

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 23, 2022

Findings Date: September 23, 2022

Project Analyst: Tanya M. Saporito

Co-Signer: Lisa Pittman

Project ID #: Q-12223-22

Facility: Vidant Medical Center

FID #: 933410

County: Pitt

Applicant: Pitt County Memorial Hospital, Incorporated

Project: Convert 1 fixed PET scanner to a mobile PET scanner pursuant to Policy TE-1 for a total of no more than 1 fixed PET scanner and 1 mobile PET scanner

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.

C

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 convert one fixed PET scanner to a mobile PET scanner pursuant to Policy TE-1. Upon project completion, VCM will be licensed for one fixed PET scanner and one mobile PET scanner.

Need Determination

There are no need determinations applicable to this review.

Policies

There is one policy in the 2021 SMFP which is applicable to this review: *Policy TE:1: Conversion of fixed PET scanners to mobile PET scanners.*

Policy TE:1, on page 28 of the 2022 SMFP states:

“Facilities with an existing or approved fixed PET scanner may apply for a Certificate of Need (CON) to convert the existing or approved fixed PET scanner to a mobile PET scanner if the applicant(s) demonstrates in the CON application that the converted mobile PET scanner:

- 1. Shall continue to operate as a mobile PET scanner at the facility, including satellite campuses, where the fixed PET scanner is located or was approved to be located;*
- 2. Shall be moved at least weekly to provide services at two or more host facilities; and*
- 3. Shall not serve any mobile host site that is not owned by the PET certificate holder or an entity related to the PET certificate holder such as a parent or subsidiary that is located in the county where any existing or approved fixed PET scanner is located, except as required by subpart (1).”*

In Section B, page 25, the applicant explains why it believes its application is conforming to Policy TE-1. The applicant states it was awarded a CON for a second PET scanner in 2021, pursuant to Project ID #Q12138-21. The applicant affirms it will operate one fixed PET scanner and one mobile PET scanner. The mobile unit will operate at least one day per two week rotation at VMC and as shown in the following table:

Proposed Schedule for Mobile MRI Scanner

PROPOSED HOST SITES	COUNTY	PROPOSED DAYS
Vidant Duplin	Duplin	Week 1 – Monday
Vidant Edgecombe	Edgecombe	Week 1 – Tuesday
Vidant North	Halifax	Week 1 – Wednesday
Vidant Roanoke-Chowan	Hertford	Week 1 – Thursday
Vidant Bertie	Bertie	Week 1 – Friday
Vidant Chowan	Chowan	Week 2 – Monday
The Outer Banks Hospital	Dare	Week 2 – Tuesday
Vidant Beaufort	Beaufort	Week 2 – Wed. & Thurs.
Vidant Medical Center	Pitt	Week 2 - Friday

Source: Application page 25

On page 25, the applicant states the mobile PET scanner will be moved routinely on a two-week schedule as illustrated in the table above. The applicant states it will use weekends as needed to account for holidays and other potential schedule disruptions, thus ensuring the

mobile PET scanner will be moved at least weekly to provide PET services at two or more host facilities.

On page 25, the applicant states that all proposed host sites are related entities to VMC, the certificate holder. The applicant states there are no approved or existing PET scanners in any of the counties proposed as host sites in the table above.

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 adequately demonstrates that the proposal is consistent with Policy TE-1 for the following reasons:
 - The applicant adequately documents that the converted mobile PET scanner will continue to operate as a mobile PET scanner at VMC and satellite campuses;
 - The applicant adequately documents that the converted mobile PET scanner will be moved at least weekly to provide services at two or more host facilities; and
 - The applicant adequately documents that the converted mobile PET scanner will not serve any mobile host site that is not owned by VMC or related entities.

(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 convert one fixed PET scanner to a mobile PET scanner pursuant to Policy TE-1.

Patient Origin

Policy TE-1 mandates that the applicant *“Shall not serve any mobile host site that is not owned by the PET certificate holder or an entity related to the PET certificate holder such as a parent or subsidiary that is located in the county where any existing or approved fixed PET scanner*

is located....” VMC proposes to locate the fixed PET scanner in Pitt County, which is in HSA VI. On page 69 the applicant states it is not proposing to provide mobile PET services state-wide but will provide PET scans to VMC and its related entities only, consistent with Policy TE-1. The applicant also states it is the only provider of fixed PET services in its primary service area.

