

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

July 19, 2022

COPN Request No. VA-8625

The Cardiovascular Group, PC d/b/a Virginia Heart
 Falls Church, Virginia

Introduce PET/CT services with one fixed PET/CT scanner limited to cardiology

Applicant

The Cardiovascular Group, PC (Virginia Heart) is a Virginia stock corporation. No shareholder has an ownership interest of 5% or more in Virginia Heart. Virginia Heart is located in Falls Church, Virginia, Planning District (PD) 8, Health Planning Region (HPR) II.

Background

Virginia Heart is a 50-physician cardiovascular group, consisting of 47 board-certified cardiologists, and 3 board certified sleep specialists. Virginia Heart has ten locations, including the Fairfax office location where the proposed Positron Emission Tomography/Computed Tomography (PET/CT) scanner would be placed. Division of Certificate of Public Need (DCOPN) records show that there are currently seven COPN authorized fixed PET scanners in PD 8. The applicant asserts that only one of these PET scanners, operated by Carient Heart & Vascular, performs cardiac PET scans. This assertion is repeated by Carient Heart and Vascular in a recent COPN application¹. In 2020, the last year for which the DCOPN has data available from Virginia Health Information (VHI), the then four operational fixed PET scanners in PD 8 operated at 29.1% of the of the SMFP utilization threshold (Table 6).

Table 1. PD 8 COPN Authorized Fixed PET Units

Facility	Number of Scanners
Carient Heart & Vascular	1
Inova Reston MRI Center (Inova Center for Personalized Health)	1
Kaiser Permanente Woodbridge Imaging Center	1
Metro Region PET Center	1
PET of Reston	1
Sentara Northern Virginia Medical Center	1
Virginia Hospital Center	1
Total	7

Source: DCOPN records

¹ COPN Request No. VA-8626

Proposed Project

The applicant proposes to establish a specialized center for the provision of PET/CT services through the addition of one fixed PET/CT scanner to their Fairfax Office location. 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. The total capital cost of the proposed project is \$2,491,617 (**Table 2**). The PET/CT scanner would be leased and paid for using operating expenses. All other costs associated with the project would be paid for using accumulated reserves. The applicant asserts that the cost of the proposed project would not affect the existing costs of patient care.

Table 2. Capital and Financing Costs

Direct Construction Costs	\$310,000
Equipment Not Included in Construction Contract	\$2,084,961
Site Acquisition Costs	\$26,956
Architectural and Engineering Fees	\$35,700
Other Consultant Fees	\$15,000
Taxes During Construction	\$19,000
Total Capital Costs	\$2,491,617

Source: COPN Request No. VA-8625

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;**

The applicant proposes to establish a specialized center for the provision of PET/CT services through the addition of one fixed PET/CT scanner to their Fairfax Office location. The applicant asserts that only one PET/CT provider in PD 8, Carient Heart & Vascular, performs cardiac PET/CT scans. As stated above, Carient Heart & Vascular also asserts this in their recent application. As such, approval of the proposed project would introduce a second provider of cardiac PET/CT services and introduce beneficial competition into the planning district. As the sole provider of this service is located 20 miles from the proposed project, DCOPN concludes the proposed project would increase access to cardiac PET/CT imaging in the planning district.

Geographically, Virginia Heart’s Fairfax office is located 0.4 miles from US-29 and 0.4 miles from I-495. The applicant states that the Dunn Loring-Merrifield Metro is located one mile from the facility with the Fairfax connector Bus 402 available to transport patients from the station to within 0.3 miles of the facility. The applicant additionally states that parking would be available on site for patients, including handicapped spaces closest to the building.

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. With regard to Fairfax County specifically, Weldon-Cooper projects a total population increase of 162,299, 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. With regard to the 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)

2. 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 four letters of support from; an executive vice president MedAxiom, a network of over 400 cardiovascular programs, and three physicians associated with Inova Health System. Collectively, these letters asserted that cardiac PET/CT scans provided better quality and quicker scans with less radiation than SPECT imaging. Additionally, these letters discussed the benefits of using PET/CT to determine myocardial blood flow.

DCOPN received one letter of opposition from PET of Reston. This letter of opposition arrived on June 28, 2022. This date was after the closure of the public comment period, the public hearing of the Health Systems Agency of Northern Virginia (HSANV), the regional health planning agency, and the vote by the HSANV board on this project. PET of Reston did not speak in opposition of the proposed project at HSANV’s public hearing. PET of Reston first stated that sufficient current PET capacity exists to meet the needs of patients in PD 8. PET of Reston next stated that they had built a foundation to develop a cardiac PET/CT program that could be readily available as soon as requested by referring cardiologists. Finally, PET of Reston alleges that the leasehold expenses are underreported. PET of Reston alleges that this underreporting requires that the project be delayed until the next cycle to amend the reported capital costs.

