

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 11, 2022

Findings Date: March 11, 2022

Project Analyst: Kim Meymandi

Co-Signer: Gloria C. Hale

COMPETITIVE REVIEW

Project ID #: G-12142-21

Facility: Novant Health Forsyth Medical Center

FID #: 210829

Service Area: Statewide

Applicant(s): Forsyth Memorial Hospital, Inc.

Novant Health, Inc.

Project: Acquire a second mobile PET/CT Scanner pursuant to the need determination in the 2021 SMFP

Project ID #: G-12156-21

Facility: Alliance Mobile PET/CT 2021

FID #: 210836

Service Area: Statewide

Applicant(s): Alliance Healthcare Services, Inc.

Project: Acquire a mobile PET/CT scanner pursuant to the need determination in the 2021 SMFP

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

REVIEW CRITERIA

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

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

C-Alliance
NC-Novant Health Forsyth Medical Center

Need Determination

The 2021 State Medical Facilities Plan (SMFP) includes a need determination for one statewide mobile positron emission tomography (PET) scanner. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) proposing to develop a total of two new mobile PET scanners. However, pursuant to the need determination, only one additional mobile PET scanner may be approved in this review.

Policies

Two policies in Chapter 4 of the 2021 SMFP are applicable to the applications received in response to the need determination.

Policy GEN-3 on page 29 of the 2021 SMFP states:

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

Policy GEN-3 applies to both applications in this review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 29 of the 2021 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities is only applicable to the application submitted by Forsyth Memorial Hospital, Inc. and Novant Health, Inc. [Project ID# G-12142-21].

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

Forsyth Memorial Hospital, Inc. and Novant Health, Inc., hereinafter collectively referred to as “the applicant” or “NHFMC”, propose to acquire a second mobile PET/CT scanner to serve nine host sites pursuant to the need determination in the 2021 SMFP. NHFMC currently operates one fixed PET/CT unit and one mobile PET/CT serving sites in HSA II and III. Therefore, at the completion of this project, NHFMC would have a total of two mobile PET/CT scanners. NHFMC is owned by Novant Health, Inc. (Novant).

It should be noted that the 2020 and 2021 SMFPs incorrectly state that NHFMC operates two fixed PET/CT units. The 2022 SMFP correctly shows NHFMC operating one fixed PET/CT unit.

Need Determination. The applicant does not propose to develop more mobile PET scanners than are determined to be needed.

Policy GEN-3. In Section B.2, pages 28-33, the applicant explains why it believes its application is conforming to Policy GEN-3. On pages 28-33, the applicant states:

"The proposed project will allow NHFMC to keep up with the increasing demand for PET/CT services in its service area by expanding the capacity of its mobile PET/CT services to better meet patients' needs and expectations.

....

NHFMC also provides services to all persons regardless of race, sex, age, and religion, creed, disability, national origin, or ability to pay. With increased capacity for PET/CT services, providers at NHFMC and all host facilities will help more patients who may require some type of financial assistance.

....

Patients who receive PET/ CT services at NHFMC and its host sites will benefit from Novant Health's aforementioned system-wide improvements to maximize the value of healthcare for resources expended in the delivery of healthcare services. "

Policy GEN-4. The proposed capital expenditure is greater than \$2 million but less than \$5 million. In Section B.2, page 34, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant states that efforts to improve energy efficiency and reduce consumption include:

- *"Assigning oversight to a Corporate Energy Manager*
- *Actively managing utility purchases and agreements*
- *Benchmarking portfolio efficiency by performing utility assessments;*
- *Progressively converting to more efficient equipment, environmentally preferable products, and practices; and*
- *Applying retro-commissioning strategies to Building Automation Systems and HVAC Equipment."*

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the following:

- The applicant does not adequately demonstrate that the proposal is consistent with Policy Gen-3 because the applicant does not adequately demonstrate how the project will maximize healthcare value for the resources expended based on the following:
 - The applicant does not demonstrate the need the population proposed to be served has for the proposed project. The discussion regarding need found in Criterion (3) is incorporated herein by reference.
 - Since the applicant does not demonstrate the need it has for the proposed project, it cannot maximize healthcare value for the resources expended.

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc., hereinafter referred to as “the applicant” or “Alliance”, proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP. The applicant currently owns and operates two mobile PET/CT scanners.

Need Determination. The applicant does not propose to develop more mobile PET scanners than are determined to be needed.

Policy GEN-3. In Section B.2, pages 27-31, the applicant explains why it believes its application is conforming to Policy GEN-3. On pages 27-31, the applicant states:

“The proposed mobile PET/ CT scanner will promote safety and quality in accordance with Policy GEN-3 and compliance with licensure requirements and Joint Commission accreditation standards as well as the Quality Improvement Program, Risk Management Program, employee training and competency evaluations and Safety Policies.

....

The proposed mobile PET / CT will promote equitable access in the delivery of health care services because the proposed services will be provided at hospital host sites that are committed to serve Medicare, Medicaid and low-income patients.

.....

The proposed project will maximize value because PET/ CT service will be more accessible and more cost effective.”

Policy GEN-4. The proposed capital expenditure is less than \$2 million. Therefore, Policy GEN-4 is not applicable.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

- The applicant does not propose to acquire more mobile PET scanners than are determined to be needed.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of PET scanner services;
 - The applicant adequately documents how the project will promote equitable access to PET scanner services; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

(2) Repealed effective July 1, 1987.

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

**C
Alliance**

**NC
NHFMC**

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP. Novant Health (NH) the parent company of NHFMC currently operates two fixed PET/CT units (one at NHPMC and one at NHFMC) and one mobile PET/CT serving sites in HSA II and III. Therefore, at the completion of this project, NHFMC would have a total of two mobile PET/CT scanners.

NHFMC proposes to acquire the second mobile PET/CT scanner to serve four new and six existing host sites affiliated with Novant. In Section C, pages 36-45, the applicant states that

the existing mobile PET/CT scanner currently serves six host sites. Three of the existing sites are located in the greater Winston Salem market or Health Service Area (HSA) II and three are located in the Charlotte market or HSA III. The applicant states that if their proposal for a second mobile PET/CT scanner is approved they will use one PET/CT scanner to serve the greater Winston-Salem market and the other PET/CT scanner will be used to serve the Charlotte market. The applicant proposes to add four additional host sites and provide additional days or additional partial days at existing host sites, as shown in the table below.

Existing and Proposed Host Sites	Current Mobile Days	County	Proposed Mobile Days
Charlotte Market			
NH Huntersville Medical Center	1.5 days per week	Mecklenburg	2.5 days per week
NH Matthews Medical Center	1.5 days per week	Mecklenburg	2.0 days per week
NH Mint Hill Medical Center	0.5 days per week	Mecklenburg	1.0 day per week
NH Imaging University*	-	Mecklenburg	0.5 days per week
NH Ballantyne Medical Center*	-	Mecklenburg	1.0 day per week
Greater Winston Salem Market			
NH Rowan Medical Center	1.00 day per week	Rowan	1.5 days per week
NH Thomasville Medical Center	0.5 days per week	Davidson	0.5 days per week
NH Kernersville Medical Center	1.0 day per week	Forsyth	2.0 days per week
NH Forsyth Medical Center*	-	Forsyth	1.5 days per week
NH Cancer Institute-Mount Airy*	-	Surry	1.0 day per week

Source: Section C, pages 38-43 of the application

*Proposed site

Patient Origin

On page 367, the 2021 SMFP defines the service area for a mobile PET scanner as, “statewide”. Thus, the service area for this proposal is statewide.

In Section C.2, pages 44-45, the applicant provides historical patient origin for fixed and mobile PET services provided at NHFMC for the last full operating year (CY2020), as summarized in the tables below.

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NHFMC Fixed PET/CT Services		
County	Last Full FY (1/1/2020-12/31/2020)	
	# of Patients	% of Total
Forsyth	1,007	43.4%
Davidson	204	8.8%
Surry	192	8.3%
Stokes	179	7.7%
Davie	158	6.8%
Yadkin	140	6.0%
Guilford	48	2.1%
Iredell	26	1.1%
Rowan	11	0.5%
Mecklenburg	6	0.3%
Cabarrus	4	0.2%
All Other NC Counties*	294	12.7%
Out of State**	49	2.1%
Total	2,318	100.0%

*Includes: Wilkes, Ashe, Carroll, Allegheny, Rockingham, Randolph, Watauga, Alexander, Moore, Stanly, Alamance, Avery , Buncombe, Burke, Caldwell, Bedford, Brunswick, Catawba, Graham, Lincoln, Robeson, and Wake counties.

**Includes: Virginia, South Carolina, Florida, Massachusetts, Pennsylvania and New York

The Project Analyst notes that Carroll and Bedford counties listed in All Other NC Counties by the applicant are not counties in NC.

NHFMC Mobile PET/CT Services		
County	Last Full FY (1/1/2020-12/31/2020)	
	# of Patients	% of Total
Mecklenburg	607	30.5%
Rowan	301	15.1%
Forsyth	210	10.5%
Iredell	201	10.1%
Union	165	8.3%
Davidson	77	3.9%
Cabarrus	62	3.1%
Guilford	58	2.9%
Stokes	24	1.2%
Davie	16	0.8%
Surry	7	0.4%
Yadkin	6	0.3%
All Other NC Counties*	209	10.5%
Out of State**	49	2.5%
Total	1,992	100.0%

*Includes: Lincoln, Gaston, Catawba, Stanly, York, Rockingham, Anson, Randolph, Wilkes, Alamance, Cleveland, Caldwell, Carteret, Montgomery, Richmond, Alexander, Bladen, Brunswick, and Watauga Counties.

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**Includes: South Carolina, Virginia, New Hampshire, Texas, Arizona, New York, and Florida.

The Project Analyst notes that York county listed in All Other NC Counties by the applicant is not a county in NC.

The following tables summarize projected patient origin for the fixed PET/CT scanner and both mobile PET/CT scanners for the first three full fiscal years of operation:

County	NHFMC FIXED PET/CT Services					
	1st Full FY (1/1/2023-12/31/2023)		2nd Full FY (1/1/2024-12/31/2024)		3rd Full FY (1/1/2025-12/31/2025)	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Forsyth	918	45.4%	941	45.4%	965	45.4%
Davidson	80	4.0%	82	4.0%	85	4.0%
Surry	40	2.0%	41	2.0%	42	2.0%
Stokes	192	9.5%	197	9.5%	202	9.5%
Davie	169	8.4%	174	8.4%	178	8.4%
Yadkin	150	7.4%	154	7.4%	158	7.4%
Guilford	51	2.5%	53	2.5%	54	2.5%
Iredell	28	1.4%	29	1.4%	29	1.4%
Rowan	12	0.6%	12	0.6%	12	0.6%
Mecklenburg	6	0.3%	7	0.3%	7	0.3%
Cabarrus	4	0.2%	4	0.2%	5	0.2%
Union	-	0.0%	-	0.0%	-	0.0%
All Other NC Counties*	315	15.6%	323	15.6%	332	15.6%
Out of State**	53	2.6%	54	2.6%	55	2.6%
Total	2,020	100.0%	2,071	100.0%	2,124	100.0%

County	NHFMC Mobile PET/CT [^] Services					
	1st Full FY (1/1/2023-12/31/2023)		2nd Full FY (1/1/2024-12/31/2024)		3rd Full FY (1/1/2025-12/31/2025)	
	# of Patients	% of Total	# of Patients	% of Total	# 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%

Source: Section C.3, page 47

*Includes: Wilkes, Ashe, Carroll, Alleghany, Rockingham, Randolph, Watauga, Alexander, Moore, Stanly, Alamance, Avery, Buncombe, Burke, Caldwell, Bedford, Brunswick, Catawba, Graham, Lincoln, Robeson, and Wake Counties.

**Includes: Virginia, South Carolina, Florida, Massachusetts, Pennsylvania, and New York.

[^]projections are for both mobile units.

The Project Analyst notes that neither Carroll nor Bedford Counties are in NC.

In Section C.3, page 46 the applicant provides the assumptions and methodology used to project its patient origin. The applicant states that projected patient origin is based on federal fiscal year (FFY) 2020 patient origin for fixed PET/CT services at NHFMC and the patient origin for the mobile PET services at the existing host sites. The applicant's assumptions are reasonable and adequately supported because the applicant bases the projected patient origin on the historical patient origin of NHFMC's fixed and mobile PET/CT sites.

Analysis of Need

In Section C.4, pages 49-67, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

Service Area Population Trends [pages 53-55]

The applicant states that projected growth in the service area, particularly the 65+ age cohort, demonstrates the need for the project. The applicant uses 2019 data from the North Carolina Office of State Budget and Management (NCOSBM) to illustrate the total service area projected population growth from July 2021 to July 2026 and calculates the service area population compounded annual growth rates (CAGRs). The applicant calculates the CAGR

for counties proposed to be primarily served by NHFMC as 1.4% overall and 3.6% for the 65+ cohort.

Expanding PET Scanning Capabilities [pages 55-56]

The applicant states that the technological advancements of PET/CT scanners and the demand for PET/CT scanner services continues to increase.

Factors Impacting Service Area Demand for Mobile PET/CT Services [pages 56-60]

The applicant provides data from State Cancer Profiles at www.cancer.gov to demonstrate that four of the top ten counties for cancer incidence rates in the 65+ age population are in the proposed service area. The applicant states that COVID-19 has caused delays in cancer screening, treatment and diagnosis. The applicant provides further data from State Cancer Profiles showing HSAs II and III had the highest average annual cancer cases in 2014-2018 while PET volume from 2021 License Renewal Applications (LRAs) shows fewer PET scans were done in these areas than in comparison to other areas.

