

**COMPETITIVE COMMENTS SUBMITTED BY ALLIANCE HEALTHCARE SERVICES
REGARDING THE 2021 MOBILE PET SCANNER CERTIFICATE OF NEED APPLICATIONS**

Two applications were submitted in response to the need determination in the 2021 State Medical Facilities Plan for one additional mobile PET scanner to serve the statewide service area:

CON Project ID # G-12156-21, Alliance Healthcare Services, Inc. – Acquire one mobile PET scanner in response to the need determination in the 2021 State Medical Facilities Plan (“**Alliance**”).

CON Project ID # G-012142-21, Novant Health Forsyth Medical Center – Acquire a second mobile PET scanner in response to the need determination in the 2021 State Medical Facilities Plan (“**NHFMC**”).

The following comments are submitted in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) and address facts relating to the service area proposed in the NHFMC Certificate of Need (“**CON**”) application; facts relating to the representations made by NHFMC in its application and its ability to perform or fulfill the representations made; and discussion and argument as to whether the NHFMC application complies with relevant criteria, plans, and standards, including an analysis of factors reflecting that the Alliance application is comparatively superior to the NHFMC application. Alliance’s comments herein do not include any additional information that would represent an amendment to its application.

OVERVIEW OF THE NHFMC APPLICATION

The NHFMC application to acquire a mobile PET scanner should not be approved due to the numerous deficiencies and omissions that result in the NHFMC application being non-conforming with the relevant review criteria, plans, and standards. Alliance identifies the following specific issues, each of which demonstrates NHFMC’s non-conformity:

- Failure to adequately identify the population to be served by the proposed mobile PET scanner;
- Unreasonable utilization projections;
- Lack of conformity with the PET performance standards;
- Failure to demonstrate financial feasibility;
- Omission of project start-up and initial operating costs for the project;
- Inability to demonstrate that the proposed project would not result in unnecessary duplication of existing or approved health service capabilities;
- Lack of adequate management staff;
- Absence of information for the construction of a mobile services pad that requires capital outlay, architectural plans, cost certification and the DHSR Construction Section approval; and
- Inadequate showing that the proposed project would enhance competition and have a positive impact upon the cost effectiveness, quality, and access to the services.

Accordingly, and as discussed further herein, NHFMC’s application fails to conform to CON Review Criteria (1), (3), (4), (5), (6), (7), (12) and (18a) and the PET Performance Standards of 10A NCAC 14C .3703.

According to Table 17F-5, the 2021 SMFP contained a need determination for **one mobile PET scanner** statewide. Each of the existing mobile PET scanners included in the 2021 SMFP function independently and have their own unique mobile route, set of host sites, patient origin data and annual utilization. The NHFMC application is based on the flawed concept that its project is to acquire a “second mobile PET scanner” pursuant to the need determination in the 2021 SMFP. NHFMC’s mischaracterization of its proposed project as one that involves two mobile PET scanners (with its existing and proposed mobile PET scanners **combined**) causes its utilization and financial projections to be unreasonable, unreliable and unsupported. As discussed more fully below:

- 1) The NHFMC application omits the patient origin projections for its proposed mobile PET scanner standing alone that are specific to its proposed host sites. Instead, NHFMC provides patient origin projections for its **combined** existing mobile PET scanner and its proposed mobile PET scanner, which makes it impossible to identify the population to be served by NHFMC’s proposed new mobile PET scanner.
- 2) NHFMC fails to adequately demonstrate the need the population has for its proposed mobile PET scanner to serve the five proposed Novant host sites in the “Greater Winston-Salem Market”.
- 3) Financial projections for NHFMC’s proposed project are incorrect as a result of overstated utilization projections for its **combined** existing and proposed mobile PET scanners.
- 4) The applicant and related parties have existing fixed and mobile PET scanners that do not meet the PET performance standards.

The reasons that NHFMC’s “second PET scanner” approach is incorrect are as follows:

- The 2021 SMFP shows a need determination for **one mobile PET scanner** without regard to an applicant’s existing fixed and mobile PET inventory.
- The 2021 SMFP PET inventory in Tables 17F-2 and 17F-3 correctly identifies each mobile PET scanner as a separate unit, each with its own assigned host sites.
- Each mobile PET scanner in North Carolina is required to annually submit individual Mobile PET Equipment Inventory Forms.
- The 2021 SMFP Chapter 17 and the Inventory Forms do not combine the mobile PET utilization for more than one PET scanner.
- NHFMC’s existing mobile PET scanner (Project ID #G-11051-15) did not result from a mobile PET need determination in a previous SMFP, but from a conversion of an underutilized NHFMC fixed PET scanner, which was converted to a mobile PET scanner with specific and unique CON conditions under Policy TE-1. Page 22 of the Agency Findings for the existing NHFMC mobile PET scanner (Project ID #G-11051-15) state, “The acquisition of the mobile PET/CT scanner shall constitute development of one mobile diagnostic program.”
- NHFMC’s proposed new mobile PET scanner has already been assigned its own FID # 210829, which is separate and distinct from the existing NHFMC mobile PET that was obtained through Project ID #G-11051-15.
- NHFMC’s existing and proposed mobile PET scanners are projected to have separate routes with different host sites. Thus, the two NHFMC mobile PET scanners will be operationally and physically separate.
- NHFMC’s existing and proposed mobile PET scanners would have separate vehicle identification numbers and separate Radioactive Materials Licensure requirements.

- Many of the CON application questions and the CON Review Criteria (Criteria 3, 6 and 18a) relate specifically to the need determination for one mobile PET scanner.

In addition, NHFMC’s application alleges that the 2020 and 2021 SMFP PET Inventories are incorrect because these inventories show NHFMC as having two fixed PET scanners, but NHFMC claims it actually has only one fixed PET scanner. NHFMC fails to explain why this alleged error was not previously pointed out in 2020 during the development of the 2021 SMFP. Now, NHFMC complains about the alleged PET inventory discrepancy to falsely claim that its PET utilization for its existing fixed and mobile PET scanners meets the PET performance standard. But in reality, NHFMC lacks the authority to change the published fixed and mobile PET scanner inventory in the 2021 SMFP that is the basis of the need determinations for the PET scanners that were recommended by the State Health Coordinating Council and approved by the Governor.

CON REVIEW CRITERIA COMMENTS

Criterion (1)

NHFMC does not adequately demonstrate the need for the proposed project based on reasonable utilization projections. Instead, due to NHFMC’s flawed utilization projections, NHFMC fails to adequately demonstrate how its proposed project will promote equitable access while maximizing healthcare value for resources expended in meeting the need identified in the 2021 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3. The NHFMC application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

Criterion (3)

NHFMC’s application does not conform to Criterion 3 because it fails to provide patient origin projections that are based on a reasonable and adequately supported methodology and assumptions for the proposed mobile PET to serve the following host sites:

- Novant Health Rowan Regional Medical Center (Rowan County);
- Novant Health Thomasville Medical Center (Davidson County);
- Novant Health Kernersville Medical Center (Forsyth County);
- Novant Health Forsyth Medical Center (Forsyth County); and
- Novant Health Medical Group Mount Airy (Surry County).

