



COMMONWEALTH of VIRGINIA

Karen Shelton, MD
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

August 15, 2024

Sarah Oliver
1830 Town Center Drive, Suite 405
Reston, VA 20190

RE: **COPN No. VA-04893**
Cardiac Care Associates, PC
Establish a specialized center for cardiac PET/CT imaging

Dear Ms. Oliver:

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 Cardiac Care Associates, PC to establish a specialized center for cardiac PET/CT imaging at Cardiac Care Associates in Reston, Virginia.

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. The proposal to establish a specialized center for PET/CT services at Cardiac Care Associates, PC's Reston office improves access to cardiac PET/CT for its large and growing patient base, which currently does not have access to the standard of care in cardiac imaging, in a fast-growing area of Virginia.
2. The 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, especially as it has been applied to recent cardiac PET projects.
3. The project will be restricted to cardiac PET studies.
4. The project has community support.
5. The HSANV voted to recommend approval of the proposed project.

Ms. Sarah Oliver
Cardiac Care Associates, PC
August 15, 2024
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6. The capital costs of the proposed project are reasonable.
7. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of PET Services in PD 8.
8. The proposed project appears to be financially viable in the immediate and long-term.
9. There is no known opposition to the project.

This certificate is valid for the period August 15, 2024 through August 14, 2025.
The total authorized capital cost of the project is \$1,500,971.

Please file two copies of the application for a certificate extension with the Department and one copy with the regional health planning agency 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,



Karen Shelton, MD
State Health Commissioner

Enclosure

cc: Allyson Tysinger, Senior Assistant Attorney General, Commonwealth of Virginia
Erik Bodin, Director, Division of Certificate of Public Need
Deborah K. Waite, Chief Operating Officer, Virginia Health Information
Gloria Addo-Ayensu, MD, MPH, District Director, Fairfax Health District

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

THIS CERTIFIES THAT Cardiac Care Associates, PC is authorized to initiate the proposal as described below.

NAME OF FACILITY: Cardiac Care Associates

LOCATION: 1830 Town Center Drive, Suite 402, Reston, Virginia 20190

OWNERSHIP AND CONTROL: Cardiac Care Associates, PC

SCOPE OF PROJECT: Establish a specialized center for cardiac PET/CT imaging at Cardiac Care Associates, PC. Capital costs authorized for this project total \$1,500,971. The project is expected to be completed by October 1, 2024. 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-04893

Date of Issuance: August 15, 2024

Expiration Date: August 14, 2025

A handwritten signature in black ink, appearing to read "Karen Shelton".

Karen Shelton, MD, State Health Commissioner

Cardiac Care Associates, PC will provide PET services to all persons in need of this service, 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 8 in an aggregate amount equal to at least 3.5% of Cardiac Care Associates, PC's gross patient revenue derived from PET 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. Cardiac Care Associates, PC will accept the revised charity condition based on 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 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.

Cardiac Care Associates, PC will provide PET 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. Additionally, Cardiac Care Associates, 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.



The Heart of Excellence

Consultative, Preventative, Diagnostic, Interventional, Research and Clinical Cardiology

Bhanu Krishnan, M.D., FACC *Young D. Park, M.D., FACC* *Jonathan E. Yager, M.D., FACC* *Michael R. Banihashemi, M.D., FACC* *Douglas A. Hill, M.D, FACC* *Junsoo A. Lee, M.D., FACC* Dr. Elliot Mahlof, M.D. *

July 22, 2024

Via Electronic Mail (erik.bodin@vdh.virginia.gov)

Mr. Erik O. Bodin, III
Director, Division of Certificate of Public Need
Virginia Department of Health
9960 Mayland Drive, Suite 401
Henrico, Virginia 23233

**Re: COPN Request No. VA-8754
Cardiac Care Associates, PC
Planning District 8
Establish a specialized center for cardiac PET/CT imaging**

Dear Mr. Bodin:

I am writing to you on behalf of Cardiac Care Associates to express our gratitude for the conditional approval of cardiac PET/CT by the Division of Certificate of Public Need ("DCOPN") of Virginia.

We accept DCOPN's recommendation of conditional approval of COPN Request No. VA-8754, including the recommended charity care conditions as set forth in the DCOPN staff report.

Thank you for your review and conditional approval. Please let me know if you need anything further.

Sincerely,



Dr. Young D. Park, MD, FACC
Managing Partner
Cardiac Care Associates

cc: Sharon Honaker, Project Analyst, Division of Certificate of Public Need
Vanessa C. MacLeod, J.D., Office of Adjudication, Virginia Department of Health
Dean Montgomery, Executive Director, Health Systems Agency of Northern Virginia

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

July 19, 2024

COPN Request No. VA-8754

Cardiac Care Associates, PC

Reston, Virginia

Establish a specialized center for cardiac PET/CT imaging

COPN Request No. VA-8758

Woodburn Nuclear Medicine/Metro Region PET Center

Annandale, Virginia

Add one fixed PET/CT scanner

Applicants

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

CCA is a professional stock corporation established in Virginia in 2000, owned by the physicians in the practice. The leased facility is at 1830 Town Center Drive, Suite 402 in Reston, Virginia in Planning District (PD) 8, Health Planning Region (HPR) II.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

Woodburn Nuclear Medicine, LTD (Woodburn) is a corporation formed in 2013 under the laws of the Commonwealth of Virginia. Eric H. Norby, M.D. is the owner of the corporation.

Woodburn operates Woodburn Nuclear Medicine/Metro Region PET Center in a leased facility at 3289 Woodburn Road in Annandale, Virginia. The facility is in Planning District (PD) 8, Health Planning Region (HPR) II.

Background

Positron emission tomography (PET) involves the injection of a small amount of a “positron-emitting” radioactive material (called a radiopharmaceutical). A PET scanner is then used to take images of the body. The PET camera detects emissions coming from the injected radiopharmaceutical, and the integrated computer creates two and three-dimensional images of the area being examined. Areas where the injected radiopharmaceutical gathers (for example, fast-growing cancer cells) appear brighter than normal tissues on the images. Most PET scanners are now combined with a CT scanner so that the PET images can be merged with the CT images to allow examination of the structural information from the CT scan together with the PET’s

functional information. This improves the accuracy of the test.¹ Though PET/CT scanners may take CT scans separate from PET scans, most providers have acknowledged that they don't utilize the CT component in this way, but only take CT scans concurrently with PET scans. Note that, for purposes of this report, PET is the technology under evaluation and mention of the CT component may be omitted.

PET scans can detect cancers, as well as organs that are not working normally, such as areas of the brain affected by Alzheimer's disease. Of particular relevance to CCA's request (VA-8754), PET/CT has emerged as the standard of care for myocardial perfusion, recommended by the Centers for Medicare & Medicaid Services (CMS),² the American Society of Nuclear Cardiology (ASNC) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI).³ Despite single-photon emission computerized tomography (SPECT) being the most used nuclear imaging technique for 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.⁴ This transition from cardiac SPECT has contributed to rapid growth in PET imaging in recent years.⁵

According to the Health Systems Agency of Northern Virginia (HSANV) report that recommended approval of the latest cardiac PET/CT service in PD 8 (COPN No. VA-04882 issued April 15, 2024), most of the PET services in PD 8 were organized, structured and equipped to serve oncology patients.⁶ Such was the case with the applicant WNM (Metro Region PET Center) (COPN Request No. VA-8758). **Table 1** shows utilization of fixed site PET scanners in PD 8, as reported to VHI for 2022, the latest year for which such data are available. None of these PET services in **Table 1** offer PET-based myocardial perfusion, though Carient Heart & Vascular was operational and did not report volumes in 2022. WNM, at 63.4% of the State Medical Facilities Plan (SMFP) threshold of 6,000 procedures per PET scanner, had the highest utilization in PD 8. Including an estimate of Carient's PET volumes, PD 8 fixed PET providers performed an average of 2,504 per scanner in 2022, or 41.7% of the SMFP standard. This PD 8 average is about 10% higher than average utilization of all fixed PET scanners across the Commonwealth (2,282).