Growth in Demand for Novant Health PET Services [pages 60-62]

The applicant states that the need for PET/CT scans has grown significantly across the entire Novant Health System and using annualized data from FFY 2021 cites a 25.3% CAGR across all current host sites for NHFMC's one existing mobile scanner for the period FFY 2016 to FFY 2021.

Inaccurate Data in the 2020 and 2021 SMFPs [pages 62-64]

The 2020 and 2021 SMFPs show an inventory of two fixed PET scanners for NHFMC. The applicant states NHFMC only has one fixed PET scanner and states that the volume for the one PET scanner should have triggered a need for an additional PET/CT scanner in the 2020 and 2021 SMFPs.

Growth in Market Demand for PET/CT Services [pages 64-65]

The applicant states that both the Charlotte and Greater Winston Salem fixed and mobile PET/CT market volumes increased steadily from FY 2017 to FY 2019. The applicant notes a -9.2% volume decrease in FY 2020 attributable to the impact of COVID-19 and states that annualized data for FY 2021 shows an increase of 1.5%. The applicant expects volumes will continue to increase as each existing site rebounds from COVID and new mobile host sites are open for service.

Benefits of Mobile Routes by Geographic Marker [pages 65-66]

The applicant states that if their proposal is approved, they would establish two mobile routes with one mobile PET/CT scanner serving the Greater Charlotte Market and the other unit serving the Greater Winston-Salem Market. The applicant states this would minimize wear

and tear on the equipment, optimize travel time, geographic proximity and accessibility and provide timely access for patients.

NHFMC's utilization and the unmet need [page 67]

The applicant states that their system wide need for PET/CT services has gone unmet due to the Agency's denial for a mobile PET/CT scanner in 2018 and subsequent litigation which was recently resolved in favor of another provider. The applicant states that the approved applicant has no existing sites and has not served any patients resulting in an identified need going unmet.

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2021 SMFP for one statewide mobile PET/CT scanner.
- The applicant provides population growth projections for the proposed service area based on data from NCOSBM showing growth among the 65+ age cohort.
- The applicant relies on growth trends and historical utilization across all host sites of its existing mobile PET/CT scanner.
- The applicant demonstrates growth in cancer rates in the proposed service area.

Projected Utilization

In Section Q, pages 127-131, the applicant provides historical and projected utilization for the existing and proposed PET/CT scanners, as illustrated in the following table:

	Previous Full FY2020	Interim Annualized Full FY2021*	Interim Full FY2022	PY1 1 st Full FY CY2023	PY2 2 nd Full FY CY2024	PY3 3 rd Full FY CY2025
NHPC Fixed PET/CT	1,997	2,061	2,052	2,152	2,278	2,411
NHFMC Fixed PET/CT	2,318	2,373	2,473	2,020	2,071	2,124
NHFMC Existing Mobile PET/CT	1,992	2,178	2,390			
NHFMC Combined Mobile PET/CTs				3,715	4,123	4,351

*Actual internal data through August 31, 2021 annualized

In Section Q, pages 133-149, the applicant provides the assumptions and methodology used to present the historical and projected utilization on Form C.2.a which is summarized below:

- NH's fiscal year is January 1 to December 31.
- **FY2020 utilization:** (page 134) The applicant uses actual internal data.
- **FY2021 utilization:** (pages 134-135) FY2021 utilization is based on, "...internal data through August to present total mobile volume instead of LRA data and annualized. (Volume through August ÷ 8 *12)."

- **FY2022 utilization:** (pages 135-138) The applicant states FY2022 utilization is based on $\frac{3}{4}$ of Interim FFY2022 (1/1/22-9/30/22) + Interim Quarter FFY2023 (10/1/22-12/31/22).
 - On page 137, the applicant states that Interim FFY2022 is “*projected by reviewing a month-over-month trend of PET/CT volume to assess the COVID-19 pandemic’s impact on volumes and recent recovery.*”
 - In Section C.4, page 61, the applicant states, “*While there is a slight and steady upward trend in volume across the unit volume from the low point of March-May 2020, the three most recent months (June, July, and August 2021) reflect a level of utilization much more consistent with pre-COVID utilization, reflecting more “normal” volumes for each.*”
 - In Section C.4, page 62, the applicant provides the three-month PET/CT volumes for June 2021 through August 2021 (Figure 13b) as shown in the following table.

	June-August 2021 Volume
NHFMC	656
NHPMC	541
NHFMC Mobile	586

- In Section Q, pages 137-138, the applicant states that the June-August 2021 volumes are annualized to project interim FFY2022 volumes with a footnote from Figure Q.2 on page 137 stating, “*Interim FFY2022 annualized based on review of data trend from 9/1/2020-8/31/2021. The FFY annualization based on the average of the last three months of*” The Project Analyst notes that raw data for the time period 9/1/2020-8/31/2021 is not provided and while Figure 13a. on page 136 depicts some upward trends there are also some notable declines in utilization for this period.
- **FYs 2023, 2024 and 2025 (project years 1-3):** (pages 135-146) The applicant provides various methodologies for calculating projected utilization for the fixed PET/CTs and mobile host sites.
- On page 135 the applicant presents historical utilization of Novant-affiliated fixed and mobile sites as illustrated in the tables below in FFY format and states that these numbers serve as a starting point for the utilization for many existing sites.

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Provider	Location	FFY2014^	FFY2015^	FFY2016^	FFY2017^^	FFY2018
		2015 LRA	2016 LRA	2017 LRA	2018 LRA	2019 LRA
NHPMC		1,619	1,970	1,838	1,711	2,018
NHFMC		2,518	2,726	3,025	2,969	2,857
NHFMC	Mobile Host Sites					
	Huntersville	218	232	297	235	475
	Matthews	119	119	145	217	465
	Mint Hill**	-	-	-	-	-
	Rowan (Julian Rd. Imaging)	239	232	236	134	351
	Thomasville	85	68	87	114	154
	Kernersville***	-	-	-	174	335
Total Mobile Unit		661	651	765	874	1,780
Forsyth TOTAL (Fixed + Mobile)		3,179	3,377	3,790	3,843	4,637
Novant Health Total		4,798	5,347	5,628	5,554	6,655

Source: 2019-2021 SMFPs and Proposed 2022 SMFP

^Mobile PET services were provided through a contract with Alliance

^^Mobile PET services were provided through a contract with Alliance up until January 2017. Progress report from Project ID#G-11051-15 shows NH's mobile PET became operational February 27, 2017. Data obtained by the Project Analyst from NH's 2018 LRAs and Alliance's 2018Mobile PET Registration and Inventory are inconsistent with numbers presented by the applicant.

**Began offering services in FY2019

***NH-Kernersville opened in FFY 2017 therefore the growth rate is provided for FFY2017-FFY2021

Provider	Location	FFY2019	FFY2020	FFY2021	FFY 2016-2021 CAGR%	FFY 2014-2019 CAGR%
		2020 LRA	2021 LRA	Annualized*		
NHPMC		2,151	2,039	2,028	2.0%	5.8%
NHFMC		2,855	2,397	2,340	-5.0%	2.5%
NHFMC	Mobile Host Sites					
	Huntersville	632	634	692	18.4%	23.7%
	Matthews	513	387	556	30.9%	33.9%
	Mint Hill**	102	190	111		
	Rowan (Julian Rd. Imaging)	338	348	370	9.4%	7.2%
	Thomasville	129	64	25	-22.0%	8.7%
	Kernersville***	354	361	397	22.9%	
Total Mobile Unit		2,068	1,984	2,151	23.0%	25.6%
Forsyth TOTAL (Fixed + Mobile)		4,923	4,381	4,491	3.5%	9.1%
Novant Health Total		7,074	6,420	6,519	3.0%	8.1%

Source: 2019-2021 SMFPs and Proposed 2022 SMFP

*Internal data Novant Health, 10/1/2020-8/31/2021 annualized

**Began offering services in FY2019

***NH-Kernersville opened in FFY 2017 therefore the growth rate is provided for FFY2017-FFY2021

- On page 136, the applicant states that when projecting volumes for each mobile host site they considered various analyses including:

- Actual growth rates by market, unit, and host site for existing fixed and mobile host sites.
- Drive time and related geographic accessibility analyses by county.
- County patient origin analysis by host site.
- Month-over-month analysis of care during the COVID-19 pandemic and recovery.
- Current and expected referral patterns of Novant Health-affiliated oncologists.

The following table from Section Q, page 137 summarizes the applicant's assumptions for each site location:

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Location / Host Site	Interim FFY2022	Partial Year	Project Year 1	Project Year 2	Project Year 3	Assumptions
NHPMC-Fixed	*	5.8%	5.8%	5.8%	5.8%	Historical CAGR FFY 2014-2019 minus shift to NH Ballantyne and NH Mint Hill
NHFMC-Fixed	*	2.5%	2.5%	2.5%	2.5%	Historical CAGR FFY 2014-2019 minus shift to mobile unit at NH Forsyth NMG Mt. Airy
Forsyth Mobile Charlotte Sites						
NH Huntersville	*	1.0%	7.9%	4.0%	4.0%	<u>Partial Yr:</u> 1% growth due to capacity constraints <u>PY 1:</u> Historical CAGR FY 2014-19 ÷ 3 & minus shift to NHI-University <u>PYs 2 & 3:</u> ½ of PY1 CAGR
NH Matthews	*	5.7%	11.3%	5.7%	5.7%	<u>Partial Yr:</u> Historical CAGR ÷ 6 <u>PY 1:</u> Historical CAGR FY 2014-19 ÷ 3 <u>PYs 2 & 3:</u> Historical CAGR ÷ 6
NH Mint Hill	Rebound	1.0%	15.8%	7.9%	7.9%	Rebound to FFY2020 volume <u>Partial Yr:</u> 1% growth due to capacity constraints <u>PY 1:</u> ½ Charlotte mobile PET/CT market + shift from NH - Presbyterian <u>PYs 2 & 3:</u> Charlotte market mobile CAGR + 4
NHI-University (NEW)			Shift	4.0%	4.0%	<u>PY 1:</u> Shift from Huntersville based on patient origin <u>PYs 2 & 3:</u> Based on NH-Huntersville proposed CAGR
NH Ballantyne (NEW)			Shift	5.8%	5.8%	<u>PY 1:</u> Opening June 2023. Shift from NH-Presbyterian based on patient origin <u>PYs 2 & 3:</u> Based on NH-Presbyterian historical CAGR
Forsyth Mobile Winston-Salem Sites						
NH Rowan	*	1.0%	17.0%	8.5%	8.5%	<u>Partial Yr:</u> 1% growth due to capacity constraints <u>PY 1:</u> Based on Winston-Salem mobile PET/CT market CAGR <u>PYs 2 & 3:</u> ½ of Winston-Salem mobile PET/CT market CAGR
NH Thomasville			Rebound	17.0%	8.5%	No current or interim days of service. No partial year days. <u>PY 1:</u> Rebound to FY 2019 pre-COVID levels <u>PY 2:</u> Based on mobile PET/CT market CAGR <u>PY3:</u> ½ of mobile PET/CT market CAGR
NH Kernersville	*	1.0%	11.5%	11.5%	5.7%	<u>Partial Yr:</u> 1% growth due to capacity constraints <u>PY 1:</u> ½ of historical CAGR (FFY 2017-2021) minus shift to NMG-Mt. Airy <u>PY 2:</u> ½ of historical CAGR <u>PY 3:</u> ½ of historical CAGR
NH Forsyth			Shift	2.5%	2.5%	<u>Partial Yr:</u> No current or interim days of service. No partial year days. <u>PY 1:</u> 15% redirection of volume from fixed unit at NH-Forsyth <u>PYs 2 & 3:</u> Same CAGR as NH-Forsyth fixed unit
NMG-Mt. Airy (NEW)			Shift	4.5%	4.5%	<u>PY 1:</u> Shift from NH-Forsyth & NH-Kernersville based on patient origin (90% Forsyth, 10% Kernersville) <u>PYs 2 & 3:</u> NH-Forsyth CAGR + 2% new market growth

*Interim FFY 2022 annualized based on review of data trend from 9/1/2020-8/31/2021. The FFY annualization is based on the average of the last three months.

The applicant provides detailed formulas on pages 138-141 for projecting volumes in the first three fiscal years at all existing PET/CT fixed and mobile sites. For all existing locations except NHTMC, the applicant begins with FFY2022 volume and multiplies this “*by the growth rate for 1.25 years to convert to PY1 (CY2023)*.” The applicant then utilizes various historical CAGRs and shifts in volume to arrive at volumes for the three project years.

On pages 142-145 the applicant provides detailed formulas for projecting volumes in the first three fiscal years at all proposed sites.

On page 146, the applicant provides a table illustrating PET/CT scan volume before the proposed second PET /CT unit is added in FFY format and after the proposed second PET/CT unit is added in CY/FY format as shown below.

