

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 27, 2024

Findings Date: March 5, 2024

Project Analyst: Ena Lightbourne

Co-Signer: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: G-12425-23
Facility: Moses Cone Hospital
FID #: 943494
County: Guilford
Applicant(s): The Moses H. Cone Memorial Hospital
The Moses H. Cone Memorial Hospital Operating Corporation
Project: Develop no more than one PET scanner at a medical office building on the main campus of Moses Cone Hospital pursuant to the need determination in the 2023 SMFP for a total of no more than one PET scanner

Project ID #: G-12432-23
Facility: Novant Health Forsyth Medical Center
FID #: 923174
County: Forsyth
Applicant(s): Forsyth Memorial Hospital, Inc.
Novant Health, Inc.
Project: Acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 SMFP for no more than two fixed PET scanners

Project ID #: G-12433-23
Facility: Piedmont Cardiovascular, P.A.
FID #: 230805
County: Guilford
Applicant(s): Piedmont Cardiovascular, P.A.
Project: Acquire no more than one fixed PET scanner pursuant to the need determination in the 2023 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
Cone Health
Novant Health

NC
Piedmont

Need Determination

The 2023 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional PET scanners in North Carolina by service area. Application of the need methodology in the 2023 SMFP identified a need for one fixed PET scanner in the Health Service Area (HSA) II service area. Three applications were received by the Healthcare Planning and Certificate of Need Section (CON Section), each proposing to acquire one fixed PET scanner, for a total of three fixed PET scanners. However, pursuant to the need determination, only one fixed PET scanner may be approved in this review.

Policies

There are two policies in the 2023 SMFP that are applicable to this review: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3 in Chapter 4 of the 2023 SMFP applies to all applications received in response to the need determination. *Policy GEN-4* in Chapter 4 of the 2023 SMFP applies to the application submitted by Forsyth Memorial Hospital, Inc. and Novant Health, Inc.

Policy GEN-3

Policy GEN-3 on page 30 of the 2023 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-4

Policy GEN-4 on page 30 of the 2023 SMFP states:

“Any person proposing a capital expenditure greater than \$4 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.”

G-12425-23 / The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation / Acquire one fixed PET scanner

The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation (hereinafter referred to as “Cone Health” or “the applicant”) propose to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area. The fixed PET scanner will be located in the Cone Health Heart and Vascular Center, an existing outpatient department on the Moses Cone Hospital (“MCH) campus in Guilford County.

Need Determination. The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA II PET scanner service area.

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

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 than the one fixed PET scanner that is determined to be needed in the service area.
- 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 services in HSA II service area;
 - The applicant adequately documents how the project will promote equitable access to PET services in the HSA II service area;
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

G-12432-23 / Forsyth Memorial Hospital, Inc. and Novant Health, Inc. / Acquire one fixed PET scanner

Forsyth Memorial Hospital, Inc. and Novant Health, Inc. (hereinafter referred to as “Novant Health” or “the applicant”) propose to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area. The fixed PET scanner will be located at Novant Health Forsyth Medical Center (NHFMC) in Forsyth County.

Need Determination. The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA II PET scanner service area.

Policy GEN-3. In Section B, pages 27-28, the applicant explains why it believes its application is conforming to Policy *GEN-3*.

Policy GEN-4. The proposed capital expenditure for this project is more than \$5 million. In Section B, page 28, the applicant explains why it believes its application is conforming to *Policy GEN-4*.

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 than the one fixed PET scanner that is determined to be needed in the service area.
- 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 services in HSA II service area;
 - The applicant adequately documents how the project will promote equitable access to PET services in the HSA II service area;
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
 - The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

Piedmont Cardiovascular, P.A. (hereinafter referred to as “Piedmont” or “the applicant”) proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area. The applicant is proposing to develop cardiac PET/CT services at Piedmont Cardiovascular, P.A., an existing diagnostic center in Guilford County.

Need Determination. The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA II PET scanner service area.

Policy GEN-3. In Exhibit 1, the applicant explains why it believes its application is conforming to Policy *GEN-3*. However, the applicant does not adequately demonstrate projected volumes that incorporate the concept of maximizing healthcare value for resources expended. The applicant does not adequately demonstrate the need to develop the project and does not adequately demonstrate that developing the project would not be an unnecessary duplication of existing and approved services. Because of these reasons, the applicant cannot demonstrate that it will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. Thus, the applicant is not consistent with *Policy GEN-3*.

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 the need to develop a fixed PET scanner or that developing one would not be an unnecessary duplication of existing and approved health services.
- Therefore, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum healthcare value for resources expended as required in *Policy GEN-3*.

- (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
 Cone Health
 Novant Health

NC
 Piedmont

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Patient Origin

On page 360, the 2023 SMFP defines the service area for a fixed dedicated PET scanner as “the HSA in which it is located (Table 17F-1).” Cone Health (Project ID #G-12425-23) proposes to locate the proposed fixed PET scanner in Guilford County, which is in HSA II. Novant Health, (Project ID #G-12432-23) and Piedmont, (Project ID #G-12433-23) propose to locate the proposed fixed PET scanner in Forsyth County, which is also in HSA II. Thus, the service area for each proposal is HSA II. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

Cone Health-Wesley Long Hospital PET Services Historical Patient Origin		
Last Full FY 10/01/2021-09/30/2022		
	# of Patients	% of Total
Guilford	1,362	67.9%
Rockingham	256	12.8%
Randolph	132	6.6%
Forsyth	43	2.1%
Alamance	26	1.3%
Other^	186	9.2%
Total	2,005	100.0%

Source: Section C, page 37

^Includes 21 other counties and other states.

Cone Health* PET Services Projected Patient Origin						
County	1st Full FY		2nd Full FY		3rd Full FY	
	10/1/25 to 09/30/26		10/1/26 to 09/30/27		10/1/27 to 09/30/28	
	FY2026		FY2027		FY2028	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Guilford	2,584	62.7%	2,956	61.6%	3,306	60.8%
Rockingham	545	13.2%	638	13.3%	723	13.3%
Randolph	334	8.1%	403	8.4%	465	8.5%
Forsyth	81	2.0%	92	1.9%	103	1.9%
Alamance	229	5.6%	317	6.6%	400	7.4%
Other^	344	8.4%	392	8.2%	437	8.0%
Total	4,118	100.0%	4,799	100.0%	5,435	100.0%

Source: Section C, page 39

*Moses Cone Hospital (proposed PET Scanner) and Wesley long campus (existing PET Scanner)

^Includes 36 other counties and other states.

In Section C, page 39, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported. Projected patient origin is based on the FY2022 historical patient origin of patients that are currently receiving PET services at Wesley Long Hospital that are projected to shift to the new fixed PET scanner upon project completion. The patients expected to shift consists of patients who receive PET services at Welsey Long Hospital, patients receiving myocardial SPECT procedures at Cone Health Hearth and Vascular Center and patients receiving new PET services for Alzheimer’s disease.

Analysis of Need

In Section C, pages 41-54, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The benefits of expanding PET imaging for cardiac care and the treatment of Alzheimer’s disease. (paged 42-45)
- The need to expand PET services at Cone Health based on the historical growth in utilization of the existing PET scanners located at Wesley Long Hospital and Alamance Regional Medical Center (ARMC) and the utilization of oncology services in the HSA II, which is used in conjunction with PET services. (pages 45-47)
- Locating the proposed PET scanner at the Heart and Vascular Center on the MCH campus will expand capacity for those patients, including oncology patients receiving PET services at Wesley Long Hospital. (pages 47-48)

- Guilford County is the most populous county in HSA II and has the largest population per scanner in the services area. Moreover, the county has experienced the highest growth among those age 65 and older, the group that can experience higher incidences of cancer and higher utilization of PET services. (pages 48-53)

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

- The applicant provided reasonable and clearly identified information to support the need for a fixed PET scanner at MCH based on the existing and projected incidence of diseases for which patients benefit from PET services in the service area.
- There is a need determination in the 2023 SMFP for one additional PET scanner in HSA II, which includes Guilford County.
- The applicant used its own internal historical utilization of the two existing PET scanners and the utilization of oncology services in the service area to illustrate the increasing demand for PET services.
- The applicant used reasonable and clearly identified demographic data to make assumptions supporting identification of the population to be served, the projected growth of that population, and the need the identified population has for the proposed PET services.

Projected Utilization

In Section Q, Forms C.2a and C.2b, the applicant provides historical and projected utilization, as illustrated in the following tables.

Cone Health Historical Utilization			
	Last Full FY	Interim Full FY	Interim Full FY
	FY2022	FY2023	FY2024
Wesley Long Hospital			
#PET Scanners	1	1	1
# of Procedures	2,005	2,665	2,590
ARMC			
#PET Scanners	1	1	1
# of Procedures	809	652	1,047

Cone Health Projected Utilization				
	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	4/1/2025- 9/30/2025	FY2026	FY2027	FY2028
Cone Health				
#PET Scanners	1	1	1	1
# of Procedures	790	2,059	2,399	2,718
Wesley Long Hospital				
#PET Scanners	1	1	1	1
# of Procedures	2,279	2,059	2,399	2,718
ARMC				
#PET Scanners	1	1	1	1
# of Procedures	1,089	1,132	1,177	1,224

In Section Q, Form C Utilization-*Methodology and Assumptions*, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant begins with the historical utilization of the existing fixed PET scanners owned and operated by Cone Health.

Table 1: Cone Health Historical PET Scans FY 2019-2023						
Facility	FY19	FY20	FY21	FY22	FY23*	CAGR**
Wesley Long Hospital	1,992	1,816	1,818	2,005	2,665	7.5%
ARMC	845	692	744	809	652	-6.3%
Total PET Scans	2,837	2,508	2,562	2,814	3,317	4.0%

Source: Section Q, Form C Utilization, page 1; Cone Health internal data.

*FY 2023 is annualized using data from October 2022 through July 2023

**Compound Annual Growth Rate

As illustrated in the table above, there was a significant growth in PET scans in the most recent five years. The existing fixed PET scanners experienced an annual growth rate of 4.0 percent. The applicant states that the decrease in PET scans at ARMC was due largely to equipment installation delays and the need to use a temporary mobile PET scanner beginning April 2023. The following table illustrates ARMC’s mobile PET scans by month, which demonstrates a growth despite the service interruptions.

Month	Scans
May	73
June	72
July	63
Total	208
Annualized ARMC PET Scans	832

Source: Section Q, Form C Utilization, page 2; Cone Health internal data.

The following table illustrates the historical utilization of the existing fixed PET scanners and the mobile PET scanner that was operational at ARMC in 2023.

Facility	FY19	FY20	FY21	FY22	FY23	CAGR
Wesley Long Hospital	1,992	1,816	1,818	2,005	2,665	7.5%
ARMC	845	692	744	809	832	-0.4%
Total PET Scans	2,837	2,508	2,562	2,814	3,497	5.4%

Source: Section Q, Form C Utilization, page 2; Cone Health internal data.

To project utilization of the existing fixed PET scanners, the applicant applies the historical growth rate of 4.0 percent. See the table below. The applicant states that using this growth rate is reasonable considering the historical growth rate of ARMC's existing mobile scanner.

Facility	FY23	FY24	FY25	FY26 (PY1)	FY27 (PY2)	FY28 (PY3)	CAGR
Total PET Scans	3,497	3,637	3,781	3,932	4,089	4,252	4.0%

Source: Section Q, Form C Utilization, page 3

The applicant determined the percentage of the total number of PET scans performed on the two existing PET scanners during FY2019-FY2022 at each facility.

Facility	FY19	FY20	FY21	FY22	Average
Wesley Long Hospital	70%	72%	71%	71%	71%
ARMC	30%	28%	29%	29%	29%
Total PET Scans	100%	100%	100%	100%	100%

Source: Section Q, Form C Utilization, page 3; Cone Health internal data.

The applicant applied the average percentage of PET scans performed by each facility, as illustrated in the table above, to the projected number of PET scans to be performed by each facility during the interim and first three years of the project. See table below.

