



COMMONWEALTH of VIRGINIA

B. Cameron Webb, MD, JD  
State Health Commissioner

Department of Health  
P O BOX 2448  
RICHMOND, VA 23218

TTY 7-1-1 OR  
1-800-828-1120

April 24, 2026

Erin Whaley  
Troutman Pepper Locke, LLP  
1001 Haxall Point  
Richmond, Virginia 23218

RE: **COPN No. VA-04987 (COPN Request No. VA-8862)**  
**Advanced Health Care and Wellness, LLC d/b/a Heart and Vascular Group**  
**Virginia Beach, Virginia**  
**Establish a Center for PET/CT services with one fixed PET/CT scanner limited to**  
**cardiology**

Dear Ms. Whaley:

In accordance with Chapter 4, Article 1.1 of Title 32.1 of the Code of Virginia of 1950 (the Code), as amended, I reviewed the application and all supporting documents submitted by Advanced Health Care and Wellness, LLC d/b/a Heart and Vascular Group to establish a specialized center for the provision of PET services, restricted to cardiovascular imaging, with one fixed PET/CT unit at Heart and Vascular Group in Virginia Beach.

As required by Section 32.1-102.3B of the Code, I have considered all factors that must be taken into account in a determination of public need, and I have concluded that **conditional approval** of the request is warranted based on the following findings:

1. Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group's proposal is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
2. The proposed project improves access in an area with a relatively fast-growing population over 65.
3. The existing patient base and cardiovascular restriction make it unlikely that the proposal will negatively impact existing providers.

Ms. Erin Whaley  
Advanced Health Care and Wellness, LLC  
April 24, 2026  
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4. There is no alternative identified to the proposed project, and it is more beneficial than the status quo.
5. Projected costs are reasonable, and the proposal is wholly feasible.

This certificate is valid for the period April 24, 2026 to April 23, 2027. The total authorized capital cost of the project is \$1,630,684.

Please file two copies of the application for a certificate extension with the Department no later than 30 days before the expiration date of the certificate. Part VIII of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations identifies the filing requirements and review procedure for certificate extension requests.

Sincerely,



Dr. Cameron Webb  
State Health Commissioner

Enclosure

cc:

Charis A. Mitchell, Assistant Attorney General, Commonwealth of Virginia

April Dovel, Director, VDH, Office of Licensure and Certification

Antwon Jacobs, Supervisor, Division of Certificate of Public Need

James Jenkins, Deputy Director, VDH, Office of Licensure and Certification

Deborah K. Waite, Chief Operating Officer, Virginia Health Information

Caitlin S. Pedati, MD MPH, FAAP, District Director, Virginia Beach Health District

**COMMONWEALTH OF VIRGINIA**  
**DEPARTMENT OF HEALTH**  
**MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED**

**THIS CERTIFIES THAT Advanced Health Care and Wellness, LLC is authorized to initiate the proposal as described below.**

**NAME OF FACILITY: Heart and Vascular Group**

**LOCATION: 389 Edwin Drive, Virginia Beach, Virginia 23462**

**OWNERSHIP AND CONTROL: Advanced Health Care and Wellness, LLC**

**SCOPE OF PROJECT: Establish a specialized center for the provision of PET services with one PET/CT scanner at Heart and Vascular Group, restricted to cardiovascular imaging. The CT component of the equipment will not be used independently. Capital costs authorized for this project total \$1,630,684. The project is expected to be completed by November 24, 2026. This certificate is issued with the condition that appears on its reverse.**



Pursuant to Chapter 4, Article 1:1 of Title 32.1, Sections 32.1-102.1 through 32.1-102.12 of the Code of Virginia (1950), as amended and the policies and procedures promulgated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial and continuing progress towards implementation of the proposal within twelve (12) months from the date of issuance. A progress report shall be submitted to the State Health Commissioner within twelve (12) months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Commissioner reserves the right not to renew this Certificate in the event the applicant fails to fulfill these conditions. This Certificate is non-transferable and is limited to the location, ownership, control and scope of the project shown herein.

**Certificate Number: VA-04987**

**Date of Issuance: April 24, 2026**

**Expiration Date: April 23, 2027**

  
**Dr. Cameron Webb, State Health Commissioner**

Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group will provide cardiovascular 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 will facilitate the development and operation of primary medical care services to medically underserved persons in PD 20 in an aggregate amount equal to at least 1.8% of Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group's gross patient revenue derived from PET/CT services. 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. Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group 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.

Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group will provide PET/CT services 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. Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

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

**Staff Analysis**

March 23, 2026

**COPN Request No. VA-8862**

Advanced Health Care and Wellness, LLC

Virginia Beach, Virginia

Establish a Center for PET/CT services with one fixed PET/CT scanner limited to cardiology

**Applicant**

Advanced Health Care and Wellness LLC (AHC&W) is a limited liability company that is authorized to conduct business in Virginia. It is member-managed by Dr. Michael Gen and Dr. Vishwanatha S. Nadig. It is not a subsidiary of any organization and does not have any subsidiaries. The proposed site of the facility, Advance Health Care and Wellness, LLC d/b/a Heart and Vascular Group (H&V), is leased space at 389 Edwin Drive, Virginia Beach, Virginia, Health Planning Region (HPR) V, Planning District (PD) 20.