The following table illustrates current patient origin for VMC’s existing PET scanner, from page 33 of the application:

**VMC PET Services Historical Patient Origin
 Last Full Fiscal Year (10/1/20 – 9/30/21)**

COUNTY	# OF PATIENTS	% OF TOTAL
Pitt	964	30.4%
Beaufort	311	9.8%
Edgecombe	249	7.9%
Martin	205	6.5%
Lenoir	172	5.4%
Wilson	129	4.1%
Wayne	120	3.8%
Halifax	104	3.3%
Nash	91	2.9%
Craven	91	2.9%
Bertie	80	2.5%
Greene	79	2.5%
Washington	74	2.3%
Northampton	73	2.3%
Hertford	69	2.2%
Duplin	60	1.9%
Onslow	57	1.8%
Chowan	45	1.4%
Carteret	31	1.0%
Dare	25	0.8%
Tyrrell	21	0.7%
All other	116	3.7%
Total	3,166	100.0%

Source: Application page 33
 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 fixed and mobile PET services, from pages 35-36 of the application:

VMC Fixed 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	1,148	44.1%	1,205	44.1%	1,265	44.1%
Lenoir	205	7.9%	215	7.9%	226	7.9%
Wilson	154	5.9%	161	5.9%	169	5.9%
Wayne	143	5.5%	150	5.5%	158	5.5%
Nash	108	4.2%	114	4.2%	119	4.2%
Craven	108	4.2%	114	4.2%	119	4.2%
Beaufort	97	3.7%	102	3.7%	107	3.7%
Greene	94	3.6%	99	3.6%	104	3.6%
Edgecombe	78	3.0%	82	3.0%	86	3.0%
Onslow	68	2.6%	71	2.6%	75	2.6%
Martin	64	2.5%	67	2.5%	71	2.5%
Carteret	37	1.4%	39	1.4%	41	1.4%
Halifax	33	1.2%	34	1.2%	36	1.2%
Bertie	25	1.0%	26	1.0%	28	1.0%
Washington	23	0.9%	24	0.9%	26	0.9%
Northampton	23	0.9%	24	0.9%	25	0.9%
Hertford	22	0.8%	23	0.8%	24	0.8%
Duplin	19	0.7%	20	0.7%	21	0.7%
Chowan	14	0.5%	15	0.5%	16	0.5%
Dare	8	0.3%	8	0.3%	9	0.3%
Tyrrell	7	0.3%	7	0.3%	7	0.3%
All Other	128	4.9%	135	4.9%	142	4.9%
Total	2,605	100.0%	2,735	100.0%	2,872	100.0%

Source: Application page 35

Percentages may not sum due to rounding

VMC Mobile 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
Beaufort	284	14.5%	300	14.5%	315	14.5%
Edgecombe	255	13.0%	268	13.0%	282	13.0%
Dare	185	9.4%	194	9.4%	204	9.4%
Martin	183	9.4%	193	9.4%	203	9.4%
Duplin	181	9.2%	190	9.2%	200	9.2%
Halifax	164	8.4%	173	8.4%	182	8.4%
Hertford	127	6.5%	134	6.5%	141	6.5%
Pitt	100	5.1%	105	5.1%	111	5.1%
Northampton	96	4.9%	101	4.9%	107	4.9%
Bertie	96	4.9%	101	4.9%	106	4.9%
Washington	69	3.5%	72	3.5%	76	3.5%
Chowan	50	2.6%	53	2.6%	56	2.6%
Tyrrell	23	1.2%	24	1.2%	25	1.2%
Lenoir	20	1.0%	21	1.0%	22	1.0%
Currituck	18	0.9%	19	0.9%	20	0.9%
Hyde	18	0.9%	18	0.9%	19	0.9%
All Other	91	4.6%	96	4.6%	101	4.6%
Total	1,960	100.0%	2,064	100.0%	2,168	100.0%

Source: Application page 36. Applicant states patient origin projections reflect all mobile host sites combined. 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 38-44, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The mobile unit will alleviate current and projected capacity constraints on its existing fixed PET scanner and thus will improve operational efficiencies and patient outcomes. A mobile PET scanner will also allow the applicant to provide mobile PET services to a greater number of underserved persons who live in rural areas and for whom travel is often costly and burdensome (pages 38-41).
- Address current cancer mortality disparities in Eastern North Carolina – the applicant states cancer remains a top health concern in the nation and in North Carolina. The applicant states approximately 8,100 residents in Eastern North Carolina are diagnosed with cancer every year, and approximately 38% die from cancer. Half of the counties comprising Eastern North Carolina have mortality rates in the bottom two quartiles for

cancer mortality. Improving access to PET services to those patients in rural areas of Eastern North Carolina will positively impact the applicant’s ability to detect and treat cancer in the service area (pages 41-43).

