Perspective PET Imaging, LLC

DELIVERED VIA EMAIL 12/28/2018

December 28, 2018

Ms. Lisa Pittman, Section Chief
Bernetta Thorne-Williams, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Comments on Competing Applications for a Certificate of Need for a mobile PET/CT scanner statewide; CON Project ID Numbers:

- **InSight Health Corp. application to acquire a mobile PET/CT scanner, Project ID# E-011630-18**
- **Novant Health Forsyth Medical Center application to acquire a mobile PET/CT scanner, Project ID# G-011640-18**
- **Mobile Imaging Partners of North Carolina, LLC application to acquire a mobile PET/CT scanner, Project ID# F-011627-18**

Dear Ms. Thorne-Williams and Ms. Pittman:

On behalf of Perspective PET Imaging, LLC (PPI), Project ID G-011647-18, thank you for the opportunity to comment on the above referenced applications for a statewide mobile PET/CT scanner. During your review of the projects, I trust that you will consider the comments presented herein.

We recognize that the State's Certificate of Need (CON) award for the proposed mobile PET/CT scanner will be based upon the State's CON health planning objectives, as outlined in G.S. 131E-183. In comparing the applications, we request that the CON Section give careful consideration to the extent to which each applicant:

1. Offers a truly new statewide competitor for mobile PET/CT services;
2. Demonstrates access to patients by increasing the number of PET/CT scans provided;
3. Demonstrates a reduction in patient and third-party payor cost per scan;
4. Demonstrates low charges to the host sites, that will support value-based care;
5. Proposes a reasonable and achievable market share;
6. Maximizes patient safety and value through clinical expertise of subspecialty radiologists for both oversight of the program and interpretation of the proposed scans;
7. Demonstrates clinical leadership that has the knowledge and expertise to implement new and upcoming approvals for PET/CT exams that involve non-FDG isotopes;

8. Demonstrates capacity of the applicant or host sites to provide required support services for the PET/CT scanner, specifically a dedicated patient toilet, hot lab, and management services;
9. Demonstrates specific support and referrals from community physicians;
10. Provides adequate financial resources to cover the expected costs of the project;
11. Demonstrates capacity to staff the proposed mobile efficiently; and
12. Offers a proposed host site payor mix that is well grounded in experience with outpatient imaging services.

The following tables show how PPI is competitively superior among the four applicants. Table 1 contains the raw data. Table 2 ranks the data with 1 being the most desirable. The applicant with the lowest total score provides the most competitive value. Scores for ties in Table 1 are the sum of the ranks to the next score divided by the number of ties. For example, two competitors tie for second and third place; the score is ((2+3)/2 = 2.5).

Table 1: Recommended Comparative Analysis

Ref. #	Competitive Enhancement	Metric	Applicants				Source
			MIPNC / Alliance	InSight	Novant	PPI	
1	Access	New Competitor	N	Y	N	Y	Section A, Exhibits, Document Text
2	Access	Number of Counties Proposing to Serve	36	8	39	42	Section C
3	Access	Number of New Unmet Patients in PY 3	(375)	1,765	2,041	2,624	Section C and Form C
4	Access	Proposed Start Date of Project	January 2020	October 2019	April 2020	January 2020	Section C and Form C
5	Value / Cost Effective	Physician Billing Rate to Patients	N	N	Partial (2 of 9 Sites)	Y	Section C
6	Value / Cost Effective	Per Scan Charge to Host, PY 2	$952.00	$746.00	$1,722.56	$882.00	Form F.5
7	Access	Reasonable Market Share PY 3	Not provided	80 to 95%	Not provided	6.3% of need in target counties, all new no shift	Section C and Form C
8	Quality	Number of PET Trained (Nuclear Medicine) Interpreters at Host Site	5 out of 9 sites	0	2 to cover 7 mobile and 2 fixed sites; none for clinics	18 to serve three sites	Letters in Exhibits
9	Quality	Qualified NC Medical Director	N	N	Y	Y	Section H and Letters in Exhibits

Ref. #	Competitive Enhancement	Metric	Applicants				Source
			MIPNC / Alliance	InSight	Novant	PPI	
10	Quality	Pad Available to Host Mobile PET at Each Proposed Host Site	not confirmed, said will have at site	not confirmed, said will have at site	did not answer	each site provides, confirmed in letters	Section C and Letters from Host Sites
11	Quality	Hot Lab Available at Each Proposed Host Site	Y	N	Y	Y	Section C and Letters from Host Sites
12	Quality	Dedicated Patient Toilet Available at Each Host Site	N	N	N	Y	Section C and Letters from Host Sites
13	Access	Number of Referrals to New Mobile PET	65	0	0	2,544	Letters in Exhibits
14	Value / Cost Effective	Efficiency: Cost per Procedure PY 3	$678.69	$578.99	$473.70	$605.16	Form F.4
15	Quality	Total Staff of Mobile PET excluding Truck Driver	5.8	3.3	3.8	4.12	Form H
16	Quality	Technical Staff per Mobile PET PY 3	5.6	3	3.6	2.52	Form H
17	Quality	Salary - Nuclear Med Tech PY 3	$86,151.00	$67,626.00	$85,476.00	$99,300.24	Form H
18	Quality	Salary – Nuclear Med Tech Asst. PY 3	N/A	$27,267.00	$30,416.00	$33,100.08	Form H
19	Value / Cost Effective	Efficiency (days/week)	7	6	6	6	Section C and Methodology with Form C
20	Value / Cost Effective	Efficiency (hours/week)	84	42	60	52.5	Section C and Methodology with Form C

Table 2: Metrics from Table 1 Ranked, with 1= Best.

Ref #	Competitive Enhancement	Metric	Applicants			
			MIPNC / Alliance	InSight	Novant	PPI
1	Access	New Competitor	3.5	1.5	3.5	1.5
2	Access	Number of Counties Proposing to Serve	3	1	4	2
3	Access	Number of New Unmet Patients in PY 3	4	3	2	1
4	Access	Proposed Start Date of Project	2.5	1	4	2.5
5	Value / Cost Effective	Physician Billing Rate to Patients	3.5	3.5	2	1
6	Value / Cost Effective	Per Scan Charge to Host PY 2	3	1	4	2
7	Access	Reasonable Market Share PY 3	3.5	2	3.5	1
8	Quality	Number of PET Trained (Nuclear Medicine) Interpreters at Host Site	2.5	4	2.5	1
9	Quality	Qualified NC Medical Director	3.5	3.5	1.5	1.5
10	Quality	Pad Available to Host Mobile PET at Each Proposed Host Site	2.5	2.5	4	1
11	Quality	Hot Lab Available at Each Proposed Host Site	2	4	2	2
12	Quality	Dedicated Patient Toilet Available at Each Host Site	3	3	3	1
13	Access	Number of Referrals to New Mobile PET	2	3.5	3.5	1
14	Value / Cost Effective	Efficiency Cost per Procedure PY 3	4	2	1	3
15	Quality	Total Staff of Mobile PET excluding Truck Driver	1	4	3	2
16	Quality	Technical Staff per Mobile PET PY 3	1	3	2	4
17	Quality	Salary - Nuclear Med Tech PY 3	2	4	3	1
18	Quality	Salary - Nuclear Med Tech Asst. PY 3	4	3	2	1
19	Value / Cost Effective	Efficiency (days/week)	1	2	2	2
20	Value / Cost Effective	Efficiency (hours/week)	1	4	3	2
		Total Score	***52***	***54***	***56.5***	***34.5***

Scoring based on rank order best (1) to worst (4). In case of a tie, score assigns the remaining ranks to the tie, sums the ranks, and divides by the number tied (e.g. two applicants tied for second place: (2+3)/2=2.5, remaining applicants are scored 1 and 4).

CON comparative reviews often include payor mix. Because the mobile provider does not control the payor mix, comparing that metric should not apply in this review. Applicants used different proxies for estimating host payor mix.

Medicare and Medicaid are among the underserved groups mentioned in the statutes. Both MIPNC and InSight explain in their applications that they based payor mix on all outpatient services excluding ED and surgery at host sites. This could include primary care clinics and laboratory – both high-use payors for Medicaid. PPI however, based its payor mix percentages on historical outpatient imaging services it currently provides – a more accurate capture of a mobile PET imaging payor mix. Novant provided payor mix for its mobile PET/CT service component only. Comparatively, PPI's proxy use of historical data calculates more similarly to Novant's actual data than the other competitors. Table 3 details this discrepancy with regard to Medicare and Medicaid. Because applicants have not provided accurate or similar data, Medicare and Medicaid payor mix percentage should not be a comparative factor.