In 2019, Carient Heart & Vascular (Carient), a cardiology group in Northern Virginia, opened the first cardiac-only PET service in PD 8, providing access to this service, primarily for its own cardiology patients. Five PET scanners have been authorized since the 2022 VHI reporting period, including a second site for Carient. Four of the five are cardiac-only PET services:

- Kaiser Permanente Woodbridge Imaging Center (COPN No. VA-04700, completed June 2022) is exclusive to Kaiser Health Plan subscribers.

¹ <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/pet-scan>

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

³ <https://www.asnc.org/files/Guidelines%20and%20Quality/PET%20GuidelineASNC%20SNMMI2016.pdf>

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10170052/#:~:text=High%20Resolution&text=PET%20provides%20a%20substantial%20advantage,in%20PET%20vs%20SPECT%20machines.>

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10170052/>

⁶ HSANV Report: Amelia Heart & Vascular Center, COPN Request No. VA-8722, March 6, 2024, p. 4.

- Amelia Heart & Vascular Center (COPN No. VA-04882, expected complete in September 2024) is cardiac-only.
- Carient Heart and Vascular in Vienna (COPN No. VA-04825, completed July 2023) is cardiac-only.
- Nova Cardiovascular Care, Inc. (COPN No. VA-04836, completed August 2023) is cardiac-only.
- Virginia Heart (COPN No. VA-04806, completed August 2023) is cardiac-only.

Table 1. PD 8 COPN Authorized Fixed PET Units and Utilization: 2022

Facility	Number of Scanners	Number of Scans	Utilization
Fairfax PET/CT Imaging Center	1	2,834	47.23%
Metro Region PET Center	1	3,802	63.37%
PET of Reston	1	1,076	17.93%
Virginia Hospital Center	1	1,063	17.72%
PD 8 Total	4	9,335	38.90%

Source: 2022 VHI

Note: Carient Heart & Vascular in Manassas did not report volumes in 2022 but reported 3,185 PET scans in 2021. Using this as its 2022 estimated volumes, PD 8 averaged 2,504 procedures per PET unit.

The current inventory of PET scanners authorized in PD 8 is shown in **Table 2**. There are twelve total sites, each with one PET scanner. Two are mobile and ten are fixed site scanners. The SMFP does not distinguish between PET scanners utilized for cardiac conditions versus other conditions; however, PET providers in PD 8 have developed as either 1) general PET providers that perform few if any cardiac PET procedures, or 2) PET providers restricted to cardiac PET imaging. Five of the ten authorized fixed site PET services in PD 8 are now cardiac-only, each owned by a cardiology group and each providing PET imaging primarily to (or prioritizing) that cardiology group’s established patients.

Table 2. PD 8 COPN Authorized PET Services

Facility	Total Authorized Scanners	Authorized Fixed-Site Scanners	Authorized Mobile Sites	Cardiac Only
Amelia Heart & Vascular Center	1	1	0	1
Carient Heart & Vascular (Ashton Avenue, Manassas)	1	1	0	1
Carient Heart & Vascular (Church Street NE, Vienna)	1	1	0	1
Inova Reston MRI Center (Inova Center for Personalized Health)	1	1	0	0
Kaiser Permanente Woodbridge Imaging Center	1	1	0	0
Metro Region PET Center	1	1	0	0
Nova Cardiovascular Care, Inc.	1	1	0	1
UVA Cancer Center - Gainesville	1	0	1	0
PET of Reston	1	1	0	0
Sentara Northern Virginia Medical Center	1	0	1	0
Virginia Heart	1	1	0	1
Virginia Hospital Center	1	1	0	0
PD 8 Total	12	10	2	5

Source: DCOPN Records

Proposed Project

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

CCA proposes to establish a specialized center for PET/CT at 1830 Town Center Drive, Suite 402 in Reston, Virginia, one of its five locations serving the Fairfax and Loudoun County areas, primarily to serve its own cardiac patients. CCA currently offers electrocardiograms (ECG), SPECT imaging, echocardiograms (EKGs), sleep studies and cardiac catheterization procedures at this location. The lead-shielded camera room and an adjoining control room will be constructed in 800 square feet situated within the existing office. The Siemens Biograph Horizon PET/CT equipment will be leased from a nationwide provider specializing in cardiac imaging services, CDL Nuclear Technologies, LLC. Projected capital costs of the proposed project are \$1,500,971 (**Table 3**). CCA will meet its lease obligations utilizing operating revenues. Should the proposed project be approved, the target date to become operational is October 1, 2024.

Table 3: Cardiac Care Associates, PC Capital Costs, Establish PET/CT Center

Direct Construction Costs	\$250,000
Equipment Not Included in Construction Contract	\$704,000
Site Acquisition Costs	\$528,971.00
Architectural and Engineering Fees	\$18,000
Other Consulting Fees	\$0
Total Capital Costs	\$1,500,971

Source: COPN Request No. VA-8754

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)
WNM proposes to add a second PET/CT scanner at its existing site at 3289 Woodburn Road in Annandale, Virginia, asserting that its scanner is “fully utilized and has a workload of what would typically be for two scanners.” Projected capital costs of the proposed project are \$1,137,150 (**Table 4**). Construction costs of the project will be funded with the landlord’s Tenant Improvement allowance and WNM’s cash reserves. Equipment will be funded with accumulated reserves. Should the proposed project be approved, the target date to become operational is November 1, 2024.

Table 4: Woodburn Nuclear Medicine, Capital Costs Add PET/CT

Direct Construction Costs	\$250,000
Equipment Not Included in Construction Contract	\$850,000
Site Acquisition Costs	\$0.00
Architectural and Engineering Fees	\$22,150
Other Consulting Fees	\$15,000
Total Capital Costs	\$1,137,150

Source: COPN Request No. VA-8758

Project Definition

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

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...”

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

Section 32.1 of the Code of Virginia defines a project, in part as, “The addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of... positron emission tomographic (PET) scanning... A medical care facility includes “[a]ny specialized center or clinic or that portion of a physician's office developed for the provision of ...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 service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.**

PD 8 is a large and fast-growing area of Virginia, estimated to grow to 2.8 million people, adding nearly 280,000 people between 2020 and 2030. This projected growth rate of 10.9% for PD 8 in the current decade is nearly twice the growth rate projected for Virginia at 5.8% (Table 5). Reston and Annandale, where the two competing PET/CT proposals are located, are both in Fairfax County. Fairfax County makes up about 42% of PD 8’s population (Figure 2). It is projected that there will be over 51,000 more people in Fairfax County in 2030 versus 2020, including about 36,500 additional people over age 65 (Table 5 & Figure 3).

