

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

July 21, 2025

COPN Request No. VA-8816

Inova Health Care Services

Fairfax, Virginia

Establish a medical care facility for PET/CT services with one fixed PET/CT scanner limited to cardiology in Fairfax, Virginia

Applicant

Inova Health Care Services is a 501 (c)(3) Virginia nonstock corporation. The sole member of Inova Health Care Services is the Inova Health System Foundation, also a 501 (c)(3) Virginia nonstock corporation. Inova Health Care Services is based in Fairfax, Virginia, which is in Planning District (PD) 8, Health Planning Region (HPR) II.

Background

A positron emission tomography (PET) scan is an imaging test that can help reveal the metabolic or biochemical function of tissues and organs. The PET scan uses a radioactive drug called a tracer to show both typical and atypical metabolic activity. A PET scan can often detect the atypical metabolism of the tracer in diseases before the disease shows up on other imaging tests, such as computerized tomography (CT) and magnetic resonance imaging (MRI). The tracer is most often injected into a vein in the hand or arm. The tracer will then collect into areas of the body that have higher levels of metabolic or biochemical activity. This often pinpoints the location of the disease. The PET images are typically combined with CT or MRI and are called PET/CT or PET/MRI scans.¹

Regarding 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

¹ <https://www.mayoclinic.org/tests-procedures/pet-scan/about/pac-20385078>

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.²

According to DCOPN records, PD 8 has 17 authorized PET scanners – 15 fixed site scanners and two mobile sites (**Table 1**). Eight of the 15 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.

Table 1. Authorized PD 8 PET Inventory

Facility	Total Scanners	Scans	% of 6,000 Scan Threshold
PET and PET/CT Restricted to Cardiac Imaging			
Carent Heart & Vascular (Manassas)	1	3,314	55.2%
Nova Cardiovascular Care, Inc.	1	334	5.6%
Open Restricted to Cardiac Imaging	2	3,648	30.4%
Amelia Heart & Vascular Center ¹	1		
Carent Heart & Vascular (Vienna) ²	1		
Virginia Heart (Falls Church) ³	1		
Virginia Heart (Alexandria) ⁴	1		
Virginia Heart (Leesburg) ⁵	1		
Cardiac Care Associates ⁶	1		
Unopened Restricted to Cardiac Imaging	6		
Total Restricted to Cardiac Imaging	8		
Unrestricted PET and PET/CT Scanners			
Fairfax PET/CT Imaging Center	1	3,813	63.5%
Sentara Northern Virginia Medical Center	1	109	1.8%
Kaiser Permanente Woodbridge Imaging Center ⁶	1		
Metro Region PET Center ⁷	2		
UVA Cancer Care Gainesville	1	606	10.1%
PET of Reston	1	1,499	25.0%
Virginia Hospital Center	1	1,061	17.7%
Open Un-Restricted	8	7,088	14.8%
Inova Reston MRI Center, LLC	1		
Unopened Un-Restricted	1		
Total Authorized PD 8 PET Inventory	17		

1 Expected open 9/9/24, reported project delays

2 Open 7/30/23

3 Open 5/31/23

4 Expected complete 3/31/26

5 Expected complete 9/30/25

6 Open 6/19/22. Did not Report utilization to VHI

7 Second PET/CT scanner expected open 1/1/24, no report of being open. Did not report volume on first PET/CT scanner to VHI

Source: DCOPN Records

² 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).

Proposed Project

Inova Health Care Services proposes to establish Inova Cardiac Diagnostics PET/CT – Willow Oaks, a PET/CT service restricted to cardiac studies, by installing one PET/CT scanner at 8280 Willow Oaks Corporate Drive, Suite 100, Fairfax, Virginia. Inova Health Care Services does not discuss any intention to use the CT component independent of the PET/CT scanner to assess coronary calcium or any other use. Renovation of the existing medical office building is required in the proposed first floor location. Projected capital and financing costs are \$3,807,237 (**Table 2**). Should the proposed project be approved, the target date of opening is prior to March 31, 2026.

