

**Comments Submitted by Alliance Healthcare Services Regarding the
2021 Fixed PET Scanner (Health Service Area V) Certificate of Need Applications**

In response to the need determination in the 2021 State Medical Facilities Plan for one additional fixed PET scanner to serve the Health Service Area V, the following applications were submitted:

CON Project ID # O-12143-21 by Novant Health New Hanover Regional Medical Center, LLC (NHRMC) and Novant Health, Inc. (NHI) (collectively, “**NHRMC/NHI**”) to add one fixed PET scanner to Novant Health New Hanover Regional Medical Center Emergency Department North – Scotts Hill Hospital (NHRMC-SH) in response to the need determination in the 2021 State Medical Facilities Plan.

CON Project ID #O-012159-21 by Wilmington Health on Medical Center Drive to acquire one fixed PET scanner in response to the need determination in the 2021 State Medical Facilities Plan.

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 NHRMC-SH and Wilmington Health Certificate of Need (“**CON**”) applications, facts relating to the representations made by NHRMC/NHI and Wilmington Health in their applications and their ability to perform or fulfill the representations made; and discussion and argument as to whether the NHRMC-SH and Wilmington Health applications comply with relevant criteria, plans, and standards, including an analysis of comparative factors used by the CON Section in prior fixed PET scanner reviews.

Alliance Healthcare Services Inc. (Alliance) is an affected person regarding these two CON applications because Alliance is a statewide mobile PET services provider that serves hospital host sites in southeastern North Carolina, including Columbus Regional Hospital, Vidant Duplin Hospital and Onslow Memorial Hospital. These hospitals are located in counties where one or both applicants project to capture increased PET market share. Furthermore, the NHRMC/NHI application, CON Project ID # O-12143-21, specifically discusses the Alliance mobile PET scanners in its responses regarding Criterion 4, Criterion 6 and Criterion 18a.

For many years, the Alliance mobile PET scanners have been utilized to expand patient access at community hospitals throughout North Carolina. This has enabled some hospitals to build their mobile PET utilization to the point where the hospital host sites can seek CON approval to implement fixed PET. For example, Southeastern Regional Medical Center in HSA V recently implemented its fixed PET scanner after contracting for mobile PET service with Alliance. In this way, Alliance supports hospitals to reduce outmigration of patients from their home counties and increase their offerings of PET/CT imaging services.

As discussed in detail below, the NHRMC/NHI and Wilmington Health CON applications are each nonconforming with relevant statutory review criteria and performance standards.

Historically, Novant Health has utilized its fixed and mobile PET scanners to solely benefit the Novant Health System in urban markets and take market share away from competing hospitals. The NHRMC/NHI application seeks to capture PET market share in Columbus, Duplin and Onslow Counties and undermine the non-Novant hospitals that rely on mobile PET/CT services. .

Similarly, Wilmington Health’s application projects unrealistic market share gains by overstating its projected PET volumes with high percentages and numbers of patients from New Hanover, Brunswick and Pender and Onslow Counties. Wilmington Health unreasonably proposes to divert Onslow patients from using the mobile PET service that is already available at Onslow Memorial Hospital and where patients have access to oncologists, cardiologists and neurologists in their home county.

Alliance Comments Regarding NHRMC/NHI CON Project ID # O-12143-21

As discussed in the following comments, the NHRMC/NHI CON Project ID # O-12143-21 does not conform to Criteria (1), (3), (4), (5), (6), (7), (8), (18a) and the PET Performance Standards.

Criterion (1) Comments Regarding NHRMC/NHI

The NHRMC/NHI CON application does not adequately demonstrate the need for the proposed project based on reasonable utilization projections. Instead, due to NHRMC/NHI’s erroneous patient origin and utilization projections, the application 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 NHRMC-SH fixed PET 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) Comments Regarding NHRMC/NHI

The NHRMC/NHI application does not conform to Criterion (3) because the patient origin and utilization projections are not based on reasonable and adequately supported assumptions.