Page 47 of the NHFMC application shows the **combined** patient origin projections for the existing NHFMC mobile PET for the “Charlotte Market” and the proposed mobile PET assigned to the “Greater Winston-Salem Market”. The **combined** patient origin projections for NHFMC’s two mobile PET scanners (one existing and one proposed) are inaccurate, unreliable, unreasonable, and unsupported for three reasons:

- 1) The application unreasonably predicts that PET utilization will shift from NHFMC’s existing fixed PET service to the proposed mobile PET scanner at its same hospital location in Winston-Salem even though there is available fixed PET capacity on NHFMC’s fixed PET scanner.

- 2) The application lacks adequate support for its projections of “Out of State” patients that far exceed its historical volumes and percentages with 241 patients projected for Year 1, 268 patients projected for Year 2, and 283 patients projected for Year 3.
- 3) The applicant’s PET utilization projections are overstated due to erroneous projections of increased numbers of patients from Guilford, Iredell and Union Counties that each have existing fixed PET capacity.

Underutilized Existing NHFMC Mobile PET Scanner

As documented on page 369 of the Proposed 2022 State Medical Facilities Plan, the existing NHFMC mobile PET scanner performed procedures at a utilization rate that is 24 percent less than the regulatory capacity threshold of 2,600 annual procedures.

Table 17F-2: PET Scanner Provider of Mobile Dedicated Scanners*

Mobile Provider	Procedures	Utilization Rate
		Year 2019-2020 Procedures, 2,600 as Capacity
Alliance Imaging I	3,959	152%
Alliance Imaging II	3,299	127%
Novant Health Forsyth Medical Center (NHFMC)	1,984	76%
TOTAL	9,242	

* 2018 SMFP Need Determination for 1 mobile PET scanner. 2021 SMFP Need Determination for 1 mobile PET scanner.

The following table provides the actual utilization for the Novant Health fixed and mobile PET scanners based on the utilization as reported in the 2020 SMFP, 2021 SMFP and Proposed 2022 SMFP. These three reporting periods are most relevant to the proposed project because they reflect the trend of PET utilization for the three-year timeframe when the NHFMC mobile PET scanner was fully implemented. Looking at PET utilization data prior to FFY 2018 would be irrelevant because the existing NHFMC mobile PET was not operational for the entire year prior to FFY 2018.

Facility	Type	FFY 2018	FFY 2019	FFY 2020	FFY 2020-20 CAGR
Novant Presbyterian	Fixed	2,018	2,151	2,039	0.40%
Novant Forsyth	Fixed	2,857	2,855	2,397	-8.40%
NHFMC Mobile	Mobile	1,780	2,068	1,984	5.57%
Combined Novant Health	Combined	6,655	7,074	6,420	-1.78%

As seen in the above table, the NHFMC PET scanner has not increased the total combined PET utilization for the Novant Health combined fixed and mobile PET locations. The negative Compound Annual Growth Rate (CAGR) means that the population served by these specific scanners does not have a need for additional fixed or mobile PET capacity.

While the NHFMC application provides “2021 FFY Annualized” PET utilization, this information is not credible because the applicant omits the 11 months of actual utilization that is the basis of the annualized projection. If NHFMC submits its 2022 Hospital License Renewal Applications and its 2022 Mobile PET

Equipment Inventory Forms in a timely manner, the Agency will have the option to evaluate the reported PET utilization in these documents during the course of the CON review.

For the past six years, NHFMC has not achieved its PET utilization projections for its existing mobile PET scanner. In fact, the existing NHFMC mobile PET scanner has **failed to fulfill its potential for every one of its performance metrics** as described in its application for Project ID # G-11051-15.

Page 6 of the Agency Findings for Project ID # G-11051-15 states that in Section III.1, page 42, NHFMC stated that it will initially serve the following PET host sites:

- Novant Health Kernersville Medical Center, Forsyth County, (NHKMC)
- Novant Health Rowan Medical Center, Rowan County, (NHRMC)
- Novant Health Huntersville Medical Center, Mecklenburg County, (NHHMC)
- Novant Health Matthews Medical Center, Mecklenburg County, (NHMMC)
- Novant Health Thomasville Medical Center, Davidson County, (NHTMC)
- Lenoir Memorial Hospital, Lenoir County, (LMH), and
- Morehead Memorial Hospital, Rockingham County, (MMH).

These seven host sites were projected to achieve total PET utilization of 2,472 annual procedures in Project Year 3, based on a total of 6.75 days per week of service as reported on pages 16 and 18 of the Agency Findings.

Now, in NHFMC Project ID # G-012142-21, the applicant provides its actual mobile PET utilization, which demonstrates that its mobile PET scanner failed to meet its previously stated objectives. In Section Q, pages 145 and 146 of the application, the existing NHFMC mobile PET scanner provided a total of 1,984 annual procedures for the most recent fiscal year ending September 30, 2020. This utilization was reported for 5 host sites, based on 6.0 days per week of service instead of the originally approved 6.75 days per week of service for 7 host sites.

The following tables provide the comparison of the utilization projections from the previous application (CON Project ID # G-11051-15) and the actual PET utilization as included in NHFMC's CON Project ID # G-012142-21. This analysis demonstrates that the NHFMC mobile PET scanner has **not achieved any of its own projections** for its utilization of its existing mobile PET scanner.

	CON # G-11051-15	CON # G-012142-21	Variance
	Year 3 Projections	2020 Actual	Actual vs Projections
Days per Week	6.75	6.00	-0.75
# Host Sites	7	6	-1.00
# Counties	6	4	-2.00
Annual Utilization	2,472	1,984	-488.00
Percent of 2,600	95.08%	76.31%	-18.77%

The NHFMC existing mobile PET scanner is underutilized because:

- The NHFMC mobile PET scanner provided 39 fewer days per year (0.75 days per week x 52 weeks) of mobile PET service than its own projections.
- NHFMC's existing mobile PET service was never implemented at two of the originally approved host sites, Lenoir Memorial Hospital and Morehead Memorial where no fixed PET scanners are

located. Instead, the mobile PET service was implemented at Novant Health Mint Hill Hospital in Mecklenburg County which has multiple fixed PET scanners.

- The NHFMC mobile PET scanner primarily serves Novant facilities in Mecklenburg and Forsyth County where fixed PET service is readily available.
- In 2020, the NHFMC scanner is underutilized at 18.77% less than its projected utilization from CON Project ID # G-11051-15.

Underutilized Existing Fixed PET Capacity at NHFMC

NHFMC fails to demonstrate the need to provide mobile PET services to the Novant Health Forsyth Medical Center location because that location has existing fixed PET capacity that is not fully utilized and has declined over the last several years. The next table shows the consistent decline in the NHFMC fixed PET utilization over the most recent five years.

	2015-16	2016-17	2017-18	2018-19	2019-20
NHFMC Fixed PET Procedures	3,025	2,969	2,857	2,855	2,340

Sources: 2018 SMFP through 2022 Proposed SMFP

The reason that NHFMC’s fixed PET utilization has declined is because Novant Health Kernersville Medical Center’s mobile PET volumes have shifted utilization away from NHFMC. Additionally, NHFMC is continually losing market share for fixed PET services to North Carolina Baptist Hospital as seen in the next table.

