

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-8816

Inova Health Care Services

Establish Cardiac PET/CT Services

March 28, 2025

SECTION I FACILITY ORGANIZATION AND IDENTIFICATION

A. Inova Cardiac Diagnostics PET/CT - Willow Oaks

Official Name of Facility

8280 Willow Oaks Corporate Drive, Suite 100

Address

Fairfax	VA	22031
City	State	Zip

Not Applicable

Telephone

B. Inova Health Care Services

Legal Name of Applicant

8095 Innovation Park Drive

Address

Fairfax	VA	22031
City	State	Zip

C. Chief Administrative Officer

Christopher O'Connor, MD, President, Inova Schar Heart and Vascular

Name

8095 Innovation Park Drive

Address

Fairfax	VA	22031
City	State	Zip

703-776-6393

Telephone

D. Person(s) to whom questions regarding application should be directed:

Jessica Parker, Senior Director, Strategy and Planning, Inova

Name

8095 Innovation Park Drive

Address

Fairfax	VA	22031
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City

State

Zip

703-517-9320

Jessica.Parker@inova.org

Telephone

E-mail

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

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

Owner of the Facility
(Check one)

Proprietary

Operator of Facility
(Check one)

(1) _____

(1) Individual

(1) _____

(2) _____

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

(2) _____

(3) _____

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

(3) _____

(4) _____

(4) Other _____ Identify

(4) _____

Non-Profit

(5) **X**

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

(5) **X**

Please see Attachment A

(6) _____

(6) Other _____ Identify

(6) _____

Governmental

(7) _____

(6) State

(7) _____

(8) _____

(8) County

(8) _____

(9) _____

(9) City

(9) _____

(10) _____

(10) City/County

(10) _____

(11) _____ (11) Hospital Authority or Commission (11) _____

(12) _____ (12) Other _____ Identify (12) _____

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) _____ Leasehold interest for not less than _____ years
(4) X Renewable lease, renewable every 12 years.
(5) _____ Other _____ Identify

The proposed project will be located in an existing medical office building on the first floor in Suite 100. Please see Attachment B for a memorandum of understanding documenting the planned lease arrangement between Inova Health Care Services and the landlord, BOF II VA Willow Oaks, LLC.

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.

Inova Cardiac Diagnostics PET/CT - Willow Oaks is owned by Inova Health Care Services, a 501(c)(3) Virginia nonstock corporation. The sole member of Inova Health Care Services is the Inova Health System Foundation, which is also a 501(c)(3) Virginia nonstock corporation. The corporate address for Inova Health Care Services is as follows:

**Inova Health Care Services
8095 Innovation Park Drive
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.
(2) A list of the officers of the corporation.
(3) The name and address of the registered agent for the corporation.

Not applicable.

(b) In the case of a non-profit corporation also attach:

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

Please see Attachment C for the names of the board members. Please direct any questions to board members at the following address:

**c/o Nena Jaspers
8095 Innovation Park Drive
Fairfax, VA 22031**

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

The Inova Health Care Services Board members and officer names are set forth in Attachment C.

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

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

- (c) In the case of a partnership also attach:

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

Not applicable.

- (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.

Please see Attachment D for a comprehensive corporate organization chart.

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

Inova Health System Foundation d/b/a Inova Health System

- J. 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.

Not applicable.

- K. 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.

Not applicable.

SECTION II

ARCHITECTURE AND DESIGN

A. Location of the Proposed Project

1. Size of site: 4.20 acres
2. Located in Fairfax County / Planning District 8
3. Address or directions 8280 Willow Oaks Corporate Drive, Suite 100, Fairfax, VA 22031
4. Has site been zoned for type of use proposed:
 X Yes (attach copy of zoning or use permit).

Please see Attachment E.

 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

Establish cardiac PET/CT services through the acquisition of a fixed PET/CT machine.

C. Design of the facility

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

Long range planning is guided by the mission, vision, and values of Inova Health System, set forth in Attachment F.

Inova Health System's mission is:

- **To provide world-class healthcare – every time, every touch – to each person in every community we have the privilege to serve.**

Our vision is:

- **To be among the leading healthcare systems in the nation.**

- (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.

Inova Health Care Services is seeking approval to establish cardiac PET/CT services through the acquisition of a fixed PET/CT unit to be located at 8280 Willow Oaks Corporate Drive, Suite 100, Fairfax, Virginia. If approved, the facility will be established as an Independent Diagnostic Testing Facility (IDTF).

The proposed project will be located on the first floor of an existing medical office building. The proposed space will include patient check-in, reception/waiting area, sub-waiting area with changing rooms, camera control room, PET/CT camera room, camera equipment room, hot lab, two patient restrooms, one staff rest room, four exam/ prep rooms, stress room, provider & director office, tech/fellow/APP work area, training/conference room, support rooms (IT, storage, clean & linen areas) and a staff break room. Both patient flow and potential for radiation exposure were closely evaluated when designing the facility. Appropriate lead lining and shielding will be installed at the direction of our health/radiation physicist.

This project is consistent with the Inova Health System mission and vision (as identified above and set forth in Attachment F). This project relates to Inova Health System's commitment to excellence in patient care and will enable the detection and management of complex cardiac diseases with greater precision, support improved diagnostic accuracy, and facilitate the provision of comprehensive care.

Cardiac PET/CT imaging is a well-established technology used in clinical practice for non-invasive imaging of the heart for a variety of cardiovascular conditions and has been extensively reported upon in scientific and medical journals.

Cardiac PET/CT is the recommended modality for non-invasive cardiac stress testing. The American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging released a joint statement confirming that cardiac PET/CT imaging meets all CMS national patient safety goals and is the gold standard for non-invasive cardiac imaging.

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

The proposed project, to be located at 8280 Willow Oaks Corporate Drive, is easily accessible. The site is located ½ mile west of the Capital Beltway (Interstate 495) and 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 within walking distance off of Gallows Road. The Dunn Loring Metro station is approximately three miles from the proposed site with bus service available to transport patients to and from the metro station to a near-by bus stop.

- (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 site of the proposed project is zoned and developed to accommodate parking for this use. Water, sewer and solid waste services are existing services to the site and capacity exceeds the loads required to support this use within the building.

- (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.