The applicant submitted a response to this letter of opposition from PET of Reston on July 1, 2022. In response to the allegation regarding sufficient capacity, the applicant raises many of the same points raised by DCOPN in 12VAC5-230-210 below. The applicant additionally notes that PET of Reston called these standards “obsolete” in its own application in 2020. As such, DCOPN concurs with the applicant that this objection is not valid. With regards to the alleged cardiac PET program, the applicant states that PET of Reston has not, upon their last conversation, identified a supplier for the specific tracer necessary to perform cardiac PET

scans. Additionally, the applicant states that PET of Reston does not have medical staff to oversee cardiac stress tests that are required as part of the scanning process. As PET of Reston has ordered, but has not accepted delivery for, the additional hardware and software necessary to provide cardiac-focused services, the lack of existing contracts for these services seems highly likely. Based on these factors, DCOPN concurs with the applicant that PET of Reston has not made sufficient efforts to be considered an alternative to the proposed project.

With regards to the allegation regarding the rental costs, the applicant first argues that they already use this space, have incurred the cost to control it, and does not have to incur additional costs to acquire more space. DCOPN disagrees with this assertion. While they have paid the costs to control, these costs have not been accounted for to establish a medical facility under §32.1-102.1:3 of the Virginia Code. However, the argument made by PET of Reston that this should be pushed to the next available review cycle because it would result in a significant change following issuance of the certificate is incorrect. While the cost of the rent is significant, DCOPN's analysis of the additional rental costs finds that the additional costs would not meet the threshold necessary for the filing of a significant change. While DCOPN does not find that this should rise to the level of necessitating the delay of the review of this project, it finds this discrepancy incredibly troubling and strongly urges Virginia Heart to be more thorough and accurate in its accounting of costs in future applications.

Public Hearing

DCOPN provided notice to the public regarding this project on May 10, 2022. The public comment period closed on June 24, 2022. On June 27, 2022, HSANV held a public hearing for the proposed project. The project was presented by three representatives of the applicants. One member of the public additionally spoke in support of the proposed project. No members of the public spoke in opposition of the proposed project.

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

The proposed project is a preferable alternative to the status quo. Under the status quo, patients at Virginia Heart will continue to receive diagnostic imaging using SPECT. As discussed in detail below, 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 interventions².

(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;

² American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indication for Myocardial Perfusion PET. The Journal of Nuclear Cardiology. 2016, doi:10.1007/s12350-016-0626-9

HSANV considered this proposed project at its June 27, 2022 meeting. The Board voted nine in favor and none opposed to recommend that the application be approved. HSANV stated that their recommendation was based on its review of the application, on the HSANV staff report on the proposal, on the information presented at the June 27, 2022 Board of Directors meeting, and on several findings and conclusions, including:

1. The service The Cardiovascular Group proposes to develop, cardiac PET-CT scanning using the isotope rubidium 82 to perform myocardial perfusion imaging, is not widely available in the planning region.
2. PET myocardial perfusion imaging appears to be superior to other myocardial perfusion studies (e.g., SPECT scans). It provides more information and superior images which should result in greater clinical certainty, more effective treatment and, ultimately, fewer unnecessary diagnostic cardiovascular interventions.
3. Virginia Heart has a large patient base of about 150,000 patient visits annually, which generates sufficient demand to support an efficient PET-CT service.
4. Though there is substantial unused PET-CT capacity in the region, medical referral practices and patterns, and related market conditions are such that there is little prospect of these low volume services offering PET based myocardial perfusion imaging in the near term.
5. The project will result in a significant increase in the total cost of (and charges for) cardiac imaging in the region, but some of the additional costs should be offset by more definitive coronary artery disease assessment and an associated reduction in the number of unnecessary cardiac catheterizations.
6. Projected capital costs are reasonable for the service described, within the capital expenditure range seen for similar projects.

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

The total capital cost of the proposed project is \$2,491,617 (**Table 2**). The PET/CT scanner would be leased and paid for using operating expenses. All other costs associated with the project would be paid for using accumulated reserves. The applicant asserts that the cost of the proposed project would not affect the existing costs of patient care. The costs of this project are reasonable and consistent 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. As discussed above, there is some discrepancy regarding the accounted costs. Even with the addition of these costs, they are still reasonable and consistent with previously approved projects to establish fixed PET/CT services. For example, COPN VA- 04151 issued to Virginia Hospital Center Arlington Health System to add one fixed PET/CT service, which cost approximately \$2,613,500.

