

Health Systems Agency of Northern Virginia
3040 Williams Drive, Suite 200
Falls Church, Virginia 22031
Phone: 703-573-3100 Fax 703-573-3101
Email: hsanv@aol.com

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, 2017-2022 ⁵							
Service	Equipment Type	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 Gainesville	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 201³ 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.**

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 Amelia 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.

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, 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.