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

Staff Analysis

January 21, 2025

COPN Request No. VA-8782
The Cardiovascular Group, PC d/b/a Virginia Heart
Leesburg, Virginia
Establish a Center for PET/CT services with one fixed PET/CT scanner limited to cardiology

COPN Request No. VA-8783
Inova Reston MRI Center, LLC
Centreville, Virginia
Introduce PET/CT imaging in an existing medical care facility

Applicants

COPN Request No. VA-8782: Virginia Heart

The Cardiovascular Group, PC (Virginia Heart) is a Virginia stock corporation. No shareholder has an ownership interest of 5% or more in Virginia Heart. Virginia Heart owns 9.041% of Virginia Cardiac Network, LLC. Virginia Heart is located in Falls Church, Virginia and proposes to establish a center for PET/CT services in Leesburg, Virginia. Both localities are in Planning District (PD) 8, Health Planning Region (HPR) II.

COPN Request No. VA-8783: IRMC

Inova Reston MRI Center, LLC (IRMC) is a Virginia limited liability company jointly owned by Inova Health Care Services, the majority member, and Fairfax Radiological Consultants, PLLC, the minority member. The applicant has no subsidiaries. Inova Reston MRI Center, LLC does business as Centreville MRI and PET Center in Centreville, Virginia, which is located in Planning District (PD) 8, within Health Planning Region (HPR) II.

Background

As explained by the applicant for COPN Request No. VA-8783:

> A positron emission tomography (PET) scan is a type of nuclear medicine imaging test. It is used to examine various body tissues to identify certain conditions by looking at blood flow, metabolism, and oxygen use. PET scans may also be used to see how well the treatment of certain diseases works. For a PET scan, a tiny amount of a radioactive substance, called a radioactive tracer, is used to show the metabolism of a particular organ or tissue. This test gives the healthcare provider information about the function and structure of the organ or

> tissue. It also gives information about its biochemical properties. A PET scan may detect biochemical changes in an organ or tissue that are signs of a disease process before physical changes related to the disease can be seen with other imaging tests. PET scans are often combined with CT scans (called a PET/CT scan) to give more definitive information about metabolism changes and exactly where they are happening in the body. A PET/CT scan produces a highly detailed three-dimensional image of functional processes in the body. It creates these intricate images using X-rays of cross-sections, or "slices," of the body. This process provides for earlier and more accurate detection of diseases. A PET/CT scan is frequently ordered and used for the detection, staging and follow up treatment of cancer and to monitor the effectiveness of cancer treatment. It also is used to plan medical, surgical or radiation treatment. In addition, PET/CT scans may be used to assess a person's risk of heart disease or detect damage to blood vessels in the form of aneurysms or blockages.

With regard to cardiac PET/CT, 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 preferred test for patients who meet appropriate criteria for a stress imaging test and who require pharmacologic stress.[1]

According to DCOPN records, PD 8 has 14 authorized PET services – 12 fixed site scanners and two mobile sites. Six of the 14 authorized fixed site PET services in PD 8 are cardiac-only, each owned by a cardiology group and each providing PET imaging primarily to (or prioritizing) that cardiology group's patients.

[1] Bateman et.al. *American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET*. 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).

Table 1. PD 8 COPN Authorized PET Services

Facility	Total Authorized Scanners	Authorized Fixed-Site Scanners	Authorized Mobile Sites	Cardiac Only
Amelia Heart and Vascular Center	1	1	0	1
Cardiac Care Associates	1	1	0	1
Carient Heart & Vascular (Ashton Avenue)	1	1	0	1
Carient Heart & Vascular (Church Street NE)	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	2	2	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	**14**	**12**	**2**	**6**

Source: DCOPN Records

DCOPN records show that there are currently 79 COPN Authorized Computed Tomography (CT) scanners in PD 8 (**Table 2**).

Table 2. PD 8 COPN Authorized Fixed CT Units

Facility	# of Scanners
Centreville-Clifton Imaging Center - Fairfax Radiology	1
Chantilly ER[2]	1
Fair Oaks Imaging Center	1
Fairfax Diagnostic Imaging Center	1
Fairfax ENT & Plastic Surgery Center	1
Fairfax MRI and Imaging Center at Tysons	1
Fairfax Radiology Center at Prosperity	2
Fairfax Radiology Center of Reston-Herndon	1
Fairfax Radiology Center of Springfield[3]	1
Fairfax Radiology Center at Woodburn	2
Inova Alexandria Hospital[4]	4
Inova Ashburn Healthplex	1
Inova Emergency Room of Fairfax City	1
Inova Fair Oaks Hospital	3
Inova Fairfax Hospital	7

[2] COPN No. VA-04900 authorized Northern Virginia Hospital, LLC to establish CT services with one CT unit at Chantilly ER.
[3] COPN No. VA-04878 authorized IFRC, LLC to establish CT services with one CT unit at Fairfax Radiology Center of Springfield. The project is expected to be completed by October 1, 2024.
[4] COPN No. VA-04793, issued July 7, 2022, authorized the addition of one fixed CT scanner at the relocated Inova Alexandria Hospital (Landmark).

Facility	# of Scanners
Inova Health Center – Woodbridge[5]	1
Inova HealthPlex - Franconia/Springfield	1
Inova Imaging Center – Leesburg	1
Inova Imaging Center-Mark Center	1
Inova Lorton HealthPlex	1
Inova Loudoun Hospital	3
Inova Mount Vernon Hospital	2
Inova Oakville Ambulatory Center in the City of Alexandria	1
Inova Springfield Hospital[6]	1
Kaiser Permanente - Reston Medical Center	1
Kaiser Permanente - Tysons Corner Imaging Center	2
Kaiser Permanente - Woodbridge Imaging Center	1
Leesburg Emergency and Imaging Center[7]	1
Loudoun Medical Group, P.C.	1
Metropolitan ENT & Facial Plastic Surgery	1
Orthopaedic Foot and Ankle Center	1
Radiology Imaging Associates at Lansdowne	1
Radiology Imaging Associates at Sterling	1
Rayus Radiology - Arlington (formerly known as Insight Imaging - Arlington)	1
Rayus Radiology - Fairfax	1
Rayus Radiology - Woodbridge[8]	1
Reston Hospital Center	4
Sentara Advanced Imaging Center - Alexandria	1
Sentara Lake Ridge Ambulatory Care Center	1
Sentara Northern Virginia Medical Center	2
Sentara Northern Virginia Medical Center - Century Medical Office Building	1
StoneSprings Hospital Center	2
Tysons Corner Emergency Center	1
Tysons Corner Diagnostic Imaging	1
UVA Outpatient Imaging – Gainesville[9]	1
UVA Outpatient Imaging - Centreville	1
UVA Health Haymarket Medical Center	1
UVA Health Prince William Medical Center	2
VHC Emergency & Imaging Center[10]	1

[5] COPN No. VA-04896 authorized IFRC, LLC to establish CT services with one CT unit at Inova Health Center – Woodbridge.
[6] COPN No. VA-04832 authorized the relocation and replacement of Inova Alexandria, including the addition of one CT scanner.
[7] COPN No. VA-04863 authorized Reston Hospital Center, LLC to establish a specialized center for CT imaging, Leesburg Emergency and Imaging Center. The project is expected to be completed by November 30, 2025.
[8] COPN No. VA-04879 authorized Insight Health Corporation to establish CT services with one CT unit at Rayus Radiology – Woodbridge. The project is expected to be completed by October 31, 2024.
[9] COPN No. VA-04906 authorized UVA Outpatient Imaging Centreville, LLC to establish a specialized center for the provision of CT services with one CT unit. The project is expected to be completed by April 30, 2026.
[10] COPN No. VA-04775 authorized VHC to establish a specialized center for CT imaging at VHC Emergency and Imaging Center with one CT scanner. VHC Emergency and Imaging Center is expected to open in the fourth quarter of 2024.

Facility	# of Scanners
VHC Health Outpatient Imaging Center[11]	1
Virginia Hospital Center	4
Washington Radiology Associates	1
Woodburn Nuclear Medicine/Metro Region PET	1
Total	**79**

Source: DCOPN records

COPN Request No. VA-8782: Virginia Heart

The applicant proposes to establish PET/CT services at its existing cardiology office at 19450 Deerfield Avenue, Suite 100, Leesburg, Virginia. In addition to the PET/CT function, the applicant also seeks COPN authorization to use the CT for the limited purpose of stand-alone cardiac calcium scoring. As explained at the Health System Agency of Northern Virginia's (HSANV) December 16, 2024 Board of Directors meeting, "[c]alcium scoring to assess cardiovascular risk entails using the CT component of the PET-CT system independent of the PET element but is inherent in diagnostic protocols and does not entail a separate charge or billable event." The applicant explains that space within the suite will be renovated to accommodate the Cardiovascular PET/CT unit.