Table 6: Cone Health Projected PET Scan Volume by Existing Facility FY 2024-2028					
Facility	FY24	FY25	FY26 (PY1)	FY27 (PY2)	FY28 (PY3)
Wesley Long Hospital*	2,590	2,693	2,800	2,911	3,027
ARMC**	1,047	1,089	1,132	1,177	1,224
Total PET Scans	3,637	3,781	3,932	4,089	4,252

Source: Section Q, Form C Utilization, page 3

*Wesley Long Hospital Projected Scans = (Total x 71%). Some scans projected to shift to the proposed scanner as shown in Table 12 below.

**ARMC = (Total x 29%)

Based on the advantages of PET imaging over SPECT imaging, Cone Health began introducing cardio PET imaging to patients instead of SPECT imaging. This has resulted in a decline in the number myocardial SPECT scans performed at the Cone Health facilities, as illustrated in the table below.

Table 7: Cone Health Historical Myocardial SPECT Scans FY 2019-2023						
Facility	FY19	FY20	FY21	FY22	FY23*	CAGR
Total Myocardial SPECT Scans	4,933	4,078	4,359	4,139	3,530	-8.0%

Source: Section Q, Form C Utilization, page 4; Cone Health internal data.

*FY 2023 is annualized using data from October 2022 through July 2023.

As Cone Health continues to move toward performing cardiovascular PET scans, the applicant assumes that the number of myocardial SPECT scans will continue to decrease. The following table illustrates the applicant's projected number of potential PET scans to shift from myocardial SPECT scans. The applicant states that FY2023 and FY2024 numbers are for demonstrative purposes only since the shift of scans will not occur until the proposed project is developed.

Table 8: Cone Health Projected PET Scans to Shift from Myocardial SPECT Scans FY 2023-2028							
Facility	FY23	FY24	FY25	FY26 (PY1)	FY27 (PY2)	FY28 (PY3)	CAGR
Myocardial SPECT Scans	3,530	3,247	2,987	2,747	2,527	2,324	-8.0%
Shift Percentage to PET Scans	60%	60%	60%	60%	60%	60%	
Potential PET Scans	2,118	1,948	1,792	1,648	1,516	1,394	-8.0%

Source: Section Q, Form C Utilization, page 5

As previously discussed, the proposed PET scanner will be used for cardiovascular, oncology and neurology patients. To project the potential number of neurology scans, the applicant examines Cone Health's historical patients with Alzheimer's disease.

Table 9: Cone Health Historical Patients with Alzheimer's Disease FY 2019-2023						
Facility	FY19	FY20	FY21	FY22	FY23*	CAGR
Patients with Alzheimer's Disease	2,717	2,704	2,837	2,875	2,856	1.3%

Source: Section Q, Form C Utilization, page 4; Cone Health internal data.

*FY 2023 is annualized using data from October 2022 through July 2023.

The applicant projects that the number of Alzheimer's disease patients will increase by the historical growth rate of 1.3 percent and one third of those patients will receive a PET scan. The applicant states that its projections are reasonable considering that the 65+ age group in Guilford County is projected to grow by 2.6 percent from 2023 to 2028, according to NCOSBM, and Cone Health's initiative to support PET imaging for these patients.

Table 10: Cone Health Projected PET Scans for Alzheimer's Disease FY 2023-2028							
Facility	FY23	FY24	FY25	FY26 (PY1)	FY27 (PY2)	FY28 (PY3)	CAGR
Patients with Alzheimer's Disease	2,856	2,892	2,928	2,965	3,002	3,040	1.3%
Percentage of Patients Receiving PET Scans	33%	33%	33%	33%	33%	33%	
Potential PET Scans	952	964	976	988	1,001	1,013	1.3%

Source: Section Q, Form C Utilization, page 6

The applicant assumes an incremental ramp-up period due to the limited capacity of the existing PET scanner at Wesley Long Hospital as the proposed PET scanner expands capacity for all of the PET scanners owned and operated by Cone Health. See table below.

Table 11: MCH Projected Incremental PET Scans				
	FY25*	FY26 (PY1)	FY27 (PY2)	FY28 (PY3)
Incremental PET Scans from Myocardial SPECT Procedures	1,792	1,648	1,516	1,394
Incremental Scans for Patients with Alzheimer's Disease	976	988	1,001	1,013
Total Incremental Potential PET Scans	2,768	2,636	2,517	2,408
Ramp-Up	25%	50%	75%	100%
Total Incremental Projected PET Scans with Ramp-Up	346	1,318	1,887	2,408

Source: Section Q, Form C Utilization, page 6

*FY 2025 is a partial project year, representing April 1, 2025 through September 30, 2025. The totals shown have been annualized.

The applicant added the total incremental projected PET scans with ramp-up to Wesley Long Hospital total projected scans (*Table 6*).

Table 12: Wesley Long Hospital and Moses Cone Hospital Projected PET Scans FY 2025-2028				
	FY25	FY26 (PY1)	FY27 (PY2)	FY28 (PY3)
Growth of Scans at Wesley Long Hospital	2,693	2,800	2,911	3,027
Incremental Cardiology and Neurology PET Scans	346	1,318	1,887	2,408
Total PET Scans at WLH and MCH	3,039	4,118	4,798	5,435

Source: Section Q, Form C Utilization, page 7

The applicant projects the total number of PET scans performed at Wesley Long Hospital and MCH, as illustrated in the table above.

The applicant assumes that MCH and Wesley Long Hospital will perform an equal number of PET scans for the first three years of the project based on scheduling, availability and patient preference.

Table 13: Wesley Long Hospital and Moses Cone Hospital Projected PET Scans FY 2025-2028				
	FY25*	FY26 (PY1)	FY27 (PY2)	FY28 (PY3)
WLH Projected Scans	2,279	2,059	2,399	2,718
MCH Projected Scans	760	2,059	2,399	2,718
Total PET Scans	3,039	4,118	4,799	5,435

Source: Section Q, Form C Utilization, page 7

*FY 2025 is a partial project year, representing April 1, 2025 through September 30, 2025. The totals shown have been annualized. FY 2025 is also adjusted to reflect an equivalent split for only six months of the annualized total.

The applicant projects that existing and proposed PET scanners will perform an average 2,220 per scanner by the project year, which exceeds the PET performance standard of 2,080 or more procedures during the third full fiscal year of operation.

Table 14: Cone Health Projected PET Procedures, FY 2028	
Facility	FY28 (PY3)
Wesley Long Hospital	2,718
MCH	2,718
ARMC	1,224
Total PET Procedures	6,659

Source: Section Q, Form C Utilization, page 7

Table 15: Cone Health Projected PET Procedures for Performance Standards	
	FY28 (PY3)
Total PET Procedures	6,659
Total Pet Scanners	3
Average Procedures per PET Scanner	2,220
Performance Standard	2,080
Percent of Performance Standard	107%

Source: Section Q, Form C Utilization, page 8

Projected utilization is reasonable and adequately supported based on the following:

- The applicant relies on historical utilization data on the existing PET scanners to project future utilization of PET services.
- The applicant makes reasonable and conservative assumptions regarding projected PET utilization based on documented population data, historical growth rates and the shift in the application of PET imaging.
- The projected utilization of the applicant’s proposed fixed PET scanner meets the Performance Standards in 10A NCAC 14C .3703.

Access to Medically Underserved Groups

In Section C, page 61, the applicant states:

“...Cone Health does not discriminate against low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent, the uninsured and the underinsured. In general, the health services of Cone Health are available to any patient in need without restriction of any kind. Access to hospital services by disadvantaged groups is provided in an organized setting through Cone Health’s hospital-based outpatient clinics. Cone Health’s well-established community education and screening programs are available to the general public and ensure adequate access to Cone Health services for medically underserved persons. The proposed project will not alter the current level of accessibility to patients of Cone Health.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons*	20.5%
Racial and ethnic minorities	43.8%
Women	62.0%
Persons with Disabilities	
Persons 65 and older	35.0%
Medicare beneficiaries	37.4%
Medicaid recipients	20.5%

Source: Section C, page 61

*Cone Health assumes that low income persons are represented by Medicaid recipients and therefore assumes the same percentage of patients

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 documents historical and projected access to all of Cone Health services, including PET services, for all residents of the service area, including underserved groups.
- The applicant provides its projected payor mix, which includes underserved groups, based on its historical experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Patient Origin

On page 360, the 2023 SMFP defines the service area for a fixed dedicated PET scanner as “*the HSA in which it is located (Table 17F-1).*” Cone Health (Project ID #G-12425-23) proposes to locate the proposed fixed PET scanner in Guilford County, which is in HSA II. Novant Health, (Project ID #G-12432-23) and Piedmont, (Project ID #G-12433-23) propose to locate the proposed fixed PET scanner in Forsyth County, which is also in HSA II. Thus, the service area for each proposal is HSA II. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

NHFMC PET Services Historical Patient Origin		
Last Full FY 01/01/2022-12/31/2022		
	# of Patients	% of Total
Forsyth	1,080	41.7%
Davidson	283	10.9%
Stokes	224	8.6%
Surry	210	8.1%
Yadkin	163	6.3%
Davie	148	5.7%
Wilkes	97	3.7%
Guilford	66	2.5%
Other^	321	12.4%
Total	2,592	100.0%

Source: Section C, page 30

^Includes <1 percent patient origin from the remaining counties in North Carolina and other states.

NHFMC PET Services Projected Patient Origin						
County	1st Full FY		2nd Full FY		3rd Full FY	
	1/1/26 to 12/31/26		1/1/27 to 12/31/27		1/1/28 to 12/31/28	
	CY2026		CY2027		CY2028	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Forsyth	1,584	43.9%	1,744	44.5%	1,935	45.1%
Davidson	389	10.8%	442	11.3%	506	11.8%
Stokes	281	7.8%	296	7.5%	312	7.3%
Surry	297	8.2%	313	8.0%	329	7.7%
Yadkin	224	6.2%	236	6.0%	249	5.8%
Davie	234	6.5%	249	6.4%	266	6.2%
Wilkes	131	3.6%	137	3.5%	145	3.4%
Guilford	158	4.4%	167	4.3%	178	4.1%
Other^	311	8.6%	338	8.6%	369	8.6%
Total	3,608	100.0%	3,923	100.0%	4,289	100.0%

Source: Section C, page 32

^Includes <1 percent patient origin from the remaining counties in North Carolina and other states.

In Section C, page 32, the applicant provides the assumptions and methodology used to project patient origin for the proposed fixed PET scanner. The applicant's assumptions are

reasonable and adequately supported because they are based on historical patient origin for fixed PET services provided by NHFMC.

Analysis of Need

In Section C, pages 34-53, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The need for one additional fixed PET scanner in HSA II identified in the 2023 SMFP that was generated by NHFMC's existing PET scanner. (page 35)
- The clinical need for an additional PET scanner at NHFMC. (pages 35-41)
- North Carolina's growth in the PET use rate and the historical growth in the number of PET procedures performed during FY2019-FY2022. (pages 41-42)
- The high volume of PET procedures performed on NHFMC's existing PET scanners. (pages 42-46)
- Projected population growth in the service area, particularly among the 65+ group, the group more likely to utilize PET services (pages 47-49)
- The incidence of diseases that PET services may be used as part of diagnosis and/or treatment. (pages 49-52)
- NHFMC's physician network support. (pages 52-53)

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

- There is a need determination in the 2023 SMFP for one additional PET scanner in HSA II, which includes Forsyth County.
- The applicant uses NHFMC's historical utilization of the mobile PET scanner and the statewide PET use rate data to illustrate the increasing demand for PET services in the service area.
- The applicant uses reasonable and clearly identified demographic data to make assumptions supporting identification of the population to be served, the projected growth of that population, and the need the identified population has for the proposed PET services.
- The applicant provides reasonable and clearly identified information to support the need for a fixed PET scanner at NHFMC based on the existing and projected incidence of diseases for which patients benefit from PET services in the service area, as well as the support of NHFMC's physician network.

Projected Utilization

In Section Q, page 110, the applicant provides historical and projected utilization, as illustrated in the following tables.