The use of PET/CT for cardiac imaging offers several benefits over SPECT, to current method use by the applicant. First, cardiac PET/CT offers a better quality image than SPECT. MexAxiom, who wrote a letter of support for the proposed project, asserts this is particularly with true for patients with a high body mass index. Additionally, cardiac PET/CT scans are faster and exposes the patient to 75% less radiation than SPECT imaging. Finally, PET/CT scanners allow for the ability to non-invasively quantify myocardial blood flow, which is not possible with SPECT imaging. The ability to quantify myocardial blood flow improves accuracy, risk stratification, and patient selection for interventions³. Additionally, as the sole existing provider of cardiac PET/CT services in PD 8 is located over 20 miles from the proposed project, approval of the proposed project would increase access to a cardiac imaging service that offers several important advantages over the current imaging modality.

(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. As the proposed project involves the establishment of Virginia Heart’s first medical care facility under COPN law, DCOPN does not have a record of charity care provided by the applicant. In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project be approved, IAH 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.

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

³ American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indication for Myocardial Perfusion PET. The Journal of Nuclear Cardiology. 2016, doi:10.1007/s12350-016-0626-9

(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, by November 1, 2022, 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 or expansion of CT 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.

Currently, there are seven COPN authorized fixed PET service providers and one COPN authorized mobile PET service provider in PD 8. The heavy black line in **Figure 1** is the boundary of PD 8. The blue H icons indicate facilities that currently offer PET scanning services. The white H icon indicates the proposed Virginia Heart fixed PET service location. The grey 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.

Figure 1



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

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

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 =
 6,991 scans in the PD / 6,000 scans / scanner = 1.2 (2) scanners needed

PD 8 Calculated Need = 2 CT scanners

PD 8 Calculated Surplus = 5 CT scanners

Table 6. PD 8 COPN Authorized Fixed PET Units: 2020

Facility	Number of Scanners	Number of Scans	Utilization Rate
Carient Heart and Vascular	1	1,793	29.9%
Fairfax PET/CT Imaging Center	1	1,797	30.0%
Metro Region PET Center	1	2,691	44.9%
Virginia Hospital Center	1	710	11.8%
2020 Total and Average	4	6,991	29.1%

Source: VHI & DCOPN interpolations

Based on internal SPECT data, the applicant anticipates that the proposed fixed PET/CT scanner will meet the 6,000 procedure threshold within 2-4 years. Based on the data provided by the applicant on their SPECT usage, this predicted utilization is possible. However, because this data is internal and unverifiable, DCOPN concludes that such calculations cannot be significantly relied on to support approval. Given the number of Virginia Heart locations that provide SPECT, seven in total, it is reasonable to predict that the cardiac PET/CT scanner would be utilized at the level equivalent to Carient Heart and Vascular, the sole existing cardiac PET/CT service in PD 8. While the overall utilization in PD 8 and the projected utilization of the proposed PET/CT unit is lower than the SMFP's current utilization threshold, the Commissioner has historically recognized that the SMFP's PET utilization thresholds are too high, outdated, and do not appropriately capture pediatric

needs. The DCOPN staff report for COPN Request No. VA-7191, which ultimately resulted in COPN No. VA-04151, states:

“[T]here are few PET services in the state that have actually met [the SMFP’s] goal[s]” which reflect “a misconception about the utilization of this modality at the time the SMFP was written.”

Similarly, the Health Systems Agency of Northern Virginia staff report for COPN Request No. VA-8327, which ultimately resulted in COPN No. VA-04629, states:

“...it is arguable that the public need determination provisions of the [SMFP] are dated and do not offer meaningful advice and guidance...[and accordingly, they have] been ignored routinely.

DCOPN notes that no PET services in the Commonwealth actually met the SMFP’s utilization thresholds of 6,000 procedures per existing and approved fixed site PET scanner in 2020. Furthermore, DCOPN notes that both applicant and the sole existing provider of cardiac PET/CT services stated that the proposed project would not adversely affect the utilization Carient Heart and Vascular’s cardiac PET/CT services. As such, while the applicant does not meet this threshold, 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.

The applicant stated that 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.

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;

As discussed throughout this report, cardiac PET/CT scanning is only currently available from one provider in PD 8. Approval of the proposed project would introduce a second provider, creating the first institutional competition for this service in the planning district. Moreover, as discussed above, both the applicant and the existing provider, who is located over 20 miles from Virginia Heart, do not anticipate that the proposed project would detrimentally impact the existing provider. As such, while the introduction of a second provider will create some degree of institutional competition, the distance between the two locations is sufficient to minimize the impact of this competition.