- Expand capacity to benefit neuroscience and cardiovascular patients – the applicant states PET technology is recently expanded into detecting and monitoring neurological and cardiovascular disease by monitoring blood flow and the biochemical functions of the brain. 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 existing PET scanner is primarily used for cancer detection and diagnosis, and the added capacity with the mobile unit will provide additional services for the neurosciences and cardiovascular patients who need PET services (pages 43-44).
- Increase patient and provider satisfaction – the applicant states that, while a second fixed PET scanner would alleviate capacity constraints that exist at VMC, the conversion of the approved fixed PET scanner to a mobile unit will allow the applicant to provide PET services to a wider range of patients in rural areas, which would increase patient and provider satisfaction (page 44).
- Increase research, education and clinical trial capacity – the applicant states adding the proposed additional PET scanner will not only serve existing and future patients but also provide additional opportunity for critical clinical research and education (page 44).

Projected Utilization

In Section Q, Forms C.2a and C.2b, the applicant projects utilization on both the fixed and mobile PET scanners, as summarized below:

Historical and Interim Utilization, VMC PET Services

	PRIOR FULL FY (FY 2021)	INTERIM FULL FY (FY 2022)	INTERIM FULL FY (FY 2023)
Fixed PET scanner	1	1	1
Number of Procedures	3,166	3,458	3,700

Projected Utilization, VMC PET Services

	1 ST FULL FY (FY 2024)	2 ND FULL FY (FY 2025)	3 RD FULL FY (FY 2026)
Fixed PET scanner	2,605	2,735	2,872
Mobile PET scanner	1,960	2,064	2,468
Total Procedures	4,565	4,799	5,040

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

Projected Utilization

Step 1: Forecast PET volume – the applicant examined its fixed PET scanner volume projections of 10% as approved in Project ID #Q-12138-21. The applicant states the COVID-19 Pandemic continued to impact PET volume into FY 2021, and the annualized fiscal year to date (FYTD) PET volume at VMC indicates a 2.2% increase in PET services. The applicant states PET volume is continuing to increase as the number of patients who seek PET services is beginning to normalize following the COVID-19 decrease. The applicant projects a 9.2% increase in PET volume for the remainder of FY 2022, which the applicant states reflects the normalization in patients seeking PET services following COVID-19 and is consistent with its projections approved in Project ID #Q-12138-21. The applicant states its own PET volume increased by 11.2% from FY 2015-FY 2021, while PET volume state-wide increased by 5.3% during the same time. The applicant projects that future PET volume will increase at a higher rate than the state average until the impact of COVID-19 wanes, and will level out to a 5.3% increase, which it states is conservative. See the tables in Section Q, page 1 for illustration.

Step 2: Determine future PET scans that could be diverted to a mobile site – the applicant examined the FYTD 2022 PET scans performed at VMC and the residence county of patients who received PET services at VMC. Based on the patients' residence county, the applicant determined that 67% of the FYTD 2022 patients who received PET services at VMC could be better served at a mobile host site that is closer to their residence. See the tables in Section Q page 3 for illustration.

Step 3: Project volume at existing VH mobile sites – the applicant obtained utilization data from existing mobile PET sites in the service area that are currently served by Alliance Imaging. The applicant states pent-up demand during and immediately following the COVID-19 Pandemic created high utilization rates that the applicant projects will not continue. Despite a mobile PET utilization growth rate from FY 2018-FY 2021 of 10.6%, the applicant projects its proposed mobile PET scanner utilization will increase at a rate consistent with the state average of 5.3% through the end of the third operating year, FY 2026. See the tables in Section Q pages 5-6 for illustration.

