

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

January 19, 2023

COPN Request No. VA-8626
Carient Heart & Vascular, P.C., Vienna, Virginia
Planning District 8
Establish Cardiac PET/CT Services with one PET/CT scanner

Applicant

Carient Heart & Vascular, P.C. (Carient) is a Virginia stock corporation. Fourteen physicians each has an ownership interest of 5% or more in Carient. Carient currently offers cardiac PET at its location in Manassas, Virginia and proposes to establish Cardiac Positron Emission Tomography with Computer Tomography attenuation (PET/CT) at its office in Vienna, Virginia in Planning District (PD) 8, Health Planning Region (HPR) II.

Background

Cardiac PET/CT is a non-invasive state-of-the-art technology and standard of care for routine cardiac diagnostic imaging. The applicant states that “Cardiac PET/CT has many advantages over traditional cardiac imaging, including high diagnostic accuracy, low radiation exposure, fast protocols and cost-effectiveness.” The American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging published a joint position paper in 2016 stating, “There are no clinical scenarios where [Cardiac] 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

The applicant has 16 board-certified cardiologists, one board-certified vascular surgeon and ten advanced care practitioners. Carient has seven office locations in Northern Virginia. Its Manassas site began offering cardiac PET in February 2020. Carient reports that the majority of the cardiac PET scans performed there are from within its own practice, with less than 1% coming from outside. The applicant reports high and increasing patient volumes.

PD 8 has nine authorized PET scanners, seven fixed site scanners and two mobile sites. Virginia Heart, another cardiovascular physician group in Northern Virginia, was authorized in 2022 to offer cardiac PET, bringing the total number of authorized cardiac-only PET units in PD 8 to two (**Table 1**). In 2021, the last year for which the DCOPN has data available from Virginia Health Information (VHI), the four fixed PET scanners in PD 8 that reported volumes operated at 39.5% of the State

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*. *J Nucl Cardiol* (2016), at 1071-3581, available at <https://link.springer.com/article/10.1007/212350-016-0626-9>.

Medical Facilities Plan (SMFP) utilization threshold. Carient’s PET scanner, the only cardiac-only PET scanner in PD 8 at that time, operated at 53.1% of the SMFP threshold (**Table 6**).

Table 1. PD 8 COPN Authorized PET Units

Facility	Total Authorized Scanners	Authorized Fixed-Site Scanners	Authorized Mobile Sites	PET Only	PET/CT	Cardiac Only
Carient Heart & Vascular	1	1	0	1	0	1
Inova Reston MRI Center (Inova Center for Personalized Health)	1	1	0	0	1	0
Kaiser Permanente Woodbridge Imaging Center	1	1	0	0	1	0
Metro Region PET Center	1	1	0	1	0	0
UVA Cancer Center - Lake Manassas	1	0	1	0	1	0
PET of Reston ¹	1	1	0	0	1	0
Sentara Northern Virginia Medical Center	1	0	1	0	1	0
Virginia Heart ²	1	1	0	0	1	1
Virginia Hospital Center	1	1	0	0	1	0
PD 8 Total	9	7	2	2	7	2

Source: DCOPN Records

¹Approved in February 2022 to convert from a mobile to fixed site.

²Approved in August 2022

Proposed Project

The applicant proposes to establish a new, fixed cardiac PET/CT site at its Vienna office. Carient intends to lease a Discovery STE 16-slice PET/CT from CDL Nuclear Technologies to establish the service, and proposes minimal modifications to its existing office, converting an existing nuclear imaging room into a cardiac PET/CT imaging lab. The new PET/CT scanner is intended to complement Carient’s Manassas PET service which has grown quickly since its inception to 3,185 cardiac PET scans in 2021. 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.

Table 2. Capital and Financing Costs

Direct Construction Costs	\$125,000
Equipment Not Included in Construction Contract	\$385,000
Site Acquisition Costs	\$165,000
Site Preparation Cost	\$20,000
Architectural and Engineering Fees	\$21,500
Other Consultant Fees	\$60,000
Taxes During Construction	\$8,000
Total Capital Costs	\$784,500

Source: COPN Request No. VA-8626

The total capital cost of the proposed project is \$784,500 (**Table 2**). The PET/CT scanner would be leased and paid for using operating expenses. The applicant asserts that the cost of the proposed project would not affect the existing costs of patient care. If approved, Carient has stated it targets April 2023 to begin seeing patients.