The total capital costs of the proposed project are $3,816,902 of which approximately 19% represents direct construction costs (**Table 3**). The applicant states that the proposed project will be funded through a combination of income from operations and commercial loans. The applicant explains that the cost of the leasehold improvements, $724,576, will be funded through commercial loans and the remainder, $3,092,326, will be funded from operations.

Table 3. Virginia Heart Capital Costs

Direct Construction Costs	$724,576
Equipment Not Included in Construction Contract	$2,433,469
Site Acquisition Cost	$588,621
Architectural and Engineering Fees	$50,000
Taxes During Construction	$20,236
Total	**$3,816,902**

Source: COPN Request No. VA-8782

Construction for the proposed project is expected to begin two months after COPN approval, and to be completed four months after COPN approval. The applicant anticipates an opening date in the September 2025.

COPN Request No. VA-8783: IRMC

IRMC proposes to introduce PET/CT services with one PET/CT unit at its existing medical care facility located at 6211 Centreville Road, Centreville, Virginia (Centreville Location). The Centreville Location currently offers CT and magnetic resonance imaging (MRI), as well as non-COPN regulated services such as X-ray, ultrasound, mammography and DEXA. The applicant has

[11] COPN No. VA-04880 authorized Virginia Hospital Center Arlington Health System d/b/a VHC Health to establish a specialized center for CT and MRI with one CT unit and one MRI unit. The project is expected to be completed by June 16, 2025.

provided assurances that the CT portion of the requested PET/CT unit will not be used independently and will only be used for attenuation correction.

The total capital costs of the proposed project are $5,193,991, of which approximately 23% represents direct construction costs (**Table 4**). The applicant states that the renovation and build-out costs associated with the proposed project will be funded from a bank line of credit. The PET/CT equipment will be leased from the vendor pursuant to a capital lease whereby, at the end of the lease term, IRMC will own the PET/CT unit.

Table 4. IRMC Capital Costs

Direct Construction Costs	$1,025,704
Equipment Not Included in Construction Contract	$3,131,937
Site Acquisition Cost	$976,350
Architectural and Engineering Fees	$60,000
Taxes During Construction	$0
Total	**$5,193,991**

Source: COPN Request No. VA-8783

Construction for the proposed project is expected to begin on October 1, 2025, and to be completed on March 15, 2026. The applicant anticipates an opening date of April 1, 2026.

Project Definitions

COPN Request No. VA-8782: Virginia Heart

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-8783: IRMC

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "[t]he 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…"

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;**

According to regional and statewide data regularly collected by Virginia Health Information (VHI), for 2022, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 1.9% of all reported total gross patient revenues (**Table 5**).

Table 5. HPR II Charity Care Contributions: 2022

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
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	2.7%
Inova Alexandria Hospital	$1,197,261,807	$29,265,924	2.4%
Virginia Hospital Center	$1,986,450,290	$47,061,276	2.3%
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	1.8%
Dominion Hospital	$171,735,320	$1,891,758	1.1%
Reston Hospital Center	$1,890,705,104	$16,603,148	0.8%
StoneSprings Hospital Center	$442,376,284	$3,383,896	0.7%
North Spring Behavioral Healthcare	$72,918,890	$259,529	0.3%
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 Inpatient Hospital Median			1.9%
HPR II Total Inpatient $ & Mean %	$15,219,740,016	$308,216,610	2.0%
Lake Ridge Ambulatory Surgical Center	$12,134,108	$210,500	1.7%
Stone Springs Ambulatory Surgery Center	$3,999,113	$59,669	1.5%
Northern Virginia Eye Surgery Center, LLC	$14,479,800	$63,197	0.4%
Haymarket Surgery Center	$51,205,003	$50,954	0.1%
Northern Virginia Surgery Center	$59,865,180	$47,316	0.1%
Reston Surgery Center	$140,221,295	$58,510	0.0%
Prince William Ambulatory Surgery Center	$50,752,301	$4,623	0.0%
Fairfax Surgical Center	$141,540,392	$209	0.0%
HealthQare Services ASC, LLC	$8,526,020	$0	0.0%
Inova Ambulatory Surgery Center at Lorton	$1,977,872	$0	0.0%
Inova Loudoun Ambulatory Surgery Center	$86,732,059	$0	0.0%
Inova Surgery Center @ Franconia-Springfield	$86,936,077	$0	0.0%
Kaiser Permanente Caton Hill Ambulatory Surgery Center	$10,357,476	$0	0.0%
Kaiser Permanente Tysons Corner Surgery Center	$55,063,020	$0	0.0%
McLean Ambulatory Surgery Center	$38,502,416	$0	0.0%
Pediatric Specialists of Virginia Ambulatory Surgery Center	$9,138,277	$0	0.0%
VHC Ambulatory Surgery Center	Not Open until Nov 2022	$-	--
Total Outpatient Hospitals:			16
HPR II Outpatient Hospital Median			0.0%
HPR II Total Outpatient Hospital $ & Mean %	$771,430,409	$494,978	**0.1%**
Total Hospitals:			30
HPR II Total Hospital $ & Mean %	$15,991,170,425	$308,711,588	**1.9%**

Source: VHI (2022)

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 6**). The population over age 65 is projected to grow faster than the overall population, about 32%, in PD 8 during the same decade, compared with 26.3% across Virginia (**Table 6**).

Table 6. 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 County	238,643	265,794	27,151	11.4%	25,333	28,501	3,168	12.5%
Fairfax County	1,150,309	1,201,420	51,111	4.4%	158,687	195,132	36,445	23.0%
Loudoun County	420,959	522,015	101,056	24.0%	41,497	65,844	24,347	58.7%
Prince William County	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	46.3%
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%**
Virginia	**8,631,393**	**9,129,002**	**497,609**	**5.8%**	**1,395,291**	**1,762,641**	**367,350**	**26.3%**

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

COPN Request No. VA-8782: Virginia Heart

Geographically, the proposed facility will be located at 19459 Deerfield Avenue, Suite 100, Leesburg, Virginia, just off State Route 901/Route 7 interchange and approximately five miles from U.S. Route 15. Loudoun County Transit has a public bus stop at Inova Loudoun Hospital on its Route 70 bus, which is directly across the street from the proposed location.

Regarding socioeconomic barriers to access to the applicant's services, according to regional and statewide data regularly collected by VHI, for 2022, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 1.9% of all reported total gross patient revenues (**Table 5)**. Accordingly, should the Commissioner approve the proposed project, Virginia Heart should be subject to a charity care condition no less than the 1.9% HPR II average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

DCOPN is not aware of any other distinct and unique geographic, socioeconomic, cultural, transportation, or other barriers to care that this project would address.

COPN Request No. VA-8783: IRMC

Geographically, Chantilly ER will be located at 6211 Centreville Road, Centreville, Virginia. The proposed site is located approximately one mile southeast of Interstate – 66 with easy access to Route 28/Centreville Road. Centreville Road is a major thoroughfare in the area. The proposed site is also accessible via public transportation, with stops within walking distance of the facility.

Regarding socioeconomic barriers to access to the applicant's services, pursuant to § 32.1-102.4B of the Code of Virginia DCOPN must now place a charity care condition on every applicant seeking a COPN. DCOPN notes that the applicant is part of the Inova Health System, and should the Commissioner approve the proposed project, it would be subject to the 3.9% system-wide charity care condition currently in place.

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;

COPN Request No. VA-8782: Virginia Heart
DCOPN received five letters of support for the proposed project, which addressed:

- Inova and Virginia Heart are aligned in mission, vision and values, which emphasizes our commitment to providing excellent patient care.
- Virginia Heart is a nationally recognized provider of cardiovascular care and has been serving the community of Northern Virginia for over 40 years.
- The population is Northern Virginia is growing and aging. With an aging population comes an increase in cardiovascular diseases.
- Traditional SPECT imaging does not give accurate diagnoses to people with larger body types.
- Cardiac PET/CT services are the best way to diagnose and identify these at-risk populations, and provide equitable, timely, and accurate care that reduces the need for downstream testing and reduces costs.
- A PET/CT scanner at Virginia Heart in Loudoun would be an appropriate step to increase geographic accessibility to this well-established technology and elevate the quality of care.
- In the past 10 years, PET/CT imaging has been discussed as a means of improving quality and reducing unnecessary procedures for cardiac patients. Noninvasive imaging is an important tool for our members as they diagnose patients with potential life-threatening cardiac issues.
- The benefits of cardiac PET/CT include:
    - Less radiation exposure for the patient compared to SPECT imaging.

