



COMMONWEALTH of VIRGINIA

Karen Shelton, MD
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

TTY 7-1-1 OR
1-800-828-1120

April 15, 2024

Azita Moalemi, MD, FACC
Amelia Heart and Vascular Center
6136 Brandon Avenue
Springfield, Virginia 22150

**RE: COPN No. VA-04882
Amelia Heart and Vascular Center, Inc.
Planning District 8
Establish a specialized center for cardiac PET/CT imaging**

Dear Dr. Moalemi:

In accordance with Chapter 4, Article 1.1 of Title 32.1 of the Code of Virginia of 1950 (the Code), as amended, I reviewed the application and all supporting documents submitted by Amelia Heart and Vascular Center, Inc. to establish a specialized center for cardiac positron emission tomography/computed tomography (PET/CT) imaging with one PET/CT unit.

As required by Section 32.1-102.3B of the Code, I have considered all factors that must be taken into account in a determination of public need, and I have concluded that **conditional approval** of the request is warranted based on the following findings:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The PET/CT scanner's use will be limited solely to cardiac imaging.
3. The CT functionality of the PET/CT scanner will only be utilized in conjunction its PET functionality.
4. The project will improve access to the preferred cardiac imaging modality with numerous benefits over SPECT.
5. The project will introduce beneficial competition without adversely affecting existing providers of cardiac PET/CT services.

Dr. Azita Moalemi
Amelia Heart and Vascular Center, Inc.
April 15, 2024
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6. The project is more beneficial than the alternative of the status quo.
7. The capital costs are reasonable.
8. The Health Systems Agency of Northern Virginia recommended approval of the proposed project.

This certificate is valid for the period April 15, 2024 through April 14, 2025. The total authorized capital cost of the project is \$1,441,605.

Please file two copies of the application for a certificate extension with the Department and one copy with the regional health planning agency no later than 30 days before the expiration date of the certificate. Part VIII of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations identifies the filing requirements and review procedure for certificate extension requests.

Sincerely,



Karen Shelton, MD
State Health Commissioner

Enclosure

cc: Allyson Tysinger, Senior Assistant Attorney General, Commonwealth of Virginia
Erik Bodin, Director, Division of Certificate of Public Need
Deborah K. Waite, Chief Operating Officer, Virginia Health Information
Gloria Addo-Ayensu, MD, MPH, District Director, Fairfax Health District

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH
MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED

THIS CERTIFIES THAT Amelia Heart and Vascular Center, Inc. is authorized to initiate the proposal as described below.

NAME OF FACILITY: Amelia Heart and Vascular Center, Inc.

LOCATION: 6136 Brandon Avenue, Springfield, Virginia 22150

OWNERSHIP AND CONTROL: Amelia Heart and Vascular Center, Inc.

SCOPE OF PROJECT: Establish a specialized center for cardiac positron emission tomography/computed tomography (PET/CT) imaging with one PET/CT unit. Capital costs authorized for this project total \$1,441,605. The project is expected to be completed by September 9, 2024. This certificate is issued with the condition that appears on its reverse.



Pursuant to Chapter 4, Article 1:1 of Title 32.1, Sections 32.1-102.1 through 32.1-102.12 of the Code of Virginia (1950), as amended and the policies and procedures promulgated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial and continuing progress towards implementation of the proposal within twelve (12) months from the date of issuance. A progress report shall be submitted to the State Health Commissioner within twelve (12) months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Commissioner reserves the right not to renew this Certificate in the event the applicant fails to fulfill these conditions. This Certificate is non-transferable and is limited to the location, ownership, control and scope of the project shown herein.

Certificate Number: VA-04882

Date of Issuance: April 15, 2024

Expiration Date: April 14, 2025

A handwritten signature in black ink, appearing to read "Karen Shelton".

Karen Shelton, MD, State Health Commissioner

Amelia Heart and Vascular Center, Inc.'s PET/CT service will be limited solely to cardiac imaging. Amelia Heart and Vascular Center, Inc. will provide cardiac PET/CT services to all persons in need of these services, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount equal to at least 3.5% of Amelia Heart and Vascular Center, Inc.'s total patient services revenue derived from PET/CT services as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Amelia Heart and Vascular Center, Inc. will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided to individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

Amelia Heart and Vascular Center, Inc. will provide cardiac PET/CT care to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. Additionally Amelia Heart and Vascular Center, Inc. will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.



6136 Brandon Ave
Springfield, VA 22150
Ph 703 866 3131
F 703 866 3131

2800 S Shirlington Rd,
Suite 300
Arlington, VA 22206
Ph 703 844 7770
F 703 866 3133

7906 Andrus Rd,
Suite 8
Alexandria, VA 22306
Ph 571 895 7730
F 703 866 3133

2445 Army Navy Dr,
Suite 303
Arlington, VA 22206
Ph 571 616 0166
F 703 866 3133

**Azita Moalemi, MD, Naghmeh Tebyanian, MD, Arehzo Jahangiri, MD, Jody Ritter, DO,
Zakeih Chaker, MD, Maryam Mohammadi, MD, Daniel Gates, MD,
Maryam Esfahani Zareh, PA, Jonathan Kiemel, PA, Kyla Nguyen, NP**

Attention: Mr. Erik Bodin
Director, Division of Certificate of Public Need

Re: COPN Request Number VA- 8722
Amelia Heart and Vascular Center, Inc.
Planning Division - 8
Establishing Specialized Center for Cardiac PET/ CT imaging

Dear Mr. Bodin:

I am writing on behalf of Amelia Heart and Vascular Center to express our heartfelt gratitude for the conditional approval of Cardiac PET/CT by the DCOPN of Virginia. We are honored and humbled by the confidence placed in our institution and its mission to provide exemplary cardiac care.

We wholeheartedly accept the conditions outlined in your approval letter, including the commitment to provide at least 3.5% of our care as charitable services. We understand the importance of documenting our efforts in this regard and are prepared to submit comprehensive reports on an annual basis. Furthermore, we acknowledge and are prepared to adjust our percentage of charity care in alignment with the regional average as suggested.

At Amelia Heart and Vascular center, our commitment to diversity and inclusion remains unwavering. This commitment encompasses, not only cultural and linguistic aspects, but extends to ensuring economic inclusivity. We take pride in our track record of never refusing care to anyone in need and plan to continue this tradition. Dedication to serving the community with compassion and respect is at the core of everything we do. As part of our ongoing efforts to maintain transparency and accountability, we are more than willing to provide financial audits, and other relevant reports as required. We believe that these documents will further attest to our commitment to both quality care and community service.

In closing, I wish to extend my deepest thanks once again for your consideration and approval. It is a privilege to serve our patients and to contribute to the health and well-being of our community. On behalf of our entire team at Amelia Heart and Vascular center, including our dedicated staff, and the patients we serve, thank you.

Azita Moalemi, MD, FACC

cc: Vanessa MacLeod, JD. Office of Adjudication, Virginia Dept of Health
cc: Valerie Cheatham, JD. Certificate of Public Need Analyst, Office of Licensure and Certification



COMMONWEALTH of VIRGINIA

Department of Health

Office of Licensure and Certification

Karen Shelton, MD
State Health Commissioner

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1-800-828-1120

9960 Mayland Drive, Suite 401
Henrico, Virginia 23233-1485
Fax (804) 527-4502

March 20, 2024

Azita Moalemi, MD, FACC
Amelia Heart and Vascular Center
6136 Brandon Avenue
Springfield, Virginia 22150

RE: **COPN Request No. VA-8722**
Amelia Heart and Vascular Center, Inc.
Planning District 8
Establish a specialized center for cardiac PET/CT imaging

Dear Dr. Moalemi:

For your consideration, I enclose the Division of Certificate of Public Need (DCOPN) report and recommendation on the above referenced project. DCOPN is recommending **conditional approval** of this application for the reasons listed in the attached staff report.

If Amelia Heart and Vascular Center, Inc. is willing to accept the recommendation for conditional approval of this project, please provide documentation of this acceptance *no later than March 25, 2024*. If not willing to accept, before the State Health Commissioner makes her decision on this project, the Department will convene an informal-fact-finding conference (IFFC) pursuant to *Title 2.2 of the Code of Virginia*. This IFFC has been scheduled for Monday, April 1, 2024 beginning at 10:00 a.m. in Board Room 3 of the Perimeter Center located at 9960 Mayland Drive in Henrico, Virginia. A copy of the procedures for conduct at IFFCs may be found at <http://www.vdh.virginia.gov/OLC/copn/>

Persons wishing to participate in an IFFC have four days from the date of this letter to submit written notification to the State Health Commissioner, DCOPN and the applicant stating a factual basis for good cause standing. If no person has submitted written notification stating grounds and providing a factual basis for good cause standing and Amelia Heart and Vascular Center, Inc. accepts the conditional approval, DCOPN will then notify you of the cancellation of the scheduled IFFC. DCOPN would then anticipate action by the State Health Commissioner within a few weeks of transmission.