Patient Origin Projections

Per the 2021 SMFP, a fixed PET scanner’s ***service area*** is the Health Service Area (HSA) in which it is located. The map and table on page 373 of the 2021 SMFP show that HSA V includes Anson, Bladen, Brunswick, Columbus, Cumberland, Harnett, Hoke, Montgomery, Moore, New Hanover, Pender, Richmond, Robeson, Sampson, and Scotland Counties. NHRMC/NHI submitted historical county-specific PET patient origin data in its 2021 Hospital License Renewal Application (LRA). In contrast to the service area definition in the 2021 SMFP and NHRMC’s 2021 LRA patient origin data that is defined by county, the applicant’s service area definition and patient origin projections for the existing PET scanner and the proposed PET are a contrived combination of zip codes and counties that are irrational. The applicant’s gerrymandered service area is not based on the PET service area as defined in the 2021 SMFP. Nor is the proposed PET service area based on travel distances because the zip codes are irregularly shaped and travel times vary greatly due to traffic congestion during peak tourism months. Pages 44 through 46 of the NHRMC/NHI application provides the jumbled patient zip code and county patient origin data that obfuscate the patient origin projections.

The following table consolidates the applicant’s historical PET patient origin data (2019-20) and Year 3 patient origin projections obtained from pages 44 to 46 of the NHRMC/NHI application shows the applicant’s numbers and percentages of patients by county without the applicant’s extraneous zip codes. The highlighted portions of the following table show the incongruity between the patient origin projections for NHRMC’s existing PET at NHRMC-Medical Mall and the Year 3 PET projections for both the proposed fixed PET at NHRMC-SH and the existing fixed PET at the Medical Mall.

	NHRMC Medical Mall Page 44		Proposed NHRMC-SH Page 45		NHRMC Medical Mall Page 46	
	2119-20 Historical PET	Historical %	PET YR 3	Projected %	PET YR 3	Projected %
New Hanover (All)	1,124	40.20%	1,109	50.05%	850	34.10%
Pender	325	11.62%	513	23.15%	95	3.81%
Onslow	158	5.65%	209	9.43%	39	1.56%
Brunswick	893	31.94%	185	8.35%	1,238	49.66%
Duplin	83	2.97%	108	4.87%	20	0.80%
Columbus	94	3.36%	38	1.71%	112	4.49%
Bladen	41	1.47%	32	1.44%	36	1.44%
Sampson	18	0.64%	16	0.72%	17	0.68%
All Other	35	1.25%	5	0.23%	66	2.65%
Out of State	25	0.89%	1	0.05%	20	0.80%
	2,796	100.00%	2,216	100.00%	2,493	100.00%

According to the applicant, hundreds of patients from New Hanover County will shift from the existing NHRMC PET at Medical Mall to the proposed PET at NHRMC-SH allegedly due to proximity and convenience. However, the proposed location of the applicant’s project at 151 Scotts Hill Medical Drive is at the extreme northeast border of New Hanover County as compared to the location of NHRMC’s existing PET at NHRMC-Medical Mall, which is centrally located within New Hanover County. Therefore, it is unreasonable for the applicant to assume and project that in Year 3, the proposed PET scanner at the NHRMC-SH will serve substantially higher numbers and percentages of patients from New Hanover County than the existing PET at NHRMC-Medical Mall.

It is also unreasonable for the applicant to project that 75 to 80 percent of patients from New Hanover Zip Codes 28429, 28401 and 28405 would shift to the proposed PET scanner at NHRMC-SH because many patients within these zip codes are in fact closer to the existing PET scanner at NHRMC-Medical Mall. New Hanover County is shaped like a slice of pie with the highest density of the population in the center close to the existing fixed PET at NHRMC-Medical Mall. Therefore, based on geographic proximity for the majority of New Hanover population, the applicant’s projected shift of patients is unreasonable.

The applicant’s assumptions of a 75 percent shift in partial Year 1 that increases to 80 percent in Year 2 lacks adequate support because travel distance is not the sole reason that patients may choose a different facility location. The existing fixed PET scanner at NHRMC Medical Mall will still be staffed and operational and close to the radiation oncologists’ office on 16th Street. Since the

PET charges for the proposed PET scanner at NHRMC-SH are based on NHRMC’s hospital-based PET charges, there are **no** cost savings for patients to utilize the proposed NHRMC-SH PET scanner.