Table 2. Inova Health Care Services Capital and Financing Costs

Direct Construction Costs	\$ 1,525,416
Equipment Not Included in Construction Contract	\$ 2,418,293
Site Acquisition Cost	\$ 4,533,550
Architectural and Engineering Fees	\$ 138,000
Total	\$ 8,615,259

Source: COPN Request No. VA-8816

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the “[e]stablishment of a medical care facility described in subsection A.” A medical care facility includes “[a]ny specialized center or clinic or that portion of a physician's office developed for the provision of... 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 5.8% growth rate projected for Virginia (**Table 3**). 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 3**).

Table 3. 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	46.3%
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.

Geographically, the proposed facility will be located in Fairfax, Virginia, a short 0.6 mile (four minute drive) from Inova Fairfax Hospital and within 0.2 miles of a Fairfax Connector bus stop. The proposed site is easily accessible by major highways. It is just off the intersection of Interstate 495 (I-495) and US 50/Arlington Boulevard. Ample parking is available onsite for patients.

Table 4. 2023 Poverty Rates, PD 8

Locality	% in Poverty
Arlington County	7.1%
Fairfax County	6.1%
Loudoun County	4.1%
Prince William County	6.7%
Alexandria City	8.5%
Fairfax City	7.4%
Falls Church City	5.1%
Manassas City	10.7%
Manassas Park City	7.7%
PD 8	6.2%
Virginia	10.2%

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

Regarding socioeconomic barriers to access, PD 8 has a lower poverty rate at 6.2% than that of Virginia at 10.2% (**Table 4**). Fairfax County's poverty rate, at 6.1%, is the third lowest of localities in PD 8 and significantly less than Virginia's poverty rate. 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 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.**

DCOPN received 5 letters of support within Inova Health Care Services' application, one from Virginia Heart, a competitor with three cardiac PET/CT sites in PD 8, and four from Inova associated cardiologists.

Public Hearing

DCOPN provided notice to the public regarding this project on January 10, 2025. The public comment period closed on February 24, 2025. On June 9, 2025, the Health Systems Agency of Northern Virginia (HSANV) held a public hearing for the project. Inova Health Care Services presented the project. There was no public comment regarding the project. 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.**

Initially, in Virginia, PET scanners were envisioned for cardiac imaging and the criteria for their review under COPN reflected that. However, utilization of cardiac PET did not initially advance as expected but PET was found to be a useful tool in neurology and in the treatment and staging of cancers. While some PET scanners in the Commonwealth are used for cardiac, neurologic and cancer imaging the first PET scanner dedicated to cardiac imaging became operational in PD 15 in 2018. The first dedicated cardiac PET became operational in PD 8 in 2020. Since 2018 12 PET scanners dedicated to cardiac imaging have been authorized in the Commonwealth, eight of which are in PD 8. About 30% of the population of Virginia lives in PD 8, which has 67% of the dedicated cardiac PET scanners.

All of the current PD 8 cardiac PET scanners are operated by individual cardiology practices, ranging from 4 to 51 cardiologists. With at most three years of reported utilization volume, and in some cases only one, or no years, of reported utilization, it is clear that PET/CT is developing into a significant tool for cardiac diagnostics.

Inova Schar Heart and Vascular practice has over 70 physicians practicing at 65 sites in PD 8, including Inova's five acute care hospitals. As cardiac PET/CT progresses as a tool in cardiac diagnostics it is reasonable for one of PD 8's largest cardiovascular practices to have access to the technology. As current capacity is in the hands of other, individual practices the alternative of accessing existing capacity is unlikely to be a viable option for Inova Health Care Services and the physicians of Inova Schar Heart and Vascular.

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. Inova Health Care Services seeks to offer an emerging use of technology which provides higher quality, faster imaging and exposes

patients to less radiation when compared to Single Photon Emission Computed Tomography (SPECT). PET/CT is becoming the standard of care for cardiac imaging.

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.”³. According to this Society Position Statement, “[m]yocardial 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.”⁴

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.

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

At its June 9, 2025 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 nine in favor, none opposed, to recommend approval of Inova Health Care Services’ COPN Request number VA-8816. 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 June 9, 2025 public hearing and Board of Directors meeting, and on several basic findings and conclusions, including:

1. Inova Health Care Service (Inova) is the region’s leading medical care system, serving large numbers of cardiovascular patients in multiple locations.
2. PET scanning is the preferred diagnostic imaging option for many patients with coronary artery disease. Demand for cardiac PET imaging is increasing regionwide.
3. Existing and authorized cardiac PET services are organized and operated to serve patients of specific cardiology practices.
4. A cardiac PET service operated by the largest local provider of cardiovascular care should extend access to residents not served by cardiology practices offering cardiac PET scanning.
5. Projected capital costs are within the capital expenditure range seen for similar projects.
6. There is no indication that, in expanding access to cardiac PET scanning region wide, the project would affect other services negatively.

