

COMMONWEALTH OF VIRGINIA

APPLICATION FOR A

MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED

(CHAPTER 4, ARTICLE 1:1 OF TITLE 32.1,

SECTIONS 32.1 – 102.1 THROUGH 32.1 – 102.12 OF

THE CODE OF VIRGINIA OF 1950, AS AMENDED)

OUTPATIENT FACILITIES

COPN Request No. VA- 8783

Inova Reston MRI Center, LLC

**Introduce Fixed PET/CT Services
at an Existing IRMC Site with One Fixed PET/CT Unit**

October 1, 2024

SECTION I FACILITY ORGANIZATION AND IDENTIFICATION

- A. **Inova Reston MRI Center, LLC d/b/a Centreville MRI and PET Center**
Official Name of Facility
- 6211 Centreville Road**
Address
- Centreville** **Virginia** **20121**
City State Zip
- (703) 204-4411**
Telephone
- B. **Inova Reston MRI Center, LLC**
Legal Name of Applicant
- 8260 Willow Oaks Corporate Drive, Suite 750**
Address
- Fairfax** **Virginia** **22031**
City State Zip
- C. Chief Administrative Officer
Lance Boyd, CEO
Name
- 8260 Willow Oaks Corporate Drive, Suite 750**
Address
- Fairfax** **Virginia** **22031**
City State Zip
- (703) 698-4444** **N/A**
Telephone Facsimile
- D. Person(s) to whom questions regarding application should be directed:
Carol Burchett, Chief Strategy Officer, Fairfax Radiology Centers, LLC
Name
- 8260 Willow Oaks Corporate Drive, Suite 750**
Address
- Fairfax** **Virginia** **22031**
City State Zip
- (703) 698-4444** **N/A**

- E. Telephone _____ Facsimile _____
 Type of Control and Ownership (Complete appropriate section for both owner and operator.)

Will the facility be operated by the owner? Yes _____ No X _____

Owner of the Facility
 (Check one)

(1) _____

(2) _____

(3) _____

(4) X _____

Proprietary

(1) Individual

(2) Partnership-attach copy of Partnership Agreement and receipt showing that agreement has been recorded

(3) Corporate-attach copy of Articles of Incorporation and Certificate of Incorporation

(4) Other _____ Identify

Operator of Facility
 (Check one)

(1) _____

(2) _____

(3) _____

(4) X _____

The owner is Inova Reston MRI Center, LLC (“IRMC”). Please see Attachment A-1 for IRMC’s Articles of Organization and Attachment A-2 for IRMC’s Certificate of Organization.

The operator is Fairfax Radiology Centers, LLC (“FRC, LLC”). Please see Attachment B for Fairfax Radiology Centers, LLC’s Articles of Organization.

Non-Profit

(5) _____

(5) Corporation-attach copy of Articles of Incorporation and Certificate of Incorporation

(5) _____

(6) _____

(6) Other _____ Identify

(6) _____

Governmental

(7) _____

(7) State

(7) _____

(8) _____

(8) County

(8) _____

(9) _____

(9) City

(9) _____

(10) _____

(10) City/County

(10) _____

(11) _____

(11) Hospital Authority or

(11) _____

Commission

F. Ownership of the Site (Check one and attach copy of document)

- (1) _____ Fee simple title held by the applicant
 (2) _____ Option to purchase held by the applicant
 (3) X Leasehold interest for not less than 11.5 years
 (4) _____ Renewable lease, renewable every _____ years
 (5) _____ Other

See Attachment C-1a for a copy of a signed letter agreement to expand the current leased space at the existing FRC of Centreville facility which sets forth an 11.5-year lease term on the expansion space beginning July 1, 2025, and ending December 31, 2036. The letter agreement also extends the end date of the existing lease on the current leased space to December 31, 2036. The First Amendment to the original lease can be found at Attachment C-2 and the original lease can be found at Attachment C-3. As referenced in the lease documents, IFRC, LLC ("IFRC") leases the current leased space from the landlord, and IFRC subleases the space utilized for IRMC's MRI services to IRMC. The space to be utilized by the PET/CT unit will be subject to an arrangement consistent with the current lease. See signed proposal letter for sublease between IFRC (sublandlord) and IRMC (subtenant) at Attachment C-1b.

G. Attach a list of names and addresses of all owners or persons having a financial interest of five percent (5%) or more in the medical care facility.

IRMC is a Virginia limited liability company with two members (i.e., owners):

Inova Health Care Services (Majority Owner)
8095 Innovation Park Drive
Fairfax, Virginia 22031

Fairfax Radiological Consultants, PLLC (Minority Owner)
8260 Willow Oaks Corporate Drive, Suite 750
Fairfax, Virginia 22031

(a) In the case of proprietary corporation also attach:

- (1) A list of the names and addresses of the board of directors of the corporation.

IRMC is a Virginia limited liability company. Its board members are set forth below. Board members appointed by Inova Health Care Services may be reached at the Inova Health Care Services address set forth above and board members appointed by Fairfax Radiological Consultants, PLLC may be reached at the Fairfax Radiological Consultants, PLLC address set forth above.

Toni Ardabell, MSN, MBA, Chief of Clinical Enterprise Operations, Inova
Susan Carroll, President of Inova Loudoun Hospital and Senior VP, Inova

Rina Bansal, MD, MBA, President of Inova Alexandria Hospital and Senior VP, Inova

Sean McCleary, Administrator, Clinical Platforms and VP, Professional Services, Inova

David Spinoso, MD, Fairfax Radiological Consultants, PLLC

Patrick Oliverio, MD, Fairfax Radiological Consultants, PLLC (Chair)

Edward Greenberg, MD, Fairfax Radiological Consultants, PLLC

- (2) A list of the officers of the corporation.

As reflected above, IRMC is a Virginia limited liability company. Its officers are as follows:

Lance Boyd, Chief Executive Officer

Kim Masters, Chief Operating Officer

Anna Toth, Chief Financial Officer

- (3) The name and address of the registered agent for the corporation.

**CT Corporation System
4701 Cox Road, Suite 285
Glen Allen, Virginia 23060**

- (b) In the case of a non-profit corporation also attach: **Not Applicable.**

- (1) A list of the names and addresses of the board of directors of the corporation
- (2) A list of the officers of the corporation
- (3) The name and address of the registered agent for the corporation

- (c) In the case of a partnership also attach: **Not Applicable.**

- (1) A list of the names and addresses of all partners.
- (2) The name and address of the general or managing partner.

- (d) In the case of other types of ownership, also attach such documents as will clearly identify the owner. **Not Applicable.**

- H. List all subsidiaries wholly or partially owned by the applicant.

Not Applicable. IRMC has no subsidiaries.

- I. List all organizations of which the applicant is wholly or partially owned subsidiary.

IRMC is owned by Inova Health Care Services and Fairfax Radiological Consultants, PLLC, each of which are members.

If the operator is other than the owner, attach a list of the names(s) and addresses

of the operator(s) of the medical care facility project. In the case of a corporate operator, specify the name and address of the Registered Agent. In the case of the partnership operator, specify the name and address of the general or managing partner.

The operator is FRC, LLC. Its address is as follows:

**Fairfax Radiology Centers, LLC
8260 Willow Oaks Corporate Drive, Suite 750
Fairfax, Virginia 22031
Attention: Lance Boyd**

FRC, LLC's registered agent is CT Corporation System:

**CT Corporation System
4702 Cox Road, Suite 285
Glen Allen, Virginia 23060**

- J. If the operator is other than the owner, attach an executed copy of the contract or agreement between the owner and the operator of the medical care facility.

Pursuant to this COPN application, IRMC proposes to introduce fixed PET/CT services through the acquisition of one (1) fixed PET/CT unit at the existing FRC of Centreville facility located at 6211 Centreville Road. Subject to timely COPN approval, the PET/CT unit is expected to be operational by April 1, 2026.

Imaging services at the FRC of Centreville facility are and will remain under the management/operation of FRC, LLC. Please see Attachment D for a copy of the Administrative Services Agreement between IRMC, LLC and FRC, LLC. Note: Some items were redacted as they are confidential in nature but do not affect compliance with this item.

