

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 24, 2022

Findings Date: March 24, 2022

Project Analyst: Tanya M. Saporito

Co-Signer: Gloria C. Hale

COMPETITIVE REVIEW

Project ID #: O-12143-21
Facility: Novant Health New Hanover Regional Medical Center Scotts Hill Hospital
FID #: 200732
County: New Hanover
Applicant(s): Novant Health, Inc., Novant Health New Hanover Regional Medical Center, LLC
Project: Acquire one fixed PET/CT scanner pursuant to the need determination in the 2021 SMFP

Project ID #: O-12150-21
Facility: Wilmington Health on Medical Center Drive
FID #: 210833
County: New Hanover
Applicant: Wilmington Health, PLLC
Project: Acquire one fixed PET/CT scanner pursuant to the need determination in the 2021 SMFP

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of both 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 – Both Applications

Need Determination

The 2021 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed PET/CT scanners in North Carolina by service area. Application of the need methodology in the 2021 SMFP identified a need for one additional fixed PET/CT scanner in Health Service Area (HSA) V. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) proposing to develop a total of two new fixed PET/CT scanners in HSA V. However, pursuant to the need determination, only one fixed PET/CT scanner may be approved in this review.

Policies

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

Policy GEN-3

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

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

Policy GEN-4

Policy GEN-4 on page 29 of the 2021 SMFP states:

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

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

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of 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."

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC (hereinafter referred to as "the applicant" or "NHNHRMC") operates New Hanover Regional Medical Center in Wilmington, an acute care hospital that provides tertiary services, including services related to PET imaging, such as oncology, neurology and cardiac services. NHNHRMC was awarded a certificate of need in April 2021 to develop an acute care hospital, NHRMC-Scotts Hill, on a campus that currently offers outpatient emergency services, ambulatory surgery services, and diagnostic imaging services. In this application, the applicant proposes to acquire one fixed PET scanner which will also be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. On page 37 of the application, the applicant states the proposed PET scanner will help to address existing PET capacity issues at the NHRMC Medical Mall location in Wilmington and will address patient needs in the Scotts Hill area, north of downtown Wilmington. Following project completion, NHNHRMC would be licensed for two fixed PET scanners: one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

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

Policy GEN-3. In Section B, pages 27-35 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 greater than \$5 million. In Section B, page 36, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

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 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 and Policy GEN-4 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of PET services in the HSA V service area;
 - The applicant adequately documents how the project will promote equitable access to PET services in the HSA V service area;
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

O-12150-21 Wilmington Health, PLLC (hereinafter referred to as “the applicant” or “Wilmington Health”) proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2021 SMFP for a total of one fixed PET scanner. The applicant proposes to develop the PET scanner in renovated space in an existing physician practice, Wilmington Health on Medical Center Drive in Wilmington from which the applicant currently provides cardiology, primary care, gastroenterology, podiatry and orthopedic services.

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

Policy GEN-3. In Section B, pages 28-32 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 less than \$2 million; therefore, Policy GEN-4 does not apply. However, in Section B, pages 32-33, the applicant describes the project's plan to improve energy efficiency and conserve water.

The Agency reviewed the:

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

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

- The applicant does not propose to acquire more than one fixed PET/CT 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 the HSA V service area;
 - The applicant adequately documents how the project will promote equitable access to PET services in the HSA V service area; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended

(2) Repealed effective July 1, 1987.

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

C - NHRMC
NC - WH

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant proposes to acquire one fixed PET scanner which will be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHRMC would be licensed for two fixed PET scanners; one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

On page 37, the applicant describes the project as follows:

“In April 2021, NHRMC was approved (Project ID# O-11947-20) to build an acute care hospital on the Scotts Hill Campus (or ‘NHRMC-Scotts Hill’) wherein the existing [free standing emergency department] and hospital-based outpatient imaging department (HOPD), NHRMC Health & Diagnostics-North Campus, will become part of Scotts Hill Hospital. The proposed fixed PET unit will serve as part of an expanded imaging suite of services that will connect to and also serve the community hospital project. NHRMC-Scotts Hill is slated to open in October 2024. The proposed fixed PET unit will address the immediate outpatient PET needs for the rapidly growing Scotts Hill and surrounding community that cannot be adequately addressed with the current PET capacity at Medical Mall, and once NHRMC-Scotts

Hill opens, the unit will be part of the hospital's radiology department, offering hospital-based PET services."

Patient Origin

On page 367, the 2021 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." (emphasis in original) The applicant proposes to locate the fixed PET scanner in New Hanover County which, according to Appendix A on page 373 is in HSA V. Thus, the service area for this proposal is HSA V. Facilities may also serve residents of counties not included in their service area.

The applicant currently offers PET services at the NHRMC Medical Mall campus in central Wilmington. The following table illustrates historical patient origin for PET services at the Medical Mall location and projected patient origin for Scotts Hill PET services, from pages 44 and 46, respectfully:

COUNTY /ZIP CODE	HISTORICAL – NHRMC MEDICAL MALL OCTOBER 1, 2019 – SEPTEMBER 30, 2020	
	PATIENTS	% OF TOTAL
28405-New Hanover	166	5.9%
28411-New Hanover	162	5.8%
28443-Pender	126	4.5%
28401-New Hanover	120	4.3%
28425-Pender	62	2.2%
28457-Pender	53	1.9%
28429-New Hanover	45	1.6%
28445-Onslow	31	1.1%
28435-Pender	14	0.5%
28480-New Hanover	5	0.2%
Primary Service Area	784	28.0%
Other New Hanover	626	22.4%
Other Pender	70	2.5%
Other Onslow	127	4.5%
Duplin	83	3.0%
Brunswick	893	31.9%
Columbus	94	3.4%
Bladen	41	1.5%
Sampson	18	0.6%
Secondary Service Area	1,952	69.8%
All Other NC	35	1.3%
Out of State	25	0.9%
Total	2,796	100.0%

Source: Application page 44

COUNTY /ZIP CODE	PROJECTED – NHRMC SCOTTS HILL OCTOBER 1, 2025 – SEPTEMBER 30, 2026	
	PATIENTS	% OF TOTAL
28401-New Hanover	38	1.5%
28405-New Hanover	41	1.6%
28411- New Hanover	49	2.0%
28429- New Hanover	16	0.7%
28480- New Hanover	3	0.1%
28425-Pender	33	1.3%
28435- Pender	19	0.8%
28443-Pender	15	0.6%
28457- Pender	8	0.3%
28445-Onslow	5	0.2%
Primary Service Area	228	9.1%
Other New Hanover	703	28.2%
Other Pender	20	0.8%
Other Onslow	34	1.4%
Duplin	20	0.8%
Brunswick	1,238	49.6%
Columbus	112	4.5%
Bladen	36	1.4%
Sampson	17	0.7%
Secondary Service Area	2,181	87.4%
All Other NC	66	2.6%
Out of State	20	0.8%
Total	2,494	100.0%

Source: Application page 46

In Section C, page 44, the applicant provides the assumptions and methodology used to project its patient origin which is based on the applicant’s experience in providing PET services on its existing PET scanner.

The applicant’s assumptions are reasonable and adequately supported because they are based on historical patient origin for the applicant’s other PET scanner located at NHRMC Medical Mall in HSA V.

Analysis of Need

In Section C.4, pages 47-83, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- There is a need determination in the 2021 SMFP for one additional PET scanner in HSA V, and the applicant proposes to locate the proposed PET scanner at the NHRMC Scotts Hill cancer center campus in northern Wilmington in HSA V.

- Need for additional PET capacity in HSA V – the applicant states the utilization of its existing PET scanner at the NHRMC Medical Mall is what generated the need for the PET scanner identified in the 2021 SMFP for HSA V. The applicant states the existing PET scanner is primarily utilized for oncology scans, though PET scans are used to diagnose and stage oncology, cardiac and neurologic conditions. Locating the proposed PET scanner at the Scotts Hill cancer center campus will permit the applicant to improve accessibility to oncology PET services for a greater population that needs those services and will help to alleviate existing capacity constraints. (pages 47-48)
- Established and highly utilized oncology and cardiac services – The applicant states NHRMC currently operates the Zimmer Cancer Center, accredited as a Teaching Hospital Cancer Program by the American College of Surgeon’s Commission on Cancer. As such, its cancer program and its PET scanner are highly utilized. Despite the impact of COVID-19 on the hospital, NHRMC experienced an increase in PET and linear accelerator utilization during FY 2020. The applicant also states the cardiac program at NHRMC is highly utilized. Further, NHRMC is one of three state-certified Level II trauma centers and joined the Novant Health system in 2021. (page 49)
- Service area providers – Using its own internal data as discussed on pages 44-46, the applicant analyzed ZIP codes in the counties in HSA V that it serves. The applicant defines a primary and secondary service area to determine a patient base that would be close to the Scotts Hill campus in northern Wilmington. The applicant describes the locations of the other fixed and mobile PET scanners in HSA V and the distance from the location of the proposed scanner. (pages 52-55)
- Service area population trends – Citing data obtained from Claritas, the applicant states the population of the service area is projected to grow faster than the population in North Carolina as a whole from 2021-2026. Similarly, the over 65 population in the service area is projected to grow faster in the service area than in the state as a whole during the same time. (pages 56-57).
- Chronic conditions and diseases that support the need for a PET scanner – the applicant states that PET technology is most often used to diagnose and stage cancer and is also used to detect cardiac and brain abnormalities. The applicant examined data from the North Carolina State Center for Health Statistics which show cancer and heart disease rank as the two leading causes of death in North Carolina and in New Hanover County. In fact, the age-adjusted cancer mortality rates in the counties in and around PET Service Area V are higher than in the state as a whole. Similarly, obesity rates in the service area range from one-third to one-half of the population. Notably, the applicant states the American Psychological Association found that 42% of Americans gained an average of 29 pounds during the beginning of the COVID-19 pandemic. The following table, from page 60, shows the obesity rates in and around the service area:

COUNTY	OBESITY RATE
Bladen	49%
Brunswick	31%
Columbus	45%
Duplin	36%
New Hanover	29%
Onslow	29%
Pender	29%
Sampson	39%

The applicant states obesity is linked to cardiovascular disease, which can be diagnosed with PET imaging. (pages 58-60)

- Access to PET services in the service area – The applicant states the NHRMC Medical Mall experiences capacity constraints for its existing PET services. The applicant states PET volume increased by a compound annual growth rate (CAGR) of 12.03% from FY 2018 – FY 2021 (annualized). By comparison, the population of the service area increased by a CAGR of 3.1% during the same time. The applicant states cancer care and PET services continued to increase during the COVID-19 pandemic. The applicant states the capacity constraints negatively impact patient care, since patients who are already stressed about a cancer diagnosis experience delays in scheduling a PET scan, which ultimately delays treatment for patients. The applicant includes excerpts from NHRMC radiology staff support letters which detail their experiences with patients who must delay cancer treatment because of delays in PET services. The applicant includes copies of those letters in Exhibit 4.1. (pages 60-62)
- Travel issues – The applicant states patients who reside in its service areas would benefit from having a PET scanner located in northern New Hanover County at the Scotts Hill campus rather than in central Wilmington at the NHRMC Medical Mall campus. Traffic congestion in and around Wilmington make travel into the city for PET services burdensome for many patients who reside outside of downtown Wilmington and in surrounding counties. The applicant states traffic congestion is even more difficult for the 65 and over population, which is the population most likely to be diagnosed with some form of cancer. The applicant again cites correspondence from a NHRMC staff member who accounts the negative experience of lengthy travel to the Medical Mall campus for an elderly cancer patient who resided in rural Pender County and had to travel to downtown Wilmington for PET services. (pages 62-68)
- PET technology and oncology – the applicant explains PET scan technology and its effectiveness in staging and diagnosing many types of cancer, cardiovascular disease and neurological diseases, including dementia, brain tumors and epilepsy. The applicant states the proposed PET scanner will help to alleviate capacity issues currently faced by NHRMC and will allow for continued growth in oncology and non-oncology PET services in the service area. (pages 69-74)

- Unique benefits of the proposed PET – the applicant describes several benefits to developing the proposed PET scanner on the Scotts Hill campus, summarized as follows:
 - Capacity constraints – the applicant states its current PET scanner, which is the only one in the service area, routinely operates at or over capacity, which negatively impacts scheduling and ultimately the patients. The proposed additional PET scanner will alleviate those issues and more effectively serve patients.
 - Geographic access – the applicant states population growth and traffic congestion in Wilmington make travel from northern New Hanover County or even contiguous counties burdensome for patients. Locating the proposed PET scanner at the Scotts Hill campus will help to address these issues.
 - Expand scope of PET services – the applicant states PET services are used for oncology, cardiac and neurologic conditions, and the proposed additional PET scanner will improve access to a wider range of services for patients.
 - Financial access – the applicant states locating the proposed PET scanner in northern Wilmington will improve access to PET services for low income persons for whom the expense of travel is often burdensome.
 - Continuity of care and cost effectiveness– the applicant states locating the proposed PET scanner at the Scotts Hill campus cancer center provides continuity of care at that campus as well as for the entire NHRMC system in Wilmington. Additionally, the applicant states decreased wait times and travel times and locating the scanner on an existing campus will increase operational efficiencies and ultimately provide cost effective PET services to patients.