Table 3: Medicare and Medicaid Percent Payor Mix Comparison, Second Full Year of Operation

Applicants	Host Sites	Percent of Utilization		Data source
		Medicare	Medicaid	
InSight	Harris Regional Hospital	43.5	12.2	All hospital outpatient department excluding surgery and ED, can include primary care clinics and laboratory; p89.
	Caldwell Memorial	45.7	15.3	
Alliance	UNC Rockingham Health Care	44.0	17.0	All hospital outpatient department excluding surgery and ED, can include primary care clinics and laboratory; p97.
	Northern Hospital of Surry County	31.0	20.0	
	Caldwell Memorial Hospital	46.0	15.0	
	Onslow Memorial Hospital	39.0	19.0	
	Wayne UNC Health Care	47.0	15.0	
	Wilson Medical Center	42.0	14.0	
	Maria Parham Hospital	55.0	15.0	
	Margaret Pardee Hospital	61.0	8.0	
	CHS Lincoln	46.0	16.0	
Novant	Mobile PET/CT (Service Component)	65.7	3.1	PET/CT mobile actual based on NHFMC internal data; p119.
PPI	Raleigh Radiology Blue Ridge	30.1	3.7	Based on historical payor mix of outpatient imaging for each host site; p119.
	Greensboro Radiology	41.3	4.2	
	Raleigh Radiology Fuquay Varina	30.1	3.7	

The application from PPI is conforming to all statutory review criteria. We believe that the proposal by PPI offers a unique, one-time opportunity to gain the positive impact of a new competitor in the mobile PET/CT market. PPI alone offers clinical leadership and oversight of local North Carolina nuclear radiologists, who have the knowledge and expertise of not only FDG isotopes, but also have training, skills, and are national leaders with the new PET/CT isotopes. Finally, PPI proposes to meet the largest amount of unmet need among all applicants. It alone will offer all patients the lower physician-based charge schedule.

For reasons described in the attached documents, other applications do not meet all statutory criteria.

Thank you for your time and consideration. Please do not hesitate to call me if you have any questions.

Sincerely,

Satish Mathan, MD
Managing Member
Perspective PET Imaging, LLC

Attachment(s)

ATTACHMENTS

Attachment A

Competitive Review of Insight Health Corp.

Project ID# E-011630-18

COMPETITIVE REVIEW OF –
INSIGHT HEALTH CORP.
APPLICATION FOR MOBILE PET/CT SCANNER
PROJECT ID# E-011630-18

Overview

InSight Health Corp. application to develop a mobile PET/CT scanner is non-conforming with statutory review criteria 1, 3, 5, 6, 7, 8, 12, 13, 18(a), and does not meet the performance standard in 10A NCAC 14C .3703(a)(1).

This applicant proposes to acquire a mobile scanner to serve two western hospitals, Caldwell Memorial in Caldwell County and Harris Regional in Jackson County. It proposes to provide 2,126 PET/CT scans to residents from seven counties, with a combined total population of 393,200 in 2022.

CON Review Criteria

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, ambulatory surgery operating rooms, or home health offices that may be approved.

Overview

InSight proposes to offer a competitive alternative to Alliance Imaging, the only provider of mobile PET/CT services that is not captive to a health care system. However, the application falls short in consistency with Policy Gen-3 with regard to Quality.

Quality

Accreditation and certification standards require a dedicated waiting area and a dedicated patient toilet. This protects others from exposure to radioactivity of the patient prior to the exam and the waste that patients excrete after the exam. This application makes provisions for neither.

The proposed medical director for this project resides in Missouri and the application provides no evidence that this person holds a license to practice in North Carolina.

These critical shortcomings illustrate what happens when clinical leadership is not closely integrated with a mobile imaging service.

For these reasons, the application is non-conforming to Criterion 7. See further detail below.

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.

The proposed project would provide part-time PET/CT service at two hospitals; each would get three days of service a week.

This application forecasts need for PET/CT scans by applying trended North Carolina use rates to population changes in counties it proposes to serve. By the third project year, the use rate is 6.12 per 1,000 residents and the applicant proposes to attract 80 to 95 percent of patients in need to one of the two sites. This is ambitious and unproven for these sites and the application fails to demonstrate that the goal is achievable.

This project will require a substantial change in patient patterns of care. As demonstrated in the historical market shares for acute care, MRI, and PET/CT at these sites (Attachment E) the majority of patients do not seek tertiary care at either proposed hospital site. As illustrated in the following table of market share for the hospitals' home counties, UNC Caldwell and Harris Regional attracted no more than 60 percent of the total home county patients in any of the last three reported years. In fact, with the exception of PET at Caldwell, the market share of the home county for all services declined over the three-year period, 2015 to 2017. The application provides no evidence that InSight could achieve a 95 percent market share of the home and other counties. Yet, the forecast utilization assumes market shares of 80 to 95 percent by project year 3.

Table 1: Home County Market Share of Acute Care, MRI, and PET/CT

	2015	2016	2017
UNC Caldwell Memorial Hospital (Caldwell County)			
Acute Inpatient	41.07%	40.76%	39.03%
MRI	44.69%	37.98%	37.24%
PET/CT	17.96%	12.11%	21.32%
Harris Regional Hospital (Jackson County)			
Acute Inpatient	51.37%	49.22%	46.44%
MRI	62.66%	61.45%	59.75%
PET/CT	52.94%	38.66%	46.23%

Source: Attachment D, NC Hospital License Renewal Applications and NC DHSR database.

MRI is an important reference, because both hospitals have full-time MRI.

The proposed case counts also depend on the PET/CT use rates for these counties reaching 6.12 per 1,000 residents. The application provides no such documentation. The application describes new uses of PET, health status, and aging of the population as reasons for increased use rates. Yet, the application shows no evidence of specialized PET/CT interpreters at either hospital.

The application asserts that InSight marketing staff will educate referring physicians about the value of PET/CT. However, referring physicians are not using these two hospitals for any service at the level proposed in the application's market shares. Moreover, the application provides no evidence that InSight's marketing staff has successfully redirected patient use patterns at the order of magnitude suggested in this application.

The application presents information about new isotope tracers. However, it provides no evidence that either hospital has physicians who are skilled in interpreting any PET/CT scans using the new isotopes. Nor does it propose to use any of the new isotopes.

Neither UNC Caldwell nor Harris Regional hospital has a service program that would attract 80 to 95 percent of PET/CT patients. The applicant proposes a cancer-based PET/CT program. Harris Regional reported 157 Linear Accelerator patients and 264 PET/CT scans on its 2018 LRA. UNC Caldwell Memorial reported only 85 Linear Accelerator patients in 2018, and a closely related 94 PET/CT scans on its 2018 License Renewal Application (LRA). (See data in Attachment E.) The application indicates that the proposed scanner would take over the Alliance PET/CT contracts, but provides no data on expiration date or conditions for termination.

Careful review of the total proposed cases the market shares by county, at each of the two sites suggests that the applicant manipulated market shares to produce high scan counts. Each year, the Harris Regional scans are 103 percent of the Caldwell scans. See table on application page 110. The applicant required high scan counts to support its forecast expenses at the proposed low charge rate.

The proposed scans at Caldwell are 5 times more than forecast by MIPNC/Alliance in its application (see Alliance patient origin page 233 Exhibit c.2). Moreover, the UNC Caldwell 2018 LRA PET patient origin is very different from what this application proposes. That shows 92 percent of UNC Caldwell patients originated from Caldwell County, in 2017.

For these reasons, the application is non-conforming to Criterion 3.

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.

Capital Cost

See discussion of tractor, shipping, and taxes in Criterion 8

Operating Expenses

The income statement in Form F.3 shows positive net income after expense. However, this sustains only if the applicant achieves the case forecasts in Form C. As discussed in Criterion 3, those case forecasts are hyperinflated. Hence the proformas are not reliable.

Achieving the proposed market share requires "marketing assistance" from InSight. However, the budget has no line item for such assistance.

The per scan charge listed in Form F.5 includes the isotope, FDG. The application does not mention glucose testing, an essential element of patient safety in use of FDG, which is a glucose derivative. The assumptions cite "InSight Imaging" as the source of the isotope cost. The application contains no commitment from an isotope vendor and neither proposed site has a cyclotron to produce it.

The application includes FDG in the proposed unit charge on Form F.5, but the cost associated with the isotope in Assumption (4) makes no allowance for waste that occurs when this short half-life isotope is unusable because of a patient no show. Isotopes must be pre-ordered at least a day before the scan. The application contains no information about costs of other isotopes. At a cost of $4,000+ for some of the isotopes mentioned in the narrative, the Income Statement in Form F.3 would be negative.

Operating costs provide for Wake County property taxes, without an explanation of why the applicant chose Wake County.

The application provides no management agreement, but the working capital calculations assume that payment for services occurs in advance, implying that InSight will charge the host sites on the basis of forecast scans. Without this assumption, working capital would be much higher.

Although the proforma assumptions include a line item for fuel, Assumption (5) there is no line item for the use cost of the InSight tractor. Nor is there clear evidence that the North Carolina tractors have time available for this project.

Sources and Cost of Funds

Exhibit 10 is a letter from Siemens Financial Services, Inc. committing $2.0 million to fixed and working capital. This letter fails to mention interest rates. Therefore, the reviewer is unable to validate the operating pro formas. The working capital calculations in Assumption (10) appear to anticipate prepayment by the host site. The assumption provides only a calculation and not the underlying basis.

For these reasons, the application is non-conforming to Criterion 5.