DIRECTOR
(804) 367-2102

ACUTE CARE
(804) 367-2104

COPN
(804) 367-2126



www.vdh.virginia.gov

COMPLAINTS
1-800-955-1819

LONG TERM CARE
(804) 367-2100

Dr. Azita Moalemi
COPN Request No. VA-8722
March 20, 2024
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Should you have questions or need further clarification of this report and/or its recommendations, please feel free to call me at (804) 367-1889 or email me at Erik.Bodin@VDH.Virginia.Gov.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Erik Bodin', with a date '2/20/24' written below it.

Erik Bodin, Director
Division of Certificate of Public Need

Enclosures

cc: Vanessa MacLeod, J.D., Office of Adjudication, Virginia Department of Health

VIRGINIA DEPARTMENT OF HEALTH
Office of Licensure and Certification
Division of Certificate of Public Need

Staff Analysis

March 20, 2024

COPN Request No. VA-8722

Amelia Heart and Vascular Center, Inc.

Springfield, Virginia

Establish a specialized center for cardiac PET/CT imaging

Applicant

Amelia Heart and Vascular Center, Inc. (Amelia Heart) is a Virginia stock corporation formed in 2007. Two physicians each have an ownership interest of 50% in Amelia Heart. Amelia Heart is located in Springfield, Virginia in Planning District (PD) 8, Health Planning Region (HPR) II.

Background

Cardiac positron emission tomography/computed tomography (PET/CT) is a non-invasive state-of-the-art technology and standard of care for routine cardiac diagnostic imaging. The applicant states that “[t]he adoption of PET/CT technology has emerged as the preferred and cutting-edge method for conducting Myocardial Perfusion Imaging (MPI), an essential diagnostic tool crucial for the identification and effective management of Coronary Artery Disease (CAD). The American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging published a joint position paper in 2016 stating, “[t]here are no clinical scenarios where PET should not be considered a preferred test for patients who meet appropriate criteria for a stress imaging test and who require pharmacologic stress.”¹

Amelia Heart is comprised of six cardiologists, two physician assistants, and one nurse practitioner. Amelia Heart currently offers EKG, exercise stress testing comprehensive 2-D echocardiography including strain imaging, stress echocardiography, comprehensive vascular imaging including carotid dopplers, renal dopplers, mesenteric dopplers, lower extremity arterial dopplers with segmental pressures, lower extremity venous dopplers with venous mapping, exercise stress, single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), pharmacologic stress SPECT MPI, pacemaker interrogation, Holter monitoring and mobile cardiac telemetry at its Springfield office.

¹ Bateman et.al. *American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET*. Journal of nuclear cardiology (2016): official publication of the American Society of Nuclear Cardiology. <https://pubmed.ncbi.nlm.nih.gov/27528255/> (accessed March 5, 2024).

According to DCOPN records, PD 8 has 11 authorized PET services – nine fixed site scanners and two mobile sites. Of these 11 services, four are dedicated to cardiac PET/CT.

Table 1. PD 8 COPN Authorized PET Services

Facility	Total Authorized Scanners	Authorized Fixed-Site Scanners	Authorized Mobile Sites	Cardiac Only
Carient Heart & Vascular (Ashton Avenue)	1	1	0	1
Carient Heart & Vascular (Church Street NE)	1	1	0	1
Inova Reston MRI Center (Inova Center for Personalized Health)	1	1	0	0
Kaiser Permanente Woodbridge Imaging Center	1	1	0	0
Metro Region PET Center	1	1	0	0
Nova Cardiovascular Care, Inc.	1	1	0	1
UVA Cancer Center - Gainesville	1	0	1	0
PET of Reston	1	1	0	0
Sentara Northern Virginia Medical Center	1	0	1	0
Virginia Heart	1	1	0	1
Virginia Hospital Center	1	1	0	0
PD 8 Total	11	9	2	4

Source: DCOPN Records

Proposed Project

The applicant proposes to establish a new, fixed cardiac PET/CT site at its existing office in Springfield, Virginia. Amelia Heart intends to lease a Siemens Biograph Horizon PET/CT from CDL Nuclear Technologies to establish the service. The PET/CT service will be offered Monday through Saturday, from 8:00 a.m. to 4:30 p.m. The proposed project requires construction of a camera room and control room within Amelia Heart’s Springfield office. The proposed PET/CT scanner would be limited to cardiac imaging. The applicant asserts that the CT functionality of the proposed PET/CT scanner would not be utilized independent of the PET functionality and will only be used for attenuation correction of the perfusion images.

The projected capital costs of the proposed project are \$1,441,605.10, approximately 18% of which are attributed to direct construction costs (**Table 2**). Amelia Heart and CDL Technologies have entered into a service agreement outlining the payment of capital expenditures, including facility renovations. Capital costs will be funded through the operating revenues of the applicant. If the State Health Commissioner (Commissioner) approves the project, construction is expected to on July 15, 2024, and is projected to be complete on September 1, 2024. The target date of opening is September 9, 2024.

Table 2: Amelia Heart Projected Capital Costs

Direct Construction Costs	\$263,000
Equipment Not Included in Construction Contract	\$942,000
Site Acquisition Costs	\$218,105.10
Architectural and Engineering Fees	\$18,500
Total Capital Costs	\$1,441,605.10

Source: COPN Request No. VA-8722

Project Definitions

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the “[e]stablishment of a medical care facility described in subsection A.” A medical care facility includes “[a]ny specialized center or clinic or that portion of a physician's office developed for the provision ...positron emission tomographic (PET) scanning...”

Required Considerations -- §32.1-102.3, of the Code of Virginia

In determining whether a public need for a project exists, the following factors shall be considered:

- 1. The extent to which the proposed project will provide or increase access to health care services for people in the area to be served and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care;**

Geographically, Amelia Heart is located at 6136 Brandon Avenue, Springfield, Virginia, which is 2.7 miles from Interstate 395 and five miles from Interstate 495. Additionally, the site is accessible by public transportation using the Fairfax Connector bus, which has a stop 0.2 miles and the MetroBus, which has a stop 0.4 miles away.

Table 3 shows projected population growth in PD 8 through 2030. Overall, the planning district was projected to add an estimated 356,377 people in the 10-year period ending in 2020. For the 10-year period ending in 2030, the planning district is projected to add an estimated 350,128 people. DCOPN notes that the population of PD 8 as a whole is expected to increase approximately 16% for the period ending in 2020 and approximately 14% for the period ending in 2030, rates nearly double that of the statewide average. With regard to the 65 and older age cohort in PD 8, Weldon-Cooper projects a much more rapid increase (Table 3). Specifically, Weldon-Cooper projects an increase of approximately 56% for the period ending in 2020 and approximately 38% for the period ending in 2030.

Table 3. Population Projections for PD 8, 2010-2030

Locality	2010	2020	% Change 2010-2020	Avg Ann % Change 2010-2020	2030	% Change 2020-2030	Avg Ann % Change 2020-2030
Arlington	139,966	166,261	18.79%	1.69%	182,067	9.51%	0.91%
Fairfax County	207,627	249,298	20.07%	1.80%	274,339	10.04%	0.96%
Loudoun	22,565	25,047	11.00%	1.02%	26,397	5.39%	0.53%
Prince William	1,081,726	1,162,504	7.47%	0.71%	1,244,025	7.01%	0.68%
Alexandria City	12,332	14,988	21.54%	1.92%	17,032	13.64%	1.29%
Fairfax City	312,311	430,584	37.87%	3.18%	554,808	28.85%	2.57%
Falls Church City	37,821	43,099	13.96%	1.28%	46,332	7.50%	0.73%
Manassas City	14,273	17,086	19.71%	1.77%	20,284	18.72%	1.73%
Manassas Park City	402,002	478,134	18.94%	1.71%	571,844	19.60%	1.81%
Total PD 8	2,230,623	2,587,000	15.98%	1.46%	2,937,128	13.53%	1.28%
PD 8 65+	192,589	300,491	56.03%	4.44%	413,269	37.53%	3.24%
Virginia	8,001,024	8,655,021	8.17%	0.77%	9,331,666	7.82%	0.76%
Virginia 65+	976,937	1,352,448	38.44%	3.22%	1,723,382	27.43%	2.45%

Source: U.S. Census, Weldon Cooper Center Projections (August 2019) and DCOPN (interpolations)

According to regional and statewide data regularly collected by Virginia Health Information (VHI), for 2021, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 2.63% of all reported total gross patient revenues (Table 4). If the Commissioner approves the proposed project, Amelia Heart has committed to a 3.5% charity care condition.