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 exists for a proposed project, the following factors shall be taken into account when applicable.

- 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;**

Carient proposes to establish a cardiac PET/CT service in existing space within its Vienna office location through the addition of one fixed cardiac PET/CT unit. Carient’s existing cardiac PET service, located at its Manassas office is the only one in operation in PD 8, though Virginia Heart was recently authorized to establish the second cardiac PET site in PD 8. Carient states that more than 99% of its cardiac PET volumes are referred from within the Carient network and due to increasing referrals, it has a backlog of approximately one month. Furthermore, Carient has expanded imaging hours from 6:30 a.m. to 6:30 p.m. (sometimes 8 p.m.) Monday through Saturday and some Sundays. The proposed project would increase access by spreading its PET scans to an additional site and reducing wait times. Carient’s Vienna, Annandale and Woodbridge locations are geographically closer to the proposed new location than to the existing cardiac PET site in Manassas, so the proposed project would improve access for patients closer to Vienna.

Geographically, the proposed service is located 3.2 miles from Exit 16 on VA-267 (Dulles Toll Road), 2.3 miles from Exit 46A on I-495 and two miles from Tyson’s Corner. The applicant states that there is an abundance of parking on-site. The Fairfax Connector bus service runs multiple routes daily to two stops that are within 0.3 miles of Carient’s Vienna office.

Weldon-Cooper data projects a total PD 8 population of 2,937,128 residents by 2030 (**Table 3**), which represents an approximate 31.7% increase in total population from 2010 to 2030. This is a much larger percentage increase than the total for Virginia, which will increase by approximately 16.6% for the same period. Fairfax County, where Vienna is located, has the largest population of the municipalities in PD 8. Weldon-Cooper projects a total population increase of 162,299 in Fairfax County, or approximately 15%, from 2010 to 2030. This total population increase is third among the nine areas listed in **Table 3**, and last in percentage increase among the nine areas listed.

With regard to the 65 and older age cohort, Weldon-Cooper projects a total PD 8 population of 413,269 by 2030 (**Table 4**), which represents an approximate 114.6% increase in total population from 2010 to 2030. This is a much larger percentage increase than the total for Virginia, which will increase by approximately 76.4% for the same period. Regarding Fairfax County specifically, Weldon-Cooper projects a total population increase of 77,928, or approximately 73.3% from 2010 to 2030. This total population increase is the largest among the nine areas listed in **Table 4**, and sixth in percentage increase among the nine areas listed.

Table 3. PD 8 and Statewide Total Population Projections, 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Alexandria City	139,966	166,261	18.8%	182,067	9.5%	30.1%
Arlington	207,627	249,298	20.1%	274,339	10.0%	32.1%
Fairfax City	22,565	25,047	11.0%	26,397	5.4%	17.0%
Fairfax County	1,081,726	1,162,504	7.5%	1,244,025	7.0%	15.0%
Falls Church City	12,332	14,988	21.5%	17,032	13.6%	38.1%
Loudoun	312,311	430,584	37.9%	554,808	28.9%	77.6%
Manassas City	37,821	43,099	14.0%	46,332	7.5%	22.5%
Manassas Park City	14,273	17,086	19.7%	20,284	18.7%	42.1%
Prince William	402,002	478,134	18.9%	571,844	19.6%	42.2%
Total PD 8	2,230,623	2,587,000	16.0%	2,937,128	13.5%	31.7%
Virginia	8,001,024	8,655,021	8.2%	9,331,666	7.8%	16.6%

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

Table 4. PD 8 Population Projections for 65+ Age Cohort, 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Alexandria City	12,806	17,359	35.6%	22,175	27.7%	73.2%
Arlington	18,054	22,515	24.7%	26,951	19.7%	49.3%
Fairfax City	3,088	3,754	21.6%	4,611	22.8%	49.3%
Fairfax County	106,290	151,585	42.6%	184,218	21.5%	73.3%
Falls Church City	1,293	1,908	47.5%	2,317	21.5%	79.2%
Loudoun	20,425	45,314	121.9%	84,522	86.5%	313.8%
Manassas City	2,607	3,930	50.8%	5,387	37.0%	106.6%
Manassas Park City	806	1,426	76.9%	2,258	58.3%	180.1%
Prince William	27,220	52,698	93.6%	80,830	53.4%	197.0%
Total PD 8	192,589	300,491	56.0%	413,269	37.5%	114.6%
Virginia	976,937	1,352,448	38.4%	1,723,382	27.4%	76.4%