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

On page 93 the applicant "assumes no adverse impact on the two existing scanners because NC needs more" PET scanner capacity. The application does not address current patterns in the proposed market. In fact, to sustain the required market share, the application requires market shift from other providers who have been serving these counties. As illustrated in Attachment F, PET patient origin from the 2018 LRA for Mission Hospital, Mission served a substantial number of PET patients from Cherokee, Haywood, Jackson, Macon, and Swain Counties. These represent five of the eight identified in the InSight patient origin on application page 20. The market shift would represent 50 percent and more of current patient patterns. Attachment F to these comments also shows that, in FY 2017, the Mission PET/CT scanner was not used to capacity as defined by the 2018 SMFP.

The required high market share and high use rate presume high adoption of the PET/CT imaging tool by referring physicians and allow very few patients to seek lower-cost physician-based settings or alternative isotopes elsewhere.

For these reasons, the application is non-conforming to Criterion 6.

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.

This application fails to show evidence of the availability of resources including health manpower and management personnel for the provision of the services it proposes to provide. It is non-conforming to Criterion 7.

Physician Staffing

This application refers to a medical director who is based in St. Louis Missouri. Dr Kanterman's bio in application Exhibit 2 indicates that he trained in Vascular / Interventional Radiology and has done research in CT. It shows no evidence of training or experience in PET/CT. Without training and current experience, the medical director will not have the clinical background to monitor the program for patient safety.

This criterion requires evidence of availability of resources for provision of services to be provided. The forecast cases indicate that the services are PET/CT scans. Hence, it is incumbent on the applicant to demonstrate that patients will receive full service, including interpretation.

In Section H, the application discusses referring physicians. On page 76, it notes that the project does not require a physician recruitment plan "because physicians who are currently on the medical staff at each host facility will refer their patients to the mobile PET/CT scanner …. Also, the PET scans will be interpreted by physicians at the local facility, not via InSight." The application provides no evidence that either host site has physicians on the medical staff trained in PET/CT interpretation.

Calibration

Exhibit 4 contains resumes for Physicists from West Physics and annual physics services, but no calibration cost for the new equipment. The application contains budget for the services West Physics propose to provide.

Staffing

The application proposes six days of service a week, three at each site. It proposes to staff the facility with full time, dedicated staff. An 8-hour day at each site means the PET/CT scanner will be staffed 48 hours a week. To provide patient and staff safety, it should have two technical staff on duty at all times it is in service. That would require 96 tech/ assistant-staffed hours a week. The application barely provides this in year 01. Pro forma form F.3 includes a cost for overnight stay and staff transportation.

Staffing includes no clerical staff. The job description in Exhibit 6 suggests that the Radiology Tech not only will assemble data for the interpreting physician, but also will do equipment maintenance on both the truck and the PET/CT scanner.

Management services

Form F.3 indicates that management services will be provided at a cost of 4 percent of revenue. The application provides no documentation for services included in the management and/ or how the percentage was derived or whether it is of net or gross revenue. There is no management services agreement in the application.

Mobile Pad with Required Power and Data

The application provides no evidence that a mobile pad with required power and data will be available at each site three days a week. This is important, especially at rural hospitals that often use other mobile services, such as cardiac catheterization and lithotripsy.

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.

Equipment and Facility

Form F.1.a in Section Q lists the capital expenditures associated with the project. The list includes no allowance for taxes or shipping. The application has a contingency allowance of $20,000. However, North Carolina Sales Tax is 4.75 percent. That would add $73,252.46 to the capital cost, which exceeds the contingency. Shipping at 2 percent of the equipment cost would add $30,843. The application has not included all required costs. Quotes in Exhibit 3 identify FOB factory, which indicates that shipping would not be included, and specifically exclude taxes.

The application includes no cost for a new tractor. The Tractor Roster in Exhibit 3 shows only two active tractors in North Carolina. It does not demonstrate the extent to which either has capacity to move the proposed trailer; nor does the application indicate the number of times the trailer would move each week. Form F.4. does not include a line item for tractor use. It includes only fuel and repair, not depreciation and use of the capital asset.

The Siemens equipment quote in Exhibit 3, a "Preliminary Quote," lists a hot lab. The Biograph Horizon Typical Room Plan provided as part of the quote (page 1 of 6) does not show location of the hot lab. In fact, the first note (one of three at the top of the page) says, "Siemens highly recommends the customer's architect designates space for a hot lab, patient waiting area, and uptake room." The application describes none of these elements. The budget contains no fees for such an architect., or description of where the hot lab will be located.

In Section H, the application indicates that all employees will be new. Yet the preliminary proposal used to build capital costs indicates that the only training provided will be via on-line course (page 3 of 4).

Radiopharmaceuticals

FDG has a very short half-life. This application has no allowance for FDG *delivered* to the site *but not used* because the patient does not show, or shows up and does not pass clinical clearance tests. The application makes no allowance for glucose testing which is prerequisite to use of the FDG pharmaceutical.

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.

Project does involve construction but applicant p 81 claims it does not. The application proposes to increase use of mobile pad sites at the two facilities, but provides no information to indicate that the mobile pads will be available for each of the proposed three days a week.

As mentioned with regard to Criterion 7, the application provides no information about the design and location of the required hot lab. The application is similarly silent about the availability of the required dedicated patient toilet at each site.

For this reason, the application is non-conforming to Criterion 12.

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:

(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;

The applicant is an existing provider of mobile imaging services in North Carolina.

InSight proposes a charity allowance of 1.0 percent of net revenue, but tries to claim credit for the historic charity provided by Harris Regional and UNC Caldwell Memorial, which it presents as 8.2 percent and 6.2 percent of cases on page 89. The Agency should not credit InSight for that level of charity.

Although the applicant proposes to serve only two sites, and both sites offer PET/CT services, the application does not provide payor mix for PET/CT services at either site, claiming that the data are not publicly available. Absence of the host site profiles is further evidence that payor mix presented on page 89 is a questionable representation of the payor mix for the proposed project.

The applicant provided no evidence that it has provided charity care in the past.

For this reason, the application is non-conforming to Criterion 13b.

18 a. 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 the service for which competition will not have a favorable impact.

Competition

This is a new applicant. However, because its projections are based on unsupported and unsupportable market shares, claims about cost effectiveness and access are over stated and cannot be used to support this criterion.

CON Review Criteria G.S. 131E-183(B)
North Carolina Administrative Code – 10A NCAC 14C .3703

(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;

Because claims of market share are overstated, the extent to which the application meets performance standards are also over-stated and the application does not meet performance standard 10A NCAC 14C.3703(a)

Attachment B

Competitive Review of Novant Health Forsyth Medical Center
Project ID# G-011640-18

COMPETITIVE REVIEW OF –
NOVANT HEALTH FORSYTH MEDICAL CENTER
APPLICATION FOR MOBILE PET/CT SCANNER
PROJECT ID# G-011640-18

Overview

Novant Health Forsyth Medical Center application to develop a mobile PET/CT scanner is non-conforming with statutory review criteria 1, 3, 3a, 4, 5, 7, 8, 13c, 18a, and does not meet the performance standard in 10A NCAC 14C .3703(a)(1) or (2).

This applicant proposes to increase its inventory of PET/CT scanners from three to four. It would have fixed units at Novant Forsyth Medical Center (NHFMC) and Novant Presbyterian Medical Center (NHPMC) and two mobile units serving other Novant facilities. The applicant is Novant Forsyth Memorial. Because the application excludes information from Novant Presbyterian from many of its performance metrics, it masks the fact that Novant Presbyterian PET/CT scanner is underused.

The application proposes to serve Greater Forsyth and Greater Charlotte reaching five existing hospital sites:

1. NH Matthews - Mecklenburg
2. NH Huntersville– Mecklenburg
3. NH Rowan -Rowan
4. NH Thomasville– Davidson
5. NH Kernersville– Forsyth

and four new sites:

1. NH Mint Hill – Mecklenburg
2. NH University Imaging --Mecklenburg
3. NH Wilkes Oncology Specialists – Wilkes
4. NH Mountainview Medical - Stokes

CON Review Criteria

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, ambulatory surgery operating rooms, or home health offices that may be approved.

Access

Novant's policies with respect to charity care and uninsured discounts ensure access to traditionally underserved populations (uninsured, underinsured, and indigent patients). Therefore, it is reasonable to assume that Novant's policies will be exercised with respect to the proposed mobile PET/CT. Based on the pro forma financial statements (presented in Section Q of the application), however, it appears that Novant does not expect underserved patients to utilize the proposed mobile PET/CT service at the same levels of Novant overall. Based on financial estimates presented on page 146 of the application, Novant is expecting 5.1% of its total revenue in Year 3 of the project to derive from self-pay and charity patients. Expected self-pay and charity volume (based on revenue estimates shown on page 149) for the proposed mobile service is expected to be only 2.1% of total revenue in Year 3.

In addition, Novant is proposing to increase geographic access to new markets currently unserved by local, on-site PET/CT (Wilkes and Stokes Counties) as well as increase availability of PET/CT in markets with existing PET technologies (Forsyth and Mecklenburg Counties). However, expected volume at each of the proposed host sites is likely volume that otherwise has historically been (and can be) served by existing Novant PET/CT units. As stated on page 50 Novant is expecting to "redirect" volume from existing sites to proposed new host sites.

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.