NHFMC Historical Utilization				
	Last Full FY	Interim Full FY	Interim Full FY	Interim Partial FY
	CY2022	CY 2023	CY 2024	1/1/25- 3/31/25
#PET (fixed) Scanners	1	1	1	1
# of Procedures	2,592	2,974	3,151	835
#PET (mobile) Scanners	1	1	1	1
# of Procedures	2,620	3,639	3,369	910

NHFMC Projected Utilization				
	Partial FY	Project Year 1	Project Year 2	Project Year 3
	4/1/25- 12/31/25	CY 2026	CY 2027	CY 2028
#PET (fixed) Scanners	2	2	2	2
# of Procedures	2,504	3,608	3,923	4,289
#PET (mobile) Scanners	1	1	1	1
# of Procedures	2,729	3,639	3,639	3,639

In Section Q, pages 111-118, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Identify the projected population growth in the service area.

NHFMC Fixed PET Service Area: Projected Population						
County	2023	2024	2025	2026	2027	2028
Davidson	173,876	175,339	176,800	178,261	179,724	181,184
Davie	44,223	44,691	45,158	45,624	46,093	46,558
Forsyth	388,365	390,943	393,717	396,647	399,693	402,829
Guilford	546,934	550,216	553,974	558,089	562,482	567,076
Stokes	45,205	45,337	45,444	45,530	45,596	45,649
Surry	71,283	71,236	71,191	71,145	71,099	71,055
Wilkes	65,600	65,502	65,408	65,312	65,225	65,139
Yadkin	37,082	37,057	37,040	37,025	37,016	37,007
Total	1,372,568	1,380,321	1,388,732	1,397,633	1,406,928	1,416,497

Source: Section Q, page 111, NCOSBM, Vintage 2022

Step 2: Calculate the historical statewide PET use rate using state population data and the number of PET procedures performed statewide.

North Carolina PET Use Rate			
Fiscal Year	State Population	Number of PET Procedures	Use Rate/1,000
FY2016	10,080,436	45,006	4.46
FY2017	10,181,491	48,066	4.72
FY2018	10,284,335	52,167	5.07
FY2019	10,381,670	54,416	5.24
FY2020	10,463,226	50,572	4.83
FY2021	10,556,299	54,837	5.19
FY2022	10,667,874	63,698	5.97

Source: Section Q, page 112; population data obtained from NCOSBM, Vintage 2022; PET volumes (fixed & mobile) obtained from SMFPs (including the Proposed 2024 SMFP).

The table above illustrates the increase in the statewide use rate during FY2016 - FY2022. The number of statewide PET procedures experienced a CAGR of 6.5 percent prior to the COVID-19 pandemic (FY2016 – FY2019) and a CAGR of 5.4 percent during FY2019 – FY2022. The applicant states that the demand for PET procedures will continue to increase based on factors such as population aging, disease incidence, and increasing clinical indications. The applicant projects that the statewide use rate will increase by the historical CAGR (FY2019 - FY2022) of 5.4 percent.

North Carolina PET Procedure Use Rate (per 1,000 population)						
	2023	2024	2025	2026	2027	2028
PET Use Rate	6.29	6.63	6.99	7.37	7.76	8.18

Source: Section Q, page 112

Step 3: Project the PET procedure demand by applying the statewide use rate to the projected population of NHFMC's service area counties.

Projected PET Procedure Demand Based on PET Use Rate						
County	2023	2024	2025	2026	2027	2028
Davidson	1,094	1,163	1,236	1,313	1,395	1,482
Davie	278	296	316	336	358	381
Forsyth	2,444	2,593	2,752	2,922	3,103	3,296
Guilford	3,442	3,649	3,872	4,111	4,367	4,640
Stokes	284	301	318	335	354	373
Surry	449	472	498	524	552	581
Wilkes	413	434	457	481	506	533
Yadkin	233	246	259	273	287	303
Total	8,637	9,154	9,707	10,295	10,922	11,589

Source: Section Q, page 113; Novant Health internal data, NCOSBM
 Formula: (Step 1 Population / 1000) x Step 2 PET Use Rate

Step 4: Estimate NHFMC fixed PET market share for CY2023 based on the CY2023 annualized PET procedure demand.

NHFMC Estimated Fixed PET Market Share, CY2023				
County	2023 Population	PET Procedure Demand Based on Statewide PET Use Rate	Number of CY23 Fixed PET Patients [^]	CY2023 Estimated Market Share
Davidson	173,876	1,094	308	28.1%
Davie	44,223	278	194	69.7%
Forsyth	388,365	2,444	1,288	52.7%
Guilford	546,934	3,442	132	3.8%
Stokes	45,205	284	238	83.7%
Surry	71,283	449	254	56.6%
Wilkes	65,600	413	112	27.1%
Yadkin	37,082	233	192	82.3%

Source: Section Q, page 114; Novant Health internal data; NCOSBM

[^]Annualized based on six months data.

Formula: (2023 Population / 1000) x Step 2 PET Use Rate

The following table illustrates the projected incremental fixed PET market share increase during the first three years of the project for the two largest counties of patient origin for NHFMC's fixed PET services, Davidson and Forsyth counties.

NHFMC Incremental Fixed PET Market Share Increase			
County	Project Year 1	Project Year 2	Project Year 3
	2026	2027	2028
Davidson	1.5%	2.0%	2.5%
Forsyth	1.5%	2.0%	2.5%

Source: Section Q, page 114

The applicant projects the fixed PET market share for each county in the proposed service area and projects that the market share will remain consistent with the CY2023 market share, excluding Davidson and Forsyth counties. The applicant projects the incremental market share increase for Davidson and Forsyth counties based on increased capacity and expanded capabilities. The applicant states that the projected market share is supported by factors such as growth and aging population, cancer incidence rates in the service area, and the continued growth of service lines that refer patients to NHFMC’s PET services.

NHFMC Projected Fixed PET Market Share					
County	Interim Year	Partial Year	Project Year 1	Project Year 2	Project Year 3
	2024	2025	2026	2027	2028
Davidson	28.1%	28.1%	29.6%	31.6%	34.1%
Davie	69.7%	69.7%	69.7%	69.7%	69.7%
Forsyth	52.7%	52.7%	54.2%	56.2%	58.7%
Guilford	3.8%	3.8%	3.8%	3.8%	3.8%
Stokes	83.7%	83.7%	83.7%	83.7%	83.7%
Surry	56.6%	56.6%	56.6%	56.6%	56.6%
Wilkes	27.1%	27.1%	27.1%	27.1%	27.1%
Yadkin	82.3%	82.3%	82.3%	82.3%	82.3%

Source: Section Q, page 115

Step 5: Summarize NHFMC’s projected fixed PET procedures based on the projected annual market share applied to the projected PET demand.

NHFMC Fixed PET Procedures					
County	Interim Year	Partial Year	Project Year 1	Project Year 2	Project Year 3
	2024	2025	2026	2027	2028
Davidson	327	348	389	442	506
Davie	207	220	234	249	266
Forsyth	1,366	1,450	1,584	1,744	1,935
Guilford	140	149	158	167	178
Stokes	252	266	281	296	312
Surry	268	282	297	313	329
Wilkes	118	124	131	137	145
Yadkin	202	213	224	236	249

Source: Section Q, page 116

Formula: Step 4 Market Share x Step 3 Projected PET Procedure Demand

The applicant states that approximately 8.6 percent of NHFMC’s PET patients were from other counties and states during CY2023. The following table summarizes NHFMC’s projected number of fixed procedures including an 8.6 percent in-migration of procedures performed on patients from other counties and states.

NHFMC Fixed PET Procedures					
County	Interim Year	Partial Year	Project Year 1	Project Year 2	Project Year 3
	2024	2025	2026	2027	2028
Davidson	327	348	389	442	506
Davie	207	220	234	249	266
Forsyth	1,366	1,450	1,584	1,744	1,935
Guilford	140	149	158	167	178
Stokes	252	266	281	296	312
Surry	268	282	297	313	329
Wilkes	118	124	131	137	145
Yadkin	202	213	224	236	249
In-migration (8.6%)	271	287	311	338	369
Total	3,151	3,339	3,608	3,923	4,289

Source: Section Q, page 116

The following table illustrates NHFMC’s mobile PET historical utilization.

NHFMC Mobile PET Utilization		
Year	Mobile PET Procedures	Utilization Rate (Mobile PET Capacity: 2,600 Procedures)
FY2017*	830	31.9%
FY2018	1,780	68.5%
FY2019	2,068	79.5%
FY2020	1,984	76.3%
FY2021	1,750	67.3%
FY2022^	2,376	91.4%
FY2023	3,500	134.6%

Source: Section Q, page 117

*Placed in service 2/27/2017. Reporting period 2/27/2017-9/30/2017

^Annualized based on 10 months data (Oct-July)

Note that mobile PET utilization during FFY2020 and FFY2021 was negatively impacted by the COVID-19 pandemic.

The applicant projects that mobile PET scanner utilization will remain constant through CY2028. The applicant states that the projected utilization of the mobile PET scanner is conservative considering the historical demand for the existing mobile PET scanner and the historical growth at each host site. See table below.

NHFMC Mobile PET Utilization By Host Site						
Host Site Facility	CY2019	CY2020	CY2021	CY2022	CY2023*	CAGR
Novant Health Huntersville Medical Center	670	642	723	901	1,135	14.1%
Novant Health Kernersville Medical Center	357	364	428	438	711	18.8%
Novant Health Matthews Medical Center	372	534	566	692	939	26.1%
Novant Health Mint Hill Medical Center	236	79	132	194	391	13.4%
Novant Health Rowan Julian Road	380	343	353	395	463	5.1%
NHFMC Mobile PET Scanner Total	2,015	1,962	2,202	2,620	3,639	15.9%

Source: Section Q, page 117; Novant Health internal data.

*Annualized based on seven months data (Jan-July).

NHFMC Mobile PET Utilization					
	CY2024	CY2025	CY2026	CY2027	CY2028
Mobile PET Procedures	3,639	3,639	3,639	3,639	3,639

Source: Section Q, page 118

Projected utilization is reasonable and adequately supported based on the following:

- The applicant makes reasonable and conservative assumptions regarding projected PET utilization based on documented population data, statewide PET use rates, and NHFMC historical market share.
- The applicant relies on historical utilization data of the existing mobile PET scanner to project future utilization of mobile PET services.
- The projected utilization of the applicant's existing and proposed PET scanners meets the Performance Standards in 10A NCAC 14C .3703.

NHFMC Projected PET Procedures for Performance Standards	
	CY28 (PY3)
Total PET Procedures	7,928
Total Pet Scanners	3
Average Procedures per PET Scanner	2,643
Performance Standard	2,080
Percent of Performance Standard	127%

Access to Medically Underserved Groups

In Section C, page 57, the applicant states:

“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will [have] continue to have access to NHFMC, as clinically appropriate. NHFMC does not discriminate based on race, ethnicity, age, gender, or disability. Policies to provide access to services by low-income, medically indigent, uninsured, or underinsured patients are described and provided in Exhibit C.6. As set forth in the pro formas, a significant proportion of NHFMC’s proposed services will be provided to Medicare, Medicaid, and uninsured patients.

NHFMC’s services will continue to be accessible to persons with disabilities, as required by the Americans with Disabilities Act.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	6.5%
Racial and ethnic minorities	31.3%
Women	58.3%
Persons with Disabilities	
Persons 65 and older	69.4%
Medicare beneficiaries	69.4%
Medicaid recipients	4.3%

Source: Section C, page 57

The applicant states that Novant Health does not retain data that includes the number of disabled persons it serves and NHFMC does not deny access to services to disabled persons.

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 because NHFMC is an established medical facility in the service area currently serving Medicare and Medicaid patients and providing documented charity care to patients identified as underserved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Patient Origin

On page 360, the 2023 SMFP defines the service area for a fixed dedicated PET scanner as “the HSA in which it is located (Table 17F-1).” Cone Health (Project ID #G-12425-23) proposes to locate the proposed fixed PET scanner in Guilford County, which is in HSA II.