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

- There is a need determination in the 2021 SMFP for one additional PET scanner in HSA V, which includes New Hanover County.
- The applicant uses its own internal historical utilization on the existing PET scanner at the Medical Mall campus 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 information to support the need for an additional PET scanner at the new Scotts Hill cancer center campus based on documented historical utilization and future plans for expanded diagnostic and treatment use of the proposed unit.

Projected Utilization

In Section Q, Forms C.2a and C.2b, the applicant provides historical and projected utilization for the last full fiscal year (FY) and the interim and projected FYs for the existing and proposed PET scanners at both the Medical Mall and Scotts Hill campuses, as illustrated in the following tables:

NHRMC Medical Mall Historical Utilization

NMRMC MEDICAL MALL	PRIOR FULL FY	INTERIM FULL FY	INTERIM FULL FY	PARTIAL INTERIM FY
	10/2/19-9/30/20	10/2/20-9/30/21	10/2/21-9/30/22	10/1/22-3/31/23
# PET Scanners	1	1	1	1
# Procedures	2,796	3,041	3,235	1,764

Source: Application Section Q, Form C2a, page 147

NHRMC All Campuses Projected Utilization

NMRMC	PARTIAL FY	FIRST FULL FY	SECOND FULL FY	THIRD FULL FY
	4/1/23-9/30/23	10/2/23-9/30/24	10/2/24-9/30/25	10/1/25-3/31/26
# PET Scanners	2	2	2	2
# Procedures	1,924	4,069	4,449	4,709

Source: Application Section Q, Form C2b, page 148

NHRMC Scotts Hill Projected Utilization

NMRMC SCOTTS HILL	PARTIAL FY	FIRST FULL FY	SECOND FULL FY	THIRD FULL FY
	4/1/23-9/30/23	10/2/23-9/30/24	10/2/24-9/30/25	10/1/25-3/31/26
# PET Scanners	1	1	1	1
# Procedures	814	1,890	2,104	2,214

Source: Application Section Q, Form C2b, page 148

In Section C, pages 76-83, the applicant provides the assumptions and methodology used to project utilization as summarized below:

Step 1: Establish historical ZIP code and county level PET patient origin for PET services – Using FY 2020 and FY 2021 YTD data, the applicant established a ZIP code level patient origin at the Medical Mall campus and examined volume from those ZIP codes and counties. The applicant assumes the annualized FY 2021 YTD volume will be the base volume from which it projects future utilization. See the following table from page 76 that illustrates this step:

**Historical ZIP Code Level Patient Origin
 Based on FY 2021 Medical Mall PET Volume**

ZIP CODE/COUNTY	FY 2020	FY 2021 YTD	FY 2021 ANNUALIZED
28405-New Hanover	166	113	151
28411-New Hanover	162	136	181
28443-Pender	126	91	121
28401-New Hanover	120	104	139
28425-Pender	62	53	71
28457-Pender	53	40	53
28429-New Hanover	45	45	60
28445-Onslow	31	23	31
28435-Pender	14	13	17
28480-New Hanover	5	8	11
Primary Service Area	784	626	835
Other New Hanover	626	515	687
Other Pender	70	55	73
Other Onslow	127	94	125
Duplin	83	55	73
Brunswick	893	756	1,008
Columbus	94	77	103
Bladen	41	33	44
Sampson	18	16	21
Secondary Service Area	1,952	1,601	2,135
All other NC	32	38	51
Out of State	25	16	21
Total PET Volume	2,796	2,281	3,041

Step 2: Project service area PET patient volume by ZIP code based on FY 2021 annualized utilization – using its own internal data and other data, the applicant calculated an historical compound annual growth rate (CAGR) by averaging the total service area population growth from 2021-2026 and the historical PET volume from FY 2018-FY 2021, as shown in the following table:

CAGR Calculation for Projected Utilization

Total SA Population CAGR (2021-2026)	0.8%
Medical Mall CAGR (FY 2019-FY 2021)*	12.03%
Average	6.4%

*Annualized

Source: application page 77

The applicant applied the 6.4% CAGR to the base PET volume from annualized FY 2021 to project service area PET volume, as shown in the following table from page 77:

Projected Service Area Volume Based on FY 2021 Annualized Volume and CAGR

ZIP CODE/COUNTY	AVG. CAGR	FY 2021 ANNUALIZED	INTERIM FY 2022	INTERIM FY 2023	PARTIAL YEAR 1	FY 2024 (PY 1)	FY 2025 (PY 2)	FY 2026 (FY 3)
28401-New Hanover	6.4%	139	148	157	79	167	178	190
28405-New Hanover	6.4%	151	161	171	85	182	194	206
28411-New Hanover	6.4%	181	193	205	103	219	233	247
28429-New Hanover	6.4%	60	64	68	34	72	77	82
28480-New Hanover	6.4%	11	12	12	6	13	14	15
28425-Pender	6.4%	71	76	80	40	85	91	96
28435-Pender	6.4%	17	18	20	10	21	22	24
28443-Pender	6.4%	121	129	137	69	146	156	166
28457-Pender	6.4%	53	56	60	30	64	68	73
28445-Onslow	6.4%	31	33	35	17	37	39	42
Primary Service Area		835	888	945	473	1,006	1,070	1,139
Other New Hanover	6.4%	687	731	778	359	827	881	937
Other Pender	6.4%	73	78	83	42	88	94	100
Other Onslow	6.4%	125	133	142	71	151	161	171
Duplin	6.4%	73	78	83	42	88	94	100
Brunswick	6.4%	1,008	1,073	1,141	571	1,215	1,293	1,376
Columbus	6.4%	103	110	116	58	124	132	140
Bladen	6.4%	44	47	50	25	53	56	60
Sampson	6.4%	21	22	24	12	26	27	29
Secondary Service Area		2,135	2,272	2,417	1,209	2,572	2,737	2,913
All other NC	6.4%	51	54	57	61	61	65	69
Out of State		21	22	21	21	21	21	21
Total PET Volume		3,042	3,237	3,441	1,764	3,661	3,894	4,143

Numbers may not sum due to rounding by Project Analyst

The applicant did not explain how it calculated the volume for its “*Partial Year*”, occurring between the second interim year and project year one (FY 2024). However, in Forms C.2a and C.2b in Section Q, the applicant provides tables that identify the “*Partial Interim FY*” as the period of time between October 1, 2022 to March 31, 2023 and a “*Partial FY*” as the period of time between April 1, 2023 and September 30, 2023. The applicant’s PYs are fiscal years, measured from October 1 to September 30. The Project Analyst concluded, based on the information in Sections Q and C, that the “*Partial Year*” in the table above represents the six months between April 1 and September 30, 2023. Therefore, the numbers in that column represent one-half of the “*Interim 2023*” year, which means that the applicant grew the “*Interim FY 2023*” volume by 6.4% to project volume for the first PY, FY 2024.

Step 3: Establish cardiac PET volume at Scotts Hill – the applicant states it treats a large number of obese and cardiovascular patients who receive single photon emission computed tomography (SPECT) scans, which are nuclear imaging scans that integrate CT technology and a radioactive tracer to detect blood flow patterns and aid in detection of abnormalities.¹ The applicant grew total SPECT volume by a 2% CAGR each year, based on an average of the overall population CAGR and the 65 and older population CAGR. The applicant states its cardiologists’ experience indicates that one-third of the SPECT patients are appropriate

¹<https://mayfieldclinic.com/pspect.htm#:~:text=A%20single%20photon%20emission%20computed,and%20tumors%20in%20the%20spine.>

candidates for PET services. To be conservative, the applicant projects a ramp up from 15% of patients in PY 1 to 25% by PY 3 will be referred for cardiac PET scans, and provides a table on page 78 to illustrate historical and projected SPECT and PET volume at NHRMC. See the following table from page 78:

	FY 2019	FY 2020*	FY 2021 YTD	FY 2021 ANNUALIZED	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
NHRMC Main	1,933	1,652	521	1,042	1,063	1,084	1,106	1,128	1,150
NHRMC Cape Fear	4,226	3,599	2,556	5,112	5,214	5,319	5,425	5,533	5,644
Total SPECT Volume	6,159	5,251	3,077	6,154	6,277	6,403	6,531	6,661	6,795
Partial Project Year						4/1/23- 9/30/23	FY 2024	FY 2025	FY 2026
						3,201	6,531	6,661	6,795
# Pts Appropriate for PET	33.33%	33.33%		33.33%	33.33%	33.33%	33.33%	33.33%	33.33%
# PET Appropriate Cardiac Pts	2,053	1,750		2,051	2,092	15%	20%	25%	25%
% Referred for Cardiac PET						160	435	555	566

*Annualized

Source: application page 78

Step 4: Establish a patient shift to Scotts Hill campus – the applicant analyzed ZIP codes in its service area and its historical experience to determine the patient ZIP codes that would be more effectively served at the Scotts Hill campus. The applicant assumes a greater percent shift from those patients whose ZIP codes are closer to the Scotts Hill campus and a smaller percent shift from those patients whose ZIP codes are closer to the Medical Mall campus. The applicant assumes all cardiac PET volume will be served on the Scotts Hill campus. The applicant presents the projected shift in a series of tables, each reproduced below, to illustrate projected utilization at the Scotts Hill campus. The applicant states the projected shift is reasonable, given the full scope of clinical services that will be offered on the Scotts Hill campus and the number of patients who reside in ZIP codes that are closer to the Scotts Hill campus, as well as those patients who reside in counties that are closer to northern Wilmington and the Scotts Hill campus. The applicant provides letters of support from physicians in Exhibit C-4.1 that clearly indicate the scheduling difficulties for PET services that currently exist at the Medical Mall campus that support the projected shift.

Step 4A: the applicant states that, during the partial PY 2023, it assumes a 5% lower initial shift in patients from the applicant’s primary service area to the Scotts Hill campus as the proposed PET scanner becomes established. The applicant assumes a gradual ramp up of patients from outside the primary service area and includes cardiac volume, as illustrated in the following table:

Projected PET Volume at Scotts Hill and Medical Mall – Partial Year

ZIP CODE/COUNTY	2023 TOTAL PET VOLUME	PROJECTED % SHIFT TO SH*	2023 PROJECTED SH PET SCANS	2023 PROJECTED MM^ PET SCANS POST SHIFT
28401-New Hanover	79	75%	59	20
28405-New Hanover	85	75%	64	21
28411-New Hanover	103	75%	77	26
28429-New Hanover	34	75%	25	8
28480-New Hanover	6	75%	5	2
28425-Pender	40	75%	30	10
28435-Pender	10	75%	7	2
28443-Pender	69	75%	52	17
28457-Pender	30	75%	23	8
28445-Onslow	17	75%	13	4
Primary Service Area	473	75%	354	118
Other New Hanover	359	25%	97	292
Other Pender	42	75%	31	10
Other Onslow	71	75%	53	18
Duplin	42	75%	31	10
Brunswick	571	10%	57	514
Columbus	58	20%	12	47
Bladen	25	40%	10	15
Sampson	12	40%	5	7
Secondary Service Area	1,209	25%	296	912
All other NC	61	3%	2	59
Out of State	21	5%	1	20
Cardiac PET Volume	160		160	
Total	1,924	42%	814	1,110

*Scotts Hill

^Medical Mall

Numbers may not sum due to rounding

Step 4B: The following table shows the full projected shift in case volume, including cardiac volume, after the ramp up period:

Projected PET Volume at Scotts Hill and Medical Mall – Post Shift First Full PY

ZIP CODE/COUNTY	2024 TOTAL PET VOLUME	PROJECTED % SHIFT TO SH*	2024 PROJECTED SH PET SCANS	2024 PROJECTED MM^ PET SCANS POST SHIFT
28401-New Hanover	167	80%	134	33
28405-New Hanover	182	80%	145	36
28411-New Hanover	219	80%	175	44
28429-New Hanover	72	80%	58	14
28480-New Hanover	13	80%	10	3
28425-Pender	85	80%	117	29
28435-Pender	21	80%	68	17
28443-Pender	146	80%	51	13
28457-Pender	64	80%	30	7
28445-Onslow	37	80%	17	4
Primary Service Area	1,006	80%	805	201
Other New Hanover	827	25%	207	621
Other Pender	88	80%	71	18
Other Onslow	151	80%	121	30
Duplin	88	80%	71	18
Brunswick	1,215	10%	121	1,093
Columbus	124	20%	25	99
Bladen	53	40%	21	32
Sampson	26	40%	10	15
Secondary Service Area	2,572	25%	647	1,926
All other NC	61	3%	2	59
Out of State	21	5%	1	20
Cardiac PET Volume	435		435	
Total	4,096	46%	1,890	2,206