³ 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).

⁴ Id.

7. The Virginia State Medical Facilities Plan (SMFP) does not contain planning guidance specific to cardiac PET imaging. The project is consistent with applicable provisions of the Virginia SMFP as they have been applied to similar projects in recent years.

(iv) Any costs and benefits of the project.

Total projected capital costs for the proposed project are \$8,615,259, funded entirely from accumulated reserves. The estimated costs are consistent with other recently approved PD 8 projects to introduce cardiac PET/CT as noted in Table 5. COPN No. VA-04919 issued to Virginia Heart also incurred financing costs. Review of equipment cost and direct construction cost on a per square foot basis removes the variability and volatility of the cost to acquire or lease real estate.

TABLE 5. Project Cost Compare, Recent PD 8 Cardiac PET/CT

COPN #	Facility	Cap Cost	Direct Construction Cost/SF	Equipment Cost
VA-04919	Virginia Heart	\$3,816,902	\$431	\$2,433,469
VA-04920	IRMC, LLC	\$5,200,000	\$340	\$3,131,937
<i>Applicant</i>	<i>Inova Health Care Services</i>	<i>\$8,615,259</i>	<i>\$236</i>	<i>\$2,418,293</i>

DCOPN Application Review Records

SPECT has long been the means for conducting myocardial perfusion imaging (MPI) studies. In an MPI study, sometimes referred to a nuclear stress test, the heart is imaged using a dye before and after exercise to determine areas of poor blood flow. The applicant currently performs SPECT based MPI at 12 sites in PD 8, reporting 7,691 studies in 2024.

The applicant has described several benefits to PET/CT MPI over SPECT based studies. PET/CT based MPI reportedly has a higher sensitivity (how well true positives are identified) and specificity (how well true negatives are identified) and is overall more accurate.

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 addition of a cardiac PET/CT by Inova Health Care Services is unlikely to produce a reduction in utilization of existing cardiac PET/CT services within PD 8. Other providers of cardiac PET/CT serve their own distinct patient population and given the large population of the Northern Virginia area, no reduction in services is anticipated.

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

Inova Health Care Services will provide cardiac PET/CT to all patients regardless of their ability to pay for services or of their payor source. In 2023, the most recent year for which Virginia Health Information (VHI) has reported data, Inova Health Care Services, as a system, reported a charity care rate of 2.3% in aggregate of their 11 reporting facilities, well above the 1.9% average rate for

all reporting providers in PD 8. In its proforma (Attachment X to their application) Inova Health Care Services allows for charity contributions at the proposed Inova Cardiac Diagnostics PET/CT – Willow Oaks facility equal to 1.0% of revenues. Inova Health Care Services' projects, if approved, are subject to Inova Health Care Services' systemwide condition charity care rate of 3.9%. 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.