- Greater patient satisfaction as scanning time is significantly reduced. Many patients are elderly and have trouble with keeping their arms raised above their heads, lying flat, etc. It can be very painful. PET/CT reduces the amount of time and patients appreciate it.

- Improved images, especially for patients with a high BMI, large breasts, who cannot walk on a treadmill, etc. The improved sensitivity results in more patients being identified for treatment that might otherwise go undetected. Greater Specificity means fewer patients will be referred for cardiac catheterization.

- The increased use of the technology to determine myocardial blood flow allows the cardiologist to determine if a coronary occlusion would benefit from an intervention. Essentially a noninvasive equivalent to FFR in the catheterization lab, myocardial blood flow provides the opportunity to avoid a cardiac catheterization that would have resulted in no intervention.

DCOPN did not receive any letters in opposition to the proposed project.

Public Hearing
DCOPN provided notice to the public regarding these projects on November 8, 2024. The public comment period closed on December 23, 2024. On December 16, 2024, HSANV held a public hearing for the project. Virginia Heart's project was presented by Audrey Fisher, CEO of Virginia Heart, Ibrahim Saeed, MD and Peter Mellette, Counsel for Virginia Heart. There was no public comment regarding the project.

COPN Request No. VA-8783: IRMC
DCOPN received three letters of support for the proposed project, which addressed:

- The value of PET/CT imaging in the detection, staging and management of care for cancer patients cannot be overstated. It is the most advanced diagnostic tool available for this population.

- Availability of timely appointments is paramount. The current PET/CT at the Schar Center is fully utilized which has the potential to delay care for patients.

- Creating more capacity via the introduction of PET/CT services at another site in the Northern Virginia region is needed to avoid delays in care.

- The proposed diagnostic imaging services location will offer improved access to patients in the western part of PD 8.

- The PET/CT will include the most up-to-date capabilities, including deep learning artificial intelligence, enhanced features for patient comfort, enhanced image quality, and reduced scan times.

DCOPN did not receive any letters in opposition to the proposed project.

Public Hearing
DCOPN provided notice to the public regarding these projects on November 8, 2024. The public comment period closed on December 23, 2024. On December 16, 2024, HSANV held a public hearing for the project. IRMC's project was presented by Elizabeth Breen, counsel for IRMC, Lance Boyd, CEO of Fairfax Radiology Centers and Patrick Oliverio, MD. There was no public comment regarding the project.

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

COPN Request No. VA-8782: Virginia Heart
DCOPN did not identify any reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner. Moreover, the proposed project is a preferable alternative to the status quo. Virginia Heart seeks 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 applicant provided the comparison of SPECT to PET/CT in **Figure 1** below.

Figure 1: Comparison of SPECT and PET/CT

	SPECT	PET	PET/CT
Radiation Exposure	Moderate	**Low**	**Low**
Anatomical Accuracy	Low	Moderate	**Excellent**
Image Quality	Suboptimal	Better	**Optimal**
Spatial Resolution	Fair	Better	**Optimal**
Quantitative Estimate of Blood Flow	N/A	**Yes**	**Yes**
Diagnostic Accuracy	Good	Better	**Optimal**
Quality in High BMI or Central Obesity	Poor	Good	**Optimal**
Calcium Scoring for Early Detection	N/A	N/A	**Yes**
Prognostic Value of Normal Results	Good	Very Good	**Excellent**

Source: COPN Request No. VA-8782

As discussed in detail throughout this staff analysis report, cardiac PET/CT imaging offers several important advantages over SPECT. The American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging have issued a joint Society Position Statement "to highlight the attributes that make rest/stress myocardial perfusion PET both **Preferred** and **Recommended** in the era of high value initiative for appropriate patients." [12]. According to this Society Position Statement, "[m]yocardial perfusion PET image quality, high

[12] 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 March 5, 2024).

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."[13]

With regard to the request to use the CT portion of the proposed PET/CT unit for calcium scoring (not for diagnostic CT services), the applicant explains the importance of this procedure:

> The combination of measuring myocardial blood flow reserve (part of the Cardiovascular PET data) and coronary calcium score by CT provides valuable information regarding the necessity for cardiac catheterization after the Cardiovascular PET/CT study. The calcium score in conjunction with blood flow results can help decide which patients do not need catheterization, and this cannot be determined by blood flow data alone. Additionally, the ability to assess cardiovascular risk by standalone calcium scoring via CT is an important component of diagnosing cardiovascular disease and stroke risk. Virginia Heart seeks COPN authorization to use the CT for the limited purpose of stand-alone cardiac calcium scoring.

Furthermore, the applicant proposes to use the PET/CT unit to serve its existing patient population. Therefore, DCOPN concludes that the proposed project is unlikely to adversely affect the utilization and efficiency of existing services.

COPN Request No. VA-8783: IRMC

Neither DCOPN nor the applicant identified a reasonable alternative to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner. The applicant reports that the PET/CT unit is needed to address capacity constraints within its current practice. The schedule at IRMC's Fairfax facility has been expanded and has reached capacity. The PET/CT unit at the Fairfax facility operates Monday through Friday from 7 a.m. to 6:30 p.m. The applicant explains that it is not possible to further extend the hours of operation because of the limited shelf life of the isotope. The applicant states:

> It is not possible to further extend the hours of operation per day because of the limited shelf life of the isotope and the inability to access radiopharmaceuticals after the last dose arrives at 2 PM each day. The radioactive isotope that has a limited shelf life (3 hours) before the PET/CT scan can be performed. The pharmacy delivers the last dose at 2 PM with a window of 3 hours after which the isotope is no longer usable. Nor is there a consistent radiopharmaceutical delivery schedule available on weekends.

With regard to current wait times, the applicant says:

> Due to the nature of the patient population who utilizes these services, who tend to be very sick, there are frequent cancellations and/or no shows due to worsening illness, hospitalizations or because the patient's blood sugar requirements are not 9 adequate at

[13] Id.

> the time of the appointment. Patients waiting for PET/CT services at Fairfax are waiting approximately 2 1/2 weeks. It is disheartening to have to tell a patient sick with cancer that they must wait two to three weeks to get their cancer staged so their oncologist/radiation oncologist can design the appropriate treatment plan.

If the proposed project is approved, IRMC will offer appointments on the fixed site unit Monday through Friday from 7 a.m. to 6:30 p.m. For these reasons, DCOPN concludes that the proposed project is more favorable 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;

HSANV considered the proposed projects at its December 16, 2024 meeting.

COPN Request No. VA-8782: Virginia Heart

At its December 16, 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 10 in favor, none opposed, to recommend approval of Virginia Heart's COPN Request number VA-8782. The HSANV based its recommendation on its review of the application, on the HSANV staff report on the proposal, on the information presented at the December 16, 2024, public hearing and Board of Directors meeting, and on several basic findings and conclusions, including:

1. The cardiac PET service in Cardiovascular Group's Falls Church office (Telestar Court) is operating at capacity. It is unable to accommodate many referrals from within the practice.
2. Virginia Heart has a large patient base that is generating more than 170,000 patient visits annually. There is sufficient demand within the Virginia Heart patient based to support multiple cardiac PET imaging systems.
3. Adding a second cardiac PET service at its Lansdowne (Loudoun County) office would improve access to care and convenience within Virginia Heart.
4. PET-CT scanning is the preferred diagnostic imaging option for many patients with coronary artery disease. Demand for cardiac PET imaging is increasing regionwide.
5. Projected capital costs are reasonable, within the capital expenditure range seen for similar projects.
6. There is no private equity economic involvement in the project or within Virginia Heart.
7. There is no indication that the project would affect any other service negatively.
8. The project is consistent with applicable provisions of the Virginia SMFP as it has been applied to similar projects in recent years.

