

# VIRGINIA DEPARTMENT OF HEALTH

## Office of Licensure and Certification

### Division of Certificate of Public Need

#### Staff Analysis

January 19, 2021

#### **COPN Request No. VA-8531**

Inova Reston MRI Center, LLC

Fairfax, Virginia

Establish a specialized center for PET/CT services with one PET/CT unit at the Inova Center for Personalized Health on the Inova Fairfax Hospital campus through the relocation and replacement of the one PET/CT unit currently located at 8503 Arlington Boulevard, Fairfax

#### **COPN Request No. VA-8537**

PET of Reston L.P.

Reston, Virginia

Convert a mobile PET to a fixed PET/CT

#### **Applicants**

##### COPN Request No. VA-8531: Inova Reston MRI Center, LLC

Inova Reston MRI Center, LLC (IRMC) is a Virginia limited liability company jointly owned by Inova Health Care Services and Fairfax Radiological Consultants, P.C. IRMC proposes to establish the new positron emission tomography/computed tomography (PET/CT) service at the Inova Center for Personalized Health on the Inova Fairfax Hospital campus located in Planning District (PD) 8, Health Planning Region (HPR) II.

##### COPN Request No. VA-8537: PET of Reston L.P.

PET of Reston (POR) is a limited partnership between PET Management, Inc., a Virginia corporation and Reston Hospital Center, LLC. POR is located in PD 8, HPR II.

#### **Background**

According to Division of Certificate of Public Need (DCOPN) records, there are five fixed site PET/CT scanners and three PET/CT mobile sites in PD 8. DCOPN notes that the mobile PET/CT site at Sentara Northern Virginia Medical Center, authorized pursuant to COPN No. VA-04629, was expected to be operational by December 2020, and the fixed site PET/CT scanner at Kaiser Permanente Woodbridge Imaging Center, authorized by COPN No. VA-04700, is expected to be operational by November 2021.

**Table 1. PET/CT Services in PD 8**

<b>Fixed PET Services</b>	<b>Units</b>
Carient Heart & Vascular	1
Fairfax PET/CT Imaging Center	1
Kaiser Permanente Woodbridge Imaging Center	1
Metro Region PET Center	1
Virginia Hospital Center	1
<b>Fixed PET Total</b>	<b>5</b>
<b>Mobile PET Services</b>	<b>Units</b>
Novant Health UVA Cancer Center	1
PET of Reston	1
Sentara Northern Virginia Medical Center	1
<b>Mobile PET Total</b>	<b>3</b>
<b>Grand Total</b>	<b>8</b>

Source: DCOPN Records

**Proposed Projects**

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

IRMC proposes to establish a specialized center for PET/CT imaging at the Inova Center for Personalized Health on the campus of Inova Fairfax Hospital through the relocation and upgrade of an existing PET/CT unit from Fairfax PET/CT Imaging Center at 8503 Arlington Boulevard, Suite LL-120, Fairfax, Virginia. The Inova Center for Personalized Health is located at 8081 Innovation Park Drive, Fairfax, Virginia. The requested PET/CT unit will be operated by Fairfax Radiology Centers. IRMC has provided assurances that it will use the CT modality of the requested PET/CT scanner only in conjunction with the PET modality. If the State Health Commissioner (Commissioner) approves the proposed project, the imaging center on Arlington Boulevard will close.

The projected capital costs of the proposed project are \$5,011,046, approximately 17.6% of which are attributed to direct construction costs (**Table 2**). Capital costs will be funded through the accumulated reserves and operational cash flow of the applicant. Accordingly, there are no financing costs associated with this project. If the Commissioner approves the project, construction is expected to begin in June 2021 and is projected to be completed in September 2021. The target date of opening is October 1, 2021.

**Table 2. Capital and Financing Costs: Inova Reston MRI Center**

Direct Construction Costs	\$880,000
Equipment Not Included in Construction Contract	\$3,300,000
Site Acquisition Costs	\$731,046
Site Preparation Costs	\$50,000
Architectural and Engineering Fees	\$50,000
<b>TOTAL Capital Costs</b>	<b>\$5,011,046</b>

Source: COPN Request No. VA-8531

COPN Request No. VA-8537: PET of Reston L.P.

POR proposes to convert its mobile PET/CT site on the campus of Reston Hospital Center located at 1800 Towne Center Drive, Suite 115 Reston, Virginia to a fixed site PET/CT service. The applicant currently offers mobile PET/CT services on Monday and Thursday through the mobile vendor Alliance Imaging, occasionally adding an additional weekday to the schedule. The applicant asserts that if the proposed project is approved, it will cease the mobile service and it will offer appointments on the fixed site unit five days per week with the potential to offer evening and weekend appointments, in accordance with the demand for services. Further, POR has provided assurances that the PET/CT unit will not be used to provide CT imaging services alone.

The projected capital costs of the proposed project are \$1,671,742, approximately 8% of which are attributed to direct construction costs (**Table 3**). Capital costs will be funded through the accumulated reserves and operating revenue of the applicant and a commercial loan, for which the applicant has received pre-approval from Old Dominion National Bank. The applicant will finance \$1,350,000 and will fund the remaining \$454,359 through accumulated reserves and operating revenue. If the Commissioner approves the project, construction is expected to begin six months after COPN approval and is projected to be completed nine months after COPN approval. The target date of opening is nine months after COPN approval.