Novant Health, (Project ID #G-12432-23) and Piedmont, (Project ID #G-12433-23) propose to locate the proposed fixed PET scanner in Forsyth County, which is also in HSA II. Thus, the service area for each proposal is HSA II. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

Piedmont Historical Patient Origin		
Last Full FY 01/01/2022-12/31/2022		
	# of Patients	% of Total
Guilford	3,662	83.49%
Rockingham	257	5.86%
Randolph	168	3.83%
Forsyth	80	1.823%
Alamance	54	1.23%
Davidson	28	0.64%
Other	137	3.12%
Total	4,386	100.0%

Source: Section C, page 40, Exhibit 2
 Project Analyst's calculation in brackets.

Piedmont Projected Patient Origin						
County	1st Full FY		2nd Full FY		3rd Full FY	
	1/1/22 to 12/31/22		1/1/24 to 12/31/24		1/1/25 to 12/31/25	
	CY2022*		CY2024		CY2025	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Guilford	3,662	83.49%	3753.55	86.21%	3941.2275	86.21%
Rockingham	257	5.86%	263.425	6.05%	276.59625	6.05%
Randolph	168	3.83%	172.2	3.95%	180.81	3.95%
Forsyth	80	1.80%	80.975	1.86%	85.02375	1.86%
Alamance	54	1.23%	55.35	1.27%	58.1175	1.27%
Davidson	28	.64%	28.7	.66%	30.135	.66%
Other	137	3.12%				
Total	4,386	100.0%	4354.2	100.0%	4,289 [4,571.91]	100.0%

Source: Section C, page 41, Exhibit 2

*The Project Analyst assumes that the first project year as CY 2022 is a typographical error, and the second project year is 2024 and the third year 2025.

Project Analyst's calculation in brackets.

The applicant does not provide assumptions nor a methodology to project patient origin. Also, the data provided on pages 40 and 41 of the application does not equal the data provided in Exhibit 2. Therefore, the Project Analyst cannot determine whether the applicant's assumptions are adequately supported.

Analysis of Need

The applicant does not explain why it believes the population projected to utilize the proposed services needs the proposed services.

Projected Utilization

The applicant does not provide projection utilization nor provide any assumptions and a methodology to project utilization.

Access to Medically Underserved Groups

In Section C, page 48, the applicant states:

“Piedmont Cardiovascular, P.A. does not capture data on Medically Underserved groups to provide percentage information.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	NA
Racial and ethnic minorities	668.36%
Women	359.73%
Persons with Disabilities	NA
Persons 65 and older	189.77%
Medicare beneficiaries	390.04%
Medicaid recipients	17.22%

Source: Section C, page 48

The applicant does not adequately describe the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services because the applicant does not provide reasonable or adequately supported assumptions upon which it bases its projected number of medically underserved patients. Therefore, its estimated payor mix is not reasonable or adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

- (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-All Applications

None of the applicants 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
Cone Health
Novant Health

NC
Piedmont

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section E, pages 73-74, 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 currently operates two fixed PET scanners on two separate campuses. The applicant states that the fixed PET scanner located on the Wesley Long Hospital campus is typically fully scheduled three months in advance which delays needed PET scans. Moreover, the use of cardiac scans as the standard and the inclusion of PET services for the diagnosis and treatment of Alzheimer's disease will increase the demand for the existing PET scanners. Therefore, maintaining the status quo is not an effective alternative.

Add an Additional PET Scanner at a Different Location-The applicant states that adding an additional PET scanner at a different location disregards utilization trends and growth projections. Additionally, locating the fixed PET scanner at another location will duplicate existing services.

Utilize Mobile PET Services to Meet the Identified Need-The applicant states that utilizing mobile PET services may help lower volumes of the existing PET scanners, however, it would not be able to provide adequate services to Cone Health's large patient base.

On pages 73-74, the applicant states that its proposal is the most effective alternative because:

- Developing fixed PET services on the MCH campus will meet the growing demand for cardiac scans and help alleviate the delays in diagnostic testing.
- The applicant's proposal to develop PET services in Cone Health's Heart and Vascular Center will allow patients to receive cardiac PET services as part of their treatment for their heart and vascular issues in one location, thereby ensuring continuity of care.

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 applicant's proposal will meet the growing demand for cardiac PET scans and enhance access by reducing utilization demand on the existing PET scanner at Wesley Long Hospital, expand access by offering more convenient times for scheduling patient treatment and allow the equipment to operate more efficiently with less risk of downtime.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Remarks made at the public hearing)
- Responses to comments

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section E, pages 67-68, 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 maintaining the status quo is not an effective alternative because of the 2023 SMFP need determination for one fixed PET scanner in HSA II service area. Also, maintaining the status quo may force the facility to add evening hours. This is not feasible because of the fasting period required for the procedure or for older patients who are reluctant to travel late in the day.

Develop a Fixed PET Scanner at Another Location-Novant Health operates two other hospitals in Forsyth County. However, both facilities serve as community hospitals providing services to lower acuity patients than NHFMC. Not only does NHFMC serve patients from a larger geographic area, but the facility also serves patients with more complex acute care needs.

On page 68, the applicant states that its proposal is the most effective alternative because of the 2023 SMFP need determination for one fixed PET scanner in the HSA II service area.

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

- NHFMC's existing PET services have generated the 2023 SMFP need in the service area.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional fixed PET scanner in HSA II.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section E, page 60, the applicant states that patients are experiencing long waits for PET services at Wesley Long Hospital and some patients are required to drive for more than an hour to receive services at Duke or UNC hospitals. However, the applicant does not provide any alternative method that would meet the need for the fixed PET scanner. The applicant 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
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reason 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
Cone Health
Novant Health

NC
Piedmont

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 6, the applicant projects the total capital cost of the project, as shown in the table below.

Capital Costs	
Construction Contract	\$948,916
Architect/Engineering Fees	\$50,291
Medical Equipment	\$1,193,155
Consultant Fees (CON Fees)	\$80,000
Total	\$2,272,362

In Section Q, Form F.1a, page 7, 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. The applicant projects capital costs based on the vendor's quotation of medical equipment costs and the architect's experience with similar projects.

In Section F, page 78, the applicant states there will be no start-up costs or initial operating expenses because the proposal does not involve a new service.

Availability of Funds

In Section F, page 76, the applicant states that the capital cost will be funded by Cone Health. In Exhibit F.2-1, the applicant provides a letter from the Chief Financial Officer for Cone Health, documenting its commitment to fund the capital cost of the project through accumulated reserves. The letter also states that as of December 2022, The Moses H. Cone Memorial Hospital and affiliates had sufficient funds to finance the project.

The applicant adequately demonstrates the availability of sufficient funds for the 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 the first three full fiscal years following completion of the project, as shown in the table below.

Cone Health* Fixed PET Scanners	Partial Year	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
	10/1/24- 9/30/25	FY2026	FY2027	FY2028
Total Procedures	4,128	5,250	5,975	6,660
Total Gross Revenues (Charges)	\$27,310,852	\$38,493,784	\$46,651,589	\$54,948,428
Total Net Revenue	\$9,172,856	\$12,748,893	\$15,343,916	\$17,964,517
Average Net Revenue per Procedure	\$2,222	\$2,428	\$2,568	\$2,697
Total Operating Expenses (Costs)	\$3,865,280	\$5,471,910	\$6,549,687	\$7,768,234
Average Operating Expense per Procedures	\$936	\$1,042	\$1,096	\$1,166
Net Income	\$5,307,576	\$7,276,983	\$8,794,229	\$10,196,283

*Includes the Wesley Long and Moses Cone Hospital Campuses.

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 based its projections on Cone Health’s FY2022 PET services historical experience adjusted to reflect the new cardiac and neurology patients.
- 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
- Remarks made at the public hearing
- Responses 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 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 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.

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Capital and Working Capital Costs

In Section Q, page 119, the applicant projects the total capital cost of the project, as shown in the table below.

Capital Costs	
Construction Contract	\$2,409,763
Architect/Engineering Fees	\$230,000
Medical Equipment	\$2,682,477
Non-Medical Equipment	\$52,639
Furniture	\$73,512
Consultant Fees	\$74,500
Other	\$552,289
Total	\$6,075,180

In Section Q, page 126, 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 which are based on the cost to renovate a PET-related and support space, the architect's construction cost estimate, and Novant Health's experience with developing similar projects.

In Section F, page 71, the applicant states there will be no start-up costs or initial operating expenses because NHFMC currently offers fixed PET services.

Availability of Funds

In Section F, page 69, the applicant states that the capital cost will be funded by Novant Health, Inc. In Exhibit F.2, the applicant provides a letter from the Senior Vice President of Operational Finance and Revenue Cycle for Novant Health, Inc., documenting its commitment to fund the capital cost of the project through accumulated reserves. The letter also states that as of December 2022, Novant Health, Inc. had sufficient funds to finance the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and 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 the first three full fiscal years following completion of the project, as shown in the table below.

NHFMC Fixed PET Scanners	Partial Year	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
	4/1/25- 12/31/25	CY2026	CY2027	CY2028
Total Procedures	3,339	3,608	3,923	4,289
Total Gross Revenues (Charges)	\$35,608,803	\$52,364,075	\$58,030,837	\$64,596,533
Total Net Revenue	\$7,187,390	\$10,569,326	\$11,713,123	\$13,038,363
Average Net Revenue per Procedure	\$2,153	\$2,929	\$2,986	\$3,040
Total Operating Expenses (Costs)	\$3,884,688	\$5,641,657	\$6,157,822	\$6,822,152
Average Operating Expense per Procedures	\$1,551	\$ 1,564	\$ 1,570	\$ 1,591
Net Income	\$3,302,702	\$4,927,669	\$5,555,301	\$6,216,211

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 projects gross revenue based on Novant Health’s FY2022 fixed PET services historical experience.
- Gross revenue per procedure is adjusted to account for the increase in Prostate Specific Membrane Antigen (PSMA) and cardiac PET scans and the change in volume between PSMA, cardiac, brain, and cancer PET cases based on the difference is gross charge per procedure.
- 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
- Remarks made at the public hearing
- Responses 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 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 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.

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Capital and Working Capital Costs

In Section E, page 61, the applicant projects the total capital cost of the project, as shown in the table below.

Capital Costs	\$57,050
Total	\$57,050

In Section E, the applicant did not provide the assumptions used to project the capital cost. Therefore, the applicant did not adequately demonstrate that the projected capital cost is based on reasonable and adequately supported assumptions.

In Section E, page 63, the applicant projects that start-up costs will be \$57,050 and initial operating expenses will be \$3,000 for a total working capital of \$60,050. However, on page 62, the applicant states that initial operating expenses will be \$1,000 for staff education sessions, supplies necessary for Cardiac PET CT scans, equipment and miscellaneous. On pages 62-63, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant does not adequately demonstrate that the projected working capital needs of the project are based on reasonable and adequately supported assumptions because of the inconsistencies in the proposed working capital.

Availability of Funds

In Section F, page 61, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Piedmont Cardiovascular, P.A.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$57,050	\$57,050
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$57,050	\$57,050

* OE = Owner's Equity

In Section E, page 63, the applicant states that the working capital needs of the project will be funded by Piedmont Cardiovascular, P.A.

The applicant did not adequately demonstrate availability of sufficient funds for the capital needs of the project because the applicant did not identify the assumptions to project the capital costs nor document the availability of funds. Therefore, the applicant does not adequately demonstrate that the projected capital cost is based on reasonable and adequately supported assumptions.

Financial Feasibility

The applicant did not provide pro forma financial statements for the first three full fiscal years of operation following completion of the project. Therefore, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported.

- The applicant does not project revenues that are based on reasonable and adequately supported assumptions.
- The applicant does not project operating expenses that are based on reasonable and adequately supported assumptions.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

- The applicant does not adequately demonstrate that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant does not adequately demonstrate availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant does not adequately demonstrate 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.