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

Carient states that it will proactively commit to provide free services to the indigent population equaling at least 5% of gross charges derived from cardiac PET/CT scans. This is above the HPR II charity care mean of 3.4% in 2020 (**Table 5**).

- The extent to which the proposed project will meet the needs of the 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;

Letters of Support

DCOPN received eight letters of support for the proposed project. Collectively, these letters asserted that cardiac PET/CT scans provided better quality and quicker scans with less radiation than SPECT imaging, reduction in unnecessary procedures and greater patient satisfaction. Additionally, these letters discussed the benefits of using PET/CT to determine myocardial blood flow and the reduced travel time for some patients. There is no documented opposition to the proposed project.

Public Hearing

DCOPN provided notice to the public regarding this project on November 22, 2022. The public comment period closed on January 6, 2022. On December 5, 2022, the Health Systems Agency of Northern Virginia (HSANV) held a public meeting for the proposed project. The project was presented by two representatives of the applicant and a physician from the University of Maryland School of Medicine. Other than letters of support, no members of the public commented.

(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;

The proposed project is a preferable alternative to the status quo. Under the status quo, patients at Carient will continue to experience lengthy wait times for state-of-the-art cardiac imaging and some of Carient's patients will face extensive travel to receive cardiac PET services. As stated by the HSANV, "Though there is substantial unused PET imaging capacity in the region, none of the programs with unused capacity has taken the steps necessary to provide the form of myocardial perfusing imaging that Carient and Virginia Heart offer."

(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 December 5, 2022 meeting, HSANV, the organization in HPR II designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 8, voted seven in favor, none opposed, with one abstention to recommend approval of Carient's COPN Request number VA-8626. The HSANV based its recommendation on the HSANV staff report, its review of the request and the following basic findings and conclusions:

1. Cardiac PET scanning is the preferred diagnostic tool for many cardiovascular patients, especially those who might benefit from myocardial perfusion imaging
2. Carient is a large, growing cardiology practice (currently 7 locations and 16 physicians) which serves large numbers of cardiac patients annually, many of whom are potential

beneficiaries of PET imaging.

3. Its cardiac PET service located in Manassas, Virginia has high use. Demand is increasing rapidly.
4. Recent service volumes and near-term projected volumes, exceed nominal capacity of a single cardiac PET scanner.
5. Given the focus on cardiovascular disease among its clientele, expansion of Carient's cardiac PET capacity is not likely to affect any other PET service negatively.
6. Projected capital costs and financing arrangements are reasonable.
7. To the extent they are applicable, the project is consistent with the diagnostic imaging provisions of the SMFP.

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

The total capital cost of the proposed project is \$784,500 (**Table 2**). The proposed PET/CT scanner would be leased and paid for as operating expenses. The applicant asserts that the cost of the proposed project would not affect the existing costs of patient care. The costs of this project compare favorably with previously approved projects to establish fixed PET/CT services. For example, COPN VA- 04625 issued to Sentara Hospitals d/b/a/ Sentara Leigh Hospital to establish a fixed PET/CT service through the acquisition of one fixed PET/CT scanner, which cost approximately \$2,452,175. The Virginia Heart PET/CT project approved most recently in PD 8 estimates a cost of \$2,491,617

The use of PET/CT for cardiac imaging offers several benefits over SPECT: cardiac PET/CT offers a better-quality image than SPECT; cardiac PET/CT scans are faster and expose the patient to 75% less radiation than SPECT imaging; cardiac PET/CT scanners allow for the ability to non-invasively quantify myocardial blood flow, which is not possible with SPECT imaging. The applicant already offers cardiac PET imaging at its Manassas site, but referral volumes have outstripped its ability to provide the service within reasonable wait times, even after expanding hours and days of operation. Additionally, the proposed new site would decrease travel time for patients residing closer to Vienna than the existing Manassas site.