**Background**

PD 20 is in the southeast corner of Virginia, bordering the Atlantic Ocean and North Carolina (**Figure 1**). It includes the counties of Southampton and Isle of Wight and the independent cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk, and Virginia Beach. Travel is difficult in parts of PD 20, due to traffic and waterways requiring bridges, tunnels and tolls to traverse.

In 2020 PD 20 had a population of about 1.2 million and is projected to grow by just over 40,000 people, an increase of 3.3%, between 2020 and 2030. This is less than the population growth rate projected for Virginia during this decade, which is 5.8% (**Table 1**). The growth rates projected for 2020-2030 in the 65 and older age group are 33.8% in PD 20 compared to 26.3% in Virginia (**Table 1**). The City of Virginia Beach, where the proposed H&V site is located, is projected to see an overall population increase of 3.2% by 2030, consistent with PD 20 growth. The population in Virginia Beach aged 65 is projected to grow by 36.8% during the 2020-2030 decade, outpacing growth rates in PD 20 and Virginia for this population segment. The older population is an important segment for the proposed project, as those aged 65+ have a significantly higher risk of coronary artery disease.<sup>1</sup>

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<sup>1</sup> <https://www.ahajournals.org/doi/10.1161/CIR.0000000000001387#:~:text=1,can%20exacerbate%20aggregate%20prognostic%20risk>