C
 Cone Health
 Novant Health

NC
 Piedmont

On page 360, the 2023 SMFP defines the service area for a fixed dedicated PET scanner as “the HSA in which it is located (Table 17F-1).” Cone Health (Project ID #G-12425-23) proposes to locate the proposed fixed PET scanner in Guilford County, which is in HSA II. Novant Health, (Project ID #G-12432-23) and Piedmont, (Project ID #G-12433-23) propose to locate the proposed fixed PET scanner in Forsyth County, which is also in HSA II. Thus, the service area for each proposal is HSA II. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing dedicated fixed PET scanners in HSA II, and the number of procedures for each PET scanner in 2020-2021 as found in Table 17F-1 on page 362 of the 2023 SMFP:

Facility	Planning Inventory	Procedures
ARMC	1	745
Cone Health	1	1,818
High Point Regional Health	1	1,013
North Carolina Baptist Hospital	2	3,216
Novant Health Forsyth Medical Center	1	2,742

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section G, page 86, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET services in HSA II. The applicant states:

“...Moses Cone Hospital needs additional capacity to meet the growing demand for PET services by patients at its facility.

As discussed in Section C.4, while two existing PET scanners operate in Guilford County, compared to the other counties with fixed PET scanners, Guilford County has less access to PET services based on the population per PET scanner.

...

Within Guilford County, Cone Health’s existing PET scanner at Wesley Long Hospital is well-utilized and has a significant wait time, particularly for cardiac studies. The proposed fixed PET scanner at Moses Cone Hospital is expected to relieve current capacity constraints at Wesley Long Hospital and enable Moses Cone Hospital to perform a higher number of cardiac PET procedures, while also providing neurology and oncology PET procedures.”

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 2023 SMFP for the proposed fixed PET scanner.
- The proposal is needed based on the high utilization of the existing PET scanners owned and operated by Cone Health.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section G, page 78, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET services in HSA II. The applicant states:

“The proposed project will not result in unnecessary duplication of existing or approved facilities in Health Service Area II. The 2023 SMFP has identified a need for one additional fixed PET scanner in the multi-county service area because PET utilization in the service area is projected to exceed the capacity of the existing and approved providers. NHFMC’s fixed PET scanner utilization generated the need.”

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 2023 SMFP for the proposed fixed PET scanner.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing or approved fixed PET scanners.
- The proposed fixed PET scanner is needed based on utilization of NHFMC’s existing PET services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section G, page 68, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET services in HSA II service area. The applicant states:

“The proposed project will not result in unnecessary duplication of services due to the following reasons: 1) Piedmont Cardiovascular, P.A. is considered a Diagnostic Center and not hospital based. 2) Present PET system at Wesley Long Hospital is not a dedicated Cardiac PET CT Scanner as it is being used to treat both oncology and cardiac patients. Treating both patients services leads to longer wait times in scheduling patients to be seen. 3) Performing a PET CT in a facility is more expensive than in a diagnostic center.”

However, the applicant did 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 reasons:

- The applicant did not provide its projected utilization that adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions.
- The applicant did not identify all the existing PET scanners in the service area.
- The applicant did not demonstrate that it was conforming to the Criteria and Standards for Positron Emission Tomography Scanner Services, 10A NCAC 14C .3703.
- Because the applicant did not demonstrate the need to develop a fixed PET scanner, it cannot demonstrate that the new fixed PET scanner is needed in addition to the existing and approved fixed PET scanner in HSA II service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

- (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-All Applications

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section Q, Form H, page 14, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Cone Health	Current Staff	Projected Staff		
	As of 09/30/2022	1 st Full FY FY 2026	2 nd Full FY FY 2027	3 rd Full FY FY 2028
Coord/Diagnostic Services	1.0	2.0	2.0	2.0
Nuclear Medicine Technologist	1.2	3.0	3.0	4.0
RN	0.2	0.5	1.0	1.5
Stress Technologist	0.2	0.5	1.0	1.5
TOTAL	2.6	6.0	7.0	9.0

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 88-89, 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’s experience in hospital staffing and employment retention.
- Appropriate degree and experience requirements and training programs consisting of departmental orientation upon hire, in-service education, and continuing education seminars.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section Q, page 124, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

NHFCM	Current Staff	Projected Staff		
	As of 09/15/2023	1 st Full FY CY 2026	2 nd Full FY CY 2027	3 rd Full FY CY 2028
Nuclear Medicine Tech	3.7	6.5	6.5	7.0
Nuclear Medicine Tech Supervisor	0.5	0.5	0.5	0.5
Radiology Operations Assistant	0.0	0.5	0.5	0.5
TOTAL	4.2	7.5	7.5	8.0

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 80-83, 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’s experience in hospital staffing and providing PET services.
- The applicant recruits appropriate staff through Novant Health’s established regional and corporate human resource departments.
- Clinical staff are required to complete orientation and training in their field and maintain continued competency.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section H, page 69, the applicant states that the staff of Nuclear Medicine Technologists and of Registered Nurses will each increase by one.

However, the applicant does not adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant does not provide projection utilization or provide any assumptions and a methodology used to project sufficient staff needed for the proposed project.
- The applicant did not provide pro forma financial statements for the first three full fiscal years of operation following completion of the project. Therefore, the applicant does not provide projected operating expenses that are adequately budgeted for the health manpower and management positions.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

- (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
Cone Health
Novant Health

NC
Piedmont

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Ancillary and Support Services

In Section I, page 91, the applicant identifies the necessary ancillary and support services for the proposed services. On page 91, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because Cone Health currently has ancillary and support services in place to support the operation of the hospital and the existing PET services that will be extended to the proposed project.

Coordination

In Section I, page 92, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on Cone Health's established relationships with other healthcare and social service providers which will continue to be in place upon the completion of the proposed project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Ancillary and Support Services

In Section I, page 84, the applicant identifies the necessary ancillary and support services for the proposed services. On page 84, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in

Exhibit I.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because Novant Health currently provides fixed PET services with ancillary and support services already in place.

Coordination

In Section I, pages 85-86, 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 Novant Health's existing relationships with local health care and social service providers. Novant Health is a well-established healthcare system in the community and collaborates with many organizations to improve the health and wellness in the community. Some of these partnerships include the YMCA, Senior Services, and Samaritan Ministries.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Ancillary and Support Services

In Section I, page 71, the applicant identifies the necessary ancillary and support services for the proposed services. In Exhibit 6, the applicant explains how Health Physics Services provided by Cardinal Health Pharmacies are available.

Coordination

In Exhibit 6, the applicant describes what Health Physics Services provide, however, the applicant does not provide any existing or proposed relationships with other local health care and social service providers. The applicant does not adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

- (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-All Applications

The applicants do 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-All 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.

C-All Applications

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section K, page 95, the applicant states that the project involves renovating 880 square feet of existing space. Line drawings are provided in Exhibit C.1-3.

On pages 95-96, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the applicant's proposal to develop the PET scanner in an existing space under development on land owned by Cone Health.

On page 96, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- Using PET for cardiac, oncological and neurological diagnostic imaging can reduce costs associated with invasive diagnostic and therapeutic procedures.
- The proposed project will be developed as part of Cone Health's large healthcare system.

On page 96, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.1-1.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section K. page 89, the applicant states that the project involves renovating 2,220 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 89-90 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant projects costs based on the cost of similar projects and construction cost data.
- The applicant is proposing to develop the PET scanner in an existing space that provides convenient access for staff and patients.
- In Exhibit K.3-I, the applicant provides the architect's certification of the proposed cost.

On page 90, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services because the development of proposed project will be consistent with the need of the population.

On page 90, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing

- Responses to comments

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

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section K, page 75, the applicant states that the project involves renovating 2,000 square feet of existing space. Line drawings are provided in Exhibit 7.

On page 75, the applicant explains why it believes that the cost, design and means of construction represent the most reasonable alternative for the proposal. However, the applicant does not adequately demonstrate that the cost, design and means of construction represents the most reasonable alternative based on the following:

- The applicant does not provide any alternative method that would meet the need for the fixed PET scanner.
- The applicant does not adequately demonstrate projected volumes that incorporate the concept of maximizing healthcare value for resources expended.
- The applicant does not project revenues that are based on reasonable and adequately supported assumptions.
- The applicant does not project operating expenses that are based on reasonable and adequately supported assumptions.

On page 75, the applicant explains why it believes that the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. However, the applicant does not adequately demonstrate that the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant does not adequately demonstrate projected volumes that incorporate the concept of maximizing healthcare value for resources expended.
- The applicant does not project revenues that are based on reasonable and adequately supported assumptions.
- The applicant does not project operating expenses that are based on reasonable and adequately supported assumptions.

The applicant fails to identify any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

- (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-All Applications

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section L, page 100, the applicant provides the historical payor mix during FY 2022 for Cone Health, as shown in the table below.

Cone Historical Payor Mix Last Full FY, FY 2022	
Payor Source	% of Total
Self-Pay	7.9%
Charity Care^	
Medicare*	37.4%
Medicaid*	20.5%
Insurance *	31.6%
Other^^	2.6%
Total	100.0%

*Including any managed care plans.

^The applicant does not include charity care as a payor source.

^^Other includes TRICARE and Workers Compensation.

On page 99 of the application, the applicant states that the Heart and Vascular Center on the MCH campus does not currently provide PET services. Historical payor mix is based on Cone Health’s historical payor mix.

In Section L, page 101, the applicant provides the following comparison.

Cone Health	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	62.0%	52.6%
Male	38.0%	47.4%
Unknown	0.0%	0.0%
64 and Younger	65.0%	83.8%
65 and Older	35.0%	16.2%
American Indian	0.3%	0.8%
Asian	1.2%	5.7%
Black or African American	35.0%	36.3%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	56.0%	47.5%
Other Race	7.2%	2.8%
Declined / Unavailable	0.2%	0.0%

*The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency

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.

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section L, page 93, the applicant provides the historical payor mix during CY 2022 for the proposed services, as shown in the table below.

NHFMC-PET Services Historical Payor Mix Last Full FY, CY 2022	
Payor Source	% of Total
Self-Pay	0.5%
Charity Care	1.6%
Medicare*	69.4%
Medicaid*	4.3%
Insurance *	22.5%
Other^	1.6%
Total	100.0%

*Including any managed care plans.

^Other included Other Govt, Institutional, Workers Comp.

In Section L, page 93, the applicant provides the following comparison.

NHFMC	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	58.3%	52.3%
Male	41.6%	47.7%
Unknown	0.0%	0.0%
64 and Younger	61.3%	82.8%
65 and Older	38.7%	17.2%
American Indian	0.3%	1.0%
Asian	0.6%	2.8%
Black or African American	22.2%	27.7%
Native Hawaiian or Pacific Islander	0.1%	0.2%
White or Caucasian	68.7%	54.8%
Other Race	5.5%	13.5%
Declined / Unavailable	2.6%	0.0%

*The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency

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.

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner
 The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section L, page 78, the applicant provides the historical payor mix during CY 2022 for the proposed services, as shown in the table below.

Piedmont Historical Payor Mix Last Full FY, CY 2022	
Payor Source	% of Total
Self-Pay	2.49%
Charity Care	
Medicare*	55.72%
Medicaid*	2.46%
Insurance *	39.12%
TRICARE	0.21%
Total	100.00%

*Including any managed care plans.

In Section L, page 79, the applicant provides the following comparison.

Piedmont	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	51.39%	51.95%
Male	48.61%	48.05%
Unknown	0.0%	0.0%
64 and Younger	72.89%	82.51%
65 and Older	27.11%	17.49%
American Indian	0.6%	0.89%
Asian	2.66%	3.41%
Black or African American	30.66%	25.74%
Native Hawaiian or Pacific Islander	0.37%	0.13%
White or Caucasian	61.19%	58.42%
Other Race-Hispanic/Latino	5.77%	11.14%
Declined / Unavailable	0.0%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing

- Responses to comments
- Information which was publicly available during the review and used by the Agency

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-All Applications

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 102, the applicant states:

“Cone Health has no obligation to provide a specific uncompensated care amount, community service, or access to care by medically underserved, minorities, or handicapped persons. However, as previously stated, Cone Health provides and will continue to provide services to all persons in need of medical care, regardless of income status, ability to pay, racial/ethnic origin, gender, age, physical or mental conditions, or any other characteristic that would classify a person as underserved or medically indigent.”

In Section L, page 103, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against Cone Health.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- Responses to comments

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

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 94, the applicant states that the facility or campus is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 94, the applicant states that during the 18 months immediately preceding the application deadline, 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
- Remarks made at the public hearing
- Responses to comments

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

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 80, the applicant states:

“Self Pay patients are offered 50% discount on services rendered. We offer handicap accessibility to clinic facility, offer Medicaid and Medicare services. We also offer patients a payment plan.”

