

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 15, 2021

Findings Date: December 15, 2021

Project Analyst: Tanya M. Saporito

Co-Signer: Gloria C. Hale

Project ID #: Q-12138-21

Facility: Vidant Medical Center

FID #: 933410

County: Pitt

Applicant: Pitt County Memorial Hospital, Incorporated

Project: Acquire one new fixed PET Scanner pursuant to the need determination in the 2021 SMFP for a total of no more than two fixed PET scanners upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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.

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Pitt County Memorial Hospital, Inc., d/b/a Vidant Medical Center (VMC), hereinafter referred to as the applicant or VMC, is an acute care hospital located in Greenville, in Pitt County. VMC is part of University Health Services of Eastern North Carolina, which is a non-profit hospital system comprised of nine hospital campuses and several ambulatory surgical facilities. In this application, VMC proposes to acquire one fixed PET scanner pursuant to the need identified in the 2021 State Medical Facilities Plan (SMFP) for Health Service Area (HSA) VI, which includes Pitt County. The applicant proposes to locate the PET scanner at the hospital in Greenville, for total of two PET scanners at the hospital.

Need Determination

Chapter 17 of the 2021 SMFP includes a methodology for determining the need for additional fixed PET scanners by service area. Application of the need methodology in the 2021 SMFP identified a need for one additional fixed PET scanner in HSA VI, the PET Service Area that includes Pitt County. One application, submitted by VMC, was received in response to the need determination. Therefore, the application is consistent with the need determination in the 2021 SMFP.

Policies

There are two policies in the 2021 SMFP which are applicable to this review: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3

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.”

In Section B, pages 24-25, the applicant explains why it believes its application is conforming to Policy GEN-3. On page 24, the applicant states that the addition of a second fixed PET scanner to serve its patients will ensure the highest quality PET services in the safest environment possible. The applicant lists some of its safety and quality system-wide policies which are also included in Exhibits 1-3.

On page 25, the applicant states: *“VMC (and VH) is a not-for-profit corporation formed for the purpose of providing quality health care services to ALL persons seeking care (emphasis in original).”* The applicant quotes its Patient Rights Policy which states in part that patients have the right to treatment without discrimination.

On page 25, the applicant states: *“Vidant Medical Center will use the proposed new PET scanner to enhance operational efficiency and to increase patient access, particularly for patients who today cannot receive services due to capacity constraints on the existing scanner.”* The applicant states the addition of a second fixed PET scanner *“will ensure VMC maximizes the value per dollar spent.”*

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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety, or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 27, the applicant explains why it believes its application is conforming to Policy GEN-4. On page 27, the applicant states:

“...all Vidant Health Facilities, including VMC, are committed to energy efficiency and sustainability, including water conservation, that balances the need for healthcare services and environmental sustainability in the communities served.”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 fixed PET scanners than are 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 for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of PET scanner services;
 - The applicant adequately documents how the project will promote equitable access to PET scanner services; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
 - The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

(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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

VMC proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP, to be located at its hospital in Greenville.

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 Pitt County which, according to Appendix A on page 373 is in HSA VI. Thus, the service area for this proposal is HSA VI. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current patient origin for VMC’s existing PET scanner, from page 30 of the application:

**VMC PET Services Historical Patient Origin
 Last Full Fiscal Year (10/1/19 – 9/30/20)**

COUNTY	# OF PATIENTS	% OF TOTAL
Pitt	779	29.4%
Beaufort	267	10.1%
Edgecombe	203	7.7%
Lenoir	164	6.2%
Martin	138	5.2%
Wilson	106	4.0%
Wayne	111	4.2%
Halifax	109	4.1%
Nash	81	3.1%
Craven	79	3.0%
Bertie	75	2.8%
Greene	65	2.5%
Hertford	64	2.4%
Onslow	66	2.5%
Duplin	58	2.2%
Northampton	49	1.8%
Washington	48	1.8%
Chowan	37	1.4%
Carteret	23	0.9%
All other (<1%)	131	4.9%
Total	2,653	100.0%

Source: Application page 30
 Percentages may not sum due to rounding

The following table illustrates projected patient origin for the first three full fiscal years (FY) of operation for VMC's PET services, from page 32 of the application:

VMC PET Services Projected Patient Origin

COUNTY	1 ST FULL FY (10/1/23 – 9/30/24)		2 ND FULL FY (10/1/24 – 9/30/25)		3 RD FULL FY (10/1/25 – 9/30/26)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Pitt	1,010	26.1%	1,061	26.1%	1,103	26.1%
Beaufort	340	8.8%	357	8.8%	371	8.8%
Edgecombe	258	6.7%	271	6.7%	282	6.7%
Lenoir	190	4.9%	200	4.9%	208	4.9%
Martin	184	4.7%	193	4.7%	201	4.7%
Wilson	140	3.6%	147	3.6%	153	3.6%
Wayne	134	3.5%	141	3.5%	146	3.5%
Halifax	122	3.2%	129	3.2%	134	3.2%
Nash	102	2.6%	107	2.6%	112	2.6%
Craven	98	2.5%	102	2.5%	107	2.5%
Bertie	89	2.3%	94	2.3%	98	2.3%
Greene	80	2.1%	84	2.1%	87	2.1%
Hertford	79	2.0%	83	2.0%	86	2.0%
Onslow	72	1.9%	76	1.9%	79	1.9%
Duplin	70	1.8%	73	1.8%	76	1.8%
Northampton	69	1.8%	72	1.8%	75	1.8%
Washington	65	1.7%	69	1.7%	71	1.7%
Chowan	46	1.2%	49	1.2%	51	1.2%
Carteret	31	0.8%	32	0.8%	34	0.8%
All other (<1%)	693	17.9%	728	17.9%	757	17.9%
Total	3,873	100.0%	4,066	100.0%	4,229	100.0%

Source: Application page 32
 Percentages may not sum due to rounding

In Section C, page 32 and Form C, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because it is based on the applicant’s historical experience in providing PET services on its existing PET scanner at the hospital.

Analysis of Need

In Section C, pages 34-40, 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 VI. The applicant states its existing PET scanner is currently operating at 104% capacity based on the SMFP defined threshold of 3,000 procedures (page 34).
- Current capacity constraints at VMC – the applicant states that since approximately 2015, PET utilization at the hospital has increased by nearly 11% annually, and currently operates above capacity. See the following table, from page 35:

VMC Historical Utilization, FY 2015-FY 2021

FISCAL YEAR	# PROCEDURES	% CHANGE	% CAPACITY
2015	1,895	--	63.2%
2016	2,044	7.9%	68.1%
2017	2,280	11.5%	76.0%
2018	2,244	-1.6%	74.8%
2019	2,442	8.8%	81.4%
2020	2,653	8.6%	103.5%
2021	3,104	17.0%	113.8%
Average % Change		10.6%	

The applicant states that to continue to operate its existing PET scanner above capacity will continue to cause access issues for its patients and will decrease operational efficiency. Many of VMC’s patients are medically underserved and are unable to travel to other sites for PET services. The applicant states that to continue to serve existing and projected patients, the existing PET scanner would operate at 141% capacity by 2026, which is not feasible (page 35).

- Address cancer mortality disparities in eastern North Carolina – The applicant cites the National Cancer Institute’s statistics regarding the incidence of cancer and the rising death rates from cancer in the US. The applicant states that, according to the National Cancer Institute, cancer expenditures were projected to be \$151 billion in 2020. Additionally, in North Carolina, cancer is the leading cause of death, accounting for nearly 1 out of 5 deaths. The applicant states that, in eastern North Carolina, including Pitt County, the incidence of cancer appears to be proportionate to the rest of the state; however, the cancer mortality rate is disproportionately high. The applicant states this data suggests that current healthcare is not reaching the cancer patients it needs to, and since PET services are instrumental in diagnosing and detecting cancer, more PET services are needed to help alleviate the disparity in mortality rates through earlier diagnosis and treatment (pages 36-37).
- Expand PET capacity to benefit neuroscience and cardiovascular patients – the applicant states that, while PET services are traditionally used to detect and monitor cancer, recent PET technology has expanded into detecting and monitoring both neurological and cardiovascular diseases. The applicant states its current PET scanner is primarily used for cancer detection but does use it minimally to detect and monitor both neurological and cardiovascular diseases. VMC is the only tertiary medical center supporting eastern North Carolina and provides a broad continuum of complex neurological and cardiovascular services to residents in the area. The applicant states the proposed PET scanner will allow VMC to increase capacity for cancer detection and the neurological and cardiovascular services that are needed in the area (pages 38-39).
- Maintain a regional resource for all of HSA VI – the applicant states that it is a regional referral center with a history of serving a broad geographic region within HSA VI. The applicant states that the other providers of fixed or mobile PET services within HSA