	2015-16	2016-17	2017-18	2018-19	2019-20
NHFMC Fixed PET	3,025	2,969	2,857	2,855	2,340
NHFMC Fixed PET %	55.9%	53.2%	48.0%	47.9%	42.9%
NC Baptist Hospital Fixed PET	2,384	2,610	3,097	3,105	3,111
NC Baptist Hospital Fixed PET %	44.1%	46.8%	52.0%	52.1%	57.1%

Sources: 2018 SMFP through 2022 Proposed SMFP

The applicant’s proposed mobile PET host sites at Novant Health Kernersville Medical Center and Novant Health Medical Group Mount Airy are projected to shift even more PET utilization away from the fixed PET capacity at NHFMC. Consequently, there is no need to provide mobile PET service at NHFMC because it is not needed given the existing fixed capacity at NHFMC and it is duplicative of the applicant’s existing fixed capacity.

As seen in the below table, the applicant’s projections without the mobile PET utilization at NHFMC cause the Year 3 total mobile PET utilization for the proposed PET scanner to fall below the performance standard of 2,080 PET procedures. The following table shows the resulting mobile PET utilization of NHFMC’s proposed mobile PET scanner after subtraction of the unreasonable utilization for the proposed mobile PET service assigned to NHFMC. This table is based on NHFMC’s projections as shown in its application on page 146, Table Q.7.

	Project Year 1	Project Year 2	Project Year 3
NHFMC Proposed Mobile PET	2023	2024	2025
Rowan	472	513	556
Thomasville	129	151	164
Kernersville	587	654	692
Forsyth (NHFMC)	406	416	427
NH Mount Airy	313	327	342
Totals w/o NHFMC	1,501	1,645	1,754

As reflected in its discussion of Criterion 3 on page 35 of the Agency Findings in the 2018 Mobile PET/CT Scanner Review, **“the primary reason for making technology mobile is for the technology to travel to sites that do not have it or are unable to generate enough volume to support fixed technology of their own.”** As seen on page 146 of the NHFMC’s application and the public information available to the CON Section, NHFMC’s proposed mobile PET scanner assigned to the Greater Winston-Salem market is reported to serve five sites, four of which are existing sites already being served by NHFMC’s existing mobile PET scanner (Rowan Medical Center, Thomasville Medical Center, Kernersville Medical Center) and existing fixed PET scanner (NHFMC). Moreover, NHFMC’s fixed PET scanners are underutilized as seen in Table 17F-1 in the 2021 SMFP and Proposed 2022 SMFPs. Accordingly, NHFMC’s proposal is inconsistent with the purpose of having a mobile PET scanner.

Unreasonable Patient Origin Projections

NHFMC does not adequately demonstrate in its application that it is reasonable to assume that residents of the counties it proposes to serve would travel from where they live to the proposed host sites. Therefore, it is unreasonable for the NHFMC application to project for Year 3:

- That 283 “Out of State” patients will utilize the existing and proposed mobile NHFMC PET scanners with no explanation as how and why any of the NHFMC mobile host site locations would provide improved access for the patients as compared to the existing fixed PET scanners in Forsyth and Mecklenburg Counties.
- That 288 patients from Iredell County would utilize the existing and proposed mobile PET scanners because Iredell Memorial Hospital has a fixed PET scanner with available capacity.
- That 237 patients from Union County would utilize the existing and proposed mobile PET scanners because CMC Union Hospital in Union County has an existing fixed PET scanner with available capacity.
- That 83 patients from Guilford County would utilize the existing and proposed mobile PET scanners because Cone Health and High Point Hospital in Guilford County both have existing fixed PET scanners with available capacity.

The following table shows NHFMC’s unreasonable patient origin projections for the highlighted counties (Iredell, Union and Guilford) with existing fixed PET and NHFMC’s unsupported increase for Out-of State patients.

<PET/CT Services - MOBILE PET/CT Units^>	<Novant Health Forsyth Medical Center> *					
	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2023 to 12/31/2023		01/01/2024 to 12/31/2024		01/01/2025 to 12/31/2025	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Mecklenburg	1,049	28.2%	1,164	28.2%	1,228	28.2%
Forsyth	442	11.9%	491	11.9%	518	11.9%
Rowan	369	9.9%	409	9.9%	432	9.9%
Davidson	252	6.8%	280	6.8%	296	6.8%
Iredell	246	6.6%	273	6.6%	288	6.6%
Union	202	5.4%	224	5.4%	237	5.4%
Surry	198	5.3%	220	5.3%	232	5.3%
Stokes	223	6.0%	248	6.0%	262	6.0%
Cabarrus	137	3.7%	152	3.7%	161	3.7%
Guilford	71	1.9%	79	1.9%	83	1.9%
Davie	20	0.5%	22	0.5%	23	0.5%
Yadkin	7	0.2%	8	0.2%	9	0.2%
All Other NC Counties	256	6.9%	284	6.9%	300	6.9%
Out of State	241	6.5%	268	6.5%	283	6.5%
Total	3,715	100.0%	4,123	100.0%	4,351	100.0%

The NHFMC patient origin projections on page 47 of the NHFMC application and as seen in the table above are based on erroneous projections of huge increases in the numbers and percentages of Out of State patients that are projected to obtain PET procedures for NHFMC’s existing and proposed mobile PET scanners. In contrast, the historical PET patient origin tables on pages 44 and 45 of NHFMC’s application report far lower numbers and percentages. NHFMC fails to adequately explain from where the influx of Out of State patients will originate. Page 52 of the NHFMC application identifies no counties or regions that are Out of State in the applicant’s service area definition. The map on page 66 of the NHFMC application does not show any Out of State counties or regions that would be within the 45 minute “drive-time” service area for the mobile PET host sites.

Furthermore, it is unreasonable for NHFMC to project that hundreds of additional Out of State PET patients are going to travel from other states to utilize mobile PET sites that provide service only one or two days per week, when there are multiple full-time fixed PET scanners in both the Charlotte Market and the Greater Winston-Salem Market that offer more hours of service, have available capacity and greater scheduling flexibility within their facilities.

NHFMC’s application fails to adequately demonstrate that the NH-Ballantyne facility that is now in development will serve PET patients from out-of-state. The existing fixed PET/CT scanner at Piedmont Medical Center in Rock Hill, South Carolina serves patients from York and Lancaster County. Thus, PET patients from South Carolina would have no need to drive past the existing fixed PET in Rock Hill to the mobile PET host site at NH-Ballantyne in Charlotte.

Clearly, NHFMC provides unreasonable and unsupported patient origin projections for Out of State PET patients.

	1st Full FY	2nd Full FY	3rd Full FY
Total NHFMC Mobile PET Patients	3,715	4,123	4,351
Out of State Patients	241	268	283
Totals Excluding Out of State	3,474	3,855	4,068
# Mobile PET Scanners	2	2	2
PET Patients (Procedures) per Mobile PET	1,737	1,928	2,034
PET Performance Standard			2,080
Amount Below PET Performance Standard			46

Subtracting just the unsupported Out of State patients from the NHFMC projections causes the applicant’s utilization to fail to meet the PET performance standards.