In Section L, the applicant does not identify any patient civil rights access complaints that have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina during the 18 months immediately preceding the application deadline.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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
Cone Health
Novant Health

NC
Piedmont

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section L, page 104, 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.

MCH & Wesley Long Hospital PET Services Projected Payor Mix 3rd Full FY, CY 2028	
Payor Source	% of Total
Self-Pay	2.7%
Charity Care [^]	
Medicare*	71.3%
Medicaid*	3.7%
Insurance *	19.5%
Other ^{^^}	2.9%
Total	100.0%

*Including any managed care plans.

[^]The applicant does not include charity care as a payor Source.

^{^^}Other includes TRICARE and Workers Compensation.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.7% of total services will be provided to self-pay patients, 71.3% to Medicare patients and 3.7% to Medicaid patients.

On page 103, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- FY2022 historical payor mix of Cone Health patients that are expected to utilize PET services upon project completion.
- Wesley Long Hospital's existing PET patients that are expected to shift to the proposed PET scanner which includes SPECT imaging and Alzheimer's patients.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section L, page 95, 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.

NHFMC-PET Services Projected Payor Mix 3rd Full FY, CY 2028	
Payor Source	% of Total
Self-Pay	0.5%
Charity Care	1.6%
Medicare*	72.5%
Medicaid*	4.6%
Insurance *	18.8%
Other^	2.0%
Total	100.0%

*Including any managed care plans.

^Other included Other Govt, Institutional, Workers Comp.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.5% of total services will be provided to self-pay patients, 1.6% to charity care patients, 72.5% to Medicare patients and 4.6% to Medicaid patients.

On page 94, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on current utilization of PET services by procedure type provided by NHFMC.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section L, page 81, 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.

Piedmont Projected Payor Mix Third Full FY, CY 2025	
Payor Source	% of Total
Self-Pay	17.43%
Charity Care	
Medicare*	390.04%
Medicaid*	17.22%
Insurance *	273.84%
TRICARE	1.47%
Total	100.00%

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 17.43% of total services will be provided to self-pay patients, 390.04% to Medicare patients and 17.22% to Medicaid patients. However, the applicant's total percentage does not equal 100 percent payor mix.

The projected payor mix is not reasonable and adequately supported based on the following:

- The applicant did not provide the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project.
- The applicant's percentages of total services to be provided to each group are not adequately supported.

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is not 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
Cone Health
Novant Health

NC
Piedmont

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section L, page 105, 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
- Remarks made at the public hearing
- Responses to comments

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

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section L, page 98, 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
- Remarks made at the public hearing
- Responses to comments

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

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Section L of the application form requests that the applicant indicate the means by which a person will have access to the facility's services (e.g., physician referral, self-admission, etc.). However, the applicant failed to indicate the means by which a patient will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

- (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
Cone Health
Novant Health

NC
Piedmont

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section M, pages 107-108, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- Cone Health has well-established relationships with health professional training programs in the community and continues to work with those interested in establishing or expanding their clinical training programs.
- Cone Health partners with the University of North Carolina at Chapel Hill (UNCCH) to provide a Pediatric Primary Care residency and serves as a clinical rotation site for UNCCH students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area

In Section M, page 99, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant has existing clinical education agreements with health professional training programs at several colleges and universities in Forsyth County, as stated on page 99 of the application.
- NHFMC provides opportunities for medical and health science students to participate in realistic patient care situations that are required by health professional training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section M, page 83, the applicant describes the extent to which health professional training programs in the area will have access to the facility for clinical training purposes. The applicant states that Piedmont has worked with health professional training programs to meet their clinical needs and will continue as necessary. However, the applicant did not adequately demonstrate efforts made to establish relationships with these training programs. Therefore, the applicant does not adequately demonstrate that health professional training programs in the area will have access to the facility for training purposes.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

- (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.

C
 Cone Health
 Novant Health
 NC
 Piedmont

On page 360, the 2023 SMFP defines the service area for a fixed dedicated PET scanner as “the HSA in which it is located (Table 17F-1).” Cone Health (Project ID #G-12425-23) proposes to locate the proposed fixed PET scanner in Guilford County, which is in HSA II. Novant Health, (Project ID #G-12432-23) and Piedmont, (Project ID #G-12433-23) propose to locate the proposed fixed PET scanner in Forsyth County, which is also in HSA II. Thus, the service area for each proposal is HSA II. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing dedicated fixed PET scanners in HSA II, and the number of procedures for each PET scanner in 2020-2021 as found in Table 17F-1 on page 362 of the 2023 SMFP:

Facility	Planning Inventory	Procedures
ARMC	1	745
Cone Health	1	1,818
High Point Regional Health	1	1,013
North Carolina Baptist Hospital	2	3,216
Novant Health Forsyth Medical Center	1	2,742

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 110, the applicant states:

“The proposed project will enhance competition in the service area for fixed PET services by promoting value, safety, quality, and access to PET services...Cone Health considers its mission to be a leader in providing cost-efficient, high-quality

health care services to citizens in its service area in both inpatient and outpatient settings. As part of this mission, it makes these services available to all community residents, without regard for ability to pay. The additional capacity provided by the proposed project will increase access for all community members and improve the efficiency of delivering these services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 110, the applicant states:

“...the proposed project will increase capacity for this service. Increased capacity for this extremely useful diagnostic tool will allow for quicker and more accurate diagnostics, which can effectively reduce the need for unnecessary interventions and treatments related to heart and vascular disease as well as neurological and oncological disease.

Additionally, the radiotracers utilized for PET imaging have shorter half-lives than those used for SPECT imaging, resulting in scan times that typically only require 25 minutes versus three hours for a SPECT test. This allows much greater productivity and the ability to scan more patients per day with the same staffing and hours of operation, resulting in cost savings related to overall labor and operational expenses.”

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

Regarding the impact of the proposal on quality, in Section B, page 27, the applicant states:

Cone Health’s physicians and other providers work every day to improve the systems of care, which leverage information technology, multidisciplinary teams, and processes of care to deliver the right care at the right time to the right person. Cone Health receives frequent praise and awards for its high-quality care...

...

Cone Health provides excellent quality and safety for its patients. Cone Health has policies and procedures in place that maximize and maintain quality processes and measurements, and that encompass all its facilities. These policies assure high quality, cost-effective care is provided through a variety of mechanisms, including a Patient Safety Plan (Exhibit B.20-1), a Utilization Management Plan (Exhibit B.20-2), a Utilization Review Process (Exhibit B.20-3), Nondiscrimination in Provision of Services (Exhibit B.20-4), Patient Bill of Rights and Responsibilities (Exhibit B.20-5), a Quality and Performance Improvement Plan (Exhibit B.20-6) ...”

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 111, the applicant states:

“The proposed project will increase access to high quality services at Moses Cone Hospital. As part of its community-based mission, Cone Health makes these services available to all patients, regardless of their age, race, sex, creed, religion, disability, or ability to pay.

...Cone Health projects to provide 77.7 percent of PET services to Medicare, Medicaid, and Self-Pay patients. Cone Health also expects to provide charity care to more than 6,674 patients in the third year of operation...”

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:

- 1) 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.
- 2) 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
- 3) 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
- Remarks made at the public hearing
- 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.

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 101, the applicant states:

“...additional fixed PET capacity is needed at NHFMC to alleviate capacity constraints and accommodate the increasing demand for PET procedures. The proposed project will promote cost-effectiveness, quality, and access to services and therefore will promote competition in the service area because it will allow Novant Health to expand access services to fixed PET services, to better meet the needs of its existing patient population, and to reduce scheduling delays, and improve patient satisfaction.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 101, the applicant states:

“The nominal capital expenditure for this project is necessary to ensure that NHFMC will have the capacity to continue to provide high-quality services that are accessible to patients. Locating the additional fixed PET scanner within the NHFMC facility will facilitate economies of scale of existing facility space and support services, which is efficient and cost effective.

...

Novant Health is collaborating with payors and partners to identify payment models that match Novant Health’s value-based care delivery. Getting the right care in the right setting at the right price is the future of healthcare. It is what makes healthcare affordable and more sustainable. It is Novant Health’s approach to delivering remarkable healthcare so that people can get better and stay healthy.”

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 102, the applicant states:

“In today’s world, patients have choices – especially when it comes to healthcare. Having reliable and understandable information about the quality of care that Novant Health hospitals and outpatient centers provide can help patients make the best healthcare decisions possible. There are several national organizations that define the best ways to measure quality. These organizations use research and expert calculations to decide what data to gather, how to analyze it, and how to display the information. They set standards to ensure that any hospital that participates has reliable and accurate data. This information will help patients determine what level

of care they are receiving and will help us identify areas where we can grow and improve.

...

Novant Health is committed to delivering high-quality care at all of its facilities. Novant Health has quality-related policies and procedures that are applicable to NHFMC.”

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, pages 102-103, the applicant states:

“Novant Health will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. Novant Health’s financial assistance policy will apply to the proposed services.”

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:

- 1) 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.
- 2) 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
- 3) 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

- Remarks made at the public hearing
- 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 all the reasons described above.

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Regarding the expected effects of the proposal on competition in the service area, in Exhibit 1, the applicant states:

“Due to high demand by subspecialties of medicine at the current time cardiology has very limited access to this technology (once a week) and therefore this is the rate limiting factor in providing care to citizens of the Piedmont Triad community.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 84, the applicant states:

“By having a PET/CT in clinical will provide insight on the right treatment at the right time in providing accurate care pathway. This will improve downstream costs by avoiding i.e. Cath lab, or CV surgery unless medically necessary.”

See also any exhibits.

Regarding the impact of the proposal on quality, in Exhibit 1, the applicant states:

“Our vision is to provide our patients with accurate, high quality, time appropriate, cost-effective, and safe cardiovascular care. In order to deliver this we currently have within our community several diagnostic modalities...”

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Exhibit 1, the applicant states:

“If the certificate of need is approved it will neither duplicate the current resources nor monopolize or polarize patient care. On the contrary it will promote equitable access to healthcare.”

See also Section L of the application and any exhibits.

The applicant does not adequately describe the expected effects of the proposed services on competition in the service area or 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 discussions regarding need, including projected utilization, financial feasibility, and unnecessary duplication of services in Criteria (3), (5) and (6), respectively.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- 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.

- (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-All Applications

G-12425-23 / Cone Health / Acquire one fixed PET scanner

The applicant proposes to acquire one fixed PET scanner, pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section Q, Form O, page 16, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of two hospitals located in North Carolina.

In Section O, page 115, the applicant states that, during the 18 months immediately preceding the submittal of the application, Cone Health received a notification from the Agency regarding a finding of immediate jeopardy. The applicant states that as of the date of this application, Cone Health has not made a decision nor waived its right to challenge the determination. 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, incidents related to quality of care had not occurred in any of these facilities. 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 both facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

G-12432-23 / Novant Health / Acquire one fixed PET scanner

The applicant proposes to acquire a second fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section Q, page 125, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 19 hospitals located in North Carolina.

In Section O, page 106, the applicant states that, during the 18 months immediately preceding the submittal of the application, “*Novant Health New Hanover Regional Medical Center (NH New Hanover) had a finding of immediate Jeopardy identified June 24, 2022. The North Carolina State Survey Agency complaint investigation survey was concluded on June 29, 2022.*” The applicant states that the finding was related to the evaluation and supervision of care of two patients in the Emergency Department. However, the facility was determined to be in compliance as of August 22, 2022. 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, incidents related to quality of care had not occurred in any of the 19 facilities. 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 all 19 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

G-12433-23 / Piedmont Cardiovascular, P.A. / Acquire one fixed PET scanner

The applicant proposes to acquire a fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

In Section O, the applicant does not identify any other diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 86, the applicant states that SPECT services are not owned, operated or managed by Piedmont. Imaging services are contracted as an outside service. In Exhibit 9, the applicant provides documentation of license, certified participation in Medicare/Medicaid, and accreditation. After reviewing and considering information provided by the applicant, the applicant 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
Cone Health
Novant Health

NC
Piedmont

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 fixed PET scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

(1) *identify the existing fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed fixed PET scanner service area;*

-C- Cone Health. The applicant or related entity owns and operates two existing fixed PET scanners in the proposed fixed PET scanner service area. One fixed PET scanner is located at Alamance Regional Medical Center and the other unit is located at Wesley Long Hospital.