Table 4. HPR II Charity Care Contributions: 2021

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Inova Alexandria Hospital	\$1,099,098,713	\$48,200,302	4.39%
Inova Mount Vernon Hospital	\$586,328,215	\$23,515,873	4.01%
Encompass Health Rehab Hospital of Northern Virginia	\$44,352,947	\$1,727,170	3.89%
Inova Loudoun Hospital	\$1,063,559,182	\$34,808,182	3.27%
Inova Fairfax Hospital	\$4,579,299,978	\$143,761,495	3.14%
UVA Health Prince William Medical Center	\$620,916,889	\$19,226,771	3.10%
Inova Fair Oaks Hospital	\$756,218,384	\$23,149,143	3.06%
Sentara Northern Virginia Medical Center	\$943,730,551	\$25,008,347	2.65%
Virginia Hospital Center	\$1,828,402,362	\$35,153,100	1.92%
UVA Health Haymarket Medical Center	\$334,178,317	\$3,397,874	1.02%
Dominion Hospital	\$173,930,124	\$1,370,987	0.79%
Reston Hospital Center	\$1,743,343,281	\$11,983,844	0.69%
StoneSprings Hospital Center	\$352,270,979	\$1,575,166	3.60%
North Spring Behavioral Healthcare	\$65,581,626	\$215,233	0.33%
Total Inpatient Hospitals:			14
HPR II Inpatient Hospital Median			3.08%
HPR II Total Inpatient \$ & Mean %	\$14,191,211,548	\$373,093,487	2.63%

Source: VHI (2021)

With regard to distinct and unique geographic, socioeconomic, cultural, transportation, or other barriers to care that this project would address, in its application, Amelia Heart expresses a focus on women’s cardiovascular health and a commitment to diversity and inclusion in cardiology.

The Amelia Heart team includes fluent speakers of Spanish, Farsi and Arabic. The applicant explains that its service area, including Springfield and its vicinity, is home to a diverse population with a significant Latino demographic. The applicant explains that Springfield’s population is 26.6% Latino/Hispanic. In comparison, according to the applicant, Fairfax County’s population is 16.2% Latino/Hispanic and the Commonwealth’s population is 10% Latino/Hispanic. The applicant says “... we embrace this insight by ensuring that our Hispanic patients can communicate in their native language. This commitment goes beyond mere translation; it is about fostering a deeper understanding and a more personalized approach to cardiac care.... and... [u]nderstanding the unique cardiovascular disease risk factors within the Hispanic population is pivotal.... and... “incorporating data from the U.S. Department of Health

& Human Services reinforces the severity of health disparities faced by the Hispanic population, particularly concerning cardiovascular disease and diabetes....” Finally, the applicant asserts, “[t]his underscores the critical need for specialized, culturally sensitive cardiac care. By offering state-of-the-art cardiac PET technology in our practice, we not only address the broader challenges in cardiovascular health but also ensure equitable access to cutting-edge diagnostic tools for our Hispanic patients.”

Regarding cardiovascular treatment for women, the applicant explains, “[w]omen have distinct general and cardiac anatomy, with smaller coronary arteries and hearts. The presence of breasts also poses unique challenges for conventional imaging methods. In this context, cardiac PET technology shines, offering significantly better diagnostic capabilities for women. Its precision and ability to provide detailed images make it an invaluable tool in accurately diagnosing cardiac conditions including nonobstructive coronary artery disease, especially for women with atypical symptoms or anatomical challenges.” According to the applicant, 60% of Amelia Heart’s patients are women.

DCOPN notes, that although a review of available data on Census.gov provides different population percentages, the applicants points remain valid².

2. The extent to which the proposed project will meet the needs of people in the area to be served, as demonstrated by each of the following:

(i) the level of community support for the proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;

DCOPN received six letters of support for the proposed project, which addressed:

- Cardiac PET imaging has substantial advantages over conventional nuclear stress tests, which uses a radioisotope called Technetium Myoview and Thallium-201. Specifically, PET is much safer for patients because it exposes them to much less radiation while providing superior images. The result is a test that is safer but more accurate. The exposure to radioactivity is not inconsequential for high-risk cardiac patients who are also at risk for developing cancer.
- Cardiac PET/CT stress testing is the most accurate test available for those patients who present with high risk factors of heart disease.
- Cardiac PET/CT scan with its high diagnostic accuracy offers a very good solution to all patients but particularly patients with a high BMI.
- The short scan time of cardiac PET/CT is key for older patients that often have orthopedic issues and are not able to lay down for extended periods of time.

² Census.gov lists the Hispanic/Latino population in Springfield County as 18.4%, in the Commonwealth as 10.5% and in Fairfax County as 18.1%. <https://www.census.gov/quickfacts/fact/table/fairfaxcityvirginia,VA/RHI725222> (accessed March 5, 2024).

Public Hearing

DCOPN provided notice to the public regarding these projects on January 10, 2024. The public comment period closed on February 26, 2024. On March 11, 2024, HSNV held a public hearing for the project. Amelia Heart's project was presented by Dr. Azita Moalemi and Dr. Jodi Ritter. There was no public comment regarding the project.

(ii) the availability of reasonable alternatives to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner;

DCOPN did not identify any reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner. Moreover, the proposed project is a preferable alternative to the status quo. Under the status quo, patients at Amelia Heart will continue to receive diagnostic imaging using SPECT. As discussed in detail throughout this staff analysis report, cardiac PET/CT imaging offers several important advantages over SPECT. With regard to treating women, the applicant explains, “[b]reast attenuation poses unique challenges in traditional imaging methods such as echocardiogram and nuclear SPECT imaging. It can obscure important details and compromise the accuracy of diagnosis and treatment planning. Cardiac PET/CT solves that problem.” Additionally, the applicant asserts “[c]ardiac PET/CT offers several distinct advantages [over SPECT], including enhanced accuracy, significantly reduced radiation exposure, and shorter test durations.” The American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging have issued a joint Society Position Statement “to highlight the attributes that make rest/stress myocardial perfusion PET both **Preferred** and **Recommended** in the era of high value initiative for appropriate patients.”³ According to this Society Position Statement, “[m]yocardial perfusion PET image quality, high diagnostic accuracy that is relatively independent of body habitus, ability to accurately risk stratify patients with a wide array of clinical presentations, short acquisition times, safety by virtue of low radiation exposure, and its unique ability to quantify myocardial blood flow are all significant and clinically important properties.”⁴

Furthermore, the applicant proposes to use the scanner to serve its existing patient population. Therefore, DCOPN concludes that the proposed project is unlikely to adversely affect the utilization and efficiency of existing services.

(iii) any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;

At its March 11, 2024 meeting, the HSNV, the organization in HPR II designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 8, voted nine in

³ Bateman et.al. *American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET*. Journal of nuclear cardiology (2016): official publication of the American Society of Nuclear Cardiology. <https://pubmed.ncbi.nlm.nih.gov/27528255/> (accessed March 5, 2024).

⁴ Id.

favor, none opposed, to recommend approval of Amelia Heart's COPN Request number VA-8722. The HSNV based its recommendation on the HSNV staff report, its review of the request and the following basic findings and conclusions:

1. Amelia Heart, a growing cardiology medical practice in Springfield, Virginia, proposes to establish and maintain a PET scanning service dedicated to cardiac PET imaging.
2. The proposal is comparable to, and consistent with, the four services authorized for PD 8 cardiology practices over the last five years.
3. Amelia Heart would develop the service under a lease and operating agreement with a national diagnostic imaging service vendor, CDL Nuclear Technologies of Wexford, Pennsylvania. The project does not entail a large initial capital investment by Amelia Heart.
4. With an onsite cardiac PET imaging option, Amelia Heart expects to see reductions in problematic SPECT scans and referrals for unnecessary diagnostic cardiac catheterizations.
5. The projected annual service volume, estimated at about 900 patients per year in the initial operating years, appears reasonable and attainable.
6. Given historical medical trade patterns and regional referral practices, introducing cardiac PET-CT imaging at Amelia Heart is not likely to affect demand or caseloads at other diagnostic imaging services.
7. The project is consistent with the diagnostic imaging provisions of the Virginia State Medical Facilities Plan (SMFP) as they have been applied to similar cardiac PET imaging COPN projects.

(iv) any costs and benefits of the proposed project;

As demonstrated by **Table 2**, the projected capital costs of the proposed project are \$1,441,605, approximately 18% of which are attributed to direct construction costs. As previously discussed, Amelia Heart and CDL Technologies have entered into a service agreement outlining the payment of capital expenditures, including facility renovations. Capital costs will be funded through the operating revenues of the applicant. DCOPN concludes that when compared to similar projects, these costs are reasonable. For example, COPN No. VA-04852 issued to Cardiology Associates of Fredericksburg, Ltd. to establish a specialized center for cardiac PET with one PET/CT unit is anticipated to cost approximately \$1,345,647.

The applicant identified numerous benefits of the proposed project, including:

- In today's rapidly advancing field of cardiology, cardiac PET has emerged as a vital diagnostic tool, particularly for women presenting with diverse symptoms and anatomical challenges.
- The adoption of PET/CT technology has emerged as the preferred and cutting-edge method for conducting Myocardial Perfusion Imaging (MPI), an essential diagnostic tool crucial for

the identification and effective management of Coronary Artery Disease (CAD). At Amelia Heart, our unwavering commitment to providing the highest standards of patient care quality is at the core of our mission.