Flawed Methodology and Assumptions

In NHFMC’s application, Section Q, pages 133 to 149, NHFMC provides its methodology and assumptions that are unreasonable and unsupported for a variety of reasons:

- NHFMC’s existing and proposed mobile PET scanners are not conforming to the PET Performance Standards 10 NCAC 14C.3703 because NHFMC’s utilization projections are overstated and based on erroneous patient origin data. The applicant’s projections of hundreds of additional Out of State patients are not credible.
- NHFMC’s proposed new mobile PET scanner that would serve the “Greater Winston-Salem Market” only adds one new host site in Mount Airy.
- It is incorrect to identify NHFMC as a new host site because it has existing fixed PET scanner capacity at this location.
- The existing NHFMC mobile PET scanner is regulated by its own CON conditions of Project ID #G-11051-15. Novant can request a Letter of Material Compliance to add host sites in the Charlotte Market. Thus, any host sites that are proposed for the existing NHFMC mobile PET scanner should not be attributed to the proposed NHFMC mobile PET scanner.
- Figure Q.1 on page 135 of the NHFMC application is misleading because it includes the PET utilization data for Years 2014 to 2016 for several mobile PET host sites (NH Huntersville, NH Matthews, NH Rowan and NH Thomasville) that obtained mobile PET service from Alliance prior to 2017. Therefore, the applicant’s calculations of Compound Annual Growth Rates for these four host sites are incorrect because they should not be based on historical data prior to 2017 FFY.
- The applicant fails to include the most recent actual 12 months’ utilization data for its existing mobile PET. The annualized projection for FFY 2021 that is shown in Figure Q.1 on page 135 does not demonstrate that NHFMC’s existing mobile PET scanner has exceeded 2080 annual PET procedures. Without actual mobile PET utilization for the most recent 12 months for NHFMC’s existing mobile PET scanner, the 2021 Mobile PET Equipment reports only 1,984 annual PET procedures. Therefore, the existing mobile PET scanner does not demonstrate that it meets the mobile PET performance standard.
- Figure 16 showing Novant Health Market Volume Trend for PET/CT on page 136 of the NHFMC Application is misleading because it includes the PET utilization data for Years 2014 to 2016 for several mobile PET host sites (NH Huntersville, NH Matthews, NH Rowan and NH Thomasville) that obtained mobile PET service from Alliance prior to 2017. Therefore, the historical CAGRs are not reasonable and adequately supported.

- NHFMC’s methodology and assumptions in Table Q.2 on page 137 its application are unreasonable and unsupported and its Table Q.7 projections on page 146 include unreasonable assumptions because: 1) the historical CAGR is unreasonable; 2) there are no capacity constraints because NHFMC’s existing mobile PET scanner has never performed 2,600 annual PET procedures, and; 3) the projected shift of PET procedures from the NHFMC fixed PET scanner to the proposed mobile PET scanner is unnecessary and irrational.

Omitted Information

The NHFMC application failed to adequately respond to the CON question in Section C that states:

Acquiring Mobile Medical Equipment? Include: 1) the identity of the proposed host sites by name, owner, type (e.g., hospital, physician office, diagnostic center, etc.) and physical location (i.e., street address, city and county) and 2) a description of the applicant’s efforts to contact the proposed host sites.

NHFMC omits the address and the ownership information for each of the proposed host sites. For example, no address is provided for the proposed new mobile PET host site in Mount Airy in Surry County. Furthermore, the application provided no support letters from physicians or any other host site representatives located in Mount Airy that demonstrate a willingness to implement this service. Based on these omissions, NHFMC failed to provide the information required by the Department, by its rules deems necessary to conduct the review in accordance with G.S. 131E-182.

Erroneous Support Letters

The applicant sent out draft support letters for its physicians that incorrectly states that NHFMC was dependent on mobile PET service that was inadequate to meet demand. Letters of support from numerous providers including Garrett Sherwood, MD, Erin Jepsen, MD, Tayla Brown, PA-C, Judith O Hopkins, MD, and Charles Agbemabiese, MD *include the incorrect statement that the existing NHFMC only has mobile PET services and appears to be struggling to keep up with demand.*

A portion of Dr. Sherwood’s letters is provided as follows:

Currently, we treat a large volume of patients residing throughout many counties including Forsyth, Surry, Wilkes, Iredell, Guilford and Davidson. We have historically referred our patients from these areas in need of PET/CT scans to Novant Health Forsyth Medical Center (“NHFMC”). Despite additional days of mobile service, this PET/CT location is struggling to keep pace with demand and our patients often face delays in scheduling for PET/CT scans. This can delay diagnosis and treatment as well as add stress to patients facing an oncology health concern.

Consequently, these support letters are invalid due to the mischaracterization of the existing fixed PET capacity at NHFMC.

Unreasonable Projections

In summary, the NHFMC application is fatally flawed with unreliable, unreasonable, and unsupported patient origin projections. Accompanying these are the applicant's defective, unreasonable, and unsupported methodology and assumptions. For all of these reasons, the NHFMC application does not conform to Criterion 3.

Criterion (4)

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

Criterion (5)

NHFMC's financial projections are not based on reasonable and adequately supported utilization projections as discussed in the Criterion (3) comments. Therefore, the applicant's financial projections are not based on reasonable and adequately supported operational projections.

NHFMC wrongly claims that its proposed project will incur no start-up cost or working capital because its project is erroneously characterized as the acquisition of a second mobile PET scanner. In reality, NHFMC's proposed project is for the acquisition of a mobile PET/CT scanner that will incur operating costs for staff, radiopharmaceuticals, and transportation, that precede the receipt of any revenues for scans performed with the unit of equipment that is physically and operationally separate from NHFMC's existing mobile PET scanner and NHFMC's fixed PET scanners.

Operational expenses are understated because the applicant has omitted the cost of maintenance services agreements for the existing and proposed mobile PET scanner. This omission is evident because unlike in NHFMC's application here, the \$125,000 annual cost of the PET scanner maintenance service is included in the CON application submitted by Novant Health New Hanover Regional Medical Center – Scotts Hill (Project ID # O-12143-21) for the HSA V Fixed PET Need Determination. NHFMC's application provides no documentation that NHFMC's staff is qualified to perform maintenance service to the mobile PET scanners in accordance with the manufacturer's recommendations. Furthermore, there is no documentation that, absent a services agreement for the proposed new mobile PET scanner, the manufacturer will provide a warranty in Year 1.

Additionally, the NHFMC application's salary expenses are understated because NHFMC shows no incremental salary expenses for management and supervision of the proposed new mobile PET scanner. One would expect that the proposed new mobile PET scanner would have, at minimum, the same level of management supervision as the existing NHFMC mobile PET scanner to support quality and accreditation. But this is not the case because NHFMC's application provides no increases in the FTE allocations for Radiology Director, Manager, or Safety Officer.