SECTION II

ARCHITECTURE AND DESIGN

A. Location of the Proposed Project

1. Size of site: 5.0995 acres
2. Located in **Fairfax County / PD 8** City/County/Planning District
3. Address or directions: **6211 Centreville Road, Centreville, Virginia 20121**
4. Has site been zoned for type of use proposed:

 X Yes The property/complex consists of medical office space and is zoned for C-2. In accordance with Section 4102.4.R of the Fairfax County Zoning Ordinance, the C-2 District is predominantly non-retail, low-intensity commercial uses such as offices, financial institutions and other similar uses. Medical care facilities are permitted in a C-2 zone via code SE (Special Exception). See Attachment E-1 - 6211 Centreville Road Zoning Map and Attachment E-2 Fairfax County Zoning Ordinance, excerpted provisions of Article 4 addressing C-2 zoning with SE exception.

 No

If no, explain status _____

B. Type of project for which Certificate of Public Need is requested. (Check one)

- (1) New construction
- (2) Remodeling/modernization of an existing facility
- (3) No construction or remodeling/modernization
- (4) X Other **Introduce fixed PET/CT services at an existing IRMC site with one (1) fixed PET/CT unit.**

C. Design of the facility

- (1) Does the facility have a long-range plan? If yes, attach a copy.

IRMC's plans are guided by FRC, LLC's mission, vision and values as set forth in Attachment F.

FRC, LLC's mission is:

FRC, LLC exists to provide exceptional access to world-class, patient-centered radiological care, for every patient, every time.

FRC, LLC's vision is:

To be the first choice of every patient and referring physician in our growing community.

FRC, LLC's values are:

Respect, Trust, Compassion, and Innovation.

- (2) Briefly describe the proposed project with respect to location, style and major design features, and the relationship of the current proposal to the long range plan.

The proposed project involves the introduction of fixed PET/CT services through one (1) PET/CT unit at an existing multi-modality imaging facility, FRC of Centreville (the "Centreville Facility"), located at 6211 Centreville Road, Centreville, Virginia 21021. The Centreville Facility location is optimally positioned approximately one (1) mile southeast of I-66 (Interstate 66) off Route 28/Centreville Road in a medical office building complex, which includes family medicine and orthopedics practices, a physical therapy center and an urgent care center.

The project will place one (1) PET/CT unit at the Centreville Facility which does not currently offer PET/CT services. The Centreville Facility does, however, currently offer several other diagnostic imaging modalities, including MRI and CT, as well as other imaging services that are not subject to COPN regulation, including X-ray, ultrasound, mammography, and DEXA. The MRI services are owned by IRMC, while the remaining services are owned by IFRC. IRMC sublets space from IFRC for the MRI service and will do the same for the incoming PET/CT services, if approved.

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

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

The introduction of fixed PET/CT services at the Centreville Facility is needed to address capacity constraints on IRMC's Fairfax PET/CT unit. The schedule at the Fairfax facility has been expanded and is maximized at 20 appointments per day, Monday through Friday. However, due to the nature of the patient population who utilizes these services, who tend to be very sick, there are frequent cancellations and/or no shows due to worsening illness, hospitalizations or because the patient's blood sugar requirements are not

adequate at the time of the appointment. Notwithstanding these cancellations and no shows, patients waiting for PET/CT services at Fairfax are waiting approximately 2 1/2 weeks. This is a significant dissatisfier for both patients and referring physicians wanting to get patients in sooner.

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

Moreover, placing the proposed PET/CT unit at the Centreville Facility will improve geographic access to PET/CT services for IRMC's patient population, reducing travel times for patients who reside in the western portions of the planning district. A key element of IRMC's long range plan is to optimally place services closer to where its patients live. In 2023, approximately 25% of IRMC's PET/CT patients originated from the western portions of PD 8.

- (3) Describe the relationship of the facility to public transportation and highway access.

The Centreville Facility is conveniently located approximately one (1) mile southeast of I-66 (Interstate 66) with easy access to Route 28/Centreville Road. Route 28/Centreville Road is a major thoroughfare, and the Centreville Facility is easily accessible from both the north and south directions. Public bus transportation is available within easy walking distance from the Centreville Facility.

- (4) Relate the size, shape, contour and location of the site to such problems as future expansion, parking, zoning and the provision of water, sewer and solid waste services.

The proposed PET/CT unit will be located in Building 2 of the Centre Med medical office complex (the two buildings that comprise the Centre Med medical office complex are, collectively, 52,000 square feet total) in a 1st floor suite, adjacent to the existing IRMC MRI suite. See Attachment G for Plot Plan.

There is easy access to entrances to the property from Centreville Road and New Braddock Road with adequate parking available to patients, visitors and staff, including handicapped parking optimally adjacent to an entrance door. The building was constructed in 1998, so the full complement of public utilities currently exist on site, including water, sewer, and solid waste services.

- (5) If this proposal is to replace an existing facility, specify what use will be made of the existing facility after the new facility is completed.

Not applicable. This project proposes the introduction of PET/CT services at the site of an existing imaging facility.

- (6) Describe any design features which will make the proposed project more efficient in terms of construction costs, operating costs, or energy conservation.

The proposed PET/CT unit will be located in an existing medical office building in a suite adjacent to the existing IRMC MRI suite. The space utilizes energy saving features consistent with local building ordinances, including occupancy sensor-controlled lighting in support areas. The renovations necessary for buildout of the space will be compliant with local energy calculation requirements and specifications for high efficiency mechanical equipment. The space will be designed in compliance with all applicable local, state, and federal requirements for energy efficiency and consumption to minimize cost and maximize energy efficiency and conservation while optimizing patient throughput and comfort.

- D. Describe and document in detail how the facility will be provided with water, sewer and solid waste services. Also describe power source to be used for heating and cooling purposes. Documentation should include, but is not limited to:

- (1) Letters from appropriate governmental agencies verifying the availability and adequacy of utilities,
- (2) National Pollution Discharge Elimination System permits,
- (3) Septic tank permits, or
- (4) Receipts for water and sewer connection and sewer connection fees.

Adequate public utilities currently exist on-site, including electricity, water, sewer and solid waste services. The existing space is served by a 5- ton Roof Top Unit (RTU). A new dedicated direct expansion (DX) air-cooled conditioning system will be provided for the PET/CT space. Equipment cooling for the PET/CT unit will be provided by dedicated air-cooled chillers on the roof. As part of the due diligence at the site, the water/sewer service and electrical capacity has been evaluated by the professional engineer responsible for determining the adequacy of the mechanical, electrical, and plumbing (MEP) systems. Please see Attachment H for more information addressing the adequacy of utilities.

- E. Space tabulation – (show in tabular form)

1. If Item #1 was checked in II-B, specify: **Not Applicable.**
 - a. The total number of square feet (both gross and net) in the proposed facility.
 - b. The total number of square feet (both gross and net) by department and each type of patient room (the sum of the square footage in this part should equal

the sum of the square footage in (a) above and should be consistent with any preliminary drawings, if available).

2. If Item #2 was checked in II-B, specify:

- a. The total number of square feet (both gross and net) by department and each type of patient room in the existing facility.

Item #2 was not checked; however, the space within the Centreville Facility that will be dedicated to the PET/CT unit consists of 3,422 gross square feet (3,019 net square feet).

- b. The total number of square feet (both gross and net) to be added to the facility.

The PET/CT unit will be located at the Centreville Facility in the same building as IRMC's existing imaging services at Centreville. The Centreville Facility has one (1) IRMC COPN-approved MRI unit in place. In addition, IFRC has X-ray, mammography, DEXA, and ultrasound, which are not subject to COPN regulation, as well as one (1) COPN-approved CT unit.

The space within the imaging center that will be dedicated to the PET/CT unit consists of 3,422 gross square feet (3,019 net square feet). The incremental PET/CT dedicated space dedicated to the PET/CT unit comprises 2,245 gross square feet and 1,925 net square feet, and the office and storage area is 1,497 gross square feet and 774 net square feet. Please refer to Attachment I for the preliminary design drawing.

- c. The total number square feet (both gross and net) to be remodeled, modernized, or converted to another use.

Not Applicable.

- d. The total number of square feet (both gross and net) by department and each type of patient room in the facility upon completion. (The sum of square footage in this part should equal the sum of the square footages in parts (a) and (b) above and should be consistent with any preliminary drawings, if available. (The department breakdown should be the same as in (a) above.)

Not Applicable.

3. Specify design criteria used or rationale for determining the size of the total facility and each department within the facility.