Table 5. Population by Locality, PD 8

Locality	2020 Population	2030 Projected Population	Projected Growth 2020-2030	Percent Growth 2020-2030	65+ 2020 Population	Projected 65+ 2030 Population	Projected Growth 65+	Percent Growth 65+
Arlington Co.	238,643	265,794	27,151	11.4%	25,333	28,501	3,168	12.5%
Fairfax Co.	1,150,309	1,201,420	51,111	4.4%	158,687	195,132	36,445	23.0%
Loudoun Co.	420,959	522,015	101,056	24.0%	41,497	65,844	24,347	58.7%
Prince William Co.	482,204	554,344	72,140	15.0%	50,522	76,112	25,590	50.7%
Alexandria City	159,467	176,403	16,936	10.6%	18,758	22,941	4,183	22.3%
Fairfax City	24,146	25,358	1,212	5.0%	3,871	4,726	855	22.1%
Falls Church City	14,658	16,741	2,083	14.2%	2,185	2,545	360	16.5%
Manassas City	42,772	47,039	4,267	10.0%	4,505	6,593	2,088	46.4%
Manassas Park City	17,219	19,876	2,657	15.4%	1,343	2,162	819	61.0%
PD 8	2,550,377	2,828,990	278,613	10.9%	306,701	404,555	97,854	31.9%
<i>Virginia, Statewide</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>

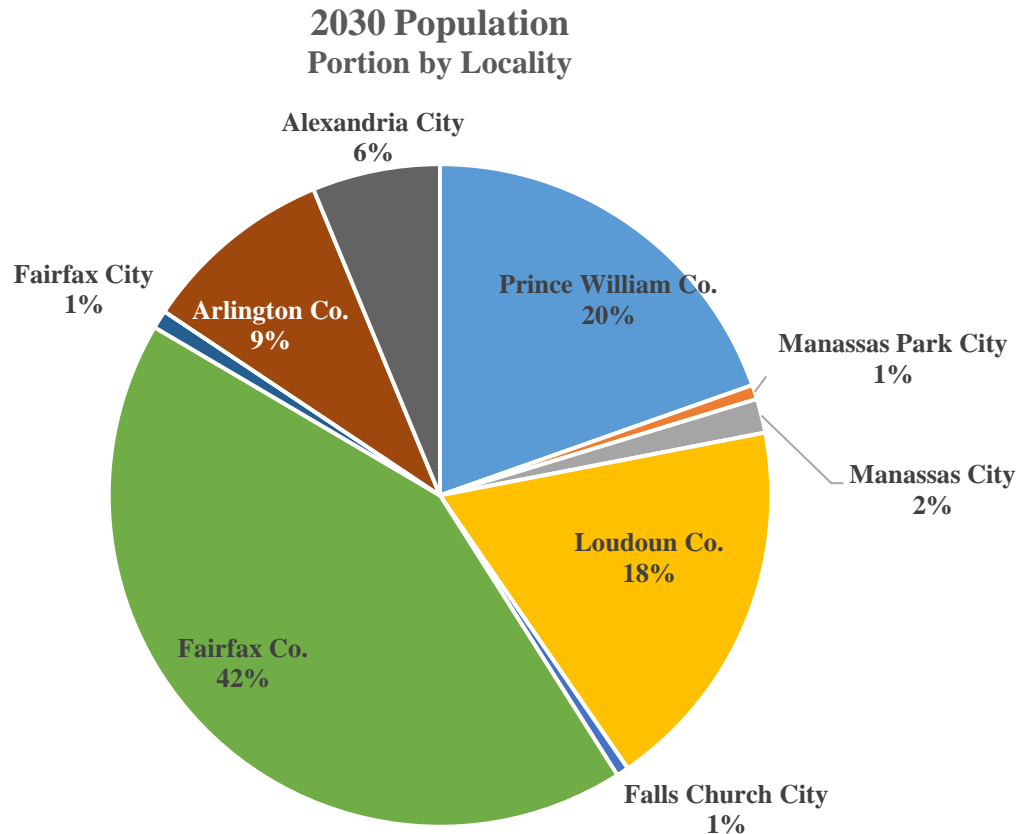
Sourced from United States Census Bureau at <https://data.census.gov/> and Weldon Cooper Center for Public Service, August 2023.

Figure 1. Map of PD 8 Localities



Incidence of heart disease increases with age⁷ as does that of cancer,⁸ so the older population is an important segment to examine when assessing PET. The number of people over 65 is expected to grow by nearly 98,000 people in PD 8 between 2020 and 2030, through in-migration and aging. This is 32% growth, compared to Virginia’s projected growth of 26.3% for the 65+ segment during the same period (**Table 4**). The growth rate in Fairfax County for the 65 and older population is 23%, lower than that of the state (**Table 5 & Figure 3**).

Figure 2. Portion of PD 8 Projected 2030 Population by Locality

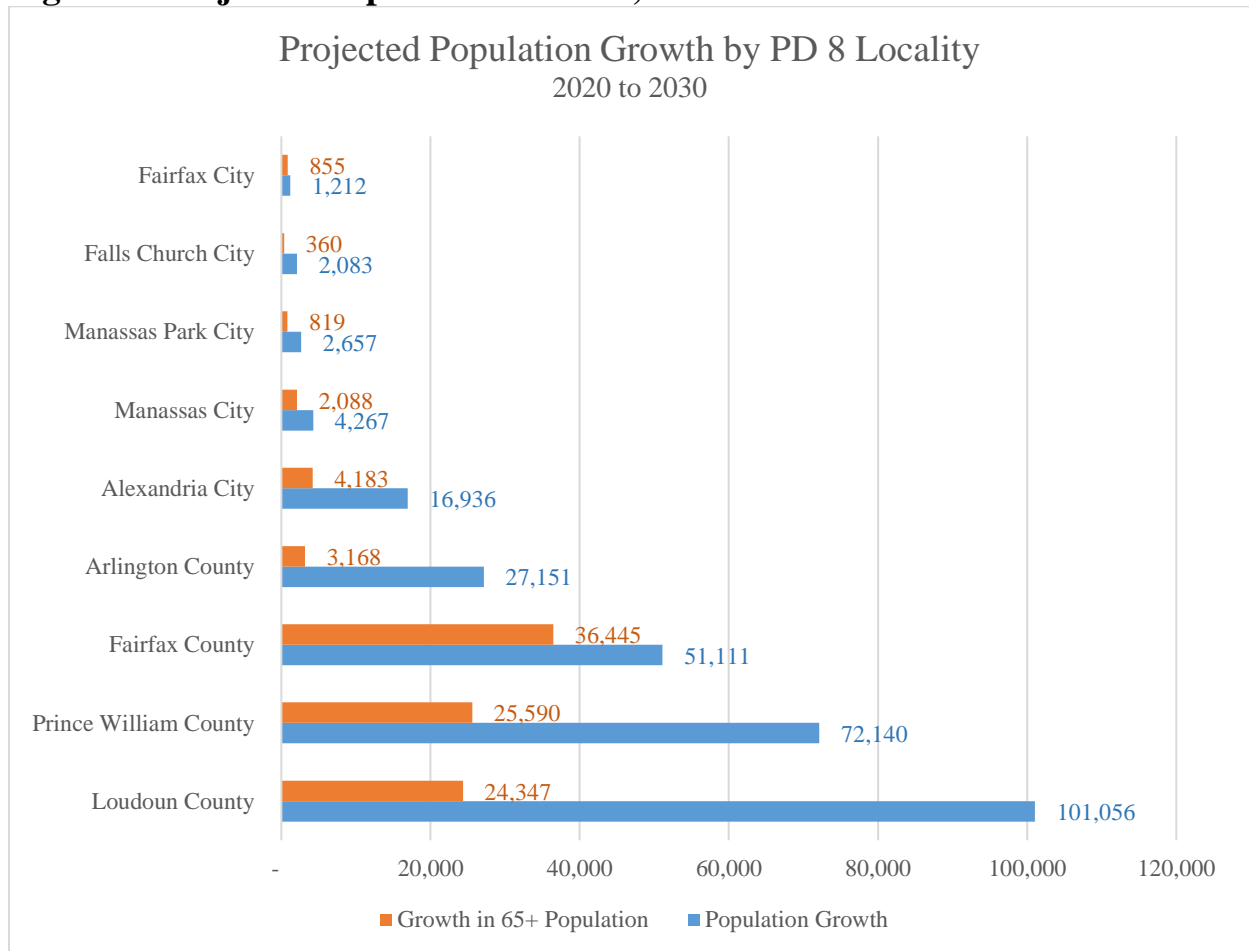


Sourced from United States Census Bureau at <https://data.census.gov/> and Weldon Cooper Center for Public Service, August 2023.