(v) the financial accessibility of the proposed project to the people in the area to be served, including indigent people; and

As **Table 5** below demonstrates, the regional charity care contribution average in HPR II was 3.4% in 2020, the last year for which DCOPN has data available from VHI. DCOPN does not have a record of charity care provided by the applicant; however, Carient states that it will proactively commit to provide free services to the indigent population equaling at least 5% of gross charges derived from cardiac PET/CT scans. In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project be approved, Carient is expected to provide a level of charity care for total gross patient revenues derived from its COPN authorized

services that is no less than the equivalent average for charity care contributions in HPR II. DCOPN recommends a charity care condition at the proffered 5% of gross charges.

Table 5: HPR II 2020 Charity Care Contributions

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Inova Alexandria Hospital	\$949,158,182	\$57,879,875	6.1%
Inova Mount Vernon Hospital	\$499,398,426	\$29,342,493	5.88%
Inova Loudoun Hospital	\$817,869,692	\$35,123,877	4.29%
UVA Health System Prince William Medical Center	\$530,326,336	\$21,923,014	4.13%
Inova Fairfax Hospital	\$3,855,962,450	\$147,813,100	3.83%
Sentara Northern Virginia Medical Center	\$823,831,674	\$29,925,512	3.63%
Inova Fair Oaks Hospital	\$649,476,560	\$21,302,369	3.28%
Virginia Hospital Center	\$1,491,327,243	\$29,205,595	1.96%
UVA Health System Haymarket Medical Center	\$284,391,247	\$4,747,340	1.67%
Reston Hospital Center	\$1,535,959,085	\$19,925,030	1.30%
StoneSprings Hospital Center	\$247,806,370	\$1,302,439	0.53%
Total \$ & Mean %	\$11,685,507,265	\$398,490,644	3.4%

Source: VHI

(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 Virginia State Health Commissioner (Commissioner) as may be relevant in determining a public need for the proposed project.

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.

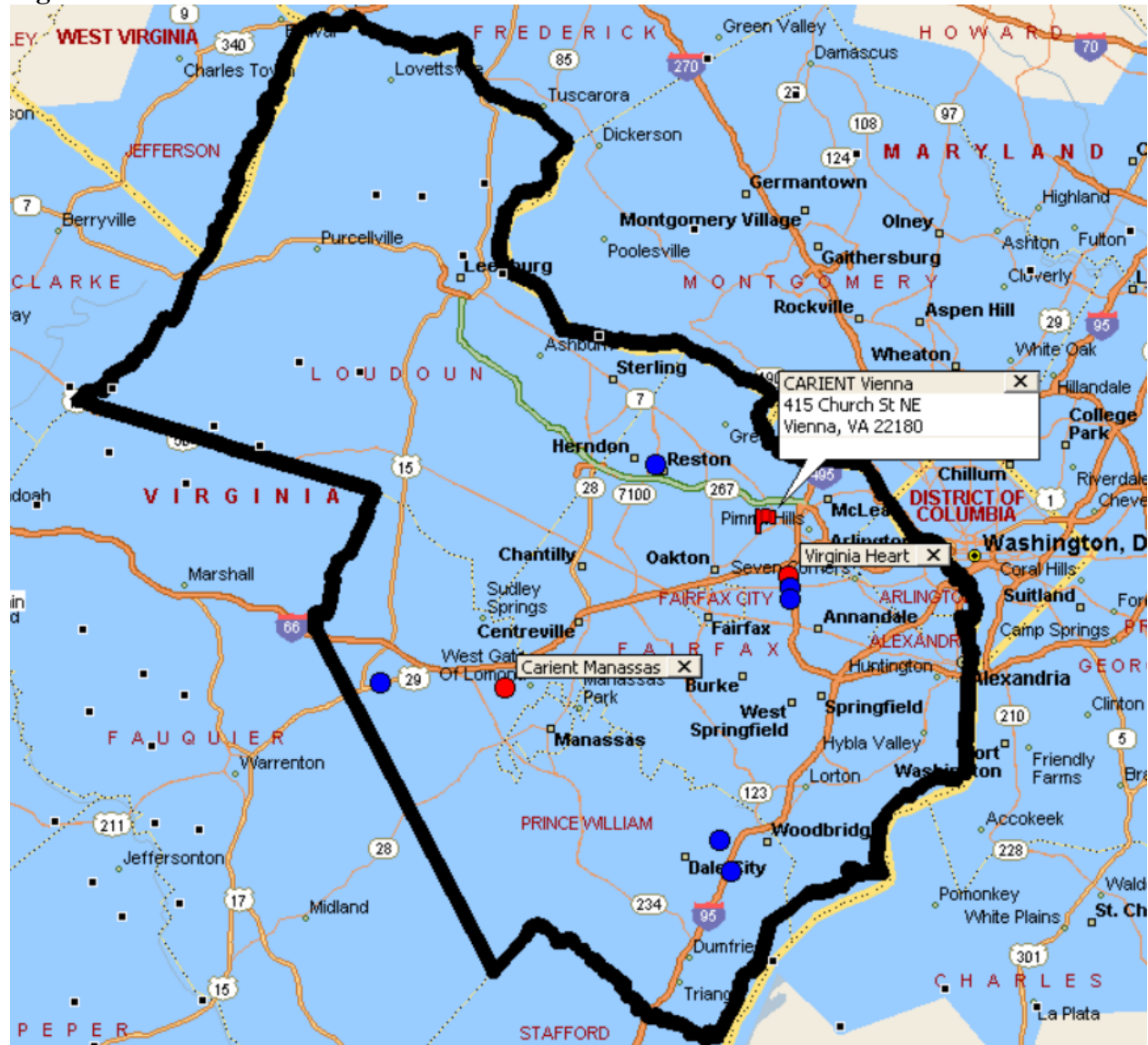
The SMFP contains criteria/standards for the establishment of PET services. They are as follows:

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.

Figure 1



Currently, there are nine COPN authorized PET services in PD 8. The heavy black line in **Figure 1** is the boundary of PD 8. The blue and red dots indicate facilities that currently offer

PET scanning services. The red dots are the two currently authorized cardiac PET sites, and the red flag is the proposed new cardiac PET/CT site. It is important to note that the SMFP does not distinguish between cardiac-specific PET services and all other PET services. The blue shading illustrates the area that is within a sixty-minute drive under normal driving conditions of all PET service providers in PD 8. **Figure 1** clearly illustrates that PET scanning services are already well within a sixty-minute drive under normal conditions for 95% of the population of the planning district and populations well beyond the boundaries of PD 8.

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.

Not applicable. The applicant is not a hospital nor are they affiliated with a hospital system.

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.

Calculated Needed Fixed PET Scanners in PD 8

COPN authorized fixed PET scanners = 7

Calculated Needed PET scanners =

10,876 scans in the PD / 6,000 scans / scanner = 1.8 (2) scanners needed

PD 8 Calculated Need = 2 PET scanners

PD 8 Calculated Surplus = 5 PET scanners

Table 6. PD 8 COPN Authorized PET Units: 2021

Facility	Fixed /Mobile	Number of Scanners	Number of Scans	Utilization
----------	---------------	--------------------	-----------------	-------------

Virginia Hospital Center	Fixed	1.0	767	12.8%
Carient Heart and Vascular	Fixed	1.0	3,185	53.1%
Fairfax PET/CT Imaging Center (Inova Center for Personalized Health)	Fixed	1.0	2,103	35.1%
Nancy Harty (Metro Region PET Center)	Fixed	1.0	3,417	57.0%
Sentara Northern Virginia Medical Center	Mobile	0.1	20	3.3%
PET of Reston	Mobile*	0.2	874	72.8%
UVA Cancer Center Gainesville (Novant Health)	Mobile	0.4	510	21.3%
PD 8 Average (all scanners)		4.7	10,876	38.6%
PD8 Average (Fixed)		4.0	9,472	39.5%

Source: VHI 2021 and DCOPN Records

*PET of Reston Converted to Fixed 2/2022

Virginia Heart Fixed, Cardiac-only, approved 8/2022

The SMFP does not distinguish between cardiac PET and other clinical uses. Overall, there is a calculated surplus of five PET scanners in the planning district. None of the scanners surpassed the SMFP’s volume threshold in PD 8 in 2021. Carient’s cardiac PET/CT had the third highest utilization rate after Metro Regional PET Center and PET of Reston, a mobile site which is available two half-days per week.