**Table 3. Capital and Financing Costs: PET of Reston**

Direct Construction Costs	\$132,617
Equipment Not Included in Construction Contract	\$1,252,000
Site Acquisition Costs	\$227,970
Architectural and Engineering Fees	\$7,500
<b>TOTAL Capital Costs</b>	<b>\$1,671,742</b>

Source: COPN Request No. VA-8537

**Project Definitions**

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

Section 32.1-102.1:3 of the Code of Virginia defines a project, in relevant part, as the [i]ntroduction into an existing medical care facility of any new... positron emission tomographic (PET) scanning. A medical care facility includes “any [s]pecialized center or clinic or that portion of a physician's office developed for the provision of... positron emission tomographic (PET) scanning ...”

COPN Request No. VA-8537: PET of Reston L.P.

Section 32.1-102.1:3 of the Code of Virginia defines a project, in relevant part, as the [i]ntroduction into an existing medical care facility of any new... positron emission tomographic (PET) scanning. A medical care facility includes “any [s]pecialized center or clinic or that portion of a physician's office developed for the provision of... positron emission tomographic (PET) scanning ...”

The two COPN requests, COPN Request Nos. VA-8531, and VA-8537, are considered competing requests. Per section 12VAC5-220-220 of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations, applications for the same or similar services

proposed for the same PD are considered competing applications. Both requests that are the subject of this review include the addition of PET/CT services in PD 8, and therefore, are considered competing with respect to diagnostic imaging services.

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

In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable.

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

The most recent Weldon-Cooper data projects a total PD 8 population of 2,937,128 persons by 2030 (Table 4). This represents an approximate 31.7% increase in total population from 2010 to 2030. Comparatively, Weldon-Cooper projects the population of Virginia as a whole to increase by only 16.6% for the same period. With regard to the 65 and older age cohort, Weldon-Cooper projects a much more rapid increase. Specifically, Weldon-Cooper projects an increase of approximately 114.6% among PD 8’s collective 65 and older age cohort from 2010 to 2030 (Table 4). This is important, as this age group uses medical care resources at a rate much higher than the rest of the population.

**Table 4. Statewide and PD 8 Total Population Projections, 2010-2030**

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Arlington	207,627	249,298	20.1%	274,339	10.0%	32.1%
Fairfax County	1,081,726	1,162,504	7.5%	1,244,025	7.0%	15.0%
Loudoun	312,311	430,584	37.9%	554,808	28.9%	77.7%
Prince William	402,002	478,134	18.9%	571,844	19.6%	42.3%
Alexandria City	139,966	166,261	18.8%	182,067	9.5%	30.1%
Fairfax City	22,565	25,047	11.0%	26,397	5.4%	17.0%
Falls Church City	12,332	14,988	21.5%	17,032	13.64%	38.1%
Manassas City	37,821	43,099	14.0%	46,332	7.5%	22.5%
Manassas Park City	14,273	17,086	19.7%	20,284	18.7%	42.1%
<b>Total PD 8</b>	<b>2,230,623</b>	<b>2,587,000</b>	<b>15.9%</b>	<b>2,937,128</b>	<b>13.5%</b>	<b>31.7%</b>
<b>Total PD 8 65+</b>	<b>192,589</b>	<b>300,491</b>	<b>56.0%</b>	<b>413,269</b>	<b>37.5%</b>	<b>114.6%</b>
<b>Total Virginia</b>	<b>8,001,024</b>	<b>8,655,021</b>	<b>8.17%</b>	<b>9,331,666</b>	<b>7.8%</b>	<b>16.6%</b>

Source: U.S. Census, Weldon Cooper Center Projections (August 2019) and DCOPN (interpolations)

DCOPN also notes that, according to regional and statewide data regularly collected by Virginia Health Information (VHI), for 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 4.1% of all reported total gross patient revenues (Table 5).

**Table 5. HPR II 2018 Charity Care Contributions**

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Novant Health UVA Health System Prince William Medical Center	\$495,433,432	\$44,647,076	9.01%
Sentara Northern Virginia Medical Center	\$789,301,159	\$56,962,621	7.22%
Inova Mount Vernon Hospital	\$479,308,693	\$25,072,214	5.23%
Inova Alexandria Hospital	\$924,056,506	\$46,277,537	5.01%
Inova Fairfax Hospital	\$3,422,077,165	\$157,062,195	4.70%
Inova Loudoun Hospital	\$730,947,536	\$26,227,153	3.59%
Novant Health UVA Health System Haymarket Medical Center	\$255,870,637	\$8,844,583	3.46%
Inova Fair Oaks Hospital	\$672,995,830	\$22,827,171	3.39%
Virginia Hospital Center	\$1,361,001,590	\$32,175,893	2.36%
StoneSprings Hospital Center	\$204,255,017	\$2,703,533	1.32%
Reston Hospital Center	\$1,323,668,487	\$14,710,834	1.20%
Total Facilities			11
Median			3.6%
<b>Total \$ &amp; Mean %</b>	<b>\$10,658,916,052</b>	<b>\$437,510,810</b>	<b>4.1%</b>

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

IRMC proposes to establish a specialized center for PET/CT services in a medical office building on the Inova Fairfax Hospital campus located at 8081 Innovation Park Drive, Fairfax, Virginia. Geographically, the Inova Fairfax Hospital campus is located ¼ mile west of the Capital Beltway (Interstate 495). The campus is accessible from the north and south via Interstates 495 and 95 and from the east and west via Route 50 and Interstate 66. Public bus transportation is available at the main entrance of the campus and metro-rail is within three miles at the Dunn Loring Metro station.

