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**February 28, 2025**

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

**FROM: Dean Montgomery**

**SUBJECT: Certificate of Public Need Application**  
**Virginia Heart, Establish Cardiac PET-CT Service, COPN Request VA-8794**

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**I. Background and Summary of the Proposal**

**A. Background**

Positron Emission Tomography (PET) is a noninvasive diagnostic imaging technology that has come into wide clinical use in recent 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.<sup>1</sup> PET is a metabolically based imaging technology. PET and PET-CT (combined PET and CT technologies in an imaging system) imaging permit assessment of chemical and physiological changes, as distinct from the structural changes and abnormalities normally seen with CT and MRI imaging.<sup>2</sup> 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, reduce 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.

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<sup>1</sup>The 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.**

<sup>2</sup> 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 review.

The initial enthusiasm for PET imaging and the potential for broad clinical application subsided after its introduction. Demand did not grow as rapidly as many predicted. Until recently, it was used principally in the diagnosis and treatment of cancer and secondarily in neurology and cardiology. Clinical interest in the utility of PET in the diagnosis, treatment, and management of cardiovascular conditions, including coronary artery disease, is now rapidly gaining clinical and commercial interest.<sup>3</sup>

There are now fourteen authorized PET services in Northern Virginia. Seven of the fourteen have been added in the last six years:

- Carient Heart and Vascular (Carient), a local cardiology group, opened a cardiac PET service in Manassas, Virginia in 2019.
- Carient obtained COPN authorization to add a second cardiac PET scanner in 2022. That service is in Carient's Vienna, VA office.
- Kaiser Foundation Health Plan opened a PET service in Woodbridge, VA in 2022. It is a dedicated service, available only to Kaiser Health Plan subscribers. Its focus is on cancer diagnosis and treatment. The Kaiser service is not part of the ongoing boom in cardiac PET service initiation.
- Virginia Heart, the region's largest cardiology practice, also obtained COPN authorization to establish a cardiac PET service in 2022. That service is in Virginia Heart's Falls Church office.
- NOVA Cardiovascular Care obtained authorization in 2023 to establish a service in Woodbridge, Virginia.
- Cardiac Care Associates, a Fairfax County cardiology practice, obtained authorization to establish a service in Reston, Virginia in 2024.
- Virginia Heart's application for a second cardiac PET service is pending before the Virginia Commissioner of Health.
- Amelia Heart and Vascular Center obtained approval for a cardiac PET service in early 2024. That service is in Amelia's Springfield (southeastern Fairfax County) office.

All recently authorized PET services are expected to be operational by the end of 2025. With these recent additions, there are now thirteen authorized PET services and fourteen PET scanners in the region. Ten services are fixed sites. Three programs, all of which focus on cancer diagnosis and treatment, are mobile services with limited operating schedules. Six of the ten full-time fixed site services are cardiac PET-CT services. All cardiac PET services are recently authorized full-time services.

## **B. Summary of the Proposal**

Virginia Heart is northern Virginia's largest cardiology practice. It has twelve widely dispersed offices in four jurisdictions: Alexandria, Arlington, Fairfax County and Loudoun County. It has grown rapidly in recent years and continues to grow.

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<sup>3</sup> Medicare extended coverage of cardiac PET imaging in 1995. Until recently most commercial medical insurance carriers have considered cardiac PET imaging unproven and have been reluctant to initiate coverage. With studies now showing greater sensitivity and specificity of cardiac PET images, compared with other diagnostic imaging technologies, e.g., single photon emission computed tomography (SPECT) scanning, commercial carriers are beginning to initiate coverage. These changes have stimulated renewed interest in the technology among cardiology practices, PET service vendors, and private equity investors.

Virginia Heart obtained COPN authorization to establish a cardiac PET service at its Telstar Court office near Falls Church in 2022. That service opened in 2023. Service volumes have grown quickly. The scanner is now used to capacity. The group has applied for a second PET-CT scanner to be in its Lansdowne office (Loudoun County). That application is pending before the Commissioner of Health. HSAHV and the Commissioner's staff have recommended approval of the project.

Virginia Heart seeks a third PET-CT scanner which would be placed in its City of Alexandria office (in Mark Center). As with its earlier COPN requests, the service would be dedicated to cardiovascular imaging.

Virginia Heart proposes establishing a third full-time fixed site service. Projected capital costs are \$3,807,237. The majority (\$2,219,758, 58.3%) would be for the scanner and associated equipment. The remainder (\$1,587,452) would be for space acquisition, interest costs, construction, and related fees.