Need Analysis

The NHRMC-SH application fails to demonstrate that the fixed PET scanner will be needed at the Scotts Hill location in 2023 prior to the development and opening of the new 66-bed hospital campus. This schedule calls into question the availability of the necessary ancillary and support services for the proposed PET scanner. In addition, the outcome of NHRMC’s August 2021 CON application for a proposed new Linear Accelerator (LINAC) and Cancer Center (Project I.D. O-12110-21) is still unknown. Therefore, the applicants’ proposal to acquire a PET scanner at NHRMC-SH is based on conjecture regarding its overall scope of services.

NHRMC/NHI irrationally projects a surge of additional PET procedures when the proposed PET scanner becomes operational as seen in the next table. The highlighted cells of the table show the unsupported increases in PET procedures during the Transition Year and also in Years 1 and 2.

	10/1/2019	10/1/2020	10/1/2021	10/1/2022	10/1/2023	10/1/2024	10/1/2025
	9/30/2020	9/30/2021	9/30/2022	9/30/2023	9/30/2024	9/30/2025	9/30/2026
	Previous	Interim	Interim	Transition	Full YR 1	Full YR 2	Full Year 3
NHRMC Medical Mall PET	2,796	3,041	3,235	2,874	2,206	2,345	2,495
Annual % Change		8.76%	6.38%	-11.16%	-23.24%	6.30%	6.40%
NHRMC-SH PET				814	1,890	2,104	2,214
Annual % Change					NA	11%	5%
Combined PET	2,796	3,041	3,235	3,688	4,096	4,449	4,709
# PET Units	1	1	1	2	2	2	2
PET Procedure # Increases		245	194	453	408	353	260
Annual % Change Combined		8.76%	6.38%	14.00%	11.06%	8.62%	5.84%

The applicant’s methodology and assumptions do not adequately explain why the projected shift in patients in 2022 from the NHRMC-Medical Mall PET scanner to the NHRMC-SH PET scanner would support a 14 percent (14.00%) annual increase in total combined PET procedures. This surge in PET procedures is unreasonable because it precedes the completion of the 66-bed hospital campus (Project I.D. O-12947-20) and the availability of ancillary and support services at this new campus. \. It also precedes the completion of the proposed LINAC (Project I.D. O-12110-21). Therefore, patients and family who have had previous PET procedures at the existing PET scanner at NHRMC–Medical Mall and are used to traveling to NHRMC–Medical Mall are more likely to choose to continue to obtain PET procedures at NHRMC–Medical Mall.

As discussed in previous paragraphs, the predicted percentage of patients that will shift from the existing PET at NHRMC–Medical Mall to the proposed new fixed PET at NHRMC–SH is neither reasonable nor adequately supported. Therefore, the applicant’s volume projections are also not credible.

Performance Standard

The NHRMC/NHI application does not conform to Criterion (3) because the application fails to meet the PET performance standards for its existing PET scanners. The following tables demonstrate that the existing Novant fixed and mobile PET scanners are underutilized as their combined average is less than 2,080 annual procedures.

Proposed 2022 SMFP	# PET Scanners	2019-20 Utilization
NH Presbyterian Medical Center Fixed	1	2,039
NHFMC Fixed PET	2	2,397
NHFMC 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	2018-19 Utilization
NH Presbyterian Medical Center Fixed	1	2,151
NHFMC Fixed PET	2	2,855
NHFMC 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 PET inventory and utilization in the 2021 SMFP and the Proposed 2022 SMFP document that the existing Novant Health PET scanners have not performed an average of 2,080 annual PET procedures. In fact, total PET utilization for the combined Novant Health fixed and mobile PET scanners declined 3.9 percent from the reporting period ending in September 20, 2019 to the more recent September 30, 2020. The NHRMC/NHI application provides unreliable PET utilization data for its existing fixed and mobile PET scanners because it is inconsistent with the PET inventory in the 2021 SMFP.

For all of these reasons, the NHRMC-SH application does not conform to Criterion (3).