Step 4: Determine volume of patients who will remain local – the applicant examined the FY 2020 PET utilization by county in its service area to determine the number of patients who received PET services at another mobile site in Eastern North Carolina, and the number of patients who received PET services at another mobile site outside of Eastern North Carolina. Based on that review, the applicant determined that 25% of those patients who left their residence county to seek PET services at another non-Vidant hospital in Eastern North Carolina will choose to remain local when VMC offers mobile PET services. In addition, the applicant determined that 33% of those patients who left their residence county for PET services at a host site outside of Eastern North Carolina will choose to remain local when VMC offers mobile PET services. See the tables in Section Q, pages 7-9 for illustration.

Step 5: Project VMC fixed and mobile PET volume – using the assumptions from Steps 1-4, the applicant projects volume for both its fixed and mobile PET scanners. Relying on its experience, the applicant determined that mobile operating days comprise 9.1% of total PET operating days, which it used to project mobile PET utilization. See the tables on page 9 for illustration.

Step 6: Project utilization – the applicant combined Steps 1-5 to project total mobile and fixed PET scans to be performed through the third project year, FY 2026. See the following table prepared by the Project Analyst that summarizes the table in Section Q page 10:

PET SCANS	FY 2024	FY 2025	FY 2026
Mobile PET Scans	1,960	2,064	2,168
Fixed PET Scans	2,605	2,735	2,872
Total PET Scans	4,565	4,799	5,040

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 account for the projections approved in Project ID #Q-12138-21.
- 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 50, 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 86-87, the applicant projects the following payor mix for VMC and mobile PET services during the third full fiscal year of operation following completion of the project, as illustrated in the following table:

PAYOR SOURCE	VMC	MOBILE PET SERVICES
Self-pay	8.9%	2.8%
Medicare*	35.8%	66.8%
Medicaid*	23.9%	7.8%
Insurance*	27.1%	21.8%
Workers Comp	0.6%	0.0%
Tri Care	1.3%	0.9%
Other	2.4%	0.8%
Total	100.0%	100.0%

Numbers may not sum due to rounding.

*Includes managed care plans

The applicant states on page 87 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 fixed and mobile 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 convert one fixed PET scanner to a mobile PET scanner pursuant to Policy TE-1.

In Section E, page 59, 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:

- Develop the project as originally approved in Project ID #Q-12138-21 – The applicant states this is not an effective alternative because the conversion of the fixed PET to a mobile PET scanner will allow the applicant to provide PET services regionally rather than at just the VMC location.
- Contract for additional mobile PET services – the applicant states this is not an effective alternative because Alliance Imaging, the current provider of mobile PET services, operates two mobile PET scanners in the state. The applicant states that the existing mobile PET scanners in the state are operating above capacity and there is no available capacity to accommodate the needs of the patients to be served by VMC.

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 applicant provides reasonable and supported information to explain why it believes the proposed project is the most effective alternative to meet the need to convert one of its fixed PET scanners to a mobile PET scanner pursuant to Policy TE-3.

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 convert no more than one fixed PET scanner to a mobile PET scanner pursuant to Policy TE-3 in the 2022 SMFP, for a total of no more than one fixed PET scanner and one mobile PET scanner.**
- 3. The certificate holder shall not change or add host sites unless it first obtains a determination from the Healthcare Planning and Certificate of Need Section authorizing the change in host sites.**

- 4. The mobile PET scanner shall not, at any time, be converted to a fixed PET scanner without Pitt County Memorial Hospital, Incorporated first obtaining a new certificate of need for a fixed PET scanner.**
 - 5. The conversion of the fixed PET scanner to a mobile PET scanner shall constitute development of a mobile diagnostic program and shall not result in the creation of a diagnostic center located at any of the host sites.**
 - 6. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on December 1, 2022.**
 - 7. 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.**
 - 8. 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.**
 - 9. 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 convert one fixed PET scanner to a mobile PET scanner pursuant to Policy TE-1.

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:

Medical Equipment	\$2,003,063
Other (IS, Truck, Wrap)	\$250,000
Total	\$2,253,063

Source: Application Section Q

In Section F, page 62, the applicant states start-up costs will be \$114,616 and states there will be no initial operating expenses.

In Section Q, the applicant provides the assumptions used to project the capital cost and start-up costs. The applicant adequately demonstrates that the projected capital cost and start-up costs are based on reasonable and adequately supported assumptions because it is based on vendor quotes provided in Exhibit 8.