- (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 project will be located in an existing medical office building on the first floor. The electrical, lighting, and lighting control systems will be designed in accordance with 2021 International Energy Conservation Code as well as additional measures above and beyond code requirements. All transformers will be selected to meet Department of Energy (DOE) energy efficiency requirements; in addition to these requirements, transformers will be specified at 115 degrees C rise temperature rating to increase energy efficiency. All feeder conductors and branch circuit conductors will be designed such that the overall voltage drop across the system is less than 5%. All lighting will be high efficiency LED luminaires equipped with integral 0-10V dimming drivers. Lighting system watts/SF will be designed to exceed energy code requirements by at least 15%. All lighting will be controlled by a combination of strategies in alignment with IECC including 0-10V dimming, occupancy sensors to turn off

lights after inactivity, and timeclock programming for circulation spaces. Occupancy sensors will also be utilized for plug-load control in all office spaces and occupant workstations in alignment with IECC.

All new mechanical systems will be designed in accordance with 2021 International Energy Conservation Code. All equipment efficiency ratings will exceed the minimum required values. Dedicated DX split system cooling units will be provided for the imaging equipment and associated rooms for individual control, allowing for room specific thermal requirements to be met without operating of the larger base building AHU's, thus reducing energy consumption. Low flow plumbing fixtures will be provided for all exam room sinks to reduce potable water consumption. Additionally, a hot water recirculation pump will be provided to reduce temperature losses through the hot water piping throughout the space.

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.

See Attachment G for letters from the relevant utility companies verifying that they will provide appropriate services to the proposed project.

E. Space tabulation – (show in tabular form)

1. If Item #1 was checked in II-B, specify:
 - 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).

Not applicable.

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

Please see Attachment H.

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

The design criteria for this project are based on, and conform to, the standards adopted by the Virginia Department of Health and the Facilities Guidelines Institute (FGI).

- 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 I.

- 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 J.

The difference between the 8,648 Rentable Square Feet (RSF) referenced in Attachment J and the 6,450 Gross Square Feet and 4,296 Net Square Feet referenced in Attachment H is attributable to hallways, common areas and other spaces shared by tenants of the medical office building.

H. Construction Time Estimates

1. Date of Drawings: Preliminary 12/1/2024 Final 05/30/2025
2. Date of Construction: Begin 09/10/2025 Completion 01/09/2026
3. Target Date of Opening: 1/23/2026

Timeline is subject to COPN approval date.

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.

Proposed Project

Inova Health Care Services is seeking approval to establish cardiac PET/CT services through the acquisition of a fixed PET/CT unit that will be exclusively used for cardiovascular imaging. If approved, the facility will be established as an Independent Diagnostic Testing Facility (IDTF). Today, all of the authorized cardiac PET/CT units in PD 8 are located in private cardiology practice locations, with patient access largely limited to patients of the relevant cardiology practice. By establishing this center as an IDTF (i.e., not a department of a hospital or part of a cardiology practice), Inova will be able to improve access to cardiac PET/CT services, a critical non-invasive cardiac diagnostic tool, to all patients needing myocardial perfusion imaging (MPI) studies.

Background

About Inova

Inova is Northern Virginia's leading not-for-profit health care system. Through our expansive network of hospitals, primary and specialty care practices, emergency and urgent care centers, and outpatient services, Inova provides care to more than 1 million unique patients every year. Total patient visits exceed 4 million annually, demonstrating our ability to deliver the best clinical care and ensuring a seamless experience for all who rely on us for their healthcare needs. Consistently ranked and recognized as a national healthcare leader in safety, quality and patient experience, Inova's world-class care is made possible by the strength and breadth of our network, our more than 25,000 team members, our technology and our innovation.

Inova is home to Northern Virginia's only Level 1 Trauma Center and Level 4 Neonatal Intensive Care Unit and is home to Inova Schar Heart and Vascular, one of the leading cardiovascular programs in the country.

About Inova Schar Heart and Vascular

Inova Schar Heart and Vascular is one of the nation's leaders in delivering state-of-the-art cardiovascular and advanced lung disease care. We offer adults and children the full spectrum of complex treatments for comprehensive cardiovascular and cardiopulmonary care – from medical evaluation and diagnostic testing to the latest minimally invasive surgical techniques and complex open surgeries, including Northern Virginia's only heart and lung transplantation program. Inova Schar Heart and Vascular

offers services across all five Inova hospitals and in nearly 60 outpatient locations interconnected to deliver seamless, consistent, high quality care. Attachment K details the comprehensive heart and vascular services provided by Inova Schar Heart and Vascular across multiple PD 8 locations.

Inova has one of the largest cardiology groups in Northern Virginia, with more than 70 physicians and 45 advanced practice providers located at 14 offices across PD 8. In addition to our employed cardiologists, an additional 127 cardiologists (representing more than 25 private cardiology practices) are credentialed at Inova's hospitals.

Inova Schar Heart and Vascular Cardiac Diagnostics – Nuclear Stress Testing

As outlined in Attachment K, Inova offers comprehensive cardiac diagnostic services, including MPI, often called nuclear stress tests.

MPI is a cardiac imaging modality performed at rest and after exercise. It utilizes the same basic principles as a treadmill exercise stress test but provides significantly more detailed information. By using a radioactive tracer and an imaging camera, MPI creates images that show blood flow to the heart muscle during rest and at peak exercise. This allows clinicians to identify areas of the heart with poor blood flow or scarring. MPI is crucial for diagnosing myocardial ischemia, managing coronary artery disease, and assessing infiltrative, inflammatory, or infectious cardiovascular conditions.

There are two types of MPI: Single Photon Emission Computed Tomography (SPECT) and Cardiac Positron Emission Tomography-Computed Tomography (PET/CT). Inova offers cardiac SPECT at 12 locations across PD 8. In 2024, these SPECT locations performed 7,691 cardiac SPECT studies. Inova does not offer cardiac PET/CT today and through this application is seeking approval to establish cardiac PET/CT services through the acquisition of a fixed PET/CT unit that will be exclusively used for cardiovascular imaging.

While SPECT has traditionally been the primary diagnostic tool for MPI, cardiac PET/CT is now recommended as a Class 1 imaging modality for non-invasive cardiac stress testing in patients with chest pain and those suspected to have coronary artery disease. Compared to SPECT, cardiac PET/CT offers higher sensitivity, specificity, and diagnostic accuracy. It also reduces radiation exposure, shortens acquisition time, and enables the quantification of myocardial blood flow. Another advantage of PET/CT over SPECT is that body habitus (i.e., physical build and shape) and patient weight have minimal impact on image quality and diagnostic accuracy.