Virginia Heart justifies the proposal on grounds similar to those cited in earlier cardiac PET services:

- PET-CT imaging is the preferred diagnostic tool for many cardiovascular patients, especially those who might benefit from myocardial perfusion imaging and calcium scoring.
- The cardiac PET-CT service Virginia Heart maintains near Falls Church (Telstar Court) is used to capacity and unable to meet demand within the practice.
- The pending Virginia Heart Lansdowne project is expected to serve those who are now served by that office. The service is expected to reach operating capacity within less than two years.
- Virginia Heart is a large cardiovascular services practice with a large patient base. As with its initial cardiac PET service, there is demand within the existing patient population to make efficient use of multiple PET-CT scanners.
- The availability of noninvasive PET imaging will make it possible for many patients to avoid riskier and less effective tests.
- With a dedication to cardiovascular imaging and a focus on serving its established patient community, an additional Virginia Heart PET-CT service would not affect directly or meaningfully demand at other cardiac PET services.
- Projected capital and operating costs are reasonable.
- The project is consistent with the Virginia State Medical Facilities Plan (SMFP) as its PET-CT provisions have been interpreted and applied to cardiac PET-CT imaging proposals in recent years.

If authorized, the service is likely to be operational in about a year, in early 2026.

## **II. Discussion**

### **A. Community, Public Need**

Northern Virginia (PD 8) has fifteen PET imaging services. Thirteen of them are full-time stationary programs. Collectively, these services account for more than 90% of regional PET scans (Table 1).<sup>4</sup> Two are part-time mobile service delivery sites with small caseloads. Recent service volumes of the operational programs that have reported service volumes are shown in Table 1.

After years of wide variations in demand, and a decade of use rate decreases which led to the closure of several mobile services, demand for PET scans has increased steadily in oncology focused services in recent years. Between 2017 and 2022, for example, the reported regional scan volume increased by about 70% at oncology focused PET services, a compound annual growth rate of 11.2%.

A notably large increase in regional PET service volumes came with the opening of the region's first cardiac PET imaging service. Carient Heart and Cardiovascular (Carient) obtained COPN authorization to establish an office based cardiac PET service in 2018. The first reported Carient service volume, 1,793 scans in 2020, was roughly twice the total increase in the local oncology focused services over the previous four years. Carient reported 3,185 cardiac PET scans in 2021, a 78% increase over the previous year (Table 1). With the opening of a second cardiac PET service in its Vienna office, Carient reported 4,166 cardiac PET scans in 2023. Demand at stationary (full-time) oncology focused services also increased sharply between 2020 and 2022.

Until recently, northern Virginia PET services were organized, structured, and equipped to serve oncology and neurology patients. They serve few cardiac patients. None offers the organized PET based myocardial perfusion imaging that the recently authorized cardiac PET services provide. Over the last five years the focus has shifted to cardiac PET-CT imaging. There is now a virtual boom in cardiac PET imaging service development in the planning region, and in some other parts of Virginia.

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<sup>4</sup> 2022 is the most recent year for which vetted service volume data is available for most local services. Anecdotal information suggests demand and service volumes increased significantly in 2023 and 2024, principally at the cardiac PET-CT services.

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Table 1. PET-CT Scanner Capacity and Use Northern Virginia, 2017-2023									
Service	Scanners	Type	2017	2018	2019	2020	2021	2022	2023
<b><u>Cancer Focused PET-CT Services</u></b>									
Metro Region PET Center	2	Stationary (Cancer)	2,738	2,592	2,652	2,691	3,417	3,700	
Fairfax PET-CT Service	1	Stationary (Cancer)	1,257	1,723	1,734	1,797	2,103	2,834	2,893
Kaiser Foundatio Health Plan <sup>2</sup>	1	Stationary (Cancer)							
PET of Reston	1	Stationary (Cancer)	615	625	711	700	874	1,076	
UVA Cancer Center Gainesville	1	Mobile (Cancer)	598	501	475		510	560	
Sentara NVMC <sup>1</sup>	1	Mobile (Cancer)					20		
Virginia Hospital Center	1	Stationary (Cancer)	838	705	897	710	767	1,063	
IRMC <sup>6</sup>	1	Stationary (Cancer)							
<b><u>Cardiac PET-CT Services</u></b>									
Amelia Heart & Vascular <sup>5</sup>	1	Stationary (Cardiac)							
Cardiac Care Associates <sup>5</sup>	1	Stationary (Cardiac)							
Carrient Heart & Vascular-Manassas <sup>1</sup>	1	Stationary (Cardiac)				1,798	3,185		
Carrient Heart & Vascular-Vienna <sup>2</sup>	1	Stationary (Cardiac)							
NOVA Cardiovascular Care <sup>3</sup>	1	Stationary (Cardiac)							
Virgina Heart-Telstar <sup>3</sup>	1	Stationary (Cardiac)							718
Virginia Heart-Lansdowne <sup>6</sup>	1	Stationary (Cardiac)							
Northern Virginia Total	16		6,046	6,146	6,469	7,696	10,876	9,233	3,611

Source: Virginia Health Information ALSD, 2017-2023; COPN Applications, 2022-2024.