The proposed PET/CT unit is to be located at the Centreville Facility. A test fit of the space was completed. The dedicated space for the PET/CT unit will be 2,245 gross square feet (1,925 net square feet) in compliance with the

equipment manufacturer (Siemens) specifications and all Facility Guidelines Institute (FGI) and other regulatory requirements.

F. Attach a plot plan of the site which includes at least the following:

1. The courses and distances of the property line.
2. Dimensions and location of any buildings, structures, roads, parking areas, walkways, easements, right-of-way or encroachments on the site.

Please see Attachment G for the plot plan.

G. Attach a preliminary design drawing drawn to a scale of not less than 1/16"-1'0" showing the functional layout of the proposed project which indicates at least the following:

1. The layout of each typical functional unit.
2. The spatial relationship of separate functional components to each other.
3. Circulatory spaces (halls, stairwells, elevators, etc.) and mechanical spaces.

Please see Attachment I for the preliminary design drawing.

H. Construction Time Estimates

1. Date of Drawings: **Preliminary 7/16/2024 Final 12/15/2024**
2. Date of Construction: **Begin 10/1/2025 Completion 3/15/2026**
3. Target Date of Opening: **4/1/2026**

SECTION III

SERVICE DATA

- A. In brief narrative form describe the kind of services now provided and and/or the kind of services to be available after completion of the proposed construction or equipment installation.

This COPN request proposes to introduce fixed PET/CT services at the Centreville Facility, an existing multi-modality imaging facility in Centreville, Virginia, through the introduction of one (1) PET/CT unit. The project is proposed to address the need for additional access to PET/CT services among IRMC's patient population.

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

A positron emission tomography (PET) scan is a type of nuclear medicine imaging test. It is used to examine various body tissues to identify certain conditions by looking at blood flow, metabolism, and oxygen use. PET scans may also be used to see how well the treatment of certain diseases works.

For a PET scan, a tiny amount of a radioactive substance, called a radioactive tracer, is used to show the metabolism of a particular organ or tissue. This test gives the healthcare provider information about the function and structure of the organ or tissue. It also gives information about its biochemical properties. A PET scan may detect biochemical changes in an organ or tissue that are signs of a disease process before physical changes related to the disease can be seen with other imaging tests.

PET scans are often combined with CT scans (called a PET/CT scan) to give more definitive information about metabolism changes and exactly where they are happening in the body.

A PET/CT scan produces a highly detailed three-dimensional image of functional processes in the body. It creates these intricate images using X-rays of cross-sections, or "slices," of the body. This process provides for earlier and more accurate detection of diseases.

A PET/CT scan is frequently ordered and used for the detection, staging and follow-up treatment of cancer and to monitor the effectiveness of cancer treatment. It also is used to plan medical, surgical or radiation treatment. In addition, PET/CT scans may be used to assess a person's risk of heart disease or detect damage to blood vessels in the form of aneurysms or blockages. The proposed PET/CT unit would not be used for cardiac related services; rather, the predominant procedural focus will be cancer patients' diagnosis, staging and treatment planning. For patients with cancer, being able to schedule timely diagnostic imaging is crucially important.

The introduction of fixed PET/CT services at the Centreville Facility is needed because of the scheduling backlog for IRMC's PET/CT services that currently exists at the Fairfax facility. With only one (1) PET/CT unit in IRMC's inventory, wait times for a PET/CT appointment have become increasingly longer, and are currently around 2 ½ weeks. It is disheartening to have to tell a patient sick with cancer that they must wait two to three weeks to get their cancer staged so their oncologist/radiation oncologist can design the appropriate treatment plan. The additional PET/CT unit will improve access for the IRMC patient population by reducing substantial scheduling backlogs for PET/CT services.

The Centreville Facility has one (1) IRMC COPN-approved MRI unit in place. In addition, IFRC has X-ray, mammography, DEXA, and ultrasound, which are not subject to COPN regulation, as well as one (1) COPN-approved CT unit.

- B. Describe measures used or steps taken to assure continuity of care.

The proposed introduction of PET/CT services will not disrupt existing services at the Centreville Facility and will improve access to care for IRMC patients residing in the western portions of PD8. Subject to COPN approval, the PET/CT unit at the Centreville Facility would be installed during non-business hours and would be located in a suite adjacent to the current suite where IRMC's MRI unit is located.

Continuity of care has always been, and remains, a priority for Inova Health Care Services and Fairfax Radiology Consultants, which own IRMC. IRMC employs several mechanisms and technologies that facilitate the inclusion of patients, referring physicians and other care providers in its processes, making IRMC staff and radiologists valuable members of the patient care team. Measures and steps to assure continuity of care include, without limitation, the following:

Record Continuity

IRMC maintains a physician portal connecting to the EMR which provides all members of the patient care teams access to pertinent patient information such as diagnostic images, radiologist reports and other pertinent information from past visits. That portal is accessible 24/7.

IRMC has the ability to securely send images and reports electronically to external EMRs.

Clinician/Patient Continuity

In addition to the physician portal, IRMC patients have access to a patient portal where they can securely view their images and the radiologist's reports.

The radiologist uses a "call center" that facilitates connecting the referring physicians to the radiologist for patient consultation.

- C. What procedures are utilized in quality care assessment?

IRMC has adopted protocols and procedures used across its facilities. These protocols and procedures are designed to ensure quality of care and incorporate the concepts and functions of continuous quality improvements. Examples are as follows:

Patient Safety

IRMC's existing PET/CT unit at its Fairfax facility is inspected annually by a physicist and receives regularly scheduled preventative maintenance several times per year. The Radiation Safety Officer (RSO) has specialized training in safety, risk factors and emergency response and works with staff and site managers to develop and implement safety protocols. Any deficiencies are handled by the equipment vendor for correction and reported to the Patient Safety Committee.

The Patient Safety Committee is composed of a multidisciplinary team. The Committee is headed by FRC's Chief Operating Officer and is comprised of clinical directors, site managers and technology specialists. In addition, this committee reports to the FRC Board of Directors Quality and Patient Safety Committee, which is chaired by an FRC, PLLC physician leader and Board member.

Quality of Radiologist and Technologist

Fairfax Radiological Consultants, PLLC staffs the existing Centreville Facility (as well as the Fairfax facility) and will continue to staff the facility following the introduction of PET/CT services. The practice is comprised of a diversified group of radiologists who are board certified in many areas of expertise. The technologists are all licensed by the Virginia Department of Health and certified by the applicable governing organization (which varies by modality) and annual competency assessments ensure their ability to perform procedures and carry out safe patient care.

- D. Describe the plan for obtaining additional medical, nursing and paramedical personnel required to staff the project following completion and identify the sources from which such personnel are expected to be obtained.

Fairfax Radiology Centers (FRC, LLC), which manages/operates IRMC's imaging services, recruits for all positions internally and has two recruiters dedicated to clinical recruitment. Additionally, FRC, LLC recently hired a recruitment manager who has different industry experience and has significantly improved our recruitment process and successful hire rate. In addition, FRC, LLC:

- Has a formal in-house training program
- Partners with outside educational institutions
- Maintains a float pool of Technologists to cover vacancies and employee absences.

Additional components of our recruitment program include:

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

E. Facilities and Services to be Provided (Check)

The response set forth below reflects the introduction of one (1) PET/CT unit to the Centreville Facility (services reflect those owned by IRMC and those owned by IFRC).