Although this application identifies patient origin by county and describes cancer incidence rates for those counties, it provides no specific calculation of need for PET/CT scans by county. The applicant based Forecast need on patterns of use at existing Novant PET/CT scanners, excluding the fixed unit at NHPMC. Novant does not support the need for a new mobile unit in its defined markets with data on current or expected unmet demand for services. On page 55, NHFMC summary of need is, in essence, a qualitative overview of need. However, nowhere in the application does Novant quantify the total or unmet net need for PET/CT services (let alone for mobile PET/CT) in the proposed service area.

Page 39 of the application indicates that Novant's existing mobile unit has not achieved the 2018 SMFP capacity utilization threshold of 2,600 scans (based on annualized volume through the first 11 months of FY2018). Moreover, Novant did not achieve 2018 SMFP capacity utilization of 3,000 scans at either of its fixed units in 2018. In fact, volume at the fixed unit at NHFMC has declined since 2016. The decline thereby challenges Novant's argument that a new unit will mitigate significant growth and capacity issues at its existing units.

Although the application proposes two new geographies, with proposed introduction of on-site services in Wilkes and Stokes Counties, the application involves redirection of patients from the declining Winston Salem NHFMC to Mountainview, an imaging center and primary care practice in Stokes and to Wilkes Oncology, an oncology clinic in Wilkes County. The application forecasts 20 percent in-migration from nearby counties to the Wilkes and Stokes clinics, but does not provide justification for the assumption.

With respect to estimating need and demand for the proposed new mobile PET/CT, Novant cites on page 47, the combined patient origin for FY 2017 for the fixed unit at NHFMC and the existing mobile unit. The data appear to exclude volume from NH Presbyterian's fixed unit. This in turn affects projected patient origin (and volume) in the markets served by future mobile PET/CT services. As a result, the application presupposes that activity and capacity at the existing fixed unit at NH Presbyterian will not influence forecast future volumes, especially from the Mecklenburg County and the Charlotte Region. Yet, this unit is located at the center of tertiary services and is under-used by state standards.

In addition, the discussion of need focuses on the capabilities of Novant Health facilities where mobile (and fixed) PET/CT services are presently available (see pages 40 ff) as it proposes to double access (as measured by days) to its mobile services.

Table 1: Proposed Distribution of NHFMC Mobile PET/CT Scanner Capacity

County	Location	Current days/ wk.	Proposed days/ wk.	Net Change days/wk.	Type of Billing	Comment
Forsyth	Kernersville	1.0	1.5	0.5	Hospital	
Davidson	Thomasville	0.5	0.5	0	Hospital	
Wilkes	Oncology Specialists Wilkesboro	0	1	1	Imaging Center	No new – all redirected
Stokes	Mountainview	0	1	1	Hospital	No new – all redirected
Mecklenburg	Huntersville	1.5	2.5	1.0	Hospital	
Mecklenburg	Matthews	1.5	2.0	0.5	Hospital	
Rowan	Rowan	1.5	1.5	0	Hospital	
Mecklenburg	Mint Hill	0	1	1	Hospital	
Mecklenburg	University	0	1	1	Hospital (a)	
	Total	***6***	***12.0***	***6.0***		

Source: (a) NH Presbyterian LRA 2018

As demonstrated in the above table, and summarized in the table below, this application proposes to add most of its new capacity to Mecklenburg County. As noted, the existing fixed Novant Health PET/CT capacity in Mecklenburg is underutilized. Other PET/ CT scanners in Mecklenburg County are also under-used, as demonstrated on page 137 of the 2018 SMFP.

Table 2: Net Days Added by County

County	Days
Forsyth	0.5
Wilkes	1
Stokes	1.0
Mecklenburg	3.5
Total	***6.0***

With no increase in days at Rowan, the application Table 17 (page 84) projects 164 additional scans by Year 3 of the project. Similarly, that same table shows that NHFMC will "transfer" 778 scans from NHFMC to the two clinic sites in Wilkes Oncology and Mountainview. That "transfer" represents 31 percent of the proposed scans (778/2,508 = 31 percent).

The application does not provide patient origin for proposed mobile PET/CT, making it difficult to evaluate the reasonableness of projections. The Patient Origin tables show fixed and mobile patient origin combined as "service component."

When compared to actual Novant history, the proposed plan is ambitious. Two years after start of operations, the existing mobile PET/CT was performing only 1,420 scans (page 85), yet Novant expects the proposed new mobile PET/CT to reach 1,818 scans by the first year (page 84).

Using data from the 2017 actual patient origin and proposed patient origin tables in Section C, one can calculate the net change in proposed scans. NHFMC, through its fixed unit in Winston-Salem and the current mobile unit, conducted more than 3,800 scans in FY 2017, and propose to provide 6,814 in its fixed and mobile units by the third project year. Notably, most of the proposed new patients served on the proposed new mobile PET/CT are from Mecklenburg, Union, Rowan, and Cabarrus Counties; NH Presbyterian or other units in Mecklenburg County could serve these counties. As illustrated in the following table, much of the net gain is from counties with no increase in PET/CT days.

Table 3: Net Increases in Proposed PET/CT Scans from Actual NHFMC 2017 Patient Origin

County	Net change in Patients Served between 2017 and Year 3	Net new Days
Alleghany	3	
Ashe	6	
Cabarrus	300	0
Catawba	20	
Davidson	137	
Davie	44	
Forsyth	252	0.5
Gaston	26	
Guilford	13	
Guilford	16	
Iredell	107	
Lincoln	59	
Mecklenburg	958	3.5
Other NC Counties**	4	
Out of State	64	
Randolph	10	
Rockingham	7	
Rowan	336	0
Stanly	3	
Stokes	112	1
Surry	121	
Union	253	0
Wilkes	89	1
Yadkin	59	
Total Net change in Patients	***2,999***	
Net change in Patients from Cabarrus, Forsyth, Mecklenburg, Rowan and Union	***2,099***	***6***

Source: Proposed Patient Origin PY 3 – Actual FY 2017 Mobile PET Patient Origin; Section C

As the table illustrates, five counties account for 70 percent of the net new scans.

Novant forecast PET/CT need based not on population but on compound annual growth rates of existing sites and expected growth rates of proposed sites. That growth is estimated from Novant regional and system averages. It is impossible to determine how this translates to forecast use rates in these counties. The application tries to backdoor a reach into Mecklenburg County without accounting for excess Novant Health PET/CT capacity in Mecklenburg County.

Based on this information, the application is non-conforming to Criterion 3.

3. a. 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.

On page 89, the application states in response to this criterion, “The proposed project does not involve the reduction, elimination or relocation of a facility or service. Section D is not applicable.”

However, the application also clearly states on pages 40 and following, and elsewhere, that NHFMC will move services from Julian Road to Rowan Hospital and that it will redirect services from NHFMC to Mountain View and Oncology Specialists in Wilkesboro.

These involve reductions in services and changes in patient billing. In the case of Oncology Specialists, Novant will need new Medicare arrangements for the IDTF that may slow implementation of services at that site.

The application fails to provide the required information, thus is non-conforming to Criterion 3a.

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 discuss potential alternatives for meeting unmet needs; rather, it justifies "unmet need" exists based on volume growth in its existing units.

On page 93 (Section E), NHFMC presents the status quo as a considered alternative. However, the application states, "the status quo would be to do nothing." This seems to contradict their argument throughout the application that NHFMC seeks to grow volume among all PET/ CT units, while also proposing the new mobile unit. Moreover, the application does not explain how "doing nothing" may in fact provide sufficient time to develop each of its existing units such that all existing units, including NH Presbyterian reach desired threshold volumes (3,000 scans for fixed, 2,600 scans for mobile).

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.

Funds are available to acquire and operate the proposed mobile PET/CT. However, at more than $3.1 million Novant's proposed capital cost for the proposed unit is significantly higher than other applicants.

Although the narrative discusses a management contract with MedQuest, Inc., and Section I.1 identifies MedQuest as a "Facility Paid Consultant/ Contractor," Pro forma Form 4, provides no documentation for the financial arrangements between Forsyth Memorial Hospital and MedQuest, Inc.

Assumptions provided for Form F.4 expenses provide little or no detail for base year line items. They do not describe any management fees for the mobile service. See page 148.

Although application page 65 and following discusses new tracers, the contract with PETNET covers only FDG. The charge to clinics includes only FDG and the charge is bundled in a fixed cost. The application does not discuss the impact of using radioisotopes that are more expensive.

The missing MedQuest information makes the financial forecasts questionable and the project is non-conforming to Criterion 5.

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.