Table 6. HPR II Charity Care Contributions: 2023

HPR II	2023 at 200%		
	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Encompass Health Rehab Hosp of Northern Virginia	\$ 47,006,703	\$1,815,624	3.9%
Sentara Northern Virginia Medical Center	\$ 1,045,324,552	\$36,160,381	3.5%
Inova Alexandria Hospital	\$ 1,429,207,087	\$37,429,423	2.6%
Inova Mount Vernon Hospital	\$ 763,866,669	\$18,931,409	2.5%
Inova Fairfax Hospital	\$ 6,178,801,539	\$147,787,884	2.4%
Inova Loudoun Hospital	\$ 1,401,069,976	\$30,988,208	2.2%
Virginia Hospital Center	\$ 2,186,532,064	\$46,172,024	2.1%
Inova Fair Oaks Hospital	\$ 1,066,144,047	\$22,481,850	2.1%
Dominion Hospital	\$ 186,176,170	\$2,045,071	1.1%
Reston Hospital Center	\$ 2,138,632,642	\$17,987,554	0.8%
StoneSprings Hospital Center	\$ 539,217,793	\$3,146,642	0.6%
North Spring Behavioral Healthcare	\$ 81,326,336	\$341,453	0.4%
UVA Health Prince William Medical Center	\$ 635,237,781	\$0	0.0%
UVA Health Haymarket Medical Center	\$ 367,868,585	\$0	0.0%
HPR II Inpatient Hospital Median			2.1%
HPR II Total Inpatient \$ & Mean %		\$ 18,066,411,944	2.0%
HealthQare Services ASC, LLC	\$ 12,393,083	\$933,007	7.5%
Stone Springs Ambulatory Surgery Center	\$ 42,421,176	\$774,214	1.8%
Northern Virginia Eye Surgery Center, LLC	\$ 16,978,280	\$45,760	0.3%
Lake Ridge Ambulatory Surgical Center	\$ 12,789,859	\$30,788	0.2%
Haymarket Surgery Center	\$ 62,445,476	\$88,885	0.1%
Reston Surgery Center	\$ 165,980,869	\$37,296	0.0%
Northern Virginia Surgery Center	\$ 63,630,227	\$13,450	0.0%
McLean Ambulatory Surgery Center	\$ 46,154,897	\$7,660	0.0%
Inova Loudoun Ambulatory Surgery Center	\$ 98,462,265	\$15,163	0.0%
Inova Surgery Center @ Franconia-Springfield	\$ 99,121,487	\$7,799	0.0%
Fairfax Surgical Center	\$ 170,498,365	\$2,356	0.0%
Prince William Ambulatory Surgery Center	\$ 58,808,176	\$0	0.0%
Kaiser Permanente Tysons Corner Surgery Center	\$ 48,527,291	\$0	0.0%
Kaiser Permanente Caton Hill Ambulatory Surgery Center	\$ 21,993,825	\$0	0.0%
Inova Ambulatory Surgery Center at Lorton	\$ 8,494,696	\$0	0.0%
Pediatric Specialists of Virginia Ambulatory Surgery Center	\$ 7,412,957	\$0	0.0%
HPR II Outpatient Hospital Median			0.0%
HPR II Total Outpatient Hospital \$ & Mean %		\$ 936,112,929	0.2%
HPR II Hospital Median			1.2%
HPR II Total Hospital \$ & Mean %		\$ 19,002,524,873	1.9%

(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 SMFP contains criteria/standards for the establishment or expansion 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 1** is the boundary of PD 8. The white squares with the blue “H” are the eight currently authorized cardiac PET sites, while the blue squares with the white “H” symbols mark the other locations of existing PET providers in PD 8 that are not restricted to cardiac use. The red cross symbol marks the location of the proposed project. 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 cardiac specific PET services in PD 8. The drive time availability for existing cardiac specific PET overlaps and covers the area that is within a 60-minute drive of all PET.