Comparison: SPECT vs Cardiac PET/CT

	Nuclear SPECT	Cardiac PET/CT
Accuracy	<ul style="list-style-type: none">Higher prevalence of artifacts limits accuracy	<ul style="list-style-type: none">Higher diagnostic accuracyExcellent sensitivity to exclude significant coronary artery disease (CAD)
Image Quality	<ul style="list-style-type: none">Lower image quality due to lower spatial resolution	<ul style="list-style-type: none">Excellent image qualityHigher spatial resolutionFewer artifacts
Exposure	<ul style="list-style-type: none">Longer image acquisition timeHigher patient and staff radiation exposure	<ul style="list-style-type: none">Shorter image acquisition timeDecreased radiation exposure
Protocol	<ul style="list-style-type: none">Acquisition times are 45 minutes.Total patient time in department ~ 3 hours	<ul style="list-style-type: none">Shorter acquisition time of 5 minutesTotal patient time in department ~ 45 minutes
Clinical Utility	<ul style="list-style-type: none">Myocardial perfusion	<ul style="list-style-type: none">Myocardial perfusionMyocardial blood flow assessmentInfection and inflammation imagingAssessment of allograft vasculopathy (heart transplant patients)

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

Record Continuity:

- Inova maintains a physician and patient portal integrated with the Epic electronic medical record (EMR) and picture archiving and communication system (PACS). This system provides all members of the patient care team with access to essential patient information, including diagnostic images, physician reports, and other relevant details from both current and past visits.**
- Inova also has the capability to securely send images and reports electronically to external EMRs.**

Clinician/Patient Continuity:

- In addition to the physician portal, Inova patients have access to a patient portal (i.e., MyChart) where they can securely view their study reports.**

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

Inova has established clinical policies, procedures, and standards to ensure the highest quality of patient care. Inova facilities are accredited by the Intersocietal Accreditation Commission (IAC) for Nuclear Cardiology, among other modalities. This standard is maintained across all Inova imaging centers, and, if approved will extend to Inova Cardiac Diagnostics

PET/CT – Willow Oaks under the supervision of the Nuclear Cardiology Medical and Technical Directors.

If approved, the proposed project will be added to the Virginia Department of Health Radioactive Materials Program (VDH RAM) license. Under the supervision of the Radiation Safety Officer (RSO), the Inova Cardiac Diagnostics PET/CT – Willow Oaks facility will adhere to strict safety protocols, including the ALARA (As Low As Reasonably Achievable) principle to limit radiation exposure to both patients and staff. All technologists staffing the facility will be registered and certified by the applicable governing organization, and annual competency assessments will ensure they are appropriately qualified to perform PET/CT procedures and provide 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.

The staffing requirements for the cardiac PET/CT are minimal. Inova does not anticipate any challenges in meeting the hiring needs. Plans for acquiring additional personnel includes:

- **Targeted recruitment initiatives aimed at underutilized labor pools in the health care industry such as minorities, seniors, retired military personnel, among others, as well as an outreach to geographic areas outside Northern Virginia. This strategy helps expand the available workforce without depleting resources from other facilities.**
- **Recruitment efforts in geographic areas beyond Northern Virginia, further broadening the pool of available workforce, while ensuring that resources are not drawn away from other Northern Virginia facilities.**
- **Ongoing initiatives to strengthen and expand the health services labor pool in Northern Virginia by promoting health care career paths to local youth, ultimately benefitting all area healthcare providers with a vibrant and enthusiastic workforce.**

Additionally, Inova plans to draw from its existing Nuclear SPECT staff, allowing for cross-training within the departments. This approach will create a flexible float pool to meet staffing needs as necessary.

- E. Facilities and Services to be Provided (Check)

	This Project To be Added	This Project to be Discontinued
<u>Existing</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	_____	_____	_____
	radioisotope	_____	<u>X</u>	_____
	CT 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	_____	_____	_____
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 (Identify)	_____	_____	_____
	<u>Cardiac PET/CT</u>	_____	<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)

All 5 Inova hospitals in the Inova Health System (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 7 a.m. to 5 p.m.
Monday – Friday (with plans to extend to Saturdays as utilization increases) days of week.
5. Does (will) the facility operate scheduled clinics?
_____ Yes
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

All cardiac PET/CT imaging performed at the facility will be read by qualified Inova cardiologists.

8. State specifically any limitations or restrictions for participation in the services of the facility.

Not applicable; any appropriately licensed physician or advanced practice provider 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.

This project proposes the establishment of a new cardiac PET/CT service. Accordingly, there is no historical utilization data.

Inova expects its cardiac PET/CT patients to originate from the following sources:

- **Existing SPECT patients that would be more appropriate for cardiac PET/CT (Inova assumes 20% of SPECT patients will convert to cardiac PET/CT patients)**

- Inova’s cardiologists, including its advanced heart failure physicians and other cardiology practices in PD 8 who do not have access to cardiac PET/CT today. Projected patient populations include:
 - Chest pain and coronary artery disease
 - Myocardial ischemia
 - Infectious cardiovascular conditions
 - Infiltrative cardiomyopathy (e.g., cardiac sarcoidosis)
 - Heart failure and transplant patients

Inova’s historical utilization for its cardiology, arrhythmia and heart failure practices and SPECT locations are included below.

Specialty	2022	2023	2024	2022-2034
Cardiology Visits	84,498	93,835	107,110	27%
Arrhythmia Visits	10,142	12,093	13,575	34%
Heart Failure Visits	8,681	9,632	10,982	27%
Total Visits	103,321	115,560	131,675	27%
SPECT Studies	8,398	8,798	7,691	-8%

The PET/CT utilization projections for Inova Cardiac Diagnostics PET/CT – Willow Oaks are as follows:

	Year 1	Year 2
Average studies per day	9	10
Studies per year	2,295	2,550

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).

	Current		Additional	Needed
	Full	Vacant	Full	
	Time	Positions	Time	TOTAL
Total number of Full-time staff	<u>n/a</u>	<u>n/a</u>	<u>7</u>	<u>7</u>
Administration-Business Office	<u>n/a</u>	<u>n/a</u>	<u>3</u>	<u>3</u>
Registered Nurses	<u>n/a</u>	<u>n/a</u>	<u>1</u>	<u>1</u>
Radiologic Technologists	<u>n/a</u>	<u>n/a</u>	<u>3</u>	<u>3</u>
Other Health Professionals, Identify _____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
All Other Personnel (Exclude Physicians and Dentists)				

- I. 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.