Figure 1. Map of Planning District 20

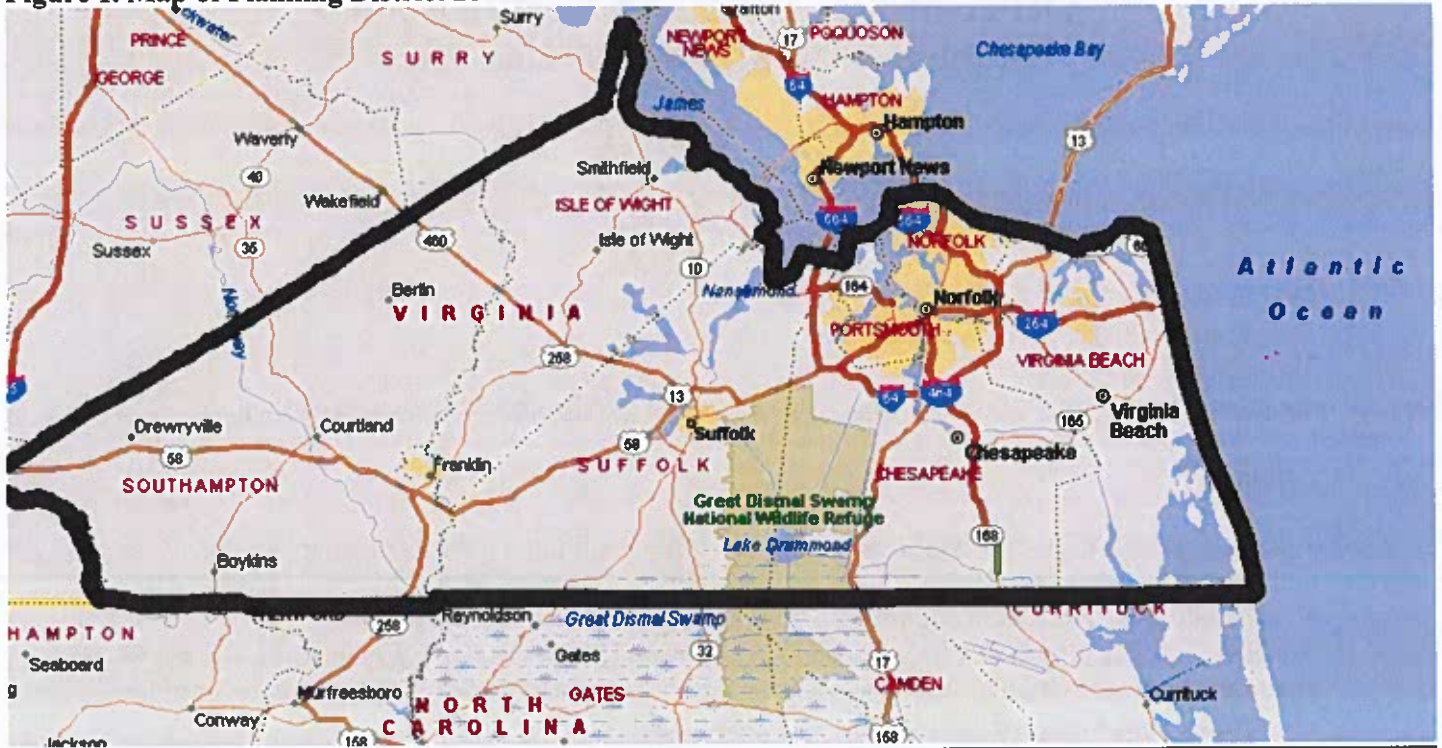


Table 1. PD 20 Population Data

Geographic Name	2020 Census	2030 Projection	Projected Population Change 2020-2030	Projected % Change 2020-2030	2020 65+ Census	2030 65+ Projection	Projected Population Change 65+ 2020-2030	Projected Percent Change 65+ 2020-2030
Isle of Wight County	38,606	41,341	2,735	7.1%	7,751	10,388	2,637	34.0%
Southampton County	17,996	17,172	-824	-4.6%	3,719	4,756	1,037	27.9%
City of Chesapeake	249,422	272,670	23,248	9.3%	36,045	50,838	14,793	41.0%
City of Franklin	8,180	7,667	-513	-6.3%	1,787	1,982	195	10.9%
City of Norfolk	238,005	229,864	-8,141	-3.4%	29,215	36,636	7,421	25.4%
City of Portsmouth	97,915	98,857	942	1.0%	15,496	19,321	3,825	24.7%
City of Suffolk	94,324	102,571	8,247	8.7%	14,708	19,474	4,766	32.4%
City of Virginia Beach	459,470	474,052	14,582	3.2%	69,375	94,903	25,528	36.8%
<b>PD 20 Totals</b>	<b>1,203,918</b>	<b>1,244,194</b>	<b>40,276</b>	<b>3.3%</b>	<b>178,096</b>	<b>238,297</b>	<b>60,201</b>	<b>33.8%</b>
<i>Virginia</i>	<i>8,631,393</i>	<i>9,129,002</i>	<i>497,609</i>	<i>5.8%</i>	<i>1,395,291</i>	<i>1,762,641</i>	<i>367,350</i>	<i>26.3%</i>

Source: Weldon-Cooper Data, updated August 2024

### PET/CT Services

A positron emission tomography (PET) scan is an imaging test that can help reveal the metabolic or biochemical function of tissues and organs. The PET scan uses a radioactive drug called a tracer to show both typical and atypical metabolic activity. A PET scan can often detect the atypical metabolism of the tracer in diseases before the disease shows up on other imaging tests, such as computerized tomography (CT) and magnetic resonance imaging (MRI). The tracer is most often injected into a vein in the hand or arm. The tracer will then collect in areas of the body that have higher levels of metabolic or biochemical activity. This often pinpoints the location of the disease. The PET images are typically combined with CT or MRI and are called PET/CT or PET/MRI scans.<sup>2</sup> Note from the State Medical Facilities Plan (SMFP): 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 one individual PET procedure and one CT procedure, respectively, unless those images are made concurrently. The applicant has stated that the CT component of the proposed PET/CT scanner will only be used concurrently with PET imaging.

H&V's COPN Request No. VA-8862 proposes a PET/CT service limited to cardiac imaging. Of particular relevance to H&V's proposal, PET/CT has emerged as the standard of care for myocardial perfusion, recommended by the Centers for Medicare & Medicaid Services (CMS),<sup>3</sup> the American Society of Nuclear Cardiology (ASNC) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI).<sup>4</sup> Despite single-photon emission computerized tomography (SPECT) being the most used nuclear imaging technique for the diagnosis of coronary artery disease (CAD), many now consider PET as a superior modality due to higher resolution, greater diagnostic accuracy and lower radiation exposure.<sup>5</sup> This transition from cardiac SPECT has contributed to rapid growth in PET imaging in recent years.<sup>6</sup>

Regarding cardiac PET, the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging published a joint position paper in 2016 (Society Joint Position Statement) stating:

The purpose of this joint Society Position Statement is to highlight the attributes that make rest/stress myocardial perfusion PET both **Preferred** and **Recommended** in the era of high value initiatives for appropriate patients. Myocardial perfusion PET image quality, high diagnostic accuracy that is relatively independent of body habitus, ability to accurately risk stratify patients with a wide array of clinical presentations, short acquisition times, safety by virtue of low radiation exposure, and its unique ability to quantify myocardial blood flow are all significant and clinically important properties. The properties of myocardial perfusion PET according to the published literature are sufficient to advance recommendations for its use in clinical practice. There are no clinical scenarios where PET should not be considered a

<sup>2</sup><https://www.mayoclinic.org/tests-procedures/pet-scan/about/pac-20385078>

<sup>3</sup> <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=292&NCDver=2>

<sup>4</sup> <https://www.asnc.org/files/Guidelines%20and%20Quality/PET%20GuidelineASNC%20SNMMI2016.pdf>

<sup>5</sup><https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10170052/#:~:text=High%20Resolution&text=PET%20provides%20a%20substantial%20advantage,in%20PET%20vs%20SPECT%20machines.>

<sup>6</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10170052/>

preferred test for patients who meet appropriate criteria for a stress imaging test and who require pharmacologic stress.<sup>7</sup>

According to 2024 VHI data, the latest such data available, PD 20 had nine PET services in operation that year--three fixed site scanners and six mobile scanners. Only the fixed units are relevant for this review. Since 2024, Sentara Norfolk General Hospital and James River Cardiology have each been authorized for fixed PET/CT scanners. The James River Cardiology service is restricted to cardiac imaging, and Sentara Norfolk General Hospital's fixed unit is unrestricted but will primarily be used for cardiac PET/CT, according to COPN Request No. VA-8767 (Table 2).