Figure 1. Map of Authorized PET Scanners in PD 8

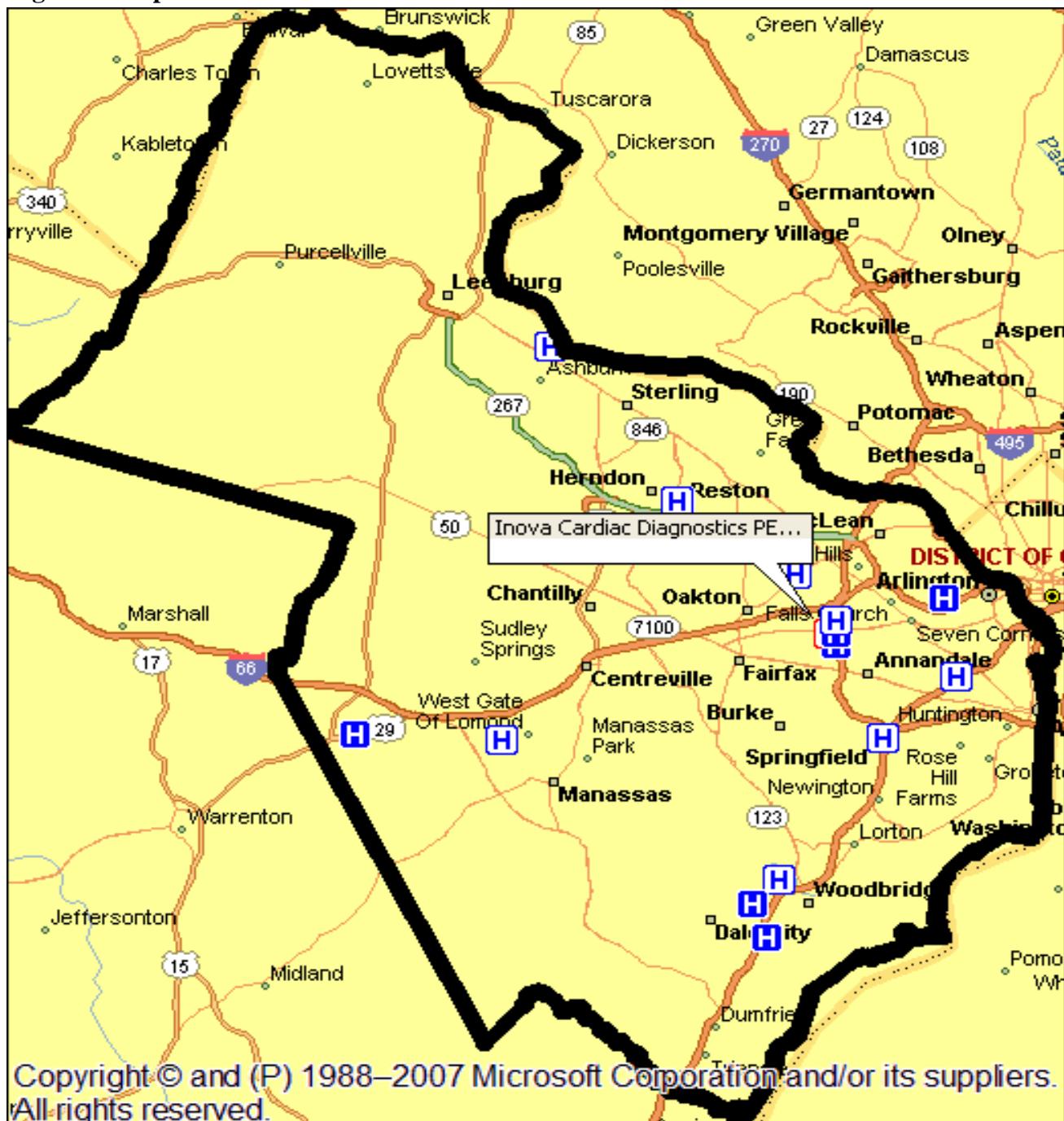
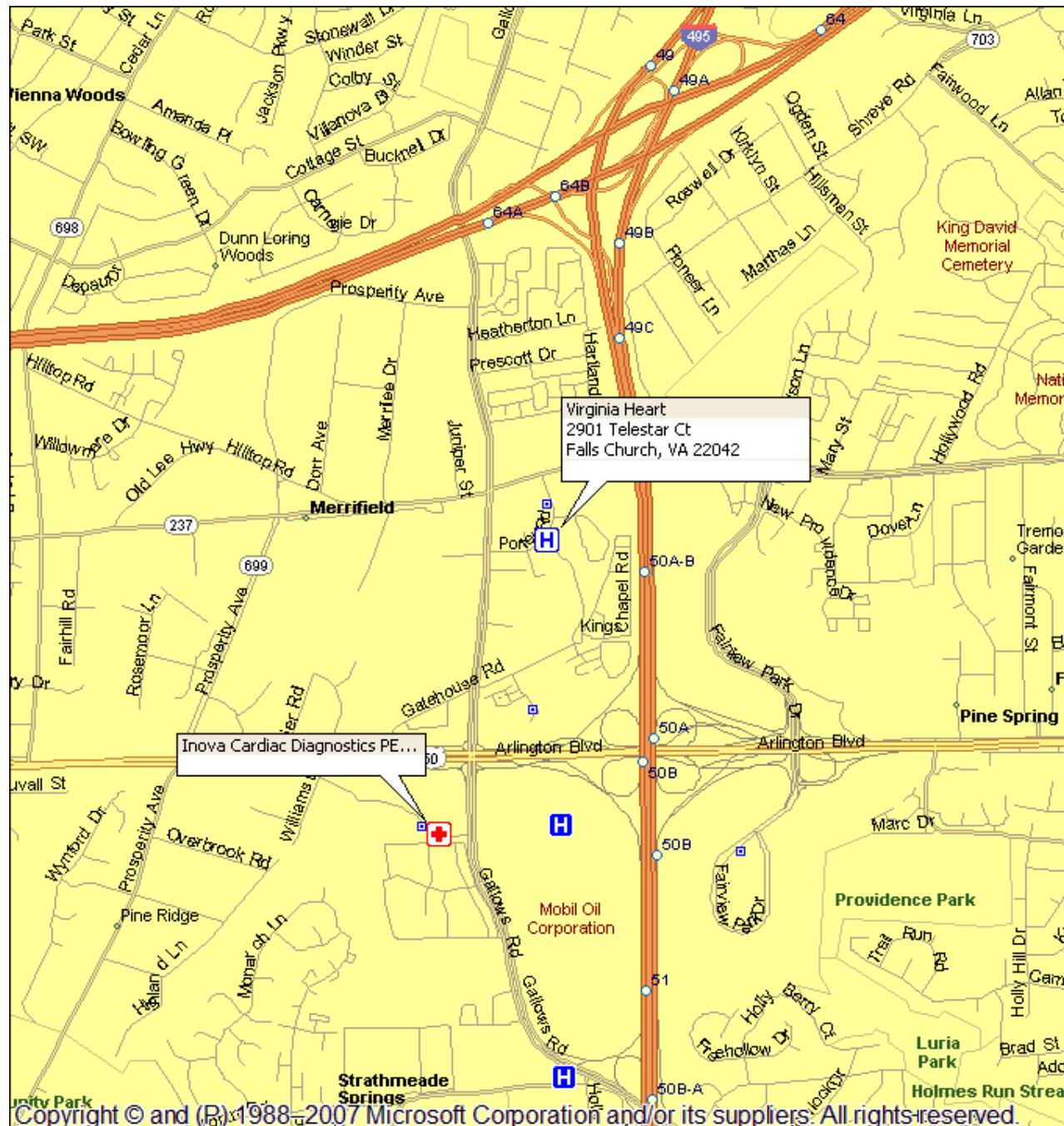