*Scotts Hill

^Medical Mall

Numbers may not sum due to rounding

Step 4C: The applicant held the percent shift from FY 2024 constant and increased the “All other NC” patient base by 2%:

Projected PET Volume at Scotts Hill and Medical Mall – Post Shift Second PY

ZIP CODE/COUNTY	2025 TOTAL PET VOLUME	PROJECTED % SHIFT TO SH*	2025 PROJECTED SH PET SCANS	2025 PROJECTED MM^ PET SCANS POST SHIFT
28401-New Hanover	178	80%	142	36
28405-New Hanover	194	80%	155	39
28411-New Hanover	233	80%	186	47
28429-New Hanover	77	80%	62	15
28480-New Hanover	14	80%	11	3
28425-Pender	91	80%	124	31
28435-Pender	22	80%	72	18
28443-Pender	156	80%	55	14
28457-Pender	68	80%	31	8
28445-Onslow	39	80%	18	4
Primary Service Area	1,070	80%	856	214
Other New Hanover	881	25%	220	660
Other Pender	94	80%	75	19
Other Onslow	161	80%	129	32
Duplin	94	80%	75	19
Brunswick	1,293	10%	129	1,163
Columbus	132	20%	26	105
Bladen	56	40%	23	34
Sampson	27	40%	11	16
Secondary Service Area	2,737	25.1%	688	2,049
All other NC	65	5%	3	62
Out of State	21	5%	1	20
Cardiac PET Volume	555		555	
Total	4,449	47.3%	2,104	2,345

*Scotts Hill

^Medical Mall

Numbers may not sum due to rounding

Step 4D: The applicant held the percent shift constant in the third PY:

Projected PET Volume at Scotts Hill and Medical Mall – Post Shift Third PY

ZIP CODE/COUNTY	2026 TOTAL PET VOLUME	PROJECTED % SHIFT TO SH*	2026 PROJECTED SH PET SCANS	2026 PROJECTED MM^ PET SCANS POST SHIFT
28401-New Hanover	190	80%	151	38
28405-New Hanover	206	80%	164	41
28411-New Hanover	247	80%	198	49
28429-New Hanover	82	80%	66	16
28480-New Hanover	15	80%	12	3
28425-Pender	96	80%	123	33
28435-Pender	24	80%	77	19
28443-Pender	166	80%	58	15
28457-Pender	73	80%	33	8
28445-Onslow	42	80%	19	5
Primary Service Area	1,139	80%	911	228
Other New Hanover	937	25%	234	703
Other Pender	100	80%	80	20
Other Onslow	171	80%	137	34
Duplin	100	80%	80	20
Brunswick	1,376	10%	138	1,238
Columbus	140	20%	28	112
Bladen	60	40%	24	26
Sampson	29	40%	12	17
Secondary Service Area	2,913	25.1%	732	2,181
All other NC	69	5%	3	66
Out of State	21	5%	1	20
Cardiac PET Volume	566		566	
Total	4,709	47.0%	2,214	2,494

*Scotts Hill

^Medical Mall

Numbers may not sum due to rounding

On pages 82-83, the applicant states that the recent approval of the Scotts Hill hospital campus affords the applicant an opportunity to provide a full continuum of care to its cancer and cardiac patients, particularly those who reside in the northern area of New Hanover County and those persons age 65 and older. The applicant states the capacity constraints that exist at Medical Mall have driven the need for a new PET scanner.

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

- The applicant relies on historical data from utilization of the existing PET scanner within the NHRMC system to project future utilization of PET services for oncology and cardiology, as well as its obese and older patients.
- The applicant makes reasonable and conservative assumptions regarding growth of cardiac and oncological PET services in order to project PET utilization of the existing and proposed PET scanners at the Medical Mall and Scotts Hill campuses.
- The projected utilization of the applicant’s existing and proposed PET scanners meets the Performance Standards in 10A NCAC 14C .3703.

Access to Medically Underserved Groups

In Section C.6, page 88, the applicant states:

“NHRMC is a not-for-profit organization that does not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay. NHRMC actively participates in both the Medicaid and Medicare programs.

...

...services are available to all persons including: (a) low-income persons, (b) racial and ethnic minorities, (c) women, (d) handicapped persons, (e) the elderly, and (f) other underserved persons, including the medically indigent referred by their attending physicians.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from page 90:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons*	8.6%
Racial and ethnic minorities	13.9%
Women	45.9%
Persons with Disabilities	NHRMC does not track this data
Persons 65 and older	70.0%
Medicare beneficiaries	70.0%
Medicaid recipients	3.8%

*the applicant states this includes charity care, self-pay and Medicaid percentages

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 NHRMC services, including PET services, to all residents of the service area, including underserved groups.
- The applicant provides its projected payor mix, which includes underserved groups, and assumes it will remain constant for the first three years of operation.

Conclusion

The agency reviewed the:

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

- Written comments
- Response to Comments

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

O-12150-21 Wilmington Health, PLLC – The applicant is a national network of multispecialty physician practices that currently operates 19 physician practices and one telehealth practice in North Carolina. The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP for a total of one fixed PET scanner in its existing physician practice on Medical Drive in Wilmington from which the applicant currently provides cardiology, primary care, gastroenterology, podiatry and orthopedic services.

Patient Origin

On page 367, the 2021 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.” (emphasis in original) The applicant proposes to locate the fixed PET scanner in New Hanover County which, according to Appendix A on page 373 is in HSA V. Thus, the service area for this proposal is HSA V. Facilities may also serve residents of counties not included in their service area.

The applicant does not currently own or operate a PET scanner and has no historical patient origin to report.

In Section C, page 41, the applicant projects the patient origin for its proposed PET scanner as shown in the table below:

Wilmington Health Projected Patient Origin

COUNTY	1 ST FY (CY 2024)		2 ND FY (CY 2025)		3 RD FY (CY 2026)	
	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL
New Hanover	430	57.2%	551	52.7%	588	52.4%
Brunswick	229	30.4%	335	32.0%	367	32.7%
Onslow	49	6.5%	100	9.5%	101	9.0%
Pender	44	5.8%	60	5.7%	65	5.8%
Total	752	100.0%	1,045	100.0%	1,121	100.0%

In Section C, page 41, the applicant states the projected patient origin is based on the number of patients it projects to serve in four counties in HSA V as shown in the table above. In Section Q, in the Assumptions supporting Form C.2b, the applicant provides more detailed assumptions and methodology to support its projected patient origin. The applicant states it will serve a certain market share of patients from each of the four counties, based on data contained in the patient origin data as reported to DHSR by providers. The applicant provides the number of patients who reside in each of the four counties listed above who travel to New Hanover County for PET services. The applicant has not provided sufficient information to

show how it will capture those patients who are currently being served by an existing PET provider. Therefore, the applicant's assumptions regarding patient origin are not reasonable or adequately supported.

Analysis of Need

In Section C.4, pages 43-64, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- There is a need determination in the 2021 SMFP for one additional PET scanner in HSA V.
- Need for additional PET capacity in HSA V – the applicant states that a comparison of the population of HSA V to other HSAs and the number of PET scanners in the area shows that there are fewer PET scanners per one million people. Additionally, HSA V is among the larger and least populous HSAs in the state, so that patients who need PET services must generally travel longer distances to receive those services. (page 44)
- Need for additional fixed PET capacity in New Hanover County – the applicant states there are several indicators of need for additional PET capacity in New Hanover County, as summarized below:
 - Population growth and aging – the applicant states the population of HSA V increased by 8.1% over the past ten years, according to population data from the North Carolina Office of State Budget and Management (NCOSBM). Additionally, the applicant states that same data shows the population growth in New Hanover County accounted for 27.5% of the total growth in HSA V during that same time. Taken alone, New Hanover County population increased by 15.1% from 2011 to 2020. The following table from page 47 shows projected population growth and compound annual growth rate (CAGR) in HSA V from 2021-2026:

Projected Population Growth in HSA V, 2021-2026

County	2021	2026	Numerical Growth	Percent Growth	2021-2026 CAGR
Cumberland	333,323	334,378	1,055	0.3%	0.0%
New Hanover	237,448	254,121	16,673	7.0%	0.7%
Brunswick	150,889	167,739	16,850	11.2%	1.1%
Harnett	138,043	147,418	9,375	6.8%	0.7%
Robeson	130,713	129,997	(716)	-0.5%	-0.1%
Moore	140,130	113,171	9,041	8.7%	0.8%
Pender	64,524	68,780	4,256	6.6%	0.6%
Sampson	63,904	63,991	87	0.1%	0.0%
Hoke	54,876	56,587	1,711	3.1%	0.3%
Columbus	55,600	54,374	(1,226)	-2.2%	-0.2%
Richmond	44,777	44,268	(509)	-1.1%	-0.1%
Scotland	35,604	35,453	(151)	-0.4%	0.0%
Bladen	34,255	33,990	(265)	-0.8%	-0.1%
Montgomery	27,693	27,854	161	0.6%	0.1%
Anson	23,755	23,476	(279)	-1.2%	-0.1%
Total	1,499,534	1,555,597	56,063	3.7%	0.4%

The applicant states the population of New Hanover County is projected to increase at a faster rate than the total population of HSA V from 2021-2026 (pages 45-47).

Similarly, the HSA V 65 and older population has increased by 45% since 2011, according to data obtained by the applicant from the NCOSBM. That same population group is projected to increase by 13.9% from 2021-2026, as shown in the following table from page 48:

Projected Population Growth, Age 65+ in HSA V, 2021-2026

County	2011	2021	2026	% Growth, 2021-2026
Brunswick	25,185	47,515	56,761	19.5%
Cumberland	32,188	45,947	52,952	15.2%
New Hanover	29,494	43,660	50,159	14.9%
Moore	20,631	28,342	32,238	13.7%
Robeson	15,703	20,976	22,803	8.7%
Harnett	12,655	18,654	21,792	16.8%
Pender	8,263	12,503	14,573	16.6%
Sampson	9,724	11,849	12,854	8.5%
Columbus	9,044	11,100	11,672	5.2%
Richmond	6,853	8,260	8,863	7.3%
Bladen	5,691	7,349	7,723	5.1%
Scotland	5,075	6,882	7,363	7.0%
Hoke	3,714	5,852	7,033	20.2%
Montgomery	4,510	6,014	6,533	8.6%
Anson	3,905	4,510	4,793	6.3%
Total	192,185	279,413	318,112	13.9%

See also the following table from page 49 illustrating the percent of HSA V age 65 and older:

**Percent of HSA V Population Age 65+
 2021 and 2026**

County	2011	% Growth, 2021-2026
Brunswick	31.5%	33.8%
Moore	27.2%	28.5%
Montgomery	21.7%	23.5%
Bladen	21.5%	22.7%
Columbus	20.0%	21.5%
Pender	19.4%	21.2%
Scotland	19.3%	20.8%
Anson	19.0%	20.4%
Sampson	18.5%	20.1%
Richmond	18.4%	20.0%
New Hanover	18.4%	19.7%
Robeson	16.0%	17.5%
Cumberland	13.8%	15.8%
Harnett	13.5%	14.8%
Hoke	10.7%	12.4%
HSA V Total	18.6%	20.4%
Total	17.3%	19.1%

The applicant states the population age 65 and older will require increasing access to services in the future, including PET services, and that population group is at a greater risk to develop cancer (pages 48-49).

- Cardiovascular disease in HSA V – the applicant states the most recent data available (2019) shows that cardiovascular disease was the leading cause of death in in New Hanover County and HSA V as a whole, and cerebrovascular disease and obesity are among the top health issues in the area (pages 50-52):
- Existing PET services – the applicant analyzed the location of existing PET scanners in HSA V and the potential travel times for patients in the service area who may need PET services. The applicant states the most highly utilized PET scanner is the scanner located at NHRMC in Wilmington and noted that the other scanners serving HSA V are a minimum of one hour drive time from Wilmington. The applicant states it would be cost-effective for patients to offer a free-standing non-hospital based PET scanner for patients in the service area who need PET services (pages 52-57).
- Additional diagnostic indicators for PET services – the applicant states PET scanners are utilized for oncology to stage and diagnose many types of cancer. Additionally, PET scanners are increasingly utilized for diagnosing cardiovascular disease, particularly PET myocardial perfusion imaging, a non-invasive method of detecting

coronary artery disease. The applicant notes the benefits of the high quality of PET scans in detecting and staging various forms of those diseases (pages 57-61).

- Other clinical indications for PET scans – the applicant notes that, while PET scans are most often used to diagnose and stage various forms of cancer, there are other clinical indications for specialized types of PET scans which yield more accurate results in terms of targeting specific types of cancer and its metastases. In addition, PET scans are increasingly utilized for detection of Alzheimer’s and other forms of dementia, movement disorders such as Parkinson’s Disease, and thoracic diseases including lung cancer (pages 61-64).