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Before 2 nd PET Unit				
	FFY 2019 10/1/18- 9/30/2019	FFY 2020 10/1/2019- 9/30/2020	Current FFY 2021 10/1/2020- 9/30/2021*	Interim FY FFY 2022 10/1/2021- 9/30/2022
Scans				
NHPCM Fixed	2,151	2,039	2,028	2,164
NHPCM Year Over Year % Change^^	6.6%	-5.2%	-0.5%	6.7%
NHFMC Fixed	2,855	2,397	2,340	2,624
NHFMC Year Over Year % Change^^	0.0%	-16.0%	-2.4%	12.1%
NH Mobile: Charlotte Route				
Huntersville	632	634	692	732
Matthews	513	387	556	528
Mint Hill	102	190	111	190
NHI University (NEW)				
Ballantyne (NEW)^				
Total Charlotte Route		1,211	1,359	1,450
Forsyth Mobile: Greater Winston-Salem Route				
Rowan	338	348	370	388
Thomasville	129	64	25	
Kernersville	354	361	397	540
Forsyth				
NHCI Mt. Airy (NEW)				
Total W-S Route		773	792	928
Total NH Mobile(s)	2,068	1,984	2,151	2,378
Mobile Year Over Year % Change^^	16.2%	-4.1%	8.4%	10.6%
Total NHFMC Mobile & Fixed	4,923	4,381	4,491	5,002
Total NH	7,074	6,420	6,519	7,166
Total Year Over Year % Change^^		-9.3%	1.5%	9.9%

*Annualized using internal data through August 31

^Set to open June 2023

^^ Project Analyst calculations using the applicant's data

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Before 2 nd PET Unit		With Second PET Unit		
	Interim Quarter	Project Year 1	Project Year 2	Project Year 3
	10/1/2022-12/31/2022	1/1/2023-12/31/2023	1/1/2024-12/31/2024	1/1/2025-12/31/2025
Scans				
NHPMC Fixed	573	2,152	2,278	2,411
NHPMC Year Over Year % Change^^		-0.5%	5.9%	5.8%
NHFMC Fixed	673	2,020	2,071	2,124
NHFMC Year Over Year % Change^^		-23.0%	2.5%	2.6%
NH Mobile: Charlotte Route				
Huntersville	185	669	695	723
Matthews	139	604	638	674
Mint Hill	48	249	269	290
NHI University (NEW)		136	141	147
Ballantyne (NEW)^		150	317	336
Total Charlotte Route	372	1,808	2,061	2,170
Forsyth Mobile: Greater Winston-Salem Route				
Rowan	98	472	513	556
Thomasville		129	151	164
Kernersville	136	587	654	692
Forsyth		406	416	427
NHCI Mt. Airy (NEW)		313	327	342
Total W-S Route	234	1,907	2,061	2,181
Total NH Mobile(s)	607	3,715	4,123	4,351
Mobile Year Over Year % Change^^		56.2%	11.0%	5.5%
Total NHFMC Mobile & Fixed	1,279	5,735	6,194	6,475
Total NH	1,852	7,888	8,472	8,887
Total Year Over Year % Change^^		10.1%	7.4%	4.9%

*Annualized using internal data through August 31

^Set to open June 2023

^^ Project Analyst calculations using the applicant's data

New Hanover Regional Medical Center (NHNHRMC) was acquired by NH on February 1, 2021 and currently operates one fixed PET/CT scanner at its Medical Mall campus and proposes in Project ID# O-12143-21, currently under review, to acquire a second fixed PET/CT scanner to be located at its Scotts Hill campus. The tables below summarize the historical and projected utilization for PET/CT scanners at NHNHRMC found in Exhibit C-4.2 pages 41 and 42.

NHNHRMC Historical Utilization PET/CT Scanner

	Prior Full FY 10/1/2019- 9/30/2020	Interim Full FY 10/1/2020- 9/30/2021	Interim Full FY 10/1/2021- 9/30/2022	Partial Interim FY 10/1/2022- 3/31/2023
NHNHRMC Medical Mall	2,796	3,041	3,235	1,764

NHNHRMC Projected Utilization PET/CT Scanner

	Partial Interim FY 4/1/2023- 9/30/2023	1st Full FY 10/1/2023- 9/30/2024	2 nd Full FY 10/1/2024- 9/30/2025	3 rd Full FY 10/1/2025- 9/30/2026
NHNHRMC Medical Mall	1,110	2,206	2,345	2,494
NHNHRMC Scotts Hill	814	1,890	2,104	2,214
NHNHRMC Total	1,924	4,096	4,449	4,709

On pages 43-51 of Exhibit C-4.1, the applicant explains the methodology and assumptions for projected utilization of the existing and proposed fixed PET/CT scanner at NHNHRMC. The applicant utilizes historical Zip Code and county PET patient origin, calculates and applies a CAGR of 6.4% for projecting utilization growth. The applicant adds growth from cardiac patients expected to shift from a SPECT scan to a PET/CT scan and also adds patients shifting care from the Medical Mall campus to the Scotts Hills campus due to volume growth and convenience.

While the NH fixed PET/CT scanner utilization projections are reasonable and adequately supported, the NH mobile PET/CT projected utilization is not based on the following:

- The applicant does not provide a reasonable basis for excluding data from the past 12 months when calculating FFY2022 utilization. The applicant relies on the most recent 3 months of data (June 2021 to August 2021) to calculate FFY2022 utilization stating this represents a recovery from COVID-19, yet fails to acknowledge and consider the increases and decreases in utilization for the previous 12 months as depicted in Figure 13a. on page 136.
- Publicly available information obtained by the Project Analyst shows that for the time period FFY2014 up until February 27, 2017 NHFMC had two fixed PET scanners in use and the NH mobile host sites utilized a mobile PET/CT scanner contracted through Alliance.
- In October 2015, NHFMC was issued a CON to replace and convert an existing PET/CT scanner to a mobile PET/CT scanner pursuant to Policy TE-1 in the 2015 SMFP (Project ID#G-11051-15). According to a Progress Report for the development of Project ID#G-11051-15 submitted to NCDHCSR-CON by NHFMC the converted PET/CT scanner was put into operation on February 27, 2017, providing seven months (March 1, 2017-September 30, 2017) of utilization for the reported FFY2017 time period. Prior to the NH mobile PET/CT scanner being put into operation , records show NH utilized a mobile PET/CT scanner contracted through Alliance. According to Registration and Inventory of Medical Equipment forms submitted by Alliance to

NCDHSR, Healthcare Planning (HCP) for 2014-2017, the contracted PET/CT scanner was utilized at numerous host sites other than those owned and operated by NH resulting in a limited capacity to serve the NH host sites and thereby limiting utilization for the NH mobile host sites for the time period FFY 2014-FFY 2017. The applicant uses FFY 2014 as a starting point for calculating CAGRs at each site. Because NH was using a contracted scanner, the utilization numbers for FFY 2014 are likely limited by the fact that the contracted scanner was committed to sites not associated with NH and therefore cannot be viewed as an accurate starting point for calculating a CAGR. The net effect of calculating a CAGR with a low starting point is an artificial inflation of the historical CAGR. Calculating the CAGR beginning with annualized data from 2017 when NH began using their own mobile scanner would produce a more accurate picture of growth. Furthermore, the total utilization for FFY 2017 increases significantly from the 874 procedures reported by the applicant to 1,499 when the 7 months of data are annualized ($874/7=124.9 \times 12 = 1,499$). Based on this discrepancy the CAGR used by the applicant is inflated and therefore, produces a projected utilization that is not reasonable and adequately supported.

- The 17% growth rate used from FY 2022 to FY 2023 (OY1) for the Rowan site is not reasonable given the site's historical CAGR from FFY2014-FFY2019 of 7.2%. In addition, the applicant provided mobile PET service to the host site 2 days per week in FY 2020 and provided 348 procedures. The applicant projects performing 472 procedures in CY 2023 (OY1) spending a lesser amount of time (1.5 days) at the site. Lastly, as reported on its 2022 Registration and Inventory form for the period FY 2021, the mobile performed only four procedures at the Rowan site.
- The 2022 Registration and Inventory form for the period FY 2021 shows that FMC's mobile PET performed 1,750 procedures. The applicant used 2,178 "*annualized*" data for the same time period. This equates to a difference of 24.5%. Therefore, the applicant used a much higher number of procedures as its base year and then projected forward. Based on this discrepancy, the applicant's overall projected utilization is inflated and therefore, not reasonable.
- The growth percentage of 4.5% used to calculate OY1 (CY 2023) for the NMG-Mt. Airy site is not reasonable given that the applicant states that 90% of the site's patients will shift there from NHFMC. NHFMC's growth rate for FY2014-FY2019 was 2.5%. The applicant does not provide any support for its additional 2% growth other than to state it is due to "*new market growth*". While the Mt. Airy site is a new host site, the applicant proposes to add two other new host sites, NHI University and NH Ballantyne, but does not apply an additional percentage for "*new market growth*". The applicant does not explain why it believes a 2% new market growth would be reasonable.
- The applicant's projected patient origin for out of state patients is not reasonable or adequately supported. From FY2018-FY2021, the number of out-of-state patients varied. The average for that time period was 69 patients, or an average of 3.7% of all patients served. In FY 2021, the mobile PET served 80 patients. The applicant projects to serve 241 out-of-state patients in FY2023 which is 6.5% of its total projected patients served and an increase of 300%. The applicant does not provide an explanation for this large increase and therefore, it is not reasonable and adequately supported.

Access to Medically Underserved Groups

In Section C.6, page 72, the applicant states:

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

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

.....Novant Health hospitals fulfilled their Hill-Burton obligations long ago.”

The applicant provides the estimated percentage for each medically underserved group it proposes to serve during the third full fiscal year, as shown in the following table.

Medically Underserved Groups	3rd FY % of Total Patients
Low income persons	2.0%
Racial and ethnic minorities	14.9%
Women	53.6%
Persons with Disabilities	NHFMC does not track
Persons 65 and older	62.2%
Medicare beneficiaries	68.3%
Medicaid recipients	3.9%

Section C, page 73

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant has historically provided access to services to underserved groups.
- The applicant provides its projected payor mix, which includes underserved groups, and assumes it will remain constant for the first three years of operation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites (three existing and four new) pursuant to the need determination in the 2021 SMFP. The applicant currently owns and operates two mobile PET/CT scanners. Therefore, at the completion of this project, Alliance would have a total of three mobile PET/CT scanners.

Alliance proposes to acquire the third mobile PET/CT scanner to serve four new and three existing host sites affiliated with the UNC Health System. The following table lists the host sites for the proposed project and the primary and secondary service areas for each site.

Host Site Service Areas

Host Site	Primary County	Secondary Counties	HSA	PET Service
UNC Rockingham	Rockingham	Virginia, Stokes, Caswell, Guilford	II	New
Margaret R Pardee Hospital	Henderson	Buncombe, Polk, Transylvania, Rutherford	I	Alliance I
Caldwell Memorial Hospital	Caldwell	Burke, Catawba, Alexander, Ashe	I	Alliance I
Wayne Memorial Hospital	Wayne	Sampson, Lenoir, Johnston, Duplin	VI	Alliance II
Chatham Hospital	Chatham	Randolph, Alamance, Lee, Moore	III	New
UNC Eastowne Medical Office Building	Orange	Wake, Cumberland, Alamance, Durham, Chatham, Lee, Moore, Harnett, Johnston, Guilford, Nash, All Other NC Counties	III	New
UNC Hospitals Hillsborough Campus	Orange	Wake, Cumberland, Alamance, Durham, Chatham, Lee, Moore, Harnett, Johnston, Guilford, Nash, All Other NC Counties	III	New

Source: Section C, pages 34-35 of application

In Section C, page 34, the applicant provides the projected weekly service for the proposed scanner at each host site as shown in the table below.

Host Site	Project Year 1	Project Year 2	Project Year 3
UNC Rockingham	0.50	0.50	0.75
Margaret R Pardee Hospital	1.00	1.00	1.25
Caldwell Memorial Hospital	0.50	0.75	0.75
Wayne Memorial Hospital	0.75	1.00	1.00
Chatham Hospital	0.50	0.50	0.50
UNC Eastowne	1.00	1.00	1.00
UNC Hillsborough Campus	0.50	0.50	0.50
Totals	4.75	5.25	5.75

Patient Origin

On page 367, the 2021 SMFP defines the service area for a fixed PET scanner as, “*statewide*”. Thus, the service area for this proposal is statewide.

In Sections C.2 and C.3, pages 40-50, the applicant provides the historical patient origin for the proposed PET/CT scanner host sites for the time period October 1, 2019 through September 30, 2020 and the projected patient origin for the first three fiscal years following project completion, CY 2023, CY 2024 and CY 2025. In Sections C.2 and C.3, pages 39-40 and 44-50, the applicant provides the assumptions and methodology it used to project patient origin.

Comments submitted by NHFMC question patient origin data provided by Alliance noting inconsistencies between the projected total patients in the patient origin tables for Margaret Pardee Hospital, Caldwell Memorial Hospital and Wayne Memorial Hospital and the projected utilization tables for the same host sites. In response to comments submitted to the Agency, Alliance acknowledges minor discrepancies in the patient numbers presented in the patient origin tables on pages 45 and 46 of the application. Alliance attributes the discrepancies to typographical errors and states that the percentages are correct. The Project Analyst noted the discrepancies in projections and found them to be de minimis.