**Table 2. PD 20 COPN Authorized Fixed PET Services, Utilization**

Facility	Total Scanners	Procedures	Procedures per Unit	% of SMFP Threshold
Chesapeake Regional Medical Center	1	1,296	1,296	21.6%
Children's Hospital of The King's Daughters	1	74	74	1.2%
Sentara Brock Cancer Center	1	2,996	2,996	49.9%
<b>PD 20 Total Operational in 2024</b>	<b>3</b>	<b>4,366</b>	<b>1,455</b>	<b>24.3%</b>
<b>Not Yet Operational:</b>				
Sentara Norfolk General Hospital <sup>8</sup>	1			
James River Cardiology <sup>9</sup>	1			
<b>PD 20 Total Authorized PET Services</b>	<b>5</b>			

Source: 2024 VHI and DCOPN Records

**Proposed Project**

H&V proposes to establish a cardiac PET service with one PET/CT scanner in leased space at 389 Edwin Drive, Virginia Beach, Virginia. The applicant has stated that it will not use the CT component of the equipment independently but will only perform PET/CT scans, restricted to cardiac use. Among a wide array of heart and vascular services, H&V currently offers nuclear cardiology, including SPECT myocardial perfusion imaging (not regulated by COPN). Underlying the proposed project is the conversion of its existing SPECT services to PET imaging for appropriate patients, as PET is now considered the superior modality for myocardial perfusion imaging in most cases.

Total capital costs of the proposed project are \$1,630,684 (Table 3). The applicant states that the proposed project will be funded fully through accumulated reserves, so no financing costs will be incurred. Should the proposed project be approved, the applicant anticipates that it will be operational seven months after the COPN is issued.

<sup>7</sup> Bateman et.al. American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET. Journal of nuclear cardiology (2016): official publication of the American Society of Nuclear Cardiology. <https://pubmed.ncbi.nlm.nih.gov/27528255/> (accessed December 17, 2024).

<sup>8</sup> Authorized by COPN No. VA-04908, unrestricted, but to be used primarily for cardiac imaging, per COPN request No. VA- 8767. The project is expected to be completed in early 2026.

<sup>9</sup> Authorized by COPN No. VA-04975, restricted to cardiac imaging. The project is expected to be completed June 2026.

**Table 3. Capital Costs, H&V Cardiac PET/CT**

Direct Construction Cost	\$ 197,434
Equipment not included in the construction contract	\$ 1,200,000
Site Acquisition Costs	\$ 175,000
Architectural & Engineering fees	\$ 8,250
Other Consulting Fees	\$ 50,000
<b>Total Capital Cost</b>	<b>\$ 1,630,684</b>

Source: COPN Request No. VA-8862

**Project Definition**

COPN Request No. VA-8842: USHV

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 of ...[or] positron emission tomographic (PET) scanning...”

**Required Considerations – §32.1-102.3, of the Code of Virginia**

In determining whether a public need for a project exists, the following factors shall be considered:

- 1. The extent to which the proposed project will provide or increase access to health care services for people in the area to be served and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care;**

The proposed project is in Virginia Beach, which has a projected growth rate of 3.2% between 2020 and 2030, comparable to the growth rate of PD 20, but lower than the 5.8% growth rate projected across Virginia during this decade. The growth rate of the population aged 65 and over in Virginia Beach is projected to be 36.8%, with the city expected to add 25,528 people in this age segment between 2020 and 2030 through aging and in-migration. This rate of growth in the older population is higher than PD 8's at 33.8% or Virginia's at 26.3% (Table 1). The proposed site is near the intersection of Interstate 264 and Holland Road and just over two miles from H&V's practice location, improving access for H&V's patient base. Hampton Roads Transit has a stop 0.2 miles from the proposed facility.

**Table 4. Poverty Rates and Median Household Income in Localities in PD 20**

Locality	Poverty Estimate	Poverty Percent	Median Household Income
Isle of Wight County	3,319	8.2%	\$ 93,107
Southampton County	2,097	12.7%	\$ 70,013
Chesapeake City	26,196	10.5%	\$ 90,226
Franklin City	1,626	19.7%	\$ 51,516
Norfolk City	32,115	15.3%	\$ 64,281
Portsmouth City	14,210	15.2%	\$ 61,783
Suffolk City	8,398	8.3%	\$ 93,557
Virginia Beach City	35,302	7.9%	\$ 93,989
<b>PD 20</b>	<b>123,263</b>	<b>10.6%</b>	<b>\$ 84,547</b>
<b>Virginia</b>	<b>839,669</b>	<b>9.8%</b>	<b>\$ 92,116</b>

Source: [https://www.census.gov/data-tools/demo/saige/#/?s\\_state=51&s\\_county=&s\\_district=&s\\_geography=county](https://www.census.gov/data-tools/demo/saige/#/?s_state=51&s_county=&s_district=&s_geography=county)

Regarding socioeconomic barriers to access to the applicant’s services, none are identified. The City of Virginia Beach has a poverty rate of 7.9%, lower than PD 20’s (10.6%) or Virginia’s (9.8%) (Table 4). DCOPN is not aware of any other distinct and unique geographic, socioeconomic, cultural, transportation, or other barriers to care that this project would address.

**2. The extent to which the proposed project will meet the needs of people in the area to be served, as demonstrated by each of the following:**

- (i) the level of community support for the proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;**

DCOPN received a letter of commitment from Drs. Gen and Nadig at H&V, and eight letters of support for the proposal from Virginia Senator Bill DeSteph, and area primary care physicians and specialists. In aggregate, these letters communicate that the proposal is a step forward in delivering state-of-the-art cardiovascular care and enhancing the ability of H&V to evaluate and manage cardiovascular patients more effectively, improving patient outcomes. It promises to produce higher quality images with reduced radiation exposure for patients and to close a gap in advanced cardiovascular testing in the region.