As discussed in Section III.D, the staffing requirements for the cardiac PET/CT are minimal. Inova does not anticipate any challenges in meeting the hiring needs. Plans for acquiring additional personnel includes:

- **Targeted recruitment initiatives aimed at underutilized labor pools in the health care industry such as minorities, seniors, retired military personnel, among others, as well as an outreach to geographic areas outside Northern Virginia. This strategy helps expand the available workforce without depleting resources from other facilities.**
- **Recruitment efforts in geographic areas beyond Northern Virginia, further broadening the pool of available workforce, while ensuring that resources are not drawn away from other Northern Virginia facilities.**
- **Ongoing initiatives to strengthen and expand the health services labor pool in Northern Virginia by promoting health care career paths to local youth, ultimately benefitting all area healthcare providers with a vibrant and enthusiastic workforce.**

Additionally, Inova plans to draw from its existing Nuclear SPECT staff, allowing for cross-training within the departments. This approach will create a flexible float pool to meet staffing needs as necessary.

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

The staffing requirements for this project are not anticipated to have an impact on the staffing of other facilities in the service area.

- K. Attach the following information or documents:

1. Copy of most recent licensing report from State Agency (existing facilities, excluding public health centers).

Inova is accredited by the Intersocietal Accreditation Commission (IAC) for Nuclear Cardiology among other modalities. This accreditation is maintained across all of Inova's cardiac nuclear imaging facilities and if approved will include Inova Cardiac Diagnostics PET/CT – Willow Oaks under the supervision of the Nuclear Cardiology Medical and Technical Directors. Please see Attachment L for a copy of Inova's IAC accreditation.

If approved, Inova Cardiac Diagnostics PET/CT – Willow Oaks will be included on a Virginia Department of Health Radioactive Materials Program (VDH RAM) license. Please see Attachment M for a copy of Inova's VDH RAM license.

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. This application proposes the establishment of a cardiac PET/CT imaging center. The imaging center will be an IDTF and accredited by the IAC.

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

Not applicable. This application proposes the establishment of a cardiac PET/CT imaging center. For reference, please see Attachment N for a list of all cardiologists credentialed at Inova hospitals.

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 O.

SECTION IV PROJECT JUSTIFICATION AND IDENTIFICATION OF COMMUNITY NEED

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

Proposed Project

Inova Health Care Services is seeking approval to establish cardiac PET/CT services through the acquisition of a fixed PET/CT unit that will be exclusively used for cardiovascular imaging. If approved, the facility will be established as an Independent Diagnostic Testing Facility (IDTF). Today, all of the authorized cardiac PET/CT units in PD 8 are located in private cardiology practice locations, with patient access largely limited to patients of the relevant cardiology practice. By establishing this center as an IDTF (i.e., not a department of a hospital or part of a cardiology practice), Inova will be able to improve access to cardiac PET/CT services, a critical non-invasive cardiac diagnostic tool, to all patients needing myocardial perfusion imaging (MPI) studies.

Background

About Inova

Inova is Northern Virginia's leading not-for-profit health care system. Through our expansive network of hospitals, primary and specialty care practices, emergency and urgent care centers, and outpatient services, Inova provides care to more than 1 million unique patients every year. Total patient visits exceed 4 million annually, demonstrating our ability to deliver the best clinical care and ensuring a seamless experience for all who rely on us for their healthcare needs. Consistently ranked and recognized as a national healthcare leader in safety, quality and patient experience, Inova's world-class care is made possible by the strength and breadth of our network, our more than 25,000 team members, our technology and our innovation.

Inova is home to Northern Virginia's only Level 1 Trauma Center and Level 4 Neonatal Intensive Care Unit and is home to Inova Schar Heart and Vascular, one of the leading cardiovascular programs in the country.

About Inova Schar Heart and Vascular

Inova Schar Heart and Vascular is one of the nation's leaders in delivering state-of-the-art cardiovascular and advanced lung disease care. We offer adults and children the full spectrum of complex treatments for comprehensive cardiovascular and cardiopulmonary care – from medical evaluation and diagnostic testing to the latest minimally invasive surgical techniques and complex open surgeries, including Northern Virginia's only heart and lung transplantation program. Inova Schar Heart and Vascular offers services across all five Inova hospitals and in nearly 60 outpatient

locations interconnected to deliver seamless, consistent, high quality care. Attachment K details the comprehensive heart and vascular services provided by Inova Schar Heart and Vascular across multiple PD 8 locations.

Inova has one of the largest cardiology groups in Northern Virginia, with more than 70 physicians and 45 advanced practice providers located at 14 offices across PD 8. In addition to our employed cardiologists, an additional 127 cardiologists (representing more than 25 private cardiology practices) are credentialed at Inova's hospitals.

Inova Schar Heart and Vascular Cardiac Diagnostics – Nuclear Stress Testing

As outlined in Attachment K, Inova offers comprehensive cardiac diagnostic services, including MPI, often called nuclear stress tests.

MPI is a cardiac imaging modality performed at rest and after exercise. It utilizes the same basic principles as a treadmill exercise stress test but provides significantly more detailed information. By using a radioactive tracer and an imaging camera, MPI creates images that show blood flow to the heart muscle during rest and at peak exercise. This allows clinicians to identify areas of the heart with poor blood flow or scarring. MPI is crucial for diagnosing myocardial ischemia, managing coronary artery disease, and assessing infiltrative, inflammatory, or infectious cardiovascular conditions.

There are two types of MPI: Single Photon Emission Computed Tomography (SPECT) and Cardiac Positron Emission Tomography-Computed Tomography (PET/CT). Inova offers cardiac SPECT at 12 locations across PD 8. In 2024, these SPECT locations performed 7,691 cardiac SPECT studies. Inova does not offer cardiac PET/CT today and through this application is seeking approval to establish cardiac PET/CT services through the acquisition of a fixed PET/CT unit that will be exclusively used for cardiovascular imaging.

While SPECT has traditionally been the primary diagnostic tool for MPI, cardiac PET/CT is now recommended as a Class 1 imaging modality for non-invasive cardiac stress testing in patients with chest pain and those suspected to have coronary artery disease. Compared to SPECT, cardiac PET/CT offers higher sensitivity, specificity, and diagnostic accuracy. It also reduces radiation exposure, shortens acquisition time, and enables the quantification of myocardial blood flow. Another advantage of PET/CT over SPECT is that body habitus (i.e., physical build and shape) and patient weight have minimal impact on image quality and diagnostic accuracy.