Moreover, the scope of NHFMC's proposed project includes the construction of a mobile pad to accommodate the proposed mobile PET scanner. The projected cost for this construction is unreliable because the capital expenditure has not been calculated by an architect or engineer.

For all of these reasons, the financial projections are unreliable, unreasonable, and unsupported causing MHFMC’s application to be nonconforming to Criterion (5).

Criterion (6)

NHFMC proposes to acquire a second mobile PET scanner that is unnecessary and duplicative of its existing mobile PET that is underutilized. The following tables provide the comparison of the utilization projections from the previous application (CON Project ID # G-11051-15) and the actual PET utilization as included in NHFMC’s CON Project ID # G-012142-21. This analysis demonstrates that the NHFMC mobile PET scanner has **not achieved any of its own projections** for its utilization of its existing mobile PET scanner.

	CON # G-11051-15	CON # G-012142-21	Variance
	Year 3 Projections	2020 Actual	Actual vs Projections
Days per Week	6.75	6.00	-0.75
# Host Sites	7	6	-1.00
# Counties	6	4	-2.00
Annual Utilization	2,472	1,984	-488.00
Percent of 2,600	95.08%	76.31%	-18.77%

The NHFMC existing mobile PET scanner is underutilized because:

- The NHFMC mobile PET scanner provided 39 fewer days per year (0.75 days per week x 52 weeks) of mobile PET service than its own projections.
- NHFMC’s existing mobile PET service was never implemented at two of the originally approved host sites, Lenoir Memorial Hospital and Morehead Memorial where no fixed PET scanners are located. Instead, the mobile PET service was implemented at Novant Health Mint Hill Hospital in Mecklenburg County which has multiple fixed PET scanners.
- The NHFMC mobile PET scanner primarily serves Novant facilities in Mecklenburg and Forsyth County where fixed PET service is readily available. The scanner provides only 1.25 days per week of service to Rowan and Davidson Counties.
- In 2020, the NHFMC scanner is underutilized at 18.77% less than its projected utilization from CON Project ID # G-11051-15.

This analysis demonstrates that the proposed project is duplicative of the existing NHFMC mobile PET that was obtained in CON Project ID # G-11051-15.

The applicant’s proposed mobile PET host sites at Novant Health Kernersville Medical Center and Novant Health Medical Group Mount Airy are projected to shift even more PET utilization away from the fixed PET capacity at NHFMC. Consequently, there is no need to provide mobile PET service at NHFMC because it is duplicative of the applicant’s existing fixed capacity.

In the 2015 CON application (G-11051-15) to convert a fixed PET scanner to a mobile PET, NHFMC made the following representation:

“The patients who will continue to utilize fixed PET/CT services at NHFMC will have more than adequate access to PET/CT imaging and services based on the availability of the newly installed state-of-the-art PET/CT scanner at NHFMC. This fixed PET/CT scanner benefits from advanced technology and faster

scanning times than the older fixed PET/CT unit that will be converted to a mobile PET/CT unit. NHFMC has the ability to increase operational hours for the fixed PET/CT scanner in order to meet any fluctuations in demand for this service. Furthermore, NHKMC’s patients that have traveled from Kernersville to Winston-Salem for PET/CT imaging will be more efficiently served by the local mobile PET/CT service that will be onsite at NHKMC two days per week.”

These statements in Project ID# G-11051-15 were accompanied by NHFMC projections that the fixed PET utilization would exceed 2,800 annual procedures. But NHFMC’s present application (CON Project ID # G-012142-21) reflects that the actual PET volume in 2019-2020 was 2,340 annual procedures, which is more than 8 percent less than what was projected in its previous application. Furthermore, NHFMC still has the ability to increase operational hours for its fixed PET scanner in order to meet fluctuations in demand for service.

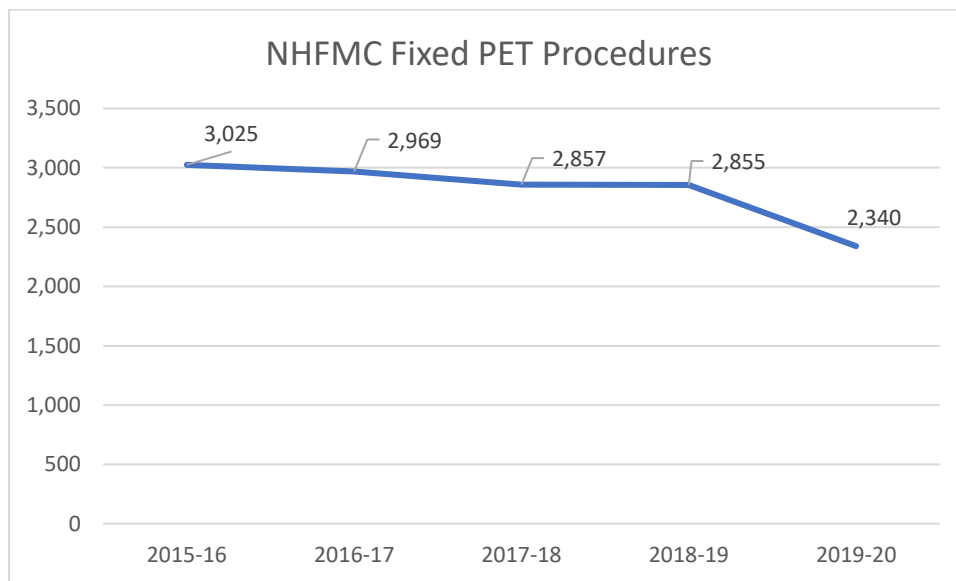
NHFMC fails to demonstrate that its proposal would not result in unnecessary duplication of mobile PET service because its utilization projections are unreliable. NHFMC’s assumption that it would shift utilization from its existing fixed PET scanner at NHFMC to a proposed mobile PET scanner at the same facility is not credible. As discussed on page 35 of the 2018 Mobile PET/CT Scanner Review, **“the primary reason for making technology mobile is for the technology to travel to sites that do not have it or are unable to generate enough volume to support fixed technology of their own.”**

The following table shows the NHFMC PET procedure annual volumes with the percentages of capacity based on the 2020 SMFP, 2021 SMFP and the Proposed 2022 SMFP.

	2017-18	2018-19	2019-20
NHFMC Fixed PET	2,857	2,855	2,340
SMFP Table 17F-1 % of Capacity	47.62%	47.58%	39.95%

As seen in the table above that is based on the 2020 through 2022 SMFPs, NHFMC has experienced a consistent decline in fixed PET utilization and therefore has no need for additional PET capacity.

Over the previous five annual reporting periods (2015-16 through 2019-20), the PET utilization at NHFMC has decline by a total of 685 procedures for a **-6.22** Compound Annual Growth Rate.



For these reasons and the reasons stated in the comments herein regarding Criterion 3, the NHFMC application does not conform to Criterion (6).