DCOPN received a letter of opposition from Bon Secour Hampton Roads Health System, LLC (BSHR) arguing that DCOPN recommended denial of a project on January 20, 2026, of a “functionally identical” project in the same geographic region in PD 20, US Health Virginia, LLC’s (USHV) COPN Request No. VA-8842. The BSHR letter also argues that the SMFP volume standard for new PET services is not met and that the Commissioner has not set aside that SMFP standard of 6,000 procedures. Furthermore, it references the State Health Services Plan (SHSP) Task Force and its subcommittee, which is in the process of developing new standards to better reflect current utilization patterns for diagnostic imaging facilities and services. The Diagnostic Imaging Facilities & Services Committee has discussed the reduction

of the PET volume standard for the establishment of a PET service to 3,000 procedures. Additionally, it has considered separate volume standards for restricted PET services, such as the proposed cardiovascular-restricted PET service. To date, these possible recommendations have not been finalized or adopted through the proper regulatory process. Finally, BSHR argues that the “unchecked proliferation” of cardiac-specific PET services threatens the expansion of general PET services, such as its plans to offer cardiac PET/CT at Harbourview’s mobile site.

DCOPN received a response from H&V to BSHR’s letter of opposition. It argues that a cardiac PET/CT service on Harbourview’s mobile unit, should BSHR implement it, would not meet H&V’s needs as it is too far away for H&V’s patients and would be a disconnect in H&V’s continuity of care. H&V also asserts that the case cited by BSHR’s letter discussing the SMFP threshold substantiates that the SMFP standard is outdated, and that the Commissioner may look beyond the numerical standard to consider the needs of cardiac patients in the community. Additionally, H&V establishes that COPN Request No. VA-8842, the recently denied USHV proposal that BSHR references as being “functionally identical” to H&V’s proposal, is different in that the USHV proposal had theoretical volumes only, as USHV has no historical presence in PD 20. H&V has a longstanding practice owned and operated by local physicians with an established patient base, including SPECT imaging patients, and a clinically appropriate pathway to convert SPECT patients to PET, as indicated. This presence substantiates H&V’s PET volume projections and ability to establish a PET service without reducing volumes of existing providers.

BSHR responded to this letter, asserting that H&V’s proposal and response to its opposition ask the Commissioner to disregard the inconsistency with the SMFP and authorize PET services at cardiology practices for the sake of convenience. BSHR notes that the SMFP drive time threshold is 60 minutes, and H&V’s patients have access within that time; BSHR points out that H&V argues cardiac PET/CT should be treated differently in the SMFP, but it is not, and the current SMFP volume standard of 6,000 remains in effect. H&V responded to this letter with a letter on March 26, 2026 making several points: The Commissioner has treated the SMFP PET/CT standard as outdated; H&V’s patients have a demonstrated need for PET/CT; Bon Secours’ Mobile PET/CT has limited capacity for cardiac patients that will be utilized by its own systemwide providers; a lower-cost, office-based cardiac PET/CT service is better for H&V’s patients and the community; and H&V’s proposal is similar to several other projects approved for cardiac PET/CT.

#### Public Hearing

§32.1-102.6B of the Code of Virginia directs DCOPN to hold one public hearing on each application in the case of competing applications, or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8862 is not competing with another project, and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

DCOPN provided notice to the public regarding this project, inviting public comment on January 9, 2026. The public comment period closed on February 24, 2026. Other than the letters referenced above, 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;**

Authorizations for cardiac PET/CT scanners have increased in Virginia in the past several years. These scanners are primarily operated by individual cardiology practices and are generally used for their own patients. The proposed project will be open to other practices to utilize, as well as H&V's patient base. PET/CT is developing into a significant technology for cardiac diagnostics. It is the preferred and recommended modality for myocardial perfusion by the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging, replacing SPECT as the standard of care.

The status quo entails travel for H&V patients to access a higher-cost, hospital-based PET/CT with cardiac imaging capabilities, such as the one that was recently authorized at Sentara Norfolk General Hospital (expected to be operational early 2026), or continued use of SPECT imaging for myocardial perfusion, which is currently offered at H&V's office site. PET/CT is superior to SPECT in diagnostic accuracy, ability to accurately risk-stratify patients with a wide array of clinical presentations, short acquisition times, safety by virtue of low radiation exposure, and its unique ability to quantify myocardial blood flow. H&V has SPECT patients and a patient base that would benefit from access to the superior, recommended imaging modality for myocardial perfusion. The proposed project is more beneficial than the status quo. No reasonable alternative is identified that serves the population in a less costly, more efficient or more effective manner. Because the applicant proposes to use the PET/CT unit primarily (but not exclusively) to serve its existing patient population, and it will be limited to cardiac use, DCOPN concludes that the proposed project is unlikely to adversely affect the utilization and efficiency of existing services.

**(iii) any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;**

Currently, there is no organization in HPR V designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 20. Therefore, this consideration does not apply to the review of the proposed project.

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

The projected capital costs of the proposed project are \$1,630,684 (Table 3), funded entirely by accumulated reserves and revenue generated from the provision of cardiac PET/CT services, such that no financing costs will be incurred. Some similar projects authorized in the past year, in which physician practices established cardiovascular PET services, had capital costs of \$1.3 million (COPN No. VA-04949 issued to James River Cardiology), \$3.8 million (COPN No. VA-04930 issued to Virginia Heart) and \$3.8 million (COPN No. VA-04919, also issued to Virginia Heart). DCOPN concludes that when compared to similar projects, the capital costs of the proposed project are reasonable.