COPN Request No. VA-8783: IRMC

At its December 16, 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 10 in favor, none opposed, to recommend approval of IRMC's COPN Request number VA-8783. The HSANV based its recommendation on its review of the application, on the HSANV staff report

on the proposal, on the information presented at the December 16, 2024, public hearing and Board of Directors meeting, and on several basic findings and conclusions, including:

1. The PET service in Inova Reston MRI Center's central Fairfax office (Innovation Drive) is operating at capacity. It is unable to accommodate service requests from within its patient base.
2. IRMC has a large primary service area and patient base. There is sufficient demand within the IRMCs patient based to support multiple PET imaging systems.
3. Adding a second cardiac PET service at its Centreville (southwest Fairfax County) office would improve access to care and convenience among IRMC patients.
4. PET-CT scanning is the preferred diagnostic imaging option for an increasing number of clinical applications and larger numbers of patients. Demand for PET imaging of all types is increasing regionwide.
5. Projected capital costs are reasonable, within the capital expenditure range seen for similar projects.
6. There is no private equity economic involvement in the project or within IRMC.
7. There is no indication that the project would affect any other service negatively.
8. The project is consistent with applicable provisions of the Virginia SMFP as it has been applied to similar projects in recent years.

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

COPN Request No. VA-8782: Virginia Heart

As demonstrated by **Table 3**, the projected capital costs of the proposed project are $3,816,902, approximately 19% of which are attributed to direct construction costs. As previously discussed, the applicant states that the proposed project will be funded through a combination of income from operations and commercial loans. The applicant explains that the cost of the leasehold improvements, $724,576, will be funded through commercial loans and the remainder, $3,092,326, will be funded from operations. DCOPN concludes that when compared to similar projects, these costs are reasonable. For example, COPN No. VA-04874 issued to University of Virginia Medical Center to establish a specialized center for PET/CT with one PET/CT unit is anticipated to cost approximately $4,000,000.

The applicant identified numerous benefits of the proposed project, including:

- Cardiovascular PET/CT offers patients the access to "preferred" and the "recommended" myocardial perfusion imaging (MPI) test.

- The Deerfield Avenue office location in Leesburg for the second PET/CT will enhance Virginia Heart patient access to needed MPI tests, making those tests more accessible to more patients located in Western PD 8.

- Given that Virginia Heart has 12 locations throughout Northern Virginia, provides over 170,000+ patient encounters a year, and has maximized capacity on its current PET/CT scanner in the Telestar Court office location in Falls Church, the additional capacity will

enable Virginia Heart to better meet the demand of its approximately 170,000+ patient encounters.

- Myocardial Perfusion Imaging (MPI) is used in standard clinical practice for non-invasive imaging of the heart for the characterization of a variety of cardiac conditions and has been extensively reported upon in scientific literature. While Single Photon Emission Computed Tomography (SPECT) imaging has been the long-standing modality used for MPI, Cardiovascular PET/CT is a newer yet well-established technique that is superior to standard SPECT.

- Cardiovascular PET/CT has demonstrated several technical advantages over SPECT that account for improved image quality and diagnostic ability.

- As the space is already controlled and utilized by Virginia Heart, there will be no acquisition or additional lease costs associated with establishing this new service.

- The combination of Cardiovascular PET with CT provides the patient with the most accurate study, which is significantly better than PET cameras without CT because CT provides a more rapid study with a high-quality attenuation map. The study with CT is several minutes shorter. Shorter scan times result in less motion and improved diagnostic accuracy, thereby avoiding unnecessary cardiac catheterizations.

- The CT also allows for an assessment of coronary calcium simultaneously with the cardiac PET study. The presence or absence of calcium in a patient's coronary arteries can be easily determined with no additional radiation exposure or time. This information is very important in treating patients, especially those with no known diagnosis of CAD.

- The combination of measuring myocardial blood flow reserve (part of the Cardiovascular PET data) and coronary calcium score by CT provides valuable information regarding the necessity for cardiac catheterization after the Cardiovascular PET/CT study. The calcium score in conjunction with blood flow results can help decide which patients do not need catheterization, and this cannot be determined by blood flow data alone.

- Virginia Heart does not foresee a reduction in utilization of existing fixed site PET/CT services within PD 8. As other providers serve a distinct patient population and given the large population of the Northern Virginia area, no reduction in services is anticipated. Given the size of Virginia Heart's patient population and service area, Virginia Heart's additional Cardiovascular PET/CT scanner is expected to be fully utilized within 1-2 years.

COPN Request No. VA-8783: IRMC

As demonstrated by **Table 4**, the projected capital costs of the proposed project are $$5,193,991, of which approximately 23% represents direct construction costs. As previously discussed, the applicant states that the renovation and build-out costs associated with the proposed project will be funded from a bank line of credit. The PET/CT equipment will be leased from the vendor pursuant to a capital lease whereby, at the end of the lease term, IRMC will own the PET/CT unit. DCOPN concludes that when compared to similar projects, these costs are reasonable. For example,

COPN No. VA-04739 issued to Inova Reston MRI Center LLC to establish a specialized center for PET/CT imaging with one PET/CT unit is anticipated to cost approximately $5,011,046 and COPN No. VA-04908 issued to Sentara Hospitals d/b/a Sentara Norfolk General Hospital wo introduce PET/CT services with one PET/CT unit is anticipated to cost approximately $5,432,498.

The applicant identified numerous benefits of the proposed project, including:

- Physicians refer to IRMC because they recognize that their patients will have the highest quality interpretation of studies performed by board-certified, fellowship-trained radiologists who are subspecialized within areas of expertise. This has resulted in the need for additional institutional capacity to ensure patients can be scheduled and have their studies performed in a timely manner.

- Currently, IRMC has only one (1) PET/CT unit located at 8081 Innovation Park Drive in Fairfax. This existing PET/CT unit is very busy, performing 3,893 PET/CT procedures in 2023. Based on actual PET/CT procedure volume through August 2024, IRMC expects to perform 4,152 PET/CT procedures at its Fairfax facility in 2024 – a 6.7% increase over 2023 volume.

- The introduction of fixed PET/CT services at the Centreville Facility is needed to address capacity constraints on IRMC's Fairfax PET/CT unit. The schedule at the Fairfax facility has been expanded and is maximized at 20 appointments per day, Monday through Friday. However, due to the nature of the patient population who utilizes these services, who tend to be very sick, there are frequent cancellations and/or no shows due to worsening illness, hospitalizations or because the patient's blood sugar requirements are not 9 adequate at the time of the appointment. Notwithstanding these cancellations and no shows, patients waiting for PET/CT services at Fairfax are waiting approximately 2 1/2 weeks. It is disheartening to have to tell a patient sick with cancer that they must wait two to three weeks to get their cancer staged so their oncologist/radiation oncologist can design the appropriate treatment plan.

- Introducing fixed PET/CT services at the Centreville Facility will help to reduce the backlog and improve the patient experience through greater efficiency and reduced wait times. This will improve access to services for IRMC's PET/CT patient population as PET/CT is often used for restaging patients suspected of having a recurrence after curative therapy so the shorter the wait, the better.

- Placing the proposed PET/CT unit at the Centreville Facility will improve geographic access to PET/CT services for IRMC's patient population, reducing travel times for patients who reside in the western portions of the planning district.

- IRMC has already maximized the number of appointments (twenty (20)) per day on its Fairfax PET/CT unit. It is not possible to further extend the hours of operation per day because of the limited shelf life of the isotope and the inability to access radiopharmaceuticals after the last dose arrives at 2 PM each day. The radioactive isotope

that has a limited shelf life (3 hours) before the PET/CT scan can be performed. The pharmacy delivers the last dose at 2 PM with a window of 3 hours after which the isotope is no longer usable. Nor is there a consistent radiopharmaceutical delivery schedule available on weekends.

- Because the proposed project involves IRMC's own patient base and is proposed to address PET/CT capacity constraints at IRMC's Fairfax facility, IRMC does not expect the expansion of PET/CT services to its Centreville Facility to negatively impact other existing PET/CT providers in PD 8. Moreover, by placing the PET/CT unit in the Centreville Facility, the service will be located in an area of PD 8 with comparatively fewer PET/CT providers.