Regarding socioeconomic barriers to access to the applicant’s services, according to regional and statewide data regularly collected by VHI, for 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 4.1% of all reported total gross patient revenues (**Table 5**). For that same year, Inova Fairfax Hospital, the majority owner of IRMC, provided 4.7% of its gross patient revenue in the form of charity care. Pursuant to Section 32.1 – 102.4 of the Code of Virginia, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition no less than the 4.1% HPR II average.

COPN Request No. VA-8537: PET of Reston L.P.

POR proposes to convert its mobile PET/CT site to a fixed site PET/CT service by building out a pre-existing office suite on the first floor of a medical office building, across the hall from its existing mobile service check in, on the campus of Reston Hospital Center. The Reston Hospital Center campus is located at 1800 Towne Center Drive, Suite 115 Reston, Virginia. The proposed site is located less than one mile from Dulles Toll Road (Route 267), three miles from Route 7 and is adjacent to Fairfax County Parkway – major arteries serving Loudoun and Fairfax Counties. The Reston Hospital Center campus is on the route of public bus services, with a stop less than 250 yards

from the proposed site. Reston Hospital Center is accessible via the Metro system using the Wiehle-Reston East station, located less than two miles from the hospital campus. A new station at Reston Town Center is expected to open in Spring of 2021 and is approximately one mile from the hospital campus.

Regarding socioeconomic barriers to access to the applicant's services, according to regional and statewide data regularly collected by VHI, for 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 4.1% of all reported total gross patient revenues (**Table 5**). For 2018 and 2019, POR reported to DCOPN that it provided 2.5% of its gross patient revenue from its PET/CT service in the form of charity care, satisfying the condition set pursuant to COPN No. VA-03852. Pursuant to Section 32.1 – 102.4 of the Code of Virginia, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition no less than the 4.1% HPR II average.

**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-8531: Inova Reston MRI Center, LLC

The applicant provided four letters of support for the proposed project from medical professionals associated with Inova and IRMC. Collectively, these letters addressed the following:

- The Inova Schar Cancer Institute is a unique state of the art cancer center that serves thousands of patients every year from diagnosis to treatment to survivorship.
- Consolidating PET/CT services with the cancer center will lead to a better patient experience and improved continuity of care for patients.

DCOPN received no letters in opposition to the proposed project.

Section 32.1-102.6 B of the Code of Virginia requires DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. Because COPN Request No. VA-8531 represents a competing application, the Health Systems Agency of Northern Virginia (HSANV) conducted the required public hearing on December 7, 2020. There was no public comment on the proposal other than the statements of support submitted with the application.

COPN Request No. VA-8537: PET of Reston L.P.

The applicant provided 18 letters of support for the proposed project from medical professionals associated with POR, Sen. Barbara A. Favola, Member of the Senate of Virginia and Delegate

Ibraheem S. Samirah, Member of the Virginia House of Delegates. Collectively, these letters addressed the following:

- PET imaging is a vital component for cancer patient care and is often used for staging or restaging purposes.
- The current mobile service fails to meet the growing needs of Reston Hospital Center's patients because of limited availability, patient (who often have mobility issues) exposure to uncomfortable temperatures, service interruptions from mechanical breakdowns, older technology and limited ability to provide specialized imaging.
- The downtime for mobile PET/CT services is estimated to be four times that of PET/CT services offered in a permanent and stationary setting.
- POR is the only service provider in the northern part of PD 8 and many patients have to travel for PET/CT scans, as this portion of the service area is not conveniently served by other providers.
- Approval of the proposed project will allow for more efficient treatment.
- As a non-hospital based facility, POR is significantly less expensive for patients.

DCOPN received no letters in opposition to the proposed project.

Section 32.1-102.6 B of the Code of Virginia requires DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. Because COPN Request No. VA-8537 represents a competing application, the HSANV conducted the required public hearing on December 7, 2020. Three individuals spoke in support of the application.

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

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

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. While it can be argued that the status quo is a reasonable alternative to the proposed project, IRMC's request to relocate an existing COPN approved PET/CT unit is inventory-neutral. Furthermore, IRMC will move the unit less than a mile away to a location that is more convenient and accessible to patients of the Schar Cancer Institute on the Inova Fairfax Hospital campus. Finally, the existing unit is nearing the end of its useful life and IRMC will upgrade the PET/CT unit to one that can more efficiently serve its patients. For these

reasons, DCOPN concludes that the proposed project to convert the mobile PET/CT service to a fixed-site PET/CT unit is more favorable than maintaining the status quo.