The applicant identified numerous benefits of the proposed project, including access to the preferred and recommended imaging modality for myocardial perfusion in a lower-cost, outpatient setting. PET/CT is superior to SPECT in its image quality, higher diagnostic accuracy and confidence in diagnostic conclusions, and reduced radiation dose for both patients and staff. The applicant asserts that the proposed project will improve continuity of care as it completes H&V's cardiovascular diagnostic capabilities within the practice, eliminating the need for referrals to and coordination with external facilities. The patient will experience consultation, advanced imaging and follow-up in the same clinical environment; rapid interpretation of results and timely treatment; effective monitoring of disease progression and incorporation of cardiac PET/CT into the existing electronic health record for comprehensive patient history, supporting informed decision-making.

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

§ 32.1-102.4B of the Code of Virginia requires DCOPN to place a charity care condition on every applicant seeking a COPN. According to regional and statewide data regularly collected by Virginia Health Information VHI, for 2024, the most recent year for which such data are available, the average amount of charity care provided by HPR V facilities was 1.8% of all reported total gross patient revenues (**Table 5**). According to its application, H&V projects 0.5% in charitable care should this project be approved, far lower than the HPR average. If approved, the proposed project would be conditioned to provide charity care equal to 1.8% of gross patient revenues. Pursuant to the Code of Virginia language, any COPN issued for this project will also be conditioned on the applicant's agreement to accept patients who are the recipients of Medicare and Medicaid.

**Table 5: HPR V Charity Care Contributions, 2024**

HPR V	2024 at 200%		
	Gross Pt Rev	Total Charity Care Provided Below 200%	%
<b>Inpatient Hospitals</b>			
Riverside Shore Memorial Hospital	\$354,364,851	\$16,373,174	4.6%
Riverside Doctors' Hospital Williamsburg	\$297,237,405	\$12,131,900	4.1%
Riverside Walter Reed Hospital	\$387,098,512	\$11,102,707	2.9%
Sentara Careplex Hospital	\$1,313,698,788	\$37,496,919	2.9%
Sentara Obici Hospital	\$1,352,671,244	\$35,372,773	2.6%
Sentara Virginia Beach General Hospital	\$1,825,705,099	\$47,186,982	2.6%
Sentara Leigh Hospital	\$2,192,444,921	\$50,952,088	2.3%
Sentara Norfolk General Hospital	\$4,894,539,810	\$107,248,394	2.2%
Riverside Regional Medical Center	\$3,356,990,790	\$63,591,379	1.9%
Chesapeake Regional Medical Center	\$1,357,755,934	\$21,073,675	1.6%
Sentara Williamsburg Regional Medical Center	\$873,857,607	\$13,241,461	1.5%
Sentara Princess Anne Hospital	\$1,544,557,025	\$25,184,203	1.6%
Virginia Beach Psychiatric Center	\$54,267,999	\$582,000	1.1%
VCU Health Tappahannock Hospital	\$235,011,627	\$1,062,189	0.5%
Bon Secours Southampton Medical Center	\$230,185,097	\$2,072,911	0.9%
Bon Secours Maryview Medical Center	\$1,541,147,853	\$10,718,119	0.7%
Bon Secours Mary Immaculate Hospital	\$802,263,279	\$3,656,976	0.5%
Bon Secours Rappahannock General Hospital	\$117,738,136	\$595,586	0.5%
The Pavilion at Williamsburg Place	\$61,494,600	\$227,828	0.4%
Newport News Behavioral Health Center	\$35,970,167	\$108,740	0.3%
Children's Hospital of the King's Daughters	\$1,575,120,453	\$3,920,403	0.3%
Hospital For Extended Recovery	\$34,590,910	\$16,000	0.1%
Riverside Rehabilitation Hospital	\$109,190,304	\$0	0.0%
Select Specialty Hospital-Hampton Roads	\$121,007,932	\$0	0.0%
Kempsville Center for Behavioral Health	\$51,735,416	\$0	0.0%
Lake Taylor Transitional Care Hospital	\$46,192,534	\$0	0.0%
Total Inpatient Facilities:			26
<b>HPR V Inpatient Total \$ &amp; Mean%</b>	<b>\$24,766,838,293</b>	<b>\$463,916,407</b>	<b>1.9%</b>