Figure 2 shows the proximity of the proposed Inova Cardiac Diagnostics PET/CT – Willow Oaks site to the site of the existing Virginia Heart – Falls Church cardiac PET/CT, approximately one driving mile. Virginia Heart has three authorized cardiac PET/CT scanners in PD 8. The Falls Church unit was authorized in August 2022 (COPN number VA-04806) and opened in May 2023.

Figure 2. Proximity of Closest Cardiac PET/CT to Applicant's Site



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

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

The applicant is not a hospital.

B. No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such health planning district.

Note: For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as one PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as one individual PET procedure and one CT procedure respectively, unless those images are made concurrently.

In 2023, the latest year for which VHI has reported utilization data, PD 8 had PET scanners at 17 authorized sites, two mobile and 15 stationary units. Four of the stationary units have not yet reported being open. Of the nine currently (2025) operational scanners, only nine were operational to report utilization in 2023, and only seven reported. Utilization of the seven reporting scanners for 2023 is presented in **Table 1**. These scanners performed an average of 1,534 scans, or 25.6% of the SMFP standard in 2023. Those PET and PET/CT scanners restricted to cardiac imaging performed slightly more scans per scanner at 1,824 scans, or 30.4% of the SMFP threshold.

Calculated Needed Fixed PET Scanners in PD 8

2025 COPN authorized fixed PET scanners = 17

Calculated Needed Fixed PET scanners = $10,816 \text{ (2023 PET procedures)} \div 6,000 = 1.8$ (2) scanners needed

PD 8 Calculated Need = 2 PET scanners

PD 8 Calculated Surplus = 15 PET scanners (2025 PET Scanners (17) – Calculated Need (2))

The SMFP does not distinguish between cardiac PET and PET used for other clinical uses. As shown above, there is a calculated surplus of 14 PET scanners in PD 8. DCOPN notes, as shown in **Table 1**, no PET services in PD 8 surpassed the SMFP's volume threshold in 2023.

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 Northern 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....”