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin based on historical patient origin at the proposed sites as reported on 2021 LRAs.
- The applicant utilizes LINAC and MRI historical patient origin data as reported on 2021 LRAs from UNC Rockingham and Chatham Hospital respectively, to project PET/CT patient origin at these facilities.
- The applicant utilizes PET/CT historical patient origin data as reported on UNC Hospital’s 2021 LRA to project PET/CT patient origin at UNC Hillsborough Campus and UNC Eastowne.
- The applicant increases the number of projected future patients based on a reasonable growth rate attributable to the addition of the proposed project.
- Projected patient origin percentages are consistent with historical patient origin percentages.

Analysis of Need

In Section C.4, pages 51-67, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

2021 SMFP Need Determination [pages 53-57]

Tables 17F-2 and 17F-3 in the 2021 SMFP show that the two mobile PET scanners owned by the applicant operated above the regulatory capacity of 2,600 procedures in 2018-2019. The applicant states that based on continued growth in utilization and expansion of services at the proposed host sites supports their need for acquiring a third mobile PET/CT scanner.

Population Growth and Aging [pages 57-58]

The applicant cites data from the NCOSBM and United States Census Quickfacts, to illustrate 2020 through 2025 projected growth rates of the statewide population (4.92%), the statewide 65+ population (16.5%) and the individual county growth rates where the mobile PET/CT scanner host sites will be located.

Cancer Incidence and Cardiovascular and Alzheimer's Disease Rates [pages 58-59]

The applicant cites data from the North Carolina Center for Health Statistics, the National Cancer Institute, the North Carolina Institute of Medicine, the Alzheimer's Association and the Centers for Disease Control and states that the elevated incidences of cancer, heart disease and Alzheimer's disease supports an increase in the future demand for PET procedures, particularly in counties without PET scanners.

Clinical Indications and Reimbursement for PET/CT [page 59]

The applicant states that advances in PET/CT imaging, the greater availability of radioisotopes and the reimbursement approval for additional types of PET/CT scans support an increased demand in PET/CT services.

Historical PET/CT Utilization [pages 59-62]

The applicant states that their provision of mobile PET service with two existing mobile PET scanners has enabled hospitals to transition from mobile PET to fixed PET, thereby allowing the applicant to serve new host sites and reallocate capacity to existing host sites. The applicant also states that they have the highest historical mobile PET utilization on a per scanner basis of any fixed or mobile provider and their two existing mobile PET scanners exceeded regulatory capacity in 2021. Based on the most recent 11-month data, the applicant projects a 9.2 percent average increase in overall utilization for the two existing mobile PET/CT scanners in 2021.

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2021 SMFP for one statewide mobile PET/CT scanner.
- The applicant provides population growth projections for the proposed service area based on data from NCOSBM showing growth among the 65+ age cohort.
- The applicant relies on growth trends and historical utilization across all host sites of its existing mobile PET/CT scanners.
- The applicant demonstrates growth in cancer incidence and cardiovascular and Alzheimer's disease rates in the proposed service area.

Projected Utilization

In Section C, page 64 and Section Q, page 139, the applicant provides projected utilization for the proposed mobile PET/CT scanner as illustrated in the following table.

Host Site	Utilization of the Proposed Mobile PET/CT Scanner		
	1st Full FY CY2023	2nd Full FY CY2024	3rd Full FY CY2025
UNC Rockingham	200	224	251
Margaret R Pardee Hospital	650	729	816
Caldwell Memorial Hospital	260	291	326
Wayne Memorial Hospital	398	446	499
Chatham Hospital	180	202	226
UNC Eastowne	240	269	301
UNC Hillsborough Campus	400	448	502
Total	2,328	2,608	2,921

In Section C, page 66 and Section Q, pages 136-137, the applicant provides historical and projected utilization for the two existing mobile PET/CT scanners owned by the applicant, as illustrated in the following table.

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Alliance PET/CT I & II Host Sites	FFY2019 10/1/19-9/30/20	FFY2020 10/1/20-9/30/21*	CY2021	CY2022	1st Full FY CY2023	2nd Full FY CY2024	3rd Full FY CY2025
Alliance I Host Sites							
Caldwell Memorial Hospital	183	211	214	232	0	0	0
Annie Penn Hospital	183	228	231	240	250	260	270
Blue Ridge UNC (2 sites)	274	325	330	343	357	371	386
Atrium Health Lincoln	272	263	267	277	288	300	312
Cleveland Regional	806	855	867	902	938	976	1015
Haywood Regional	188	192	195	202	211	219	228
Lake Norman Regional	145	100	102	106	110	114	119
Margaret Pardee Hospital	504	528	535	581	0	0	0
Northern Regional	132	175	177	184	191	199	207
AdventHealth Hendersonville	244	242	246	255	266	276	287
Randolph Hospital	126	94	95	99	103	107	111
Rutherford Regional	174	161	164	170	177	184	192
Stanley Regional	265	298	302	314	327	340	353
Watauga Medical Center	196	193	196	204	212	220	229
Lexington Medical Center	10	99	101	105	109	113	118
Wilkes Regional	6	159	162	168	175	182	189
WestCare Health System	251	323	327	341	354	368	383
Alliance I Totals	3,959	4,447	4,509	4,723	4,067	4,229	4,399
Alliance II Host Sites							
Columbus Regional	106	130	132	137	142	148	154
Carteret General	413	423	429	446	464	483	502
Johnston Health	265	291	295	307	319	332	346
UNC Lenoir	196	201	204	212	220	229	238
Maria Parham	124	151	153	159	165	172	179
Onslow Memorial	338	324	329	342	355	370	384
Sentara Albemarle	393	415	420	437	455	473	492
Scotland Memorial	168	172	175	182	189	197	204
Southeast Regional	332	297	301	Obtained Fixed PET			
Outer Banks Hospital	130	152	154	160	166	173	180
Vidant Chowan	82	98	100	104	108	112	116
Wayne Memorial Hospital	284	323	327	355	369 [0]	384 [0]	399 [0]
Wilson Medical Center	431	439	445	462	481	500	520
Vidant Duplin	37	63	64	67	69	72	75
Alliance II Totals	3,299	3,478	3,527	3,668	3,504	3,644	3,790
Combined Alliance Totals	7,258	7,925	8,036	8,391	7,571 [7,202]	7,873 [7,489]	8,188 [7,789]

*Annualized based on 11 months actual utilization

Note: Information in brackets represents data corrections noted in written comments received from NHFMC and subsequent calculations made by the Project Analyst.

In Section Q, pages 132-140, the applicant provides the assumptions and methodology used to project utilization as summarized below.

- Beginning in January 2023, the applicant assumes three existing mobile PET/CT scanner host sites, Margaret R. Pardee Memorial Hospital, Caldwell Memorial Hospital and Wayne Memorial Hospital will shift from using an existing mobile PET/CT scanner to using the proposed mobile PET/CT scanner.
- In calendar year 2022, the applicant assumes a 10% annual growth rate for Margaret R. Pardee Memorial Hospital, Caldwell Memorial Hospital and Wayne Memorial Hospital.
- In the Fall of 2021 when Southeastern Regional Medical Center discontinues its mobile PET/CT service with Alliance due to its fixed PET scanner becoming operational, the applicant assumes the existing Alliance mobile PET scanners will accommodate the 2022 added capacity at Margaret R. Pardee Memorial Hospital, Caldwell Memorial Hospital and Wayne Memorial Hospital.
- In 2021, the applicant shifts from a historical annual reporting period of October 1 through September 30 to January 1 through December 31 for future projections and assumes a 1.4% growth factor.
- In project years 1-3 (CY 2023-CY 2025), the applicant assumes utilization at the current Alliance PET/CT scanner sites will increase 4% annually.
- In project years 1-3 (CY 2023-CY 2025), the applicant assumes utilization at the new proposed PET/CT scanner host sites will increase 12% annually and provides the following table regarding schedules and weekly volumes.

Host Sites for the Proposed Alliance Mobile PET/CT	Schedule Days/Week			Projected PET/CT Procedures per Week		
	Project Year 1	Project Year 2	Project Year 3	Project Year 1	Project Year 2	Project Year 3
UNC Rockingham	0.50	0.50	0.75	3.8	4.3	4.8
Margaret R Pardee Hospital	1.00	1.00	1.25	12.5	14.0	15.7
Caldwell Memorial Hospital	0.50	0.75	0.75	5.0	5.6	6.3
Wayne Memorial Hospital	0.75	1.00	1.00	7.7	8.6	9.6
Chatham Hospital	0.50	0.50	0.50	3.5	3.9	4.3
UNC Eastowne	1.00	1.00	1.00	4.6	5.2	5.8
UNC Hillsborough Campus	0.50	0.50	0.50	7.7	8.6	9.6
Totals	4.75	5.25	5.75	44.8	50.1	56.2

Source: Section Q, page 139

- The applicant assumes a full day equals 10 to 12 hours of PET service and half days equal five to six hours of PET service.

Comments submitted by NHFMC question the projected utilization by host site and the growth rates calculated by Alliance for its existing mobile PET scanners. NHFMC provides historical utilization data from recent SMFPs and cites underutilization of scanners within close proximity of the proposed sites. In its response to comments, Alliance refers to the

demographic and disease statistics as well as utilization growth rates for their existing and proposed PET/CT scanners cited in the application as adequate support. The applicant provides its assumptions for its growth rates by host site in Section Q, pages 138-140.

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

- The 2021 SMFP identifies a need for an additional mobile PET scanner.
- The applicant reasonably projects an increase in utilization of the two existing Alliance mobile PET scanners based on historical increases in utilization, aging of the population, disease incidence rates, physician recruitment and improved scheduling.
- The applicant reasonably projects utilization for the proposed mobile PET/CT scanner based on historical data at existing sites, expanded patient access at new sites, population growth and disease incidence rates and physician recruitment.
- The applicant relies on historical annual utilization and calculated CAGRs of their existing mobile PET/CT scanners to project future utilization.
- Continued demand for PET/CT services is supported by projected population growth and disease incidence rates particularly in the 65+ cohort.
- The 2021 and 2022 SMFPs show that Alliance's two existing mobile PET/CT scanners exceeded performance standards for 2018-2020. For the period 2018-2019 (2021 SMFP) Alliance I had a utilization capacity of 143% and Alliance II had a utilization capacity of 153%. For the period 2019-2020 (2022 SMFP) Alliance I had a utilization capacity of 152% and Alliance II had a utilization capacity of 127%.
- Based on the SMFP mobile PET/CT capacity threshold (2,600) and the current annualized utilization of 7,924 procedures for Alliance mobile PET/CT scanners, the applicant demonstrates a need for up to three mobile PET/CT scanners ($7,924 / 2,600 = 3.05$).
- The applicant adequately demonstrates that Alliance's two existing mobile PET/CT scanners and the proposed mobile PET/CT scanner are reasonably expected to perform more than 2,080 scans in the third year of operation following completion of the proposed project, as required by 10A NCAC 14C .3703.

Access to Medically Underserved Groups

In Section C.6, page 73, the applicant states:

"Alliance is committed to promote equitable access through its non-discrimination and charity care policies also included in Exhibit B.2.b.

.....

This proposal promotes improved access to care in rural counties by establishing new PET host sites at UNC Rockingham and Chatham Hospital.

.....

The proposed project will improve access for patients by providing weekly PET service and expanding hours of PET/CT service at the existing and new host sites. This will

decrease the need for patients to leave their home counties to obtain PET procedures, especially in rural counties (Caldwell, Chatham, Henderson, Rockingham and Wayne Counties), where between 36 percent and 100 percent of patients have historically traveled from their home counties to obtain PET procedures. The lack of transportation for low income and medically underserved patients in these rural counties is a barrier to access for diagnostic services including PET procedures.

....

The proposed project will also promote equitable access by expanding the availability of mobile PET/CT services to hospitals in rural counties where the overall percentages of Medicare, Medicaid and low-income persons are higher as compared to the urban counties.”

The applicant provides the estimated percentage for each medically underserved group it proposes to serve during the third full fiscal year, as shown in the following table.

Medically Underserved Groups	3rd FY % of Total Patients
Low income persons	23.2%
Racial and ethnic minorities	Alliance does not track
Women	56.5%
Persons with Disabilities	Alliance does not track
Persons 65 and older	46.9%
Medicare beneficiaries	55.8%
Medicaid recipients	9.2%

Section C, page 75

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will

be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA-Both Applications

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

C
Alliance

NC
NHFMC

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

In Section E.2, pages 84-85, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the status quo – The applicant states that this alternative fails to address the current and growing demand for mobile PET services.

Convert the existing fixed PET/CT scanner to a mobile unit – The applicant states this is not a feasible alternative because the existing fixed PET/CT scanner is highly utilized, and this would not address the need for additional PET services across the state.

Add a second fixed PET/CT scanner at NHRMC – The applicant states that it submitted an application for a second fixed PET/CT scanner at New Hanover Regional Medical Center (NHRMC). However, due to geographic constraints, this alternative will not serve to alleviate

the need at NHFMC, and the host sites proposed in this application and is not an interchangeable alternative.

On page 85, the applicant states that this proposal is the most effective alternative because the proposed project will respond to the high utilization and increased demand of their existing fixed and mobile PET/CT scanners while increasing geographic access to care.

However, the applicant does not adequately demonstrate the alternative proposed in this application is the most effective alternative to meet the identified need for the following reasons:

- The applicant explains why it believes the proposed project is the most effective alternative; however, the applicant does not adequately support the claims it makes because its projected utilization is not based on reasonable and adequately supported assumptions.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

In Section E.2, pages 88-89, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain Status Quo-The applicant states that maintaining the status quo would limit patient access and not address the need for additional PET/CT scan capacity.