**Table 5: HPR V Charity Care Contributions, 2024 -Cont.-**

HPR V	2024 at 200%		
	Gross Pt Rev	Total Charity Care Provided Below 200%	%
<b>Outpatient Hospitals</b>			
Riverside Peninsula Surgery Center	\$39,509,332	\$1,248,200	3.2%
Careplex Orthopaedic Ambulatory Surgery Center	\$63,138,487	\$1,593,954	2.5%
Sentara BelleHarbour Ambulatory Surgery Center	\$6,636,653	\$138,219	2.1%
Riverside Hampton Surgery Center	\$39,901,658	\$386,418	1.0%
Riverside Doctors Surgery Center	\$48,292,467	\$345,699	0.7%
CHKD Health & Surgery Center (Virginia Beach)	\$41,975,738	\$159,916	0.4%
Sentara Princess Anne Ambulatory Surgery Management, LLC	\$49,297,412	\$174,534	0.4%
CHKD Health & Surgery Center (Newport News)	\$26,304,861	\$80,552	0.3%
Bon Secours Mary Immaculate Ambulatory Surgery Center	\$26,840,062	\$52,417	0.2%
Leigh Orthopedic Surgery Center, LLC	\$148,643,492	\$4,500	0.0%
Bon Secours Surgery Center at Harbour View, LLC	\$103,392,678	\$3,358	0.0%
Surgical Suites of Coastal Virginia	\$36,498,457	\$0	0.0%
Sentara Obici Ambulatory Surgery LLC	\$60,137,996	\$0	0.0%
Sentara Virginia Beach Ambulatory Surgery Center	\$30,832,912	\$0	0.0%
Surgery Center of Chesapeake	\$28,311,404	\$0	0.0%
CVP Surgery Center	\$59,660,549	\$0	0.0%
Sentara Port Warwick Surgery Center	\$33,026,922	\$0	0.0%
Bayview Medical Center, Inc	\$4,592,699	\$0	0.0%
Advanced Vision Surgery Center LLC	\$1,858,446	\$0	0.0%
Virginia Beach Health Center	\$2,647,444	\$0	0.0%
Sentara Leigh Orthopedic Surgery Center, LLC	\$58,117,293	\$0	0.0%
Total Outpatient Facilities:			21
<b>HPR V Outpatient Total \$ &amp; Mean%</b>	\$909,616,962	\$4,187,767	0.5%
Total Facilities:			47
<b>HPR V Total \$ &amp; Mean%</b>	\$25,676,455,255	\$468,104,174	1.8%

Source: VHI, 2024

(vi) at the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a proposed project.

DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant to determining a public need for the proposed projects.

**3. The extent to which the proposed project is consistent with the State Health Services Plan;**

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

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

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

**12VAC5-230-200. Travel Time.**

**PET services should be within 60 minutes driving time one way under normal conditions of 95% of the health planning district using a mapping software as determined by the commissioner.**

The heavy black line in **Figure 2** is the boundary of PD 20. The blue “H” symbols mark the locations of existing fixed PET providers in PD 20. The black circles represent mobile PET sites, and the red square icon locates the existing authorized fixed PET site that is restricted to cardiology, and the red flag locates the proposed cardiac PET project. The blue shaded area includes the area that is within 60 minutes driving time one-way under normal conditions of existing PET services in PD 20. **Figure 2** clearly illustrates that PET services are already well within a 60-minute drive under normal conditions for more than 95% of the residents of PD 20. Approval of COPN Request VA-8862 would not improve geographic access to PET services. DCOPN notes that the SMFP does not distinguish between cardiac-restricted and general diagnostic PET, but the only other cardiac-restricted PET service in PD 20 is one hour away from the proposed site.

**Figure 2. Authorized PET Sites in PD 20**



Source: 2024 VHI, Microsoft Streets and Trips

**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.**

The applicant is not a hospital.

**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.**

Fixed PET providers in PD 20 performed an average of 1,455 per scanner in 2024, or 24.3% of the SMFP standard of 6,000 average procedures per unit in the PD. See **Table 2**, which displays only fixed PET/CT units.

Calculated Needed Fixed PET Scanners in PD 20

Current COPN authorized fixed PET scanners in PD 20 = 5

Calculated Needed Fixed PET scanners =  $4,366 \div 6,000 = 0.73$  (1) scanners needed

PD 20 Calculated Need = 1 PET scanner

PD Calculated Surplus = 5 authorized PET scanners - Calculated Need (1) = **Surplus of 4**

There is a calculated surplus of 4 PET scanners in PD 20. DCOPN notes that every PET provider operational in 2024 in PD 20 had less than 50% of the 6,000-procedure threshold required for expansion. DCOPN has previously acknowledged that the SMFP's utilization standards for PET/CT services are outdated and that expecting a PET service to reach the threshold suggested by the SMFP amounts to a misconception about the utilization of this modality at the time the SMFP was written and should be treated as such. DCOPN has previously recommended approval for PET services even though the PD did not meet the SMFP threshold for expansion.

According to VHI data for 2024, the average number of PET procedures performed across all PET providers in the Commonwealth was 2,372. DCOPN notes that the SMFP makes no distinction between unrestricted PET services and specialty-restricted PET services, such as the proposed PET service restricted to cardiovascular. The applicant expects to convert 1,020 of its current SPECT patients to PET in year one and 1,362 in year two. H&V will additionally offer PET to its patients who were previously not suitable candidates for SPECT.

Due to the distinct nature of the patient base, its ability to convert its own SPECT patients to the superior PET imaging, and the restricted scope of the PET/CT service to only cardiovascular procedures, DCOPN does not anticipate that approval of the proposed project would negatively

affect utilization of other PET services in PD 20. Instead, approval of the proposed project would create an overall improvement in access to cardiovascular PET for H&V's patients. While the applicant does not meet the computational analysis of this SMFP standard, DCOPN recommends that the Commissioner, in this specific instance, not allow this standard to bar the establishment of this cardiac PET/CT service.