Availability of Funds

In Section F, page 60, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	VMC	TOTAL
Loans	\$0	\$0
Accumulated reserves or OE *	\$2,253,063	\$2,253,063
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,253,063	\$2,253,063

*OE = Owner's Equity

Exhibit 9 contains a letter dated June 14, 2022 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 10 contains the audited financial statements of Vidant Health that show that as of September 30, 2021, Vidant Health had \$156 million in cash and cash equivalents and \$776 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 9 contains a letter from the Chief Financial Officer for Vidant Health that documents the availability of sufficient funds to finance the proposed project.
- Exhibit 10 contains a copy of VH’s balance sheet as of September 30, 2021, documenting 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 for the proposed mobile PET scanner. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, fiscal years (FY) 2024-2026, as shown in the table below:

Revenue Projections, First Three Full Fiscal Years, VMC and Host Sites

VMC AND HOST SITES	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
Total Scans Mobile and Fixed PET	4,565	4,799	5,040
Total Gross Revenues (Charges)	\$19,235,947	\$20,859,170	\$22,458,717
Total Net Revenue	\$7,598,138	\$8,200,936	\$8,829,810
Average Net Revenue per Scan	\$1,644	\$1,709	\$1,752
Total Operating Expenses (Costs)	\$5,057,489	\$5,391,104	\$5,739,465
Average Operating Expense per Scan	\$1,108	\$1,123	\$1,139
Net Income	\$2,540,649	\$2,809,832	\$3,090,345

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 convert one fixed PET scanner to a mobile PET scanner pursuant to Policy TE-1.

Policy TE-1 mandates that the applicant “*Shall not serve any mobile host site that is not owned by the PET certificate holder or an entity related to the PET certificate holder such as a parent or subsidiary that is located in the county where any existing or approved fixed PET scanner is located....*” VMC proposes to locate the fixed PET scanner in Pitt County, which is in HSA VI. On page 69 the applicant states it is not proposing to provide mobile PET services state-wide but will provide PET scans to VMC and its related entities only, consistent with Policy TE-1. The applicant also states it is the only provider of fixed PET services in its primary service area.

The following table identifies the service area as defined by the applicant:

VMC Service Area, Mobile PET Services, Policy TE-1

COUNTY	% OF TOTAL PROCEDURES	SERVICE AREA
Beaufort	14.5%	Primary
Edgecombe	13.0%	Primary
Dare	9.4%	Primary
Martin	9.4%	Primary
Duplin	9.2%	Primary
Halifax	8.4%	Primary
Hertford	6.5%	Primary
Pitt	5.1%	Primary
Northampton	4.9%	Primary
Bertie	4.9%	Primary
Washington	3.5%	Primary
Chowan	2.6%	Primary
Tyrrell	1.2%	
Lenoir	1.0%	
Currituck	0.9%	
Hyde	0.9%	
All Other	4.6%	
Total	100.0%	

In Section G, page 70 the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PET services in its service area. 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:

- The applicant proposes to convert an existing or approved fixed PET scanner to a mobile PET scanner to serve VMC and its related entities.
- The applicant is the only provider of fixed PET services in the service area.

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	2.50	2.50	2.50
Clerical	1.50	1.50	1.50
Tractor/Cab Driver	1.50	1.50	1.50
Manager, Radiology	0.10	0.10	0.10
Total	6.60	6.60	6.60

Source: Application Section Q.

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 71-72, 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 convert one fixed PET scanner to a mobile PET scanner pursuant to Policy TE-1.

Ancillary and Support Services

In Section I, page 74 the applicant identifies the necessary ancillary and support services for the proposed services. On pages 74-75, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit 11. 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 75-76 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.

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.

NA

VMC proposes to convert one fixed PET scanner to a mobile PET scanner pursuant to Policy TE-1.

In Section K, page 78, the applicant states that the project will not involve any renovation to existing space or new construction. Therefore, this Criterion is not applicable to this review.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 83, the applicant provides the historical payor mix during fiscal year 2021 for the existing PET services, as shown in the table below:

PAYOR SOURCE	VMC PET SCANS AS % OF TOTAL
Self-pay	8.9%
Medicare*	35.8%
Medicaid*	23.9%
Insurance*	27.1%
Workers Comp	0.6%
TriCare	1.3%
Other	2.4%
Total	100.0%

Numbers may not sum due to rounding.

*Includes managed care plans

In Section L, page 84 the applicant state it does not have a separate classification of “charity care”. Charity care, according to the applicant, represents the amount of uncollected debts that are “forgivable” based on special circumstances. The applicant provides a copy of its charity care policies in Exhibit 14.