While PET scanners in PD 8 fall short of the SMFP standard of 6,000 scans per year, the applicant has submitted that the standards do not account for the highly specialized nature of cardiac PET/CT. The attached HSANV memorandum dated November 29, 2022 describes local market dynamics regarding PET services and specifically the provision of cardiac PET. Though PET scanning is the preferred diagnostic tool for many who might benefit from myocardial perfusion imaging, providers of PET services across PD 8 have not taken the steps to support this clinical application until Carient was approved to offer cardiac-specific PET at its Manassas office. Prior to this, cardiologists relied on Single Proton Emission Computer Tomography (SPECT). There is now a shift underway from SPECT to PET as a more beneficial modality for cardiac imaging. For patients to utilize this more advantageous modality, they must have access to it.

Carient asserts that a typical cardiac PET unit operates eight hours a day, five days a week and performs approximately 2,000 cardiac PET scans per year. Carient does not specifically cite a source for this assertion but may rely on the experience of the technology lessee and/or the cardiac PET/CT imaging consultant it has engaged. A Google search yields time per scan benchmarks of about 30 minutes for a PET scan and 90 minutes for a cardiac PET scan, providing some support that one third of the SMFP threshold might be a reasonable point of reference for utilization of a cardiac-only PET service. Nevertheless, with a volume at its Manassas site of 3,185 PET scans in 2021, increasing referrals, and a backlog of approximately one month, despite its very expanded hours, Carient’s existing PET scanner clearly has high utilization that is a barrier to access.

Carient states that more than 99% of cardiac PET volumes at its existing site are referred from within the Carient network. It projects that the proposed new site at its Vienna location would exceed 1,350 scans by year two and provide access for its existing and growing patient base that is more proximal to that site. Although these projections do anticipate a significant decrease in utilization at the existing Manassas site, that would alleviate the current access barrier that exists due

to high utilization. DCOPN does not anticipate that the proposed project would impact utilization of other PET services in PD 8. It would create an overall improvement in access to cardiac PET/CT in PD 8 and specifically for Carient's patients.

While the applicant does not meet 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 seeking to establish a new fixed PET 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 mobile PET or PET/CT services or to convert authorized mobile PET or PET/CT scanners to fixed site scanners.

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.

Carient states that it employs 16 board certified cardiologists, including 3 board certified in nuclear cardiology and the proposed PET/CT scanner would be under the direction and supervision of qualified physicians who are appropriately authorized and licensed to interpret cardiac PET/CT studies.

The CT portion of the requested PET/CT is included as an adjunct to the PET scanner. The CT is used to provide anatomical definition to the image produced by the PET scanner. As the CT scanner will not be used independently to produce CT images it will not be separately evaluated under the SMFP.

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 only currently available from one provider in PD 8, but a second provider, Virginia Heart, is authorized and plans to begin PET operations early in 2023 (COPN Number VA-04806). Carient has to-date served patients from within its own patient base almost exclusively, and Virginia Heart expressed intentions also to serve its respective existing patient base. Since Virginia Heart is much larger than Carient, its single PET/CT service is expected to experience high utilization as well. The cardiac PET/CT market dynamics in PD 8 bear watching as two cardiac providers now have the strategic advantage of operating cardiac PET/CT imaging within their practices. Surely, other cardiac providers will follow, and potentially existing PET providers will see the benefit of expanding their offerings to cardiac PET/CT, further providing access to this beneficial service. The proposed project fosters beneficial institutional 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;

Carient and Virginia Heart have large and growing patient bases and their cardiac PET services represent the beginning of a shift from SPECT to the more accurate and advantageous cardiac PET imaging, as access is made available. In addition, the age 65+ population in PD 8 is projected to grow faster than in Virginia overall and will likely continue to increase demand for cardiac PET/CT. DCOPN concludes that the proposed project would not adversely affect the utilization and efficiency of existing services and would improve efficiency of the existing highly utilized cardiac PET site.