- One of the pivotal challenges we address with Cardiac PET/CT is breast attenuation, a significant barrier in cardiac imaging for women, particularly those with higher BMI, which includes Latina women. Breast attenuation poses unique challenges in traditional imaging methods such as echocardiogram and nuclear SPECT imaging. It can obscure important details and compromise the accuracy of diagnosis and treatment planning. Cardiac PET/CT solves that problem.
 - The Cardiac PET/CT lab will be seamlessly integrated into currently unused space within Amelia Heart's Springfield office. This expansion will not impose any capacity issues in the shared office spaces.
 - Cardiac PET/CT offers several distinct advantages, including enhanced accuracy, significantly reduced radiation exposure, and shorter test durations.
 - A significant advantage of Cardiac PET/CT is the low radioisotope dosing protocol. The short half-life of Rb82 (10 minutes) results in markedly reduced radiation exposure for patients compared to the commonly used Technetium-99 (Tc99) (half-life 6 hours) in SPECT imaging.
 - An appraisal of the benefits of Cardiac PET/CT wouldn't be complete without acknowledging its positive economic impact. The early and accurate detection it provides enables cost-effective management of CAD through drug therapies, reducing the need for future invasive procedures. The quantification of myocardial blood flow (MBF) by Cardiac PET/CT can potentially negate the requirement for interventional angiography, thus averting costly downstream treatments. In addition, the quantification of myocardial blood flow which only Cardiac PET can provide (as opposed to SPECT) is crucial for determination of non-obstructive CAD and microvascular angina in women. Studies indicate that Cardiac PET can decrease CAD management costs by up to 30% when compared to traditional SPECT and Computed Tomography Angiography.
- (v) the financial accessibility of the proposed project to the people in the area to be the financial accessibility of the proposed project to the people in the area to be served, including indigent people; and**

The applicant asserts that it has never refused care to anyone based on their ability to pay and accepts Medicare, most commercial insurances, various Medicaid products and self-pay patients. The applicant further asserts that for those facing financial constraints, it offers subsidized or free care depending on the patient's economic status to ensure that no one in the community is denied access to care. If the Commissioner approves the proposed project, Amelia Heart has committed to a 3.5% charity care condition.

(vi) at the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a proposed project.

DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant to determining a public need for the proposed projects.

3. The extent to which the proposed project is consistent with the State Health Services Plan;

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the SMFP.

The SMFP contains criteria/standards for the establishment of PET services. They are as follows:

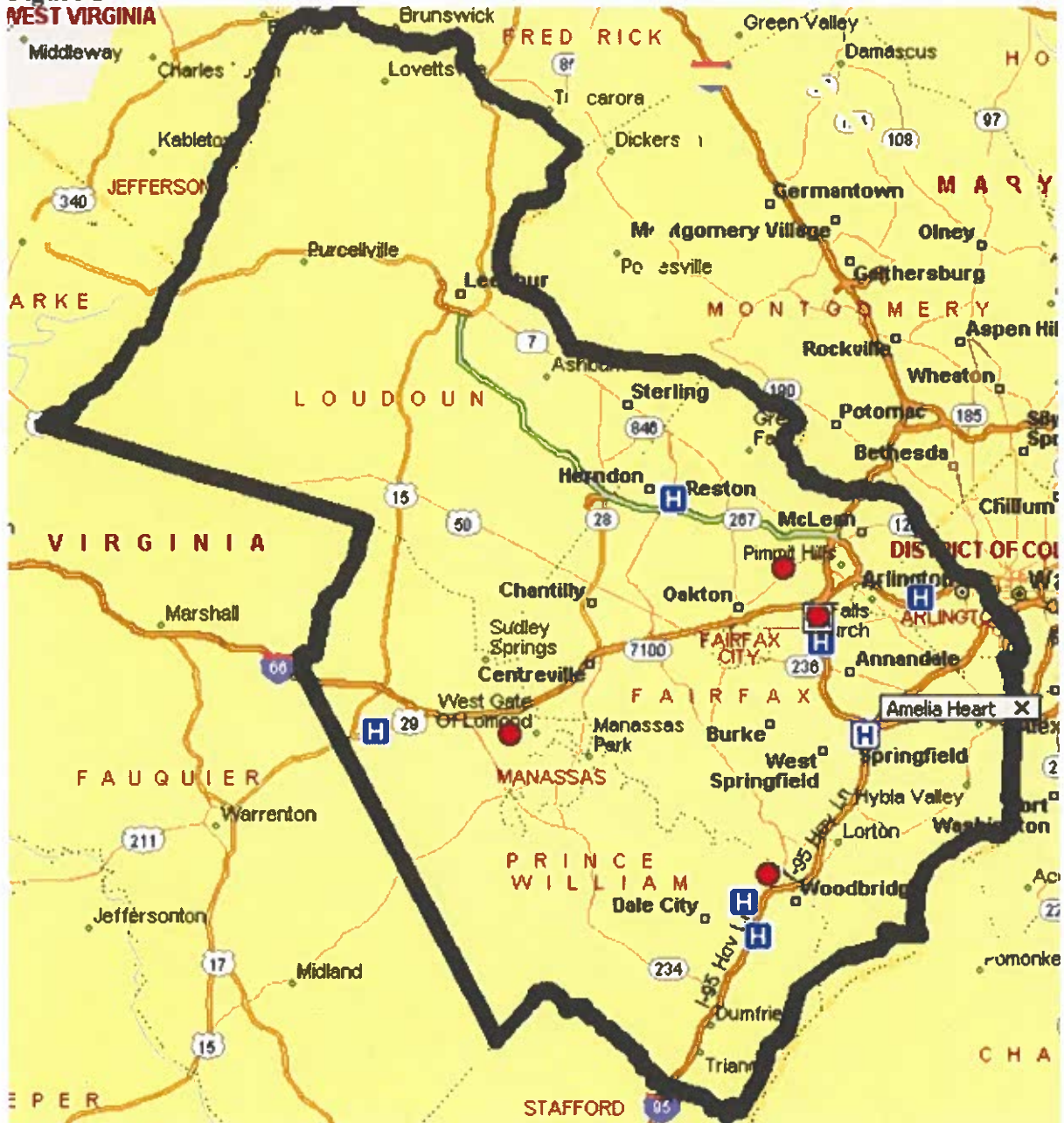
Part II
Diagnostic Imaging Services
Article 4 Criteria and Standards for Positron Emission Tomography

12VAC5-230-200. Travel Time.

PET services should be within 60 minutes driving time one way under normal conditions of 95% of the health planning district using a mapping software as determined by the commissioner.

The heavy black line in **Figure 1** is the boundary of PD 8. The blue “H” symbols mark the locations of existing PET providers in PD 8. The white “H” symbol marks the location of the proposed project. The red dots are the four currently authorized cardiac PET/CT sites. It is important to note that the SMFP does not distinguish between cardiac-specific PET services and all other PET services. The yellow shaded area includes the area that is within 60 minutes driving time one-way under normal conditions of existing PET services in PD 8. **Figure 1** clearly illustrates that PET services are already well within a 60-minute drive under normal conditions of 95% of the residents of PD 8 and approval of the proposed project will not increase geographic access to PET services.

Figure 1



12VAC5-230-210. Need for New Fixed Site Service.

- A.** If the applicant is a hospital, whether free-standing or within a hospital system, 850 new PET appropriate cases shall have been diagnosed and the hospital shall have provided radiation therapy services with specific ancillary services suitable for the equipment before a new fixed site PET service should be approved for the health planning district.

- B.** No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning

district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such health planning district.

Note: For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as one PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as 1 individual PET procedure and CT procedure respectively, unless those images are made concurrently.

DCOPN notes that several PET/CT scanners have been added to the PD 8 inventory since the preparation of the VHI data as displayed in Table 5, such as Carient Heart and Vascular, Nova Cardiovascular Care, Inc., and Virginia Heart. Additionally, it does not appear that Kaiser Permanente Woodbridge Imaging Center reported any PET/CT procedures to VHI for 2022. Finally, the table below displays only fixed PET/CT units. Table 1 above displays the current inventory of both mobile and fixed PET/CT scanners in PD 8.

Calculated Needed Fixed PET Scanners in PD 8
 2024 COPN authorized fixed PET scanners = 9

Calculated Needed Fixed PET scanners = $8,775$ (2022 fixed PET procedures) \div $6,000$ = 1.46 (2) scanners needed

PD 8 Calculated Need = 2 PET scanners

PD 8 Calculated Surplus = 7 PET scanners (2024 PET Scanners – Calculated Need)

Table 5. PD 8 COPN Authorized Fixed PET Units and Utilization: 2022

Facility	Number of Scanners	Number of Scans	Utilization
Fairfax PET/CT Imaging Center	1	2,834	47.23%
Metro Region Pet Center	1	3,802	63.37%
PET of Reston	1	1,076	17.93%
Virginia Hospital Center	1	1,063	17.72%
PD 8 Total	4	9,335	38.9%

Source: VHI (2022)

The SMFP does not distinguish between cardiac PET and PET used for other clinical uses. As shown above, there is a calculated surplus of seven PET scanners in PD 8. DCOPN notes, as shown in Table 5, no PET services in PD 8 surpassed the SMFP’s volume threshold in 2022. In fact, according to VHI data for 2022, the average number of PET procedures performed across all PET providers in the entire Commonwealth was 1,163.