	<u>Existing</u>	<u>This Project To be Added</u>	<u>This Project to be Discontinued</u>
1. Outpatient Surgery	_____	_____	_____
2. Post Operative Recovery Room	_____	_____	_____
3. Pharmacy with full-time pharmacists part-time pharmacists	_____ _____	_____ _____	_____ _____
4. Diagnostic Radio- logical Services			
x-ray	<u> X </u>	_____	_____
radioisotope	_____	_____	_____
MRI scanning	<u> X </u>	_____	_____
5. Therapeutic Radio- logical Services	_____	_____	_____
Specify Source(s) or Type(s) or Equipment Used	_____ _____	_____ _____	_____ _____
6. Clinical Pathology Laboratory	_____	_____	_____
7. Blood Bank	_____	_____	_____
8. Electroencephalo- graphy	_____	_____	_____
9. Electrocardiography	_____	_____	_____
10. Ultrasonography	<u> X </u>	_____	_____
11. Respiratory Therapy	_____	_____	_____

12.	Renal Dialysis			
	chronic outpatient			
	home dialysis training			
13.	Alcoholism Service			
14.	Drug Addiction			
	Service			
15.	Physical Therapy			
	Department			
16.	Occupational			
	Therapy Department			
17.	Medical Rehabilitation			
	outpatient			
18.	Psychiatric Service			
	outpatient			
	emergency service			
19.	Clinical Psychology			
20.	Outpatient Emergency			
	Service			
21.	Social Service			
22.	Family Planning			
	Service			
23.	Genetic Counseling			
	Service			
24.	Abortion Service			
25.	Pediatric Service			
26.	Obstetric Service			
27.	Gynecological			
	Service			
28.	Home Care Service			
29.	Speech Pathology			
	Service			
30.	Audiology Service			

- | | | | | |
|-----|------------------------------|--------------|--------------|-------|
| 31. | Paramedical Training Program | _____ | _____ | _____ |
| 32. | Dental Service | _____ | _____ | _____ |
| 33. | Podiatric Service | _____ | _____ | _____ |
| 34. | Pre-Admission Testing | _____ | _____ | _____ |
| 35. | Pre-Discharge Planning | _____ | _____ | _____ |
| 36. | Multiphasic Screening | _____ | _____ | _____ |
| 37. | Other PET/CT | _____ | <u> X </u> | _____ |
| | CT | <u> X </u> | _____ | _____ |
| | Mammography | <u> X </u> | _____ | _____ |
| | DEXA | <u> X </u> | _____ | _____ |

F. Program

1. Is (will) this outpatient facility (be) a department, unit or satellite of a hospital?

_____ Yes (Give name of hospital) _____

 X No

2. Is this outpatient facility affiliated with or does it have a transfer agreement with a hospital?

 X Yes (Give name of hospital)

Inova Fairfax Hospital, Inova Fair Oaks Hospital, Inova Alexandria Hospital, Inova Mount Vernon Hospital, and Inova Loudoun Hospital

_____ No

3. Is (will) there (be) an arrangement whereby medical records can readily be transferred between this outpatient facility and an inpatient facility (ies)?

 X Yes (give name of facility)

Medical records can be shared with any Inova hospital

_____ No

4. Outpatient services are (will be) available from: **Monday through Friday, 7 AM to 6:30 PM**
5. Does (will) the facility operate scheduled clinics?
 _____ Yes (Attach clinic schedule list)
 X No
6. Are there other organized outpatient services in your primary service area?
 X Yes _____ No
7. The outpatient facility is (will be) staffed:
 (a) Only by physicians on call: _____ Yes X No
 (b) By full time physicians: X Yes _____ No
 (c) By physicians who limit their practice to this outpatient service? _____ Yes X No
8. State specifically any limitations or restrictions for participation in the services of the facility. **Not applicable; any appropriately licensed physician can refer a patient to the imaging facility.**

G. Please provide historical and/or project utilization statistics for the facility including number of patients, number of patient visits and number of patient services.

	Historical (Fairfax Facility)			Projected (Fairfax and Centreville Facilities)	
	2022	2023	Aug 2024 YTD Ann	Year 1 2026	Year 2 2027
# PET CT Units	1	1	1	2	2
Procedures	2,834	3,893	4,152	7,340	8,000
% of SMFP Utilization	47%	65%	69%	31%	33%
Patient Visit Count	2,788	3,813	4,071	7,197	7,844

Projected Year 1 (2026) and Year 2 (2027) assumes approval of the second (2nd) PET/CT unit; the projected volumes cannot be accommodated on the existing one (1) PET/CT unit without the addition of a second (2nd) PET/CT unit.

	Centreville Only			Projected	
	2022	2023	Aug 2024 YTD Ann	Year 1 2026	Year 2 2027
# PET CT Units	0	0	0	1	1
Procedures	N/A	N/A	N/A	2,920	3,580
Patient Visit Count	N/A	N/A	N/A	2,863	3,510

In the DCOPN Staff Report dated March 20, 2024 (COPN Request No. VA-8722), DCOPN acknowledged that the State Medical Facilities Plan (“SMFP”) utilization standards for PET services (average of 6,000 procedures per PET scanner per year) are outdated:

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, as discussed in the DCOPN Staff Report dated July 19, 2024 (COPN Request No. VA-8758), which approved a COPN application for PET/CT services that did not meet the 6,000-procedure threshold, DCOPN noted that the SMFP threshold for PET scans “has been acknowledged as outdated for current clinical applications of PET technology.”

IRMC has already maximized the number of appointments (twenty (20)) per day on its Fairfax PET/CT unit. It is not possible to further extend the hours of operation per day because of the limited shelf life of the isotope and the inability to access radiopharmaceuticals after the last dose arrives at 2 PM each day. Nor is there a consistent radiopharmaceutical delivery schedule available on weekends.

When a patient comes in for a PET/CT, they must first drink barium and then wait an hour for it to take effect. The isotope is then administered intravenously before the scan can commence. Accomplishing all these steps in concert and monitoring the movement of patients throughout the process requires careful coordination of care amongst all staff members. In addition, the isotope dosing is customized to each patient and must be strictly adhered to and administered properly.

H. Staffing of Existing and/or Proposed Facility

In the following categories, indicate the number of full-time equivalent personnel (at least 35 hours per week).

The staffing discussed below is specific to the proposed PET/CT unit at the Centreville Facility.

	Current Full Time	Vacant Positions	Additional Needed Full Time	TOTAL
Total number of Full-time staff	<u>0</u>	<u>0</u>	<u>5</u>	<u>5.0</u>
Administration-Business Office	<u>0</u>	<u>0</u>	<u>2</u>	<u>2.0</u>
Radiologic Technologists	<u>0</u>	<u>0</u>	<u>3</u>	<u>3.0</u>

Present a plan for obtaining all additional personnel required to staff the project following completion and identify the sources from which such personnel are expected to be obtained.

Fairfax Radiology Centers (FRC, LLC) which manages/operates IRMCs imaging services, recruits for all positions internally and has two recruiters dedicated to clinical recruitment. Additionally, FRC, LLC

- **Recently hired an experienced Recruitment Manager**
- **Has a formal in-house Tech training program**
- **Partners with outside educational institutions**
- **Maintains a float pool of Technologists to cover vacancies and employee absences.**

Additional components of the recruitment program include:

- **Posting of open positions internally**
- **Placing special advertisements strategically in Indeed and other national job search engines**
- **Implementing an employee referral bonus program**

J. Describe the anticipated impact that the project will have on the staffing of other facilities in the service area.

We do not anticipate any impact on other facilities in the service area as PET/CT Technologist continues to be a desirable career advancement opportunity internally from X-ray and other technologist positions.

K. Attach the following information or documents:

1. Copy of most recent licensing report from State Agency (existing facilities, excluding public health centers). **Not Applicable.**
2. Current accreditation status and copy of latest accreditation report from Joint Commission on Accreditation of Hospitals (existing facilities excluding public health centers). **Not Applicable.**

3. Roster of medical staff (existing facilities). Indicate their specialty, Board Certification, Board eligibility and staff privileges (active, associate, etc.).

See attached medical roster at Attachment Q. Fairfax Radiological Consultants, PLLC is contracted to provide professional interpretation of the PET/CT scans. This coverage is consistent with the current PET/CT services at the Fairfax facility and would continue with the introduction of PET/CT services at the Centreville Facility.

4. Copies of letters of commitment or statement of intent from physicians indicating they will staff the proposed new facility or service upon completion (existing and proposed facilities).

Please see Attachment J.

SECTION IV

PROJECT JUSTIFICATION AND IDENTIFICATION OF
COMMUNITY NEED

A. Please provide a comprehensive narrative description of the proposed project.

The proposed project involves the introduction of fixed PET/CT services through one (1) fixed PET/CT unit at the Centreville Facility, an existing multi-modality imaging facility in Centreville, Virginia. IRMC proposes to introduce PET/CT services at its Centreville Facility to address capacity constraints on IRMC's existing PET/CT unit at its Fairfax facility and provide enhanced geographic access to a critical diagnostic imaging service at a site that is optimally located to address the needs of IRMC patients who live in western PD 8. This will ensure timely care for our existing patients and referring physicians who are oftentimes waiting for the results to inform the next step in the care process.