(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

COPN Request No. VA-8782: Virginia Heart

Virginia Heart asserts that it will provide cardiac PET/CT services to patients regardless of ability to pay or payor source. § 32.1-102.4B of the Code of Virginia requires DCOPN to place a charity care condition on every applicant seeking a COPN. DCOPN notes that, if approved, the proposed project should be subject to a charity care condition no less than the 1.9% HPR II average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 7. Virginia Heart Pro Forma Income Statement

	Year 1	Year 2
Total Gross Patient Revenue	**$3,710,828**	**$4,416,395**
Total Operating Expenses	$2,828,492	$2,913,261
Net Income	**$882,336**	**$1,503,134**

Source: COPN Request No. VA-8782

COPN Request No. VA-8783: IRMC

The Pro Forma Income Statement provided by the applicant indicates that it expects that the proposed project will be subject to Inova's system-wide charity care condition (**Table 8**). As previously discussed, should the Commissioner approve the proposed project, IRMC should be subject to the system-wide charity care condition applicable to Inova Health Care Services d/b/a Inova Heath System pursuant to COPN No. VA-04381 (issued April 2, 2013), as amended by the State Health Commissioner by letter dated January 4, 2016 (the Inova System-Wide Condition). Pursuant to the 2016 reconsideration, the Inova System-Wide Condition reset to 3.9% as of January 1, 2022.

Table 8. IRMC Pro Forma Income Statement

	Year 1	Year 2
Total Gross Patient Revenue	**$17,439,000**	**$22,243,000**
Contractuals/Other Discounts	($9,998,000)	($12,938,000)
Charity Discounts	($217,000)	($271,000)
Net Operating Revenue	**$7,225,000**	**$9,034,000**
Total Operating Expenses	$2,813,000	$3,373,000
Net Income	**$4,412,000**	**$5,661,000**

Source: COPN Request No. VA-8783

(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 SMFP.

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

Part II Article 1
Diagnostic Imaging Services
Criteria and Standards for Computed Tomography

12VAC5-230-90. Travel time.
CT services should be available within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

The CT portion of the requested PET/CT unit will be used for calcium scoring and not for diagnostic CT services. As explained at the Health System Agency of Northern Virginia's (HSANV) December 16, 2024 Board of Directors meeting, "[c]alcium scoring to assess cardiovascular risk entails using the CT component of the PET-CT system independent of the PET element but is inherent in diagnostic protocols and does not entail a separate charge or billable event." Therefore, access to diagnostic CT services will not be affected by approval of the proposed project.

12VAC5-230-100. Need for new fixed site or mobile service.

A. No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing 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 CT scanners in such health planning district.

COPN Request No. VA-8782: Virginia Heart

The CT portion of the requested PET/CT unit will be used for calcium scoring and not for diagnostic CT services. Thus, approval of the proposed project will have no effect on the utilization of diagnostic CT units in PD 8. However, DCOPN includes the information below to present a full picture of the existing CT inventory and diagnostic needs in PD 8.

DCOPN notes that several CT scanners have been added to the PD 8 inventory since the preparation of the VHI data as displayed in **Table 9**. **Table 2** displays the current inventory of CT scanners in PD 8.

As noted in **Table 9** below, in 2022, the utilization of existing CT scanners in the planning district was 129.5% of the 7,400 procedures per scanner necessary to introduce CT scanning services to a new location under this section of the SMFP. Moreover, DCOPN calculates a need for three fixed CT scanners in the planning district.

Calculated Needed Fixed CT Scanners in PD 8

Calculated Needed CT scanners = 603,733 scans in the PD in 2022 / 7,400 scans = 81.59 (82) scanners needed

PD 8 Calculated Need = 82 CT scanners based on 2022 utilization data
2024 COPN authorized CT scanners = 79
PD 8 Calculated Need = 3 CT scanners

Table 9. PD 8 COPN Authorized Fixed CT Units and Utilization: 2022

Facility	# of Scanners	# of Scans	Procedures / Unit	Utilization Rate
Centreville / Clifton Imaging Center	1	8,445	8,445	114.12%
Fair Oaks Imaging Center	1	2,864	2,864	38.70%
Fairfax Diagnostic Imaging Center	1	6,237	6,237	84.28%
Fairfax ENT & Facial Plastic Surgery	1	622	622	8.41%
Fairfax MRI and Imaging Center at Tysons	1	4,224	4,224	57.08%
Fairfax Radiology Center of Reston-Herndon	1	7,096	7,096	95.89%
Fairfax Radiology Center of Sterling	1	5,808	5,808	78.49%
Inova Alexandria Hospital	3	45,955	15,318	207.00%
Inova Ashburn Healthplex	1	8,267	8,267	111.72%
Inova Fair Oaks Hospital	3	40,468	13,489	182.29%
Inova Fairfax Hospital	7	120,057	17,151	231.77%
Inova Emergency Room of Fairfax City	1	4,629	4,629	62.55%

Table 9. PD 8 COPN Authorized Fixed CT Units and Utilization: 2022

Facility	# of Scanners	# of Scans	Procedures / Unit	Utilization Rate
Inova Franconia Springfield HealthPlex	1	16,498	16,498	222.95%
Inova Emergency Room - Leesburg	1	10,402	10,402	140.57%
Inova Lorton HealthPlex	1	8,725	8,725	117.91%
Inova Imaging Center-Mark Center	1	4,953	4,953	66.93%
Inova Loudoun Hospital	2	49,444	24,722	334.08%
Inova Mount Vernon Hospital	2	24,116	12,058	162.95%
Rayus Radiology - Arlington (formerly known as Insight Imaging - Arlington)	1	1,978	1,978	26.73%
Rayus Radiology - Fairfax (formerly known as Insight Imaging - Fairfax / Medical Imaging Center of Fairfax)	1	3,491	3,491	47.18%
Kaiser Permanente - Reston Medical Center	1	6,399	6,399	86.47%
Kaiser Permanente - Woodbridge Imaging Center (AKA Caton Hill Center)[14]	1	3,738	3,738	50.51%
Kaiser Permanente - Woodbridge Medical Center	-	8,259	8,259	111.61%
Kaiser Permanente Tysons Corner[15]	2	19,394	9,697	131.04%
Lakeside @ Loudoun Tech Center 1	1	3,522	3,522	47.59%
Metro Region Pet Center	1	2,763	2,763	37.34%
Orthopaedic Foot and Ankle Center of Washington	1	136	136	1.84%
Prosperity Imaging Center	1	9,151	9,151	123.66%
Radiology Imaging Associates at Lansdowne	1	8,234	8,234	111.27%
Reston Hospital Center	4	33,224	8,306	112.24%
Sentara Advanced Imaging Center - Lake Ridge	1	9,232	9,232	124.76%
Sentara Advanced Imaging Center - Springfield	1	0	0	0.00%
Sentara Northern Virginia Medical Center	3	25,673	8,558	115.64%
Stone Springs Hospital Center	1	8,936	8,936	120.76%
Tysons Corner Diagnostic Imaging	1	911	911	12.31%
Tysons Corner Emergency Room	1	1,160	1,160	15.68%
UVA Health Haymarket Medical Center	1	8,298	8,298	112.14%
UVA Health Prince William Medical Center	2	12,720	6,360	85.95%
UVA Outpatient Imaging Centreville	1	1,306	1,306	17.65%
Virginia Cancer Specialists	1	731	731	9.88%
Virginia Hospital Center	3	52,263	17,421	235.42%
Woodburn Diagnostic Center	2	13,404	6,702	90.57%
Total/Average	**63**	**603,733**	**9,583**	**129.5%**

Source: VHI (2022) and DCOPN records.

[14] VHI data for 2022 contains entries for Kaiser Permanente - Woodbridge Imaging Center (AKA Caton Hill Center) and Kaiser Permanente - Woodbridge Medical Center. In mid-2022, the Kaiser Woodbridge facility relocated to Caton Hill. Therefore, the Kaiser Permanente - Woodbridge Medical Center entry contains utilization for the first part of 2022 and the Kaiser Permanente - Woodbridge Imaging Center (AKA Caton Hill Center) entry contains utilization for the rest of 2022.

[15] VHI data for 2022 reported that Kaiser Permanente - Tyson's Corner had two CT scanners and Kaiser Permanente Tysons Corner Surgery Center had two CT scanners. These entries are duplicative and have been corrected in **Table 9** to reflect the correct inventory of two CT scanners at Kaiser Permanente - Tyson's Corner.

COPN Request No. VA-8783: IRMC

Not applicable. The applicant is not seeking to add a new fixed or mobile CT service. As previously discussed, the applicant has provided assurances that the CT portion of the requested PET/CT unit will not be used independently and will only be used for attenuation correction.

B. Existing CT scanners used solely for simulation with radiation therapy treatment shall be exempt from the utilization criteria of this article when applying for a COPN. In addition, existing CT scanners used solely for simulation with radiation therapy treatment may be disregarded in computing the average utilization of CT scanners in such health planning district.

