake County will further obviate the remaining unmet need for PET services.

Perspective’s need methodology is defective due to incorrect and unreasonable assumptions:

- Perspective wrongly asserts that “The total number of host sites served by the Alliance scanners makes it logistically impossible to accommodate additional capacity requests.” This assertion is false because Alliance has worked collaboratively with numerous hospitals to implement new mobile PET service as capacity became available, as discussed in its application. In 2017 and 2018 Alliance acquired new replacement mobile PET/CT scanners that have much faster

throughput so that scan times are much shorter. The new scanners combined with robust staffing enable Alliance to perform 18 to 20 PET scans per day at some high volume mobile sites. This new technology has greatly increased productivity and scheduling capacity at host sites served by Alliance throughout North Carolina.

- The Perspective Section Q, Form Q pages 37 and 38 include statements regarding the lack of capacity of the existing fixed PET scanners to serve additional patients. These statements are incorrect because these existing facilities have available capacity and can replace older fixed PET/CT equipment and boost physician recruitment to serve higher volumes of PET patients.
- Perspective's market share assumptions in Section Q, Form Q pages 41 arbitrarily assume that its mobile PET will serve 35%, 45% and 60% of the supposed unmet need for PET scans **from 42 counties**. These market share percentages are unsupported because the applicant does not identify physicians or hospitals that will refer patients from all 42 of these counties. Furthermore, it is unrealistic for cancer patients and family members from many of these counties to travel to Guilford or Wake County due to the extended travel distances. It is also unreasonable to assume that patients are going to drive past existing fixed and mobile PET sites to reach the proposed Perspective sites.
- The patient origin table on pages 49 and 50 of the application is unreasonable because it shows that 43 percent of patients are projected to originate from Buncombe, Cabarrus, Durham and Mecklenburg Counties where fixed PET scanners with available capacity are conveniently located in each County. Oncologists and physicians in these four counties are unlikely to refer patients to the Perspective mobile PET scanner because the proposed scanner is not coordinated with the cancer programs and healthcare systems in these four counties.
- The applicant's methodology and assumptions are not reasonable because Perspective has no experience in operating mobile PET scanners; the proposal lacks adequate support from referring physicians and the proposed staffing model with only 1 FTE technologist is insufficient to perform the projected utilization.

Criterion (4) *“Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.”*

Perspective does not adequately demonstrate that the alternative proposed in its application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the Perspective application is not conforming to Criterion (4).

Criterion (5) *“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”*

Perspective's financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments. Consequently, the financial projections are unreliable causing the application to not conform the Criterion 5.

The Perspective application fails to adequately demonstrate the availability of funds for the total capital cost and working capital amounts. The funding letter from Dr. Matham in Exhibit F.2 indicates Perspective’s willingness to fund no more than \$2,000,000. However the total capital cost and working capital amount combined is \$2,105,175 which means a funding shortfall of \$105,175.

Capital Cost (page 86)	\$1,966,581
Working Capital (Page 89)	\$138,594
Total Combined Amount	\$2,105,175
Financing Letter from Satish Matham, MD (Exhibit F.2)	\$2,000,000
Funding Shortfall	-\$105,175

Salary expenses are inaccurate because in Year 1 Perspective budgets only \$55,543 for the PET Technologist salary which is not sufficient to fund the 1 FTE position with an hourly rate is \$45 per hour and 2080 annual hours.

The Form H staffing table in Section Q is incorrect because it shows only 1 FTE for the PET Technologist position for Years 2 and 3 which is not sufficient to provide service 6 days per week and cover sick time and vacation time. Total staffing consists of only 3.6 FTEs and includes 1 FTE PET technologist, 1 FTE Assistant Tech, 1 FTE Marketing position and additional part-time positions. This low level of total staffing is substandard because the Marketing position and the Assistant Tech do not have the clinical training to perform PET scans to cover the 1 FTE PET Technologist position for the absences due to sick time and vacation.

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

Perspective fails to demonstrate that its proposal will not result in unnecessary duplication of mobile PET service because the utilization projections are unreliable. The proposed host site locations are in counties where existing fixed PET scanners with available capacity are located. The applicant wrongly contends that patients would be willing to drive considerable distances to utilize a PET scanner that is less costly. The application is not conforming to Criterion (6).

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

The application is not conforming to Criterion (7) because the staffing tables and salary projections are inaccurate. The Form H staffing table in Section Q is incorrect because it shows only 1 FTE for the PET technologist position which is not sufficient to provide service 6 days per week and cover sick time and vacation time. Total staffing consists of only 3.6 FTEs and includes 1 FTE PET technologist, 1 FTE Assistant Tech, 1 FTE Marketing position and additional part-time positions. This low level of total staffing is substandard because the Marketing position and the Assistant Tech lack the clinical training to perform PET scans to cover the PET technologist position.