Criterion (4) Comments Regarding NHRMC/NHI

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

Criterion (5) Comments Regarding NHRMC/NHI

NHRMC/NHI's financial projections for its proposed fixed PET scanner are not based on reasonable or adequately supported operational projections as discussed in the Criterion (3) comments. Therefore, the applicant's financial projections are not based on reasonable operational projections.

The applicants' staffing projections are unreasonable because no part time or full-time staff are assigned for on-site management and supervision. Staff positions are omitted for patient registration, billing, and housekeeping for the proposed NHRMC-SH PET scanner. The NHRMC-SH application includes no allocation of general and administrative hospital overhead expenses for the proposed project. Consequently, the applicant's projected expenses are incorrect and understated.

For all of these reasons, the NHRMC/NHI application is not conforming to Criterion (5).

Criterion (6) Comments Regarding NHRMC/NHI

The application fails to demonstrate that its proposal would not result in unnecessary duplication of PET service because its utilization projections are unreliable as explained in the comments regarding Criterion (3), which are incorporated herein by reference. The applicant's assumptions that it would shift utilization from its existing fixed PET scanner at NHRMC-Medical Mall to a proposed fixed PET at NHRMC-SH are not credible.

NHRMC/NHI's project is duplicative of existing mobile PET capacity at hospitals serving patients in Onslow, Columbus and Duplin Counties where patients have more convenient access and existing referral relationships with non-Novant facilities and physicians.

Therefore, the application is not conforming to Criterion (6).

Criterion (7) Comments Regarding NHRMC/NHI

The NHRMC/NHI proposal does not conform to Criterion (7) because Form H shows only 1 FTE RN position and 2.1 FTE for Nuclear Medicine Technologists in Year 1. Moreover, these positions lack supervision because no management positions are included in the staffing table and the New Hanover Regional Medical Center – Scotts Hill Project I.D. #O-11947-20 will not be operational. Even after the hospital campus becomes operational, no management positions are included in the Form H staffing table to demonstrate adequate supervision of staff and implementation of quality assurance and accreditation measures.

Furthermore, the NHRMC-SH proposed project fails to demonstrate adequate staffing for patient registration, business office, medical records, pharmacy and housekeeping. The NHRMC-SH application lacks adequate staff to implement the project and serve the projected numbers of patients.

For these reasons, the NHRMC/NHI application is nonconforming to Criterion (7).

Criterion (8) Comments Regarding NHRMC/NHI

The NHRMC-SH application does not conform to Criterion (8) because Section I does not adequately explain how the PET patients at the proposed NHRMC-SH location will be registered, billed or obtain their medical records. In Year 1 that begins in 10/1/2023, the NHRMC-SH Project I.D. #O-11947-20 for the hospital services will not yet be operational. It is unreasonable for the proposed PET scanner to be implemented at this location prior to the availability of basic hospital services.

The NHRMC-SH application fails to demonstrate that any existing or new ancillary and support positions at the NHRMC main campus or at the NHRMC-SH Emergency Department will be assigned to support the proposed project in 2023. No explanation is provided to explain how the proposed fixed PET scanner can function absent these necessary services.

For these reasons, the NHRMC-SH application is nonconforming to Criterion (8).

Criterion (18a) Comments Regarding NHRMC/NHI

The NHRMC-SH 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. Projected expenses are not based on reasonable assumptions as discussed in the Criterion (5) comments, which comments are incorporated herein by reference. For these reasons, the NHRMC-SH application is nonconforming to Criterion (18a).

**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;

NHRMC/NHI utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in the Criterion (3) discussion in these comments is incorporated herein by reference. Therefore, the NHRMC-SH 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 NHRMC/NHI application failed to adequately demonstrate that Novant Health’s existing fixed and mobile PET scanners performed an average of at least 2,080 procedures per PET scanner in the last year because the 2021 SMFP and Proposed 2022 SMFP demonstrate that the averages for the Novant Health PET scanners are less than 2,080 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
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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 regarding projected utilization found in the Criterion (3) discussion in these comments is incorporated herein by reference. Therefore, the NHRMC/NHI 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.

NHRMC/NHI utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in the Criterion (3) discussion of these comments is incorporated herein by reference. For the reasons stated in the discussion regarding Criterion (3) above, the NHRMC-SH 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.