DCOPN has previously acknowledged the SMFP’s utilization standards for PET/CT services are outdated and that expecting a PET service to reach the threshold suggested by the SMFP amounts to a misconception about the utilization of this modality at the time the SMFP was written, and should be treated as such:

Consistency with SMFP planning guidance in this case is, in effect, an academic exercise. The assumptions underlying the service volume standards, for example, have been superseded by technological developments (e.g., shorter average scan times) and the failure to identify additional clinical applications for the technology. Moreover, none of the existing services met fully the SMFP review criteria and standards when they obtained COPN authorization. (Source: Health Systems Agency of Northern Virginia Staff Report RE: COPN Request No. VA-8327, November 28, 2017).

More recently, in its November 29, 2022 report for COPN Request No. VA-8626, the HSANV observed “[i]t is evident that there is a wholesale shift underway from SPECT to PET-CT imaging as the preferred imaging modality in cardiovascular care...” and “[c]ardiac PET imaging in Northern Virginia has developed separately from other PET imaging services. This may not be desirable but is an operational reality that must be acknowledged...” and “[u]ntil recently Northern Virginia PET services have been organized, structured and equipped to serve oncology patients. Few cardiac patients are referred for PET scans. Metro Region PET, the region’s largest PET service, reports less than a dozen cardiac patient scans (less than 0.5% of Metro PET’s caseload) in recent years. None of the older services offer the PET based myocardial perfusion imaging....”

Amelia Heart anticipates performing 832 PET/CT studies in Year 1 and 912 PET/CT studies in Year 2. To determine these projections, Amelia Heart examined its SPECT procedures for the most recent six months, accounted for two new cardiologists joining the practice, and applied the appropriate use criteria for cardiac PET/CT to the population of SPECT patients. DCOPN contends that Amelia Heart’s projections are reasonable. DCOPN notes that these projections are slightly below the Commonwealth’s average across all PET providers of 1,163.

With regard to the effect that the proposed project would have on existing providers, Amelia Heart has indicated that the primary purpose of the PET/CT service will be to serve its existing patient base. There are two existing providers of cardiac PET services, Carient Heart & Vascular, and Virginia Heart, and one approved but not yet operational service - Nova Cardiovascular Care, Inc. (COPN No. VA-04836). Carient has to-date served patients from within its own patient base almost exclusively and Virginia Heart and Nova Cardiovascular Care, Inc. have both expressed intentions also to serve their respective existing patient bases. Because of the distinct nature of the patient base and the restricted scope of the PET/CT service to only cardiac procedures, DCOPN does not anticipate that approval of the proposed project would negatively affect utilization of other PET services in PD 8. Instead, approval of the proposed project would create an overall improvement in access to cardiac PET/CT in PD 8 and specifically for Amelia Heart’s patients.

While the applicant does not meet the computational analysis of this SMFP standard, DCOPN recommends that the Commissioner, in this specific instance, does not allow this standard to bar the establishment of this cardiac PET/CT service.

12VAC5-230-220. Expansion of Fixed Site Services.

Proposals to increase the number of PET scanners in an existing PET service should be approved only when the existing scanners performed an average of 6,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing fixed site providers in the health planning district.

Not applicable. The applicant is not proposing to expand an existing fixed-site PET service, but rather, is proposing to establish a new fixed-site service.

12VAC5-230-230. Adding or Expanding Mobile PET or PET/CT Services.

- A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.**
- B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district.**

Not applicable. The applicant is not proposing to add or expand an existing mobile PET/CT service, but rather, is proposing to establish a new fixed-site service.

12VAC5-230-240. Staffing.

PET services should be under the direction or supervision of one or more qualified physicians. Such physicians shall be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

The applicant provided assurances that PET services will be under the supervision of qualified physicians with the necessary training and licensure.

Eight Required Considerations Continued

- 4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served;**

Cardiac PET/CT scanning is currently available from three providers in PD 8 – Carient Heart & Vascular, Nova Cardiovascular Care and Virginia Heart. By introducing another provider choice in PD 8, the proposed project is likely to foster beneficial institutional competition. However, as previously noted, Carient has to-date served patients from within its own patient base almost exclusively and Virginia Heart, Nova Cardiovascular Care, Inc., and the applicant have expressed intentions also to serve their respective existing patient bases. The distinct nature of the anticipated patient bases may minimize the impact of the competition.

5. The relationship of the proposed project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities;

As previously discussed, the applicant and the existing providers of cardiac PET/CT services intend to serve patients from their own patient bases. Therefore, DCOPN concludes that the proposed project is unlikely to adversely affect the utilization and efficiency of existing services.

6. The feasibility of the proposed project, including the financial benefits of the proposed project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital;

As already discussed, DCOPN contends that the projected costs for the proposed project of \$1,441,605 are reasonable when compared to similar projects. For example, COPN No. VA-04852 issued to Cardiology Associates of Fredericksburg, Ltd. to establish a specialized center for cardiac PET with one PET/CT unit is anticipated to cost approximately \$1,345,647. Furthermore, the Pro Forma Income Statement provided by the applicant anticipates a net profit of \$1,544,671.92 in the first year of operation and \$1,644,246.70 by year two, illustrating that the proposed project is financially feasible both in the immediate and the long-term. (Table 6).

Table 6. Amelia Pro Forma Income Statement

	Year 1	Year 2
Total Gross Patient Revenue⁵	\$3,224,400.00	\$3,385,620
Total Operating Expenses	\$1,679,728.08	\$1,741,373.30
Net Income	\$1,544,671.92	\$1,644,246.70

Source: COPN Request No. VA-8722

With regard to staffing, the applicant does not anticipate the need to hire any additional staff, as it already employs a Certified Nuclear Medicine/CT technologist and registered nurse to staff the PET/CT service.

7. The extent to which the proposed project provides improvements or innovations in the financing and delivery of health care services, as demonstrated by (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) the potential for provision of health care services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate;

The proposed project would provide improvements in the delivery of health care services by increasing the provision of cardiac PET/CT scanning services on an outpatient basis. As there is an existing provider of cardiac PET/CT scanning services in PD 8 and the applicant has not raised any arguments regarding the unique nature of the proposed PET/CT scanner, the proposed project would not provide improvements or innovations in the financing and delivery of health care services, as demonstrated by the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. The applicant does not make any

⁵ Amelia Heart provided this amount after the Rb82 isotope cost.

arguments regarding any cooperative efforts to meet regional health care needs. DCOPN did not identify any other factors as may be appropriate to bring to the Commissioner's attention. DCOPN did not identify any other factors as may be appropriate to bring to the Commissioner's attention.

8. **In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served, (i) the unique research, training, and clinical mission of the teaching hospital or medical school and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care services for citizens of the Commonwealth, including indigent or underserved populations.**

The proposed project is not proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served. Accordingly, this standard is not applicable to the proposed project.

DCOPN Staff Findings and Conclusions

DCOPN finds that Amelia Heart's proposed project to establish a specialized center for cardiac PET/CT imaging is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. The applicant has stated that the CT functionality of the PET/CT scanner will be used only in conjunction with its PET functionality and that the PET/CT scanner would be used solely for cardiac imaging. While the planning district does not meet the utilization threshold for the establishment of a new service, DCOPN notes that precedent has been established by the Commissioner regarding this threshold not barring the establishment of new PET/CT services when sufficiently compelling circumstances exist. As such compelling reasons exist, such as the unique population of patients the PET/CT will serve, the applicant's commitment to charity care, and the clinical advantages of PET/CT over SPECT, DCOPN recommends that the Commissioner, in this specific instance, not allow this standard to bar the establishment of cardiac PET/CT services at this location.

Additionally, DCOPN finds that the proposed project is more beneficial than the alternative of the status quo. Furthermore, the proposed project would introduce beneficial competition into the planning district and is unlikely to negatively affect the utilization of existing providers. Moreover, the HSANV Board voted nine in favor, none opposed to recommend approval of Amelia Heart's COPN request. Finally, DCOPN finds that the total capital costs of the proposed project compare favorably to similar, recently approved projects.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of Amelia Heart and Vascular Center, Inc. COPN Request No. VA-8722 to establish a specialized center for cardiac PET/CT imaging with one PET/CT unit for the following reasons:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.

2. The PET/CT scanner's use will be limited solely to cardiac imaging.
3. The CT functionality of the PET/CT scanner will only be utilized in conjunction its PET functionality.
4. The project will improve access to the preferred cardiac imaging modality with numerous benefits over SPECT.
5. The project will introduce beneficial competition without adversely affecting existing providers of cardiac PET/CT services.
6. The project is more beneficial than the alternative of the status quo.
7. The capital costs are reasonable.
8. The Health Systems Agency of Northern Virginia recommended approval of the proposed project.