Developing a mobile PET/CT scanner that serves a minimal number of high-volume host sites–The applicant states this alternative would limit geographic accessibility and not adequately address statewide access to include rural counties.

On pages 88-89, the applicant states that this proposal is the most effective alternative because:

- The proposed project will improve patient access while responding to statewide utilization and capacity constraints.
- The proposed project will offer a broader scope of PET/CT scans.
- The proposed project will provide greater access for low-income patients residing in rural counties.
- The proposed project will enable compressed coordination of diagnostic and clinical services between the host sites and UNC Health.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The proposed mobile PET/CT scanner will address statewide issues of high utilization and capacity constraints.
- The proposed mobile PET/CT scanner will offer a broader range of PET/CT scans and improved access.
- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

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

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

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

**C
Alliance**

**NC
NHFMC**

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

Capital and Working Capital Costs

In Form F.1a, Section Q, the applicant projects the total capital cost of the project, as shown in the table below.

NHFMC Capital Costs	
Site Costs	NA
Construction / Renovation Costs	NA
Medical Equipment	\$2,668,128
Miscellaneous Costs	\$355,000
Total	\$3,023,128

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit F-2.2, the applicant provides documentation to support prices for all the items associated with the delivery and installation of the proposed equipment and these costs are included in the projected capital cost.
- The applicant bases miscellaneous costs on its experience developing other institutional services in the state.
- In Section F, page 89, the applicant states that there will be no start-up or initial operating costs associated with this project.

Availability of Funds

In Section F.2, page 86, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

TYPE	NHFMC	TOTAL
Loans	\$0	\$0
Accumulated reserves or OE *	\$3,023,128	\$3,023,128
Bonds	\$0	\$0
Other (Funding from parent company)	\$0	\$0
Total Financing	\$3,023,128	\$3,023,128

*OE = Owner's Equity

In Exhibit F-2.1, the applicant provides a letter dated October 7, 2021, from the Senior Vice President of Operational Finance and Revenue Cycle for Novant Health, Inc. documenting its intention to provide intercompany funding to finance the proposed project. Novant Health, Inc. is the ultimate parent company of the applicant. Exhibit F-2.3, contains the Consolidated

Financial Statements for Novant Health, Inc. for the years ending December 31, 2020, and 2019.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F-2.1 contains a letter from the Senior Vice President of Operational Finance and Revenue Cycle for Novant Health, Inc. documenting that Novant Health, Inc. intends to fund the total projected cost of the project through accumulated reserves.
- Exhibit F-2.3 contains a copy of Novant Health, Inc.'s consolidated balance sheet as of December 31, 2020, showing cash and cash equivalents in excess of \$700 million and over \$4.0 billion in assets to fund the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in all three full fiscal years following completion of the project, as shown in the table below.

	NHFMC		
	1 ST FFY CY 2023	2 ND FFY CY 2024	3 RD FFY CY 2025
Total PET Scans for 2 Mobile PET/CT Units	3,715	4,123	4,351
Total Gross Revenues (Charges)	\$4,227,099	\$4,690,373	\$4,950,377
Total Net Revenue	\$4,227,099	\$4,690,373	\$4,950,377
Average Net Revenue per PET scan	\$1,138	\$1,138	\$1,138
Total Operating Expenses (Costs)	\$3,553,376	\$3,861,271	\$4,099,919
Average Operating Expense per PET scan	\$956	\$937	\$942
Net Income	\$673,723	\$829,102	\$850,458

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable because the projected utilization is not based on reasonable and adequately supported assumptions; and, financial feasibility, including costs and charges are impacted by utilization. See the discussion regarding projected utilization found in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

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

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

Capital and Working Capital Costs

In Form F.1a, Section Q, the applicant projects the total capital cost of the project, as shown in the table below.

Alliance Capital Costs	
Site Costs	NA
Construction / Renovation Costs	NA
Medical Equipment	\$1,859,191
Miscellaneous Costs (sales tax)	\$139,439
Total	\$1,998,630

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides documentation of equipment costs in Exhibit C.1.
- The applicant bases non-medical miscellaneous costs on its experience and review of vendor quotes.

In Section F.3, pages 91-92, the applicant projects that start-up costs will be \$12,000 and initial operating expenses will be \$50,000 for a total working capital of \$62,000. On page 92 and in Section Q, page 141, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant identifies the initial operating period needed before revenues will exceed expenses.
- The applicant identifies the costs included in the estimated start-up costs and bases its projections on its experience operating other mobile PET/CT scanners.

Availability of Funds

In Section F.2, page 89, the applicant states that the capital cost will be funded by the applicant as shown in the table below.

SOURCES OF CAPITAL COST FINANCING	
TYPE	AMOUNT
Loans	\$0
Accumulated reserves or OE *	\$1,998,630
Bonds	\$0
Other (Line of credit)	\$0
Total Financing	\$1,998,630

*OE = Owner's Equity

In Section F.3, page 92, the applicant states that the working capital needs of the project will be funded as shown in the table below.

SOURCES OF FINANCING FOR WORKING CAPITAL	AMOUNT
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or OE	\$62,000
Lines of credit	\$0
Bonds	\$0
Total	\$62,000

In Exhibit F.3, the applicant provides a letter dated October 14, 2021, from the Chief Financial Officer of Akumin, Inc., documenting its intention to provide intercompany funding to finance the capital and working capital costs of the proposed project with accumulated reserves. Akumin, Inc. is the ultimate parent company of the applicant. Exhibit F.3 also contains a balance statement for Akumin, Inc. from Donnelley Financial indicating the applicant had \$122.7 million in cash and cash equivalents as of March 31, 2021.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides a letter from the Chief Financial Officer of Akumin, Inc. documenting that Akumin, Inc. intends to fund the total projected capital and working capital needs of the project with accumulated reserves.
- The applicant provides a balance statement from Akumin, Inc. documenting cash reserves in excess of the amount of the proposed capital and working capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in all three full fiscal years following completion of the project, as shown in the table below.

ALLIANCE

	1ST FFY CY 2023	2ND FFY CY 2024	3RD FFY CY 2025
Total PET Scans	2,328	2,608	2,921
Total Gross Revenues (Charges)	\$2,188,320	\$2,451,520	\$2,745,740
Total Net Revenue	\$2,166,437	\$2,427,005	\$2,718,283
Average Net Revenue per PET scan	\$931	\$931	\$931
Total Operating Expenses (Costs)	\$1,528,856	\$1,746,502	\$1,874,505
Average Operating Expense per PET scan	\$657	\$670	\$642
Net Income	\$637,581	\$680,503	\$843,777 [\$843,778]

[] denotes Project Analyst calculations

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant bases its revenues and operating expense projections on annual procedure volumes, average charge per procedure and other revenue attributable to specialty radiopharmaceuticals.
- Procedure charges are based on Alliance's historical experience of providing mobile PET scans in other states and current agreements in place with existing host sites.
- The applicant accounts for projected operating expenses, such as salaries, equipment maintenance and administrative support, consistent with projections elsewhere in the application and allows for 3% annual inflation rate.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC - NHFMC
C - Alliance

On page 367, the 2021 SMFP defines the service area for a fixed PET scanner as, “*statewide*”. Thus, the service area for this proposal is statewide.

The first table below identifies the existing mobile PET scanners as reported in Table 17F-2, on page 370 of the 2021 SMFP. The second table identifies the existing mobile PET scanners as reported in Table 17F-2, page 368 of the 2022 SMFP.

Table 17F-2 2021 SMFP*

Mobile Provider	Procedures	Utilization Rate	
		Year 2018-2019 Procedures, 2,600 as Capacity	
Alliance Imaging I	3,716		143%
Alliance Imaging II	3,975		153%
Novant Health Forsyth Medical Center (NHFMC)	2,068		80%
Total	9,759		

*2018 Need determination for 1 mobile scanner

Table 17F-2 2022 SMFP

Mobile Provider	Procedures	Utilization Rate	
		Year 2019-2020 Procedures, 2600 as Capacity	
Alliance Imaging I	3,959		152%
Alliance Imaging II	3,299		127%
Insight Health Corp.	0		0%
Novant Health Forsyth Medical Center (NHFMC)	1,984		76%
Total	9,242		

The following table identifies the host sites for the existing mobile PET/CT scanners and the number of procedures for each site as reported in Table 17F-3, page 368 of the 2022 SMFP.

Mobile Site	Provider	Number of Sites	County	Procedures
				2019-2020
Caldwell Memorial Hospital	Alliance I	1	Caldwell	183
Annie Penn Hospital	Alliance I	1	Rockingham	183
Carolinas HealthCare System Blue Ridge	Alliance I	2	Burke	274
Atrium Health Lincoln	Alliance I	1	Lincoln	272
Cleveland Regional Medical Center	Alliance I	1	Cleveland	806
Columbus Regional Healthcare System	Alliance II	1	Columbus	106
Carteret General Hospital	Alliance II	1	Carteret	413
Haywood Regional Medical Center	Alliance I	1	Haywood	188
Johnston Health	Alliance II	1	Johnston	265
Lake Norman Regional Medical Center	Alliance I	1	Iredell	145
UNC Lenoir Healthcare	Alliance II	1	Lenoir	196
Margaret R. Pardee Memorial Hospital	Alliance I	1	Henderson	504
Maria Parham Medical Center	Alliance II	1	Granville	124
Northern Regional Hospital	Alliance I	1	Surry	132
Novant Health Huntersville Medical Center	NHFMC	1	Mecklenburg	634
Novant Health Kernersville Medical Center	NHFMC	1	Forsyth	361
Novant Health Matthews Medical Center	NHFMC	1	Mecklenburg	387
Novant Health Rowan Medical Center-Julian Road	NHFMC	1	Rowan	348
Novant Health Thomasville Medical Center	NHFMC	1	Davidson	64
Novant Health Mint Hill Medical Center	NHFMC	1	Mecklenburg	190
Onslow Memorial Hospital	Alliance II	1	Onslow	338
AdventHealth Hendersonville	Alliance I	1	Henderson	244
Randolph Hospital	Alliance I	1	Randolph	126
Rutherford Regional Medical Center	Alliance I	1	Rutherford	174
Sentara Albemarle Medical Center	Alliance II	1	Pasquotank	393
Scotland Memorial Hospital	Alliance II	1	Scotland	168
Stanley Regional Medical Center	Alliance I	1	Stanley	265
Southeastern Regional Medical Center	Alliance II	1	Robeson	332
The Outer Banks Hospital	Alliance II	1	Dare	130
Vidant Chowan Hospital	Alliance II	1	Chowan	82
Watauga Medical Center	Alliance I	1	Watauga	196
Wayne Memorial Hospital	Alliance II	1	Wayne	284
Wilson Medical Center	Alliance II	1	Wilson	431
Lexington Medical Center	Alliance I	1	Davidson	10
Wilkes Regional Medical Center	Alliance I	1	Wilkes	6
WestCare Health System	Alliance I	1	Jackson	251
Vidant Duplin Hospital	Alliance II	1	Duplin	37
Total		38		9,242

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host pursuant to the need determination in the 2021 SMFP.

In Section G, pages 94-95, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved mobile PET scanner services. The applicant states:

"NHFMC proposes to acquire a second mobile PET/CT unit to meet the growing demand for PET/CT services in the service area and to increase access to PET/CT services throughout HSA II and III as well as the contiguous counties.

.....

The ability to improve accessibility for patients served by Novant Health will not result in any unnecessary duplication of PET/CT services in the service area. The existing sites to be served require additional capacity and the planned host sites currently do not offer PET/CT services."

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- Because the applicant does not demonstrate the need for the proposed project, it cannot demonstrate that the proposed mobile PET/CT scanner is needed in addition to the existing and approved mobile PET/CT scanners in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written comments
- Responses to comments

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

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

In Section G, page 101, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved mobile PET scanner services. The applicant states:

“As seen in Table 17F-2 and 17F-3, the high utilization of the Alliance mobile PET/CT scanners supports the need for additional capacity. Both of the Alliance scanners far exceed the regulatory threshold capacity.

....

The need determination for a mobile PET scanner in the 2021 State Medical Facilities Plan resulted from the approval of a petition for an adjusted need determination that was submitted in the summer of 2020. Even with the pending implementation of the CON-approved InSight unit, the Agency and SHCC confirmed that additional mobile PET capacity will be needed.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2021 SMFP for the proposed mobile PET scanner.
- The current and historical utilization of mobile PET procedures provided by the applicant warrants the need for access to additional PET services.
- The applicant adequately demonstrates that the proposed mobile PET scanner is needed in addition to the existing mobile PET scanners.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written comments
- Responses to comments

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

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

C – Both Applications

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

In Section Q, Form H the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

NHFMC Current and Projected Staffing

Position	Current and Projected FTE Positions			
	Current FTE as of 6/30/21	1st Full FY (CY 2023)	2nd Full FY (CY 2024)	3rd Full FY (CY 2025)
Nuclear Medicine Technologist	4.8	9.6	9.6	9.6
Director of Radiology	0.1	0.1	0.1	0.1
Manager of Radiology	0.1	0.1	0.1	0.1
Radiology Safety Officer	0.1	0.1	0.1	0.1
Tractor/Cab Driver	1.2	2.4	2.4	2.4
Total	6.3	12.3	12.3	12.3

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 96-98, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant has access to Novant Health's existing corporate and regional human resources personnel for purposes of recruiting staff.
- Novant Health's existing corporate employee education department offers classes such as computer skills, Basic and Advanced Cardiac Life Support, clinical orientation and other continuing education programs.