DCOPN has excluded existing CT scanners used solely for simulation prior to the initiation of radiation therapy from its inventory and average utilization of diagnostic CT scanners in PD 8.

12VAC5-230-110. Expansion of fixed site service.

Proposals to expand an existing medical care facility's CT service through the addition of a CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The commissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.

COPN Request No. VA-8782: Virginia Heart and COPN Request No. VA-8783: IRMC

Not applicable. Neither applicant is seeking to expand CT services.

12VAC5-230-120. Adding or expanding mobile CT services.

A. Proposals for mobile CT scanners shall demonstrate that, for the relevant reporting period, at least 4,800 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing CT providers in the health planning district.

B. Proposals to convert authorized mobile CT scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, at least 6,000 procedures were performed by the mobile CT scanner and that the proposed conversion will not significantly reduce the utilization of existing CT providers in the health planning district.

COPN Request No. VA-8782: Virginia Heart and COPN Request No. VA-8783: IRMC

Not applicable. The applicants do not propose to add or expand mobile CT services or to convert authorized mobile CT scanners to fixed site scanners.

12VAC5-230-130. Staffing.
CT services should be under the direction or supervision of one or more qualified physicians.

COPN Request No. VA-8782: Virginia Heart

The applicant confirmed that CT services would be under the direct supervision of certified and trained radiologists.

COPN Request No. VA-8783: IRMC

Not applicable. The applicant is not seeking to add a new fixed or mobile CT service.

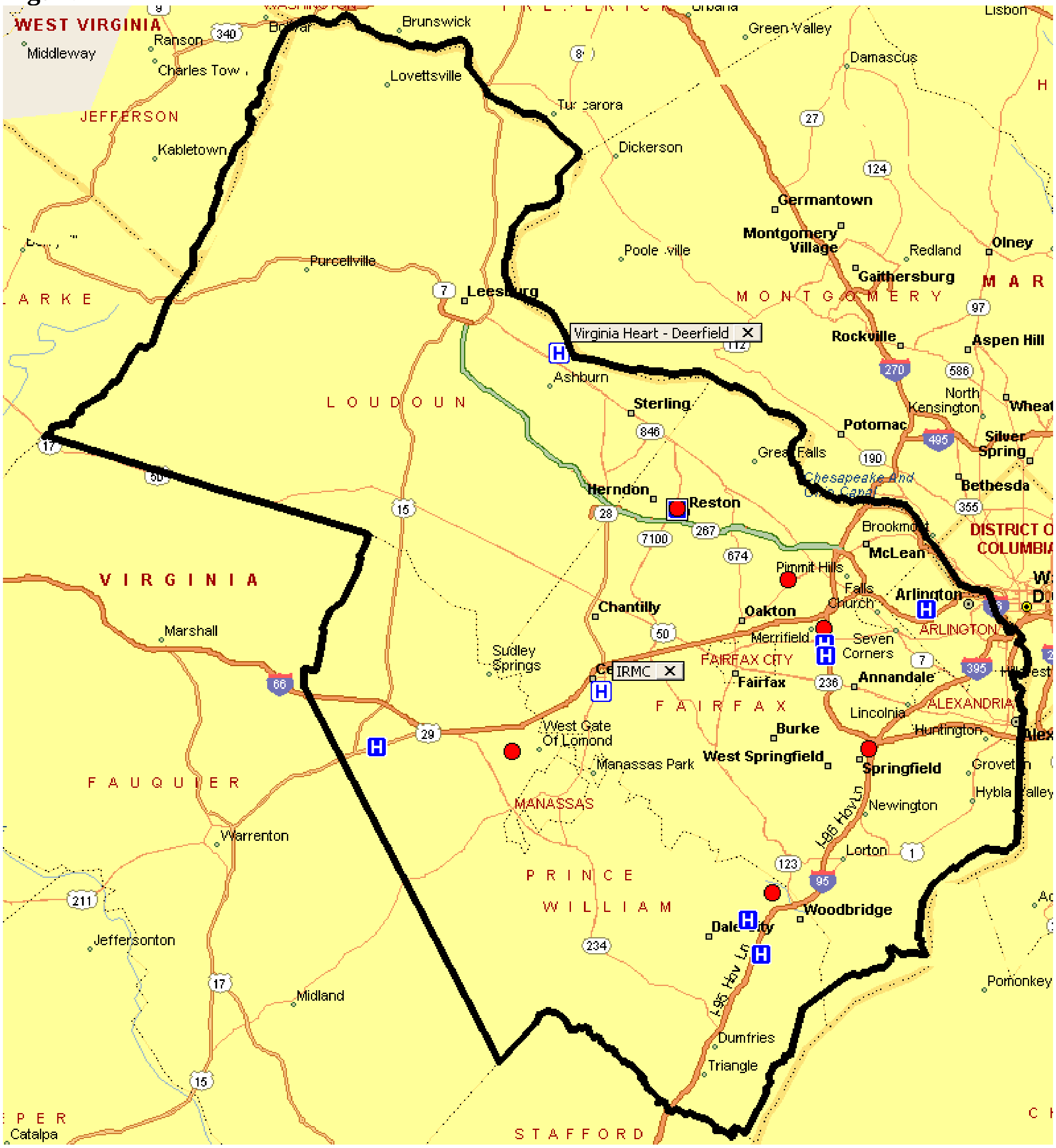
The SMFP also contains criteria/standards for the establishment of PET services. They are as follows:

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 8. The blue "H" symbols mark the locations of existing PET providers in PD 8. The white "H" symbols mark the locations of the proposed projects. The red dots are the six currently authorized cardiac PET/CT sites. It is important to note that the SMFP does not distinguish between cardiac-specific PET services and all other PET services. The yellow 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 2** clearly illustrates that PET services are already well within a 60-minute drive under normal conditions of 95% of the residents of PD 8 and approval of the proposed project will not increase geographic access to PET services.

Figure 2


WEST VIRGINIA
Middleway
Ranson
Brunswick
Green Valley
Damascus
Lovettsville
JEFFERSON
Dickerson
Kabletown
Germantown
Montgomery Village
Redland
Olney
Purcellville
Gaithersburg
M O N T G O M E R Y
Virginia Heart - Deerfield
Rockville
Aspen Hill
Ashburn
L O U D O U N
Sterling
North Kensington
Potomac
Silver Spring
Bethesda
Herndon
Reston
Brookmont
DISTRICT OF COLUMBIA
McLean
V I R G I N I A
Chantilly
Oakton
Arlington
Marshall
Sudley Springs
Merrifield
Seven Corners
ARLINGTON
FAIRFAX CITY
IRMC
Fairfax
Annandale
F A I R F A X
ALEXANDRIA
Lincolnia
West Gate Of Lomond
Burke
Huntington
West Springfield
Springfield
Manassas Park
F A U Q U I E R
MANASSAS
Newington
Hybla Valley
Warrenton
Lorton
P R I N C E
W I L L I A M
Woodbridge
Jeffersonton
Pomonkey
Midland
Dumfries
Triangle
Catalpa
S T A F F O R D

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.

DCOPN notes that several PET/CT scanners have been added to the PD 8 inventory since the preparation of the VHI data as displayed in **Table 10**, such as Amelia Heart and Vascular Center, Cardiac Care Associates, Carient Heart and Vascular, Nova Cardiovascular Care, Inc., and Virginia Heart. DCOPN notes that it does not appear that Carient Heart and Vascular reported any PET/CT procedures to VHI for 2022, though it was operational. In 2021, Carient Heart and Vascular reported 3,185 procedures to VHI. Using this number as an estimate of Carient's 2022 PET volumes, PD 8 fixed PET providers performed an average of 2,392 per scanner in 2022, or 39.87% of the SMFP standard, which is slightly higher than the average utilization of all fixed PET scanners across the Commonwealth (2,282) for the same year. Finally, the table below displays only fixed PET/CT units. **Table 1** above displays the current inventory of both mobile and fixed PET/CT scanners in PD 8.