On page 109, Novant states, "Qualified radiologists at each mobile PET host site hospital facility will continue to read the PET scans as is the current practice. In the event there is ever a time that a host site does not have a specialized Nuclear Medicine/PET radiologist available locally to interpret the mobile PET scan images, those scans can be sent by tele-radiology to one of two local radiology groups: Triad Radiology based at NHFMC in Winston-Salem or MRA Mecklenburg Radiology Associates in Charlotte." However, this statement seems to contradict Novant's stated provider responsibilities in its **MOBILE PET/CT SERVICES AGREEMENT** (Exhibit C-1.1, pages 294 - 305) that

> *"Provider and its Designated Physicians, without exception, shall be responsible for (i) arranging for the medical interpretation of all PET/CT scans performed on the mobile PET/CT Unit, (ii) the preparation and delivery of reports for each PET/CT scan performed, and (iii) the labeling of any anatomical or pathologic structure on a diagnostic film. FMC shall not, under any circumstances, interpret PET/CT scans, label films, render medical advice or perform any medical diagnosis or treatment or prepare a report related thereto, for any patient receiving a PET/CT scan on the mobile PET/CT Unit."*

Exhibit H.4.2, letters from Triad and MRA radiologists, indicate availability to interpret PET/CT scans at all times the PET/CT scanner is in service. The letters do not mention interpretation via tele-radiology and do not mention relationships with NH Kernersville, Mountainview Medical, or Wilkes Oncology. As such, coverage for these three sites is unclear.

NHFMC nuclear medicine department is available only at Forsyth and Kernersville (p632). It is staffed only Monday – Friday p 633. The application is unclear about coverage of the PET/CT on other days.

Absent complete information about physician coverage and the MedQuest deployment service, the application is non-conforming to Criterion 7.

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.

The application indicates that MedQuest Associates, Inc. manages deployment of NHFMC mobile PET/CT (page 54). The application contains no service contract from this vendor and the pro forma shows no expense for this service.

The application fails to address availability of a dedicated patient toilet at the new locations. The dedicated patient toilet is necessary for elimination of the radioisotope following the procedure, and is required for accreditation and certification.

Absent complete information about the MedQuest deployment service and the dedicated patient toilet at the new sites, the application is non-conforming to Criterion 8.

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:

(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

Application refers to deemed status of hospital sites for Medicare certification, but two of the proposed sites are not hospitals. It does not say how these will be addressed.

Item 13 on the Section P schedule is marked NA, but the two physician office buildings will need Medicare credentialing for the PET/CT. These are not radiology physician offices.

Absent this information, the application is non-conforming to Criterion 13(c)

18 a. 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 the service for which competition will not have a favorable impact.

Although the application proposes that this facility will enhance competition, in fact it will not. Novant is one of only two providers, operating three mobile PET/CT units in the state.

This criterion requires that the applicant meet all three tests to qualify as enhanced competition. It fails on cost-effectiveness and access.

Cost Effectiveness

The applicant provides the highest charge per scan among all applicants.

In all but one site, Wilkes Oncology, patients will be billed at hospital OPD rates. License Renewal applications for 2018 show all other proposed NHFMC mobile PET/CT sites are on the license of either Novant Forsyth or Novant Presbyterian.

Access

The proposed PET/CT scanner will be available to only Novant Health sites. Thus if approved, all other host sites in the state will be forced to contract with the only other vendor of mobile services in North Carolina (Alliance). That vendor would then have a virtual monopoly on mobile PET/CT services not provided by Novant.

Thus, the application is non-conforming to Criterion 18(a).

CON Review Criteria G.S. 131E-183(B)
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;

(2) if an applicant operates an existing dedicated PET scanner, its existing dedicated PET scanners, including those used exclusively for research, performed an average of at least 2,080 PET procedures per PET scanner in the last year;

Page 85 of the application includes Table 18 (see below) that details actual PET scans performed on its existing scanners in the previous 12 months.

Table 18 NHFMC Utilization – Rule Criteria

Unit	Location	Actual (9/1/17 - 8/31/2018)
Forsyth	Fixed	2,886
Forsyth	Converted Fixed to Mobile	
	NH Huntersville	469
	NH Matthews	459
	NH Rowan	337
	NH Thomasville	155
	NH Kernersville	338
Total Mobile Unit		1,420
Forsyth TOTAL		4,306
Utilization per unit		2,153

However, this table fails to include data from Presbyterian.

Scan volume at the fixed Forsyth PET/CT scanner has declined since 2016; see application Table 1 on p39.

Attachment C

Competitive Review of Mobile Imaging Partners of North Carolina, LLC Project ID# F-011627-18

COMPETITIVE REVIEW OF –
MOBILE IMAGING PARTNERS OF NORTH CAROLINA, LLC
APPLICATION FOR MOBILE PET/CT SCANNER
PROJECT ID# F-011627-18

Overview

Mobile Imaging Partners of North Carolina, LLC (MIPNC) application to develop a mobile PET/CT scanner is non-conforming with statutory review criteria: 1, 3, 3a, 5, 6, 7, 8, and 18a.

This applicant's declared intent is to add PET/CT service to one new site and increase service to eight existing hospital host sites located in rural counties characterized by comparatively limited access to healthcare services and high percentages of medically underserved and low-income patients (p28). The applicant proposes nine sites, scattered throughout eastern and western North Carolina.

This is a confusing application. It is difficult to separate the applicant, MIPNC from its member, Alliance Imaging, Inc.

CON Review Criteria G.S. 131E-183(a)

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, ambulatory surgery operating rooms, or home health offices that may be approved.

Overview

MIPNC has indicated in the application that introduction of a new mobile PET/CT unit will double the scheduling frequency at the eight existing host sites. However, the application provides neither documentation of unmet need, nor evidence that increased scheduling opportunities in fact will address unmet need. The application is not consistent with Policy Gen-3 regarding Quality, Access, and Value.

Quality

The application contains no evidence of necessary provisions for patient safety. Specifically, it is missing medical directors at four proposed host sites and it provides no evidence that required dedicated patient toilets will be available at every host site. See the discussion in Criterion 7.

Access

Throughout its application, MIPNC discusses offering/expanding services in locations with high percentages of medically underserved and low-income patients. However, there is no indication in the application that MIPNC will in fact be serving these patients.

The application contains no information about the income status or medically underserved status of any of the counties it proposes to serve.

Value

The application is internally inconsistent and it is impossible to determine what value the project would add

This applicant appears to be a shell pass-through company for Alliance Imaging. Throughout, the application refers to control of schedule and program by Alliance. On page 73, Alliance is the sole source of funds for the project.

This applicant has no experience providing mobile PET/CT or any other service. It is an entirely new entity. Exhibit A.9, a Draft management services agreement with the host sites, indicates that MIPNC will provide management and technical expertise for the proposed mobile PET/CT. The agreement indicates that the "LLC will hire radiologists to interpret the scans," but the application indicates that Alliance Imaging will hire staff (p 83) and the host sites will hire the radiologists (p84). That document also directs that all correspondence for the facility to a Chief Legal Officer, Eric T. Olson, in Irvine, California (page 33 of Exhibit A.9). Home offices of Alliance Imaging are in Irvine, California. Clearly, MIPNC functions as an agent of Alliance Imaging.

The management services agreement with MIPNC indicates that the laws of the State of Delaware will govern all legal disputes. (p34 of Exhibit A.9)

The management services agreement provides no information about the contractual obligations of host sites, for example, whether charges will involve minimum daily payments, as is the practice with Alliance, the experienced member of the group, or whether hosts must pay for the service a month in advance.

The application indicates that the proposed mobile PET/CT will add "slots" and later indicates that a scan takes a little more than an hour. On page 29, it proposes 96 to 110 new slots a week, but on page 31, it proposes to staff and schedule "up to 84 hours a week." That schedule would not support the proposed slots.

For these reasons, the application is non-conforming to Criterion 7 below contains more detail.

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.

The application is non-conforming to Criterion 3.

The application focuses on host sites, rather than the population to be served. Section C contains no discussion of the population to be served. Even the mention of use rates, on page 45, addresses only statewide historical use rates through 2017, which is the fiscal year associated with SMFP-19.

The application presents a business plan for Alliance, for example, on page 12, "Alliance PET scanners have the highest utilization in the country on two existing scanners; 7 days a week."

In describing equitable access, the application provides the following table of Alliance host sites.

Route for New PET/CT		
Host Site	County	Currently Served by
UNC Rockingham Health Care	Rockingham	NA
Northern District Hospital Of Surry County	Surry	Alliance I
Onslow Memorial Hospital	Onslow	Alliance II
Wayne UNC Health Care	Wayne	Alliance II
Wilson Medical Center	Wilson	Alliance II
Maria Parham Medical Center	Vance	Alliance II
UNC Pardee	Henderson	Alliance I
CHS Lincoln	Lincoln	Alliance I
Caldwell Memorial Hospital	Caldwell	Alliance I

Source: MIPNC page 23.

A careful review of what is actually new, versus what Alliance Imaging proposes to achieve with its two existing scanners, indicates that the new PET/CT scanner will add very little new capacity to the state. The net new scans provided by the combined capacity of Alliance and MIPNC are only 547 scans by year 3. Although the proposed PET/CT scans are all for cancer patients, the applicant proposes only FDG as a tracer isotope – one of the proposed sites does not have a full cancer program, CHS Lincolnton does not have a linear accelerator.

In fact, the application proposes only one new site, UNC Rockingham. Other Alliance units presently serve the eight additional sites proposed for the MIPNC unit.

According to the table on page 110, Alliance I and II completed 7,619 scans at 29 sites in FY 2018. However, according to the tables on page 112, the application proposes that Alliance/MIPNC will perform fewer scans on three mobile PET/CT scanners by the third project year, than Alliance performed alone on its two scanners in FY 2018, even after accounting for projected incremental growth at each of the eight existing proposed host sites. Table 1 below compares historical and proposed PET/CT scans as presented in the application.