DCOPN's recommendation is contingent upon Amelia Heart and Vascular Center, Inc.'s agreement to the following charity care condition:

Recommended Condition

Amelia Heart and Vascular Center, Inc.'s PET/CT service will be limited solely to cardiac imaging. Amelia Heart and Vascular Center, Inc. will provide cardiac PET/CT services to all persons in need of these services, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount equal to at least 3.5% of Amelia Heart and Vascular Center, Inc.'s total patient services revenue derived from PET/CT services as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement Amelia Heart and Vascular Center, Inc. will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided to individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

Amelia Heart and Vascular Center, Inc. will provide cardiac PET/CT care to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. Additionally Amelia Heart and Vascular Center, Inc. will facilitate the development and

operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

Health Systems Agency of Northern Virginia
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March 13, 2024

Erik Bodin, Director, DCOPN
Office of Licensure and Certification
Virginia Department of Health
9960 Mayland Drive, Suite 401
Richmond, VA 23233-1463

Dear Mr. Bodin:

The Health Systems Agency of Northern Virginia (HSANV) Board of Directors reviewed at its March 11, 2024, meeting the certificate of public need (COPN) application filed by Amelia Heart and Vascular Center (Amelia Heart) seeking authorization to establish a cardiac PET-CT imaging service in Springfield, VA (COPN Request # VA-8722). The board voted nine in favor, and none opposed, to recommend approval of the application.

The board bases the recommendation on its review of the application, on the agency staff report on the proposal, on the information and testimony presented by the applicant at the March 11, 2024, board of directors meeting, and on several basic findings and conclusions, including:

1. Amelia Heart, a growing cardiology medical practice in Springfield, Virginia, proposes to establish and maintain a PET scanning service dedicated to cardiac PET imaging.
2. The proposal is comparable to, and consistent with, the four services authorized for PD 8 cardiology practices over the last five years.
3. Amelia Heart would develop the service under a lease and operating agreement with a national diagnostic imaging service vendor, CDL Nuclear Technologies of Wexford, Pennsylvania. The project does not entail a large initial capital investment by Amelia Heart.
4. With an onsite cardiac PET imaging option, Amelia Heart expects to see reductions in problematic SPECT scans and referrals for unnecessary diagnostic cardiac catheterizations.
5. The projected annual service volume, estimated at about 900 patients per year in the initial operating years, appears reasonable and attainable.
6. Given historical medical trade patterns and regional referral practices, introducing cardiac PET-CT imaging at Amelia Heart is not likely to affect demand or caseloads at other diagnostic imaging services.

Erik Bodin
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March 13, 2024
Page 2

7. The project is consistent with the diagnostic imaging provisions of the Virginia State Medical Facilities Plan (SMFP) as they have been applied to similar cardiac PET imaging COPN projects.

Copies of the HSANV staff report on the application and minutes of the March 11, 2024 board meeting held on the proposal are enclosed.

If we can provide additional information, please let me know.

Sincerely,



Dean Montgomery
Executive Director

cc: Azita Moalemi, MD, Amelia Heart & Vascular Center
Pam Kincheloe, RN, Chairperson, HSANV
Valerie Gresham, Analyst, DCOPN, VDH
DCOPN

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March 6, 2024

**TO: HSANV Board of Directors
Interested Parties**

FROM: Dean Montgomery

**SUBJECT: Certificate of Public Need Application
Amelia Heart & Vascular Center
Establish Cardiac PET Service, COPN Request VA-8722**

I. Background and Summary of the Proposal

A. Background

Positron Emission Tomography (PET) is a noninvasive diagnostic imaging technology. It has been available in some form since the 1970s and has come into wide clinical use over the last three decades, principally in the diagnosis and treatment of cancer and cardiovascular disease. Imaging technologies such as x-ray, CT, and MRI are anatomically based modalities.¹ PET is a metabolically based imaging modality. PET and PET-CT (combined PET and CT technologies in a single imaging system) imaging permit assessment of chemical and physiological changes related to metabolism, as distinct from the structural changes and abnormalities normally seen with CT and MRI.² Because biochemical and functional changes often precede detectable physical changes, PET images may identify pathology before imaging technologies such as CT and MRI can reveal abnormalities.

Used appropriately, PET imaging provides diagnostic information that may alter patient management, eliminate the need for other diagnostic tests, or eliminate the need for surgical intervention. Thus, PET imaging has the potential of reducing the total cost of care for some conditions and some patients.

¹The Virginia State Medical Facilities Plan (SMFP) defines PET as “a noninvasive diagnostic or imaging modality using the computer-generated image of local metabolic and physiological functions in tissues produced through the detection of gamma rays emitted when introduced radio-nuclides decay and release positrons. A PET device or scanner may include an integrated CT to provide anatomic structure definition.” Source: Virginia SMFP, p. 4.

² The Virginia State Medical Facilities Plan (SMFP) defines a PET-CT scanner as a single machine capable of producing a PET image with a concurrently produced CT image overlay to provide anatomic definition to the PET image. The Board of Health has designated PET-CT as a specialty clinical service (§ 32.1-102.2 A 6 of the Code of Virginia). A PET-CT scanner is reviewed under the PET criteria as an enhanced PET scanner unless the CT unit will be used independently. In such cases, a PET-CT scanner that will be used to take independent PET and CT images will be reviewed under the applicable PET and CT services criteria. Source: Virginia SMFP, p. 4.

Note: the terms PET and PET-CT are used interchangeably here. Service providers with PET systems that do not incorporate CT technology are free to upgrade to a PET-CT service at will, outside of COPN controls.

**Amelia Heart & Vascular Center
Establish Cardiac PET Service, COPN Request VA-8722
March 6, 2024**

The initial enthusiasm for PET imaging and the potential for broad clinical application subsided somewhat after its introduction. Demand has not grown as rapidly as many predicted. It is now used principally in the diagnosis and treatment of cancer and secondarily in cardiology and neurology. Clinical interest in the utility of PET in the diagnosis, treatment, and management of cardiovascular conditions, including coronary artery disease, is now gaining clinical and commercial interest.³

There are now eleven authorized PET services in Northern Virginia. Five of the eleven have been added in the last five years. Carient Heart and Vascular (Carient), a local cardiology group, opened a cardiac PET service in Manassas, Virginia in 2019. It obtained COPN authorization to add a second dedicated cardiac PET scanner in 2022. That service is in Carient's Vienna, VA office. Kaiser Foundation Health Plan opened a service in Woodbridge, VA in 2022. It is a dedicated service, available only to Kaiser Health Plan subscribers. Virginia Heart, a large cardiology group practice, also obtained COPN authorization to establish a dedicated cardiac PET service in 2022. That service is in Virginia Heart's Falls Church office. Carient's Vienna service and the Virginia Heart services opened recently. NOVA Cardiovascular Care obtained authorization in 2023 to establish a service in Woodbridge, Virginia.

With these recent additions, there are now eleven authorized PET services in the region. Eight are fixed site services. Three are mobile services with limited operating schedules. Four of the eight full-time fixed site services are dedicated to cardiac PET imaging. Three of the ten service providers and four of the eleven PET systems are cardiac services. All cardiac PET services are recently authorized full-time stationary services.

B. Summary of the Proposal

Amelia Heart and Vascular Center (Amelia Heart) is a local cardiology medical practice. Its central service site is in Springfield, Virginia. The applicant indicates that the service would be dedicated to cardiovascular imaging. There is no intention to serve oncology or neurology patients.

Approval of the application would authorize Amelia Heart to acquire and operate a PET-CT scanner. The applicant could purchase a scanner and associated technology or arrange to offer the service through a diagnostic imaging service vendor. In this instance Amelia Heart plans to establish the service by means of a contract with CDL Nuclear Technologies, a PET imaging vendor located in Wexford, Pennsylvania, to establish and maintain a fulltime fixed site cardiac PET imaging service.⁴ Projected capital costs are \$1,441,605.

³ Medicare extended coverage cardiac PET imaging in 1995. Until recently most commercial medical insurance carriers have considered cardiac PET imaging unproven and have been reluctant to extend coverage. With studies now showing greater sensitivity and specificity of cardiac PET images, compared with other diagnostic imaging technologies, e.g., SPECT scanning, commercial carriers are beginning to initiate coverage. These changes have stimulated renewed interest in the technology among PET service vendors and cardiology practices.

⁴ CDL Nuclear Technologies describes itself as "the end-to-end Cardiac PET and PET/CT solutions provider trusted by more cardiologists than any other in the United States." Information on CDL Nuclear Technologies is available at <https://cdlnuclear.com>.