Criterion (7)

The NHFMC application does not conform to Criterion 7 because its Form H Staffing Table is based on the projected staffing for both its existing mobile PET scanner and its proposed additional mobile PET scanner. This obfuscation of the staffing projections prevents the Agency from evaluating the adequacy of staffing for the proposed new mobile PET scanner. Furthermore, NHFMC projects no incremental increases for management positions, which is unreasonable since the proposal involves additional host sites, new staff, and modifications to the existing mobile PET route.

Criterion (12)

Criterion 12 in Section K of the CON application requires applications involving construction to demonstrate that the cost, design, and means of construction proposed represents the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services. At the outset of Section K (Criterion 12) of the application form, NHFMC stated Criterion 12 was not applicable and did not answer any of the questions contained in Section K of the application form. Novant’s claim that Criterion 12 is not applicable is incorrect as demonstrated by other information provided in NHFMC’s application.

The NHFMC application included as Exhibit F-2.1 a project funding letter from Novant Health, Inc.’s Geoffrey Gardner, which clearly reflects that the scope of **the project includes the construction of a mobile services pad** at Novant Health Medical Group – Mount Airy. Mr. Gardner specifically states “Novant Health will fund any and all other expenses associated with the proposed project, including the construction of a mobile pad at Novant Health Medical Group – Mr. Airy location (approximately \$150,000)”.

While Mr. Gardner’s letter states that mobile PET services pad is estimated at \$150,000, the letter does not indicate that this amount was obtained from an architect’s cost estimate. Construction projects at healthcare facilities are required to submit architectural plans to the DHSR Construction Section and

obtain inspections and approvals. Mr. Gardner's letter does not indicate that he is an architect, but rather the Senior Vice President of Novant Health, Inc.'s Operational Finance & Revenue Cycle.

Criterion (12) relates to projects involving construction regardless of the total project capital cost. In its responses to Section K of the application form, NHFMC failed to provide the address of the proposed mobile PET services pad and the physical location of the \$150,000 construction cost and capital expenditure. Instead, Section K of the NHFMC application erroneously states that Criterion 12 (Applications Involving Construction...) is not applicable. The NHFMC responses to the Section K questions are plainly wrong because Mr. Gardner's letter documents that the mobile PET services pad is a necessary component of the total project capital cost. If this new construction was not necessary and essential to the project, Mr. Gardner's letter would not have stated that funds were committed to this construction project capital cost.

NHFMC's application fails to identify the specific address and property owner in Mount Airy related to the proposed new construction of a mobile services pad. Furthermore, the NHFMC application lacks the certification of construction costs that is typically provided by an architect or engineer that has developed preliminary plans for the proposed mobile services pad, utilities and scope of construction. Based on these omissions, NHFMC failed to provide such information as required by the Department, by its rules deems necessary to conduct the review in accordance with G.S. 131E-182.

Additionally, the feasibility of implementing mobile PET service at Novant Health Medical Group - Mount Airy (if it is to be located 865 Westlake Drive), is not adequately demonstrated because that potential host site currently lacks a mobile pad with utilities. As seen in the publicly available information on Google Earth in Attachment 1, the existing parking lot and site at the Novant Medical Group Building at 865 Westlake Drive in Mount Airy are not designed to accommodate a mobile pad and still maintain sufficient parking without extensive construction that would involve changes to the one entrance to the parking area to allow a mobile PET scanner to enter and exit.

For these reasons the NHFMC application does not conform to Criterion (12).

Criterion (18a)

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

SECTION .3700 - CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER 10A NCAC 14C .3703 PERFORMANCE STANDARDS

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

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

NHFMC’s utilization projections are not based on reasonable and adequately supported assumptions. The discussion in these comments regarding projected utilization found in Criterion (3) is incorporated herein by reference. For the reasons stated in the discussion regarding Criterion (3), the NHFMC application is not conforming to this Rule.

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

The NHFMC application failed to adequately demonstrate that its existing fixed and mobile PET scanners performed an average of at least 2,080 PET procedures per PET scanner in the last year because the 2021 SMFP and Proposed 2022 SMFP demonstrate that the average is less than 2080 annual procedures as reflected in the following table

Proposed 2022 SMFP	# PET Scanners	2019-20 Utilization
NH Presbyterian Medical Center Fixed	1	2,039
NHFMC Fixed PET	2	2,397
NRHFMC Mobile PET	1	1,984
NH New Hanover Medical Center Fixed	1	2,796
Totals	5	9,216
Average per PET Scanner		1,843

2021 SMFP	# PET Scanners	2019-20 Utilization
NH Presbyterian Medical Center Fixed	1	2,151
NHFMC Fixed PET	2	2,855
NRHFMC Mobile PET	1	2,068
NH New Hanover Medical Center Fixed	1	2,512
Totals	5	9,586
Average per PET Scanner		1,917

The discussion in these comments regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.

(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.

NHFMC’s utilization projections are not based on reasonable and adequately supported assumptions. The discussion in these comments regarding projected utilization found in Criterion (3) is incorporated herein by reference. For the reasons stated in the discussion regarding Criterion (3), the NHFMC application is not conforming to this Rule.

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

NHFMC’s utilization projections are not based on reasonable and adequately supported assumptions. The discussion in these comments regarding projected utilization found in Criterion (3) is incorporated herein

by reference. For the reasons stated in the discussion regarding Criterion (3), the NHFMC application is not conforming to this Rule.

COMPARATIVE ANALYSIS

The Alliance PET application (G-12156-21) and the NHFMC application (G-012142-21) each proposed to acquire one mobile PET scanner in response to the need determination in the 2021 State Medical Facilities Plan. Given that two applicants propose to meet the need for the one mobile PET scanner, both proposals cannot be approved. To determine the comparative factors that are applicable in this review, Alliance examined recent Agency Findings for competitive PET scanner reviews. As a result, Alliance considered the following comparative factors:

- Conformity to Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility
- Access by Service Area Residents
- Access by Underserved Groups
- Projected Average Net Revenue per Procedure
- Projected Average Expense per Procedure

Conformity with Review Criteria

Alliance adequately demonstrated that its application is conforming to all applicable statutory and regulatory review criteria. By contrast, NHRMC did not adequately demonstrate that its application is conforming to all applicable statutory and regulatory review criteria and therefore is not approvable. NHFMC’s application fails to conform to CON Review Criteria (1), (3), (4), (5), (6), (7), (12) and (18a) and the PET Performance Standards 10A NCAC 14C .3703 for the reasons expressed in these comments. Therefore, the application submitted by Alliance is the most effective with regarding to conformity with review criteria and the NHRMC is not an effective alternative regarding conformity with review criteria.

Scope of Services

With regard to scope of services, the applications submitted by NHFMC and Alliance are both in response to the 2021 State Medical Facilities Plan (SMFP) need determination for one mobile PET scanner for the statewide service area. The following table compares the scope of services proposed to be offered. Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor.

	Oncological PET	Cardiac PET	Neurologic PET
NHFMC	Yes	No	No
Alliance Mobile PET	Yes	Yes	Yes

Pages 56 to 60 of the NHFMC application discusses the need for the proposed mobile PET scanner to respond to increases in cancer cases in the regions served by the NHFMC proposed and existing mobile PET scanners. But, the NHFMC application does not document that its proposed mobile PET/CT will be utilized for Cardiac and Neurologic PET procedures and also is not an approvable application.