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

As stated above, both the applicant and the existing provider of cardiac PET/CT services do not anticipate the proposed project impacting the existing provider's utilization. This is supported by the applicant's projections based on patients that have received SPECT imaging that would have received cardiac PET/CT imaging had it been available at Virginia Heart. As such, DCOPN concludes that the proposed project would not adversely affect the utilization and efficiency of existing services.

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

The Pro Forma Income Statement (**Table 7**) provided by the applicant projects a net profit of \$1,009,897 by the end of the first year of operation and a net profit of \$1,446,066 by the end of year two for the proposed project. The total capital cost of the proposed project is \$2,491,617 (**Table 2**). The PET/CT scanner would be leased and paid for using operating expenses. All other costs associated with the project would be paid for using accumulated reserves. Approximately 83.7% of the total costs are attributed to equipment not included in the construction contract and 12.4% of the total costs are attributed to the direct construction costs.

Approximately 41% of the total costs of the proposed project are attributed to the costs of equipment. The remaining cost areas each amount to less than 2% of the total cost. The applicant asserts that the cost of the proposed project would not affect the existing costs of patient care. Looking at the applicant's accumulated reserves, the applicant has sufficient available funds to pay for the projected costs without unduly effecting the applicant's finances. The projected profits are sufficient to cover the necessary lease costs without unduly effecting Virginia Heart. 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 they intend to staff the proposed project using existing staff. The applicant further provides a detailed explanation of how they intend to adjust the distribution of staff at their locations to account for the staffing requirements for this project. DCOPN finds the applicant's staffing plan modest and 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	\$3,825,600	\$3,825,600
Deductions from Revenue	\$174,036	\$174,036
Net Patient Services Revenue	\$3,651,564	\$3,651,564
Total Operating Expenses	\$2,641,667	\$2,205,498
Excess Revenue Over Expenses	\$1,009,897	\$1,446,066

Source: COPN Request No. VA-8625 & 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. Currently, there is only one provider of cardiac PET/CT scanning services, who is located over 20 miles from the proposed project. Cardiac PET/CT scanning, at both the existing and the proposed location, are performed solely on an outpatient basis. As such, approval of the proposed project would provide improvements in the delivery of health care services by increasing the provision of cardiac PET/CT scanning services on an outpatient basis

As there is an existing provider of cardiac PET/CT scanning services in PD 8 and the applicant has not raised any arguments regarding the unique nature of the proposed PET/CT scanner, the proposed project would not provide improvements or innovations in the financing and delivery of health care services, as demonstrated by the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. The applicant does not make any 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 specialized center for the provision of PET/CT services through the addition of one fixed PET/CT scanner to their Fairfax Office 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 proffered that the CT functionality of the PET/CT scanner will be used only in conjunction with its PET functionality. Moreover, the applicant further 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 no service in Commonwealth, individually, met this threshold. Moreover, substantial 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 reason 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.

Moreover, DCOPN finds that the proposed project is more beneficial than the alternative of the status quo. Under the status quo, patients at Virginia Heart will continue to receive diagnostic imaging using SPECT. 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 without adversely affecting the existing provider of cardiac PET/CT services.

Additionally, the HSNV Board voted nine in favor and none opposed to recommend that the application be approved. Finally, DCOPN finds that the total capital costs of the proposed project are \$2,491,617 (**Table 2**). The PET/CT scanner would be leased and paid for using operating expenses. All other costs associated with the project would be paid for using accumulated reserves. The applicant asserts that the cost of the proposed project would not affect the existing costs of patient care. The costs of this project are reasonable and consistent 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.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of Cardiovascular Group, PC d/b/a Virginia Heart's request to establish PET/CT services with one fixed PET/CT scanner limited to cardiology at Virginia Heart's Fairfax Office 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 introduce beneficial competition without adversely affecting the existing provider of cardiac PET/CT services.
5. The project is more beneficial than the alternative of the status quo.
6. The capital costs are reasonable and consistent with the projects of this type.
7. The Health Systems Agency of Northern Virginia voted unanimously to recommend approval of the proposed project.

DCOPN's recommendation is contingent upon Cardiovascular Group, PC d/b/a Virginia Heart's agreement to the following charity care condition:

Cardiovascular Group, PC will provide PET services to all persons in need of these services, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount equal to at least 3.4% of Cardiovascular Group, PC's total patient services revenue derived from PET 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. Cardiovascular Group, PC 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.

Cardiovascular Group, PC will provide PET 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 Cardiovascular Group, PC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.