COPN Request No. VA-8537: PET of Reston L.P.

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. Mobile PET/CT services are currently available at POR two days per week on Monday and Thursday (with an occasional additional weekday) through the mobile vendor Alliance Imaging. The applicant reports efficiency issues resulting from the limited availability of the mobile PET/CT equipment, including the inability to schedule appointments on other weekdays, evenings or weekends. If the proposed project is approved, POR will offer appointments on the fixed site unit five days per week with the potential to offer evening and weekend appointments, in accordance with the demand for services. POR further describes logistical difficulties with the mobile PET/CT service, including requiring patients who are sick, immunocompromised, elderly and/or have mobility issues to go outside to reach the trailer, even in inclement weather. The introduction of a fixed-site service will protect patients from the weather and better preserve patient privacy. For these reasons, DCOPN concludes that the proposed project to convert the mobile PET/CT service to a fixed-site PET/CT unit 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;**

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

The HSNV Board of Directors reviewed at its December 7, 2020 meeting the COPN application filed by IRMC. The Board voted unanimously (14 in favor) to recommend approval of the application.

The Board bases the recommendation on its review of the application, on the HSNV staff report on the proposal, on the information and testimony presented at the December 7, 2020 public hearing and Board of Directors meeting, and on several basic findings and conclusions, including:

1. The Inova Reston MRI Center PET services is an established imaging program with a substantial caseload.
2. The PET-CT scanner now in use at the center is 10 years old, is near the end of its useful life and needs to be replaced.
3. The proposed site, adjacent to other cancer diagnosis and treatment services at Inova Schar Cancer Institute, is a more appropriate location than the current site.
4. A service upgrade, replacement and relocation of the Inova Reston MRI Center service should not affect negatively other PET-CT services.

5. Inova Reston MRI Center is an experienced provider of imaging services and has acceptable charity care policies and practices.
6. Projected capital and operating costs are within the ranges reported locally and elsewhere in Virginia.

The DCOPN agrees with, and adopts the conclusions of, the HSANV staff report and the Board's recommendation for approval of COPN Request No. VA-8531.

COPN Request No. VA-8537: PET of Reston L.P.

The HSANV Board of Directors reviewed at its December 7, 2020 meeting the COPN application filed by POR. The Board voted unanimously (14 in favor) to recommend approval of the application.

The Board bases the recommendation on its review of the application, on the HSANV staff report on the proposal, on the information and testimony presented at the December 7, 2020 public hearing and Board of Directors meeting, and on several basic findings and conclusions, including:

1. PET of Reston is an established imaging program. Service volumes have risen substantially over the past three years.
2. A part-time service is no longer adequate to meet demand and permit efficient operations. A fulltime service would permit POR to serve those referred for PET scans more conveniently, and arguably, more effectively.
3. Though the project entails expansion from a part-time to a fulltime service, and a substantial increase in the number of operating hours, it should not affect other local services negatively.
4. PET of Reston is an experienced service provider and has acceptable charity care policies.
5. Projected capital and operating costs are within the ranges reported locally and elsewhere in Virginia.

The DCOPN agrees with, and adopts the conclusions of, the HSANV staff report and the Board's recommendation for approval of COPN Request No. VA-8537.

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

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

As demonstrated by **Table 2**, the projected capital costs of the proposed project are \$5,011,046, approximately 17.6% of which are attributed to direct construction costs. Capital costs will be funded through the accumulated reserves and operational cash flow of the applicant.

Accordingly, there are no financing costs associated with this project. DCOPN concludes that when compared to similar projects, these costs are reasonable. For example, COPN No. VA-

04715 issued to Children's Hospital of the King's Daughters to establish PET/CT services, which cost approximately \$4,024,979.

The applicant identified the following benefits of the proposed project:

- Placing the service, which is primarily used in cancer treatment, in the same building/complex as the Inova Schar Cancer Institute will improve patient access, allow for enhanced continuity of care and coordination of care for cancer patients.
- The relocation of the PET/CT service will allow cancer patients to receive all their necessary medical services in one location.
- Replacement of the 10-year-old PET/CT unit will allow IRMC to accommodate more patients per day.
- The proposed project is inventory neutral.
- Staff from the Fairfax PET/CT Imaging Center, the location from which the PET/CT unit will be transferred, will staff the new imaging center.

COPN Request No. VA-8537: PET of Reston L.P.

As demonstrated by **Table 3**, the projected capital costs of the proposed project are \$1,671,742, approximately 8% of which are attributed to direct construction costs. Capital costs will be funded through the accumulated reserves and operating revenue of the applicant and a commercial loan, which has received pre-approval. DCOPN concludes that when compared to similar projects, these costs are reasonable. For example, COPN No. VA-04619 issued to Bon Secours St. Mary's Hospital to convert a mobile PET/CT site to a fixed-site PET/CT unit, which cost approximately \$2,796,834.