⁷ <https://www.cdc.gov/nchs/hs/topics/heart-disease-prevalence.htm#:~:text=In%202019%2C%20the%20prevalence%20of,adults%20aged%2075%20and%20over.>

⁸ <https://www.cancer.gov/about-cancer/causes-prevention/risk/age#:~:text=Age%20and%20Cancer%20Risk,-Advancing%20age%20is&text=The%20incidence%20rates%20for%20cancer,groups%2060%20years%20and%20older.>

Figure 3. Projected Population Growth, PD 8 Localities



Sourced from United States Census Bureau at <https://data.census.gov/> and Weldon Cooper Center for Public Service, August 2023.

Poverty rates in PD 8 are lower in each locality than that of Virginia, indicating relatively less socio-economic barriers to address.

Table 5. 2022 Poverty Rates, PD 8

Locality	% in Poverty
Arlington County	6.8%
Fairfax County	5.9%
Loudoun County	3.8%
Prince William County	6.9%
Alexandria city	9.0%
Fairfax city	7.6%
Falls Church city	4.1%
Manassas city	9.1%
Manassas Park city	8.9%
PD 8	6.1%
Virginia	10.6%

Source: US Census Bureau, Small Area Income and Poverty Estimates

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

The CCA office is accessible through private and public transportation, off Fairfax County Parkway (Highway 286). Fairfax Connector Service offers public transportation via routes 552 and 950 with stops at the Town Center Parkway and the Town Center Drive intersection located just 0.2 miles away. An additional stop in front of Reston Hospital Center is 0.02 miles to the CCA office.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

WNM is one mile from Dunn Loring Metro station and a quarter mile from the Gallows Road exit of the Capital Beltway. In addition, WNM has offered free transportation to patients who do not have access to transportation to the facility for the past ten years. It is located close to several oncology offices and research facilities that refer patients to WNM.

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

(i) The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served.

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

DCOPN received a physician statement from the president of Cardiac Care Associates, PC and five letters of support, all from physicians in PD 8. There were ten physician signatures on the letters, one from an existing provider of cardiac PET/CT. These letters, in aggregate, expressed the following:

- Cardiac Care Associates, PC is a full-service cardiology practice with seven board certified cardiologists and two additional cardiologists to join the practice in the fall.
- The practice has served Fairfax and Loudoun Counties since 1986.

- The practice has been using SPECT studies for over 25 years, conducting about 2500 SPECT studies per year.
- Cardiac Care Associates has a commitment to provide the highest quality cardiovascular care using the best, proven technology.
- The need for accurate, non-invasive evaluation of patients with potentially life-threatening heart conditions remains high.
- The addition of cardiac PET/CT is in line with CCA's mission.
- Cardiac PET/CT has significant benefits over SPECT.
- The superior quality of PET/CT imaging has led to fewer "false positives" and a reduction in cardiac catheterizations.
- Images can be obtained faster with PET, and with less radiation exposure, leading to higher patient satisfaction.
- Image quality is high with PET/CT even in patients with very high BMI or advanced pulmonary disease.
- The addition of cardiac PET/CT will significantly benefit the practice's patients.
- Many surgical patients require pre-operative cardiac risk assessment.
- There are currently no locations in Reston that offer Cardiac PET/CT.
- This service is not readily available to patients at any other facility in close proximity.
- Hopefully this service will allow (internists) to co-manage heart disease within the community.
- With congestion in the Northern Virginia area, distance is a barrier to care, especially for elderly and mobility limited patients.
- The innovative and cost-effective technology proposed will be a great benefit to patients.

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. The Health Services Agency of Northern Virginia (HSANV) held its board of directors meeting Monday, June 17, 2024, which included public hearings for COPN Request Nos. VA-8754 and VA-8758.

Young Park, MD and Sarah Oliver, NP from CCA presented key elements of CCA's proposal to establish a cardiac PET/CT service in Reston, Virginia. Some considerations emphasized were:

- Cardiac PET/CT is now the standard of care for myocardial perfusion studies in coronary artery disease diagnosis, monitoring and treatment planning.
- Cardiac/PET's greater sensitivity and specificity, compared with alternative imaging modalities such as SPECT, permits greater diagnostic certainty, reducing the number of false positive and false negative tests and avoiding the consequences of those errors.
- Cardiac/PET scans require less than half the time of a SPECT study and entail far less radiation exposure.

- CCA is a large and growing cardiology practice serving thousands of coronary artery disease patients in eastern Loudoun and western Fairfax counties. Many, perhaps most of these patients would be better served with PET imaging rather than SPECT scans.
- The service would be established by contracting with CDL Nuclear Technologies, a national PET imaging vendor. Contracting with a national vendor such as CDL is the most practical and cost-effective way to offer the service at CCA.
- CCA expects about 40% of its patients would receive cardiac PET scans rather than SPECT scans were the service available on site.

DCOPN provided notice to the public regarding these projects inviting public comment on May 10, 2024. The public comment period closed on June 24, 2024. Other than the letters of support referenced above, no members of the public commented. There is no known opposition to the project.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)
DCOPN received physician statements from WNM's owner, Dr. Norby as well as letters from three physicians at WNM, and four letters of support from specialists that utilize WNM for PET services. These letters, in aggregate, expressed the following:

- Physicians at WNM have been in practice from 17 to 33 years.
- WNM was established in 1992 and acquired its first PET scanner in 1999.
- WNM was the first entity in Virginia to Provide PET and the first fully independent PET provider in the U.S.
- WNM's services have markedly improved the quality of medical care.
- Physicians at WNM have provided nuclear medicine training to radiology residents at George Washington University.
- WNM has excellent communications with local physicians.
- It is actively participating in clinical trials by providing PET scans for the management of lung cancer as well as treatment of Alzheimer's disease.
- A rigorous quality assurance preserves high quality of services.
- WNM physicians accommodate patients regardless of difficult circumstances or their ability to pay.
- WNM's special relationship with their patients and their physicians is built on providing the most accessible service possible.
- WNM provides door to door transportation to those unable to travel on their own.
- The dedication of WNM employees is extraordinary.
- WNM is quite accommodating allowing for dialogue and discussion about clinical concerns to help in complex decision making.
- WNM's PET/CT schedule has been stretched due to increasing PET/CT referrals and scheduling restraints associated with the growing array of PET agents.
- Over the past two decades cancer therapies are directly linked to the patient's response to a PET scan to risk stratify further therapies.
- Outcomes of curability are directly linked to therapies that are heavily dependent on a quality PET scan.