Table 1: Historical and Projected Scans for the Alliance PET/CT System

Year	Machine	Total Scans	Source
2017-2018	Historical Data Alliance I and II	7,619	p110, Table
PY3, 2022	Projected Data Alliance I and II and MIPNC	7,590	p112, Tables (a)

Notes: a. Proposed total scans from each scanner PY 3, p112: 2,510 + 2,356 + 2,724 = 7,590

Furthermore, page 25 of the application states, "The MIPNC scanner will maximize value by providing expanded access to more host sites..." However, according to the tables provided by the applicant on pp110 and 112, Alliance/MIPNC will actually be serving fewer locations in PY3 than Alliance serves are today. Table 2 summarizes this and shows three sites eliminated from the historical host roster and only one site added to the proposed new scanner route.

Table 2: Historical and Proposed Host Site Locations for the Alliance System

Historical Host Sites 2017-2018 (p110)	Proposed Host Sites PY3 2022(p112)
Caldwell Memorial Hospital	Caldwell Memorial Hospital
CHS Blue Ridge	CHS Blue Ridge
CHS Cleveland Regional Medical Center	CHS Cleveland Regional Medical Center
CHS Stanly Regional Medical Center	CHS Stanly Regional Medical Center
CHS Columbus Regional	CHS Columbus Regional
Carolina Medical Center Lincolnton	Carolina Medical Center Lincolnton
Carteret General Hospital	Carteret General Hospital
Duke Raleigh Hospital	***UNC Rockingham***
Duplin General	Duplin General
Harris Regional	Harris Regional
Haywood Regional Medical Center	Haywood Regional Medical Center
Johnston Health	Johnston Health
Lake Norman Regional Medical Center	
Lenoir Memorial Hospital	Lenoir Memorial Hospital
Margaret R. Pardee Memorial Hospital	Margaret R. Pardee Memorial Hospital
Mariah Parham Medical Center	Mariah Parham Medical Center
Northern Hospital of Surry	Northern Hospital of Surry
Onslow Memorial Hospital	Onslow Memorial Hospital
Park Ridge Health	Park Ridge Health
Randolph Hospital	Randolph Hospital
Rutherford Regional Health System	Rutherford Regional Health System

Historical Host Sites 2017-2018 (p110)	Proposed Host Sites PY3 2022(p112)
Sentara-Albemarle Hospital	Sentara-Albemarle Hospital
Scotland Memorial Hospital	Scotland Memorial Hospital
Southeastern Regional Medical Center	Southeastern Regional Medical Center
The Outer Banks Hospital	The Outer Banks Hospital
Vidant Chowan	Vidant Chowan
Watauga Medical Center	
Wayne Memorial Hospital	Wayne Memorial Hospital
Wilson Medical Center	Wilson Medical Center
Total: 29	***Total: 27***

Note: Shaded cells indicate host sites added or deleted between FY 2018 and PY 2022.

Although the table shows Duke Raleigh Hospital replaced by UNC Rockingham –the only new site proposed by the applicant –Alliance/ MIPNC actually proposes to omit two more locations AFTER adding a new mobile PET/CT. This is in direct contradiction to the application's claim of expanding service to the entire state.

With nine sites and service seven days a week, not every site will have weekly service. The application does not tell which site will get less than weekly service. In fact, the application does not provide a site schedule. Hence, it is impossible to link the service proposed with the need in the population.

3 a. 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.

The application is non-conforming to Criterion 3a. As discussed with regard to Criterion 3, Alliance/MIPNC proposes to eliminate service to two locations, and does not discuss the impact on persons served by these locations.

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.

The project involves a high management fee to Alliance at 5 percent of net revenue. In this case, the LLC structure distorts the perception of costs. The income statement in Form F.3 includes no interest cost, but with no indication to the contrary, the project appears to be passing all of the Net Income to the Alliance member as return on equity invested. The UNC Rockingham member makes no capital contribution to the project. In fact, this absence of financial participation by the UNC Rockingham member may disqualify it as an applicant under current interpretation of CON rules that an applicant is one who makes a financial contribution to the project.

The equipment quote does not include training for the new staff.

The project involves 7 days, 12 hours a day of in-service each week. This leaves no downtime for repair and servicing.

The application is not clear about the source of the truck to haul the trailer. It is not in the capital cost.

Operating pro forma does not include calibration and accreditation fees, Form F.3.

Thus, the application does not demonstrate the availability of funds for capital and operating needs and the application is non-conforming to Criterion 5.

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

The application proposes specific host sites and specific numbers of scans at each. However, it contains no physician support letters form Onslow or Wilson hospitals and even the host letters indicate only that they are willing to be “on the route with commitment to increase the time slots.” The letters do not tie back to the time slots on page 29.

Thus, the applicant does not demonstrate that the proposed project will not result in unnecessary duplication of existing capabilities and is non-conforming to Criterion 4.

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 provides technical and management staffing, but evidence of radiologists with capabilities to read the PET/CT scans is missing. In Section H, question 4(a) the application indicates that each host site has a medical director and minimum of two radiologists, a total of 18 radiologists routinely providing professional services. It refers to Exhibit C.4 (b) for letters. However, four of the proposed host sites provided no letters from radiologists with skills to interpret PET/CT scans:

- Northern District Surry Hospital
- Onslow Memorial
- Wilson Medical Center
- DLP Maria Parham Hospital.

The radiation safety officer for the program is in Midland Park, New Jersey. The application does not show this person is a physician or licensed in North Carolina.

Thus, the application does not demonstrate the availability of resources and the application is non-conforming to Criterion 7.

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.

Accreditation and certification standards require a dedicated patient toilet. The application contains no evidence that any site has the required dedicated patient toilet. Other sites have service, but the UNC Rockingham site will be new, so one cannot assume that it has this essential resource.

The applicant did not demonstrate that each proposed host site has a pad with the required power to accommodate the proposed service at the proposed time of service.

Thus, the application does not demonstrate the availability of required ancillary services and the application is non-conforming to Criterion 8.

18 a. 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 the service for which competition will not have a favorable impact.

Competition

The applicant is a new legal entity. However, the operator, funder, and major beneficiary of the project are each Alliance Imaging. Alliance is one of two current providers of mobile PET/CT services in the state. In addition, the applicant states on page 32 that "MIPNC offers hospitals a new choice of mobile PET/CT as an alternative to both Alliance and Novant." However, even accounting for Novant as a competitive alternative it is unlikely that existing and proposed host hospitals will consider a unit co-owned and managed by Alliance as an alternative to Alliance's other operating units.

The application is not clear about the nature of the joint venture applicant. It does not describe distribution of ownership between the two members. The UNC Rockingham member will likely get at most 10 hours a week of service, less than 10 percent of the proposed new slots developed.

Cost Effectiveness

While MIPNC offers discussion on achieving economies and efficiencies nowhere does the application indicate how and how much savings the applicant expects to realize. Moreover, the applicant, MIPNC, discusses how two replacement units put into service by Alliance in 2017 and 2018 are already increasing productivity. It is not clear, however, how a third unit will impact productivity.

Meeting proposed performance requires average scan to complete in less than 46 minutes. The applicant proposes 110 new weekly slots in 84 hours a week. (84 hours per week/ 110 total scans * 60 minutes per hour = 45.8 minutes). The application does not indicate that this is an achievable goal.

Quality

Although back in compliance, the proposed new location UNC Rockingham was out of compliance with CMS Conditions of Participation in the last 18 months. The missing dedicated patient toilet would make it out of compliance for the PET/CT program.

Access

This project does not conform to Criterion 18a because it will not have a positive effect on competition.

20. An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

The application indicates that the new host site at UNC Rockingham, is currently in compliance but this quality history makes this a less effective competitor with regard to this criterion.

CON Review Criteria G.S. 131E-183(B)
North Carolina Administrative Code – 10A NCAC 14C .3703

(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;

(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.

For performance standards (1) and (3), the application achieves the required performance standards by redistributing cases from Alliance scanners to the proposed MIPNC scanner. Yet, the application claims that MIPNC is a new entity. Clearly, it is not a new entity, or it could not control the distribution and schedule. Without the redistribution, the proposed project involves only 547 net new scans.

Applicant	Estimated Scans in Interim Year	PY3 Proposed Scans	Net New Patients Served by PY 3 (c-b)	Sources
a	b	c	d	e
MIPNC	2,155	2,702	547	p112

Attachment D

2018 Hospital License Renewal Application Excerpts,
Caldwell Memorial Hospital and Harris Regional Hospital

REC'D JAN 16 2018

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
Regular Mail: 1205 Umstead Drive
2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Overnight UPS and FedEx only: 1205 Umstead Drive
Raleigh, North Carolina 27603
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only
License # H0061 Medicare # **340041**
FID #: 933051
PC LJ Date 1/19/18

License Fee: **$2,375.00**

2018
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant: **Caldwell Memorial Hospital, Inc.**
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: **Caldwell Memorial Hospital, Inc.**
Other: d/b/a CALDWELL
Other:

Facility Mailing Address: P.O. Box 1890
Lenoir, NC 28645

Facility Site Address: 321 Mulberry St SW
Lenoir, NC 28645
County: Caldwell
Telephone: (828)757-5100
Fax: (828)757-5512

Application Rec'd Date 1-16-18
Fee Paid-Ck # 45857
Amount $2,375
Initials
DHSR Acute and Home Care L&C

Administrator/Director: Laura J Easton
Title: PRESIDENT/CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: Laura J. Easton **Title:** President/CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: Jackie G. Berry **Telephone:** (828) 757-5214
E-Mail: jackie.berry@unchealth.unc.edu

All responses should pertain to **October 1, 2016 through September 30, 2017**.