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

- PET/CT scans are an indispensable component to the diagnosis, staging, management and treatment of many types of cancers and POR serves a critical role within Reston Hospital Center's oncology service line.
- With the introduction of fixed PET service, POR will operate five days per week and will also have the flexibility to offer services on a schedule more convenient to patients, including evening and weekend hours.
- The project will allow POR to meet patient needs with improved capabilities, expanded availability, and better flexibility while preserving the cost benefits of a freestanding, outpatient imaging center.
- Indoor placement of the fixed scanner will streamline the patient experience without requiring patients to navigate through the building or across the parking lot.
- The project will be built out in an existing space, which will limit necessary construction costs.
- The introduction of the fixed service will allow for technology improvements and improved image quality.

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

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

The Pro Forma Income Statement provided by the applicant includes the provision of charity care in the amount of 3% (**Table 6**). DCOPN notes that, according to VHI data from 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 4.1% of all reported total gross patient revenues (**Table 5**). Pursuant to Section 32.1 – 102.4 of the Code of Virginia, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition of no less than the 4.1% HPR II average.

**Table 6. Inova Reston MRI Center’s Pro Forma Income Statement**

	<b>Year 1</b>	<b>Year 2</b>
<b>Gross Patient Revenue</b>	<b>\$14,595,423</b>	<b>\$14,887,331.42</b>
Contractual/Other Discounts	(\$8,757,254)	(\$8,932,398.85)
Charity Care Charity Deductions	(\$437,863)	(\$446,619.94)
<b>Total Operating Revenue</b>	<b>\$5,400,306</b>	<b>\$5,508,313</b>
Operating Expenses	(\$3,005,558)	(\$3,039,159)
<b>Excess of Revenue over Expenses</b>	<b>\$2,394,749</b>	<b>\$2,469,153</b>

Source: COPN Request No. VA-8531

COPN Request No. VA-8537: PET of Reston L.P.

The Pro Forma Income Statement provided by the applicant includes the provision of charity care in the amount of 4% (**Table 7**). DCOPN notes that, according to VHI data from 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 4.1% of all reported total gross patient revenues (**Table 5**). Pursuant to Section 32.1 – 102.4 of the Code of Virginia should the Commissioner approve the proposed project, DCOPN recommends a charity care condition of no less than the 4% HPR II average.

**Table 7. PET of Reston’s Pro Forma Income Statement**

	<b>Year 1</b>	<b>Year 2</b>
<b>Total Gross Revenue</b>	<b>\$4,102,000</b>	<b>\$4,207,000</b>
Contractuals and Bad Debt	(\$1,853,377)	(\$1,896,299)
Charity Care (4%)	(\$164,080)	(\$168,280)
<b>Net Revenue</b>	<b>\$2,084,543</b>	<b>\$2,142,421</b>
Total Operating Expenses	(\$1,041,455)	(\$1,181,694)
Depreciation Expense	(\$651,616)	(\$390,970)
<b>Net Income</b>	<b>\$391,472</b>	<b>\$569,757</b>

Source: COPN Request No. VA-8537

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

Section 32.10-102:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop, by November 1, 2022, recommendations for a comprehensive State Health Services

Plan (SHSP). In the interim, DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

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

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

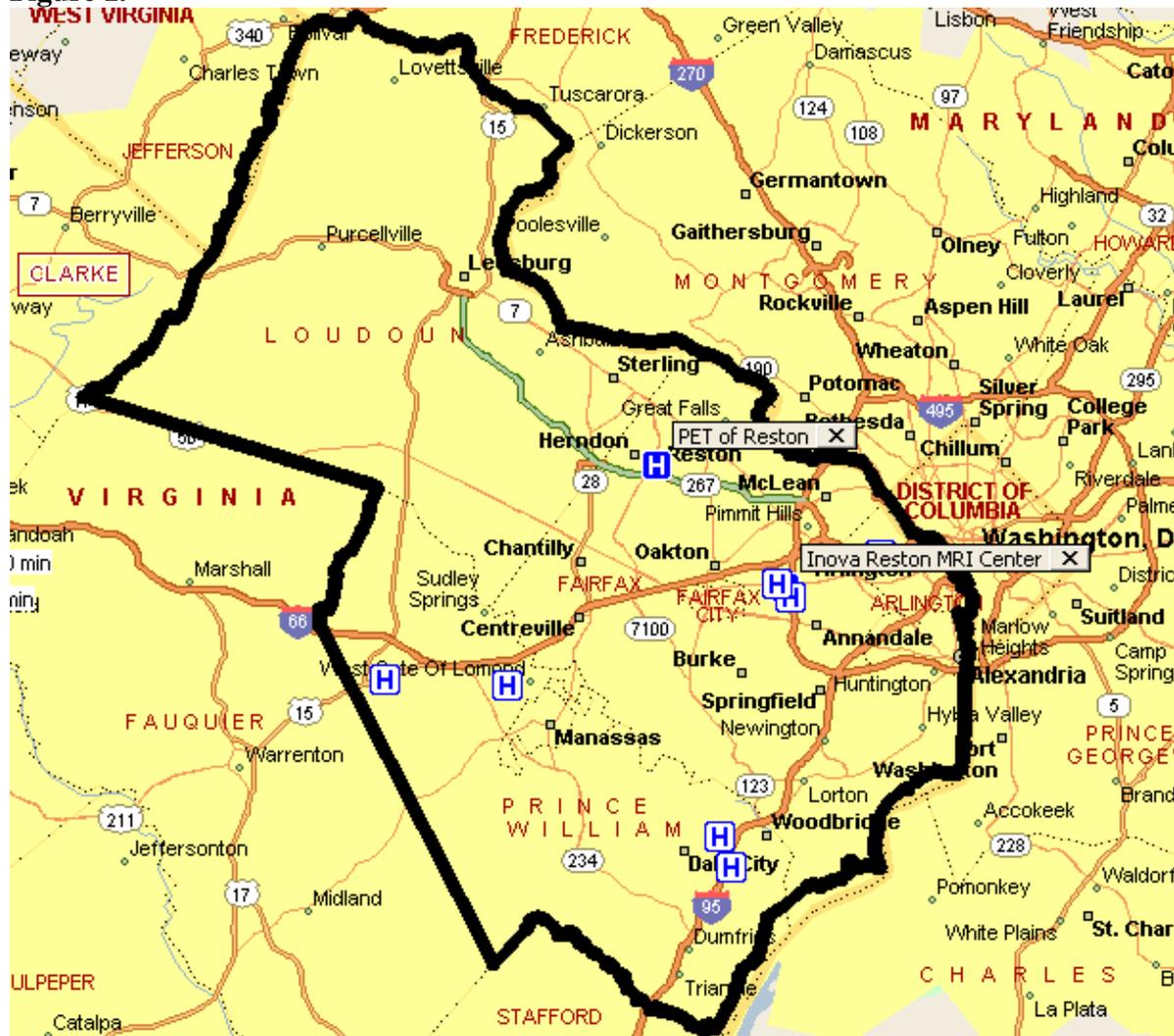
**Part II. Diagnostic Imaging Services  
Article 4. Positron Emission Tomography**