NHRMC/NHI utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in the Criterion (3) discussion of these comments is incorporated herein by reference. For the reasons stated in the discussion regarding Criterion (3) above, the NHRMC-SH application is not conforming to this Rule.

Alliance Comments Regarding Wilmington Health CON Project ID # O-12159-21

As discussed in the following comments, the Wilmington Health CON Project ID # O-12159-21 does not conform the Criteria (1), (3), (4), (5), (6), (7), (8), (18a) and the PET Performance Standards.

Criterion (1) Comments Regarding Wilmington Health

Wilmington Health does not adequately demonstrate the need for the proposed project based on reasonable utilization projections due to faulty patient origin projections and overstated volumes. Wilmington Health 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 the Criterion (3) discussion of the comments below is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3. Wilmington Health's 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) Comments Regarding Wilmington Health

The Wilmington Health application does not conform to Criterion (3) because the applicant's PET patient origin and utilization projections are not based on reasonable and adequately supported assumptions.

Wilmington Health is a multi-specialty medical group with approximately 161 providers. However, Wilmington Health does not provide radiation therapy and has only one medical oncologist in its multi-specialty group. While other types of physician specialists can and do refer patients for PET/CT procedures, Wilmington Health provides a very limited scope of cancer treatment services and does not meet the definition of a major cancer treatment center. Consequently, most cancer patients in HSA V are unlikely to utilize Wilmington Health for continued cancer treatment, but instead would choose other providers. Based on these factors, the applicant's market share assumptions on pages 3 and 4 of its Form C Assumptions and Methodology are unreasonable and lack adequate support.

Wilmington Health's methodology and assumptions are based on the incorrect assumption that its PET patients will obtain an average of 2 PET procedures per year. This assumption is unreasonable because Wilmington Health offers such a limited scope of cancer services. Since Wilmington Health lacks radiation therapy services, patients that might initially obtain a PET scan at Wilmington Health likely would seek any necessary follow-up care from other physician groups that are affiliated with major cancer centers, including NHRMC, Vidant, Duke or UNC hospitals, each of which offer a full range of cancer specialists and services. Thus, most patients likely would obtain follow-up PET procedures at these other comprehensive cancer centers rather than at Wilmington Health.

The Wilmington Health patient origin assumptions in Section Q Form C, (page 5), include the assertion that 9.0% of its PET patients will originate from Onslow County based on the historical data reflecting 9.1% of all ambulatory surgical facility patients from Onslow have utilized facilities in New Hanover County.

This assertion is misleading because although Onslow County has mobile PET services, it has no ambulatory surgical facilities. So, while Onslow County patients can choose to obtain PET procedures at Onslow Memorial, they do not have access to any freestanding ASF in their home county. The application fails to adequately demonstrate a correlation between PET patient origin and ambulatory surgery patient origin

Therefore, the applicant's statement that ambulatory surgery services are similar to PET services is false. Furthermore, the applicant's patient origin projection of 9.0% of patients from Onslow County is unreasonable and overstated because Onslow County is not adjacent to New Hanover County and there are no oncologists practicing at the Wilmington Health Jacksonville (Onslow County) office location.

Wilmington Health's application indicates that its proposed PET/CT services would include oncology, cardiology and neurology PET procedures, but the application does not quantify the types of procedure by these categories. There is no information provided to demonstrate that the applicant's assumption of 2 PET procedures per patient would be applicable to cardiology and neurology patients as well as oncology patients. For all of these reasons, the Wilmington Health application is nonconforming to Criterion (3).

Criterion (4) Comments Regarding Wilmington Health

Wilmington Health's application does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because the application is not conforming to all statutory and regulatory review criteria. Since Wilmington Health is not a major cancer treatment center nor a hospital, its need for a fixed PET scanner lacks adequate support.

An application that cannot be approved cannot be the most effective alternative. Therefore, the Wilmington Health application is not conforming to Criterion (4).