Section C of the Alliance application provides extensive documentation regarding the need for the proposed mobile PET/CT scanner due to cancer incidence and cardiovascular and Alzheimer’s disease rates, the expansion of clinical indications for PET/CT, and greater availability of radiotracers. Consequently, with regard to scope of services, the Alliance application is most effective and the NHFMC is the least effective.

Historical Utilization

The following table illustrates historical utilization of each applicant as provided in the 2021 SMFP representing FY2019 reported utilization.

Historical Utilization Mobile PET	2019-2020
Novant Health Forsyth Medical Center	1,984
Alliance I	3,959
Alliance II	3,299

Both NHFMC and Alliance have existing mobile PET/CT scanners. The Alliance mobile PET scanners performed the highest number of PET procedures. Therefore, the Alliance application is the most effective alternative for this comparative factor.

Geographic Accessibility

The service area for mobile PET scanners is statewide. The need determination for a mobile PET scanner in the 2021 SMFP does not limit the applicant’s host sites. Consequently, both the Alliance and NHFMC applications have the same opportunity to propose new host sites to serve facility locations that lack access to mobile PET services and do not have volumes sufficient to support fixed PET.

The following table compares the two applications in terms of total numbers of proposed host sites, numbers of counties where the host sites are located and the absence or presence of existing fixed PET scanners in the same counties.

NHFMC Host Site Facility Names	New or Existing Site	Counties	Novant Fixed PET In Same Counties
Proposed Mobile PET			
Novant Health Rowan Medical Center	Existing Mobile	Rowan	No
Novant Health Thomasville Medical Center	Existing Mobile	Davidson	No
Novant Health Kernersville Medical Center	Existing Mobile	Forsyth	Yes
Novant Health Forsyth Medical Center	Existing Fixed	Forsyth	Yes
Novant Health Medical Group Mount Airy	New	Surry	No
Alliance Host Site Facility Names	New or Existing Site	Counties	Fixed PET In Same Counties
Proposed Mobile PET			
UNC Rockingham Health Care	New	Rockingham	No
Margaret R Pardee Hospital	Existing Mobile	Henderson	No
Caldwell Memorial Hospital	Existing Mobile	Caldwell	No
Wayne Memorial Hospital	Existing Mobile	Wayne	No
Chatham Hospital	New	Chatham	No
Eastowne Medical Office Building	New	Orange	Yes
UNC Hospitals Hillsborough Campus	New	Orange	Yes

As shown in the above table, NHFMC proposes the fewest host sites and the least number of new host sites. The NHFMC application proposes to implement its proposed mobile PET service at the same facility location as its existing fixed PET scanners. Thus, this host site at NHFMC is not a new location for patients to obtain access to PET services. NHFMC also proposes to implement mobile PET service at only one new host site, NH Medical Group in Mount Airy. As discussed in these comments, the feasibility of implementing mobile PET service at this host site is uncertain because it lacks a mobile pad with utilities.

By contrast, Alliance proposes the most sites (7) and the most counties (6). Alliance proposes the highest number of new host sites (4) with two of the new host sites located counties which have no existing fixed PET/CT scanners.

With regard to geographic accessibility, the application by Alliance is the most effective alternative and the application submitted by NHFMC is the least effective alternative.

Access by Service Area Residents

The following table compares the access by Service Area Residents for the proposed mobile PET/CT scanners in the NHFMC and Alliance applications.

	YR 3 Total Patients	# Patients from NC Counties	% Patients from NC Counties
NHFMC PET/CT (2 Units, Existing + Proposed)	4,351	4,068	93.50%
Alliance Mobile PET/CT (1 Unit Proposed)	2,921	2,851	97.60%

According to page 47 of the NHHFMC application, the **combined** patient origin for the existing and proposed mobile PET scanners will serve 93.5 percent of the 4,351 projected patients from within North Carolina.

Page 110 of the Alliance application documents that the proposed mobile PET/CT scanner is projected to serve 97.6 percent of the total 2,921 patients. Moreover, Alliance provides the patient origin for each of the proposed host sites as documented on pages 45 to 49 of its application.

As shown in the table above, Alliance is projected to serve the highest number of patients per scanner and the highest percentage of service area residents. Therefore, regarding projected service to residents of the service area, Alliance is the most effective alternative and NHHFMC is the least effective. Furthermore, the NHHFMC application is not approvable.

Access by Underserved Groups

Section L of the CON application form specifically requests projections for the payor mix of the patient population to be served by the proposed project.

NHHFMC provides historical payor mix information for its fixed PET scanner or scanners at NHHFMC on page 109 of its application and states on page 110 that this payor mix is presented as its “facility-wide” payor mix table. Also, on page 110 of the application, NHHFMC states, “As a vendor, NHHFMC does not provide charity care. NHHFMC bills the host site.” NHHFMC provides its Charity Care, Uninsured Discount, and Catastrophic Settlement Policies in Exhibit L.4.1.

In Section L of its application, Alliance provides payor mix projections for each of the proposed UNC host sites based on the historical payor mix information for the hospital host sites. The Alliance application includes the UNC Financial Assistance Policy included in Exhibit B.2.b that is applicable to all of the proposed host sites. Page 117 of the Alliance application states, “Alliance is committed to provide at least 1.0% of Charity Care in the form of no-cost procedures to the host sites. The 1.0% Charity Care is reported as a deduction from revenue.” Pages 118 to 119 of the Alliance application provide the applicant’s projections for the percentages and numbers of patients by payor category.

The following tables compares the Charity, Medicare and Medicaid percentages for the proposed mobile PET/CT scanners in the NHHFMC and Alliance applications.

	Charity %
NHHFMC Mobile PET/CT	0.0%
Alliance Mobile PET/CT	1.0%

	Medicare %	Medicaid %
NHHFMC Mobile PET/CT	63.8%	3.9%
Alliance Mobile PET/CT	55.8%	9.0%

As reported on page 117 of its application, Alliance projects to provide 1.0% Charity Care to its host sites in no-charge scans to support the host sites abilities to serve charity care and indigent patients. NHHFMC states on page 110 of its application projects that it will provide no charity care PET service to its host sites.

Based on the payor information provided in Section L of the two applications, Alliance projects to serve higher percentages of Medicaid patients. NHFMC projects to serve higher percentage of Medicare patients. However, the NHFMC application is not approvable. Therefore, the Alliance is the most effective application and NHFMC is the least effective.

Projected Average Net Revenue per Procedure

The following table shows the projected average net revenue per procedure in the third full fiscal year for the two applicants. Usually, the application proposing the lowest average net revenue per procedure is the more effective alternative with regard to this comparative factor to the extent that it reflects a more affordable service to the host sites.

	Year 3 Net Revenue	Year 3 Total Procedures	Net Revenue / Procedure
NHFMC PET/CT (2 Units, Existing + Proposed)	\$4,950,377	4,351	\$1,138
Alliance Mobile PET/CT (1 Unit Proposed)	\$2,745,740	2,921	\$940

NHFMC has a higher projected average net revenue per procedure in the third year. Alliance’s proposal projects a lower average net revenue per PET procedure in the third year of operation.