**Amelia Heart & Vascular Center
Establish Cardiac PET Service, COPN Request VA-8722
March 6, 2024**

Amelia Heart justifies the proposal on essentially the same grounds that previous cardiac PET service providers, Carient Heart and Vascular, Virginia Heart, and NOVA Cardiovascular, cited in their requests to establish dedicated cardiac PET imaging services. These include:

- With greater sensitivity and specificity than SPECT imaging, cardiac PET imaging has become the preferred diagnostic tool for many cardiovascular patients, especially those who might benefit from myocardial perfusion imaging.
- Amelia Heart is a substantial cardiology medical practice with hundreds of patients who would be likely to benefit from PET imaging.
- PET imaging is noninvasive, and it entails less exposure to radiation dose than alternative, less effective diagnostic imaging tests.
- With a dedication to cardiovascular imaging, and a focus on serving its established patient base, an Amelia Heart PET-CT service would not affect demand at, or use of, other imaging services.
- Projected capital and operating costs are reasonable, comparable to those of other service providers.
- The project is consistent with the PET service provisions of the Virginia State Medical Facilities Plan (SMFP) as they have been interpreted and applied to cardiac PET imaging proposals in recent years, including five PD 8 projects.

If authorized, the service is likely to be operational quickly, within less than six months.

II. Discussion

A. Community, Public Need

Northern Virginia (PD 8) has eleven authorized PET imaging services. Service type and recent caseloads are shown in Table 1. Eight are stationary (fixed site) full-time services. Collectively, these services accounted for more than 85% of the PET scans provided in 2021 (Table 1).⁵ The other three are part-time mobile service delivery sites with relatively small caseloads.

After many years of wide variations in demand, and nearly a decade of use rate decreases which led to the closure of several mobile service delivery sites, demand for PET scans has increased steadily in recent years. Between 2017 and 2021, for example, the reported regional scan volume increased by about 27% at oncology focused PET services, a compound annual growth rate of 6.2%.

A notably large increase came in 2020 and 2021 with the opening of Carient's cardiac PET service, which was authorized in 2018. The first reported Carient service volume, 1,793 scans in 2020, was almost twice the total increase in the other local services over the previous four years. Carient reports performing 3,185 cardiac PET scans in 2021, a 78% increase over the previous year (Table 1). This increase, far greater than expected or projected, raises questions yet to be answered. It is unclear whether this is an anomaly or indicative of rapid increases in demand that could be seen at other cardiac PET services. Carient data for 2022 and initial service volumes of more recently authorized services are not yet available.

⁵ 2021 is the most recent year for which vetted service volume data is available for all operational services.

**Amelia Heart & Vascular Center
 Establish Cardiac PET Service, COPN Request VA-8722
 March 6, 2024**

**Table 1. PET-CT Scanner Capacity & Use
 Northern Virginia, 2017-2022⁵**

Service	Equipment Type	2017-2022					
		2017	2018	2019	2020	2021	2022
Carient Heart & Cardiovascular-Manassas ¹	Stationary (Cardiac)				1,793	3,185	
Carient Heart & Cardiovascular-Vienna ²	Stationary (Cardiac)						
Metro Region PET Center	Stationary	2,738	2,592	2,652	2,691	3,417	3,700
Fairfax PET-CT Service	Stationary	1,257	1,723	1,734	1,797	2,103	2,788
UVA Cancer Center Gainsville	Mobile, Part-time	598	501	475		510	560
NOVA Cardiovascular Care ⁴	Stationary (Cardiac)						
PET of Reston	Mobile, Part-time	615	625	711	700	874	1,076
Sentara Northern Virginia Medical Center ¹	Mobile, Part-time					20	
Virginia Heart ³	Stationary (Cardiac)						
Virginia Hospital Center	Stationary	838	705	895	710	767	1,063
Kaiser Foundation Health Plan ²	Stationary						
Northern Virginia Total		6,046	6,146	6,467	7,691	10,876	9,187

Source: Annual Service Volume, Virginia Health Information, ALSD, 2017-2022

¹ Service authorized in 2018

² Service authorized in 2017 ³ Service authorized in 2022

⁴ Service authorized in 2023

⁵ Several recently authorized services have yet to report service volumes

Most northern Virginia PET services are organized, structured, and equipped to serve oncology patients. Few cardiac patients are referred for PET scans to these oncology focused services. None offer the PET based myocardial perfusion imaging that the recently authorized cardiac PET services are now offering or developing.

Planning Guidance

The Virginia State Medical Facilities Plan contains planning guidance to be consulted in the development of PET services. Amelia Heart proposes to establish a new office-based service dedicated to serving cardiac patients. Potentially applicable plan language reads:⁶

Article 4

Positron Emission Tomography

“12VAC5-230-210. Need for new fixed site service.

A. If the applicant is a hospital, whether free-standing or within a hospital system, 850 new PET appropriate cases shall have been diagnosed and the hospital shall have provided radiation therapy services with specific ancillary services suitable for the equipment before a new fixed site PET service should be approved for the health planning district.

⁶ “Potentially applicable” is used here because Virginia regulations do not distinguish PET imaging for cardiac patients from PET scanning generally. The Virginia SMFP language reflects the expectation that PET service development proposals are likely to be designed and structured to serve cancer patients. The lack of specificity notwithstanding, this provision applies to all proposals to establish new PET services, hospital based or otherwise. There are no regulatory barriers or limits as to the types of patients an authorized PET service may treat.

B. No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such health planning district.” Source: Virginia SMFP, p.12

Amelia Heart proposes to establish a full-time fixed site PET service. It would be dedicated to cardiac imaging, principally myocardial perfusion imaging for use in the diagnosis, monitoring, and treatment of coronary artery disease. The projected annual caseload is expected to come from the patient population now served by the practice, most of whom, absent an onsite PET scan option, would obtain other nuclear medicine scans, e.g., SPECT scans, arguably of less clinical value, within the practice.

B. Cost Considerations

Amelia Heart proposes a capital expenditure of \$1,441,605 to establish an office-based PET service. Most of the capital outlay would be paid through an operating lease for the scanner and related equipment and technology. The Amelia Heart-CDL agreement contains a buildout allowance of \$150,000 and a provision for additional capital expense allowances tied to incremental extensions of the lease. Other than the borrowing and financing costs subsumed in the capital lease, Amelia Heart would not incur “upfront” development costs. The application states that

“A service agreement has been established between AHV [*Amelia Heart*] and CDL Nuclear Technologies, outlining the payment of capital expenditures, including facility renovations, throughout the agreement’s term, provided they meet the criteria of capital expenditures. Utilizing operating capital revenues, AHV intends to fulfill the lease terms and meet lease obligations as stipulated in the agreement.” This contractual arrangement “will enable AHV to operate the proposed project without the need for a significant upfront capital investment.” Source: Amelia Heart, COPN Request VA-8722. pp 39-40.

The seven-year lease agreement requires a payment of \$13,000 per month (\$156,000 per year) for the scanner, associated equipment, and maintenance. Amelia Heart also agrees to pay CDL an isotope (rubidium 82) fee of \$850 per patient scanned.⁷ The lease contains an automatic one-year renewal provision. It sets a minimum caseload of 45 PET-CT patients per month, 540 cases and 1,080 rubidium 82 doses per year. If this caseload is not met, CDL has the option of converting the full-time fixed service to a part-time mobile service.

Amelia Heart expects to perform 892 cardiac PET scans in the first full year of operations and 912 in year two. Service volumes are expected to grow thereafter at about 5% annually, as the practice grows, and the utility of PET-CT is demonstrated in the diagnosis and treatment of cardiovascular disease.

⁷ The contract price of the isotope is 425 per dose. Cardiac PET patients receive two Rubidium 82 doses per study. Source: Amelia Heart-CDL Equipment Lease and Service Agreement dated June 7, 2023.

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The *pro forma* budget submitted with the application is generic, not directly related to the projected Amelia Heart service volumes, payer mix, and related operations. It is based on a hypothetical Virginia office-based cardiac PET service with a caseload of about 1,200 Medicare patients annually. Though not directly tied to projected Amelia Heart operations, it does appear reflective of potential cardiac PET service volumes and likely revenue flows, expenses, and operating margins during the early years of operations.

The *pro forma* estimates illustrate that the economic interest in cardiac PET services is perhaps as strong as the clinical interest and why entities such as CDL Nuclear Technologies are eager to offer clinicians essentially turnkey projects with little or no upfront capital investment. Projected average reimbursement (payment), is \$3,271 per case. Average net income (profit) per case is expected to be about \$1,287 during the initial years of operations. Program operating profit is projected to be \$ 1,544,672, about 48% of net revenue, in the first year of operations. Operating returns and profit will be much higher if service volumes exceed the projected caseloads, as has been the case to date with the recently opened services.

There is no reason to believe that the caseload projected is unattainable, given the number of PET-CT scans performed would be controlled by referrals from within the medical group, essentially a function of the number of Amelia Heart patients receiving PET scans in lieu of other imaging procedures, e.g., a SPECT scan.