Further justification for this project is as follows:

- 1) The need for more timely scheduling of patients. Currently, IRMC provides PET/CT services on one (1) PET/CT unit located at 8081 Innovation Park Drive in Fairfax. This existing PET/CT unit is very busy, performing 3,893 PET/CT procedures in 2023. Based on actual PET/CT procedure volume through August 2024, IRMC expects to perform 4,152 PET/CT procedures at its Fairfax facility in 2024 – a 6.7% increase over 2023 volume. To reduce wait times, IRMC expanded hours at the Fairfax facility throughout the week with the first patient starting at 7 AM and the last patient ending at 6:30 PM. This schedule provides 20 appointments per day, 5 days per week. Despite extending the hours, the wait time to appointment is approximately 2 1/2 weeks.

Because of the serious illnesses experienced by these patients, there are daily appointments that are missed or cancelled on short notice (e.g., a patient is hospitalized). Should a patient cancel on short notice, a wait list is maintained to attempt to get another waiting patient in sooner, but, even with that, due to the stringent prior authorization criteria of most payors and radiopharmaceutical dose delivery limitations, the actual number of completed procedures per day averages between 16 and 17.

- 2) The workday with the current PET/CT unit cannot be extended because a PET/CT scan requires the administration of a radioactive isotope that has a limited shelf life (3 hours) before the PET/CT scan can be performed. The pharmacy delivers the last dose at 2 PM with a window of 3 hours after which the isotope is no longer usable.
- 3) A PET/CT scan is frequently ordered and used for the detection, staging and follow-up treatment of cancer and to monitor the effectiveness of treatment. It is used to plan medical, surgical or radiation treatment. IRMC's PET/CT is used predominantly for cancer patients' diagnosis, staging and treatment planning. For patients with cancer, being able to schedule timely diagnostic imaging is critically important not just for their physical health but for their mental health

as well. Being given a diagnosis of cancer and awaiting the staging of a cancer diagnosis is very stressful for these patients. Telling them they must wait 2-3 weeks for their PET/CT appointment is a significant stressor for them, for their referring physician, and for IRMC's staff and radiologists. Every day someone is told they have to wait. Every day IRMC's staff receives calls from referring physicians' offices asking to please fit someone in. Every day 3-4 slots are lost because the patient is unwell, or their sugar level is too high. Getting to a shorter wait time is the right thing to do for these patients, their loved ones and their care providers.

- 4) The potential for future expansion in the application of PET/CT is significant. PET/CT is increasingly being recognized as a critical diagnostic tool for identifying with greater precision the state of the patient's disease and identifying specific molecular markers within a patient's tumor, allowing for tailored treatment plans with targeted therapies. With the development of new, highly specific tracers that target specific disease biomarkers, it can provide more precise information about disease activity. PET/CT is especially promising for diagnosing and treating lung cancer. It is now the standard of care for the evaluation of cardiovascular patients (although this type of usage will not be the focus of IRMC's PET/CT). It is just starting to be used in the investigation of brain function and neurodegenerative diseases like Alzheimer's by combining PET with advanced imaging techniques such as MRI.

With only one (1) PET/CT unit in IRMC's inventory, the Fairfax facility is projected to perform 4,152 PET/CT procedures in 2024, a 6.7% increase over its 2023 volume. As discussed in Section III.G above, the SMFP standard of 6,000 procedures has been acknowledged by DCOPN as an outdated utilization standard for PET/CT services and we strongly concur with that assessment. Without increasing the overall IRMC inventory to two (2) PET/CT units by introducing one (1) PET/CT unit at the Centreville Facility, given the continued population growth and growth in the use of PET/CT services to support expanded clinical criteria, IRMC will be unable to meet its patient population's need for PET/CT.

PET/CT services are a critical and growing imaging tool and accurate and prompt diagnosis and treatment is essential to patient care. Wait times for the one (1) existing PET/CT unit at the Fairfax facility are considerable with an average wait time of 2 1/2 weeks. The hours of operation have already been extended to the maximum extent reasonably possible, with the facility operating Monday through Friday from 7:00 AM to 6:30 PM. Despite those extended hours, wait times for elective PET/CT procedures persist as noted above. Timeliness is critical to patient care. Many patients are waiting for a diagnostic appointment to rule out or diagnose cancer and more precisely provide critical information for the next steps in the treatment process following the diagnostic study.

By increasing capacity through the introduction of PET/CT services at the Centreville Facility, IRMC will be able to reduce wait times and improve access, including geographic access, leading to an improved patient experience, and allowing the next phase of care to proceed.

B. Identification of Community Need

1. Describe the geographic boundaries of the facility's primary service area. (Note: Primary service area may be considered to be geographic area from which 75% of patients are expected to originate.)

Please see Attachment L for a map outlining the primary service area for the PET/CT service. No change in the primary service area is projected.

2. Provide patient origin, discharge diagnosis or utilization data appropriate for the type of project proposed.

Please see Attachment L for 2023 patient origin data for the current PET/CT unit at the Fairfax facility.

- C.
 1. Is (are) the service(s) to be offered presently being offered by any other existing facility(ies) in the Health Planning Region?

Yes, PET/CT services are currently offered at other facilities in PD 8.

2. If Yes,

- a. Identify the facility(ies)

The facilities that provide PET/CT services in PD 8 are listed in Attachment K and in the table that follows below.

Provider	Type	# Units
Amelia Heart & Vascular Center *	Fixed, Cardiac	1
Carient Heart & Vascular	Fixed, Cardiac	2
Virginia Heart *	Fixed, Cardiac	1
Cardiac Care Associates**	Fixed, Cardiac	1
Fairfax PET/CT Imaging Center (IRMC)	Fixed	1
Kaiser Permanente Woodbridge Imaging Center	Fixed	1
Metro Region PET Center **	Fixed	2
Virginia Hospital Center	Fixed	1
UVA Cancer Center	Mobile	1
PET of Reston	Mobile	1
Sentara Northern Virginia Medical Center	Mobile	1
Nova Cardiovascular Care *	Fixed, Cardiac	1
Total Authorized PET/CT Scanners		14

* Were not active in 2022 VHI Reporting

** Were approved in 2024 (2nd scanner was approved for Metro PET)

The table below reflects the PET/CT procedure volume for IRMC's Fairfax facility PET/CT imaging site:

	2022	2023	Aug 2024 YTD Ann
Procedures	2,834	3,893	4,152
% of SMFP Utilization	47%	65%	69%
Patient Visit Count	2,788	3,813	4,071

- b. Discuss the extent to which the facility(ies) satisfy(ies) the current demand for the service(s).

The project proposes to expand IRMC's PET/CT unit inventory through the introduction of one (1) PET/CT unit at the existing Centreville Facility. Increasing PET/CT capacity by placing one (1) PET/CT unit at the Centreville Facility will reduce wait times and improve access to PET/CT services, thereby improving access to care and the IRMC patient experience. The additional PET/CT unit is needed both to reduce current wait times at the Fairfax facility and avoid lengthening wait times as the population continues to grow and age in PD 8 and, more specifically, in the western region of the planning district. According to the Healthcare Advisory Board's Imaging Market Estimator, the annual expected growth rate for outpatient PET/CT in PD 8 for 2024-2029 is 4.2%, the highest outpatient growth rate of any diagnostic imaging modality (note: this was published in 2019 and may even be understated at this point; PET/CT volume at the Fairfax facility is on track to grow 6.7% between 2023 and 2024).

PET/CT volume is growing in all categories with the greatest growth in tumor, brain and myocardial. The need for PET/CT for the investigation of brain function and neurodegenerative diseases like Alzheimer's shows great promise and increasing application of use in the aging population within PD 8 is expected.

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

- c. Discuss the extent to which the facility(ies) will satisfy the demand for services in five years.

As discussed in Sections II.C.2, III.A and IV.A, PET/CT volume at IRMC's Fairfax facility is very high and the ability to provide timely access to PET/CT services to IRMC's patients is already being challenged by longer wait times due to capacity constraints. Factoring in the growing expanded clinical applications for PET/CT and the impact of population growth, IRMC will no longer be able to support additional PET/CT volume without increasing PET/CT capacity.