- Specialists (cancer research institute, ENT surgeons, endocrinologists) continually received top-quality reports and imaging and have been able to schedule patients in a reasonable timeframe; over the past several months, however, this has become more difficult.
- Without reservation, WNM offers the highest quality PET scans in Northern Virginia.
- I (oncologist) preferentially choose WNM when I have particularly challenging cases.
- Access to WNM has become more difficult s demand for PET/CT imaging has increased for oncology, dementia, and cardiac imaging.
- There are sometimes significant delays in getting patients imaged and this further delays oncologists' ability to treat patients, some of whom require prompt intervention.
- An additional PET scanner would serve patients as physicians make treatment decisions.
- Many patients are enrolled in clinical trials and have a very small window in which imaging must be performed, or they will be disqualified from the trial.
- A second PET/CT scanner will provide more timely imaging for patients.

Public Hearing

The Health Services Agency of Northern Virginia (HSANV) held its board of directors meeting Monday, June 17, 2024, which included public hearings for COPN Request Nos. VA-8754 and VA-8758. Eric Norby, MD introduced Aaron Stack, MD and reviewed the history of WNM in northern Virginia and the Washington metropolitan area and summarized the elements of the application. Some considerations emphasized were:

- After decreasing during the COVID-19 pandemic, WNM's PET service volumes have grown substantially and demand continues to increase.
- WNM is undertaking a larger number of clinical trial studies that require a series of PET scans.
- WNM serves largely oncology and neurology patients and does not offer myocardial perfusion imaging offered by recently authorized cardiac PET/CT services. It has no plans to do so.
- WNM has extended operating hours to weekday evenings and weekends, but scheduling remains challenging.
- With an annual case load of more than 4000 scans and a desire to undertake more clinical trials, WNM needs additional capacity to meet current and expected demand.
- Unused capacity at other oncology-focused PET/CT is not a practical alternative to adding needed capacity at WNM.
- Given its long history and established referral network, adding capacity at WNM is not likely to affect demand at other local PET services.

DCOPN provided notice to the public regarding these projects inviting public comment on May 10, 2024. The public comment period closed on June 24, 2024. Other than the letters of support referenced above, no members of the public commented. There is no known opposition to the project.

(ii) The availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner.

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

The project proposes to establish PET/CT in Reston Virginia at a cardiac care practice that currently offers a spectrum of services including diagnostic testing such as SPECT. The cardiologists seek to offer newer technology which provides higher quality, faster imaging and exposes patients to less radiation when compared to SPECT. Although SPECT is more appropriate for some patients, PET/CT is becoming the standard of care for cardiac imaging. The (unrestricted) PET services in PD 8 do not appear to provide cardiac PET imaging.

Several cardiology practices have sought and have been authorized for cardiac PET services in PD 8 recently because it is the preferred modality for diagnosis and prognosis of CAD. These recently authorized PET scanners, restricted to cardiac use, primarily or exclusively serve patients within the cardiology practices that own them. CCA states that Carient (the first cardiac PET service in the area) prioritizes its own patients and CCA's patients have not been able to access the service from an existing provider. Should CCA's patients have access to the cardiac PET services of existing providers, the status quo may be a reasonable alternative to the proposed project, though less convenient than a service on-site at CCA's office. At present, however, CCA's large established patient base cannot access cardiac PET services within PD 8. The proposed project would provide access to the standard of care for myocardial perfusion for CCA's existing patient base, which is more beneficial than the status quo.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

WNM proposes to add a second PET/CT scanner at its existing facility. WNM has the oldest and most highly utilized PET service in PD 8. In 2022, its volumes were 52% higher than the average in the PD. Physicians referring to WNM for PET services are highly complimentary of its quality and service, but report that patients are waiting significantly longer for PET scans in recent months, delaying essential treatment. WNM's PET demand is from patients referred by area physicians for diagnostics as well as demand in support of clinical research studies in oncology, dementia, and Parkinson's disease. These studies have a small window of time to obtain a PET scan or the patient is no longer eligible for the clinical trial. The proposed project would improve access within a shorter timeframe which is critical for cancer patients and research participants, in particular. The proposal is more beneficial than the status quo.

(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.

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

At its June 17, 2024 meeting, the HSANV, the organization in HPR II designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 8, voted thirteen in favor,

none opposed, with one abstention, to recommend approval of CCA's COPN Request number VA-8754. The HSNV based its recommendation on the HSNV staff report, its review of the request and the following basic findings and conclusions:

- Cardiac Care Associates (CCA), a cardiology medical practice in Reston, Virginia, proposes to establish a PET scanning service dedicated to cardiac PET imaging.
- The proposal is virtually identical with the five services authorized in PD 8 over the last five years.
- Like several similar proposals authorized recently, CCA would develop the service under a lease and operating agreement with a national diagnostic imaging service vendor, CDL Nuclear Technologies of Wexford, Pennsylvania. The project does not entail a significant capital investment by CCA.
- With an onsite cardiac PET imaging option, CCA expects to see reductions in false positive and false negative SPECT scans and in referrals for unnecessary cardiac catheterizations.
- The projected annual service volume, estimated at about 1,680 patients per year in the initial operating years, is attainable from within CCA's patient base.
- Given historical medical trade patterns and regional referral practices, introducing cardiac PET imaging at CCA is unlikely to affect demand or caseloads at other cardiology practices.
- The project is consistent with the diagnostic imaging provisions of the Virginia State Medical Facilities Plan (SMFP) as they have been applied to similar cardiac PET imaging COPN projects.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

HSNV voted fourteen in favor, none opposed, to recommend approval of WNM's COPN Request number VA-8758. The HSNV based its recommendation on the HSNV staff report, its review of the request and the following basic findings and conclusions:

- Woodburn Nuclear Medicine's PET scanning service has high use. Operating hours have been extended to evening and weekend hours. Demand is increasing.
- Woodburn is undertaking an increasing number of clinical trials that entail multiple PET scans. Clinical trial scans now represent more than 5% of its service volume.
- Woodburn needs additional capacity to operate efficiently and to participate in additional clinical trials.
- Adding capacity to meet current service volumes, and to accommodate additional research, is not likely to affect demand or service volumes at other PET services.
- The capital cost of the project is reasonable, within the range reported for similar projects locally and elsewhere in Virginia.

(iv) Any costs and benefits of the project.

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

Total projected capital costs for the proposed project are \$1,500,971. The space and equipment will be leased and financed through operational revenues. The estimated costs are consistent with other recently approved projects to establish PET/CT at an existing site, for example, COPN Nos. VA-04882 at \$1.4 million and VA-04861 at \$3.1 million.

The applicant has described several benefits to the proposed project. It will allow appropriate CCA patients to transition from SPECT imaging to a modality that provides faster scanning with clearer imaging and lower radiation doses. CCA anticipates approximately 52% of its SPECT volumes will transition to PET/CT, allowing patients immediate results which guide decisions on whether the patient may require treatment within the CCA facility. Used appropriately, PET/CT may eliminate the need for surgical intervention and reduce the total cost of care for some patients. Since CCA anticipates providing PET services to its own established patient base, it is unlikely that the proposal would significantly impact any existing providers.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

Total projected capital costs for the proposed project are \$1,137,150. The space renovations will be funded through the landlord's Tenant Improvement Allowance and WNM cash reserves. Equipment will be funded through the applicant's accumulated reserves, so no financing is needed for the proposed project to be implemented. These costs are reasonable and comparable to other recent projects that add a PET/CT scanner at an existing site, such as the projects referenced above (COPN Nos. VA-04882 and VA-04861).