VI primarily serve patients within their host community. VMC historically provides all services, including PET services, to patients throughout HSA VI (page 39).

- Increase patient and provider satisfaction, research, education and clinical trial capacity – the applicant states existing capacity constraints must be addressed, as the only existing option is to extend hours into late evening time slots, which is less than optimal for its patients and staff. Additionally, the applicant states that, as a tertiary academic medical center, given current capacity, the opportunities for clinical education and research is limited. The additional PET scanner will not only serve existing and future patients but also provide additional opportunity for critical clinical research (page 40).

Projected Utilization

In Section Q, Form C, the applicant provides historical and projected utilization for the proposed fixed PET scanner through the first three operating years of the proposed project (FY 2024-FY 2026) as summarized in the following tables:

Historical and Interim Utilization, VMC PET Services

	PRIOR FULL FY (FY 2020)	INTERIM FULL FY (FY 2021)	INTERIM FULL FY (FY 2022)	INTERIM FULL FY (FY 2023)
Fixed PET scanner	1	1	1	1
Number of Procedures	2,653	3,104	3,414	3,653

Projected Utilization, VMC PET Services

	INTERIM FULL FY (FY 2024)	INTERIM FULL FY (FY 2025)	INTERIM FULL FY (FY 2026)
Fixed PET scanner	2	2	2
Number of Procedures	3,873	4,066	4,229

The applicant provides its assumptions and methodology for projecting utilization for its proposed services in Section Q, which is summarized as follows:

Historical Utilization – The applicant provides historical utilization on its existing PET scanner from FFY 2019 to FFY 2021 (annualized based on nine months of data), as shown in the following table:

	# SCANS	% CHANGE	SCANS/UNIT
FY 2019	2,442	--	2,442
FY 2020	2,653	9%	2,653
FY 2021	3,104	17%	3,104

As shown above, the applicant reports that PET scanner utilization increased by 9% from FY 2019-FY 2020 and by 17% from FY 2020 to FY 2021 (annualized based on nine months of data).

Projected Utilization

The applicant projects utilization of both PET scanners as shown in the following table:

	# SCANS	% CHANGE	SCANS/UNIT
FY 2021	3,104		3,104
FY 2022	3,414	10%	3,414
FY 2023	3,653	7%	3,653
FY 2024	3,873	6%	1,936
FY 2025	4,066	5%	2,033
FY 2026	4,229	4%	2,114

The applicant states it assumes the significant increase in FY 2021 was a direct result of patients deferring care during the height of the COVID-19 pandemic. The applicant does not believe that future utilization will continue in double digits as it did from FY 2020 to FY 2021 and will actually begin to decline as the healthcare system adjusts to post-pandemic utilization, because pent up demand will be eased as time goes on.

The applicant states the PET utilization in the state as a whole from FY 2015 to FY 2020 was 4.3%. The applicant assumes that utilization of its two PET scanners will increase at a rate between its actual historical utilization and the statewide historical utilization, as shown in the table above. Thus, the applicant states the projected growth of 6%, 5% and 4% through the three project years is reasonable and conservative.

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

- The applicant’s utilization projections are supported by the historical utilization of the existing PET scanner currently operating at the hospital.
- The applicant’s utilization projections are supported by advances in technology and capabilities of PET scanners and by the expected increase in demand for oncology, neurological and cardiac PET imaging demand.
- The applicant’s utilization projections account for the temporary increase in utilization following the COVID-19 pandemic and consider the state-wide PET utilization as well.

Access to Medically Underserved Groups

In Section C, page 45, the applicant states VMC serves all persons seeking care and will continue to provide care to all persons regardless of age, ethnicity, race, color, religion, culture, language, national origin, sex, gender identity or expression, sexual orientation, physical or mental disability, socioeconomic status, or source of payment.