Calculated Needed Fixed PET Scanners in PD 8
2024 COPN authorized fixed PET scanners = 12
Calculated Needed Fixed PET scanners = 11,960 (2022 fixed PET procedures plus estimated unreported) ÷ 6,000 = 1.99 (2) scanners needed
PD 8 Calculated Need = 2 PET scanners
PD 8 Calculated Surplus = 10 PET scanners (2024 PET Scanners (12) – Calculated Need (2))

Table 10. PD 8 COPN Authorized Fixed PET Units and Utilization: 2022

Facility	Number of Scanners	Number of Scans	Utilization
Carient Heart and Vascular	*1*	*3,185*[16]	*53.08%*
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	**5**[17]	**11,960**	**39.87%**

Source: VHI (2022 & 2021)

COPN Request No. VA-8782: Virginia Heart

The SMFP does not distinguish between cardiac PET and PET used for other clinical uses. As shown above, there is a calculated surplus of 10 PET scanners in PD 8. DCOPN notes, as shown in **Table 10**, no PET services in PD 8 surpassed the SMFP's volume threshold in 2022. In fact, according to VHI data for 2022, the average number of PET procedures performed across all PET providers in the entire Commonwealth was 2,282.

DCOPN has previously acknowledged 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:

> Consistency with SMFP planning guidance in this case is, in effect, an academic exercise. The assumptions underlying the service volume standards, for example, have been superseded by technological developments (e.g., shorter average scan times) and the failure to identify additional clinical applications for the technology. Moreover, none of the existing services met fully the SMFP review criteria and standards when they obtained COPN authorization. (Source: Health Systems Agency of Norther Virginia Staff Report RE: COPN Request No. VA-8327, November 28, 2017).

More recently, in its November 29, 2022 report for COPN Request No. VA-8626, the HSANV observed "[i]t is evident that there is a wholesale shift underway from SPECT to PET-CT imaging as the preferred imaging modality in cardiovascular care…." and "[c]ardiac PET imaging in Northern Virginia has developed separately from other PET imaging services. This may not be desirable but is an operational reality that must be acknowledged…." and "[u]ntil recently Northern Virginia PET services have been organized, structured and equipped to serve oncology patients. Few cardiac patients are referred for PET scans. Metro Region PET, the region's largest PET service, reports less than a dozen cardiac patient scans (less than 0.5% of Metro PET's caseload) in recent years. None of the older services offer the PET based myocardial perfusion imaging…."

[16] DCOPN notes that it does not appear that Carient Heart and Vascular reported any PET/CT procedures to VHI for 2022, though it was operational. In 2021, Carient Heart and Vascular reported 3,185 procedures to VHI. **Table 10** uses 3,185 procedures as an estimate of Carient's 2022 PET volumes.

[17] Includes the one PET/CT unit at Carient Heart and Vascular that was not reported to VHI for 2022.

Virginia Heart anticipates performing 1,687 PET/CT studies in Year 1 and 2,008 PET/CT studies in Year 2. To determine these projections, Virginia Heart examined its SPECT procedures for the past four year, reviewed the PET/CT procedures performed at its Telestar location and the volume of orders its doctors are requesting for PET/CT studies. DCOPN contends that Virginia Heart's projections are reasonable. DCOPN notes that these projections are slightly below the Commonwealth's average across all PET providers of 2,282.

With regard to the effect that the proposed project would have on existing providers, Virginia Heart has indicated that the primary purpose of the PET/CT service will be to serve its existing patient base, as it is unable to meet the demand for cardiac PET/CT with its existing PET/CT unit in the Telestar Court office. Because of the distinct nature of the patient base and the restricted scope of the PET/CT service to only cardiac procedures, DCOPN does not anticipate that approval of the proposed project would negatively affect utilization of other PET services in PD 8. Instead, approval of the proposed project would create an overall improvement in access to cardiac PET/CT for Virginia Heart's patients.

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.

COPN Request No. VA-8783: IRMC

As shown above, there is a calculated surplus of 10 PET scanners in PD 8. DCOPN notes, as shown in **Table 10**, no PET services in PD 8 surpassed the SMFP's volume threshold in 2022. In fact, according to VHI data for 2022, the average number of PET procedures performed across all PET providers in the entire Commonwealth was 2,282.

IRMC anticipates performing 2,920 PET/CT studies in Year 1 and 3,580 PET/CT studies in Year 2. To determine these projections, IRMC examined its patient volumes and the increase from 2023 to 2024, current wait times at its Fairfax facility, the shelf life of the isotopes and the expected PD 8 population growth. DCOPN contends that IRMC's projections are reasonable. DCOPN notes that these projections are higher than the Commonwealth's average across all PET providers of 2,282.

As previously discussed, 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 proposal is unlikely to impact other providers in PD 8 because it anticipates serving existing IRMC patient demand for PET/CT services.

With regard to the effect approval of the proposed project will have on existing providers, as shown in **Figure 2**, the proposed project is located in the western portion of PD 8, where there are few nearby providers. Additionally, the proposed project is intended to address PET/CT capacity constraints at IRMC's Fairfax facility and to serve IRMC's existing patient base who are currently facing extended wait times.

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.

12VAC5-230-220. 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-8782: Virginia Heart and COPN Request No. VA-8783: IRMC
Not applicable. Neither applicant is 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.

COPN Request No. VA-8782: Virginia Heart and COPN Request No. VA-8783: IRMC
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.

COPN Request No. VA-8782: Virginia Heart and COPN Request No. VA-8783: IRMC
Both applicants confirmed that PET services would be under the direct supervision of certified and trained radiologists.

The SMFP also contains criteria/standards for when competing applications are received. They are as follows:

Part 1
Definitions and General Information

12VAC5-230-30. 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 regulation 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 demand of the particular service area.**

COPN Request No. VA-8782: Virginia Heart

Virginia Heart has one recent COPN project to analyze, COPN No. VA-04806, which was completed on time and slightly over budget (approved $2,491,617/completed $2,620,277). With respect to the proposed project, the projected capital cost is $3,816,902. As a freestanding imaging facility, the applicant is not bound by hospital state licensure and federal certification regulations. Should the Commissioner approve the proposed project, the applicant should be subject to a charity care condition no less than the 1.9% HPR II average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

COPN Request No. VA-8783: IRMC

Upon review of seven COPN projects submitted by IRMC, DCOPN observes that one was completed slightly over budget, and one was completed late. With respect to the proposed project, the projected capital cost is $5,193,991. As a freestanding imaging facility, the applicant is not bound by hospital state licensure and federal certification regulations. Should the Commissioner approve the proposed project, the applicant should be subject to the Inova System-Wide Condition 3.9% as of January 1, 2022.

Conclusion

DCOPN does not believe that any applicant warrants preference with respect to the factors discussed above.

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;

COPN Request No. VA-8782: Virginia Heart

As previously discussed, six of the 14 authorized fixed site PET services in PD 8 are cardiac-only, each owned by a cardiology group and each providing PET imaging primarily to (or prioritizing) that cardiology group's patients, as would Virginia Heart's, such that little to no competition would result from the proposed project. As Virginia Heart's proposal is restricted to cardiac use and IRMC's states in its application that is will not offer cardiac PET services, the two applications under review have separate patient markets.

COPN Request No. VA-8783: IRMC

IRMC is part of the Inova Health System, the health system that operates the vast majority of imaging services in PD 8. As such, the proposed project will not foster institutional competition that will benefit the area to be served.

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;

COPN Request No. VA-8782: Virginia Heart

As discussed above, DCOPN concluded that approval of the proposed project is unlikely to significantly affect the utilization and efficacy of existing providers in the area.

COPN Request No. VA-8783: IRMC

As previously discussed, IRMC will be located in the western portion of PD 8, where there are few nearby providers of PET/CT services. Furthermore, the proposed project is intended to address PET/CT capacity constraints at IRMC's Fairfax facility and to serve IRMC's existing patient base who are currently facing extended wait times. Therefore, DCOPN concludes that the proposed project is unlikely to foster institutional competition that would benefit the area to be served.

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;

COPN Request No. VA-8782: Virginia Heart

The total capital costs of the proposed project are $3,816,902 of which approximately 19% represents direct construction costs (**Table 3**). As already discussed, DCOPN concludes that when compared to similar projects, these costs are within range of previously approved projects. For example, COPN No. VA-04874 issued to University of Virginia Medical Center to establish a specialized center for PET/CT with one PET/CT unit is anticipated to cost approximately $4,000,000. The applicant states that the proposed project will be funded through a combination of income from operations and commercial loans. The applicant explains that the cost of the leasehold improvements, $724,576, will be funded through commercial loans and the remainder, $3,092,326,

will be funded from operations. The Pro Forma Income Statement provided by the applicant (**Table 7**) projects a net profit of $882,336 from in the first year of operation, and a net profit of $1,503,134 in the second year of operation.