-C- Novant Health. The applicant or related entity owns and operates one existing fixed PET scanner in the proposed fixed PET scanner service area. The fixed PET scanner is located at Novant Health Forsyth Medical Center.

-NA- Piedmont. The applicant nor any related entity owns nor operates any existing fixed PET scanners in the proposed fixed PET scanner service area.

(2) *identify the approved fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed fixed PET scanner service area;*

-NA- Cone Health. The applicant nor any related entity owns nor operates an approved fixed PET scanner in the proposed fixed PET scanner service area.

-NA- Novant Health. The applicant nor any related entity owns nor operates an approved fixed PET scanner in the proposed fixed PET scanner service area.

-NA- Piedmont The applicant nor any related entity owns nor operates an approved fixed PET scanner in the proposed fixed PET scanner service area.

(3) *identify the existing mobile PET scanners owned or operated by the applicant or a related entity that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period;*

-NA- Cone Health. The applicant nor any related entity owns nor operates a mobile PET scanner in the proposed fixed PET scanner service area.

-C- Novant Health. The applicant or related entity owns and operates one existing mobile PET scanner at Novant Health Forsyth Medical Center. The following table illustrates the mobile PET scanner hosts sites and the number of scans performed during CY2022.

NHFMC Mobile PET Host Site Facility	County	HSA	CY2022 PET Scans
Novant Health Huntersville Medical Center	Mecklenburg	III	901
Novant Health Kernersville Medical Center	Forsyth	II	438
Novant Health Matthews Medical Center	Mecklenburg	III	692
Novant Health Mint Hill Medical Center	Mecklenburg	III	194
Novant Health Rowan Medical Center Julian Road	Rowan	III	395
NHFMC Mobile PET Scans			2,620

-NA- Piedmont. The applicant nor any related entity owns nor operates a mobile PET scanner in the proposed fixed PET scanner service area.

(4) *identify the approved mobile PET scanners owned or operated by the applicant or a related entity that will provide services at host sites located in the proposed fixed PET scanner service area;*

-NA- Cone Health. The applicant nor any related entity owns nor operates an approved mobile PET scanner in the proposed fixed PET scanner service area.

-NA- Novant Health. The applicant nor any related entity owns nor operates an approved mobile PET scanner in the proposed fixed PET scanner service area.

-NA- Piedmont. The applicant nor any related entity owns nor operates an approved mobile PET scanner in the proposed fixed PET scanner service area.

(5) *provide projected utilization of the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner during each of the first three full fiscal years of operation following completion of the project;*

Projected Utilization				
	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	4/1/2025- 9/30/2025	FY 2026	FY 2027	FY 2028
Moses Cone Hospital				
#PET Scanners	1	1	1	1
# of Procedures	790	2,059	2,399	2,718
Wesley Long Hospital				
#PET Scanners	1	1	1	1
# of Procedures	2,279	2,059	2,399	2,718
ARMC				
#PET Scanners	1	1	1	1
# of Procedures	1,089	1,132	1,177	1,224

Source: Section Q, Form C.2b

NHFMC				
Projected Utilization				
	Partial FY	Project Year 1	Project Year 2	Project Year 3
	4/1/25-12/31/25	CY 2026	CY 2027	CY 2028
#PET (fixed) Scanners	2	2	2	2
# of Procedures	2,504	3,608	3,923	4,289
#PET (mobile) Scanners	1	1	1	1
# of Procedures	2,729	3,639	3,639	3,639

Source: Section Q, page 110

- NC- **Piedmont.** The applicant did not provide projected utilization of the proposed fixed PET scanner during each of the first three full fiscal years of operation following completion of the project.
 - (6) *provide the assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph; and*

- C- **Cone Health** In Section Q, Form C Utilization-*Methodology and Assumptions*, pages 1-8, the applicant provides assumptions and methodology used to project utilization of the existing and proposed PET scanners.

- C- **Novant Health** In Section Q, pages 111-118, the applicant provides assumptions and methodology used to project utilization of the existing and proposed PET scanners.

- NC- **Piedmont.** The applicant did not provide the assumptions nor methodology used to project utilization of the proposed fixed PET scanner.
 - (7) *project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.*

- C- **Cone Health** In Section Q, Form C.2b, page 5, the applicant projects that the proposed fixed PET scanner and the existing fixed PET scanners will perform 2,220 scans per pet scanner during the third full fiscal year of operation following project completion.

Facility	FY28 (PY3)
Wesley Long Hospital	2,718
MCH	2,718
ARMC	1,224
Total PET Procedures	6,659
Total PET Scanners	3
Average Procedures per PET Scanner	2,220

-C- Novant Health. In Section Q, page 110, the applicant projects that the existing and proposed PET scanners will perform 2,643 procedures per scanner during the third full fiscal year of operation following project completion.

NHFMC	FY28 (PY3)
Fixed PET Scanners	4,289
Mobile PET Scanner	3,639
Total PET Procedures	7,928
Total PET Scanners	3
Average Procedures per PET Scanner	2,643

-NC- Piedmont. The applicant did not provide projected utilization of the proposed fixed PET scanner during each of the first three full fiscal years of operation following completion of the project.

- (b) *An applicant proposing to acquire a mobile PET scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*
- (1) *identify the existing mobile PET scanners owned or operated by the applicant or a related entity that provided services at host sites located in the proposed mobile PET scanner service area during the 12 months before the application deadline for the review period;*
 - (2) *identify the approved mobile PET scanners owned or operated by the applicant or a related entity that will provide services at host sites located in the proposed mobile PET scanner service area during the first three full fiscal years following completion of the project;*
 - (3) *identify the existing fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed mobile PET scanner service area;*
 - (4) *identify the approved fixed PET scanners owned and operated by the applicant or a related entity and located in the proposed mobile PET scanner service area;*
 - (5) *identify the existing and proposed host sites for each mobile PET scanner identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile PET scanner;*
 - (6) *provide projected utilization of the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile PET scanner during each of the first three full fiscal years of operation following completion of the project;*

- (7) *provide the assumptions and methodology used to project the utilization required by Subparagraph (6) of this Paragraph; and*
- (8) *project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.*

-NA- Cone Health. The applicant does not propose to acquire a mobile PET scanner.

-NA- Novant Health. The applicant does not propose to acquire a mobile PET scanner.

-NA- Piedmont. The applicant does not propose to acquire a mobile PET scanner.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2023 State Medical Facilities Plan, no more than one fixed PET scanner may be approved for Health Service Area II in this review. Because the three applications in this review collectively propose to develop three additional fixed PET scanners to be located in Health Service Area II, all three applications cannot be approved for the total number of fixed PET 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 could be approved.

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

G-12425-23 / **Cone Health** / Acquire one fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

G-12432-23 / **Novant Health** / Acquire one fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

G-12433-23 / **Piedmont** / Acquire one fixed PET scanner pursuant to the 2023 need determination for one fixed PET scanner in HSA II service area.

Conformity with Statutory and Regulatory Review Criteria

The applications submitted by **Cone Health** and **Novant Health** are conforming with all applicable statutory and regulatory review criteria.

However, the application submitted by **Piedmont** is not conforming with all applicable statutory and regulatory review criteria. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, regarding this comparative factor, the applications submitted by **Cone Health** and **Novant Health** are equally effective alternatives.

Scope of Services

Regarding scope of services, all three applications were submitted in response to the need determination for one fixed PET scanner in HSA II in the 2023 State Medical Facilities Plan (SMFP). Generally, the application proposing to provide the broadest scope of services with the proposed equipment is the more effective alternative regarding this comparative factor.

The following table compares the scope of services proposed to be offered by each applicant on the proposed fixed PET scanner:

Facility	Proposed Scope of Proposed Scope of PET Services		
	Oncological PET	Cardiac PET	Neurologic PET
Cone Health	X	X	X
Novant Health	X	X	X
Piedmont		X	

Cone Health and **Novant Health** propose to provide PET services to oncology, cardiac and neurologic patients. **Piedmont** proposes to provide cardiac PET services. **Piedmont** does not comply with all applicable statutory and regulatory criteria and therefore is not approvable. Therefore, regarding scope of services, the applications submitted by **Cone Health** and **Novant Health** are equally effective alternatives.

Historical Utilization

The following table illustrates historical utilization of the existing fixed PET scanners in HSA II as provided in the 2023 and 2024 SMFPs representing FY2021 and FY2022 reported utilization:

Facility	Planning Inventory	Procedures	
		2023 SMFP	2024 SMFP
ARMC	1	745	809
Cone Health (Welsey Long Hospital)	1	1,818	1,991
High Point Regional Health	1	1,013	1,223
North Carolina Baptist Hospital	2	3,216	3,367
Novant Health Forsyth Medical Center	1	2,742	2,500

Source: 2023 and 2024 SMFPs

Cone Health and **Novant Health** are current and historical providers of fixed PET services in HSA II in this review. **Piedmont** does not currently provide fixed PET services. **Piedmont** does not comply with all applicable statutory and regulatory criteria and therefore is not approvable. As illustrated in the table above, **Novant Health** had the highest number of procedures per fixed PET scanner in FY2021 and FY2022, respectively. Therefore, regarding historical utilization, the application submitted by **Novant Health** is the more effective alternative.

Geographic Accessibility (Location within the Service Area)

The 2023 SMFP identifies the need for one fixed PET scanner in HSA II, which includes 11 counties. The following table illustrates the location of the existing and approved fixed PET scanners in HSA II:

Facility	City	County
ARMC	Burlington	Alamance
Cone Health (Wesley Long Hospital)	Greensboro	Guilford
High Point Regional Health	High Point	Guilford
North Carolina Baptist Hospital	Winston-Salem	Forsyth
Novant Health Forsyth Medical Center	Winston-Salem	Forsyth

Source: 2023 SMFP

Cone Health proposes to locate its fixed PET scanner on the Moses Cone Hospital campus in Greensboro which is approximately 3.0 miles from the existing PET scanner located at Wesley Long Hospital (licensed under Cone Health) and 0.8 miles from the existing PET scanner located at High Point Regional Health in Guilford County. **Novant Health** proposes to locate its fixed PET scanner in the radiology department at NHFMC in Winston-Salem which is approximately 2.4 miles from North Carolina Baptist Hospital in Forsyth County. **Piedmont** proposes to locate its fixed PET scanner at its existing diagnostic center in Greensboro which is approximately 3.9 miles from Wesley Long Hospital and 1.5 miles from High Point Regional Health in Guilford County. Generally, the application proposing to locate the fixed PET scanner in an area that would serve more patients would be the most effective alternative. However, there is no significant difference in the distance to an existing PET scanner each applicant is proposing to locate their proposed fixed PET scanner within their respective county. Additionally, Forsyth and Guilford counties are located in the center of HSA II. Eight of the surrounding counties in HSA II are contiguous to either Forsyth or Guilford County where there are five existing PET scanners. **Piedmont** does not comply with all applicable statutory and regulatory criteria and therefore is not approvable. Therefore, regarding this comparative factor, the applications submitted by **Cone Health** and **Novant Health** are equally effective alternatives.

Access by Service Area Residents

On page 360, the 2023 SMFP defines the service area for fixed PET scanners as follows: “A fixed PET scanner’s service area is the HSA in which it is located (Table 17F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” According to Appendix A, HSA II is comprised of 11 counties, including Forsyth and Guilford. **Cone Health** and **Piedmont** propose locating the fixed PET scanner in Greensboro, in Guilford County. **Novant Health** proposes locating its fixed PET scanner in Winston-Salem, in Forsyth County. Thus, the service area for each proposal is HSA II. 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 fixed PET services in or in close proximity to the service area in which they live. Each applicant proposes to serve counties located within HSA II and outside of HSA II. This analysis will focus on service to residents of counties within HSA II, the service area in which a need determination exists.