In Section L, pages 80-81, the applicant projects the following payor mix for VMC and PET services during the third full fiscal year of operation following completion of the project, as illustrated in the following table:

PAYOR SOURCE	VMC	PET SERVICES
Self-pay	8.5%	2.6%
Medicare*	35.7%	64.5%
Medicaid*	23.8%	7.6%
Insurance*	27.6%	23.8%
Workers Comp	0.6%	0.0%
Tri Care	1.3%	0.9%
Other	2.5%	0.6%
Total	100.0%	100.0%

Numbers may not sum due to rounding.

*Includes managed care plans

The applicant states on page 81 that it does not maintain a payor classification for “Charity Care”, but charity care represents the uncollected accounts that are forgiven based on special circumstances.

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 VMC’s PET services for all residents of the service area, including underserved groups.
- The applicant provides its projected payor mix, which includes underserved groups, 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

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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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.

CA

VMC proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP, to be located at its hospital in Greenville.

In Section E, page 54, 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 an effective alternative, given the patient demand for PET services and the applicant’s commitment to containing the cost of those services.
- Extend hours of the existing PET scanner – the applicant states this is not an effective alternative because it is not cost effective. The additional staff needed to extend PET availability into evenings and on weekends would be cost prohibitive, would negatively affect staff morale, and adversely affect patient and physician satisfaction.
- Use a mobile PET service – the applicant states this is not an effective alternative because the existing mobile PET providers in the area have PET scanners that are already operating in excess of capacity.
- Choose another location within HSA VI – the applicant states this is not an effective alternative because as a tertiary referral center and regional resource for advanced cancer services in the service area, VMC remains in a central location (Pitt County) that is best situated to serve a diverse population from all of HSA VI.

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

- The application is conforming to all statutory and regulatory review criteria.
- The proposal will meet the need for a fixed PET scanner at VMC in response to the need determination in the 2021 SMFP.
- The applicant provides reasonable and supported information to explain why it believes the proposed project is the most effective alternative to meet the need for a PET scanner in HSA VI.

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 the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Pitt County Memorial Hospital, Incorporated (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 Vidant Medical Center, for a total of no more than two fixed PET scanners.**
- 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 March 1, 2022. The second progress report shall be due on July 1, 2022 and so forth.**
- 4. 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.**
- 5. 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.

- 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (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

VMC proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP, to be located at its hospital in Greenville.

Capital and Working Capital Costs

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

Construction Costs	\$1,169,500
Medical Equipment	\$1,681,796
Miscellaneous Costs	\$617,000
Total	\$3,468,296

Source: Application Section Q

In Section F, page 58, the applicant states there will be no start-up costs or initial operating expenses since the hospital is operational.

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 bases its costs on similar projects it has undertaken in the past.
- The applicant provides a certified cost estimate in Exhibit 15 that confirms the projected construction/renovation cost.

Availability of Funds

In Section F, page 56, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

TYPE	VMC	TOTAL
Loans	\$0	\$0
Accumulated reserves or OE *	\$3,468,296	\$3,468,296
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$3,468,296	\$3,468,296

* OE = Owner's Equity

Exhibit F.2-1 contains a letter dated September 13, 2021 from the Chief Financial Officer for Vidant Health (VH), parent company to Vidant Medical Center documenting the availability of sufficient accumulated reserves for the capital needs of the proposed project. Exhibit 11 contains the audited financial statements of Vidant Health that show that as of December 31, 2020, Vidant Health had \$111 million in cash and cash equivalents and \$674 million in total assets.