In Section L.1, page 84, 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	58.20%	52.00%
Male	42.80%	48.00%
Unknown	0.00%	0.00%
64 and Younger	77.40%	84.50%
65 and Older	22.60%	14.50%
American Indian	0.20%	0.70%
Asian	0.25%	1.90%
Black or African-American	41.70%	35.80%
Native Hawaiian or Pacific Islander	0.25%	0.60%
White or Caucasian	49.20%	53.40%
Other Race	2.20%	NA
Declined / Unavailable	1.98%	NA

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;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 85-86, 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 14.

In Section L, page 86, 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 86, the applicant provides the projected payor mix for the third operating year (FY 2026) for total PET services, as shown in the table below:

PAYOR SOURCE	VMC PET SCANS AS % OF TOTAL
Self-pay	8.9%
Medicare*	35.8%
Medicaid*	23.9%
Insurance*	27.1%
Workers Comp	0.6%
TriCare	1.3%
Other	2.4%
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 8.9% of its PET scanner services will be provided to self-pay patients, 35.8% to Medicare patients, and 23.9% to Medicaid patients.

In Section L.3, page 87, the applicant provides the projected payor mix for the third operating year (FY 2026) for the proposed mobile PET services, as shown in the table below:

PAYOR SOURCE	VMC MOBILE PET SCANS AS % OF TOTAL
Self-pay	2.8%
Medicare*	66.8%
Medicaid*	7.8%
Insurance*	27.8%
Workers Comp	0.0%
TriCare	0.9%
Other	0.8%
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 2.8% of its mobile PET scanner services will be provided to self-pay patients, 66.8% to Medicare patients, and 7.8% to Medicaid patients.

In Section L.3, page 87, 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 88, 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 convert one fixed PET scanner to a mobile PET scanner pursuant to Policy TE-3.

In Section M, pages 89-90, 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 15.

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 convert one fixed PET scanner to a mobile PET scanner pursuant to Policy TE-3.

Policy TE-1 mandates that the applicant “*Shall not serve any mobile host site that is not owned by the PET certificate holder or an entity related to the PET certificate holder such as a parent or subsidiary that is located in the county where any existing or approved fixed PET scanner is located....*” VMC proposes to locate the fixed PET scanner in Pitt County, which is in HSA VI. On page 69 the applicant states it is not proposing to provide mobile PET services state-wide but will provide PET scans to VMC and its related entities only, consistent with Policy TE-1. The applicant also states it is the only provider of fixed PET services in its primary service area. The following table identifies the service area as defined by the applicant:

VMC Service Area, Mobile PET Services, Policy TE-1

COUNTY	% OF TOTAL PROCEDURES	SERVICE AREA
Beaufort	14.5%	Primary
Edgecombe	13.0%	Primary
Dare	9.4%	Primary
Martin	9.4%	Primary
Duplin	9.2%	Primary
Halifax	8.4%	Primary
Hertford	6.5%	Primary
Pitt	5.1%	Primary
Northampton	4.9%	Primary
Bertie	4.9%	Primary
Washington	3.5%	Primary
Chowan	2.6%	Primary
Tyrrell	1.2%	
Lenoir	1.0%	
Currituck	0.9%	
Hyde	0.9%	
All Other	4.6%	
Total	100.0%	

Source: Application page 69

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 92, the applicant states:

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

...

...the proposed project will improve quality, reduce patient costs and increase patient access to the latest advancements in cancer services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 93, the applicant states:

“...the proposed project will promote high quality, cost effective services, while providing enhanced access to PET 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 93, 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 O, the applicant identifies the one hospital located in North Carolina owned, operated or managed by the applicant or a related entity that provides PET services.

In Section O, page 96 the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy during the 18-month look-back period occurred at VMC or any of the proposed mobile host sites. 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.2b, the applicant projects that the proposed PET scanner will perform 2,168 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 C.2a, the applicant states that VMC's existing fixed PET scanner performed 3,066 total procedures in the last full federal fiscal year (FY 2021).
- (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 C.2b, the applicant states that the two fixed PET scanners, one fixed and one mobile, will perform a combined total of 5,040 procedures in the third full federal fiscal year of operation following project completion. The applicant projects the fixed PET scanner will provide 2,872 scans and the mobile PET scanner will provide 2,168 scans, each of which will exceed 2,080 procedures per scanner.
- (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.