<sup>1</sup> Authorized in 2018

<sup>3</sup> Authorized in 2022

<sup>5</sup> Authorized in 2024

<sup>2</sup> Authorized in 2019

<sup>4</sup> Authorized in 2023

<sup>6</sup> Authorized in 2025

## Planning Guidance

The Virginia State Medical Facilities Plan contains planning guidance for the development of PET services. Virginia Heart proposes establishing a new office-based cardiac PET service. The Virginia State Medical Facilities Plan does not differentiate as to program orientation or focus. Potentially applicable plan language reads:<sup>5</sup>

<sup>5</sup> “Potentially applicable” is used here because Virginia regulations do not distinguish PET imaging for cardiac patients from oncology focused PET services. 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 or expand 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.

**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.

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

Virginia Heart proposes to establish a medical office service dedicated to cardiac imaging, principally myocardial perfusion imaging, for the diagnosis and treatment of coronary artery disease. Section 12VAC5-230-210.B applies to the proposal.

As with earlier cardiac PET proposals, the project does not satisfy the service volume requirement of this provision. The service volume standard is dated, much too high for current procedure times and service protocols. Use of established PET services, cardiac and oncology focused alike, does not approach 6,000 scans per scanner. Given recent experience with clinical applications and treatment times, there is no prospect of meeting the service volume specified.<sup>6</sup>

The service would be in Virginia Heart’s Alexandria office. The projected annual caseload, which the applicant expects to come from the patient population now served by the practice, would largely be residents of Alexandria and eastern Fairfax County.

**B. Cost Considerations**

Virginia Heart plans to establish a cardiac PET service. Projected capital costs are \$3,807,237. About 60% (\$2.22 million) would be for equipment, the PET-CT scanner and related technology. The remainder (\$1.59 million) would be for space acquisition, interest expense, construction, and related fees. The scanner would be obtained under a capital lease (lease to own) from a vendor.

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<sup>6</sup> This problem is well known. Virginia Department of Health staff and the Commissioner of Health take the limited value of this planning guidance into account when assessing COPN applications.

The applicant seeks an additional scanner to respond to increasing demand within the practice. It expects continuing strong demand, to reach capacity service volumes in the second operational year. Virginia Heart projects a service volume of about 2,000 scans in the second year of operations. Given recent service volumes within Virginia Heart and elsewhere, there is no reason to believe that the projected caseload is exaggerated or otherwise unattainable.

The Virginia Heart *pro forma* budget illustrates the extraordinary profitability of PET scanning. The applicant projects year two volume of 2,007 cardiac PET cases, with revenue of \$5,487,693 and \$3,368,759 in expenses (including depreciation and amortization, interest expense, charity care, and bad debts). This equates to an average payment of about \$2,735 per scan, an average cost of \$1,679 per scan, and an average profit of \$1,056 per scan. The projected year two profit of \$2,118,935, equates to an operating margin of 38.6%.

Operating returns and profit margins should increase over the useful life of the scanner, as depreciation, amortization, and interest costs decrease.

### **C. Access Considerations**

Virginia Heart proposes establishing a cardiac PET imaging service in its Alexandria office, one of six locations where Virginia Heart now offers SPECT scans for myocardial perfusion imaging. The office serves principally residents of Alexandria and eastern Fairfax County.

Virginia Heart notes that its Telstar Court cardiac PET service (Falls Church area of Fairfax County), which was opened in 2023, is operating at capacity. Its Loudoun County (Lansdowne) office is expected to reach operational capacity shortly after opening. These two services are expected to accommodate less than two-thirds of current demand within the practice's patient population.

Establishing a new service, rather than expanding its authorized service, should improve access. Given the focus on serving established patient populations and, in the case of Virginia Heart, on substituting cardiac PET scans for SPECT scans, there is no indication or reason to believe that the project would affect demand at competing services.

The applicant has a history of equitable service to medically indigent patients and indicates a willingness to continue to serve them. The *pro forma* budget projects a charity care commitment of about 5% of net revenue.

### **D. Health System Considerations**

There are now fifteen authorized PET services in the region. Seven are recently authorized cardiac PET services. The focus of the other eight is cancer diagnosis and treatment planning.

There is no limitation on the type of scans authorized PET services may provide, or on the array of patients they may serve. Operators are free to respond to market conditions and demand as they see fit. There is no indication or likelihood that any of these services will change their clinical focus. Demand is increasing for both cardiac PET, and for cancer and neurology focused PET services. Cardiology

practices without in-house cardiac PET capability are likely to continue to rely on SPECT nuclear scanning for most myocardial perfusion studies, until their caseloads are large enough to justify adding the cardiac PET option.