Regarding staffing, the applicant anticipates the need to hire six full time equivalent employees (FTE), including two administration - business office FTEs, one registered nurse FTE and one radiologic technologist FTE. According to the applicant:

> Virginia Heart intends to utilize existing staff as well as hire and train additional staff. Personnel required for this project include: 2 clinical staff and 4 technical staff. Virginia Heart currently has twelve offices across the region. Virginia Heart has several nuclear-stress-trained registered nurses (RNs) that currently work full-time in its SPECT departments that will rotate through the planned PET/CT diagnostic center. Virginia Heart has 37 medical staff members trained in Nuclear Cardiology that will be reading and supervising this new diagnostic department on a rotating basis. Virginia Heart anticipates no issue in maintaining staffing levels.

The applicant is an established provider of PET/CT services and has a well-developed and effective recruitment and employee retention program. Taken together with the limited number of employees needed for this project, DCOPN concludes that the applicant will not have difficulty filling the required position or that doing so will have a negative impact on other area healthcare providers.

COPN Request No. VA-8783: IRMC

As already discussed, DCOPN concludes that when compared to similar projects, these costs are within range of previously approved projects. For example, COPN No. VA-04739 issued to Inova Reston MRI Center LLC to establish a specialized center for PET/CT imaging with one PET/CT unit is anticipated to cost approximately $5,011,046 and COPN No. VA-04908 issued to Sentara Hospitals d/b/a Sentara Norfolk General Hospital wo introduce PET/CT services with one PET/CT unit is anticipated to cost approximately $5,432,498. the renovation and build-out costs associated with the proposed project will be funded from a bank line of credit. The PET/CT equipment will be leased from the vendor pursuant to a capital lease whereby, at the end of the lease term, IRMC will own the PET/CT unit. The Pro Forma Income Statement provided by the applicant (**Table 8**) projects a net profit of $4,411,000 from in the first year of operation, and a net profit of $5,661,000 in the second year of operation.

Regarding staffing, the applicant anticipates the need to hire five FTEs, including two administration - business office FTEs, and three radiologic technologist FTEs. With regard to recruitment, the applicant provided the following information:

> Fairfax Radiology Centers (FRC, LLC) which manages/operates IRMCs imaging services, recruits for all positions internally and has two recruiters dedicated to clinical recruitment. Additionally, FRC, LLC
>
> - Recently hired an experienced Recruitment Manager
> - Has a formal in-house MRI Tech training program
> - Partners with outside educational institutions

- Maintains a float pool of Technologists to cover vacancies and employee absences.

Additional components of the recruitment program include:

- Post open positions internally
- Place special advertisements strategically in Indeed and other national job search engines
- Employee referral bonus program

The applicant is an established provider of PET/CT services and has a well-developed and effective recruitment and employee retention program. Taken together with the limited number of employees needed for this project, DCOPN concludes that the applicant will not have difficulty filling the required position or that doing so will have a negative impact on other area healthcare providers.

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;

COPN Request No. VA-8782: Virginia Heart

Cardiac PET has been found to reduce the overall cost of managing coronary artery disease by approximately 30% when it is used routinely as compared with SPECT.[18] 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. DCOPN did not identify any other factors as may be appropriate to bring to the Commissioner's attention.

COPN Request No. VA-8783: IRMC

The proposed project would not introduce new technology that would promote quality or cost effectiveness in the delivery of inpatient acute care. However, the proposed project does increase the potential for provision of services on an outpatient basis for patients who do not need imaging services performed in a hospital setting. DCOPN did not identify any other factors that have not been discussed elsewhere in this staff analysis report to bring to the attention of the Commissioner. The applicant does not make any arguments regarding any cooperative efforts to meet regional health care needs. DCOPN did not identify any other factors as may be appropriate to bring to the Commissioner's attention.

18 Merhige, M. E., Breen, W. J., Shelton, V., Houston, T., D'Arcy, B. J., & Perna, A. F. (2007, July 1). Impact of myocardial perfusion imaging with pet and 82RB on downstream invasive procedure utilization, costs, and outcomes in coronary disease management. Journal of Nuclear Medicine. https://jnm.snmjournals.org/content/48/7/1069

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.

COPN Request No. VA-8782: Virginia Heart and COPN Request No. VA-8783: IRMC

Not applicable. These facilities are 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

COPN Request No. VA-8782: Virginia Heart

DCOPN finds that Virginia Heart's proposed project to establish PET/CT services at its existing cardiology office at 19450 Deerfield Avenue, Suite 100, Leesburg, Virginia and its request to use the CT for the limited purpose of stand-alone cardiac calcium scoring is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. The applicant has stated that the 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 reasons exist, such as the unique population of patients the PET/CT will serve, 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.

Additionally, DCOPN finds that the proposed project is more beneficial than the alternative of the status quo. Furthermore, the proposed project is unlikely to negatively affect the utilization of existing providers. Moreover, the HSANV Board voted 10 in favor, none opposed to recommend approval of Virginia Heart's COPN request. Finally, DCOPN finds that the total capital costs of the proposed project compare favorably to similar, recently approved projects.

COPN Request No. VA-8783: IRMC

DCOPN finds Inova Reston MRI Center, LLC's request to introduce PET/CT services with one PET/CT unit at its existing medical care facility is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. Additionally, the proposed project is more favorable than maintaining the status quo.

Moreover, the Board of the Health Systems Agency of Northern Virginia voted to recommend that the application be approved. Furthermore, DCOPN finds that the total capital costs of the proposed project are reasonable and consistent with previously approved projects similar in scope. Additionally, DCOPN finds that the project appears to be economically feasible both in the immediate and long-term. Finally, there is no known opposition to the proposed project.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of The Cardiovascular Group, PC's (Virginia Heart) COPN Request No. VA-8782 to establish a specialized center for cardiac PET/CT imaging with one PET/CT unit for the following reasons:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.

2. The PET/CT scanner's use will be limited solely to cardiac imaging.

3. The CT functionality of the PET/CT scanner will only be utilized in conjunction its PET functionality and for calcium scoring.

4. The project will improve access to the preferred cardiac imaging modality with numerous benefits over SPECT.

5. The project will not adversely affect existing providers of PET/CT services.

6. The project is more beneficial than the alternative of the status quo.

7. The capital costs are reasonable.

8. The Board of the Health Systems Agency of Northern Virginia voted unanimously to recommend that the application be approved.

DCOPN's recommendation is contingent upon The Cardiovascular Group, PC's (Virginia Heart) agreement to the following charity care condition:

Recommended Condition
The Cardiovascular Group, PC's PET/CT service will be limited solely to cardiac imaging and cardiac calcium scoring. The Cardiovascular Group, PC will provide cardiac PET/CT services to all persons in need of these services, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount equal to at least 1.9% of The Cardiovascular Group, PC's total patient services revenue derived from PET/CT services as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement The Cardiovascular Group, PC will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided to individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers

for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

The Cardiovascular Group, PC will provide cardiac PET/CT care to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. Additionally The Cardiovascular Group, PC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

COPN Request No. VA-8783: IRMC

The Division of Certificate of Public Need recommends **conditional approval** of Inova Reston MRI Center, LLC's COPN Request No. VA-8783 to introduce PET/CT services with one PET/CT unit at its existing medical care facility:

1. The project is consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.

2. The project is more favorable than maintaining the status quo.

3. The Board of the Health Systems Agency of Northern Virginia voted unanimously to recommend that the application be approved.

4. The capital costs are reasonable.

5. The proposed project appears economically viable in the immediate and the long-term.

Recommended Condition

This project shall be subject to the system-wide charity care condition applicable to Inova Health Care Services d/b/a Inova Heath System pursuant to COPN No. VA-04381 (issued April 2, 2013), as amended by the State Health Commissioner by letter dated January 4, 2016 (the Inova System-Wide Condition). Pursuant to the 2016 reconsideration, the Inova System-Wide Condition reset to 3.9% as of January 1, 2022. Provided, however, that charity care provided under the Inova System-Wide condition shall be 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.

Inova Health System 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. In addition to any right to petition the Commissioner contained in the Inova System-Wide condition, to the extent Inova Health System expects its Inova System-Wide condition as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. or any revised percentage to materially alter the value of its charity care commitment thereunder, it may petition

the Commissioner for a modification to the Inova System-Wide condition to resolve the expected discrepancy.