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

Perspective’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate it will promote cost-effective services. The applicant’s projected utilization is not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

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 2080 PET procedures by the end of the third year following completion of the project:

(2) if an applicant operates an existing dedicated PET, its existing dedicated PET scanners, excluding those used for research, shall perform an average of 2080 PET procedures per PET scanner in the last year, and

(3) its existing and approved dedicated PET scanners shall perform an average of at least 2080 PET procedures per PET scanner during the third year following completion of the project.

(c) 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.

The Perspective application does not conform to the performance standards because the utilization projections for the proposed mobile PET/CT are not based on reasonable assumptions and methodology. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

Attachment 1



Martha Frisone, Chief
Healthcare Planning Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Rescinding Support Letter for InSight CON Project ID Application #E-11630-18

Dear Ms. Frisone:

I am writing to rescind my September 10, 2018 letter of support that was provided to InSight Imaging for their proposed mobile PET/CT scanner in the above-referenced CON application. When 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.

As I made clear in the letter of support I provided to MIPNC on November 5, 2018, Caldwell Memorial Hospital has been very satisfied with the level of service provided by Alliance, one of the MIPNC partners. Caldwell has experienced significant growth in patient referrals and requires additional PET/CT capacity to meet our patients' needs. We believe that MIPNC has the strongest proposal for providing these services and meeting our needs. Thus, please accept this letter as an indication of my full support for the MIPNC CON application.

In sum, please disregard the letter of support previously provided for InSight, and I urge you to approve the application submitted by MIPNC to provide much needed mobile PET/CT services to our patients. Thank you for your consideration of our request. Please call me if you have questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Laura J. Easton", with a long horizontal flourish extending to the right.

Laura J. Easton
President and CEO
Caldwell UNC Health Care

Attachment 2



December 20, 2018

Martha Frisone, Chief
Healthcare Planning Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Rescinding Support Letter for InSight CON Project ID #E-11630-18
Support Letter for MIPNC Project ID #F-11627-18

Dear Ms. Frisone:


I am writing to rescind my September 20, 2018 letter of support that was provided to InSight Imaging for their proposed mobile PET/CT scanner in the above-referenced CON application. When I provided that support letter to InSight, almost two months before the application due date, 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.

I have been very satisfied with the level of service provided by Alliance, the current mobile PET service provider at Caldwell Memorial Hospital, which serves McCreary Cancer Center's patients. I understand that Alliance and UNC Rockingham Health Care are partners in MIPNC, and I look forward to working with MIPNC to best serve our patients.

Caldwell Memorial Hospital, and specifically McCreary Cancer Center, has experienced significant growth in patient referrals and requires additional PET/CT capacity to meet our patients' needs. We believe that MIPNC has the strongest proposal for providing these services and meeting these needs, and I will refer my patients (as clinically appropriate) for PET/CT services on the MIPNC scanner at Caldwell Memorial Hospital. Thus, please accept this letter as an indication of my full support for the MIPNC CON application.

In sum, please disregard the letter of support previously provided for InSight, and I urge you to approve the application submitted by MIPNC to provide much needed mobile PET/CT services to our patients. Thank you for your consideration of this request. Please call me if you have questions.

Sincerely,


James W. Hathorn, MD



December 20, 2018

Martha Frisone, Chief
Healthcare Planning Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Rescinding Support Letter for InSight CON Project ID #E-11630-18
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I have been very satisfied with the level of service provided by Alliance, the current mobile PET service provider at Caldwell Memorial Hospital, which serves McCreary Cancer Center's patients. I understand that Alliance and UNC Rockingham Health Care are partners in MIPNC, and I look forward to working with MIPNC to best serve our patients.

Caldwell Memorial Hospital, and specifically McCreary Cancer Center, has experienced significant growth in patient referrals and requires additional PET/CT capacity to meet our patients' needs. We believe that MIPNC has the strongest proposal for providing these services and meeting these needs, and I will refer my patients (as clinically appropriate) for PET/CT services on the MIPNC scanner at Caldwell Memorial Hospital. Thus, please accept this letter as an indication of my full support for the MIPNC CON application.

In sum, please disregard the letter of support previously provided for InSight, and I urge you to approve the application submitted by MIPNC to provide much needed mobile PET/CT services to our patients. Thank you for your consideration of this request. Please call me if you have questions.

Sincerely,

A handwritten signature in black ink that reads "Roger E. Holland". The signature is written in a cursive style with a long, sweeping flourish at the end.

Roger E. Holland, MD



December 20, 2018

Martha Frisone, Chief
Healthcare Planning Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Rescinding Support Letter for InSight CON Project ID #E-11630-18
Support Letter for MIPNC Project ID #F-11627-18

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In sum, please disregard the letter of support previously provided for InSight, and I urge you to approve the application submitted by MIPNC to provide much needed mobile PET/CT services to our patients. Thank you for your consideration of this request. Please call me if you have questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tim Roten', is written over a white background.

Tim Roten
Director of Oncology Services
McCreary Cancer Center, a service of UNC Hospitals