Patient Origin - MRI Services

In an effort to document patterns of utilization of MRI Services in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. Submit one record for the licensed hospital. **DO NOT SUBMIT SEPARATE RECORDS FOR EACH CAMPUS.**

The total number of patients reported here should be equal to or less than the total number of MRI procedures reported in Table 10c. on page 19.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander	15	38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson		40. Greene		76. Randolph	
5. Ashe	2	41. Guilford		77. Richmond	
6. Avery	5	42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	2
9. Bladen		45. Henderson		81. Rutherford	1
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	71	47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus	1,671	49. Iredell	1	85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell	1	53. Lee		89. Tyrrell	
18. Catawba	31	54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland	1	59. McDowell	3	95. Watauga	17
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	21
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson	1	65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	
32. Durham		68. Orange		103. Tennessee	2
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	1
35. Franklin		71. Pender		106. Other	
36. Gaston		72. Perquimans		**Total No. of Patients**	1,846

All responses should pertain to **October 1, 2016 through September 30, 2017.**

Patient Origin – PET Scanner

In an effort to document patterns of utilization of PET Scanners in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. This data should only reflect the number of patients, not number of scans and should not include other radiopharmaceutical or supply charge codes. Submit one record for the licensed hospital. **DO NOT SUBMIT SEPARATE RECORDS FOR EACH CAMPUS.**

Please count each patient only once. The number of patients in this table should match the number of PET procedures reported in Table 10i on page 21.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson		81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe		47. Hoke		83. Scotland	
12. Burke	2	48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell	57	50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	2
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	2
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore	1	99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	
35. Franklin		71. Pender		106. Other	
36. Gaston		72. Perquimans		**Total No. of Patients**	94

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
Regular Mail: 1205 Umstead Drive
2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Overnight UPS and FedEx only: 1205 Umstead Drive
Raleigh, North Carolina 27603
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only
License # H0087 Medicare # 340016
FID #: 923046
PC 15 Date 1/5/18

License Fee: **$1,855.00**

2018
HOSPITAL LICENSE
RENEWAL APPLICATION

DEC 0 DEC 2 9 2017

Legal Identity of Applicant: **DLP Harris Regional Hospital, LLC**
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: **Harris Regional Hospital**
Other: _____
Other: _____

Facility Mailing Address: 68 Hospital Rd
Sylva, NC 28779-2795

Facility Site Address: 68 Hospital Rd
Sylva, NC28779-2795
County: Jackson
Telephone: (828)586-7000
Fax: (828)586-7467

Application Rec'd Date 12-29-17
Fee Paid-Ck # 00132746
Amount 1855.00
Initials QPL
DHSR Acute and Home Care L&C

Administrator/Director: Stephen L Heatherly
Title: CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: Stephen L. Heatherly **Title:** Chief Executive Officer
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: Connie Wilkinson **Telephone:** (828) 586-7710

E-Mail: Connie.Wilkinson@westcare.org

All responses should pertain to October 1, 2016 through September 30, 2017.

Patient Origin - MRI Services

In an effort to document patterns of utilization of MRI Services in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. Submit one record for the licensed hospital. **DO NOT SUBMIT SEPARATE RECORDS FOR EACH CAMPUS.**

The total number of patients reported here should be equal to or less than the total number of MRI procedures reported in Table 10c. on page 19.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance	1	37. Gates		73. Person	1
2. Alexander	1	38. Graham	243	74. Pitt	1
3. Alleghany		39. Granville		75. Polk	1
4. Anson		40. Greene		76. Randolph	3
5. Ashe		41. Guilford	2	77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	75	80. Rowan	1
9. Bladen		45. Henderson	4	81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	6	47. Hoke	1	83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus	1	49. Iredell	1	85. Stokes	1
14. Caldwell	1	50. Jackson	1,210	86. Surry	2
15. Camden		51. Johnston	3	87. Swain	480
16. Carteret	2	52. Jones		88. Transylvania	4
17. Caswell		53. Lee	1	89. Tyrrell	
18. Catawba	5	54. Lenoir		90. Union	2
19. Chatham		55. Lincoln	1	91. Vance	
20. Cherokee	88	56. Macon	468	92. Wake	4
21. Chowan		57. Madison	1	93. Warren	
22. Clay	46	58. Martin		94. Washington	
23. Cleveland	1	59. McDowell	1	95. Watauga	2
24. Columbus		60. Mecklenburg	6	96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	1
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson	1	65. New Hanover			
30. Davie		66. Northampton		101. Georgia	41
31. Duplin		67. Onslow		102. South Carolina	11
32. Durham	1	68. Orange		103. Tennessee	
33. Edgecombe	1	69. Pamlico		104. Virginia	2
34. Forsyth	6	70. Pasquotank		105. Other States	43
35. Franklin		71. Pender	1	106. Other	
36. Gaston	1	72. Perquimans		**Total No. of Patients**	2,780

Patient Origin – PET Scanner

In an effort to document patterns of utilization of PET Scanners in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. This data should only reflect the number of patients, not number of scans and should not include other radiopharmaceutical or supply charge codes. Submit one record for the licensed hospital. **DO NOT SUBMIT SEPARATE RECORDS FOR EACH CAMPUS.**

Please count each patient only once. The number of patients in this table should match the number of PET procedures reported in Table 10i on page 21.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham	13	74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	56	80. Rowan	
9. Bladen		45. Henderson		81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	1	47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson	49	86. Surry	
15. Camden		51. Johnston		87. Swain	38
16. Carteret		52. Jones		88. Transylvania	2
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee	42	56. Macon	47	92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay	11	58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	3
31. Duplin		67. Onslow		102. South Carolina	
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	2
35. Franklin		71. Pender		106. Other	
36. Gaston		72. Perquimans		**Total No. of Patients**	264

Attachment E

General Inpatient Acute Care, PET, and MRI Patient Origins for Caldwell Memorial Hospital and Harris Regional Hospital 2015-2017

General Inpatient Acute Care, PET, and MRI Patient Origins for Caldwell Memorial and Harris Regional, 2015-2017

Caldwell Memorial Inpatient Acute Care Market Share of Insight Target PET Counties

	2015			2016			2017		
County	Admissions to Caldwell Memorial	Total County Admissions	Market Share (CMH % of County)	Admissions to Caldwell Memorial	Total County Admissions	Market Share (CMH % of County)	Admissions to Caldwell Memorial	Total County Admissions	Market Share (CMH % of County)
a	b	c	d	b	c	d	b	c	d
Alexander	20	3,510	0.57%	-	3,506	0.00%	27	3828	0.71%
Caldwell	**3,389**	**8,252**	**41.07%**	**3,500**	**8,587**	**40.76%**	**3,311**	**8483**	**39.03%**
Wilkes	41	8,159	0.50%	43	7,531	0.57%	62	7,395	0.84%
Total Admissions for 3 Target Counties	3,450	19,921	17.32%	3,543	19,624	18.05%	3,400	19,706	17.25%
Total Admissions from All Counties	3,744	954,336	0.39%	3,697	947,703	0.39%	3,726	959,632	0.39%

Notes:

a: Mobile PET/CT target counties served at CMH, Section C; Caldwell is the home county of CMH

b: CMH Inpatient Acute Care Admissions for each county from LRA, 2016-2018 (2015-2017 data)

c: Total Inpatient Acute Care Admissions from County; NC DHSR Access Database, 2016-2018 (2015-2017 data)

d: b/c

Caldwell Memorial PET Patient Market Share of Insight Target PET Counties

	2015			2016			2017		
County	Admissions to Caldwell Memorial	Total County Patients for PET	Market Share (CMH % of County)	Admissions to Caldwell Memorial	Total County Patients for PET	Market Share (CMH % of County)	Admissions to Caldwell Memorial	Total County Patients for PET	Market Share (CMH % of County)
a	b	c	d	b	c	d	b	c	d
Alexander	2	189	1.06%	4	211	1.90%	-	288	0.00%
Caldwell	**65**	**362**	**17.96%**	**46**	**380**	**12.11%**	**87**	**408**	**21.32%**
Wilkes	2	258	0.78%	6	287	2.09%	2	361	0.55%
Total Admissions for 3 Target Counties	69	809	8.53%	56	878	6.38%	89	1,057	8.42%
Total Admissions from All Counties	79	41,251	0.19%	70	43,422	0.16%	94	46,766	0.20%