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the interim and projected FYs, as illustrated in the following table:

Wilmington Health Projected PET Utilization

	INTERIM FY (3/1/23-12/21/23)	1 ST FULL FY (CY 2024)	2 ND FULL FY (CY 2025)	3 RD FULL FY (CY 2026)
# PET Scanners	1	1	1	1
Procedures	852	1,505	2,090	2,241

Source: Section Q, Form C.2b

In Section Q, *Form C Utilization – Assumptions and Methodology*, pages 1-6, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

- Historical PET utilization – The applicant examined PET patient origin reports from the Division of Health Service Regulation (DHSR) in the context of the different Wilmington Health locations in HSA V and determined that the patients to be served by WH’s proposed PET scanner would originate from Brunswick, Pender, New Hanover and Onslow counties.
- The applicant calculated a CAGR to illustrate the increase in PET patients in the counties from which it proposes to serve its patients from federal fiscal year (FFY) 2016-2020. The applicant determined that the number of PET patients in the four counties increased by a CAGR of 9.1% during that time. See the following table from page 2:

PET Patients by County, FFY 2016-FFY 2020

COUNTY	FFY 2016	FFY 2017	FFY 2018	FFY 2019	FFY 2020	CAGR
Brunswick	604	729	779	944	1,034	14.4%
New Hanover	892	956	992	1,167	1,307	10.0%
Onslow	845	858	900	988	923	2.2%
Pender	236	280	300	327	385	13.0%
Total	2,577	2,823	2,971	3,426	3,649	9.1%

Source: Section Q, assumptions and methodology following Form C.2b, page 2

- The applicant assumes that the numbers of PET patients will increase at a rate that is two-thirds of the historical growth in each of the four counties, as shown in the following table:

Projected Growth in PET Patients by County, FFY 2021-FFY 2027

COUNTY	FFY 2021	FFY 2022	FFY 2023	FFY 2024	FFY 2025	FFY 2026	FFY 2027	CAGR
Brunswick	1,133	1,242	1,361	1,491	1,634	1,791	1,963	9.6%
New Hanover	1,394	1,487	1,587	1,693	1,806	1,927	2,055	6.7%
Onslow	937	951	965	979	994	1,009	1,024	1.5%
Pender	418	455	494	537	584	634	689	8.7%
Total	3,883	4,135	4,407	4,701	5,018	5,361	5,731	6.7%

Source: Section Q, assumptions and methodology following Form C.2b, page 2

The applicant states its assumption that the projected PET patient population will increase by two-thirds of its historical growth is reasonable and conservative because it represents “a fraction” of historical growth. The applicant also states expanded access to PET services will increase utilization.

- The applicant states its fiscal year corresponds to a calendar year (CY) and thus converts the projected patients from the four counties who will need PET scans from a FFY to a calendar year (CY), as shown in the following table:

Total Projected PET Patients by County

COUNTY	CY 2023	CY 2024	CY 2025	CY 2026
Brunswick	1,394	1,527	1,674	1,834
New Hanover	1,613	1,721	1,836	1,959
Pender	968	983	997	1,012
Onslow	505	549	596	648
Total	4,480	4,780	5,104	5,453

Source: Section Q, Form C.2b

- The applicant assumes it will serve a portion of the total patients projected to use PET scanners from the four counties as noted above. The applicant’s market share assumptions are summarized as follows:
 - Brunswick County: the applicant assumes it will capture a 10% market share of all Brunswick County patients projected to need PET scans as shown in the table above in the first project year, and then increase to 20% by the third project year. The applicant states this is reasonable because “*Brunswick County is adjacent to New Hanover County, Wilmington Health has an existing practice in the county, and according to the 2021 patient origin report ... 85.9 percent of PET scanner patients from Brunswick County received their PET procedure at a facility in New Hanover County.*”
 - New Hanover County: the applicant assumes it will capture a 20% market share of all New Hanover County patients projected to need PET scans as shown in

the table above in the first project year, and then increase to 30% by the third project year. The applicant states this is reasonable because *“New Hanover County is the county in which the proposed PET/CT scanner will be located, Wilmington Health has multiple existing practices in the county, and according to the 2021 patient origin report ... 85.9 percent of PET scanner patients from New Hanover County received their PET procedure at a facility in New Hanover County.”*

- Onslow County: the applicant assumes it will capture a 3% market share of all Onslow County patients projected to need PET scans as shown in the table above in the first project year, and then increase to 10% by the third project year. The applicant states this is reasonable because *“Onslow County is adjacent to New Hanover County, Wilmington Health has two existing practices in the county, and according to the 2021 patient origin report ... 16.9 percent of PET scanner patients from Onslow County received their PET procedure at a facility in New Hanover County.”*
- Pender County: the applicant assumes it will capture a 5% market share of all Onslow County patients projected to need PET scans as shown in the table above in the first project year, and then increase to 15% by the third project year. The applicant states this is reasonable because *“Pender County is adjacent to New Hanover County, Wilmington Health has an existing practice in the county, and according to the 2021 patient origin report ... 84.2 percent of PET scanner patients from Pender County received their PET procedure at a facility in New Hanover County.”*

The applicant provides a table, reproduced below, to illustrate its market share assumptions:

Wilmington Health PET Patients by County				
COUNTY	CY 2023*	CY 2024	CY 2025	CY 2026
PROJECTED PET SCANNER PATIENTS BY COUNTY				
Brunswick	1,161	1,527	1,647	1,834
New Hanover	1,344	1,721	1,836	1,959
Onslow	807	983	997	1,012
Pender	421	549	596	648
MARKET SHARE ASSUMPTIONS				
Brunswick	10%	15%	20%	20%
New Hanover	20%	25%	30%	30%
Onslow	3%	5%	10%	10%
Pender	5%	10%	15%	15%
Brunswick	116	229	335	367
New Hanover	269	430	551	588
Onslow	20	49	100	101
Pender	21	44 [55]	60 [89]	65 [97]
TOTAL PET PATIENTS	426	752 [763]	1,045 [1,075]	1,121 [1,153]

*Applicant adjusted for a March 1 start date.

Numbers may not sum due to rounding by Project Analyst

The numbers in brackets in the table above represent the Project Analyst’s calculations based on the percentages the applicant states it will serve, rather than the calculations in the table provided by the applicant [Pender County: $549 \times .10 = 54.9$ in CY 2024. $596 \times .15 = 89$ in Cy 2025. $648 \times .15 = 97$ in CY 2026]. The remainder of the analysis will include bracketed numbers that represent the Project Analyst’s calculations based on the numbers the applicant states it projects.

- The applicant compares the number of patients who will seek PET services in the future to the FFY 2020 patient data reports that provide the number of patients from each of the four counties listed in the table above who sought PET services in New Hanover County, and to its own internal data on the number of patients from those counties served by WH physicians and practices for hematology, oncology, MRI and ambulatory services as shown in the following table from page 5 of the Assumptions and Methodology:

COUNTY	WH CY 2026 PET Pts.	FFY 2020 Pts. FOR PET SCANS IN NH COUNTY*	WH HEMATOLOGY / ONCOLOGY Pts.	WH MRI Pts.	WH ASF Pts.
Brunswick	32.7%	85.9%	23.5%	19.6%	24.3%
New Hanover	52.4%	85.9%	52.2%	55.4%	42.5%
Onslow	9.0%	16.9%	4.2%	5.0%	9.1%
Pender	5.8%	84.2%	11.0%	13.2%	9.4%
Total	100.0%		94.2%	96.4%	90.1%

*Applicant states this data is from patient data reports

The applicant states on page 5 that it projects to serve 1,121 [1,153] PET patients in the third project year, CY 2026, and that number represents 65.4% of the total growth in PET scanner patients projected from the four counties from FFY 2020 to FYY 2026 (3,649 PET patients from all four counties in FFY 2020 projected to grow to 5,361 PET patients in FFY 2026 = 1,712 PET patients. $1,121 / 1,712 = 0.6513$). According to the numbers corrected by the Project Analyst, that percentage is a bit greater: $1,153 / 1,721 = 0.67$, or 67%. The applicant states that number represents “a fraction” of the projected growth in PET scanner patients, which further substantiates the reasonableness of its projections. However, neither 65% nor 67% represent a fraction of the total projected growth; it is nearly two-thirds of the projected growth in the number of patients from the four counties listed above who are projected to be served by a PET scanner in New Hanover County. Other than the market share analysis outlined above, the applicant has not provided information that supports the reasonableness of its projections. The applicant cites data that shows how many residents of each county have historically been served in New Hanover County by an existing PET provider; however, the applicant has not provided sufficient evidence to substantiate its assumptions regarding how many patients it could serve on the proposed PET scanner. It is understood that the existing PET services are at capacity; however, the applicant does not provide data or information to support its projection that it will serve those patients currently being served by existing PET services in the service area. The Project Analyst examined the location of the PET scanner proposed

by WH and notes it would be located less than one mile from the existing PET scanner operated by NHRMC. Other than an analysis of historical PET utilization in the service area, the applicant has not provided evidence to support the projections of the patients it proposes to serve and why those patients would choose to be served by its proposed scanner when the proposed PET scanner will be located less than one mile from an existing, highly utilized PET scanner.

- The applicant assumes that each projected patient will receive two procedures, citing a June 11, 2013 Decision Memo published by the Centers for Medicare & Medicaid Services (CMS), which the applicant states authorizes up to three PET procedures per patient. On page 5 of its assumptions, the applicant states: “...*Wilmington Health assumes that each projected PET/CT scanner patient will receive two PET procedures.... Wilmington Health believes this assumption is reasonable and conservative as Medicare reimburses as many as three PET procedures per patient.*” The Project Analyst examined the referenced article², which was written in response to requests that CMS eliminate the requirement for something called “*coverage with evidence development (CED)*” (requiring evidence to substantiate a certain number of PET scans) under a specific section of the Social Security Act for specific types of cancer tumors using a specific type of radioactive tracer with the PET scan. The article does not authorize, without limits, “*up to three PET procedures per patient.*” Rather, the article indicates that, with regard to certain types of cancer for which a certain type of radiotracer is appropriate, CMS ended its requirement for *Coverage with Evidence*. The article states in part: “*CMS has determined that three FDG PET scans are covered under [Section 1862(a)(1)(A) of the Social Security Act] when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anticancer therapy.*”³ (emphasis added). Furthermore, the article indicates coverage for up to three scans per patient, not procedures. According to 10A NCAC 14C .3701(6): “*‘PET Procedure’ means a single discrete study of one patient involving one or more PET scans.* 10A NCAC 14C .3701(7) states: “*‘PET scan’ means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure.*” Thus, the applicant’s reliance on the quoted CMS article as evidence to support its assumption that it will perform two scans per patient is not reasonable, since the article details specific types of cancer detection using specific types of radiotracers for which CMS previously required the submission of additional evidence before approving reimbursement for additional scans. The decision to end the CED requirement was specific to the types of cancer covered in the article. Therefore, the assumption of two scans per patient is not supported and is thus not reasonable.

On page 6 of its assumptions, the applicant provides a table to illustrate its projections, as shown below:

²<https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=263&fromTracking=Y&bc=0>

³ *Id.*, pages 1, 44

Wilmington Health Projected PET/CT Procedures

	CY 2023	CY 2024	CY 2025	CY 2026
Projected PET Patients	426	752 [763]	1,045[1,075]	1,121[1,153]
PET Procedures per Patient	2	2	2	2
Projected WH Procedures	852	1,504 [1,526]	2,090[2,150]	2,241 [2,306]

Numbers in brackets represent mathematical corrections performed by the Project Analyst

- The applicant states that, in order to be consistent with the performance standards promulgated at 10A NCAC 14C .3703(a)(1), it must show that each PET scanner will be utilized at an annual rate of at least 2,080 PET procedures by the end of the third year following project completion. The applicant states that since its project will be complete as of March 1, 2023, it will convert the numbers previously converted to CYs to what it calls its first three project years, as shown below:

- Project Year One: March 1, 2023-February 28, 2024
- Project Year Two: March 1, 2024-February 28, 2025
- Project Year Three: March 1, 2025-February 28, 2026

The applicant states it previously adjusted 2023 to account for a March start date, and its calculations to project years are as follows:

- PY 1: (CY 2023) + (CY 2023/12 x 2)
- PY 2: (CY 2024/12 x 10) + (CY 2025/12 x 2)
- PY 3: (CY 2025/12 x 10) + (CY 2026/12 x 2)

The following table illustrates the projected number of PET procedures to be performed by WH in the first three project years:

Projected WH PET/CT Procedures	1,103	1,602	2,115
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The following table illustrates the projected number of PET procedures to be performed by WH in the first three project years, using the corrected numbers performed by the Project Analyst:

Projected WH PET/CT Procedures	1,114	1,630	2,126
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On page 6 of its assumptions, the applicant states the projected number of PET scans in the third project year exceeds the minimum required by the Performance Standard at 10A NCAC 14C .3703(a)(1) of 2,080 PET procedures by the third project year.