**12VAC5-230-220. Expansion of Fixed Site Services.**

**Proposals to increase the number of PET scanners in an existing PET service should be approved only when the existing scanners performed an average of 6,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing fixed site providers in the health planning district.**

Not applicable. The applicant is not proposing to expand an existing fixed-site PET service.

**12VAC5-230-230. Adding or Expanding Mobile PET or PET/CT Services.**

- A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.**
- B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district.**

Not applicable. The applicant is not proposing to add or expand an existing mobile PET/CT service.

**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 asserts that the proposed PET service will be under the direction and supervision of qualified physicians appropriately authorized and licensed.

**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;**

The proposed project does not foster institutional competition. Its primary use will be PET imaging of the applicant's existing cardiac patient base, converted from its SPECT service, a modality that is inferior to PET imaging for myocardial perfusion. Two recently authorized PET providers in PD 20 are not yet operational, and they intend to utilize PET/CT scanners primarily or exclusively for cardiac patients. Though Sentara Norfolk General Hospital has asserted that it

will utilize its latest authorized PET/CT for cardiac patients, it is, in fact, unrestricted (COPN No. VA-04908), and expects its referral source to be Sentara's affiliated cardiologists. James River Cardiology was authorized for a cardiac PET/CT (COPN No. VA-04975) primarily for its own patients. It is in Franklin, Virginia, over one hour away from the proposed H&V site.

**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;**

H&V is a cardiovascular practice with locations in Virginia Beach and Newport News. Its physicians and advanced practice providers cover all aspects of cardiac care, performing comprehensive evaluation, preparation and diagnostic testing in their office. Procedures that require hospital facilities, such as structural heart interventions, cardiac catheterizations, and other advanced procedures, are performed in local hospitals.

**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;**

Total capital costs of the proposed project are \$1,630,684 (Table 3) to be funded fully through accumulated reserves, so no financing costs will be incurred. These costs are reasonable when compared to recently approved, similar projects. The pro forma income statement provided by the applicant (Table 6) projects a net income of \$1,050,644 in the first year of operation and \$1,741,043 in the second year of operation. The applicant asserts that the proposed project will not require additional staffing to operationalize.

**Table 6. Proforma, H&V's PET/CT Scanner**

	<b>Year 1</b>	<b>Year 2</b>
<b>Gross Revenue</b>	<b>\$3,242,009</b>	<b>\$4,329,035</b>
Charity care	\$16,210	\$21,645
Contractual Adjustments	\$324,201	\$432,904
Other deductions	\$137,785	\$183,984
<b>Net Revenue</b>	<b>\$2,763,813</b>	<b>\$3,690,502</b>
<b>Expenses</b>	<b>\$1,713,169</b>	<b>\$1,949,459</b>
<b>Net Income</b>	<b>\$1,050,644</b>	<b>\$1,741,043</b>

Source: COPN Request No. VA-8862

**7. The extent to which the proposed project provides improvements or innovations in the financing and delivery of health care services, as demonstrated by (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) the potential for provision of health care services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate;**

The proposed project would provide improvements in the delivery of health care services by providing access to the latest, most accurate cardiac imaging technology at a lower cost, in an

outpatient setting. Additionally, as there is a limited number of providers of cardiac PET/CT scanning services in PD 20, the proposed project provides access for H&V's existing patients base as well as other cardiologists in the area that anticipate referrals to H&V's proposed service. DCOPN did not identify any other factors 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.**

Not applicable. The applicant is not affiliated with a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

#### **DCOPN Staff Findings and Conclusions**

The population in PD 20 is growing at a slower rate than that of Virginia, but the 65 and older population, which has a higher risk of heart conditions, is growing significantly faster in PD 20 and Virginia Beach than it is across the Commonwealth overall. DCOPN finds Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group's request to establish a center for PET/CT services with one fixed PET/CT scanner limited to cardiovascular imaging in Virginia Beach to be generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. It improves access for the applicant's patients to the preferred and recommended imaging modality for myocardial perfusion and is unlikely to negatively impact existing PET providers. Though an existing provider opposes the proposed project, there is no evidence that approval of COPN Request No. VA-8862 is likely to reduce volumes significantly of existing providers. There is no alternative identified to the proposed project that is less costly, more efficient and more effective than the proposed project. Furthermore, it is more beneficial than the status quo. The proposal is wholly feasible and requires no recruitment or additional staffing beyond the status quo.

#### **DCOPN Staff Recommendation**

The Division of Certificate of Public Need recommends the **conditional approval** of Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group's COPN Request number VA-8862 to establish a center for PET imaging with one PET/CT scanner restricted to cardiovascular imaging, for the following reasons:

1. Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group's proposal is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
2. The proposed project improves access in an area with a relatively fast-growing population over 65.

3. The existing patient base and cardiovascular restriction make it unlikely that the proposal will negatively impact existing providers.
4. There is no alternative identified to the proposed project, and it is more beneficial than the status quo.
5. Projected costs are reasonable, and the proposal is wholly feasible.

DCOPN's recommendation is contingent upon Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group's agreement to the following charity care conditions:

**Recommended Condition**

Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group will provide cardiovascular 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 will facilitate the development and operation of primary medical care services to medically underserved persons in PD 20 in an aggregate amount equal to at least 1.8% of Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group's gross patient revenue derived from PET/CT services. 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. Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group 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.

Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group will provide PET/CT services 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. Advanced Health Care and Wellness, LLC d/b/a Heart & Vascular Group will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.