On page 39 of its application, **Cone Health** states it proposes to offer PET services in 10 of the 11 HSA II counties. The other NC counties and out of state areas comprising its proposed service area are not being considered for this comparative factor.

On page 32 of its application, **Novant Health** states it proposes to offer PET services in the majority of the HSA II counties. The other NC counties and out of state areas comprising its proposed service area are not being considered for this comparative factor.

On page 41 and Exhibit 2 of its application, **Piedmont** states it proposes to offer PET services in 10 of the 11 HSA II counties. The other NC counties and out of state areas comprising its proposed service area are not being considered for this comparative factor.

Each applicant provides the projected number of service area patients to be served in each of the fiscal years following project completion. The Project Analyst prepared the following tables to illustrate the projected number of service area patients to be served by each applicant in each applicant's three project years following project completion:

Cone Health*						
PET Services						
Projected Patient Origin						
County	1st Full FY		2nd Full FY		3rd Full FY	
	10/1/25 to 09/30/26		10/1/26 to 09/30/27		10/1/27 to 09/30/28	
	FY2026		FY2027		FY2028	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Guilford	2,584	62.7%	2,956	61.6%	3,306	60.8%
Rockingham	545	13.2%	638	13.3%	723	13.3%
Randolph	334	8.1%	403	8.4%	465	8.5%
Forsyth	81	2.0%	92	1.9%	103	1.9%
Alamance	229	5.6%	317	6.6%	400	7.4%
Other^	344	8.4%	392	8.2%	437	8.0%
Total	4,118	100.0%	4,799	100.0%	5,435	100.0%

Source: Section C, page 39

*Moses Cone (proposed PET Scanner) and Wesley long campus (existing PET Scanner)

^Includes 36 other counties and other states.

NHFMC PET Services Projected Patient Origin						
County	1 st Full FY		2 nd Full FY		3 rd Full FY	
	1/1/26 to 12/31/26		1/1/27 to 12/31/27		1/1/28 to 12/31/28	
	CY2026		CY2027		CY2028	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Forsyth	1,584	43.9%	1,744	44.5%	1,935	45.1%
Davidson	389	%.8%	442	11.3%	506	11.8%
Stokes	281	7.8%	296	7.5%	312	7.3%
Surry	297	8.2%	313	8.0%	329	7.7%
Yadkin	224	6.2%	236	6.0%	249	5.8%
Davie	234	6.5%	249	6.4%	266	6.2%
Wilkes	131	3.6%	137	3.5%	145	3.4%
Guilford	158	4.4%	167	4.3%	178	4.1%
Other^	311	8.6%	338	8.6%	369	8.6%
Total	3,608	100.0%	3,923	100.0%	4,289	100.0%

Source: Section C, page 32

^Includes <1 percent patient origin from the remaining counties in North Carolina and other states.

Piedmont Projected Patient Origin						
County	1 st Full FY		2 nd Full FY		3 rd Full FY	
	1/1/22 to 12/31/22		1/1/24 to 12/31/24		1/1/25 to 12/31/25	
	CY2022*		CY2024		CY2025	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Guilford	3,662	83.49%	3753.55	86.21%	3941.2275	86.21%
Rockingham	257	5.86%	263.425	6.05%	276.59625	6.05%
Randolph	168	3.83%	172.2	3.95%	180.81	3.95%
Forsyth	80	1.80%	80.975	1.86%	85.02375	1.86%
Alamance	54	1.23%	55.35	1.27%	58.1175	1.27%
Davidson	28	.64%	28.7	.66%	30.135	.66%
Other	137	3.12%	0	0	0	0
Total	4,386	100.0%	4354.2	100.0%	4,571.91	100.0%

Source: Section C, page 41, Exhibit 2

*The Project Analyst assumes that the first project year as CY 2022 is a typographical error.

Project Analyst's calculation in brackets.

Cone Health, Novant Health and Piedmont identify a category (“*other*”) that includes residents from other counties and other states. In Exhibit 2, **Piedmont** provides the number of patients served included in “*other*” in each of the HSA II counties. However, the Project Analyst

is unable to discern, from the information provided by **Cone Health** and **Novant Health**, how many patients are included in “*other*” that may be part of the defined service area. **Piedmont** does not comply with all applicable statutory and regulatory criteria and therefore is not approvable. Therefore, regarding this comparative factor, the results are inconclusive.

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 handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”

For access by underserved groups, applications are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is evaluated as a separate factor.

Projected Access by Medicare Recipients

For each applicant in this review, the following table compares the total number of Medicare patients as a percentage of total patients in the third full fiscal year of operations. Generally, the application proposing the highest number of Medicare patients as a percentage of total patients is the more effective alternative with regard to this comparative factor.

3rd Full FY		
Applicant	Total Number Patients	Patient as a percentage of Total Patients
Cone Health	5,436.00	71.3%
Novant Health	4,289.00	72.5%
Piedmont	4,571.91	390.04%

Source: Section L.3 and Form C.2b of the applications

As shown in the table above, **Piedmont** projects to serve the highest percentage of Medicare patients in the third full fiscal year of operation. However, Piedmont’s percentages are not reasonable. The applicant did not provide the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The applicant’s percentages of total services to be provided to each group are not adequately supported. Moreover, **Piedmont** does not comply with all applicable statutory and regulatory criteria and therefore is not approvable. Therefore, the application submitted by **Novant Health** is the most effective alternative with regard to projected access by Medicare recipients.

Projected Access by Medicaid Recipients

For each applicant in this review, the following table compares the total number of Medicaid patients as a percentage of total patients in the third full fiscal year of operations. Generally, the application proposing the highest number of Medicaid patients as a percentage of total patients is the more effective alternative with regard to this comparative factor.

3rd Full FY		
Applicant	Total Number Patients	Patient as a percentage of Total Patients
Cone Health	5,436.00	20.5%
Novant Health	4,289.00	4.6%
Piedmont	4,571.91	17.22%

Source: Section L.3 and Form C.2b of the applications

As shown in the table above, **Cone Health** projects to serve the highest percentage of Medicaid patients in the third full fiscal year of operation. **Piedmont** does not comply with all applicable statutory and regulatory criteria and therefore is not approvable. Therefore, regarding this comparative factor, the application submitted by **Cone Health** is the more effective alternative.

Competition (Access to a New or Alternate Provider)

Generally, the application proposing to increase competition in the service area is the more effective alternative regarding this comparative factor. The introduction of a new provider in the service area would be the more 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. **Piedmont** represents a new provider of fixed PET services in HSA II. However, the application submitted by **Cone Health** proposes to develop its fixed PET scanner in Greensboro, which is currently served by one existing fixed PET scanner and will be served by an approved fixed PET scanner. **Novant Health** proposes to develop its fixed PET scanner in Winston-Salem, which is currently served by three existing fixed PET scanners and will be served by an approved fixed PET scanner. Therefore, regarding this comparative factor, the application submitted by **Piedmont** is the more effective alternative because it introduces a new provider of fixed PET services in the service area. However, **Piedmont** does not comply with all applicable statutory and regulatory criteria and therefore is not approvable. Therefore, regarding this comparative factor, the applications submitted by **Cone Health** and **Novant Health** are equally effective alternatives.

Projected Average Net Revenue per PET Scan

The following table compares projected average net revenue per PET scan in the third full fiscal year following project completion for each project, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, the application proposing the lowest average net revenue per PET scan is the more effective alternative regarding this comparative factor, assuming the average net revenue per procedure could ultimately result in a lower cost to the patient or third-party payor.

3rd Full FY			
	Total # of PET scans	Total Net Revenue	Average Net Revenue / PET Scan
Cone Health	5,436.00	\$17,964,517	\$3,305
Novant Health	4,289.00	\$13,038,363	\$3,040
Piedmont	4,571.91		

Cone Health provided projected revenues (Form F.2b) for its existing fixed PET scanner located at Wesley Long Hospital and the proposed fixed PET scanner to be located on the Moses Cone Hospital campus. **Novant Health** provided projected net revenues (Form F.2b) for the existing and proposed fixed PET scanners located at the Novant Health Forsyth Medical Center. As shown in the table above, **Novant Health** projects the lowest average Net Revenue per PET scan in the third full fiscal year following project completion. However, **Piedmont** does not provide its projected net revenue nor the projected number of PET scans in the third full fiscal year following project completion for each project. The total number of PET scans in the table above is representative of the applicant’s total number of patients projected to serve in the third year. **Piedmont** does not comply with all applicable statutory and regulatory criteria and therefore is not approvable. Therefore, the application submitted by **Novant Health** is the most effective alternative with regard to this comparative factor.

Projected Average Operating Expense per PET Scan

The following table compares projected average operating expense per PET scan in the third full fiscal year following project completion, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, the application proposing the lowest average operating expense per PET scan is the more effective alternative regarding this comparative factor, assuming the average net revenue per scan could ultimately result in a lower cost to the patient or third-party payor.

3rd Full FY			
	Total # of PET scans	Total Operating Cost	Average Operating Cost / PET Scan
Cone Health	5,436.00	\$7,768,234	\$1,429
Novant Health	4,289.00	\$6,822,152	\$1,591
Piedmont	4,571.91		

Cone Health provided projected operating costs (Form F.2b) for its existing fixed PET scanner located at Wesley Long Hospital and the proposed fixed PET scanner to be located on the Moses Cone Hospital campus. **Novant Health** provided projected operating cost (Form F.2b) for the existing fixed PET scanner and proposed fixed PET scanner located at the Novant Health Forsyth Medical Center. As shown in the table above, **Cone Health** projects the lowest average operating cost per PET scan in the third full fiscal year following project completion. However,

Piedmont does not provide its projected net operating cost for the proposed fixed PET scanner. **Piedmont** does not comply with all applicable statutory and regulatory criteria and therefore is not approvable. Therefore, the application submitted by **Cone Health** is the most effective alternative with regard to this comparative factor.

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 as they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	Cone Health	Novant Health	Piedmont
Conformity with Statutory and Regulatory Review Criteria	Equally Effective	Equally Effective	Not Approvable
Scope of Services	Equally Effective	Equally Effective	Not Approvable
Historical Utilization	Less Effective	Most Effective	Not Approvable
Geographic Accessibility	Equally Effective	Equally Effective	Not Approvable
Access by Service Area Residents	Inconclusive	Inconclusive	Not Approvable
Access by Medicare Recipients	Less Effective	Most Effective	Not Approvable
Access by Medicaid Recipients	Most Effective	Less Effective	Not Approvable
Competition (Access to a New or Alternate Provider)	Equally Effective	Equally Effective	Not Approvable
Projected Average Net Revenue per PET Scan	Less Effective	Most Effective	Not Approvable
Projected Average Operating Expense per PET Scan	Most Effective	Less Effective	Not Approvable

As shown in the table above, the application submitted by **Cone Health** was determined to be a more effective alternative regarding the following factors:

- Access by Medicaid Recipients
- Projected Average Operating Expense per PET Scan

The application submitted by **Novant Health** was determined to be a more effective alternative regarding the following factors:

- Historical Utilization
- Access by Medicare Recipients
- Projected Average Net Revenue per PET Scan

DECISION

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **Novant Health** is the more effective alternative proposed in this review for the development of one fixed PET scanner in HSA II pursuant to the need determination in the 2023 SMFP.

However, the application submitted by **Piedmont** is not approvable and therefore cannot be considered an effective alternative. Consequently, the application submitted by **Piedmont** is denied.

While the application submitted by **Cone Health** is approvable standing alone, the approval of two applications would result in the approval of more fixed PET scanners than is determined to be needed, and therefore, the applications submitted by **Cone Health** is denied.

Novant Health proposes to acquire one fixed PET scanner pursuant to the need determination in the 2023 SMFP. The application submitted by **Novant Health** is approved subject to the following conditions:

1. **Novant Health (hereinafter 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 fixed PET scanner pursuant to the need determination in the 2023 SMFP, to be located at Novant Health Forsyth Medical Center in Winston-Salem, for a total of no more than two fixed PET scanners.**
3. **The certificate holder shall 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.**
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. **The first progress report shall be due on August 1, 2024.**
5. **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.**
 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.**