However, the applicant's assumptions are not reasonable or adequately supported for the reasons stated above. In addition, the applicant projects, in its first project year, to perform 1,114 procedures on a proposed PET scanner to be located less than one mile from an existing,

highly utilized PET scanner. NHRMC’s 2021 License Renewal Application (LRA), which contains data from FY 2020 (October 1, 2019-September 30, 2020) shows that NHRMC performed a total of 2,796 PET procedures, 1,123 of which were on New Hanover County residents. The applicant has not provided sufficient evidence or data to substantiate its projection that it will serve 98% of the total number of New Hanover County residents who received a PET scan from NHRMC in FFY 2020 in its first project year [$1,103 / 1,123 = 0.98$]. Additionally, the applicant has not provided sufficient evidence or data to substantiate its projection that it will serve 39% of the total number of patients who received a PET scan from NHRMC in FFY 2020 in its first project year [$1,103 / 2,796 = 0.39$]. Regarding project year three, the applicant projects to serve 188% of the total number of New Hanover County residents who received a PET scan from NHRMC in FFY 2020 [$2,126 / 1,123 = 1.88$]. Additionally, the applicant projects in project year three to serve 76% of the total number of patients who received a PET scan from NHRMC in FFY 2020 [$2,115 / 2,796 = 0.76$]. The Project Analyst’s calculations show higher percentages, which are equally unsupported and unreasonable.

Moreover, the Project Analyst examined 2015-2021 SMFPs; specifically, the existing providers of PET services in HSA V (NHRMC, Cape Fear Valley Medical Center and First Imaging of the Carolinas). The analysis will focus only on NHRMC, since each applicant in this review proposes to locate the PET scanner in New Hanover County. Cape Fear Valley Medical Center is located in Cumberland County, and First Imaging of the Carolinas is located in Moore County. See the following tables, prepared by the Project Analyst from data in the 2015-2021 SMFPs:

	2015 SMFP	2016 SMFP	2017 SMFP	2018 SMFP	2019 SMFP	2020 SMFP	2021 SMFP	CAGR
# Procedures	1,464	1,543	1,691	1,847	2,044	2,163	2,512	9.42%
Annual % Change		5.4%	9.6%	9.2%	10.7%	5.8%	16.1%	

Source: 2015-2021 SMFPs
 Numbers may not sum due to rounding

The Project Analyst also prepared a table to illustrate the applicant’s projections, as shown below:

	PY 1	PY 2	PY 3	CAGR, PY 1- PY 3
# Procedures	1,103	1,603	2,115	24.24%
Annual % Change		45.2%	32.0%	

The applicant has not provided evidence or data to support a 24.24% CAGR in its three project years. Even if the Project Analyst compared three years of SMFP data to more closely align with the projection of three years of utilization, the CAGR would be less than what the applicant projects for in its own utilization projections:

Utilization Using 2018-2020 SMFP Data

	2018 SMFP	2019 SMFP	2020 SMFP	CAGR
# Procedures NHRMC	1,847	2,044	2,163	5.4%
Annual % Change		10.7%	5.8%	

The applicant has not provided evidence or information to support the number of patients it projects to serve on its proposed PET scanner.

The information is not reasonable or adequately supported based on the analysis above and the following:

- The applicant uses unreasonable and unsupported data to make assumptions regarding the population to be served and the projected growth of that population.
- The applicant provides insufficient information to support its projections of the number of patients to be served and the number of PET procedures to be performed, as detailed above.

Access to Medically Underserved Groups

In Section C.6, page 71, the applicant states:

“Wilmington Health provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment.”

On page 72, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	WH does not maintain this data
Racial and ethnic minorities	27.4%
Women	58.8%
Persons with Disabilities	WH does not maintain this data
Persons 65 and older	27.4%
Medicare beneficiaries	65.3%
Medicaid recipients	2.0%

The applicant states on page 72 that the projected payor mix is based on CY 2020 percentages for the entire Wilmington Health practice.

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 projected access to the proposed PET services for all residents of the service area, including underserved groups, based on its CY 2020 experience.
- The applicant provides its projected payor mix, which includes underserved groups.

Conclusion

The agency reviewed the:

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA – Both Applications

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

O-12150-21 Wilmington Health, PLLC – The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

C – NHRMC
NC - WH

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant proposes to acquire one fixed PET scanner which will be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHRMC would be licensed for two fixed PET scanners;

one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

In Section E.2, pages 102-104, 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 this is not a sustainable option because NHRMC’s existing PET scanner is the only unit that serves New Hanover and surrounding counties and is highly utilized. The applicant states the existing PET scanner is not sufficient to accommodate current and future capacity in the service area and maintaining status quo would continue to strain existing services and thus is not an option.
- Add capacity at the main campus location – The applicant states this is not a reasonable alternative because the additional capacity at the main hospital campus would increase capacity there and in central Wilmington, but would not address the increasing demand for additional capacity in other areas of the county or HSA V. The applicant cites heavy traffic congestion in central Wilmington and travel burdens placed on patients seeking PET services who live outside of Wilmington. Thus, adding capacity at the existing hospital location is not a reasonable alternative.
- Extend hours of operation for the existing PET scanner – The applicant states this is not an effective alternative because PET scans require radioisotopes, which are tracers that react with the radioactive glucose injected during a PET scan⁴. The applicant states PET providers without a generator on site (as NHRMC) must order these radioisotopes through a third-party vendor, and delivery times and the number of dosages ordered must be coordinated with the PET schedule because the radioisotopes have a very short half-life and quickly lose effectiveness. Additionally, the applicant states extending hours of operation would not address the need for increased geographic access, would result in staff overtime and would only provide a temporary solution. Therefore, this is not an effective alternative.
- Use mobile PET services – The applicant considered adding mobile PET services but determined it is not a viable alternative, given that there are currently three available mobile PET units, two operated by Alliance Imaging and one by Novant Health – Forsyth Medical Center in Winston-Salem. The two units operated by Alliance Imaging are highly utilized and do not appear to have available capacity, and the unit operated by Novant Health-Forsyth Medical Center is too distant to be able to serve the coastal region effectively. The applicant states there is one additional mobile PET scanner approved for InSight Medical Corp. in 2019 that is unavailable because it is involved in litigation and thus not operational. Thus, the use of mobile PET services is not a viable alternative for the applicant.

⁴ See <https://stanfordhealthcare.org/medical-tests/p/pet-scan/what-to-expect.html>

On pages 103-104, the applicant states that this proposal is the most effective alternative because it would allow NHRMC to improve geographic access and mitigate congestion on and around the main NHRMC campus in Wilmington, thus maximizing healthcare value in the delivery of PET services.

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 provides credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional PET scanner in HSA V.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

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

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

O-12150-21 Wilmington Health, PLLC – Acquire one fixed PET/CT scanner – In Section E.2, page 83, the applicant describes the one alternative it considered and explains why that alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternative considered was:

- Develop the proposed PET scanner at another location – the applicant states this is not a reasonable alternative because construction and renovation costs are more easily minimized at the existing Medical Drive location. Furthermore, the applicant states locating the proposed PET scanner at a different location would not allow for economies of scale that would be in effect at the Medical Drive location, where the applicant can provide continuity of care for its patients. Thus, this is not an effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The application is not conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above and in the remainder of these Findings. Therefore, the application is denied.

- (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 – NHRMC
NC - WH

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant proposes to acquire one fixed PET scanner which will be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHRMC would be licensed for two fixed PET scanners; one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

Capital and Working Capital Costs

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

Site Costs	NA
Construction / Renovation Costs	\$2,468,981
Miscellaneous Costs	\$3,464,104
Total	\$5,933,085

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

- The applicant provides a September 15, 2021 letter signed by an architect in Exhibit K-3 that confirms the projected construction/renovation cost.
- The applicant provides an equipment quote in Exhibits F-1.1 and F-1.2 that confirms the equipment cost.

Availability of Funds

In Section F.2, page 105, the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing

TYPE	NOVANT HEALTH, INC.	TOTAL
Loans	\$0	\$0
Accumulated reserves, OE*, Cash/Cash Equivalents	\$5,933,085	\$5,933,085
Bonds	\$0	\$0
Other (internal revenue and/or credit)	\$	\$
Total Financing	\$5,933,085	\$5,933,085

*OE = Owner's Equity

In Exhibit F-2.1, the applicant provides a September 17, 2021 letter from the Senior Vice President, Operational Finance & Revenue Cycle for Novant Health, Inc. that documents the availability of sufficient funds to finance the capital cost and any initial operating expenses that may be incurred for proposed project. Exhibit F-2.2 contains Novant Health, Inc. and affiliates' Consolidated Financial Statements for years ending December 31, 2020 and 2019 that show cash and cash equivalents as of December 31, 2020 in the amount of \$711,822,000.

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

- Exhibit F-2.1 contains a letter from the Senior Vice President, Operational Finance & Revenue Cycle for Novant Health, Inc. that documents the availability of sufficient funds and a commitment to use those funds to finance the proposed project.
- The letter in Exhibit F-2.1 states the applicant has sufficient cash reserves to fund the capital costs of the project and any initial operating expenses that may be incurred.
- Exhibit F-2.2 contains a copy of Novant Health Inc. and Affiliates' balance sheet as of December 31, 2020, showing adequate funds and revenue necessary to cover the capital costs 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.2, the applicant projects that revenues will exceed operating expenses in all three full fiscal years following completion of the project, as shown in the table below:

NHRMC SCOTTS HILL PROJECTED PET REVENUE AND EXPENSES

	1ST FFY FY 2024	2ND FFY FY 2025	3RD FFY FY 2026
Total PET scans	1,890	2,104	2,214
Total Gross Revenues (Charges)	\$16,537,067	\$18,734,221	\$20,369,468
Total Net Revenue	\$4,213,543	\$4,812,515	\$5,159,169
Average Net Revenue per PET scan	\$2,229	\$2,287	\$2,330
Total Operating Expenses (Costs)	\$1,847,766	\$2,023,805	\$2,079,611
Average Operating Expense per PET scan	\$978	\$962	\$939
Net Income	\$2,365,777	\$2,788,710	\$3,079,558

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

- The applicant bases its projections on the NHRMC Medical Mall (main campus) PET services historical experience.
- The applicant bases projections for gross revenue and net revenue on FY 2021 year to date experience for existing PET services.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

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

- The applicant bases its projections on NHRMC’s historical experience.
- 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 needs of the proposal for all the reasons described above.
- 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.

O-12150-21 Wilmington Health, PLLC – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP for a total of one fixed PET scanner in its existing physician practice on Medical Drive in Wilmington from which the applicant currently provides cardiology, primary care, gastroenterology, podiatry and orthopedic services.

Capital and Working Capital Costs

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

Site Costs	\$29,750
Construction / Renovation Costs	\$1,661,354
Miscellaneous Costs	\$131,579
Total	\$1,822,683

In Exhibit F.1, the applicant provides a certified cost estimate that confirms a construction costs of \$1,691,104, which is \$29,750 more than the amount the applicant included in its Form F.1a [$\$1,691,104 - \$1,661,354 = \$29,750$]. However, the applicant also includes a letter from a bank in Exhibit F.2 that confirms the bank’s willingness to loan up to \$3.5 million, which is sufficient to cover the discrepancy noted between the Form F.1a and the architect’s certified cost estimate.

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 86, the applicant projects that start-up costs will be \$153,482 and initial operating expenses will be \$814,720 for a total working capital of \$968,202. On page 87, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

The applicant adequately demonstrates that the projected capital and working capital costs are based on reasonable and adequately supported assumptions based on the following:

- The applicant bases its project costs on similar projects that its project architect has undertaken in the past.
- The applicant provides an architectural certified cost estimate in Exhibit F.1 that confirms the construction/renovation cost.
- The applicant bases its equipment costs on vendor estimates included in Exhibit C.1-3.
- The applicant provides for the cost of the proposed PET scanner in an operating lease and accounts for the payments as an operating cost.
- The applicant calculates its working capital on the difference between total revenue and total operating costs for the initial operating period.

Availability of Funds

In Section F.2, page 84, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

TYPE	WILMINGTON HEALTH, PLLC	TOTAL
Loans	\$1,822,683	\$0
Accumulated reserves, OE*, Cash/Cash Equivalents	\$0	\$0
Bonds	\$0	\$0
Other	\$0	\$0
Total Financing	\$1,822,683	\$1,822,683

*OE = Owner's Equity

In Exhibit F.2, the applicant provides an October 15, 2021 letter from the Senior Vice President of Truist Bank that indicates the bank's willingness to extend a loan of up to \$3.5 million for the project. Exhibit F.2 also contains an October 15, 2021 letter signed by the Chief Financial Officer (CFO) of Wilmington Health, PLLC that confirms the applicant's commitment to designate the bank loan proceeds to the project.