Comparison: SPECT vs Cardiac PET/CT

	Nuclear SPECT	Cardiac PET/CT
Accuracy	<ul style="list-style-type: none">• Higher prevalence of artifacts limits accuracy	<ul style="list-style-type: none">• Higher diagnostic accuracy• Excellent sensitivity to exclude significant coronary artery disease (CAD)
Image Quality	<ul style="list-style-type: none">• Lower image quality due to lower spatial resolution	<ul style="list-style-type: none">• Excellent image quality• Higher spatial resolution• Fewer artifacts
Exposure	<ul style="list-style-type: none">• Longer image acquisition time• Higher patient and staff radiation exposure	<ul style="list-style-type: none">• Shorter image acquisition time• Decreased radiation exposure
Protocol	<ul style="list-style-type: none">• Acquisition times are 45 minutes.• Total patient time in department ~ 3 hours	<ul style="list-style-type: none">• Shorter acquisition time of 5 minutes• Total patient time in department ~ 45 minutes
Clinical Utility	<ul style="list-style-type: none">• Myocardial perfusion	<ul style="list-style-type: none">• Myocardial perfusion• Myocardial blood flow assessment• Infection and inflammation imaging• Assessment of allograft vasculopathy (heart transplant patients)

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.)

Inova expects the primary service area for the proposed project to be consistent with the existing primary service area for Inova's outpatient cardiology practices.

Please see Attachment P.

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

Please see Attachment Q for Inova's 2024 outpatient cardiology patient origin. This includes patients who completed visits at any Inova outpatient cardiology practice location across PD 8.

- 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.

2. If Yes,

- a. Identify the facility(ies)

There are seven authorized cardiac PET/CT scanners in PD 8 and one pending COPN approval.

- **Authorized as of March 31, 2025:**
 - **Amelia Heart & Vascular – Springfield**
 - **Cardiac Care Associates – Reston**
 - **Carient Heart & Vascular – Manassas**
 - **Carient Heart & Vascular – Vienna**
 - **NOVA Cardiovascular Care – Woodbridge**
 - **Virginia Heart – Falls Church (Telestar Ct)**
 - **Virginia Heart – Lansdowne**
- **Pending COPN Approval as of March 31, 2025:**
 - **Virginia Heart – Mark Center**

There are an additional nine authorized PET/CT scanners in PD 8 primarily serving oncology patients.

- **Authorized as of March 31, 2025:**
 - **Inova Reston MRI Center – Fairfax PET-CT**
 - **Inova Reston MRI Center - Centreville**
 - **Kaiser – Woodbridge Imaging Center**
 - **Metro Region PET Center (x2)**
 - **PET of Reston (Mobile, Part-time)**
 - **Sentara Northern Virginia Medical Center (Mobile, Part-time)**
 - **Virginia Hospital Center**
 - **UVA Cancer Center – Gainesville (Mobile, Part-time)**

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

Today, all of the authorized cardiac PET/CT units in PD 8 are located in private cardiology practice locations, with patient access largely limited to patients of the relevant cardiology practice. These practices account for less than 50% of cardiologists in Northern Virginia, which means there are a significant number of patients that would benefit from cardiac PET/CT who have limited access today.

Additionally, based on recent cardiac PET/CT applications, there is significant unmet demand for these services. For example, Virginia Heart's first cardiac PET/CT service opened in 2023 and by the end of 2024 it was operating at capacity.

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

As discussed in the prior section, all of the authorized cardiac PET/CT units in PD 8 are located in private cardiology practice locations, with patient access largely limited to patients of the relevant cardiology practice. These practices account for less than 50% of cardiologists in Northern Virginia, which means there are a significant number of patients that would benefit from cardiac PET/CT who have limited access today.

Not only has Inova Cardiology grown substantially over the past three years as demonstrated in Section III.G., but the demand for these services is also projected to grow significantly in the next five to ten years.

According to the Centers for Disease Control and Prevention, heart disease is the leading cause of death in the United States and coronary heart disease is the most common type of heart disease killing more than 370,000 people in 2022.

Nationally, the incident rates for coronary artery disease, heart failure, and atrial fibrillation are projected to increase significantly in the next decade, primarily driven by an aging population and increasing rates of risk factors like obesity, diabetes, and high blood pressure, resulting in a substantial increase in the overall burden of cardiovascular disease in the coming years.

Similar to national trends, the demand for cardiovascular services in PD 8 is projected to grow significantly in the next five to ten years. The Advisory Board, a nationally recognized healthcare consulting company, projects PD 8 inpatient cardiac services will grow 23.6% and outpatient volumes will grow 31.5% between 2023-2033.

Advisory Board – PD 8 Inpatient & Outpatient Cardiac Growth Projections

	5-Year 2023-2028	10-Year 2023-2033
Inpatient Cardiac Services	10.2%	23.6%
Outpatient Cardiac Services	16.7%	31.5%
Cardiology Nuclear Imaging	14.8%	23.3%

Similar to national trends, the primary driver for this growth is PD 8's rapidly aging population. According to Weldon Cooper Center for Public Service, PD 8's 65+ population is projected to grow 16% between 2023-2030.

Weldon Cooper Center for Public Service: PD 8 Population Projections

Age Group	2023	2030	2023-2030	
0-64	2,208,441	2,424,434	215,993	10%
65+	347,702	404,555	56,853	16%
Total	2,556,143	2,828,990	272,847	11%

- 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.

As discussed in the prior section all of the authorized cardiac PET/CT units in PD 8 are located in private cardiology practice locations, with patient access largely limited to patients of the relevant cardiology practice. These practices account for less than 50% of the cardiologists in Northern Virginia, which means there are a significant number of patients that would benefit from cardiac PET/CT who have limited access today. Not only has Inova Cardiology grown substantially over the past three years as demonstrated in Section III.G., but the need for these services is also projected to grow significantly in the next five to ten years which will place greater demands on the existing services.

Inova is seeking approval to establish cardiac PET/CT services through the acquisition of a fixed PET/CT unit that will be exclusively used for cardiovascular imaging. If approved, the facility will be established as an Independent Diagnostic Testing Facility (IDTF). By establishing this center as an IDTF (i.e., not a department of a hospital or part of a cardiology practice) Inova will be able to offer this critical non-invasive cardiac diagnostic test to all patients needing MPI studies.

Introducing cardiac PET/CT services in Fairfax will provide the most central access for our patients. The proposed location is near Inova Fairfax Medical Campus, where our current advanced heart failure, transplant programs and largest cardiology practice are located. Additionally, this is a central location to the other patients in PD 8 who can benefit from this service who do not have access today.

- 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.

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.

Cardiac PET/CT services are generally available within 60 minutes driving time one way under normal conditions of 95% of the population within PD 8. As the Northern Virginia population continues to grow and traffic congestion increases, drive times are expected to become even more lengthy and challenging.

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. The proposed project will be established as an IDTF and will not be operated as part of one of our hospitals.