Criterion (5) Comments Regarding Wilmington Health

The applicant's financial projections for its proposed fixed PET are not based on reasonable operational projections as discussed in the Criterion 3 comments. Based on these unreliable and overstated operational projections, the revenue and expense projections lack adequate support. Therefore, Wilmington Health's financial projections are not based on reasonable operational projections. Staffing expenses for the project are unreliable due to the omission of necessary positions as discussed in the Criterion (7) comments below, which are incorporated herein by reference. For these reasons, the Wilmington Health application is not conforming to Criterion (5).

Criterion (6) Comments Regarding Wilmington Health

The application fails to demonstrate that its proposal would not result in unnecessary duplication of PET service because its utilization projections are unreliable as explained in the comments regarding Criterion (3) above, which are incorporated herein by reference. Wilmington Health physicians have the option to refer patients to the existing fixed and mobile PET scanners that are located in HSA V. The applicant's assumptions that it would capture PET market share in New Hanover, Brunswick, Pender and Onslow Counties is not reasonable because the practice has only

one medical oncologist and provides no radiation therapy services. Therefore, the Wilmington Health application is not conforming to Criterion (6).

Criterion (7) Comments Regarding Wilmington Health

Wilmington Health's application does not conform to Criterion (7) because Form H shows only 2.0 FTE PET Technologists. Since Wilmington Health is not a cancer center nor a hospital, the proposed PET 2.0 technologist staffing needs to have adequate supervision to train and supervise the employees, coordinate the purchase and delivery of radiopharmaceuticals and implement quality assurance and accreditation measures. . Furthermore, the Wilmington Health application fails to demonstrate adequate on-site staffing for patient registration, business office, medical records, pharmacy and housekeeping. Accordingly, the Wilmington Health application is not conforming to Criterion (7).

Criterion (8) Comments Regarding Wilmington Health

Section I of the Wilmington Health application fails to identify the radiologist and Medical Director that will be providing professional services in support of the proposed project. The proposed project requires the injection of radiopharmaceuticals that must be supervised by qualified physicians. The names of the physicians are required in order to obtain the Radioactive Material License. The absence of this basic information causes the application to be nonconforming to Criterion (8).

Criterion (18a) Comments Regarding Wilmington Health

The Wilmington Health application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate it will promote cost-effective services. Operational and financial projections are not credible. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. Projected expenses are not based on reasonable assumptions as discussed in the Criterion (5) comments, which comments are incorporated herein by reference. For these reasons, the Wilmington Health application is nonconforming to Criterion (18a).

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;

Wilmington Health's utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in the Criterion (3) discussion in Alliance's comments on the Wilmington Health application is incorporated herein by reference. For

the reasons stated in the discussion regarding Criterion (3), the Wilmington Health 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.

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

Comparative Analysis

	Wilmington Health Fixed PET	NHRMC-SH Fixed PET	Conclusions
Conforming to CON Criteria and PET Performance Standards	Not Conforming	Not Conforming	Neither Approvable
Scope of Services	Oncology, Cardiac, Neurologic	Oncology, Cardiac, Neurologic	Neither Approvable
Geographic Access Location	Wilmington	Wilmington	Neither Approvable
Access by Service Area Residents for YR 3	1,020 Patients from HSA V	1,999 Patients from HSA V	Projections Are Unreliable Neither Approvable
Access by Charity for YR 3	% Not provided 3 Patients	2.8% 132 Patients	NHRMC Higher Charity Neither Approvable
Access by Medicare for YR 3	66.30%	70.00%	NHRMC Higher Charity Neither Approvable
Access by Medicaid for YR 3	2.00%	3.80%	NHRMC Higher Charity Neither Approvable
Year 3 Total PET Procedures	2,115	2,214	Neither Application Is Based on Reasonable Utilization Projections Neither Approvable
Total Net Revenue for YR 3	\$3,999,602	\$5,159,169	
Average Net Revenue per Procedure for YR 3	\$1,891	\$2,330	
Total Expense per Procedure for YR 3	\$2,790,868	\$2,079,611	
Average Cost per Procedure for YR 3	\$1,320	\$939	

In summary, Alliance recommends that the Agency deny both NHRMC-SH CON Project ID # O-12143-21 by and Wilmington Health CON Project ID #O-012159-21 because neither application conforms to the CON Review Criteria and PET Performance Standards.