**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** identifies the boundary of PD 8. The blue “H” signs mark the locations of the proposed projects. The white “H” signs mark the locations of all other COPN approved PET/CT services located within PD 8. The yellow shaded area in **Figure 1** illustrates the area of PD 8 and the surrounding area that is within a 60-minute drive of existing PET/CT services. Given the amount of shaded area, it is reasonable to conclude that PET/CT services are currently available within 60 minutes normal driving time, one way, under normal conditions of 95% of the population of PD 8. DCOPN concludes that approval of the proposed projects would not significantly improve access to PET/CT services in PD 8.

Figure 1.



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

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

COPN Request No. VA-8531: Inova Reston MRI Center, LLC  
Not applicable, the applicant is an outpatient imaging facility.

COPN Request No. VA-8537: PET of Reston L.P.  
Not applicable, the applicant is not seeking to add a new fixed site PET/CT service, but rather is proposing to convert a COPN authorized mobile PET/CT site to a fixed site PET/CT service.

**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.**

In 2018, the three fixed site PET scanners in PD 8 performed a collective total of 5,020 procedures (1,673 procedures per scanner), with a utilization of 27.9% of the SMFP threshold of 6,000 procedures per scanner per year (**Table 8**).

**Table 8. 2018 Fixed PET/CT Services and Utilization in PD 8**

<b>Fixed PET Services</b>	<b>Units</b>	<b>Procedures</b>	<b>Procedures/Unit</b>	<b>Utilization</b>
Fairfax PET/CT Imaging Center	1	1,723	1,723	28.7%
Metro Region PET Center	1	2,592	2,592	43.2%
Virginia Hospital Center	1	705	705	11.8%
<b>Fixed PET Total</b>	<b>3</b>	<b>5,020</b>	<b>1,673</b>	<b>27.9%</b>

Source: VHI (2018)

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

The applicant anticipates that the proposed PET/CT services will perform 1,750 procedures in the first full year of operation, and 2,500 procedures by year two. While the overall utilization in PD 8 and the projected utilization of the proposed PET/CT unit is lower than the SMFP’s current utilization threshold, the Commissioner has historically recognized that the SMFP’s PET utilization thresholds are too high, outdated, and do not appropriately capture pediatric needs. The DCOPN staff report for COPN Request No. VA-7191, which ultimately resulted in COPN No. VA-04151, states:

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

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

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

DCOPN notes that no PET services in the Commonwealth actually met the SMFP's utilization thresholds of 6,000 procedures per existing and approved fixed site PET scanner in 2018. Furthermore, DCOPN notes the proposed project is an inventory-neutral relocation of an existing, COPN approved PET/CT unit, and is therefore unlikely to negatively affect existing providers.

COPN Request No. VA-8537: PET of Reston L.P.

Not applicable, the applicant is not seeking to add a new fixed site PET/CT service, but rather is proposing to convert a COPN authorized mobile PET/CT site to a fixed site 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.**

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

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

COPN Request No. VA-8537: PET of Reston L.P.

Not applicable. The applicant is not proposing to expand an existing fixed-site PET service, but rather, is proposing to convert a COPN authorized mobile PET/CT site to a fixed site PET/CT 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.**

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

Not applicable. The applicant is not proposing to add or expand an existing mobile PET/CT service, but rather, is proposing to establish a fixed-site PET/CT service.