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;

The Pro Forma Income Statement (**Table 7**) provided by the applicant projects \$4,844,984 in excess revenue over expenses by the end of the first year of operation and \$4,045,849 by the end of year two for the proposed project. The total capital cost of the proposed project is \$784,500 (**Table 2**). This compares favorably to similar, recently approved projects. For example, Virginia Heart's authorized Cardiac PET/CT project approved in 2022 has an estimated capital cost of \$2,491,617. Carient states that the proposed PET/CT scanner would be leased and paid for using operating expenses over the time of the lease. Minimal renovation expenses to existing space will be funded with accumulated reserves. Approximately 49% of the total costs are attributed to equipment not included in the construction contract and 16% of the total costs are attributed to the direct construction costs. The applicant asserts that the cost of the proposed project would not affect the existing costs of patient care. The projected excess revenues are sufficient to cover the necessary lease costs without unduly effecting Carient. As such, DCOPN

ultimately concludes that the proposed project is feasible with regard to financial costs in both the immediate and the long-term.

With regard to staffing, the applicant states that no additional staffing will be needed to offer the proposed service. Adequate staffing exists between the Vienna and Manassas sites to provide the proposed new cardiac PET/CT. DCOPN finds the applicant’s staffing plan reasonable. As such DCOPN concludes that the proposed project is reasonable with regards to staffing and will not adversely affect the staffing of existing PET/CT providers in the planning district.

Table 7. Pro Forma Income Statement		
	Year 1	Year 2
Gross Revenue	\$5,125,564	\$4,322,304
Deductions from Revenue		
Net Patient Services Revenue	\$5,125,564	\$4,322,304
Total Operating Expenses	\$280,580	\$276,455
Excess Revenue Over Expenses	\$4,844,984	\$4,045,849

Source: COPN Request No. VA-8626 & DCOPN interpolations

- 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; and**

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. Carient has offered cardiac PET/CT in PD 8 for approximately three years, so 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 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.

- 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 the proposed project to establish a new cardiac PET/CT site through the addition of one fixed PET/CT scanner to Carient's Vienna location 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. Moreover, the applicant proffered that the PET/CT scanner would be used solely for cardiac imaging. Finally, 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, 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.

DCOPN finds that the proposed project is more beneficial than the alternative of the status quo. Under the status quo, patients of Carient will continue to experience lengthy waits for cardiac PET/CT imaging and in some cases, excessive travel to access the service. With current barriers to access, patients would continue to utilize SPECT imaging, though cardiac PET would better meet their needs. Cardiac PET/CT imaging offers several important advantages over SPECT, including faster imaging, lower dosage of radiation, better quality image, and the ability to non-invasively quantify myocardial blood flow. This last advantage is particularly important as it improves accuracy, risk stratification, and patient selection for interventions. Furthermore, the proposed project would introduce beneficial competition into the planning district and only affect utilization of the existing Carient provider, allowing that site more efficient operations.

The HSANV Board voted seven in favor, none opposed, with one abstention to recommend approval of Carient's COPN Request number VA-8626. DCOPN finds that the total capital cost of the proposed project of \$784,500 (**Table 2**) compares favorably to similar, recently approved projects. For example, Virginia Heart's authorized cardiac PET/CT project approved in 2022 has an estimated capital cost of \$2,491,617 (COPN Number VA-04806). The PET/CT scanner would be leased and paid for using operating expenses. Minimal renovation to existing space will be paid with accumulated reserves.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of Carient Heart & Vascular, P.C.'s COPN Request number VA-8626 to establish PET/CT services with one fixed PET/CT scanner limited to cardiology at Carient's Vienna location 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 and less than usual for projects of this type.
8. The Health Systems Agency of Northern Virginia recommended approval of the proposed project.

DCOPN's recommendation is contingent upon Carient Heart & Vascular, P.C.'s agreement to the following charity care condition:

Carient Heart & Vascular, P.C.'s PET/CT service will be limited solely to cardiac imaging. Carient Heart & Vascular, P.C 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 5% of Carient Heart & Vascular, P.C.'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 Carient Heart & Vascular, P.C. 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.

Carient Heart & Vascular, P.C. 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 Carient Heart & Vascular, P.C.'s will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.