IRMC projects the demand for PET/CT services will continue to grow, exceeding population growth. Growth in PET/CT service is expected to exceed population growth due to the expanded clinical application of PET/CT as described in Section IV.C.2.b above. As discussed in IV.C.2.b above, the Healthcare Advisory Board's annual expected growth rate for outpatient PET/CT in PD 8 at 4.2% is the highest outpatient growth rate of any diagnostic imaging modality while PD 8 population growth as noted in the table below is expected to increase by 1.28% per year.

PET/CT volume is growing in all categories with the greatest growth in tumor, brain and myocardial. The need for PET/CT for the investigation of brain function and neurodegenerative diseases like Alzheimer's shows great promise and increasing application of use in the aging population within PD 8 is expected.

The table below (sourced from Table 4 of the DCOPN Staff Report on COPN Request No. VA-8632) reflects projected population growth in PD 8 through 2030. As DCOPN noted in its DCOPN Staff Report on COPN Request No. VA-8632, *"the population of PD 8 as a whole was expected to increase approximately 16% for the period ending in 2020 and approximately 14% for the period ending in 2030, rates nearly double that of the statewide average.*

With regard to the 65 and older age cohort, Weldon-Cooper projects a much more rapid increase (Table 4). Specifically, Weldon-Cooper projects an increase of approximately 56% for the period ending in 2020 and approximately 38% for the period ending in 2030. This is significant, as this age group uses medical care resources, including diagnostic services, at a rate much higher than the rest of the population."

Table 4. Population Projections for PD 8, 2010-2030

Locality	2010	2020	% Change 2010-2020	Avg Ann % Change 2010-2020	2030	% Change 2020- 2030	Avg Ann % Change 2020-2030
Arlington	139,966	166,261	18.79%	1.69%	182,067	9.51%	0.91%
Fairfax County	207,627	249,298	20.07%	1.80%	274,339	10.04%	0.96%
Loudoun	22,565	25,047	11.00%	1.02%	26,397	5.39%	0.53%
Prince William	1,081,726	1,162,504	7.47%	0.71%	1,244,025	7.01%	0.68%
Alexandria City	12,332	14,988	21.54%	1.92%	17,032	13.64%	1.29%
Fairfax City	312,311	430,584	37.87%	3.18%	554,808	28.85%	2.57%
Falls Church City	37,821	43,099	13.96%	1.28%	46,332	7.50%	0.73%
Manassas City	14,273	17,086	19.71%	1.77%	20,284	18.72%	1.73%
Manassas Park City	402,002	478,134	18.94%	1.71%	571,844	19.60%	1.81%
Total PD 8	2,230,623	2,587,000	15.98%	1.46%	2,937,128	13.53%	1.28%
PD 8 65+	192,589	300,491	56.03%	4.44%	413,269	37.53%	3.24%
Virginia	8,001,024	8,655,021	8.17%	0.77%	9,331,666	7.82%	0.76%
Virginia 65+	976,937	1,352,448	38.44%	3.22%	1,723,382	27.43%	2.45%

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

- D. Discuss how project will fill an unmet need in the delivery of health care in the service area including, where applicable, geographic barriers to access.

The introduction of PET/CT services at the Centreville Facility will improve access to time-critical diagnostic imaging services. Referring physicians refer to IRMC because they recognize that their patients will have the highest quality care by board-certified, fellowship trained, radiologists subspecialized in interpreting the studies within their area of expertise.

IRMC's one (1) existing PET/CT unit, located at the Fairfax facility, is experiencing exceptionally heavy utilization and is substantially capacity constrained. IRMC must address these capacity constraints with additional PET/CT capacity and proposes to do so through the placement of one (1) PET/CT unit at the Centreville Facility. Introduction of PET/CT services at the Centreville Facility will alleviate capacity constraints on PET/CT services at the Fairfax facility and improve geographic access to PET/CT services for IRMC's patient population residing in the western portions of PD 8.

- E. Discuss the consistency of the proposed project with applicable Regional Health Plan, State Health Plan, State Medical Facilities Plan, or other plans promulgated by State agencies.

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.

IRMC's Centreville Facility is located within 60 minutes driving time one

way under normal conditions for 95% of the PD 8 population. As reflected in DCOPN's July 19, 2024 Staff Report (Pages 18-19 including Figure 4) (COPN Request No. VA-8758) PET services in PD 8 are available within a 60-minute drive under normal conditions of more than 95% of the residents of PD 8. Notably, drive times in PD8 can vary significantly based on traffic congestion.

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.*

Not applicable. IRMC's request is not for a hospital-based service; rather, the PET/CT unit would be located at the existing Centreville Facility.

- 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 individual PET procedures and CT procedures respectively, unless those images are made concurrently.

IRMC is proposing introducing one (1) PET/CT unit at its Centreville Facility. While the current average of 6,000 procedures per existing and approved fixed site PET unit is not satisfied, there is no PET service provider that has ever met the SMFP threshold. As reported by the HSAHV in their report of June 12, 2024, "[u]se of authorized PET service, cardiac and oncology focused alike, have never approached 6,000 scans per unit. There is no prospect of that happening soon."

In the DCOPN Staff Report dated March 20, 2024 (COPN Request No. VA-8722), DCOPN acknowledged that the SMFP utilization standards for PET services (average of 6,000 procedures per PET scanner per year) are outdated:

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, as discussed in the DCOPN Staff Report dated July 19, 2024 (COPN Request No. VA-8758), which approved a COPN application for PET/CT services that did not meet the 6,000-procedure threshold, DCOPN noted that the SMFP threshold for PET scans “has been acknowledged as outdated for current clinical applications of PET technology.”

As the population continues to grow and age in PD 8 and more specifically in the western part of PD 8, the need for PET/CT services will continue to increase (to include the expanding clinical application as described in Section IV.C.2.b). Approval of this project is necessary to support current and future demand for PET/CT (non-cardiac) services in PD 8.

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. IRMC is not looking to expand its PET/CT services at its Fairfax facility. The project is proposed to address capacity constraints on IRMC’s one (1) PET/CT unit at its Fairfax facility by placing the proposed PET/CT unit at the Centreville Facility, addressing the capacity constraints on the PET/CT unit at the Fairfax facility while also improving access for IRMC’s patients in western portions of PD 8.

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.

Not Applicable.

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.

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.

IRMC's PET/CT services are currently under the direct supervision of certified and trained radiologists at the Fairfax facility and will remain under the direct supervision of certified and trained radiologists once the proposed PET/CT unit is placed at the Centreville Facility.

- F. Show the method and assumptions used in determining the need for additional beds, new services or deletion of service in the proposed project's service area.

This project is to address a need for additional PET/CT capacity. IRMC's one (1) existing PET/CT unit, located at the Fairfax facility, is experiencing exceptionally heavy utilization and is substantially capacity constrained. IRMC must address these capacity constraints with additional PET/CT capacity and proposes to do so through the placement of one (1) PET/CT unit at the Centreville Facility. Introduction of PET/CT services at the Centreville Facility will alleviate capacity constraints on PET/CT services at the Fairfax facility and improve geographic access to PET/CT services for IRMC's patient population residing in the western portions of PD 8.

	Historical (Fairfax Facility)			Projected (Fairfax and Centreville Facilities)	
	2022	2023	Aug 2024 YTD Ann	Year 1 2026	Year 2 2027
# PET CT Units	1	1	1	2	2
Procedures	2,834	3,893	4,152	7,340	8,000
% of SMFP Utilization	47%	65%	69%	31%	33%
Patient Visit Count	2,788	3,813	4,071	7,197	7,844

Projected Year 1 (2026) and Year 2 (2027) assumes approval of the second (2nd) PET/CT unit; the projected volumes cannot be accommodated on the existing one (1) PET/CT unit without the addition of a second (2nd) PET/CT unit.

	Centreville Only			Projected	
	2022	2023	Aug 2024 YTD Ann	Year 1 2026	Year 2 2027
# PET CT Units	0	0	0	1	1
Procedures	N/A	N/A	N/A	2,920	3,580
Patient Visit Count	N/A	N/A	N/A	2,863	3,510

The projected PET/CT volume is based on expected population growth, plus expanding clinical applications for PET/CT. As described in Section IV.C.2b, the annual expected growth rate for outpatient PET/CT in PD 8 is 4.2% (the highest outpatient growth rate of any diagnostic imaging modality) while PD 8 population growth is expected to increase by 1.28% per year. IRMC PET/CT volume at the Fairfax facility is already constrained as evidenced by lengthy wait times. With one (1) PET/CT unit at the Centreville Facility, IRMC will be able to significantly reduce the wait time for an appointment as well as meet the increasing need for PET/CT services as a result of population growth and the utilization of PET/CT as an enhanced diagnostic tool for cancer patients and for the increased use of PET/CT for Alzheimer's and other neurodegenerative diseases.