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 Chief Financial Officer for Vidant Health that documents the availability of sufficient funds to finance the proposed project.
- The applicant provides a copy of the minutes of the Vidant Health Board of Directors meeting in Exhibit 10 that confirms the Board approved a recommendation by the finance committee to provide funding for the capital needs of the project.
- Exhibit 11 contains a copy of VH's 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.2b, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below:

VMC Revenue Projections, First Three Full Fiscal Years PET Services

	1ST FULL FISCAL YEAR 10/1/23 – 9/30/24	2ND FULL FISCAL YEAR 10/1/24 – 9/30/25	3RD FULL FISCAL YEAR 10/1/25 – 9/30/26
Total Procedures	3,873	4,066	4,229
Total Gross Revenues (Charges)	\$33,392,233	\$35,938,391	\$38,310,325
Total Net Revenue	\$10,554,483	\$11,359,262	\$12,108,974
Average Net Revenue per Procedure	\$2,725	\$2,794	\$2,863
Total Operating Expenses (Costs)	\$4,246,113	\$4,545,626	\$4,891,135
Average Operating Expense per Procedure	\$1,096	\$1,118	\$1,157
Net Income	\$6,308,370	\$6,813,636	\$7,217,839

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 VMC's historical experience.
- The applicant accounts for and explains the basis for projected operating expenses such as salaries, supplies, equipment maintenance and administrative support, consistent with projections elsewhere in the application.
- 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

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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

VMC proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP, to be located at its hospital in Greenville.

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).”* VMC proposes to locate the fixed PET scanner in Pitt County, which is in HSA VI. Thus, the service area is HSA VI. 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 VI, 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 VI

TYPE	SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2018-2019
Fixed	Carolina East Medical Center	1	781
Fixed	Nash General Hospital	1	414
Fixed	Vidant Medical Center	1	2,561

In Section G, page 64, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET scanners services in HSA VI. The applicant states:

“NCGS 131E-183(b) indicates that VMC, as an academic medical center teaching hospital, is not required ‘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’.

However, the proposed project is not designed to address the inadequacy or inability of existing providers. The proposed project is intended to increase capacity, access, and quality of the services provided by VMC and to address current and future demand.”

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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 reasons stated 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

In Form H, Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services for the first three full fiscal years (FY) of operation, as illustrated in the following table:

POSITION	1ST FULL FY (10/1/2023 -9/30/2024)	2ND FULL FY (10/1/2024 -9/30/2025)	3RD FULL FY (10/1/2025 -9/30/2026)
Registered Nurse	1.00	1.00	1.00
PET Technologists	4.50	5.00	6.00
Clerical	1.00	1.00	1.00
Manager, Radiology	0.25	0.25	0.25
Total	6.75	7.25	8.25

The assumptions and methodology used to project staffing for the PET scanner services are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 66 and 67, respectively, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

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 the reasons stated 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

VMC proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP, to be located at its hospital in Greenville.

Ancillary and Support Services

In Section I, page 69 the applicant identifies the necessary ancillary and support services for the proposed services. On pages 69-70, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit 12. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

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

Coordination

In Section I, pages 70-71 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.

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.

- (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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed

services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

VMC proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP, to be located at its hospital in Greenville.

In Section K, page 73, the applicant states that the proposed PET scanner will be located in existing non-clinical administrative space in the cancer center and will require minor renovation of 1,500 square feet.

On page 74, 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 in within the cancer suite, allowing the applicant to expand capacity and co-locate the proposed PET with its other existing cancer diagnostics.

- The applicant states the Facilities & Properties team at Vidant Health, led by a registered architect, has been recognized for the quality and cost-consciousness of the work the team does.
- The applicant provides a cost certification letter from the Facilities & Properties team architect in Exhibit 15.

On page 74, 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 not require new construction or extensive renovation, thereby minimizing capital expenditure.
- The applicant states the proposal to locate the PET in existing space in the cancer suite where all the necessary ancillary and support services are already in place will result in the most efficient operation and help to contain extra costs.

On pages 74-75, 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

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

- (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 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 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

In Section L, page 81, the applicant provides the historical payor mix during fiscal year 2020 for the existing PET services, as shown in the table below:

PAYOR SOURCE	VMC PET SCANS AS % OF TOTAL
Self-pay	2.4%
Medicare*	64.3%
Medicaid*	6.9%
Insurance*	23.1%
Workers Comp	0.1%
TriCare	0.9%
Other	1.1%
Total	100.0%

Numbers may not sum due to rounding.