Across Inova Health Care Services’ Inova Schar Heart and Vascular Cardiac Diagnostics’ 12 locations offering SPECT imaging, 7,691 SPECT studies performed in 2024, according to the applicant. Inova Health Care Services anticipates performing 2,295 cardiac PET/CT scans in the first year of operation, with 20% of the existing 7,691 SPECT scans converting to PET/CT (1,538 scans) and the remaining 757 scans resulting from new patients from Inova’s cardiologists. Given the size of Inova’s cardiology program and number of participating cardiologists the applicant’s volume projects appear reasonable for the first year of operation.

With regard to the effect that the proposed project would have on existing providers, Inova Health Care Services has indicated that the primary purpose of the PET/CT service will be to serve its existing patient base. 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 Inova Health Care Services’ 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.

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

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

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

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

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

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

12VAC5-230-240. Staffing.

PET services should be under the direction or supervision of one or more qualified physicians. Such physicians shall be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

Inova Health Care Services has confirmed that PET services would be under the direct supervision of certified and trained radiologists.

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.**

Eight of the 17 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 Inova Health Care Services' scanner such that little to no competition would result from the proposed project.

- 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.**

As the existing cardiac PET/CT services are established to serve the needs of the individual cardiology groups that operate them, as would the applicant's cardiac PET/CT service it appears there will be little impact on the health care system as a whole in PD 8, other than making cardiac PET/CT imaging available to the patients of one of the largest cardiology groups in the area.

- 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.**

The total capital and financing costs of the proposed project are \$8,615,259 of which approximately 18% represents direct construction costs (**Table 2**). As already discussed, DCOPN concludes that when compared to similar projects, these costs are within range of recently approved

similar projects. The applicant states that the proposed project will be funded through a accumulated reserves. The proforma income statement provided by the applicant (**Table 8**) projects a net profit of \$1,346,520 in the first year of operation, and a net profit of \$2,118,934 in the second year of operation.

Table 8. Proforma PET/CT at Inova Health Care Services

	Year 1	Year 2
Gross Patient Revenue	\$9,796,524	\$11,039,931
Charitable Donations	\$97,965	\$110,399
Other Deductions from Revenue	\$5,606,574	\$6,336,982
Net Patient Revenue	\$4,091,985	\$4,592,550
Total Operating Expenses	\$2,441,340	\$2,146,356
Profit (Loss)	\$1,650,645	\$2,446,194

Source: COPN Request No. VA-8795

Regarding staffing, the applicant anticipates the need to hire seven full time equivalent employees (FTE), one registered nurse FTE, three radiologic technologist FTEs and three administrative FTEs. The applicant is an established health system and has a well-developed and effective recruitment and employee retention program. While there may be some recruiting pressure on other PET scan providers in PD 8 the applicant has stated an intention to draw from existing non-PET radiological technologists and cross train. 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 significant negative impact on other area healthcare providers.

7. 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.

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.⁵ 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 outside the extensive Inova system to meet regional health care needs. DCOPN did not identify any other factors as may be appropriate to bring to the Commissioner's attention.

5 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. (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.

Not applicable. The applicant is not 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

DCOPN finds that Inova Health Care Services' proposed project to establish PET/CT services at Inova Cardiac Diagnostics PET/CT – Willow Oaks, a PET/CT service restricted to cardiac studies, by installing one PET/CT 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 PET 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 nine in favor, none opposed to recommend approval of Inova Health Care Services' COPN request. Finally, DCOPN finds that the total capital costs of the proposed project are comparable to similar, recently approved projects and the proposal is wholly feasible in the immediate and long run.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends **conditional approval** of Inova Health Care Services' COPN Request Number VA-8816 to establish Inova Cardiac Diagnostics PET/CT – Willow Oaks, a specialized center for cardiac PET/CT imaging with one PET/CT unit located at 8280 Willow Oaks Corporate Drive, Suite 100, Fairfax, Virginia 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 project will improve access to the preferred cardiac imaging modality with numerous benefits over SPECT.

4. The project will not adversely affect existing providers of PET/CT services and there is no known opposition.
5. The project is more beneficial than the alternative of the status quo.
6. The capital costs are reasonable.
7. The proposal is wholly feasible in the immediate and long term.
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 Inova Health Care Services' agreement to the following charity care condition:

This project shall be subject to the system-wide charity care condition applicable to Inova Health Care Services d/b/a Inova Health 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.