- 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.*

As with the prior authorized cardiac PET/CT services, the proposed project does not satisfy the service volume requirements of this provision. However, both HSANV and DCOPN have acknowledged the utilization standards are outdated.

In the February 28, 2025 HSANV Staff Report for COPN Request No-VA-8794, Dean Montgomery stated, “The service volume standard is

dated, much too high for current procedure times and service protocols. Use of established PET services, cardiac and oncology alike, does not approach 6,000 scans per scanner. Given recent experience with clinical applications and treatment times, there is no prospect of meeting the service volume specified.”

In the July 19, 2024 DCOPN Staff Report for COPN-Request Nos-VA 8754 – VA-8758, DCOPN stated that the, “SMFP’s utilization standards for PET/CT services are outdated and the SMFP did not adequately predict the applications for which PET would be used at the time it was written.” DCOPN went on to say, that “While the applicant does not meet the computational analysis of this SMFP standard, DCOPN recommends that the Commissioner, in this specific instance, does not allow this standard to bar the establishment of cardiac PET/CT services to serve an existing patient base currently without access to the standard of cardiac imaging.”

The approval of this project will not impact existing providers in PD 8. As discussed in the prior sections, all of the authorized cardiac PET/CT units in PD 8 are located in private cardiology practice locations, with patient access largely limited to patients of the relevant cardiology practice. These practices account for less than 50% of cardiologists in Northern Virginia, which means there are a significant number of patients that would benefit from cardiac PET/CT who have limited access today. Not only has Inova Cardiology grown substantially over the past three years as demonstrated in Section III.G., but the need for these services is also projected to grow significantly in the next five to ten years which will place greater demands on the existing services.

12VAC5-230-220. Expansion of fixed site services.

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

Not applicable, the proposed project is to establish a new service.

12VAC5-230-230. Adding or expanding mobile PET or PET/CT services.

- A. *Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.*

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

Not applicable, the proposed project is for a fixed cardiac PET/CT service.

12VAC5-230-240. Staffing.

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

Abbas Emaminia, MD, is the Director for Cardiac Diagnostics at Inova Fairfax Medical Campus and will be the Medical Director of the proposed cardiac PET/CT imaging facility. Dr. Emaminia is fellowship trained in Advanced Cardiac Imaging.

- 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.

The volume projections for Inova Cardiac Diagnostics PET/CT – Willow Oaks are as follows:

	Year 1	Year 2
Average studies per day	9	10
Studies per year	2,295	2,550

Inova expects its cardiac PET/CT patients to originate from the following sources:

- **Existing SPECT patients that would be more appropriate for cardiac PET/CT (Inova assumes 20% of SPECT patients will convert to cardiac PET/CT patients)**
- **Inova's cardiologists, including its advanced heart failure physicians and other cardiology practices in PD 8 who do not have access to cardiac PET/CT today. Projected patient populations include:**
 - **Chest pain and coronary artery disease**
 - **Myocardial ischemia**
 - **Infectious cardiovascular conditions**
 - **Infiltrative cardiomyopathy (e.g., cardiac sarcoidosis)**
 - **Heart failure and transplant patients**

Initially, Inova's proposed cardiac PET/CT service will be open Monday through Friday from 7 a.m. to 5 p.m., with plans to extend to Saturday as utilization increases. Based on the experience of the other providers in PD 8 and growth in Inova's cardiac patient volumes, programs and services, utilization is expected to quickly increase. The facility has been designed to maximize throughput and, once at full capacity, will be able to provide PET/CT services to 13 patients per day.

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.)

Inova Health System is a broad-based regional healthcare system and provides a comprehensive and coordinated range of acute, ambulatory, and tertiary services.

Pediatric Specialists of Virginia, LLC ("PSV"), a non-profit private pediatric medical group, is a 50-50 joint venture between Inova and Children's National Medical Center. PSV provide a variety of pediatric specialties including gastroenterology, hematology oncology, and orthopedics. Please see Attachment R for legal documentation of this joint venture.

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 S for the location of the proposed project and the location of other authorized PET scanners 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 Attachment T.

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

Please see Attachment U.

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 Inova Health System facilities participate in VHI.**
Provide a copy of report(s) which provide(s) the basis for comparison.

This proposal is to establish a new cardiac PET/CT service at 8280 Willow Oaks Corporate Drive, Suite 100 in Fairfax, VA. If approved this facility will be established as an IDTF and will participate in future VHI surveys.

- 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	<u>\$1,089,774</u>
2.	Cost of labor	<u>n/a</u>
3.	Equipment included in construction contract	<u>n/a</u>
4.	Builder's overhead	<u>\$98,245</u>
5.	Builder's profit	<u>\$83,161</u>

6.	Allocation for contingencies	<u>\$254,236</u>
7.	Sub-total (add lines 1 thru 6)	<u>\$1,525,416</u>

Part II – Equipment Not Included in Construction Contract

If leasehold, lease expense over entire term of lease

(List each separately)

8.	a. Siemens Camera	<u>\$2,250,000</u>
	Please see Attachment V for the quote.	
	b. PET Camera QC Source	<u>\$49,809.70</u>
	c. NMIS System	<u>\$15,906</u>
	d. GE Treadmill	<u>\$30,573.60</u>
	e. Remote Hemo/ECG Monitoring System	<u>\$22,204</u>
	f. Hot Lab Equipment	<u>\$28,000</u>
	a. Misc. Equipment	<u>\$21,799.69</u>
9.	Sub-total (add lines 8a thru 8e)	<u>\$2,418,292.99</u>

Part III – Site Acquisition Costs

10.	Full purchase price	<u>n/a</u>
11.	For sites with standing structures	<u>n/a</u>
	a. purchase price allocable to structures	<u>n/a</u>
	b. purchase price allocable to land	<u>n/a</u>
12.	Closing costs	<u>n/a</u>
13.	If leasehold, lease expense over entire term of lease	<u>\$4,533,550</u>
	Please see Attachment B for a memorandum of understanding documenting the planned lease arrangement between Inova Health Care Services and the landlord, BOF II VA Willow Oaks, LLC.	
14.	Additional expenses paid or accrued:	

a.	_____	\$ _____
b.	_____	\$ _____
c.	_____	\$ _____

15.	Sub-total (add lines 10 thru 14c)	<u>\$4,533,550</u>
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Part IV – Site Preparation Costs