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

- Exhibit F.2 contains a letter from the Senior Vice President of Truist Bank documenting the bank's willingness to provide a loan in an amount to finance the capital and working capital needs of the proposed project.
- The letter from the CFO of Wilmington Health, PLLC provided in Exhibit F.2 states the applicant will commit the bank loan proceeds to 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.2, the applicant projects that revenues will exceed operating expenses in all three full fiscal years following completion of the project, as shown in the table below:

WH PET SERVICES PROJECTED REVENUE AND EXPENSES

	1 ST FFY CY 2024	2 ND FFY CY 2025	3 RD FFY CY 2026
Total PET Procedures	1,103	1,603	2,115
Total Gross Revenues (Charges)	\$5,647,834	\$8,079,107	\$8,923,220
Total Net Revenue	\$2,531,496	\$3,621,250	\$3,999,602
Average Net Revenue per PET scan	\$2,295	\$2,259	\$1,891
Total Operating Expenses (Costs)	\$2,227,093	\$2,641,507	\$2,790,868
Average Operating Expense per PET scan	\$2,019	\$1,648	\$1,320
Net Income	\$304,403	\$979,743	\$1,208,734

Source: Forms C and F.2b, Section Q
 Numbers may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected utilization is not based on reasonable or adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

Conclusion

The Agency reviewed the:

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

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

- 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.
 - Projected utilization is not based on reasonable or adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- (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 – NHRMC
NC - WH

On page 367, the 2021 SMFP defines the service area for a fixed dedicated PET scanner as “the HSA [Health Service Area] in which it is located (Table 17F-1).” Each applicant proposes to locate the proposed fixed PET scanner in New Hanover County, in HSA V. Thus, the service area for both proposals is HSA V. 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 V, and the number of procedures for each PET scanner in 2018-2019 as found in Table 17F-1 on page 369 of the 2021 SMFP:

Fixed PET Scanners HSA V

TYPE	SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2018-2019
Fixed	Cape Fear Valley Medical Center	1	1,023
Fixed	First Imaging of the Carolinas	1	1,325
Fixed	Novant Health New Hanover Regional Medical Center	1	2,512
Fixed	Southeastern Regional Medical Center*	1	0

*CON issued pursuant to Project ID #N-11866-20, effective June 27, 2020

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant proposes to acquire one fixed PET scanner which will be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHHHRMC would be licensed for two fixed PET scanners; one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

In Section G, pages 113-114, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanner services in HSA V, including the need identified in the 2021 SMFP. The applicant states:

“...NHRMC proposes to acquire and install a fixed PET scanner on its Scotts Hill campus to meet the published need in the 2021 SMFP for one additional fixed dedicated PET scanner in HSA V. The utilization of NHRMC’s existing PER unit generated the need in HSA V. NHRMC is the only fixed provider of PET services in New Hanover County.... ...NHRMC’s proposed location on the Scotts Hill Campus is not duplicative and is instead complementary to the existing PET unit in the county, which is located in the central Wilmington area. The proposed project will allow NHRMC to expand geographic access and extend financial access to quality PET services for New Hanover County residents as well as residents of the surrounding area while simultaneously relieving the capacity constraints that currently exist due to a high and growing demand for PET services.”

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

- There is a need determination in the 2021 SMFP for the proposed fixed PET scanner in HSA V.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing or approved fixed PET scanners in HSA V.

Conclusion

The Agency reviewed the:

- Application

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

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

O-12150-21 Wilmington Health, PLLC – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP for a total of one fixed PET scanner in its existing physician practice on Medical Drive in Wilmington from which the applicant currently provides cardiology, primary care, gastroenterology, podiatry and orthopedic services.

In Section G, page 94, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanner services in HSA V, including the need identified in the 2021 SMFP. The applicant states:

“The proposed project will not result in an unnecessary duplication of the existing or approved health service facilities located in the proposed service area that provide the same service components proposed in this application. The 2021 SMFP includes a need determination for one additional fixed PET scanner in HSA V. ... while the need determination in the 2021 SMFP for additional fixed dedicated PET capacity is for the entirety of HSA V, the need was generated solely by the only fixed dedicated PET scanner in New Hanover County.”

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

- The applicant does not adequately demonstrate the need for the proposed fixed PET scanner in the service area. See the discussion regarding need and projected utilization found in Criterion (3) which is incorporated herein by reference.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion

The Agency reviewed the:

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

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 – Both Applications

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant proposes to acquire one fixed PET scanner which will be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHRMC would be licensed for two fixed PET scanners; one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

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

POSITION	1ST FULL FY (10/1/23- 9/30/24)	2ND FULL FY (10/1/24- 9/30/25)	3RD FULL FY (10/1/25- 9/30/26)
Registered Nurse	1.0	1.0	1.0
Nuclear Medicine Technologist	2.1	2.1	2.1
Total	3.1	3.1	3.1

The assumptions and methodology used to project staffing are provided in Section Q, page 153. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is in Section Q. In Section H.2 and H.3, pages 115-116, the applicant describes the methods used to recruit or fill new positions and its existing and proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services because it is based on the applicant's experience in hospital staffing and providing PET services.

Conclusion

The Agency reviewed the:

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

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

O-12150-21 Wilmington Health, PLLC – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP for a total of one fixed PET scanner in its existing physician practice on Medical Drive in Wilmington from which the applicant currently provides cardiology, primary care, gastroenterology, podiatry and orthopedic services.

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

POSITION	1ST FULL FY	2ND FULL FY	3RD FULL FY
PET Technologist	2.0	2.0	2.0
Total	2.0	2.0	2.0

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 Form F.3, which is in Section Q. In Section H.2 and H.3, pages 96-97, the applicant describes the methods used to recruit or fill new positions and its existing and proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services because it is based on the applicant's experience in staffing and operating other diagnostic centers.

Conclusion

The Agency reviewed the:

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

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

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

C – Both Applications

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant proposes to acquire one fixed PET scanner which will be

located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHRMC would be licensed for two fixed PET scanners; one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

Ancillary and Support Services

In Section I, page 119 the applicant identifies the necessary ancillary and support services for the proposed services. On pages 119-120, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1.1 and I-1.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the existing providers of existing ancillary and support services currently utilized by NHRMC and states the same providers will be available for the proposed PET services.
- The applicant explains how NHRMC currently provides similar ancillary and support services on its existing PET scanner and describes how those same relationships will be in place to provide ancillary and support services on the new proposed PET scanner at the Scotts Hill cancer center.

Coordination

In Section I, page 120 the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

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

Conclusion

The Agency reviewed the:

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

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

O-12150-21 Wilmington Health, PLLC – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP for a total of one fixed PET scanner in its existing physician practice on Medical Drive in Wilmington from which the applicant currently provides cardiology, primary care, gastroenterology, podiatry and orthopedic services.

Ancillary and Support Services

In Section I, pages 98-99 the applicant identifies the necessary ancillary and support services for the proposed PET services. On page 99, 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 based on the following:

- The applicant specifically identifies the existing providers of existing ancillary and support services in the area and states the same providers will be available for the proposed PET services.

Coordination

In Section I, page 99 the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently provides diagnostic imaging services in the service area and has established relationships with local healthcare and social services providers, which will be in place in the proposed program as well.
- The applicant demonstrates physician support for the project in Exhibit I.2.

Conclusion

The Agency reviewed the:

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

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

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

NA – Both Applications

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

O-12150-21 Wilmington Health, PLLC – Acquire one fixed PET scanner – The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

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

NA – Both Applications

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET/CT scanner – The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

O-12150-21 Wilmington Health, PLLC – Acquire one fixed PET scanner – The applicant is not 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 – Both Applications

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant proposes to acquire one fixed PET scanner which will be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHRMC would be licensed for two fixed PET scanners; one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

In Section K, page 123 the applicant states that the project involves constructing 2,878 square feet of new space to develop a PET suite. Line drawings are provided in Exhibit K-1.

On pages 123-124, 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 states the project will be developed by coordinating NHRMC's architect and design team with healthcare contractors experienced in hospital projects.
- The applicant states that the facility will be constructed with cost-effective, energy efficient design techniques.

On page 124, 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:

- The applicant states the project will provide increased geographic access and continuity of care for those patients residing in northern New Hanover County, which will enhance patient safety and increase operational efficiencies.
- The applicant states all required ancillary and support services are already in place and incremental staffing will be minimal.
- The applicant states NHRMC has a robust charity care program that will also be available to the proposed PET services at the Scotts Hill cancer center.

On pages 124-126, the applicant identifies 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
- Responses to comments

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

O-12150-21 Wilmington Health, PLLC – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP for a total of one fixed PET scanner in its existing physician practice on Medical Drive in Wilmington from which the applicant currently provides cardiology, primary care, gastroenterology, podiatry and orthopedic services.

In Section K, page 102 the applicant states that the project involves renovating 2,975 square feet of existing space in its existing facility on Medical Center Drive. Line drawings are provided in Exhibit C.1-1.

On page 103, 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 states the project will be developed in existing space that only requires renovations rather than new construction to accommodate the proposed PET scanner.

On page 103, 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:

- The applicant states the project will be developed in a resource-responsible manner because it needs only renovation rather than new construction.
- The applicant states by offering the proposed PET services in a freestanding physician practice setting, the applicant will avoid passing on large overhead costs associated with hospitals to the patients it proposes to serve.

In Exhibit B.21, the applicant identifies 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
- Responses to comments

Based on that review, the Agency concludes that the application is 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 – NHHNHRMC
 NA - WH

Novant Health New Hanover Regional Medical Center, Inc. – Acquire one fixed PET/CT scanner – In Section L, page 129, the applicant states NHRMC-Scotts Hill is not an existing facility or campus and thus has no historical payor mix to provide. However, the applicant does provide fixed PET services in the service area at the NHRMC Medical Mall campus.

In Section L, page 130, the applicant provides the following comparison based on NHRMC Medical Mall PET services:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	45.9%	50.1%
Male	54.1%	49.9%
Unknown	0.0%	0.0%
64 and Younger	30.0%	80.55%
65 and Older	70.0%	19.5%
American Indian	0.4%	1.0%
Asian	0.1%	1.2%
Black or African-American	11.2%	16.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	86.1%	72.8%
Other Race	1.9%	8.3%
Declined / Unavailable	0.2%	0.0%

The Agency reviewed the:

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

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

O-12150-21 Wilmington Health, PLLC – Neither the applicant nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

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

C – Both Applications

Novant Health New Hanover Regional Medical Center, Inc. – Acquire one fixed PET/CT scanner – Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 131, the applicant states it has no such obligation to provide uncompensated care.

In Section L, page 131, the applicant states that no civil rights access complaints were filed against NHRMC within the last five years.

The Agency reviewed the:

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

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

O-12150-21 Wilmington Health, PLLC – Acquire one fixed PET scanner – Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 108, the applicant states it has no such obligation to provide uncompensated care.

In Section L, page 109, the applicant states that during the 18 months immediately preceding the application deadline, it has not been notified of any patient civil rights equal access complaints filed against “*any affiliated entity of Wilmington Health located on Medical Center Drive.*”

The Agency reviewed the:

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

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

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

C – Both Applications

Novant Health New Hanover Regional Medical Center, Inc. – Acquire one fixed PET/CT scanner – In Section L, page 131, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project for the NHRMC Scotts Hill fixed PET scanner, as shown in the table below:

NHRMC Scotts Hill PET Projected Payor Mix, FY 2026

PAYOR SOURCE	% OF TOTAL
Self-Pay	1.3%
Charity Care	2.8%
Medicare*	70.0%
Medicaid*	3.8%
Insurance*	17.2%
Workers Compensation	0.0%
TRICARE	1.1%
Other (“Government and other”)	3.9%
Total	100.0%

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.3% of total PET services at NHRMC Scotts Hill will be provided to self-pay patients, 2.8% to charity care patients, 70.0% to Medicare patients and 3.8% to Medicaid patients.

On page 132, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the FY 2020 PET services payor mix at the NHRMC main campus.

The Agency reviewed the:

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

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

O-12150-21 Wilmington Health, PLLC – Acquire one fixed PET scanner – In Section L, page 109, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project for PET services, as shown in the tables below:

WH Projected Payor Mix, FY 2026

PAYOR SOURCE	% OF TOTAL
Self-Pay	3.1%
Charity Care	WH does not track
Medicare*	65.3%
Medicaid*	2.0%
Insurance*	27.5%
Workers Compensation	Included in “other”
TRICARE	
Other	2.1%
Total	100.0%

*Includes managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.1% of total services will be provided to self-pay patients, 65.3% to Medicare patients and 2.0% to Medicaid patients.

On page 109, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the FY 2020 payor mix for all Wilmington Health hematology/oncology and cardiology patients.