In addition, NHFMC did not adequately demonstrate the need to acquire a mobile PET scanner and cannot be approved. The discussion regarding need and projected utilization in the Criterion (3) section of these comments is incorporated herein by reference.

Therefore, the application submitted by Alliance is the most effective alternative with regard to projected average net revenue per PET procedure and NHFMC is the least effective.

Projected Average Expense per Procedure

The following table shows the projected average operating expense per procedure in the third full fiscal year for the two applications. Usually, the application proposing the lowest average operating expense per procedure is the more effective alternative with regard to this comparative factor to the extent that it reflects a more cost effective service.

	Year 3 Total Operating Expenses	Year 3 Total Procedures	Expense / Procedure
NHFMC PET/CT (2 Units, Existing + Proposed)	\$4,099,919	4,351	\$942
Alliance Mobile PET/CT (1 Unit Proposed)	\$1,874,505	2,921	\$642

As seen in the above table, NHFMC has a higher projected average operating expense for the third year as compared to the Alliance proposal, which projects a lower average expense per PET procedure in the third year of operation. In addition, NHFMC did not adequately demonstrate the need to acquire a mobile PET scanner and cannot be approved. The discussion regarding need and projected utilization in the Criterion (3) section of these comments is incorporated herein by reference. Therefore, the

application submitted by Alliance is the most effective alternative with regard to projected average cost per PET procedure and NHFMC is the least effective.

SUMMARY

The following table summarizes the comparative analysis and identifies which applicant is the most effective or least effective alternative with regard to each comparative factor.

Comparative Factor	NHFMC	Alliance
Conformity to Review Criteria	Least Effective Not Approvable	Most Effective Fully Conforming
Scope of Services	Least Effective	Most Effective
Historical Utilization	Least Effective	Most Effective
Geographic Accessibility	Least Effective	Most Effective
Access by Service Area Residents	Least Effective	Most Effective
Access by Underserved Groups	Least Effective	Most Effective
Projected Average Net Revenue per Procedure	Least Effective	Most Effective
Projected Average Expense per Procedure	Least Effective	Most Effective

CONCLUSION

NHFMC's application is not approvable, as it does not conform to Criteria (1), (3), (4), (5), (6), (7), (12) and (18a) and the PET Performance Standards of 10A NCAC 14C .3703. Conversely, Alliance's application meets all applicable criteria and standards for PET services. As shown in the comparative analysis above, Alliance is the superior applicant. Accordingly, the Alliance application should be approved, and the NHFMC applications should be denied.

Attachment 1.

Google Earth Picture of Novant Health Medical Associates at 865 Westlake Drive Mount Airy

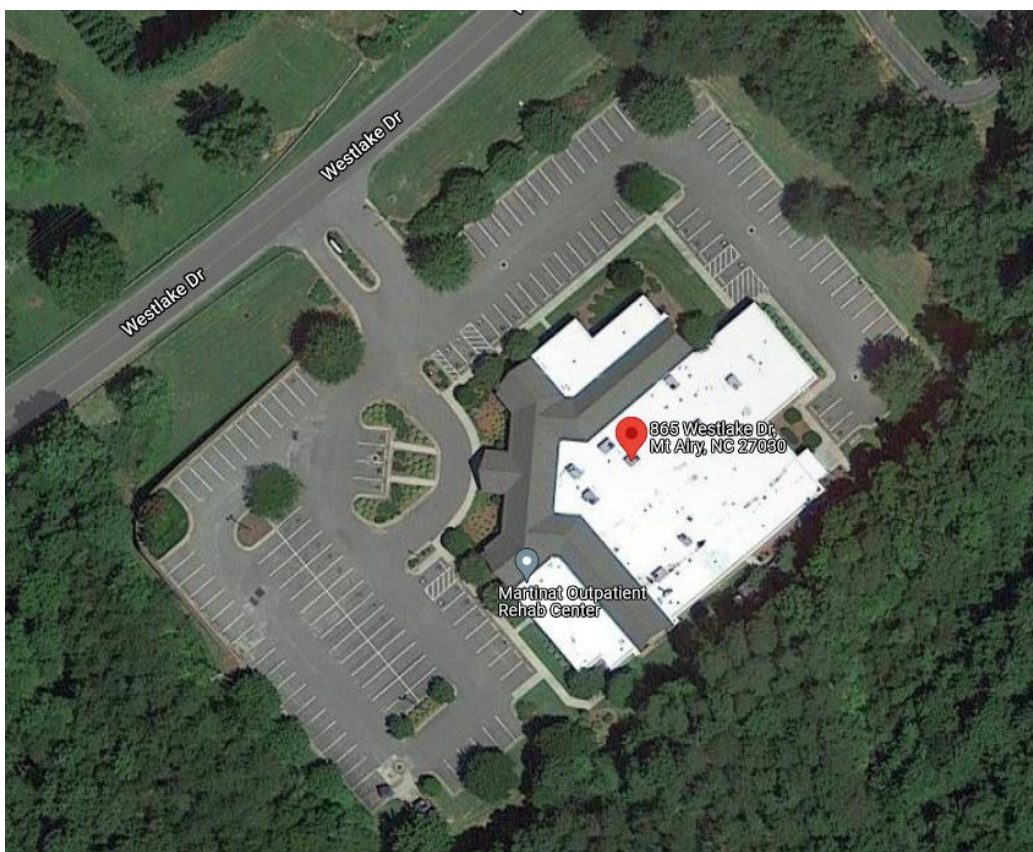


Exhibit O-2.2 of the NHFMC application identifies 865 Westlake Drive in Mount Airy, NC as a Novant hospital outpatient department location that provides oncology services and holds Joint Commission accreditation. While not specifically identified as the proposed Novant Health Mount Airy mobile PET host site in Section C of the application, this location currently provides physician visits and limited outpatient diagnostic services. Unlike all of the other NHFMC mobile PET host sites, this clinic lacks the on-site ancillary and support services to manage the advanced imaging services that are available at Novant hospitals. Furthermore, there is not sufficient information included in the NHFMC application to determine if this location is the proposed new mobile PET site in Surry County.

As seen in the Google Earth picture of 865 Westlake Drive in Mount Airy, the parking lot and medical office building do not have an existing mobile services pad to accommodate the proposed mobile PET scanner. While this practice location provides mobile mammography, it is utilizing a van that is smaller in size and does not use a mobile pad as required by a mobile PET scanner. There is no clear path within this parking lot for a mobile PET scanner tractor trailer, approximately 60 feet in length, to have an adequate turning radius to park at this location or to allow the vehicle to turn around and exit. According to Jeff Harms, Acting Section Chief of the DSHR Construction Section, if a proposed mobile services pad location is a hospital outpatient department (part of a licensed healthcare facility), the proponent must submit plans and obtain approvals from the Construction Section. However, the NHFMC application does not contain construction plans for a mobile services pad and thus fails to adequately demonstrate that construction of the proposed mobile PET host site location in Mount Airy is a cost effective and reasonable alternative.