C. Access Considerations

Amelia Heart proposes to establish a cardiac PET imaging service in Springfield, VA. Establishing a new service necessarily improves geographic access to care for some. The proposed Springfield location is near the center of the area from which the Amelia Heart obtains most of its patients, southeastern Fairfax County, Alexandria, and south Arlington. The location is roughly equidistant from the cardiac PET services established recently by Virginia Heart (Falls Church) and NOVA Cardiovascular (Woodbridge). Their primary service areas do not overlap significantly. There is no indication or reason to believe that an Amelia Heart cardiac PET service would affect demand at competing services significantly.

The applicant claims a history of equitable service to medically indigent patients and indicates a willingness to continue the practice. The *pro forma* budget projects a 3.5% charity care caseload. There is no reason to doubt the applicant's commitment to equitable service delivery. Nevertheless, it is worth noting that few freestanding (nonhospital) proprietary medical facilities serve substantial numbers of the medically indigent.⁸ If the project is authorized, a charity care condition equal to that applied to other service providers is appropriate.

D. Health System Considerations

There are now eleven authorized PET services in the region. Four are dedicated to cardiac PET imaging. The focus of the other seven is cancer diagnosis and treatment. There is no limitation on the type PET scans these services may provide, or on the patients they may serve, but there is no indication that any of the oncology focused services are likely to offer cardiac PET scanning any time soon. There is great

⁸ Under Virginia law applying for a certificate of public need is tantamount to proposing to become (to be classified, licensed, and operated as) a "medical care facility".

reluctance to refer cardiac patients for diagnostic testing outside a cardiology practice. It appears that cardiology practices without in-house cardiac PET capability are likely to continue to rely on SPECT nuclear scanning for myocardial perfusion studies.

Amelia Heart has six cardiologists and three practice sites, the original site in Springfield and expansion offices in Alexandria and south Arlington. The practice provides a wide array of cardiovascular diagnostic and treatment services, but not invasive procedures such as cardiac catheterization, diagnostic and therapeutic. The practice is also distinctive in that the most of its professional staff, and patients are female. Its primary service area is in the Interstate 395-Route One corridor, which has several modest and low-income population centers.

Near term health system effects of the Amelia Heart project are likely to be negligible. The PET-CT service developed would be dedicated to cardiovascular imaging. Most, if not all, of those served would come from the applicant's established patient base, patients who would otherwise be likely to obtain a less definitive diagnostic procedure, e.g., a SPECT scan. There are strong clinical and economic incentives to shift a large percentage of SPECT scan patients to PET scans. Amelia Heart reports providing about 1,200 SPECT per year currently. Projected service volumes suggest Amela Heart expects most of those obtaining SPECT to receive a PET-CT scan instead, to "convert" from SPECT to PET-CT for myocardial perfusion imaging. In essence, the proposal is to develop the option of substituting cardiac PET scans for less desirable nuclear scans (e.g., SPECT scans) among Amelia Heart patients.

The principal health system effect could be the reinforcement of the practice of authorizing potentially duplicative office-based specialty PET imaging services. Beyond the inherent self-referral element of the project, there are numerous cardiology group practices in the region with coronary artery disease caseloads comparable to those of the medical practices recently authorized to establish inhouse cardiac PET services.

III. Conclusions and Alternatives for Agency Action

A. Findings and Conclusions

Increasing clinical interest in cardiac PET imaging derives largely from recent studies indicating that the data and images produced with cardiac PET scanning have higher diagnostic sensitivity and specificity than the principal alternative imaging modality, Single Photon Emission Computed Tomography (SPECT). Cardiac PET studies are reported to have diagnostic specificity and specificity of about 95%, compared with SPECT study sensitivity of about 80% and specificity of about 75%.

Higher PET sensitivity, broadly applied, should reduce the number of false negative studies that are inherent in alternative diagnostic modalities, permitting those needing specific cardiovascular treatment to obtain it sooner. Greater specificity should reduce the number of false positive studies and, thereby, reduce the number of unnecessary diagnostic cardiovascular interventions such as cardiac catheterization.

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Northern Virginia has eleven PET imaging services and more than adequate capacity to meet demand. Neither additional services nor additional capacity is needed. After several years of stagnation, demand is now increasing significantly among oncology focused services but they still have substantial unused capacity. After only two years of operations, Carient Heart and Vascular reports the second highest service volume in the region and has obtained authorization to expand by adding a second service in central Fairfax County. It is unclear whether the extraordinary growth at the Carient service is an aberration or portends rapid increases in demand at other cardiac PET services. Local data to assess this question and related questions are not yet available.

Amelia Heart proposes to develop a PET service that would be dedicated to cardiac PET imaging. Nearly all of those served would be patients from within its current patient base, those who would be likely to obtain a SPECT scan or other diagnostic procedure absent an inhouse cardiac PET option.

Given the nature of the project, and the recent approval of several similar projects, there is little likelihood that an Amelia Heart service would affect other programs negatively. If there is a risk to the project, it is the self-referral potential inherent in the proposal. Charges and payments for PET imaging are notably higher than for SPECT imaging and most other alternative imaging procedures. The economic incentive to choose PET imaging is evident.

There is a credible argument that fragile, difficult to treat cardiac patients may benefit from PET imaging. The ultimate value of the additional clinical data available from PET scanning, its greater sensitivity and specificity, and the associated potential to reduce diagnostic uncertainty, remains to be proven. But the possibility of reducing the number of unnecessary cardiac interventions cannot be ignored or dismissed easily. Avoiding the risk, cost and futility of these procedures is a worthy, if illusive, goal.

B. Alternatives for Agency Action

1. The Health Systems Agency of Northern Virginia may recommend to the Commissioner of Health that a Certificate of Public Need authorizing the project be granted.

A favorable recommendation could be based on concluding that the service proposed by Amelia Heart would offer a meaningful, clinically useful diagnostic alternative for many of its coronary artery disease patients, that a dedicated Amelia Heart cardiac PET imaging service would not affect existing PET scanning services negatively, and that the potential benefits of the project outweigh the inherent risk of overuse and the unnecessary duplication of the service.

2. The Health Systems Agency of Northern Virginia may recommend to the Commissioner of Health that a Certificate of Public Need authorizing the project not be granted.

An unfavorable recommendation could be based on concluding that, with the recent authorization of four cardiac PET services, there is more than enough cardiac PET capacity to meet regional need, that additional capacity should not be authorized until these services are operational and their use and system effects assessed, and that it is unclear that the potential benefits of cardiac PET imaging outweigh the higher cost.

IV. Checklist of Mandatory Review Criteria

1. Maintain or Improve Access to Care

Northern Virginia residents have ready access to diagnostic imaging services, including PET scanning. There is no documented public need for additional PET services or capacity.

Most unused PET capacity is in services that do not offer cardiac PET imaging, the form of PET scanning Amelia Heart proposes to offer. The local PET service that provides cardiac PET scanning, Carient Heart and Vascular, reports high and increasing use. Two cardiac PET services systems being added, both in central Fairfax County, will double regional capacity.

Developing a cardiac PET imaging service at Amelia Heart has the potential to improve access by adding the service option in southeastern Fairfax County.

2. Meet Needs of Residents

Given the number and capacity of cardiac PET scanning services, and the extraordinary rapid increase in demand at the first program established, adding a fifth dedicated cardiac PET scanner should be sufficient to meet demand for cardiac PET imaging. The principal unanswered question is whether adding another service now is too much too soon.

3. Consistency with Virginia State Medical Facilities Plan (SMFP)

The PET service planning guidance in the State Medical Facilities Plan is dated. It is not useful in assessing proposals to develop additional services. Inconsistency of the Amelia Heart proposal with the SMFP is not a deficiency of the application and should not be construed as negative. The Amelia Heart proposal appears to be generally consistent the principles and policies in which the plan is grounded, and with the considerations applied recently to similar cardiac PET projects.

4. Beneficial Institutional Competition while Improving Access to Essential Care

The project is from an existing service provider which competes routinely with other cardiology practices. This would not change. Given the nature of the proposal, an Amelia Heart PET service, serving largely the applicant's current patient base, would not offer significant competition to other diagnostic imaging services. Arguably, it would expand, or otherwise improve, access to cardiac PET imaging in the communities and populations the practice serves.

5. Relationship to Existing Health Care System

No discernible negative health system effects are likely. The Amelia Heart project is not likely to affect demand at or use of other diagnostic imaging services.

6. Economic, Financial Feasibility

Amelia Heart proposes to offer the service by leasing the equipment, technology and related support services from a diagnostic imaging vendor, Cardiac Imaging of Oakbrook Terrace, Illinois. The capital cost of the project, estimated to be \$648,900, would be paid as lease expense. There is no significant direct capital investment by Amelia Heart.

The project is financially feasible and likely to generate substantial profits for both CDL and Amelia Heart.

7. Financial, Technological Innovations

The project does not involve innovative technologies, practices or distinct economic aspects that warrant special consideration.

8. Research, Training Contributions and Innovations

The project does not include research or training elements that warrant special consideration.