The Agency reviewed the:

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

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

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

C – Both Applications

Novant Health New Hanover Regional Medical Center, Inc. – Acquire one fixed PET/CT scanner – In Section L, page 134, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

O-12150-21 Wilmington Health, PLLC – Acquire one fixed PET scanner –

In Section L, pages 111-112, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

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

C – Both Applications

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant proposes to acquire one fixed PET scanner which will be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHNHRMC would be licensed for two fixed PET scanners; one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

In Section M, page 135, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- NHRMC is an existing hospital and has “*hundreds of established clinical education agreements*” in place and will continue to operate under those agreements after the addition of the proposed PET scanner.
- Exhibits M-1.1 and M-1.2 contain lists of existing clinical education agreements currently in place for Novant Health and NHRMC which will be applicable to the proposed additional PET scanner services.

Conclusion

The Agency reviewed the:

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

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

O-12150-21 Wilmington Health, PLLC – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP for a total of one fixed PET scanner in its existing physician practice on Medical Drive in Wilmington from which the applicant currently provides cardiology, primary care, gastroenterology, podiatry and orthopedic services.

In Section M, page 113, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purpose. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- Wilmington Health has a history of supporting health professional training programs in the community.
- The applicant states it will continue to offer those same programs after the addition of the proposed PET scanner.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C – NHNHRMC
 NC - WH

On page 367, the 2021 SMFP defines the service area for a fixed dedicated PET scanner as “the HSA [Health Service Area] in which it is located (Table 17F-1).” Each applicant proposes to locate the proposed fixed PET scanner in New Hanover County, in HSA V. Thus, the service area for both proposals is HSA V. 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 V, and the number of procedures for each PET scanner in 2018-2019 as found in Table 17F-1 on page 369 of the 2021 SMFP:

Fixed PET Scanners HSA V			
TYPE	SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2018-2019
Fixed	Cape Fear Valley Medical Center	1	1,023
Fixed	First Imaging of the Carolinas	1	1,325
Fixed	Novant Health New Hanover Regional Medical Center	1	2,512
Fixed	Southeastern Regional Medical Center*	1	0

*CON issued pursuant to Project ID #N-11866-20, effective June 27, 2020

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant proposes to acquire one fixed PET scanner which will be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHNHRMC would be licensed for two fixed PET scanners;

one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 137, the applicant states:

“The proposed project will not have a negative impact on competition in the proposed service area, as NHRMC is the only provider of PET services in New Hanover County and in the proposed service area. The next closest provider in HSA V is Columbus Regional Healthcare System, a mobile PET provider. The next closest PET provider after Columbus Regional Healthcare System is Southeastern Regional Medical Center which was recently approved to convert a mobile PET unit to fixed in 2020. Southeastern Regional Medical Center is a 150-mile roundtrip journey for New Hanover County residents. The next closest fixed PET provider that is currently operational is First Imaging of the Carolinas located approximately 130 miles northwest of New Hanover County (260 miles roundtrip).”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 138, the applicant states:

“...All required administrative and support services are already available through NHRMC and offered in support of the Scotts Hill Campus. Very minimal incremental staff will be needed. The proposed project cost effectively meets multiple needs by addressing capacity constraints experienced by the NHRMC-Medical Mall PET unit.”

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 N, page 138, the applicant states:

“Since the proposed fixed PET will be a department of NHRMC, an existing hospital, and will be located on the existing Scotts Hill Campus, it will follow and maintain the same quality and performance improvement policies and programs already established at NHRMC.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 138-139 the applicant states:

“The proposed PET unit at NHRMC-Scotts Hill will provide access to medically underserved groups at a rate that is consistent with NHRMC’s historical experience.

...

NHRMC has historically provided a significant amount of charity care. ... NHRMC’s affiliation with Novant Health will further enhance access to care for the medically underserved. in fact, Novant Health has expanded NHRMC’s charity care policy so

that uninsured patients with an annual family income less than or equal to 300 percent of the federal poverty level will not receive a bill.”

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

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

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

Conclusion

The Agency reviewed the:

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

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

O-12150-21 Wilmington Health, PLLC – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP for a total of one fixed PET scanner in its existing physician practice on Medical Drive in Wilmington from which the applicant currently provides cardiology, primary care, gastroenterology, podiatry and orthopedic services.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 114, the applicant states:

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to PET services in HSA V, particularly within New Hanover County.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 114, the applicant references Application Section B.20(c). The Project Analyst notes there is no Section B.20; the reference is to Section B.2(c), pages 31-32 which states in part:

“...Wilmington Health proposes an efficient and cost effective alternative for adding fixed dedicated PET capacity to the proposed service area. Wilmington Health will develop the proposed project in a resource-responsible manner as it will house the fixed dedicated PET/CT scanner in existing space located at Wilmington Health on Medical Center Drive. As a freestanding location, the costs associated with PET services are less in comparison to PET services in hospitals....”

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

Regarding the impact of the proposal on quality, in Section N, page 114, the applicant references Application Section B.20(a). The Project Analyst notes there is no Section B.20; the reference is to Section B.2(a), which provides information regarding the impact of the proposed PET scanner on the quality of services provided by WH. The applicant provides additional information in Exhibits B.20-1 through B.20-3.

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 114 the applicant references Application Section B.20(b). The Project Analyst notes there is no Section B.20; the reference is to Section B.2(b), which provides information regarding access to proposed PET services that will be provided by WH, as well as existing services provided by WH. The applicant provides additional information in Exhibits B.20-4 and B.20-5.

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

However, the applicant does not adequately describe the expected effects of the proposed services on competition in the service area and does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness because the applicant does not adequately demonstrate that the proposal is cost effective because:

- The applicant did 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments

Based on that review, the Agency concludes that the application is 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 – NHNHRMC
NA - WH

O-12143-21 Novant Health New Hanover Regional Medical Center, LLC – Acquire one fixed PET scanner – The applicant proposes to acquire one fixed PET scanner which will be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHNHRMC would be licensed for two fixed PET scanners; one at the Medical Mall adjacent to the main hospital campus in central Wilmington and one on the Scotts Hill campus in northern Wilmington.

In Section Q, Form O the applicant identifies the facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 18 facilities located in North Carolina.

In Section O, page 142 the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care resulting in a finding of “immediate jeopardy” 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 all Novant Health and NHRMC facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

O-12150-21 Wilmington Health, PLLC – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP for a total of one fixed PET scanner in its existing physician practice on Medical Drive in Wilmington from which the applicant currently provides cardiology, primary care, gastroenterology, podiatry and orthopedic services.

Neither the applicant nor any related entities own, operate, or manage an existing health service facility located in North Carolina. Therefore, Criterion (20) is not applicable to this review.

- (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 – NHHNHRMC
NC - WH

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

SECTION .3700 - CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER

10A NCAC 14C .3703 PERFORMANCE STANDARDS

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

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

-C- **NHHNHRMC.** In Section Q, Form C, the applicant projects that the proposed PET scanner will perform 2,214 procedures, which is more than 2,080 procedures by the end of the third year of operation. Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.

-NC- **WH.** In Section Q, Form C, the applicant projects that the proposed PET scanner will perform 2,115 procedures by the end of the third year of operation, which is more than 2,080 procedures. However, projected utilization is not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is not conforming to this Rule.

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

-C- **NHHNHRMC.** In Section C, page 93 and in Section Q, Form C.2a, the applicant states that the existing fixed PET scanner at NHRMC Medical Mall performed

2,796 total procedures in FY 2020, which is more than 2,080 procedures in the last full federal fiscal year. In Exhibit C-4.2, pages 70-73, the applicant states the two fixed PET scanners and one mobile PET scanner operated by Novant Health affiliates performed an average of 2,304 procedures per scanner during the same time.

-NA- WH. The applicant does not currently operate a PET scanner.

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

-C- NHRMC. In Section Q, Form C, the applicant states that the two existing and proposed fixed PET scanners at NHRMC Medical Mall and Scotts Hill will perform a total of 4,709 procedures during the third year following project completion, which is 2,354 per scanner. The applicant states the proposed PET scanner at Scotts Hill will perform 2,214 procedures and the scanner at the Medical Mall campus will perform 2,495 procedures. Both PET scanners will perform an average of over 2,080 procedures in the third full federal fiscal year of operation following project completion. In Exhibit C-4.2, page 73, The applicant projects two mobile PET units, one proposed which will not be considered in this review and one existing, operated by Novant Health Forsyth Medical Center (NHFMC) will perform 4,351 procedures in the third full federal fiscal year of operation, which is 2,175 per unit. A projection of 2,175 PET procedures on the existing mobile PET scanner exceeds the performance standards for that unit. In Exhibit C-4.2, page 74, the applicant states the fixed PET scanner at NHFMC will perform 2,124 PET procedures in the third full federal fiscal year of operation. In Exhibit C-4.2, page 75, the applicant states the fixed PET scanner at Novant Health Presbyterian Medical Center (NHPMC) will perform 2,411 PET procedures in the third full federal fiscal year of operation. Each existing PET scanner operated by the applicant projects to perform in excess of 2,080 PET procedures per scanner.

-NA- WH. The applicant does not currently operate a PET scanner and does not have any approved PET scanners.

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

-C- NHRMC. The applicant provides its assumptions and methodology in Section C, Section Q and Exhibit C-4.2. The applicant adequately demonstrates that its assumptions are reasonable and adequately supported. See the discussion found in Criterion (3) regarding projected utilization which is incorporated herein by reference. The application is conforming to this Rule.

- NC- **WH.** The applicant provides its assumptions and methodology in Section C and in the assumptions in Section Q. The applicant does not adequately demonstrate that its assumptions are reasonable or adequately supported. See the discussion found in Criterion (3) regarding projected utilization which is incorporated herein by reference. The application is not conforming to this Rule.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2021 State Medical Facilities Plan, no more than one fixed PET scanner may be approved for Health Service Area IV in this review. Because the two applications in this review collectively propose to develop two additional fixed PET scanners to be located in Health Service Area V, both 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.

- **Project ID #O-12143-21 Novant Health Inc., and Novant Health New Hanover Regional Medical Center, LLC** – Acquire one fixed PET scanner to be located on the Scotts Hill campus pursuant to the need determination in the 2021 SMFP. Following project completion, NHHNHRMC would be licensed for two fixed PET scanners; one on the main hospital campus in central Wilmington and one on the Scotts Hill cancer center campus in northern Wilmington.
- **Project ID #O-12150-21 / Wilmington Health** – Acquire 1 fixed PET/CT scanner pursuant to the need determination in the 2021 SMFP for a total of no more than one fixed PET/CT scanner in its existing physician practice on Medical Drive in Wilmington upon project completion.

Conformity with Statutory and Regulatory Review Criteria

The application submitted by **Novant Health Inc., and Novant Health New Hanover Regional Medical Center, LLC** is conforming to all applicable statutory and regulatory review criteria.

The application submitted by **Wilmington Health** is not conforming to all applicable statutory and regulatory review criteria.

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. Therefore, regarding this comparative factor, the application submitted by **Novant Health, Inc.** is the more effective alternative.

Scope of Services

Regarding scope of services, both applications were submitted in response to the need determination for one fixed PET scanner in HSA V in the 2021 State Medical Facilities Plan (SMFP). Generally, the application proposing to provide the broadest scope of services 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/CT scanner:

FACILITY	PROPOSED SCOPE OF PET SERVICES		
	ONCOLOGICAL PET	CARDIAC PET	NEUROLOGIC PET
Novant Health New Hanover Regional Medical Ctr.	X	X	X
Wilmington Health	X	X	X

Both applicants propose to provide PET services to oncology, cardiac and neurologic patients. Therefore, regarding scope of services, the applications would be equally effective, since each proposes the same scope of services. However, the application submitted by **WH** does not comply with all applicable statutory and regulatory criteria and thus is not approvable. Therefore, regarding this comparative factor, the application submitted by **NHNHRMC** is the more effective alternative.

Historical Utilization

The following table illustrates historical utilization of each applicant’s existing PET scanners in HSA V as provided in the 2021 SMFP representing FY 2019 reported utilization.

Fixed PET Scanners in HSA V*

FACILITY	# OF FIXED PET SCANNERS	FY 2019 TOTAL	2019 PET PROCEDURES PER SCANNER	FY 2020 TOTAL	2020 PET PROCEDURES PER SCANNER
Novant Health New Hanover Regional Medical Ctr.	1	2,512	2,512	2,796	2,796
Wilmington Health	0	0	0	0	0

Source: 2021 SMFP, 2022 SMFP

*Does not include those providers of PET services in HSA V that are not a part of this competitive review.

NHNHRMC is the only provider of PET services in HSA V in this review and thus performed the highest number of procedures per fixed PET scanner in FY 2019 and FY 2020. Therefore, **NHNHRMC** is the more effective alternative for this comparative factor.