The applicant has described several benefits to its proposal. Though none of the PET services in Virginia surpass the SMFP threshold, WNM is highly utilized compared to other PET scanners, operating at 67% higher utilization than average volumes of PET scanners across Virginia in 2022. This high utilization has caused delays in care for patients. The proposal would shorten waits for patients, some of which require immediate results to plan cancer treatments or to continue participating in clinical trials, for example. The second PET scanner is intended to provide timely access to existing WNM patients and it is unlikely to impact significantly other PD 8 providers of PET services.

(v) The financial accessibility of the project to the residents of the area to be served, including indigent residents.

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

CCA states that it participates in all major insurance plans and Medicare and that it intends to implement a charity care requirement specific to this service. CCA is not required to report charity care to VHI, but inpatient hospitals in HPR II averaged 2.0% charity care as a percentage of gross patient revenue in 2022 (**Table 6**). CCA proffers charity care of 3.5% of gross patient revenue in its proforma (**Table 7**).

In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care based on gross patient revenues derived from PET/CT imaging. Pursuant to 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.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)
 WNM is not required to report charity care to VHI. WNM’s proforma (**Table 8**) shows projected charity care of 0.2% of gross patient revenue.

Table 6: Charity Care, Health Planning Region II

HPR II	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Encompass Health Rehab Hosp of Northern Virginia	\$44,278,869	\$ 1,731,629	3.9%
Sentara Northern Virginia Medical Center	\$944,136,646	\$ 32,219,014	3.4%
Inova Mount Vernon Hospital	\$641,472,447	\$ 17,706,001	2.8%
Inova Alexandria Hospital	\$1,197,261,807	\$ 29,265,924	2.4%
Virginia Hospital Center	\$1,986,450,290	\$ 47,061,276	2.4%
Inova Fairfax Hospital	\$5,214,506,184	\$ 116,268,953	2.2%
Inova Loudoun Hospital	\$1,228,076,373	\$ 24,600,105	2.0%
Inova Fair Oaks Hospital	\$872,902,867	\$ 16,347,102	1.9%
Dominion Hospital	\$171,735,320	\$ 1,891,758	1.1%
Reston Hospital Center	\$1,890,705,104	\$ 16,603,148	0.9%
StoneSprings Hospital Center	\$442,376,284	\$ 3,383,896	0.8%
North Spring Behavioral Healthcare	\$72,918,890	\$ 259,529	0.4%
UVA Health Prince William Medical Center	\$329,053,447	\$ 704,161	0.2%
UVA Health Haymarket Medical Center	\$183,865,488	\$ 174,114	0.1%
Total Inpatient Hospitals:			14
HPR II Total Inpatient \$ & Mean %	\$15,219,740,016	\$ 308,216,610	2.0%

Source: 2022 VHI

In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care based on gross patient revenues derived from PET/CT imaging that is no less than the equivalent average for charity care contributions in HPR II. Pursuant to 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.

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

There are no other factors, not addressed elsewhere in the analysis, relevant to the determination of a public need for either project.

3. The extent to which the application is consistent with the State Medical Facilities 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 State Medical Facilities Plan (SMFP) contains the criteria and standards for PET services. They are as follows:

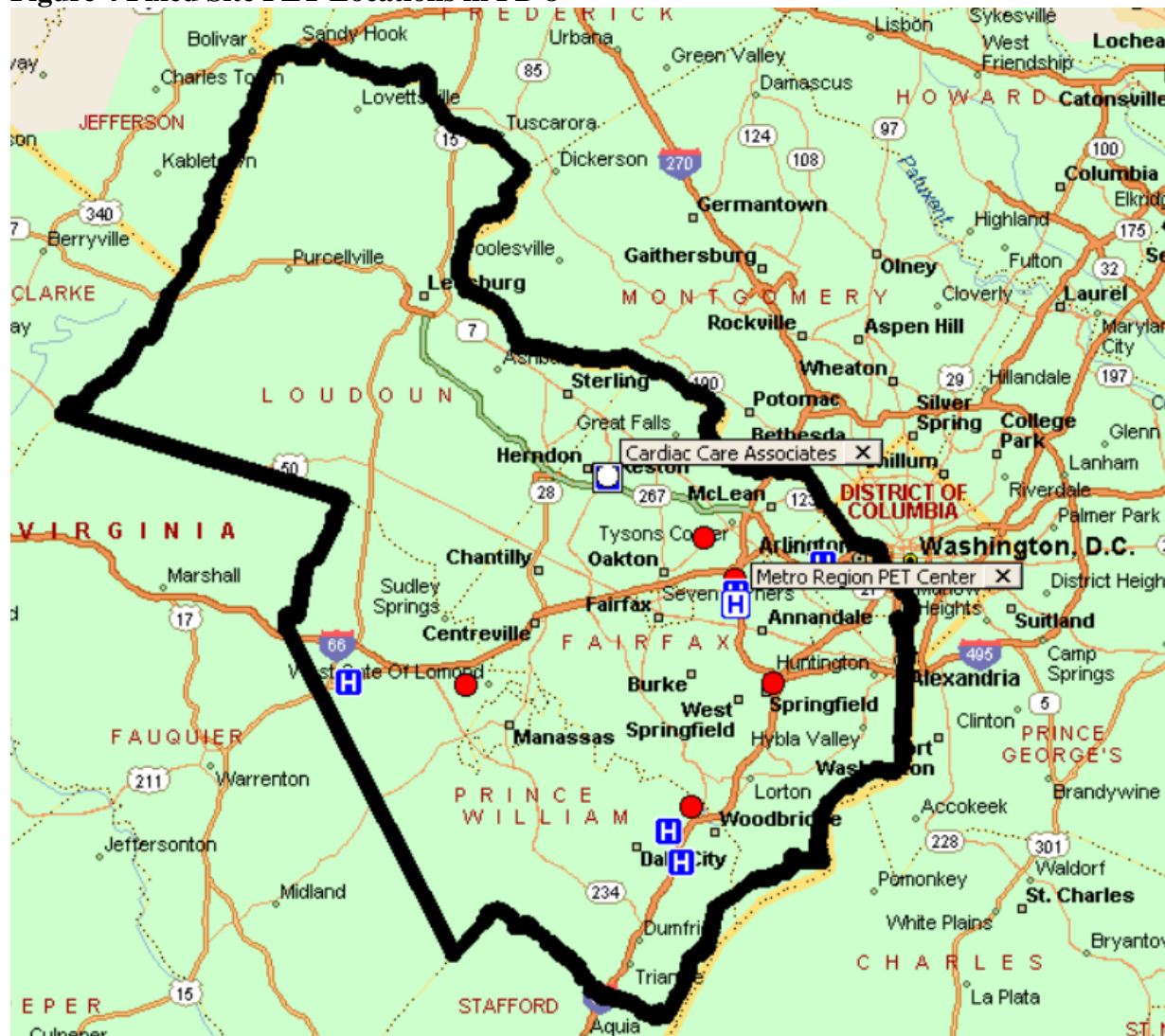
Part II
Diagnostic Imaging Services
Article 4 Criteria and Standards for Positron Emission Tomography

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 4** is the boundary of PD 8. The red dots are the five currently authorized cardiac PET/CT sites and the white dot is the proposed CCA cardiac PET/CT site. The blue “H” symbols mark the locations of existing PET providers in PD 8 that are not restricted to cardiac imaging. The white “H” symbol marks the location of the proposed second PET scanner at WNM. It is important to note that the SMFP does not distinguish between cardiac-specific PET services and all other PET services. The green shaded area includes the area that is within 60 minutes driving time one-way under normal conditions of existing PET services in PD 8. **Figure 4** clearly illustrates that PET services are already well within a 60-minute drive under normal conditions of more than 95% of the residents of PD 8 and approval of either of the proposed projects will not increase geographic access to PET services.