Conclusion

The Agency reviewed the:

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

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

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

In Section Q, Form H the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

Alliance Projected Staffing

Position	Projected FTE Positions		
	1st Full FY (CY 2023)	2nd Full FY (CY 2024)	3rd Full FY (CY 2025)
Operations Manager	0.20	0.20	0.20
PET/CT Technologist Senior	1.00	1.00	1.00
PET/CT Technologist	1.00	1.10	1.10
PET/CT Assistant	0.80	1.00	1.00
Truck Driver	1.00	1.00	1.00
Total	4.00	4.30	4.30

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 102-103, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant has existing management and operations staff to support and the recruitment of additional staff for the proposed service.
- The applicant provides documentation in Exhibit H.3 of existing staff training programs for staff involved in providing the proposed services.

Conclusion

The Agency reviewed the:

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

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

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

C – Both Applications

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

Ancillary and Support Services

In Section I, page 99 the applicant identifies the necessary ancillary and support services for the proposed services. On pages 99-100, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the existing providers of existing ancillary and support services and states the same providers will be available for the proposed mobile PET services.
- In Exhibit I-1.1, the applicant provides supporting documentation that the existing ancillary and support services will be expanded to meet the needs of the proposed additional mobile PET services.

Coordination

In Section I, page 100 the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently provides mobile PET services in the Greater Winston-Salem and Charlotte markets and has established relationships with local healthcare and social services providers, which will be in place in the proposed program as well.
- The applicant demonstrates physician support for the project in Exhibit C-4.1.

Conclusion

The Agency reviewed the:

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

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

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

Ancillary and Support Services

In Section I, pages 104-106 the applicant identifies the necessary ancillary and support services for the proposed service and explains how each ancillary and support service is or will be made available. The applicant provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant lists existing ancillary and support services and states these services will be available for the proposed PET services through existing services provided by the applicant and by the hospital host sites.
- The applicant documents the availability of radiopharmaceutical services for the proposed project in Exhibit I.1.

Coordination

In Section I, pages 106-107 the applicant states it is an existing mobile PET/CT service provider with existing relationships with multiple hospital host sites throughout the state. The applicant provides supporting documentation in Exhibits C.4 and I.1. of its existing and proposed relationships with local health care providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently provides mobile PET/CT services throughout the state and has established relationships with local healthcare, which will be in place for the proposed PET services.
- The applicant demonstrates physician support for the project and the availability of radiologists to interpret the PET scans in Exhibit C.4.
- The applicant provides letters from community healthcare providers expressing support for the proposed project in Exhibits C.4 and I.1.

Conclusion

The Agency reviewed the:

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

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

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

NA-Both Applications

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA-Both Applications

None of the applicants are an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.

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

NA-Both Applications

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

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

C-Both Applications

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

In Section L, page 106, the applicant provides the historical payor mix during CY 2020 for its existing fixed PET/CT services, as shown in the table below.

NHFMC Historical Payor Mix CY 2020	
Payor Category	PET Services as a % of Total
Self-Pay	2.0%
Charity Care	Included in Self-Pay
Medicare*	68.3%
Medicaid*	3.9%
Insurance*	24.6%
Workers Compensation	Included in Other
TRICARE	0.3%
Other (specify)	0.7%
Total	100.0%

*Includes managed care plans

In Section L, page 107, the applicant provides the following comparison:

NHFMC Fixed PET/CT Services

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY, CY2020	Percentage of the Population of the Service Area
Female	53.58%	51.70%
Male	46.42%	48.30%
Unknown	0.00%	0.00%
64 and Younger	37.79%	85.10%
65 and Older	62.21%	14.90%
American Indian	0.04%	0.50%
Asian	0.17%	4.40%
Black or African-American	12.94%	24.60%
Native Hawaiian or Pacific Islander	0.13%	0.10%
White or Caucasian	84.94%	61.70%
Other Race	1.60%	8.80%
Declined / Unavailable	0.17%	0.00%

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

In Section L, page 115, the applicant states, “*As a mobile PET/CT provider, Alliance does not have a facility or campus. Alliance does not bill patients or third-party payors for the mobile PET service. The host sites are billed by Alliance for the mobile PET service.*”

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

Alliance Healthcare Services Mobile PET/CT Scanners

	Percentage of Total Patients Served during the Last Full FY, CY2020	Percentage of the Population of the Service Area
Female	56.5%	50.8%
Male	43.5%	49.2%
Unknown	0.0%	0.0%
64 and Younger	74.0%	63.5%
65 and Older	26.0%	16.5%
American Indian	*	1.3%
Asian	*	5.9%
Black or African-American	*	13.4%
Native Hawaiian or Pacific Islander	*	0.2%
White or Caucasian	*	76.3%
Other Race	*	2.9%
Declined / Unavailable	*	0.0%

*Information not collected by applicant

The Agency reviewed the:

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

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

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

C -Both Applications

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMIC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 108, the applicant states it has no such obligation to provide uncompensated care. In regard to community service or access by minorities and persons with disabilities, on page 108 the applicant states that all NH facilities in the state comply with the community service obligation and there is no denial, restriction, or limitation of access to minorities or handicapped persons.

In Section L, page 109, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

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

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

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 116, the applicant states it has no such obligation to provide uncompensated care.

In Section L, page 116, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

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

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

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

C -Both Applications

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

In Section L, page 109, the applicant projects the following payor mix for fixed PET/CT services during the third full fiscal year following completion of the project, as shown in the table below:

NHFMC	
Fixed PET CT Services Payor Mix, CY 2025	
PAYOR SOURCE	% OF TOTAL
Self-Pay	2.0%
Charity Care	Included in Self-Pay
Medicare*	68.3%
Medicaid*	3.9%
Insurance*	24.6%
Workers Compensation	Included in Other
TRICARE	0.3%
Other (Includes Workers Comp)	0.7%
Total	100.0%

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that for NHFMC fixed PET/CT services, 2.0% of total services will be provided to self-pay and charity care patients, 68.3% to Medicare patients and 3.9% to Medicaid patients.

On page 109, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant does not bill patients for the mobile PET service. The host sites are billed a fixed fee for each mobile PET scan.
- The applicant bases payor mix projections on the historical payor mix percentages of the applicant's fixed PET/CT scanner and holds them constant.

The Agency reviewed the:

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

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

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

In Section L, pages 118-119, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below:

Payor Category	UNC Rockingham		Margaret Pardee		Caldwell Memorial	
	%	# of patients	%	# of patients	%	# of patients
Self-Pay	11.1%	28	0.6%	5	2.2%	7
Charity Care*	0.0%	0	2.4%	20	3.0%	10
Medicare	44.5%	112	73.1%	597	58.3%	190
Medicaid	15.9%	40	6.0%	49	11.1%	36
Insurance	26.3%	66	16.4%	134	23.5%	77
Other**	2.2%	6	1.6%	13	1.8%	6
Total	100.0%	251	100.0%	816	100.0%	326

*UNC Hospitals payor mix does not include Charity Care as a payor source for patients

**Includes Workers Comp, TRICARE, Department of Corrections and other payors

Payor Category	Wayne UNC		Chatham Hospital		UNC Eastowne		UNC Hillsborough	
	%	# of patients	%	# of patients	%	# of patients	%	# of patients
Self-Pay	4.8%	24	8.9%	20	6.5%	20	6.5%	33
Charity Care*	0.0%	0	0.0%	0	0.0%	0	0.0%	0
Medicare	45.1%	225	49.1%	111	49.3%	148	49.3%	247
Medicaid	11.1%	56	10.4%	23	8.1%	24	8.1%	41
Insurance	29.9%	149	30.0%	68	30.9%	93	30.9%	155
Other**	9.1%	45	1.7%	4	5.1%	15	5.1%	26
Total	100.0%	499	100.0 %	226	100.0%	301	100.0%	502

*UNC Hospitals payor mix does not include Charity Care as a payor source for patients

**Includes Workers Comp, TRICARE, Department of Corrections and other payors

As shown in the tables above, during the third full fiscal year of operation, the applicant projects that 4.7% of total services will be provided to self-pay patients, 55.8% to Medicare patients and 9.2% to Medicaid patients.

On pages 117-119, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant does not bill patients or third-party payors for the mobile PET service. The host sites are billed by the applicant for the mobile PET service.
- The applicant projects payor mix based on the hospital's 2021 License Renewal Application (LRA) data for outpatient visits.

The Agency reviewed the:

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

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

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

C -Both Applications

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

In Section L, page 113, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

In Section L, page 120, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

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

C – Both Applications

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

In Section M, page 114, the applicant describes the extent to which health professional training programs in the area will have access to the equipment for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant states it maintains clinical education agreements with numerous health education programs in the area.
- The applicant states they will continue to work collaboratively with health professional training programs to establish or expand clinical training programs with the proposed additional mobile PET/CT scanner.

Conclusion

The Agency reviewed the:

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

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

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

In Section M, page 122, the applicant describes the extent to which health professional training programs in the area will have access to the equipment for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on documentation provided in Exhibit M.1. showing their willingness to establish clinical training agreements with nuclear medicine programs at Caldwell Community College and Technical Institute and UNC Hospitals.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Responses to comments

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC - NHFMC
C – Alliance

On page 367, the 2021 SMFP defines the service area for a fixed PET scanner as, “*statewide*”. Thus, the service area for this proposal is statewide.

The first table below identifies the existing mobile PET scanners as reported in Table 17F-2, on page 370 of the 2021 SMFP. The second table identifies the existing mobile PET scanners as reported in Table 17F-2, page 368 of the 2022 SMFP.

Table 17F-2 2021 SMFP*

Mobile PET Provider	Procedures	Utilization Rate	
		Year 2018-2019 Procedures, 2,600 as Capacity	
Alliance Imaging I	3,716		143%
Alliance Imaging II	3,975		153%
Novant Health Forsyth Medical Center (NHFMC)	2,068		80%
Total	9,759		

*Need determination identified for 1 mobile PET scanner

Table 17F-2 2022 SMFP

Mobile PET Provider	Procedures	Utilization Rate
		Year 2019-2020 Procedures, 2600 as Capacity
Alliance Imaging I	3,959	152%
Alliance Imaging II	3,299	127%
Insight Health Corp.	0	0%
Novant Health Forsyth Medical Center (NHFMC)	1,984	76%
Total	9,242	

The following table identifies the host sites for the existing mobile PET/CT scanners and the number of procedures for each site as reported in Table 17F-3, page 368 of the 2022 SMFP.

2021 Statewide Mobile PET Scanner Review

Project ID #'s: G-12142-21 & G-12156-21

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Mobile Site	Provider	Number of Sites	County	Procedures
				2019-2020
Caldwell Memorial Hospital	Alliance I	1	Caldwell	183
Annie Penn Hospital	Alliance I	1	Rockingham	183
Carolinas HealthCare System Blue Ridge	Alliance I	2	Burke	274
Atrium Health Lincoln	Alliance I	1	Lincoln	272
Cleveland Regional Medical Center	Alliance I	1	Cleveland	806
Columbus Regional Healthcare System	Alliance II	1	Columbus	106
Carteret General Hospital	Alliance II	1	Carteret	413
Haywood Regional Medical Center	Alliance I	1	Haywood	188
Johnston Health	Alliance II	1	Johnston	265
Lake Norman Regional Medical Center	Alliance I	1	Iredell	145
UNC Lenoir Healthcare	Alliance II	1	Lenoir	196
Margaret R. Pardee Memorial Hospital	Alliance I	1	Henderson	504
Maria Parham Medical Center	Alliance II	1	Granville	124
Northern Regional Hospital	Alliance I	1	Surry	132
Novant Health Huntersville Medical Center	NHFMC	1	Mecklenburg	634
Novant Health Kernersville Medical Center	NHFMC	1	Forsyth	361
Novant Health Matthews Medical Center	NHFMC	1	Mecklenburg	387
Novant Health Rowan Medical Center-Julian Road	NHFMC	1	Rowan	348
Novant Health Thomasville Medical Center	NHFMC	1	Davidson	64
Novant Health Mint Hill Medical Center	NHFMC	1	Mecklenburg	190
Onslow Memorial Hospital	Alliance II	1	Onslow	338
AdventHealth Hendersonville	Alliance I	1	Henderson	244
Randolph Hospital	Alliance I	1	Randolph	126
Rutherford Regional Medical Center	Alliance I	1	Rutherford	174
Sentara Albemarle Medical Center	Alliance II	1	Pasquotank	393
Scotland Memorial Hospital	Alliance II	1	Scotland	168
Stanley Regional Medical Center	Alliance I	1	Stanley	265
Southeastern Regional Medical Center	Alliance II	1	Robeson	332
The Outer Banks Hospital	Alliance II	1	Dare	130
Vidant Chowan Hospital	Alliance II	1	Chowan	82
Watauga Medical Center	Alliance I	1	Watauga	196
Wayne Memorial Hospital	Alliance II	1	Wayne	284
Wilson Medical Center	Alliance II	1	Wilson	431
Lexington Medical Center	Alliance I	1	Davidson	10
Wilkes Regional Medical Center	Alliance I	1	Wilkes	6
WestCare Health System	Alliance I	1	Jackson	251
Vidant Duplin Hospital	Alliance II	1	Duplin	37
Total		38		9,242

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, pages 116-117, the applicant states:

"The proposed project will promote cost effective approaches, expand health care services to the medically underserved, and encourage quality health care services by improving access to mobile PET/CT scanner diagnostic imaging to the patient population served by the proposed expanded mobile PET/CT program and existing fixed and mobile PET/CT unit at NHFMC.