Notes:

a: Mobile PET/CT target counties served at CMH, Section C; Caldwell is the home county of CMH

b: CMH PET Patients for each county from LRA, 2016-2018 (2015-2017 data)

c: Total PET Patients Served from County; NC DHSR Access Database, 2016-2018 (2015-2017 data)

d: b/c

Caldwell Memorial MRI Market Share of Insight Target PET Counties

	2015			2016			2017		
County	**Admissions to Caldwell Memorial**	**Total MRI County Admissions**	**Market Share (CMH % of County)**	**Admissions to Caldwell Memorial**	**Total MRI County Admissions**	**Market Share (CMH % of County)**	**Admissions to Caldwell Memorial**	**Total MRI County Admissions**	**Market Share (CMH % of County)**
a	**b**	**c**	**d**	**b**	**c**	**d**	**b**	**c**	**d**
Alexander	11	1,771	0.62%	4	1,929	0.21%	15	2032	0.74%
Caldwell	**1,978**	**4,426**	**44.69%**	**1,769**	**4,658**	**37.98%**	**1,671**	**4,487**	**37.24%**
Wilkes	8	4,777	0.17%	10	4,720	0.21%	21	4,710	0.45%
Total Admissions for 3 Target Counties	1,997	10,974	18.20%	1,783	11,307	15.77%	1,707	11,229	15.20%
Total Admissions from All Counties	2,099	420,271	0.50%	1,887	424,758	0.44%	1,846	466,903	0.40%

Notes:

a: Mobile PET/CT target counties served at CMH, Section C; Caldwell is the home county of CMH

b: CMH MRI Patients for each county from LRA, 2016-2018 (2015-2017 data)

c: Total MRI Patients Served from County; NC DHSR Access Database, 2016-2018 (2015-2017 data)

d: b/c

General Inpatient Acute Care, PET, and MRI Patient Origins for Caldwell Memorial and Harris Regional, 2015-2017

Harris Regional Inpatient Acute Care Market Share of Insight Target PET Counties

	2015			2016			2017		
County	**Admissions to Harris Regional**	**Total County Admissions**	**Market Share (HR % of County)**	**Admissions to Harris Regional**	**Total County Admissions**	**Market Share (HR % of County)**	**Admissions to Harris Regional**	**Total County Admissions**	**Market Share (HR % of County)**
a	**b**	**c**	**d**	**b**	**c**	**d**	**b**	**c**	**d**
Cherokee	67	1,983	3.38%	72	2,000	3.60%	58	1,871	3.10%
Haywood	123	6,998	1.76%	119	7,224	1.65%	115	7,418	1.55%
Jackson	**1,721**	**3,350**	**51.37%**	**1,583**	**3,216**	**49.22%**	**1,566**	**3,372**	**46.44%**
Macon	291	3,184	9.14%	226	3,228	7.00%	274	3,420	8.01%
Swain	907	2,211	41.02%	934	2,254	41.44%	893	2,159	41.36%
Total Admissions for 5 Target Counties	3,110	17,726	17.54%	2,935	17,922	16.38%	2,907	18,240	15.94%
Total Admissions from All Counties	3,634	954,336	0.38%	3,495	947,703	0.37%	3,442	959,632	0.36%

Notes:

a: Mobile PET/CT target counties served at HRH, Section C; Jackson is the home county of CMH

b: HRH Inpatient Acute Care Admissions for each county from LRA, 2016-2018 (2015-2017 data)

c: Total Inpatient Acute Care Admissions from County; NC DHSR Access Database, 2016-2018 (2015-2017 data)

d: b/c

Harris Regional PET Patient Market Share of Insight Target PET Counties

	2015			2016			2017		
County	**Admissions to Harris Regional**	**Total County Patients for PET**	**Market Share (HR % of County)**	**Admissions to Harris Regional**	**Total County Patients for PET**	**Market Share (HR % of County)**	**Admissions to Harris Regional**	**Total County Patients for PET**	**Market Share (HR % of County)**
a	**b**	**c**	**d**	**b**	**c**	**d**	**b**	**c**	**d**
Cherokee	43	72	59.72%	59	98	60.20%	42	73	57.53%
Haywood	76	237	32.07%	60	215	27.91%	56	278	20.14%
Jackson	**54**	**102**	**52.94%**	**46**	**119**	**38.66%**	**49**	**106**	**46.23%**
Macon	65	153	42.48%	51	153	33.33%	47	140	33.57%
Swain	39	63	61.90%	30	60	50.00%	38	82	46.34%
Total Admissions for 5 Target Counties	277	627	44.18%	246	645	38.14%	232	679	34.17%
Total Admissions from All Counties	303	41,251	0.73%	283	43,422	0.65%	264	46,766	0.56%

Notes:

a: Mobile PET/CT target counties served at HRH, Section C; Jackson is the home county of CMH

b: HRH PET Patients for each county from LRA, 2016-2018 (2015-2017 data)

c: Total PET Patients Served from County; NC DHSR Access Database, 2016-2018 (2015-2017 data)

d: b/c

Harris Regional MRI Market Share of Insight Target PET Counties

	2015			2016			2017		
County	**Admissions to Harris Regional**	**Total MRI County Admissions**	**Market Share (HR % of County)**	**Admissions to Harris Regional**	**Total MRI County Admissions**	**Market Share (HR % of County)**	**Admissions to Harris Regional**	**Total MRI County Admissions**	**Market Share (HR % of County)**
a	**b**	**c**	**d**	**b**	**c**	**d**	**b**	**c**	**d**
Cherokee	53	1,532	3.46%	74	1,455	5.09%	88	1,332	6.61%
Haywood	77	3,809	2.02%	76	3,988	1.91%	75	4,425	1.69%
Jackson	1,156	**1,845**	**62.66%**	**1,183**	**1,925**	**61.45%**	**1,210**	**2,025**	**59.75%**
Macon	385	2,608	14.76%	351	2,280	15.39%	468	2,817	16.61%
Swain	499	869	57.42%	475	873	54.41%	480	886	54.18%
Total Admissions for 5 Target Counties	2,170	10,663	20.35%	2,159	10,521	20.52%	2,321	11,485	20.21%
Total Admissions from All Counties	2,670	420,271	0.64%	2,555	424,758	0.60%	2,780	466,903	0.60%

Notes:

a: Mobile PET/CT target counties served at HRH, Section C; Jackson is the home county of CMH

b: HRH MRI Patients for each county from LRA, 2016-2018 (2015-2017 data)

c: Total MRI Patients Served from County; NC DHSR Access Database, 2016-2018 (2015-2017 data)

d: b/c

Attachment F

2018 Hospital License Renewal Application Excerpt from Mission Hospital

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
Regular Mail: 1205 Umstead Drive
2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Overnight UPS and FedEx only: 1205 Umstead Drive
Raleigh, North Carolina 27603
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only
License # H0036 Medicare # **340002**
FID #: 943349
PC LS Date 2/7/18

License Fee: **$14,302.50**

2018
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant: **Mission Hospital, Inc.**
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: **Mission Hospital**
Other: Copestone Psychiatric Center
Other: _____

Facility Mailing Address: 509 Biltmore Ave
Asheville, NC 28801

Facility Site Address: 509 Biltmore Ave and 428 Biltmore Avenue
Asheville, NC28801
County: Buncombe
Telephone: (828)213-1111
Fax: (828)213-1151

Application Rec'd Date 1-16-18
Fee Paid-Ck # 886711
Amount $14,302.50
Initials
DHSR Acute and Home Care L&C

Administrator/Director: Jill Hoggard-Green
Title: CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: Jill Hoggard Green PhD, RN **Title:** CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: Linda Hummel **Telephone:** 828-213-9216

E-Mail: Linda.Hummel@msj.org

All responses should pertain to **October 1, 2016 through September 30, 2017.**

Patient Origin – PET Scanner

In an effort to document patterns of utilization of PET Scanners in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. This data should only reflect the number of patients, not number of scans and should not include other radiopharmaceutical or supply charge codes. Submit one record for the licensed hospital. **DO NOT SUBMIT SEPARATE RECORDS FOR EACH CAMPUS.**

Please count each patient only once. The number of patients in this table should match the number of PET procedures reported in Table 10i on page 21.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham	14	74. Pitt	
3. Alleghany		39. Granville		75. Polk	21
4. Anson		40. Greene		76. Randolph	
5. Ashe	1	41. Guilford	1	77. Richmond	
6. Avery	10	42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	160	80. Rowan	1
9. Bladen		45. Henderson	183	81. Rutherford	18
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	842	47. Hoke		83. Scotland	
12. Burke	27	48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell	2	50. Jackson	54	86. Surry	
15. Camden		51. Johnston		87. Swain	39
16. Carteret		52. Jones		88. Transylvania	122
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba	4	54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee	31	56. Macon	86	92. Wake	1
21. Chowan		57. Madison	92	93. Warren	
22. Clay	15	58. Martin		94. Washington	
23. Cleveland	4	59. McDowell	158	95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell	51	97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	62
29. Davidson		65. New Hanover		NC Total	2,000
30. Davie		66. Northampton		101. Georgia	3
31. Duplin		67. Onslow		102. South Carolina	9
32. Durham		68. Orange	1	103. Tennessee	10
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	18
35. Franklin		71. Pender		106. Other	
36. Gaston		72. Perquimans		**Total No. of Patients**	2,040