Virginia Heart should soon have two cardiac PET services (Fairfax County and Loudoun County). It seeks a third PET scanner, for its Alexandria office. Demand suggests that additional scanners may be warranted. The programs now operational report that their services operate at capacity. Virginia Heart asserts a need for an additional scanner to meet current and projected near-term demand. Most of those served would come from the practice's current patient population. The applicant anticipates full use of the scanner requested within two years.

### **III. Conclusions and Alternatives for Agency Action**

#### **A. Findings and Conclusions**

Increasing clinical interest in cardiac PET imaging derives from recent studies indicating that the data and images produced with PET imaging have higher diagnostic sensitivity and specificity than the principal alternative modality, single photon emission computed tomography (SPECT). Cardiac PET studies report diagnostic sensitivity and specificity of about 95%, compared with SPECT studies which have sensitivity of about 80% and specificity of about 75%.

Higher PET sensitivity, widely applied, should reduce the number of false negative studies, 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. e.g., cardiac catheterization. The broad health system effects of the substitution of cardiac PET imaging for SPECT imaging for myocardial perfusion imaging are yet to be determined.

Data from within Virginia Heart's practice lends credibility to the argument that cardiac PET imaging can result in clinically meaningful improvement in cardiovascular patient diagnosis and treatment. If their recent experience proves indicative of the potential value of cardiac PET imaging generally, the region will be well served by the ongoing, unimpeded shift to cardiac PET imaging for myocardial perfusion studies.<sup>7</sup> 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, remain to be proven. But the possibility, perhaps the likelihood, of reducing the number of unnecessary cardiac interventions cannot be dismissed easily. Avoiding the risk, cost and futility of these procedures is a worthy, if illusive, goal, as is the potential benefit of reducing the number of false negative tests.

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<sup>7</sup>Virginia Heart presents data from its experience to date with cardiac PET imaging suggesting that greater sensitivity and specificity are of substantial clinical value in reducing false positive and false negative test results.

See Section IV of the Virginia Heart COPN application, principally pages 24-34, for a discussion of the observed effects and benefits of cardiac PET imaging within the recent Virginia Heart patient population.

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 over other diagnostic procedures is evident. This has attracted private equity interest. It is worth noting that private equity is not involved in Virginia Heart or its proposal.

## **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 applicant's PET service operates at capacity, and that additional capacity is warranted to accommodate increased demand and to maintain efficient operations. Virginia Heart's experience with cardiac PET imaging suggests that the substitution of cardiac PET for SPECT imaging for many cardiovascular patients is warranted. There is no indication that the project would affect other service providers negatively or result in other health system problems.

2. The Health Systems Agency of Northern Virginia may recommend to the Commissioner of Health that a certificate of public need authorizing the project be denied.

An unfavorable recommendation could be based on concluding that, with the recent authorization of six cardiac PET services and seven scanners, there is more than enough capacity to meet projected regional need. Additional capacity should not be added until authorized services are operational and their use and system effects assessed.

## **IV. Checklist of Mandatory Review Criteria**

### **1. Maintain or Improve Access to Care**

Northern Virginia residents have reasonable 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 Virginia Heart proposes to offer.

Access to cardiac PET imaging has expanded rapidly over the last five years. Local PET services that provide cardiac PET scanning, Carient Heart and Vascular and Virginia Heart, report high use and increasing demand. Five additional cardiac PET services have been authorized recently, three in Fairfax County, one in Eastern Prince William County, and one in Loudoun County.

Developing a Virginia Heart cardiac PET imaging service in Alexandria has the potential to improve access by adding the service option in Alexandria and eastern Fairfax County.

## **2. Meeting Needs of Residents**

Virginia Heart reports that its PET imaging service operates at capacity and is unable to meet current demand. Additional capacity is needed to respond to increasing demand and to permit efficient operations. Service volumes suggest that additional capacity would be responsive to internal Virginia Heart demand and used efficiently.

## **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 or to add capacity. Inconsistency with the SMFP should not be construed as negative. The Virginia Heart proposal appears to be consistent with the principles and policies on which the plan is based, and with the considerations applied recently in assessing similar PET projects.

## **4. Beneficial Institutional Competition while Improving Access to Essential Care**

Virginia Heart competes effectively in the local medical market. This is not likely to change. The applicant proposes to serve its current patient population.

## **5. Relationship to Existing Health Care System**

No discernible negative health system effects are likely. The project is not likely to affect demand at competing services. Arguably, it would help maintain access to the heavily used Virginia Heart service.

## **6. Economic, Financial Feasibility**

The project is financially feasible. As reflected in the *pro forma* budget, the service is likely to be used to capacity and to be highly profitable.

## **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.