.....

NHFMC brings a unique option to the local mobile PET/CT market. As a vendor and a provider, NHFMC not only delivers PET/CT services but also promotes coordinated, high quality, financially accessible care for its patients. "

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 117-118, the applicant states:

"Novant Health is delivering value and quality and outcomes through its Value-Based Care programs. This approach encourages wellness and preventative care and managing existing conditions to slow or reverse the progression of disease, all while lowering the overall cost of care.

.....

Moreover, two and planned host sites will be a lower cost alternative to their hospital counterparts, Novant Health Cancer Institute-Mount Airy and Novant Health Imaging-University, which benefits insurance plans, as well as patient out of pocket costs due to high deductibles."

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 118-119, the applicant states:

"Like all facilities within the Novant Health network, NHFMC implements its projects at the standard of quality required by Novant Health.

.....

Novant Health's service standards are meant to be easy to implement, intuitive, and connect to Novant Health's mission to improve the health of communities one person at a time. NHFMC, through the proposal in this application, [strives] to meet Novant Health's high level of quality and better meet the community health care needs."

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 119, the applicant states:

"The proposed project to add an additional mobile PET/CT unit to the existing mobile PET/CT program at NHFMC will have a positive impact on all patients in the proposed service area. Accessibility will increase on a local level and thereby reduce unnecessary travel burdens and associated costs for patients. It also opens the possibility for patients who do not have transportation options out of their respective counties to obtain critical imaging services locally.

NHFMC, like all facilities within the NH network, provides services to all persons regardless of race, sex, age, religion, creed, disability, national origin, or ability to pay.

.....

NHFMC also [conforms] to all requirements of the Americans with Disabilities Act, so that access to patients and their families are available for wheelchair patients and other patients with limited mobility."

See also Sections L, B and C of the application and any exhibits.

However, the applicant does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant does not adequately demonstrate : a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable. See the discussion regarding projected utilization found in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on all the reasons described above.

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 125, the applicant states:

“The proposed mobile PET scanner will have a positive effect on competition because it will enable the seven host sites to more effectively compete in terms of enhancing patient convenience, and expanding access to cost effective MRI [sic] service with while increasing access to advanced diagnostic imaging capabilities for patients with special needs.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 126, the applicant states:

“The proposed PET/CT will provide cost effective service because the proposed project can quickly achieve high productivity that maximizes the utilization of the equipment. The Alliance team will hold down operating costs through quality improvement and preventive maintenance to minimize equipment downtime. The staff will work diligently to optimize scheduling and throughput so that more patients can obtain procedures in a 12-hour day. The weekly schedule and the compact route for the mobile unit will be efficient to conserve fuel. Purchasing contracts for the supplies and radiopharmaceuticals will be utilized to contain costs.”

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 126, the applicant states:

“The mobile PET/CT scanner will have a positive impact on quality because Alliance will achieve and maintain compliance with licensure requirements and Joint Commission accreditation standards, as well as the Quality Improvement Program, employee training and competency evaluations and Safety Policies.”

See also Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 126-127 the applicant states:

“The proposed project will also promote access by the medically underserved groups by expanding availability of mobile PET/ CT service to hospitals in rural counties where the

overall percentages of Medicare Medicaid and low-income persons are higher as compared to the urban counties.

....

The proposed project will also expand access because it establishes new host sites, extends hours for existing host sites and the unit will be staffed and operational for up to 12 hours per day and six days per week.”

See also Sections B, L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

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

C – Both Applications

Project ID# G-12142-21/ Novant Health Forsyth Medical Center / Acquire one mobile PET/CT scanner

NHFMC proposes to acquire a second mobile PET/CT scanner to serve ten host sites pursuant to the need determination in the 2021 SMFP.

In Section Q, Form O, the applicant identifies the acute care hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 18 of this type of facility located in North Carolina.

In Section O, page 123, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in an immediate jeopardy violation that occurred in these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, three incidents related to quality of care have occurred in this facility, both of which have been resolved resulting in a return to compliance. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at these facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021 / Acquire one mobile PET/CT scanner

Alliance Healthcare Services, Inc. proposes to acquire one mobile PET/CT scanner to serve seven host sites pursuant to the need determination in the 2021 SMFP.

In Section Q, Form O, the applicant identifies the two mobile PET scanners located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 129, the applicant states that, during the 18 months immediately preceding the submittal of the application, "...Alliance Healthcare Services has maintained compliance with all licensure and accreditation standards." In Exhibit O.2, the applicant provides documentation of accreditation and licensure for radioactive materials.

After reviewing and considering information provided by the applicant and considering the quality of care provided on Alliance mobile PET scanners, the applicant has provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any

facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

**C
Alliance**

**NC
NHFMC**

The Criteria and Standards for Positron Emission Tomography Scanners, promulgated in 10A NCAC 14C .3700, are applicable to this review.

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;*

-NC- NHFMC. In Section Q, page 146 the applicant projects that the proposed mobile PET scanner will perform 2,181 procedures in the third year of operation which is greater than the 2,080 PET procedures required by the Rule. However, the applicant does adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is not conforming to this Rule.

-C- Alliance Healthcare Services, Inc. In Section C, page 64 and Section Q, pages 139 and 147, the applicant projects that the proposed PET scanner will perform 2,921 procedures in the third year of operation which is greater than 2,080 PET procedures required by the Rule. Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.

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

-C- NHFMC. In Section C pages 75 and 76, the applicant provides information regarding PET scanner utilization for all Novant affiliates (three fixed and one mobile unit) in the most recent year available as shown in the table below.

Novant Affiliates Historical PET/CT Utilization

Unit/Location	Utilization for the most recent year available
NHFMC-Fixed	2,326
NHFMC-Mobile	
NHHMC	692
NHKMC	399
NHMMC	559
NHMHMC	102
NHRMC	363
NHTMC	23
Total Mobile	2,138
NHFMC Total	4,464
NHPMC	2,031
New Hanover Regional Medical Center	3,030
Average Utilization per Unit	2,381

The average utilization for Novant Affiliate's PET/CT scanners exceeds the minimum performance standard requirement of 2,080 PET procedures per PET scanner as required by this rule.

-C- Alliance Healthcare Services, Inc. In Section C, page 79 the applicant provides the historical utilization of the Alliance I and Alliance II PET/CT scanners found in the 2022 SMFP to demonstrate that these scanners performed 3,959 and 3,299 procedures respectively in 2019-2020 and the average of these procedures exceeds the minimum performance standard requirement of 2,080 PET procedures per PET scanner as required by this rule.

- (3) *its existing and approved dedicated PET scanners shall perform average of at least 2,080 PET procedures per PET scanner during the third year following completion of the project.*

-NC- NHFMC. In Section C, pages 76-77, Section Q, pages 130-132 and Exhibit C.4.2, page 42, the applicant provides projections for its existing and approved PET/CT scanners. The Project Analyst combined all information provided by the applicant and calculated that the average projected utilization of the applicant's existing and approved scanners in the third year following completion of the project will perform an average of 2,266 procedures per scanner as shown in the table below.

Projected Utilization in the Third Project Year

Unit/Location	PY3 10/1/2025- 9/30/2026
NHPCM-fixed	2,411
NHFMC-fixed	2,124
NHFMC-mobile Charlotte Route	2,170
NHFMC-mobile W-S Route*	2,181
NH New Hanover Regional Medical Center-fixed	2,494
NH New Hanover Regional Medical Center-fixed*	2,214
Average projected utilization existing and proposed (13,594/6 = 2,266)	2,266

However, the applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is not conforming to this Rule.

-C- **Alliance Healthcare Services, Inc.** In Section C, page 80 and Section Q, pages 139 and 147, the applicant projects that the existing and approved PET/CT scanners, Alliance I and Alliance II, will provide 4,399 and 3,790 procedures respectively and the proposed scanner will provide 2,921 procedures in the third project year, which is an average of 3,703 procedures per scanner and exceeds the minimum performance standard requirement of 2,080 PET procedures per PET scanner as required by 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.

-NC- **NHFMC.** In Section Q, pages 133-149, the applicant provides the assumptions and methodology used for projections. However, the applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is not conforming to this Rule.

-C- **Alliance Healthcare Services, Inc.** In Section C, page 64 and Section Q, pages 139 and 147, the applicant provides the assumptions and methodology used for projections. The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.

COMPARATIVE ANALYSIS

Pursuant to G.S. § 131E-183(a)(1) and the 2021 SMFP, no more than one mobile PET Scanner can be approved statewide in this review. Because the two applications in this review collectively propose to develop two additional mobile PET scanners, all the applications cannot be approved for the total number of mobile PET/CT scanners proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review.

- Project ID# G-12142-21 / **Novant Health Forsyth Medical Center** / Acquire one mobile PET/CT scanner
- Project I.D. #G – 12156-21 / **Alliance Mobile PET/CT 2021** / Acquire one mobile PET/CT scanner

Conformity with Statutory and Regulatory Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

The application submitted by **Alliance** is conforming to all applicable statutory and regulatory review criteria. However, the application submitted by **NHFMC** is not conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, the application submitted by **Alliance** is a more effective alternative.

Scope of Services

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.

Facility	Proposed Scope of Services		
	Oncological PET	Neurologic PET	Cardiac PET
NHFMC	Yes	No	No
Alliance	Yes	Yes	Yes

On pages 56-60, **NHFMC** discusses the need for the proposed mobile PET scanner in response to increased incidence rates of cancer in HSAs II and III. **NHFMC** does not discuss or document the need for utilizing the proposed mobile PET/CT scanner for neurological or cardiac cases. On pages 52-59, **Alliance** discusses the need for the proposed mobile PET scanner to address increased rates of cancer, Alzheimer's diseases and heart disease at multiple host sites. Therefore, **Alliance** is the more effective alternative with regard to scope of services and **NHFMC** is the less effective alternative.

Historical Utilization

The following table illustrates historical utilization for NHFMC, NHPMC and **Alliance**. Generally, regarding this comparative factor, an existing provider with higher historical utilization rates is the more effective alternative based on the assumption the provider with higher utilization has a greater need for the proposed mobile PET/CT scanner in order to serve its projected patients.

Provider	2018-2019 Procedures	Utilization Rate*	2019-2020 Procedures	Utilization Rate
NHFMC Fixed	2,855	95.17%^	2,397	79.9%
NHPMC Fixed	2,151	71.70%	2,039	67.97%
NHFMC Mobile	2,068	80%	1,984	76%
Alliance I Mobile	3,716	143%	3,959	152%
Alliance II Mobile	3,975	153%	3,299	127%

Source: 2021 and 2022 SMFP Tables 17F-1 and 17F-2

*Fixed utilization rates are based on 3,000 procedures and mobile utilization rates are based on 2,600 procedures as capacity

^Calculation performed by Project Analyst ($2,855/3,000=0.9517$) given that the inventory in the 2021 SMFP was incorrect for NHFMC fixed

As shown in the table above, Alliance has consistently had utilization rates well above 100%. Whereas the fixed PET scanners and mobile scanner owned and operated by NH have had utilization rates in 80-95% range and more recently only achieved utilization rates in the range of 67-79.9%. Therefore, regarding this comparative factor, **Alliance** is the more effective alternative than the application submitted by **NHFMC**.

Geographic Accessibility (Location within the Service Area)

As of the date of this decision, there are 38 mobile PET sites serviced by scanners owned and operated by three different mobile PET/CT providers (Alliance I, Alliance II and NHFMC). The following table illustrates where in the service area the existing and approved mobile PET/CT scanners are located.

2021 Statewide Mobile PET Scanner Review

Project ID #'s: G-12142-21 & G-12156-21

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Mobile Site	Provider	Number of Sites	County	Procedures
				2019-2020
Caldwell Memorial Hospital	Alliance I	1	Caldwell	183
Annie Penn Hospital	Alliance I	1	Rockingham	183
Carolinas HealthCare System Blue Ridge	Alliance I	2	Burke	274
Atrium Health Lincoln	Alliance I	1	Lincoln	272
Cleveland Regional Medical Center	Alliance I	1	Cleveland	806
Columbus Regional Healthcare System	Alliance II	1	Columbus	106
Carteret General Hospital	Alliance II	1	Carteret	413
Haywood Regional Medical Center	Alliance I	1	Haywood	188
Johnston Health	Alliance II	1	Johnston	265
Lake Norman Regional Medical Center	Alliance I	1	Iredell	145
UNC Lenoir Healthcare	Alliance II	1	Lenoir	196
Margaret R. Pardee Memorial Hospital	Alliance I	1	Henderson	504
Maria Parham Medical Center	Alliance II	1	Granville	124
Northern Regional Hospital	Alliance I	1	Surry	132
Novant Health Huntersville Medical Center	NHFMC	1	Mecklenburg	634
Novant Health Kernersville Medical Center	NHFMC	1	Forsyth	361
Novant Health Matthews Medical Center	NHFMC	1	Mecklenburg	387
Novant Health Rowan Medical Center-Julian Road	NHFMC	1	Rowan	348
Novant Health Thomasville Medical Center	NHFMC	1	Davidson	64
Novant Health Mint Hill Medical Center	NHFMC	1	Mecklenburg	190
Onslow Memorial Hospital	Alliance II	1	Onslow	338
AdventHealth Hendersonville	Alliance I	1	Henderson	244
Randolph Hospital	Alliance I	1	Randolph	126
Rutherford Regional Medical Center	Alliance I	1	Rutherford	174
Sentara Albemarle Medical Center	Alliance II	1	Pasquotank	393
Scotland Memorial Hospital	Alliance II	1	Scotland	168
Stanley Regional Medical Center	Alliance I	1	Stanley	265
Southeastern Regional Medical Center	Alliance II	1	Robeson	332
The Outer Banks Hospital	Alliance II	1	Dare	130
Vidant Chowan Hospital	Alliance II	1	Chowan	82
Watauga Medical Center	Alliance I	1	Watauga	196
Wayne Memorial Hospital	Alliance II	1	Wayne	284
Wilson Medical Center	Alliance II	1	Wilson	431
Lexington Medical Center	Alliance I	1	Davidson	10
Wilkes Regional Medical Center	Alliance I	1	Wilkes	6
WestCare Health System	Alliance I	1	Jackson	251
Vidant Duplin Hospital	Alliance II	1	Duplin	37
Total		38		9,242

Source: 2022 SMFP Table 17F-3 page 368

The following table illustrates where in the service area each applicant proposes to provide mobile PET services. For NHFMC only the host sites to be served by the proposed mobile PET/CT scanner are included.

