

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 |
|--|---------------------------|--------------------------------|-------------------------|--------------|
| Cariant Heart & Vascular (Ashton Avenue) | 1 | 1 | 0 | 1 |
| Cariant 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, HSANV 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 HSANV, 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 HSANV based its recommendation on the HSANV 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:

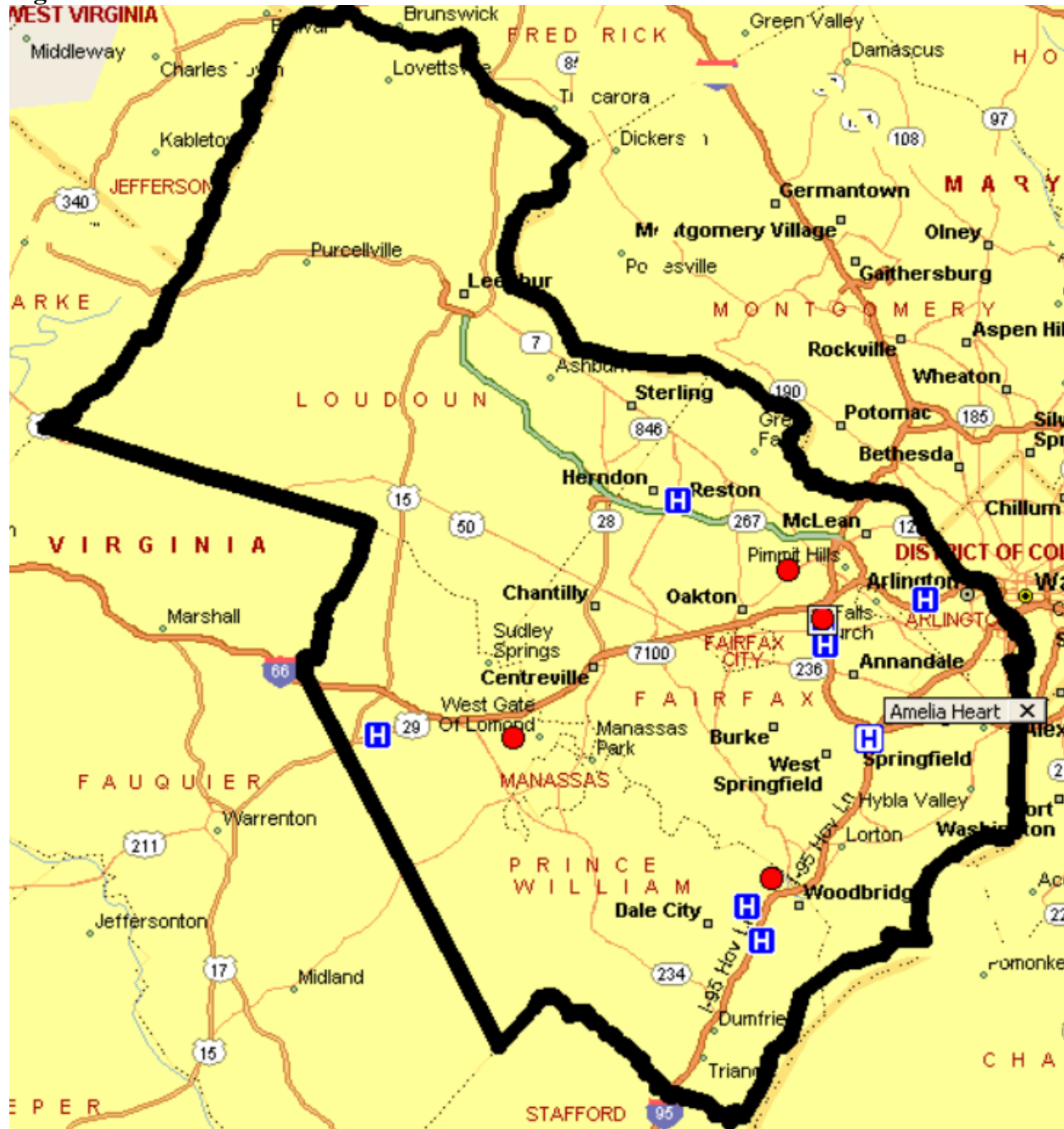
Part II
Diagnostic Imaging Services
Article 4 Criteria and Standards for Positron Emission Tomography

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 HSNV 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.