COPN Request No. VA-8537: PET of Reston L.P.

Not applicable. The applicant is not proposing to add or expand an existing mobile PET/CT service, but rather, is proposing to convert a COPN authorized mobile PET/CT site to a fixed site PET/CT service.

**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-8531: Inova Reston MRI Center, LLC

Not applicable. The applicant is not proposing to convert mobile PET or PET/CT services to fixed site scanners.

COPN Request No. VA-8537: PET of Reston L.P.

Presently, the applicant offers mobile PET/CT services at POR two days per week on Monday and Thursday (with an occasional additional weekday) through the mobile vendor Alliance Imaging. According to VHI data, for 2018, the most recent year for which such data is available, the mobile PET/CT site performed 650 scans on the two days that it was in operation, or the equivalent of 1,625 scans had the service been operational five days per week. The applicant reports that in 2019, POR performed 725 scans, or the equivalent of 1,776 annual scans had the service been operational five days per week. However, it should be noted that DCOPN cannot verify this number, as the VHI data for 2019 is not currently available. The applicant anticipates that it will perform 1,172 and 1,202 scans in years one and two of operation. While these numbers are below the SMFP conversion standard, DCOPN and HSANV have previously acknowledged the SMFP's utilization standards for PET/CT services are outdated and that 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).

Furthermore, approval of the proposed project is unlikely to negatively affect the utilization of other providers of PET/CT services in PD 8. As shown in **Figure 1**, POR is located in the western portion of PD 8, where there are no nearby providers.

**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-8531: Inova Reston MRI Center, LLC

The applicant provided assurances that the proposed PET/CT service will be under the direct supervision of certified and trained radiologists.

COPN Request No. VA-8537: PET of Reston L.P.

The applicant provided assurances that the proposed PET/CT service will be under the direction of appropriately qualified and licensed physicians.

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-8531: Inova Reston MRI Center, LLC

Based on an analysis of previous COPN projects, IRMC has a consistent history of completing projects on time and within the authorized capital costs. With respect to the proposed project, the projected capital cost is \$5,011,046. Finally, in 2018, Inova Fairfax Hospital, the majority owner of IRMC, provided 4.7% of its gross patient revenue in the form of charity care.

COPN Request No. VA-8537: PET of Reston L.P.

Based on an analysis of previous COPN projects, POR has a consistent history of completing projects on time and within the authorized capital costs. With respect to the proposed project, the projected capital cost is \$1,671,742. Finally, in 2018, POR provided 2.5% of its gross patient revenue in the form of charity care.

Conclusion

As both applicants have similar histories of on time, on budget delivery, DCOPN concludes that neither applicant warrants preference regarding completing projects on time and within the approved capital expenditure or for having lower capital costs. For the same reason, DCOPN does not believe that any applicant warrants preference with respect to displaying a commitment to charity care.

**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-8531: Inova Reston MRI Center, LLC

IRMC proposes to relocate and upgrade an existing COPN approved PET/CT unit from less than one mile away – closer to the Schar Cancer Institute on the Inova Fairfax campus. The applicant projects no change in the primary service area. As a result, the primary patient population the proposed project is intended to serve is unchanged from the existing service. For these reasons, DCOPN concludes that the proposed project is not intended to, and is unlikely to, foster institutional competition that would benefit the area to be served.

COPN Request No. VA-8537: PET of Reston L.P.

As previously discussed, POR is located in the western portion of PD 8, where there are no nearby providers of PET/CT services. Therefore, DCOPN concludes that the proposed project is unlikely to foster institutional competition that would 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-8531: Inova Reston MRI Center, LLC

As previously discussed, approval of the proposed project is inventory-neutral for fixed PET/CT units in PD 8. The proposed project would make access to PET/CT services more convenient for patients of the Schar Cancer Institute, many of whom are immunocompromised, elderly and/or have mobility issues. Furthermore, the applicant projects no change in the primary patient population the PET/CT unit will serve. Therefore, approval of the proposed project is unlikely to negatively affect the utilization of other providers of PET/CT services in PD 8.

COPN Request No. VA-8537: PET of Reston L.P.

As previously discussed, approval of the proposed project is unlikely to have a substantial negative effect the utilization of other providers of PET/CT services in PD 8. As shown in **Figure 1**, POR is located in the western portion of PD 8, where there are no nearby providers.

- 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-8531: Inova Reston MRI Center, LLC

As already discussed, DCOPN contends that the projected costs for the proposed project are reasonable when compared to previously authorized projects similar in scope. Furthermore, the Pro Forma Income Statement provided by the applicant projects income of \$2,394,749 in the first year of operation and \$2,469,153 by year two. The applicant will fund the proposed project entirely with accumulated reserves and operational cash flow. Accordingly, there are no financing costs associated with this project.

The applicant anticipates the need to hire one new full time equivalent employee (FTE), a patient coordinator. Additionally, the applicant anticipates that the staff from Fairfax PET/CT Imaging Center will relocate to the new center. DCOPN concludes that the staffing requirements are reasonable and are unlikely to adversely affect existing providers.