16.	Earth work	<u>n/a</u>
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17.	Site utilities	<u>n/a</u>
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18.	Roads and walks	<u>n/a</u>
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19.	Lawns and planting	<u>n/a</u>
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20.	Unusual site conditions:	<u>n/a</u>
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21.	Accessory structures	<u>n/a</u>
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22.	Demolition costs	<u>n/a</u>
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23.	Sub-total (add lines 16 thru 22)	<u>\$0</u>
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Part V – Off-site Costs (List each separately)

24.	_____	<u>n/a</u>
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25.	_____	<u>n/a</u>
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26.	_____	<u>n/a</u>
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27.	_____	<u>n/a</u>
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28.	Sub-total (add lines 24 thru 27)	<u>\$0</u>
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Part VI – Architectural and Engineering Fees

29.	Architect's design fee	<u>\$80,000</u>
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30.	Architect's supervision fee	<u>\$10,000</u>
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31.	Engineering fees	<u>\$40,000</u>
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32.	Consultant's fees	<u>\$8,000</u>
33.	Sub-total (add lines 29 thru 32)	<u>\$138,000</u>

Part VII – Other Consultant Fees (List each separately)

34.	a. _____	<u>n/a</u>
	b. _____	<u>n/a</u>
	c. _____	<u>n/a</u>
35.	Sub-total (add lines 34a thru 34c)	<u>\$0</u>

Part VIII – Taxes During Construction

36.	Property taxes during construction	<u>n/a</u>
37.	List other taxes:	
	a. _____	<u>n/a</u>
	b. _____	<u>n/a</u>
38.	Sub-total (add lines 36 thru 37b)	<u>\$0</u>

Part IX-A – HUD Section 232 Financing

39.	Estimated construction time(in months)	<u>n/a</u>
40.	Dollar amount of construction loan	<u>n/a</u>
41.	Construction loan interest rate	<u>n/a</u>
42.	Estimated construction loan interest costs	<u>n/a</u>
43.	Term of financing (in years)	<u>n/a</u>
44.	Interest rate on permanent loan	<u>n/a</u>
45.	FHA mortgage insurance premium	<u>n/a</u>
46.	FHA mortgage fees	<u>n/a</u>
47.	Financing fees	<u>n/a</u>

48.	Placement fees	<u>n/a</u>
49.	AMPO (non-profit only)	<u>n/a</u>
50.	Title and recording fees	<u>n/a</u>
51.	Legal fees	<u>n/a</u>
52.	Total interest expense on permanent mortgage loan	<u>n/a</u>
53.	Sub-total Part IX-A HUD Section 232 Financing (add lines 42, 45, 46, 47, 48, 49, 50 and 51)	<u>\$0</u>

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

70.	Anticipated bond discount (in dollars)	<u>n/a</u>
71.	Legal costs	<u>n/a</u>
72.	Printing costs	<u>n/a</u>
73.	Placement fee	<u>n/a</u>
74.	Feasibility study	<u>n/a</u>
75.	Insurance	<u>n/a</u>
76.	Title and recording fees	<u>n/a</u>
77.	Other fees (list each separately)	
	a. _____	<u>n/a</u>
	b. _____	<u>n/a</u>
	c. _____	<u>n/a</u>
78.	Sinking fund reserve account (Debt Service Reserve)	<u>n/a</u>
79.	Total bond interest expenses (in dollars)	<u>n/a</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)	<u>n/a</u>
82.	Dollar amount of construction loan	<u>n/a</u>
83.	Construction loan interest rate	<u>n/a</u>
84.	Estimated construction loan interest cost (in dollars)	<u>n/a</u>
85.	Term of long term financing (in years)	<u>n/a</u>
86.	Interest rate on long term loan	<u>n/a</u>
87.	Anticipated mortgage discount (in dollars)	<u>n/a</u>
88.	Feasibility study	<u>n/a</u>
89.	Finder's fee	<u>n/a</u>
90.	Legal fees	<u>n/a</u>
91.	Insurance	<u>n/a</u>
92.	Other fees (list each separately)	
	_____	<u>n/a</u>
93.	_____	<u>n/a</u>
94.	Total permanent mortgage loan	

interest expense (in dollars) n/a

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)	<u>\$1,525,416</u>
97.	Sub-total Part II	Equipment not included in construction contract (line 9)	<u>\$2,418,292.99</u>
98.	Sub-total Part III	Site Acquisition Costs (line 15)	<u>\$4,533,550</u>
99.	Sub-total Part IV	Site Preparation Cost (line 23)	<u>\$0</u>
100.	Sub-total Part V	Off-Site Costs (line 28)	<u>\$0</u>
101.	Sub-total Part VI	Architectural and Engineering fees (line 33)	<u>\$138,000</u>
102.	Sub-total Part VII	Other Consultant fees (line 35)	<u>\$0</u>
103.	Sub-total Part VIII	Taxes During Construction (line 38)	<u>\$0</u>
104.	Sub-total Part IX-A	HUD-232 Financing (line 53)	<u>\$0</u>
105.	Sub-total Part IX-B	Industrial Development Authority Revenue & General Revenue Bond Financing (line 80)	<u>\$0</u>
106.	Sub-total Part IX-C	Conventional Loan Financing (line 95)	<u>\$0</u>
107.	TOTAL CAPITAL COST (lines 96 thru 106)		\$8,615,258.99

Approximately half of the total costs are attributable to construction and the cardiac PET/CT equipment. The remaining costs reflect the aggregate lease expenses over the 12 year initial term of the lease.

108. Percent of total capital costs to be financed 0 %

109. Dollar amount of long term mortgage (line 107 x 108) n/a

110. Total Interest Cost on Long Term Financing n/a

	a. HUD-232 Financing (line 53)	<u>n/a</u>
	b. Industrial Development Authority Revenue & General Revenue Bond Financing (line 79)	<u>n/a</u>
	c. Conventional Loan Financing (line 94)	<u>n/a</u>
111.	Anticipated Bond discount	
	a. HUD-232 Financing (line 53)	<u>n/a</u>
	b. Industrial Development Authority Revenue & General Revenue Bond Financing (line 70)	<u>n/a</u>
	c. Conventional Loan Financing (line 87)	<u>n/a</u>
112.	TOTAL CAPITAL AND FINANCING COST (ADD LINES 107, 110a, b or c AND 111a, b or c)	\$8,615,258.99
D.	1. Estimated costs for new construction (excluding site acquisition costs)	<u>\$0</u>
	2. Estimated costs of modernization and renovation (excluding site acquisition costs)	<u>\$0</u>
E.	Anticipated Sources of Funds for Proposed Project	<u>Amount</u>
	1. Public Campaign	<u>\$0</u>
	2. Bond Issue (Specify Type) _____	<u>\$0</u>
	3. Commercial Loans	<u>\$0</u>
	4. Government Loans (Specify Type)_____	<u>\$0</u>
	5. Grants (Specify Type)_____	<u>\$0</u>
	6. Bequests	<u>\$0</u>
	7. Private Foundations	<u>\$0</u>
	8. Endowment Income	<u>\$0</u>
	9. Accumulated Reserves	\$8,615,258.99
	10. Other (Identify)_____	<u>\$0</u>

- 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 project will be funded through accumulated reserves of Inova Health System.