Figure 4 Fixed Site PET Locations in PD 8



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

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

- 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.

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

A. CCA is not a hospital but based on current services offered and the patient base at the practice, 1,680 cardiac PET/CT studies are estimated in year one.

B. Calculated Needed Fixed PET Scanners in PD 8:

According to **Tables 1 & 2:**

Calculated Needed Fixed PET Scanners = 12,520 (2022 fixed PET procedures reported +estimated unreported) ÷ 6,000 = 2.1 (3) scanners needed

2024 COPN authorized fixed PET scanners = 10

(2024 PET Scanners – Calculated Need) = 10 - 3

PD 8 Calculated Surplus = 7 PET scanners

As shown above, there is a calculated surplus of seven PET scanners in PD 8. DCOPN notes that **Table 1** shows no PET services in PD 8 surpassed the SMFP's volume threshold in 2022. In fact, according to VHI data for 2022 no PET scanner in the Commonwealth surpassed the SMFP threshold. The average number of PET procedures performed in 2022 across all fixed PET scanners in the Commonwealth was 2,282. This supports DCOPN's previous acknowledgements that the SMFP's utilization standards for PET/CT services are outdated and that the SMFP did not adequately predict the applications for which PET would be used at the time it was written.

The proposal is unlikely to impact other providers in PD 8 since it anticipates serving the existing patient base of cardiologists at CCA. While the applicant does not meet the computational analysis of this SMFP standard, DCOPN recommends that the Commissioner, in this specific instance, does not allow this standard to bar the establishment of this cardiac PET/CT service to serve an existing patient base currently without access to the standard of care in cardiac imaging.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

WNM is an existing provider of PET that wishes to add a second PET scanner. This section is not applicable.

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.

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

Not applicable. The applicant is not proposing to expand an existing fixed-site PET service, but rather, is proposing to establish a new fixed-site service.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM) PET services in PD 8 did not exceed the SMFP threshold of 6,000; however, this standard has been acknowledged as outdated for current clinical applications of PET technology. The applicant reported the highest utilization of PET services in PD 8 in 2022 and reports PET volumes in 2023 of 4,793 (80% of the SMFP threshold). The proposal is unlikely to impact other providers in PD 8 since it anticipates serving patient demand already coming to WNM for PET/CT services. While the applicant does not meet the computational analysis of this SMFP standard, DCOPN recommends that the Commissioner, in this specific instance, does not allow this standard to bar the addition of needed equipment.

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. Neither applicant is 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.

Both applicants have provided assurances that PET services will be under the supervision of qualified physicians with the necessary training and licensure.

12VAC5-230-80. When institutional expansion needed.

- A. Notwithstanding any other provisions of this chapter, the commissioner may grant approval for the expansion of services at an existing medical care facility in a health planning district with an excess supply of such services when the proposed expansion can be justified on the basis of a facility's need having exceeded its current service capacity to provide such service or on the geographic remoteness of the facility.**
- B. If a facility with an institutional need to expand is part of a health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant. However, underutilized services located at a health**

system's geographically remote facility may be disregarded when determining institutional need for the proposed project.

C. This section is not applicable to nursing facilities pursuant to § 32.1-102.3:2 of the Code of Virginia.

D. Applicants shall not use this section to justify a need to establish new services.

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

Not applicable. The applicant is not proposing to expand an existing fixed-site PET service, but rather, is proposing to establish a new fixed-site service.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

- A. WNM describes demand exceeding its current service capacity. The applicant states it has extended its hours during the week and on weekends to accommodate volumes and experienced a significant increase in payroll costs due to overtime. In their letters of support, referring physicians have cited longer wait times in recent months which impact their ability to diagnose and plan life-saving cancer treatments. The applicant is committed to several clinical research studies that require a series of PET scans conducted within specified timelines. The applicant reports volumes in 2023 at 80% of the SMFP volume threshold for PET, when PET scanners across Virginia average 38% of this threshold.
- B. The facility is not part of a health system
- C. The proposal is not for a nursing facility
- D. The applicant is not justifying the establishment of a new service.

12VAC5-230-60. When competing applications received.

In reviewing competing applications, preference may be given to an applicant who:

- 1. Has an established performance record in completing projects on time and within the authorized operating expenses and capital costs;**
- 2. Has both lower capital costs and operating expenses than his competitors and can demonstrate that his estimates are credible;**
- 3. Can demonstrate a consistent compliance with state licensure and federal certification regulations and a consistent history of few documented complaints, where applicable; or**
- 4. Can demonstrate a commitment to serving his community or service area as evidenced by unreimbursed services to the indigent and providing needed but unprofitable services, taking into account the demands of the particular service area.**

The only relevant information presented by applicants or available for comparison is the charity care estimated in the applicants' proformas. CCA projects charity care at 3.5% of gross patient revenue for PET/CT services and WNM projects 0.2% charity care. In addition, the two applicants do not offer PET/CT services appropriate to each other's patient base.

Required Considerations Continued

- 4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served.**

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

There are five PET/CT scanners authorized in PD 8 that are restricted to cardiac use. Each serves a cardiology practice with an established patient base, as would CCA's, such that little to no competition would result from the proposed project. As CCA's proposal is restricted to cardiac use and WNM does not offer cardiac PET services, the two applications under review have separate patient markets.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

This proposal does not foster institutional competition because it is an expansion based on current patient demand at WNM. Because CCA's proposed project is restricted to cardiac use and WNM does not offer cardiac PET services, the two applications under review have separate patient markets.

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

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

CCA is a physician practice with seven physicians and two advanced care practitioners with specializations in cardiovascular disease, interventional cardiology, peripheral vascular disease and sleep medicine. Two additional physicians will join the practice in the fall of 2024. Its original office was established in Reston, Virginia and it has since added four locations serving Fairfax and Loudoun Counties. Current providers have admitting privileges at four local community hospitals.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

WNM is an independent facility utilized by multiple primary and specialty physicians in the area for high quality imaging services for their patients. It is the preferred facility for PET imaging by several oncologists and it is the oldest PET service in PD 8 with the highest utilization in the PD. WNM's medical staff includes specialists in nuclear and internal medicine and diagnostic radiology.

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

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

Capital costs projected for the proposed project are reasonable and consistent with similar, recently authorized projects. The proforma for the proposed PET/CT service (**Table 7**) anticipates a positive net income over \$3.6 million starting the first year of operations.

Table 7. Proforma Cardiac Care Associates, PC, Establish PET/CT

	Year 1	Year 2
Gross Revenue	\$ 5,552,484	\$ 5,830,108
Charity Care	\$ 194,337	\$ 204,054
Net Revenue	\$ 5,358,147	\$ 5,626,054
Expenses	\$ 1,753,717	\$ 1,816,558
Income/Loss	\$ 3,604,430	\$ 3,809,496

Source: COPN Request No. VA-8754

As a result of contracting with CDL Nuclear Technologies, LLC, CCA anticipates that no additional staff will be needed to operationalize the proposed project.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

Capital costs projected for the proposed project are reasonable and consistent with similar, recently authorized projects. The proforma for the proposed PET/CT service (**Table 8**) anticipates a positive net income of \$3.1 million starting the first year after the addition of the proposed second PET/CT scanner (\$71,610 more than the most recent year of operations with a single PET/CT scanner).