Without the second (2nd) PET/CT unit, IRMC has no other opportunity to expand capacity and will quickly reach a point at which it is unable to accommodate additional volume on its existing one (1) PET/CT unit. Hours of operation are already Monday through Friday from 7 AM to 6:30 PM.

G. Coordination and Affiliation with Other Facilities.

Describe any existing or proposed formal agreements or affiliations to share personnel, facilities, services or equipment. (Attach copies of any formal agreements with another health or medical care facility.)

Not applicable.

H. Attach copies of the following documents:

1. A map of the service area indicating:
 - a. Location of proposed project.
 - b. Location of other existing medical facilities (by name, type (hospital, nursing home, outpatient clinic, etc.) and number of beds in each inpatient facility).

Please see Attachment K for the locations of other existing providers of PET/CT services in PD 8.

2. Any material which indicates community and professional support for this project, i.e. letter of endorsement from physicians, community organizations, local government, Chamber of Commerce, medical society, etc.

Please see Attachments P-1 through P-3.

3. Letters to other area facilities advising of the scope of the proposed project.

Please see Attachment N.

SECTION V

FINANCIAL DATA

It will be the responsibility of the applicant to show sufficient evidence of adequate financial resources to complete construction of the proposed project and provide sufficient working capital and operating income for a period of not less than one (1) year after the date of opening:

- A. Specify the per diem rate for all existing negotiated reimbursement contracts and proposed contracts for patient care with state and federal governmental agencies, Blue Cross/Blue Shield Plans, labor organizations such as health and welfare funds and membership associations.

This question requires the disclosure of confidential and proprietary information.

- B. Does the facility participate in a regional program which provides a means for facilities to compare its costs and operations with similar institutions?

 X Yes No

If yes, specify program **All of IRMC's facilities participate in VHI**

Provide a copy of report(s) which provide(s) the basis for comparison.

IRMC will continue to participate in VHI and will report utilization for its Centreville Facility PET/CT services. Please see Attachment O for a copy of IRMC's 2023 EPICS submission for the current PET/CT facility located at 8081 Innovation Park Drive in Fairfax (identifying 3,893 PET/CT procedures in 2023).

- C. Estimated Capital Costs

Please see "Instructions for Completing Estimated Capital Costs" Section of the Certificate of Need application for detailed instructions for completing this question (attached)

Part I – Direct Construction Costs

1.	Cost of materials	\$ 477,240
2.	Cost of labor	\$ 341,660
3.	Equipment included in construction contract	\$ N/A
4.	Builder's overhead	\$ 79,540
5.	Builder's profit	\$ 63,632
6.	Allocation for contingencies	\$ 63,632
7.	Sub-total (add lines 1 thru 6)	\$1,025,704

Part II – Equipment Not Included in Construction Contract
(List each separately) If leasehold, lease expense for the entire term of the initial lease

8.	a. PET/CT Unit	\$2,350,000
	b. Furnishings	\$ 50,000
	c. Signage	\$ 15,000
	d. Capital lease interest expense	\$ 662,837
	See capital lease amortization schedule at Attachment M.	
	e. LV Cabling Access and IT hardware	\$ 54,100
9.	Sub-total (add lines 8a thru 8e)	\$3,131,937

* PET/CT to be leased over 7 years; at conclusion the PET/CT will be owned.

Capital lease expense is on line d.

Part III – Site Acquisition Costs

10.	Full purchase price	\$ _____ 0 _____
11.	For sites with standing structures	\$ _____ 0 _____
	a. purchase price allocable to structures	\$ _____ 0 _____
	b. purchase price allocable to land	\$ _____ 0 _____
12.	Closing costs	\$ _____ 0 _____
13.	If leasehold, lease expense for the entire term of the initial lease	\$ 976,350 _____
	Note: Reflects lease expense for additional leased space for the PET/CT.	
14.	Additional expenses paid or accrued:	
	a. _____	\$ _____ 0 _____
	b. _____	\$ _____ 0 _____
	c. _____	\$ _____ 0 _____
15.	Sub-total (add lines 10 thru 14c)	\$ 976,350

Part IV – Site Preparation Costs

16.	Earth work	\$ _____ 0 _____
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17.	Site utilities	\$ _____ 0 _____
18.	Roads and walks	\$ _____ 0 _____
19.	Lawns and planting	\$ _____ 0 _____
20.	Unusual site conditions:	
	a. _____	\$ _____ 0 _____
	b. _____	\$ _____ 0 _____
21.	Accessory structures	\$ _____ 0 _____
22.	Demolition costs	\$ _____ 0 _____
23.	Sub-total (add lines 16 thru 22)	\$ _____ 0 _____

Part V – Off-site Costs (List each separately)

24.	_____	
25.	_____	\$ _____ 0 _____
26.	_____	\$ _____ 0 _____
27.	_____	\$ _____ 0 _____
28.	Sub-total (add lines 24 thru 27)	\$ _____ 0 _____

Part VI – Architectural and Engineering Fees

29.	Architect's design fee	\$ 60,000
30.	Architect's supervision fee	\$ included in 29.
31.	Engineering fees	\$ included in 29.
32.	Consultant's fees	\$ including in 29.
33.	Sub-total (add lines 29 thru 32)	\$ 60,000

Part VII – Other Consultant Fees (List each separately)

34.	a. _____	\$ _____ 0 _____
	b. _____	\$ _____ 0 _____
	c. _____	\$ _____ 0 _____

35. Sub-total (add lines 34a thru 34c) \$ 0

Part VIII – Taxes During Construction

36. Property taxes during construction \$ 0

37. List other taxes:

a. \$ 0

b. \$ 0

38. Sub-total (add lines 36 thru 37b) \$ 0

Part IX-A – HUD Section 232 Financing

39. Estimated construction time (in months) 0

40. Dollar amount of construction loan \$ 0

41. Construction loan interest rate %

42. Estimated construction loan interest costs \$ 0

43. Term of financing (in years) 0

44. Interest rate on permanent loan %

45. FHA mortgage insurance premium \$ 0

46. FHA mortgage fees \$ 0

47. Financing fees \$ 0

48. Placement fees \$ 0

49. AMPO (non-profit only) \$ 0

50. Title and recording fees \$ 0

51. Legal fees \$ 0

52. Total interest expense on permanent mortgage loan \$ 0

53. Sub-total Part IX-A HUD Section 232 Financing (add lines 42, 45, 46, 47, 48, 49, 50 and 51) \$ 0

Part IX-B – Industrial Development Authority Revenue and General
Obligation Bond Financing (Circle selected method of financing)

54. Method of construction financing (construction loan, proceeds of bond sales, if other, specify)

If construction is to be financed from any source other than bond sale proceeds, answer question 56 through 58. Otherwise, proceed to question 59.

55. Estimated construction time (in months) _____
56. Dollar amount of construction loan \$ _____ 0 _____
57. Construction loan interest rate _____ %
58. Estimated construction loan interest cost \$ _____ 0 _____
59. Nature of bond placement (direct, underwriter, if other, specify) _____
60. Will bonds be issued prior to the beginning of construction? _____ Yes ☒ No
61. If the answer to question 60 is yes, how long before (in months)? _____
62. Dollar amount of bonds expected to be sold prior to the beginning of construction \$ _____ 0 _____
63. Will principal and interest be paid during construction or only interest? _____
64. Bond interest expense prior to the beginning of construction (in dollars) \$ _____ 0 _____
65. How many months after construction begins will last bond be sold? _____
66. Bond interest expense during construction \$ _____ 0 _____
67. What percent of total construction will be Financed from bond issue? \$ _____ 0 _____
68. Expected bond interest rate _____ %
69. Anticipated term of bond issued (in years) _____