- 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 project will be funded through accumulated reserves and, as such, there are no debt service costs associated with the project. Inova does not expect the capital costs associated with the project to impact the cost of care at Inova.

- 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. This project involves the establishment of cardiac PET/CT services at a freestanding imaging facility.

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 W for the most recent audited financial statement for Inova Health System.

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 X.

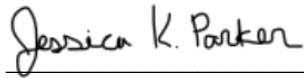
SECTION VI

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.



Signature of Authorizing Officer

8095 Innovation Park Drive

Address – Line1

Jessica Parker

Type/Print Name of Authorizing Officer

Address – Line 2

Senior Director, Strategy & Planning

Title of Authorizing Officer

Fairfax, VA 22031

City/State/Zip

703-517-9320

Telephone

March 28, 2025

Date

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.**

Inova Cardiac Diagnostics PET/CT - Willow Oaks
Establish Cardiac PET-CT Services

Financial Projections	Year 1 2026	Year 2 2027
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Statement of Revenue and Expenses

Gross Patient Revenue	\$9,796,524	\$11,039,931
Deductions from Patient Revenue		
Contractual Discounts	\$5,606,574	\$6,336,982
Provision for Charity	\$97,965	\$110,399
Total Deductions from Revenue	\$5,704,539	\$6,447,381
Net Patient Revenue	\$4,091,985	\$4,592,550
Operating Expenses		
Salaries & Benefits	\$580,269	\$603,480
Supplies	\$4,272	\$4,662
Purchased Services	\$17,863	\$274,865
Depreciation and Amortization	\$766,349	\$766,349
Other Expenses	\$1,072,587	\$497,000
Total Operating Expenses	\$2,441,340	\$2,146,356
Excess of Revenue Over Expenses	\$1,650,645	\$2,446,194
Annual Studies	2,295	2,550

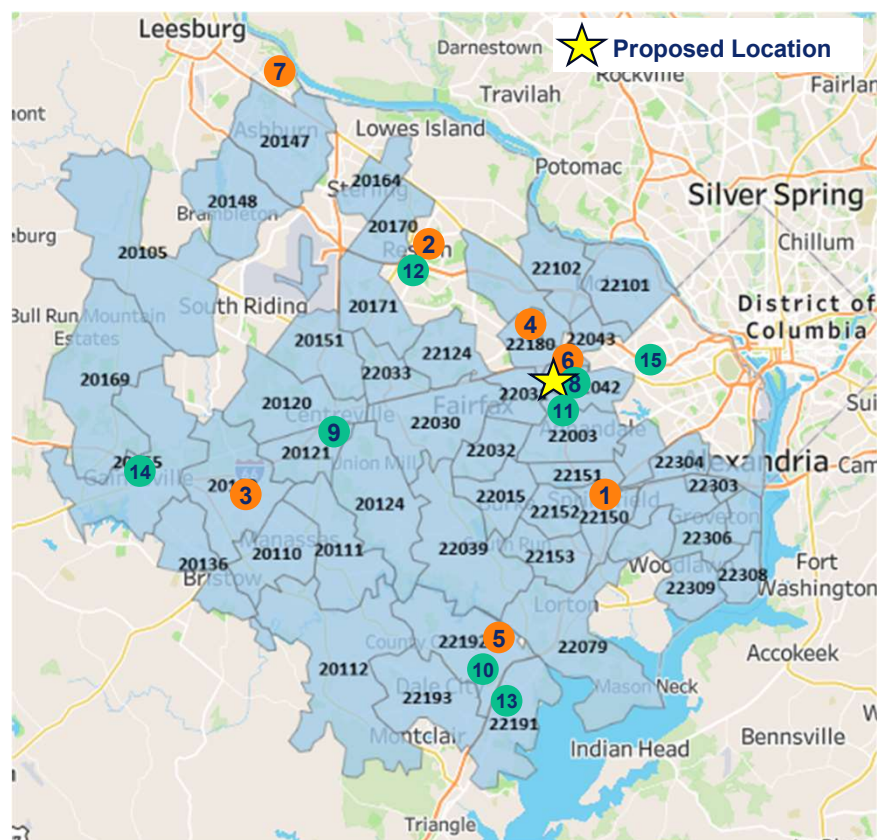
Expected Payor Mix:*	
Charity	1%
Commercial	29%
Medicaid	9%
Medicare	60%
Self Pay	1%
Total	100%

* Inova Cardiac Diagnostics PET/CT - Willow Oaks is owned by Inova and thus would fall under Inova's system-wide charity care condition.

Proforma Assumptions:

- Studies: Year 2 assumes a 11% increase
- Payor mix reimbursement consistent with internal Inova information, % of Gross Charges
- Annual inflation estimates: gross and net revenue per case =1%, expenses are 3-4%
- Equipment depreciation straight-lined for 5 years
- Construction/Renovation depreciation straight-lined for 12 years (initial lease term)
- Other Expenses - non-capitalized construction costs included in Year 1
- Purchase Services-Maintenance contract starts in Year 2, while Year 1 costs are included in equipment purchase price.

Map of Proposed Service Area and Authorized PET Scanners in PD 8



Authorized Cardiac PET/CT Scanners (as of March 31, 2025)

	Facility Name	# Scanners
1	Amelia Heart & Vascular – Springfield	1
2	Cardiac Care Associates - Reston	1
3	Carient Heart & Vascular - Manassas	1
4	Carient Heart & Vascular – Vienna	1
5	NOVA Cardiovascular Care – Woodbridge	1
6	Virginia Heart – Falls Church (Telestar Ct)	1
7	Virginia Heart – Lansdowne	1

Authorized PET/CT Scanners (Cancer Focused)

	Facility Name	# Scanners
8	Fairfax PET-CT	1
9	Inova Reston MRI Center - Centreville	1
10	Kaiser Health Foundation	1
11	Metro Region PET Center	2
12	PET of Reston	1 Mobile, Part-Time
13	Sentara Northern Virginia Medical Center	1
14	UVA Cancer Center – Gainesville	1 Mobile, Part-Time
15	Virginia Hospital Center	1