Table 8. Proforma Woodburn Nuclear Medicine, Addition of one PET/CT Scanner

	Year 1	Year 2
Gross Revenue	\$ 44,768,372	\$ 47,056,970
Charity Care	\$ 80,000	\$ 82,000
Other Deductions	\$ 26,762,459	\$ 28,811,115
Net Revenue	\$ 17,925,913	\$ 18,163,855
Expenses	\$ 14,860,839	\$ 15,080,447
Income/Loss	\$ 3,065,074	\$ 3,083,408

Source: COPN Request No. VA-8758

The applicant states that no additional staff is needed to operationalize the proposed project.

- The extent to which the project provides improvements or innovations in the financing and delivery of health 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 services on an outpatient basis. (iii) Any cooperative efforts to meet regional health care needs. (iv) At the discretion of the Commissioner, any other factors as may be appropriate.**

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

Cardiac PET has been found to reduce the overall cost of managing coronary artery disease by as much as 30% over traditional SPECT and CT angiography.⁹ Though there are existing and authorized providers of cardiac PET/CT scanning services in PD 8, PET/CT seems to be available only to cardiac patients whose cardiologists have an authorized service. The proposed project provides access to the latest, more accurate technology for the applicant's patients on an outpatient basis. The applicant does not make any arguments regarding cooperative efforts to meet regional health care needs, though cooperation on the provision of cardiac PET/CT would be beneficial in limiting the number of PET scanners needed in PD 8. DCOPN did not identify any other factors as may be appropriate to bring to the Commissioner's attention.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

The proposed project provides access to PET/CT services on an outpatient basis. The applicant does not make any arguments regarding cooperative efforts to meet regional health care needs, though the provision of cardiac PET/CT would be beneficial in limiting the number of PET scanners needed in PD 8. 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. (ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

The applicants are not teaching hospitals or associated with a public institution of higher education or a medical school in the area to be served. WNM, however, lists seven research studies in the arenas of oncology, dementia, and Parkinson's disease. These require PET imaging within narrow time windows in order for patients to continue participation.

DCOPN Staff Findings and Conclusions

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

DCOPN finds that Cardiac Care Associates' proposed project to establish a specialized center for cardiac PET/CT imaging is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia, especially as applied to recently authorized similar projects. The applicant has stated that the CT functionality of the PET/CT scanner will be used only in conjunction with its PET functionality and that the PET/CT scanner would be used solely for cardiac imaging. While the planning district does not meet the utilization threshold for the establishment of a new service, DCOPN notes that precedent has been established by the Commissioner regarding this threshold not barring the establishment of new PET/CT services when sufficiently compelling circumstances exist. As such compelling

⁹ <https://jnm.snmjournals.org/content/48/7/1069>

reasons exist, such as the unique population of patients the PET/CT will serve, the applicant's commitment to charity care, and the clinical advantages of PET/CT over SPECT, 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.

The proposal would improve access to cardiac PET services in a high-growth area of Virginia. DCOPN finds the proposed project more beneficial than the alternative of the status quo and it is unlikely to have a negative affect on the utilization of existing providers. HSANV voted to recommend approval of the proposed project. The costs of the proposed project are reasonable and the project is wholly feasible. There is no known opposition.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

DCOPN finds that Woodburn Nuclear Medicine/Metro Region PET Center's proposed project to add a PET/CT scanner is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. While the planning district does not meet the utilization threshold for the addition of a PET scanner, DCOPN notes that precedent has been established by the Commissioner regarding this threshold not barring PET/CT projects when sufficiently compelling circumstances exist. As such compelling reasons exist, such as the applicant's high and growing utilization, commitment to research studies supported by PET technology and the proximity and preference of multiple cancer centers that depend on its services for diagnosis, staging and treatment planning without delays, DCOPN recommends that the Commissioner, in this specific instance, not allow this standard to bar expansion of PET/CT services at this location.

The proposal would improve access in a high-growth area of Virginia. DCOPN finds the proposed project more beneficial than the alternative of the status quo and it is unlikely to have a negative impact on the utilization of existing providers. HSANV voted to recommend approval of the proposed project. The costs of the proposed project are reasonable and the project is wholly feasible. There is no known opposition.

DCOPN Staff Recommendations

COPN Request No. VA-8754: Cardiac Care Associates, PC (CCA)

The Division of Certificate of Public Need recommends conditional approval of Cardiac Care Associates, PC's COPN Request number VA-8754 to establish a specialized center for PET/CT services (restricted to cardiac imaging)with one PET/CT scanner located at an existing office space in Reston, Virginia for the following reasons:

1. The proposal to establish a specialized center for PET/CT services at Cardiac Care Associates, PC's Reston office improves access to cardiac PET/CT for its large and growing patient base, which currently does not have access to the standard of care in cardiac imaging, in a fast-growing area of Virginia.
2. The 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, especially as it has been applied to recent cardiac PET projects.

3. The project will be restricted to cardiac PET studies.
4. The project has community support.
5. The HSANV voted to recommend approval of the proposed project.
6. The capital costs of the proposed project are reasonable.
7. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of PET Services in PD 8.
8. The proposed project appears to be financially viable in the immediate and long-term.
9. There is no known opposition to the project.

DCOPN's recommendation is contingent upon Cardiac Care Associates, PC's agreement to the following charity care condition:

Cardiac Care Associates, PC will provide PET services to all persons in need of this service, 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 8 in an aggregate amount equal to at least 3.5% of Cardiac Care Associates, PC's gross patient revenue derived from PET 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. Cardiac Care Associates, PC will accept the revised charity condition based on 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 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.

Cardiac Care Associates, PC will provide PET 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. Additionally, Cardiac Care Associates, 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.

COPN Request No. VA-8758: Woodburn Nuclear Medicine/Metro Region PET Center (WNM)

The Division of Certificate of Public Need recommends conditional approval of Woodburn Nuclear Medicine/Metro Region PET Center's COPN Request number VA-8758 to expand its PET/CT service with one PET/CT scanner located at its outpatient facility Annandale, Virginia for the following reasons:

1. The proposal to expand PET/CT services at Woodburn Nuclear Medicine/Metro Region PET Center with the addition of one PET/CT scanner improves access to PET/CT for its patient base in a fast-growing area of Virginia.
2. The proposal to expand PET/CT imaging at Woodburn Nuclear Medicine/Metro Region PET Center's is consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
3. The applicant has demonstrated high utilization and the need for additional capacity to meet demand for PET services.
4. The capital costs of the proposed project are reasonable.
5. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of PET services in PD 8.
6. The proposed project appears to be financially viable in the immediate and long-term.
7. HSANV recommended approval of the proposed project.
8. There is no known opposition to the project.

DCOPN's recommendation is contingent upon Woodburn Nuclear Medicine/Metro Region PET Center's agreement to the following charity care condition:

Woodburn Nuclear Medicine/Metro Region PET Center will provide PET services to all persons in need of this service, 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 8 in an aggregate amount equal to at least 2.0% of Woodburn Nuclear Medicine/Metro Region PET Center's gross patient revenue derived from PET 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. Woodburn Nuclear Medicine/Metro Region PET Center will accept the revised charity condition based on 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 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.

Woodburn Nuclear Medicine/Metro Region PET Center will provide PET 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. Additionally, Woodburn Nuclear Medicine/Metro Region PET Center

will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.