70.	Anticipated bond discount (in dollars)	\$ <u>0</u>
71.	Legal costs	\$ <u>0</u>
72.	Printing costs	\$ <u>0</u>
73.	Placement fee	\$ <u>0</u>
74.	Feasibility study	\$
75.	Insurance	\$ <u>0</u>
76.	Title and recording fees	\$ <u>0</u>
77.	Other fees (list each separately)	
	a. _____	\$ _____
	b. _____	\$ _____
	c. _____	\$ _____
78.	Sinking fund reserve account (Debt Service Reserve)	\$ <u>0</u>
79.	Total bond interest expenses (in dollars)	\$ <u>0</u>
80.	Sub-total Part IX_B (add lines 58, 64, 66, 71, 72, 73, 74, 75, 76, 77a, b, c and 78)	\$ <u>0</u>

Part IX - C – Conventional Mortgage Loan Financing

81.	Estimated construction time (in months)	_____
82.	Dollar amount of construction loan	
83.	Construction loan interest rate	_____ %
84.	Estimated construction loan interest cost (in dollars)	\$ _____
85.	Term of long-term financing (in years)	_____
86.	Interest rate on long term loan	_____ %
87.	Anticipated mortgage discount (in dollars)	\$ <u>0</u>
88.	Feasibility study	\$ <u>0</u>

89.	Finder's fee	\$ _____ 0 _____
90.	Legal fees	\$ _____ 0 _____
91.	Insurance	\$ _____ 0 _____
92.	Other fees (list each separately)	
	_____	\$ _____ 0 _____
93.		\$ _____
94.	Total permanent mortgage loan interest expense (in dollars)	\$ _____ 0 _____
95.	Sub-total Part IX_C (add lines 84 & 88 thru 93)	\$ _____ 0 _____

Financial Data Summary Sheet

96.	Sub-total Part I	Direct Construction Cost (line 7)	\$1,025,704
97.	Sub-total Part II	Equipment not included in construction contract (line 9)	\$3,131,937
98.	Sub-total Part III	Site Acquisition Costs (line 15)	\$ 976,350
99.	Sub-total Part IV	Site Preparation Cost (line 23)	\$ _____ 0 _____
100.	Sub-total Part V	Off-Site Costs (line 28)	\$ _____ 0 _____
101.	Sub-total Part VI	Architectural and Engineering fees (line 33)	\$ 60,000
102.	Sub-total Part VII	Other Consultant fees (line 35)	\$ 0
103.	Sub-total Part VIII	Taxes During Construction (line 38)	\$ _____ 0 _____
104.	Sub-total Part IX-A	HUD-232 Financing (line 53)	\$ _____ 0 _____
105.	Sub-total Part IX-B	Industrial Development Authority Revenue & General Revenue Bond Financing (line 80)	\$ _____ 0 _____
106.	Sub-total Part IX-C	Conventional Loan Financing (line 95)	\$ _____ 0 _____
107.	TOTAL CAPITAL COST (lines 96 thru 106)		\$5,193,991
108.	Percent of total capital costs to be financed		78.6%

Note: IRMC intends to acquire the PET/CT unit through a capital lease with the vendor and fund the buildout via a bank LOC. This percentage reflects that portion of capital costs related to the capital lease for the PET/CT unit plus the cost of the buildout.

109.	Dollar amount of long-term mortgage (line 107 x 108) N/A - See Note at #108 above	\$
110.	Total Interest Cost on Long Term Financing	\$_____0_____
	a. HUD-232 Financing (line 53)	\$_____0_____
	b. Industrial Development Authority Revenue & General Revenue Bond Financing (line 79)	\$_____0_____
	c. Conventional Loan Financing (line 94)	\$_____0_____
111.	Anticipated Bond discount	
	a. HUD-232 Financing (line 53)	\$_____0_____
	b. Industrial Development Authority Revenue & General Revenue Bond Financing (line 70)	\$_____0_____
	c. Conventional Loan Financing (line 87)	\$_____0_____
112.	TOTAL CAPITAL AND FINANCING COST (ADD LINES 107, 110a, b or c AND 111a, b or c)	\$5,193,991
D.	1. Estimated costs for new construction (excluding site acquisition costs)	\$
	2. Estimated costs of modernization and renovation (excluding site acquisition costs)	\$_____0_____
E.	Anticipated Sources of Funds for Proposed Project	Amount
	1. Public Campaign	\$_____0_____
	2. Bond Issue (Specify Type) _____	\$_____0_____
	3. Commercial Loans	\$1,085,704
	4. Government Loans (Specify Type) _____	\$_____0_____
	5. Grants (Specify Type) _____	\$_____0_____
	6. Bequests	\$_____0_____

7.	Private Foundations	\$ <u>0</u>
8.	Endowment Income	\$ <u>0</u>
9.	Accumulated Reserves	\$1,095,450
10.	Other – Capital Lease	\$3,012,837

- F. Describe in detail the proposed method of financing the proposed project, including the various alternatives considered. Attach any documents which indicate the financial feasibility of the project.

The renovation/buildout costs associated with this project will be funded from a bank line of credit. The PET/CT equipment will be leased from the vendor pursuant to a capital lease whereby, at the end of the lease term, IRMC will own the PET/CT unit.

- G. Describe the impact the proposed capital expenditure will have on the cost of providing care in the facility. Specify total debt service cost and estimated debt service cost per patient day for the first two (2) years of operation. (Total debt service cost is defined as total interest to be paid during the life of the loan (s). Estimate debt service cost per patient day by dividing estimated total patient days for year one into amount of debt service for that year. Repeat for year two.) Please attach an amortization schedule showing how the proposed debt will be repaid.

The renovation/buildout costs associated with this project will be funded from a bank line of credit. The PET/CT equipment will be leased from the vendor pursuant to a capital lease whereby, at the end of the lease term, IRMC will own the PET/CT unit. See equipment quote at Attachment T. The introduction of PET/CT capacity at Centreville is not expected to impact the cost of providing care. See Attachment M for amortization schedules for information on debt service.

- H. Attach a copy of the following information of documents.

1. The existing and/or proposed room rate schedule, by type of accommodation.

Not applicable. The Centreville Facility is an outpatient facility and does not provide inpatient services.

2. The audited annual financial statements for the past two (2) years of the existing facility or/if a new facility without operating experience, the financial state of the owner (s). Audited financial statements are required, if available.

Please see Attachment R for the audited financial statements for the most recent two (2) years for IRMC.

3. Copy of the proposed facility's estimated income, expense and capital budget for the first two years of operation after the proposed project is completed.

Please see Attachment S for the pro forma.

SECTION VI

ASSURANCES

I hereby assure and certify that:

- a. The work on the proposed project will be initiated within the period of time set forth in the Certificate of Public Need; and
- b. completion of the proposed project will be pursued with diligence; and
- c. the proposed project will be constructed, operated and maintained in full compliance with all applicable local, State and Federal laws, rules, regulations and ordinances.

I hereby certify that the information included in this application and all attachments are correct to the best of my knowledge and belief and that it is my intent to carry out the proposed project as described.

Carol Burchett
Signature of Authorizing Officer

Fairfax Radiology Centers, LLC
Address – Line 1

Carol Burchett
Type/Print Name of Authorizing Officer

8260 Willow Oaks Corporate Dr., Suite 750
Address – Line 2

Chief Strategy Officer
Title of Authorizing Officer

Fairfax, VA 22031
City/State/Zip

October 1, 2024
Date

703-698-4444
Telephone Number

Copies of this request should be sent to:

- A. **Virginia Department of Health
Division of Certificate of Public Need
9960 Mayland Drive – Suite 401
Henrico, Virginia 23233**
- B. **The Regional Health Planning Agency if one is currently designated by the Board of Health to serve the area where the project would be located.**

FRC Centreville PET Introduction of 1 PET Scanner Unit		
Financial Projections Amounts in \$000's Statement of Revenues and Expenses	PET/CT Only	
	<u>Year 1</u>	<u>Year 2</u>
Total PET/CT Scans	2,920	3,580
Total Net Operating Revenue	7,225	9,034
Note: Net Operating Revenue reflects 3% charity deduction		
Operating Expenses		
Salaries, Wages and Benefits	438	601
Supplies	497	609
Purchased Services	311	388
Bad Debt (above in Op Rev)	-	-
Depreciation and Amortization	358	358
Indirect Expense- Occupancy	60	62
Other Expense	1,003	1,230
Debt (Financing Expense)	147	125
Total Operating Expenses	2,813	3,373
Excess of Revenue Over Expenses	4,411	5,661

Note: The facility will be subject to Inova's system-wide charity care conditions.