*Includes managed care plans

In Section L.1, page 78, the applicant provides the following comparison:

	Percentage of Total Patients Served by the Facility or Campus during FY2019	Percentage of the Population of Pitt County
Female	58.3%	53.1%
Male	41.7%	46.9%
Unknown	0.0%	0.0%
64 and Younger	75.0%	86.1%
65 and Older	25.0%	13.9%
American Indian	0.2%	0.5%
Asian	0.5%	2.1%
Black or African-American	43.9%	35.9%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	48.0%	59.1%
Other Race	6.4%	2.3%
Declined / Unavailable	1.6%	<i>Included in 'other'</i>

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 79-80, the applicant states that, as a non-profit, 501(c)(3) corporation, it has an obligation to accept any eastern North Carolina resident requiring medically necessary treatment. The applicant states it currently provides care to all persons and will continue to do so following the addition of the proposed PET scanner. The applicant provides a copy of its Charity Care and Admission policies in Exhibit 16.

In Section L, page 80, 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 the hospital.

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section L.3, page 81, the applicant provides the projected payor mix for the third operating year (FY 2026) for the proposed project, as shown in the table below:

PAYOR SOURCE	VMC PET SCANS AS % OF TOTAL
Self-pay	2.6%
Medicare*	64.5%
Medicaid*	7.6%
Insurance*	23.8%
Workers Comp	0.0%
TriCare	0.9%
Other	0.6%
Total	100.0%

Numbers may not sum due to rounding.

*Includes managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.6% of PET scanner services will be provided to self-pay patients, 64.5% to Medicare patients, and 7.6% to Medicaid patients.

In Section L.3, page 81, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience.

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section L.5, page 83, 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

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

VMC proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP, to be located at its hospital in Greenville.

In Section M, pages 84-85, 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:

- Vidant Medical Center is an Academic Medical Center Teaching Hospital and as such, clinical training is a primary component of its mission. Additionally, the applicant

states VMC has a long history of providing clinical training programs in the community.

- The applicant provides supporting documentation in Exhibit 17.

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

VMC proposes to acquire one fixed PET scanner pursuant to the need determination in the 2021 SMFP, to be located at its hospital in Greenville.

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).” VMC proposes to locate the fixed PET scanner in Pitt County, which is in HSA VI. Thus, the service area is HSA VI. 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 VI, 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 VI			
TYPE	SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2018-2019
Fixed	Carolina East Medical Center	1	781
Fixed	Nash General Hospital	1	414
Fixed	Vidant Medical Center	1	2,561

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 86, the applicant states:

“The proposed project will foster competition by promoting high quality, delivering cost effective services, and providing enhanced access to cancer services....”

...

“VMC’s mission is to improve the health status of the region. VMC is dedicated to offering needed PET services to anyone in the community, especially the medically underserved populations....”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 87, the applicant states:

“...the proposed project will promote high quality, cost effective services, while providing enhanced access to primary care, specialists and diagnostic and treatment services.”

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

Regarding the impact of the proposal on quality and access by medically underserved groups, in Section N, page 87, the applicant states:

“...the proposed project will improve quality, reduce patient costs and increase patient access to the latest advancements in primary care, specialists and diagnostic and treatment services.”

See also Sections B, C, L and O 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

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

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

C

In Section Q, Form A, the applicant identifies the hospital located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant lists a total of one of this type of facility located in North Carolina.

In Section O, page 91 the applicant states that, during the 18 months immediately preceding the submittal of the application, one incident related to quality of care occurred on September 20, 2020 in Vidant Medical Center resulting in a finding of Immediate Jeopardy. 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, one incident related to quality of care occurred in the hospital. Those files confirm that the incident was corrected and the hospital was back in compliance as of November 23, 2020. 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 DUH facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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

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- In Section Q, Form C, the applicant projects that the proposed PET scanner will perform 2,114 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.
- (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- In Section Q, Form C2a, the applicant states that VMC's existing fixed PET scanner performed 2,653 total procedures in the last full federal fiscal year (FY 2020).
- (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- In Section Q, Form C2b, the applicant states that the two fixed PET scanners, one existing and one proposed, will perform a total of 4,229 procedures, or 2,114 procedures per PET scanner, which is more than 2,080 procedures in the third full federal fiscal year of operation following project completion.
- (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- The applicant provides its assumptions and methodology in Section C and Section Q. 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.