Host Site	New or Existing	County	Fixed PET in Same County
NHFMC Proposed Mobile PET			
NHRMC	Existing Mobile	Rowan	No
NHTMC	Existing Mobile	Davidson	No
NHKMC	Existing Mobile	Forsyth	Yes
NHFMC	Existing Fixed	Forsyth	Yes
NHCl-Mt. Airy	New	Surry	No
Alliance Proposed Mobile PET			
UNC Rockingham	New	Rockingham	No
Margaret 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

	NHFMC	Alliance
Total # of Sites	5	7
# of New Sites	1	4
# of Counties	4	6

As shown in the table above, **NHFMC** proposes to serve a total of five host sites; one site is new, three sites are currently served by an existing mobile PET/CT scanner and one site is currently being served by an existing fixed PET/CT scanner. The host sites for **NHFMC**'s proposal are located in four different counties with one county already having an existing fixed PET/CT scanner in the same county. **Alliance** proposes to serve a total of seven host sites; four sites are new, and three sites are currently being served by an existing mobile PET/CT scanner. The host sites for **Alliance**'s proposal are located in six different counties with one county already having an existing PET/CT scanner in the same county. Therefore, **Alliance** is the more effective alternative with regard to geographic accessibility and **NHFMC** is less effective.

Access by Service Area Residents

The 2021 SMFP defines the service area for mobile PET scanners as “*statewide*”. Thus, the service area for this review is statewide. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional PET scan procedures in the service area where they live.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

	# of Patients in the 3 rd Full FY	Number of PET/CT mobile Units	# of Patients from NC Counties [^]	# of NC Patients Served per PET/CT Mobile [^]	% of Patients from NC Counties [^]
NHFMC	4,351	2 (1 existing + 1 proposed)	4,068	2,034	93.50%
Alliance	2,921	1	2,833	2,833	96.99%

Source: Section C.3, page 47 of the NHFMC application & pages 44-47 of the Alliance application

[^]Calculations performed by the Project Analyst with data provided by the applicant

As shown in the table above, **Alliance** projects to serve the highest number of service area residents per PET/CT mobile unit and **Alliance** also projects to serve the highest percentage of service area residents during the third full fiscal year following project completion. Therefore, regarding projected service to residents of the service area, the application submitted by **Alliance** is a more effective alternative.

Access by Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”

For access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid patients as a percentage of total patients
- Charity care, Medicare or Medicaid patients per & (*bed, OR or type of equipment*) (*do not include for home health and hospice home care*)
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total net revenues
- Charity care, Medicare or Medicaid dollars per & (*bed, OR or type of equipment*) (*do not include for home health and hospice home care*)

Whether the Agency used all the metrics listed above in this review was determined by whether every application included in this review included data that could be compared for each metric.

Projected Charity Care, Medicaid and Medicare

Projected Charity Care

Generally, the application projecting to serve a larger number of charity care patients is the more effective alternative for this comparative factor. However, **NHFMC** states on page 110 that their payor mix is presented as “*facility-wide*” and states, “*As a vendor, NHFMC does not provide charity care. NHFMC bills the host site.*” Because **NHFMC** does not provide a method to calculate only the PET/CT scan charity care patients served and neither applicant provides dollar amounts for charity care for the proposed PET/CT scanner, the applicants cannot be compared for this metric. Therefore, the result of this analysis is inconclusive.

Projected Medicaid

Generally, the application proposing to serve a larger number of Medicaid patients is the more effective alternative for this comparative factor. However, **NHFMC** states on page 110 that their payor mix is presented as “*facility-wide*” and further states, “*As it relates to mobile PET/CT service component, there is no payor mix because no patient revenue is charged by the vendor-NHFMC Mobile PET/CT.*” Because **NHFMC** does not provide a method to calculate only the PET/CT scan Medicaid patients served and neither applicant provides dollar amounts for Medicaid care for the proposed PET/CT scanner, the applicants cannot be compared for this metric. Therefore, the result of this analysis is inconclusive.

Projected Medicare

Generally, the application proposing to serve a larger number of Medicare patients is the more effective alternative for this comparative factor. However, **NHFMC** states on page 110 that their payor mix is presented as “*facility-wide*” and further states, “*As it relates to mobile PET/CT service component, there is no payor mix because no patient revenue is charged by the vendor-NHFMC Mobile PET/CT.*” Because **NHFMC** does not provide a method to calculate only the PET/CT scan Medicare patients served and neither applicant provides dollar amounts for Medicare care for the proposed PET/CT scanner, the applicants cannot be compared for this metric. Therefore, the result of this analysis is inconclusive.

Competition (Access to a New or Alternate Provider)

The following tables illustrate the existing and approved providers located in the service area. Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer mobile PET/CT scanners than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

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Mobile Site	Provider	Number of Sites	County	Procedures
				2019-2020
Caldwell Memorial Hospital	Alliance I	1	Caldwell	183
Annie Penn Hospital	Alliance I	1	Rockingham	183
Carolinas HealthCare System Blue Ridge	Alliance I	2	Burke	274
Atrium Health Lincoln	Alliance I	1	Lincoln	272
Cleveland Regional Medical Center	Alliance I	1	Cleveland	806
Columbus Regional Healthcare System	Alliance II	1	Columbus	106
Carteret General Hospital	Alliance II	1	Carteret	413
Haywood Regional Medical Center	Alliance I	1	Haywood	188
Johnston Health	Alliance II	1	Johnston	265
Lake Norman Regional Medical Center	Alliance I	1	Iredell	145
UNC Lenoir Healthcare	Alliance II	1	Lenoir	196
Margaret R. Pardee Memorial Hospital	Alliance I	1	Henderson	504
Maria Parham Medical Center	Alliance II	1	Granville	124
Northern Regional Hospital	Alliance I	1	Surry	132
Novant Health Huntersville Medical Center	NHFMC	1	Mecklenburg	634
Novant Health Kernersville Medical Center	NHFMC	1	Forsyth	361
Novant Health Matthews Medical Center	NHFMC	1	Mecklenburg	387
Novant Health Rowan Medical Center-Julian Road	NHFMC	1	Rowan	348
Novant Health Thomasville Medical Center	NHFMC	1	Davidson	64
Novant Health Mint Hill Medical Center	NHFMC	1	Mecklenburg	190
Onslow Memorial Hospital	Alliance II	1	Onslow	338
AdventHealth Hendersonville	Alliance I	1	Henderson	244
Randolph Hospital	Alliance I	1	Randolph	126
Rutherford Regional Medical Center	Alliance I	1	Rutherford	174
Sentara Albemarle Medical Center	Alliance II	1	Pasquotank	393
Scotland Memorial Hospital	Alliance II	1	Scotland	168
Stanley Regional Medical Center	Alliance I	1	Stanley	265
Southeastern Regional Medical Center	Alliance II	1	Robeson	332
The Outer Banks Hospital	Alliance II	1	Dare	130
Vidant Chowan Hospital	Alliance II	1	Chowan	82
Watauga Medical Center	Alliance I	1	Watauga	196
Wayne Memorial Hospital	Alliance II	1	Wayne	284
Wilson Medical Center	Alliance II	1	Wilson	431
Lexington Medical Center	Alliance I	1	Davidson	10
Wilkes Regional Medical Center	Alliance I	1	Wilkes	6
WestCare Health System	Alliance I	1	Jackson	251
Vidant Duplin Hospital	Alliance II	1	Duplin	37
Total		38		9,242

Source: 2022 SMFP Table 17F-3 page 368

Statewide mobile PET Scanners

Facility	# of Fixed PET Scanners	Location
NHFMC	1	HSA II & III
Alliance	2	HSA I, II, III, IV, V, VI

NHFMC currently operates one mobile PET scanner in HSAs II and III. Alliance currently operates two mobile PET scanners in HSAs I, II, III, IV, V, and VI. Therefore, with regard to the introduction of a new provider of fixed PET services in the service area, the application submitted by **NHFMC** is a more effective alternative. However, **NHFMC**'s application is not approvable. Therefore, the application submitted by **NHFMC** cannot be an effective alternative. Thus, the application submitted by **Alliance** is the more effective alternative.

Projected Average Net Revenue per Patient Day, Surgical Case or Procedure

The following table compares projected average net revenue per procedure in the third full fiscal year following project completion for each provider. Generally, regarding this factor, the application proposing the lowest average net revenue per procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

Average Net Revenue per Procedure 3 rd Full FY			
Applicant	Total # of Procedures	Net Revenue	Average Net Revenue per Procedure
NHFMC (2 Units, 1 existing + 1 proposed)	4,351	\$4,950,377	\$1,138
Alliance	2,921	\$2,745,740	\$940

Source: Form F.2b each application

As shown in the table above, **Alliance** projects the lowest average net revenue per procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **Alliance** is a more effective alternative.

Projected Average Operating Expense per Patient Day

The following table compares projected average operating expense per procedure in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average operating expense per procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Average Operating Expense per Procedure 3 rd Full FY			
Applicant	Total # of Procedures	Operating Expenses	Average Net Expense per Procedure
NHFMC (2 Units, 1 existing + 1 proposed)	4,351	\$4,099.919	\$942
Alliance	2,921	\$1,874,505	\$642

Source: Form F.2b each application

As shown in the table above, **Alliance** projects the lowest average operating expense per patient day, surgical case or procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **Alliance** is a more effective alternative.

Summary

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	NHFMC	Alliance
Conformity with Statutory and Regulatory Review Criteria	Not approvable	More effective
Scope of Services	Not approvable	More effective
Historical Utilization	Not approvable	More effective
Geographic Accessibility (Location within the Service Area)	Not approvable	More effective
Access by Service Area Residents	Not approvable	More effective
Access by Charity Care Patients	Inconclusive	Inconclusive
Access by Medicaid Patients	Inconclusive	Inconclusive
Access by Medicare Patients	Inconclusive	Inconclusive
Competition (Access to a New or Alternate Provider)	Not approvable	More effective
Projected Average Net Revenue per Procedure	Not approvable	More effective
Projected Average Operating Expense per Procedure	Not approvable	More effective

As shown in the table above, **Alliance** was determined to be a more effective alternative for the following seven factors:

- Conformity with statutory and regulatory review criteria
- Scope of services
- Historical utilization
- Geographic accessibility (location within the service area)
- Access by service area residents
- Competition (access to a new or alternate provider)
- Projected average net revenue per procedure
- Projected average operating expense per procedure

As shown in the table above, **NHFMC** was not determined to be an effective alternative because it was not approvable. The application submitted by NHFMC was not conforming to all statutory and regulatory review criteria.

DECISION

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of mobile PET/CT scanners that can be approved by the Healthcare Planning and Certificate of Need Section. Approval of all applications submitted during this review would result in mobile PET/CT scanners in excess of the statewide need determination. However, the application submitted by **NHFMC** is not approvable and therefore cannot be considered an effective alternative. Consequently, the application submitted by **NHFMC, Project I.D. #G-12142-21**, is denied. The application submitted by **Alliance, Project I.D. #G-12156-21** is the more effective alternative proposed in this review for a statewide mobile PET/CT scanner and is therefore approved as conditioned below.

Based upon the independent review of each application and the Comparative Analysis, the following application is approved as submitted:

- **Project I.D. #G – 12156-21 / Alliance Mobile PET/CT 2021** / Acquire one mobile PET/CT scanner

And the following application is denied:

- **Project ID# G-12142-21/ Novant Health Forsyth Medical Center** / Acquire one mobile PET/CT scanner

Project I.D. #G-12156-21 is approved subject to the following conditions.

1. **Alliance Healthcare Services, Inc. (herein after “the certificate holder”) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall acquire no more than one mobile PET scanner pursuant to the need determination in the 2021 SMFP.**
3. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project’s proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
4. **Progress Reports:**
 - a. **Pursuant to G.S. § 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**

- c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on July 1, 2022. The second progress report shall be due on November 1, 2022 and so forth.
5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.