Geographic Accessibility (Location within the Service Area)

The 2021 SMFP identifies the need for one fixed PET scanner in HSA V, which includes sixteen counties. Following is a table that illustrates the location of the existing and approved fixed PET scanners in HSA V:

Fixed PET Scanners in HSA V

FACILITY	CITY	COUNTY
Cape Fear Valley Medical Center	Fayetteville	Cumberland
First Imaging of the Carolinas	Pinehurst	Moore
New Hanover Regional Medical Center	Wilmington	New Hanover
Southeastern Regional Medical Center*	Lumberton	Robeson

*Southeastern Regional Medical Center (SRMC) was awarded a Certificate of Need for one fixed PET scanner on June 20, 2020. See Project ID #N-11866-20.

All the existing and approved fixed PET scanners in HSA V are located in either Cumberland, Moore, Robeson or New Hanover counties. The PET scanner awarded to SRMC was pursuant to an adjusted need determination in Robeson County. According to the SMFPs from 2015-2021, the existing PET

scanners in Cumberland, Moore and Robeson counties are underutilized. The utilization of the PET scanner operated by NHRMC in Wilmington resulted in a need determination in HSA V. The city of Wilmington and the area surrounding it in New Hanover County is densely populated, particularly with population groups that would utilize PET services, as NHRMC’s historical utilization has shown. See the following table prepared by the Project Analyst:

PET Scanners in HSA V, Number of Procedures and Percent of Capacity

PROVIDER	2015 SMFP		2016 SMFP		2017 SMFP		2018 SMFP		2019 SMFP		2020 SMFP		2021 SMFP	
	# PR	%CAP	# PR	%CAP	# PR	%CAP	# PR	%CAP	# PR	%CAP	# PR	%CAP	# PR	%CAP
NHRMC	1,464	48.8%	1,543	51.4%	1,691	56.4%	1,847	61.6%	2,044	68.1%	2,163	72.1%	2,512	83.3%
CFVMC	1,047	39.9%	882	29.4%	1,023	34.1%	986	32.9%	1,301	43.4%	953	31.8%	1,023	34.1%
First Imaging	973	32.4%	885	29.5%	1,023	34.1%	1,005	33.5%	1,120	37.3%	1,113	37.1%	1,325	44.2%

Numbers may not sum due to rounding
 Source: 2015-2021 SMFPs

The table shows that NHRMC’s existing PET scanner, the scanner that generated the need determination, is in the area within HSA V that most utilizes existing PET services. Each applicant in this review proposes to locate its fixed PET scanner in Wilmington. However, **WH** proposes to locate its PET scanner in Wilmington, less than one mile from the existing fixed PET scanner. **NHNHRMC** proposes to locate its PET scanner in a medical office building on the Scotts Hill hospital campus, located in the northern portion Wilmington in New Hanover County; therefore, its PET scanner would provide more access to patients for whom the congestion of Wilmington traffic is burdensome. Thus, regarding this comparative factor, the proposal submitted by **NHNHRMC** is the more effective alternative, since it proposes to locate the proposed PET scanner in an area that would serve more patients in the northern portion of Wilmington and New Hanover County. The application submitted by **WH**, if approvable, would be less effective, because it proposes to locate the linear accelerator in downtown Wilmington, less than one mile from an existing PET scanner.

Access by Service Area Residents

On page 367, the 2021 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.” Each applicant proposes to locate the fixed PET scanner in New Hanover County which, according to Appendix A on page 373 is in HSA V. Thus, the service area for each proposal is HSA V. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional PET services in or in close proximity to the service area in which they live. Each applicant proposes to serve counties located within HSA V and outside of HSA V. This analysis will focus on service to residents of counties within HSA V, the service area in which a need determination exists.

On page 45 of its application, **NHNHRMC** states it proposes to offer PET services at the Scotts Hill location, but bases the population to be served on existing PET services at the Medical Mall location and includes the following HSA V counties: New Hanover, Pender, Columbus, Brunswick, Bladen,

and Sampson counties. The other counties comprising its proposed service area are not being considered for this comparative factor.

On page 41 of its application, **WH** states its service area consists of the following HSA V counties: New Hanover, Brunswick and Pender counties. The other counties comprising its proposed service area are not being considered for this comparative factor. Each applicant provides the projected number of PET scans to be provided in each of the fiscal years following project completion. The Project Analyst totaled the number of scans to be provided by each applicant in the counties that comprise HSA V in the third fiscal year following project completion, FY 2026. See the following table, prepared by the Project Analyst:

HSA V COUNTY	NHNHRMC	WH
New Hanover	825	1,176
Pender	366	130
Brunswick	138	734
Columbus	28	0
Bladen	24	0
Sampson	12	0
Total	1,393	2,040

NHNHRMC projects to provide fewer PET scans to residents in counties that comprise HSA V than **WH**. Therefore, regarding access by service area residents, the application submitted by **WH** would be more effective because it proposes to provide PET scans to a greater number of service area residents than the application submitted by **NHNHRMC**. However, the application submitted by **WH** does not comply with all applicable statutory and regulatory criteria and thus is not approvable. Therefore, regarding this comparative factor, the application submitted by **NHNHRMC** is the more effective alternative.

Access by Underserved Groups

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

“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is evaluated as a separate factor.

Projected Charity Care

Generally, the application proposing to provide the most charity care is the more effective alternative regarding this comparative factor, since the provision of charity care can indicate an applicant's provision of care to medically underserved groups.

The following table prepared by the Project Analyst compares projected charity care in the third full fiscal year following project completion for each facility's proposed PET services using the following metrics: charity care dollars and charity care as a percent of gross revenue:

	NHNHRMC-SCOTTS HILL CAMPUS	WH
Dollars	\$575,532	\$192,969
Gross Revenue	\$20,369,468	\$8,923,220
Charity Care as % of Gross Revenue	2.8%	2.2%

As shown above, **NHNHRMC** proposes to provide the highest dollar amount of charity care and the greatest percentage of gross revenue as charity care.

In Section L, page 133, **NHNHRMC** states:

"...NHRMC also projected the number of charity care patients for PET services provided by NHRMC as a whole. This is based on the projected PET volume presented in Section Q, Form C Utilization Assumptions...."

In Section Q, Form Utilization Assumptions, **NHNHRMC** states:

"Charity care is based on NHRMC existing experience for PET charity care.

...

Projection is 2.8% of Gross Revenue and based on historic experience. Charity Care percentage is held constant for all 3 project years."

In Section L, page 102, **WH** states:

"Wilmington Health's internal data does not track charity care as a payor source for patients. Patients in any payor category can and do receive charity care."

In Section Q, Form Utilization Assumptions, **WH** states:

"Charity care is the difference between gross and net revenue for self pay."

As shown above, each applicant, in response to Section L.4a and in the assumptions to Forms F.2 and F.3 in Section Q, describes the provision of charity care differently, so it is a factor that cannot be compared as set forth in each application. Since each applicant defines charity care differently, it is not possible to

compare the provision of charity care as a percent of gross revenue. Therefore, regarding the provision of charity care, the result of this analysis is inconclusive.

Projected Medicaid

The following table shows each applicant’s percentage of gross revenue and dollar amount projected to be provided to Medicaid patients for PET services in each applicant’s third full year of operation following completion of the project, based on the information provided in each applicant’s pro forma financial statements in Section Q for total facility services. Generally, the application proposing to provide a higher percentage and/or dollar amount of gross revenue to Medicaid patients is the more effective alternative regarding this comparative factor, since the provision of Medicaid can indicate an applicant’s provision of care to medically underserved groups.

PROJECTED MEDICAID			
PROJECT YEAR 3, PET SERVICES			
	Medicaid Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
NH NHRMC	\$624,592	\$20,369,468	3.1%
WH	\$179,272	\$8,923,220	2.0%

As shown in the table above, **NHNHRMC** projects the highest percentage and dollar amount of Medicaid dollars for PET services as a percent of gross revenue in the third project year. Therefore, **NHNHRMC** is the more effective alternative regarding this comparative factor.

Projected Medicare

The following table shows each applicant’s percentage and dollar amount of gross revenue projected to be provided to Medicare patients for PET services in the applicant’s third full year of operation following completion of their project, based on the information provided in the applicant’s pro forma financial statements in Section Q for total facility. Generally, the application proposing to provide a higher percentage and/or dollar amount of gross revenue to Medicare patients is the more effective alternative regarding this comparative factor since the provision of Medicare can indicate an applicant’s provision of care to medically underserved groups.

PROJECTED MEDICARE			
PROJECT YEAR 3, PET SERVICES			
	Medicare Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
NH NHRMC	\$13,454,760	\$20,369,468	66.1%
WH	\$5,828,759	\$8,923,220	65.3%

As shown in the table above, **NHNHRMC** projects the highest percentage and highest dollar amount of gross revenue for PET services that will be provided to Medicare patients. Therefore, **NHNHRMC** is the more effective alternative regarding this comparative factor.

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. **WH** represents a new provider of PET services in New Hanover County, since **NHRMC** is currently the only provider of PET services in New Hanover County. Therefore, regarding this comparative factor, the proposal submitted by **WH** would be the more effective alternative because it introduces a new provider of PET services in the county. However, the application submitted by **WH** does not comply with all applicable statutory and regulatory criteria and thus is not approvable. Therefore, regarding this comparative factor, the application submitted by **NHNHRMC** is the more effective alternative.

Projected Average Net Revenue per PET Scan

The following table compares projected average net revenue per PET procedure in the third full fiscal year following project completion for each facility, 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 procedure 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.

AVERAGE NET REVENUE PER PET PROCEDURE			
PROJECT YEAR 3			
	TOTAL # OF PROCEDURES	Total Net Revenue	Average Net Revenue / PET Procedure
NH NHRMC	2,214	\$5,159,169	\$2,330
WH	2,115	\$3,999,602	\$1,891

As shown in the table above, **WH** projects the lowest average net revenue per PET procedure in the third full fiscal year following project completion. Therefore, **WH** would be the most effective alternative regarding this comparative factor. However, the application submitted by **WH** does not comply with all applicable statutory and regulatory criteria and thus is not approvable. Therefore, regarding this comparative factor, the application submitted by **NHNHRMC** is the more effective alternative.

Projected Average Operating Expense per PET Scan

The following table compares projected average operating expense per PET procedure in the third full fiscal year following project completion for each facility, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, regarding this factor, the application proposing the lowest average operating expense per procedure is the more effective since a lower average operating cost per procedure may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

AVERAGE OPERATING COST PER PET PROCEDURE			
PROJECT YEAR 3			
	TOTAL # OF PROCEDURES	Total Operating Cost	Average Operating Cost / PET Procedure
NH NHRMC	2,214	\$2,079,611	\$939
WH	2,115	\$2,790,868	\$1,320

As shown in the table above, **NHNHRMC** projects the lowest average operating cost per PET procedure in the third full fiscal year following project completion. Therefore, **NHNHRMC** is the most effective alternative regarding 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 they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

COMPARATIVE FACTOR	NHNHRMC	WH
Conformity with Statutory and Regulatory Review Criteria	Yes	No
Scope of Services	Equally Effective	Not Approvable
Historical Utilization	More Effective	Not Approvable
Geographic Accessibility (Location within the Service Area)	More Effective	Not Approvable
Access by Service Area Residents	Less Effective	Not Approvable
Provision of Charity Care	Inconclusive	Not Approvable
Access by Medicaid Patients	More Effective	Not Approvable
Access by Medicare Patients	More Effective	Not Approvable
Competition (Access to a New or Alternate Provider)	Less Effective	Not Approvable
Projected Average Net Revenue per PET Procedure, 3 rd PY	Less Effective	Not Approvable
Projected Average Operating Cost per PET Procedure, 3 rd PY	More Effective	Not Approvable

As shown in the table above, the application submitted by **Novant Health New Hanover Regional Medical Center** was determined to be a more effective alternative regarding the following factors:

- Conformity with Statutory and Regulatory Review Criteria
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Medicaid Patients
- Access by Medicare Patients
- Projected Average Operating Cost per PET Procedure in the third project year

The application submitted by **Wilmington Health** is not conforming to the applicable statutory and regulatory review criteria and thus cannot be an effective alternative. Consequently, the application submitted by **Wilmington Health** is denied.

DECISION

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **Novant Health New Hanover Regional Medical Center** is the more effective alternative proposed in this review for the development of one additional fixed PET scanner in HSA V pursuant to the need determination in the 2021 SMFP.

Novant Health New Hanover Regional Medical Center proposes to acquire one fixed PET/CT scanner to be located at the Scotts Hill Cancer Center campus in north Wilmington pursuant to the need determination in the 2021 SMFP. The application submitted by **Novant Health New Hanover Regional Medical Center** is approved subject to the following conditions:

1. **Novant Health, Inc. and Novant Health New Hanover Regional Medical Center, LLC (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 2021 SMFP, to be located at the Scotts Hill Cancer Center campus, for a total of no more than two fixed PET scanners, one at the Medical Mall campus and one at the Scotts Hill Cancer Center Hospital campus.**
3. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on August 1, 2022. The second progress report shall be due on November 1, 2022 and so forth.**
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. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. **Payor mix for the services authorized in this certificate of need.**

- b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
- 7. 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.**