COPN Request No. VA-8537: PET of Reston L.P

As already discussed, DCOPN contends that the projected costs for the proposed project are reasonable when compared to previously authorized projects similar in scope. Furthermore, the Pro Forma Income Statement provided by the applicant projects income of \$391,472 in the first year of operation and \$569,757 in year two. Capital costs will be funded through the accumulated reserves and operating revenue of the applicant and a commercial loan, for which POR has received pre-approval.

The applicant anticipates the need to hire two FTEs to staff the proposed project – one radiologic technologist and one patient access employee. The applicant asserts that it has already identified the likely individuals to fill these positions. 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 bases; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate; and**

Neither proposed project offers the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. However, both proposed projects increase the potential for provision of services on an outpatient basis, offering considerably lower costs than those offered in a hospital setting.

DCOPN did not identify any other factors that have not been addressed elsewhere in this staff analysis report to bring to the attention of the commissioner.

- 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-8531: Inova Reston MRI Center, LLC

Not applicable. The applicant is not a teaching hospital or affiliated with a public institution of higher education or medical school in the area to be served. Approval of the proposed project would not contribute to the unique research, training or clinical mission of a teaching hospital or medical school.

COPN Request No. VA-8537: PET of Reston L.P.

Not applicable. The applicant is not a teaching hospital or affiliated with a public institution of higher education or medical school in the area to be served. Approval of the proposed project would not contribute to the unique research, training or clinical mission of a teaching hospital or medical school.

**DCOPN Staff Findings and Conclusions**

COPN Request No. VA-8531: Inova Reston MRI Center, LLC

DCOPN finds that the proposed project to establish a specialized center for PET/CT imaging at the Inova Center for Personalized Health on the campus of Inova Fairfax Hospital through the relocation and upgrade of an existing PET/CT unit is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. The proposed project is an inventory neutral relocation and replacement of an existing COPN approved PET/ET unit. Furthermore, IRMC will move the unit less than a mile away to a location that is more convenient and accessible to patients of the Schar Cancer Institute on the Inova Fairfax Hospital campus. Finally, the existing unit is nearing the end of its useful life and IRMC will upgrade the PET/CT unit to one that can more efficiently serve its patients. For these reasons, DCOPN concludes that the proposed project is more favorable than maintaining the status quo.

DCOPN finds that the total capital costs of the proposed project are reasonable and consistent with previously approved projects similar in scope. Furthermore, DCOPN finds that the project appears to be economically feasible both in the immediate and long-term. Additionally, DCOPN concludes that approval of the proposed project is not likely to have a significant negative impact on the staffing or utilization of existing PET/CT providers. Finally, there is no known opposition to the proposed project.

COPN Request No. VA-8537: PET of Reston L.P.

DCOPN finds that the proposed project to convert a mobile PET/CT site to a fixed PET/CT unit 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. The introduction of fixed site PET/CT services at POR will allow for greater scheduling availability and protect patients from the weather and logistical issues the current mobile PET/CT site presents. For these reasons, DCOPN concludes that the proposed project is more favorable than maintaining the status quo.

DCOPN finds that the total capital costs of the proposed project are reasonable and consistent with previously approved projects similar in scope. Furthermore, DCOPN finds that the project appears to be economically feasible both in the immediate and long-term. Additionally, DCOPN concludes that approval of the proposed project is not likely to have a significant negative impact on the staffing or utilization of existing PET/CT providers. Finally, there is no known opposition to the proposed project.

### **DCOPN Staff Recommendation**

#### **COPN Request No. VA-8531: Inova Reston MRI Center, LLC**

The Division of Certificate of Public Need recommends the **conditional approval** of Inova Reston MRI Center LLC's request to establish fixed PET/CT services through the relocation and replacement of an existing PET/CT unit for the following reasons:

1. The proposed 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 capital costs are reasonable.
3. The proposed project appears economically viable in the long-term.
4. There is no known opposition to the proposed project.
5. The project is inventory neutral and is more favorable than maintaining the status quo.

### **Recommended Condition**

Inova Reston MRI Center LLC will provide PET/CT services to all persons in need of this service, regardless of their ability to pay, and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 8 in an aggregate amount equal to at least 4.1% of Inova Reston MRI Center LLC's gross patient revenue derived from PET/CT services. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Inova Reston MRI Center LLC 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 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.

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

COPN Request No. VA-8537: PET of Reston L.P.

The Division of Certificate of Public Need recommends the **conditional approval** of PET of Reston L.P.'s request to convert a mobile PET/CT site to a fixed PET/CT unit for the following reasons:

1. The proposed 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 capital costs are reasonable.
3. The proposed project appears economically viable in the long-term.
4. There is no known opposition to the proposed project.
5. The project is more favorable than maintaining the status quo.

**Recommended Condition**

PET of Reston L.P. will provide PET/CT services to all persons in need of this service, regardless of their ability to pay, and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 8 in an aggregate amount equal to at least 4.1% of PET of Reston L.P.'s gross patient revenue derived from PET/CT services. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. PET of Reston L.P. 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 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.

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