

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

428 McLaws Cir. Suite 200

Address

Williamsburg

City

VA

State

23185

Zip

(757) 259-9200

Telephone

(757) 259-9201

Facsimile

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) **X**

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

(3) **X**

(4) _____

(4) Other _____ Identify

(4) _____

See Attachment I.E. (Articles of Incorporation)

Non-Profit

(5) _____

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

(5) _____

(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) X leasehold interest for not less than 11 years
- (4) _____ Renewable lease, renewable every _____ years
- (5) _____ Other _____ Identify

See Attachment I.F (Letter of Intent to Lease) and I.F (Alexandria Executed Lease)

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.

No shareholders have ownership of 5% or more in Virginia Heart. All owners are practicing cardiologists within the group practice.

(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.

See Attachment I.G (Board of Directors, Managing Partners, and Registered Agent)

(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
- (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:

- (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.

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

Virginia Cardiac Network, LLC is partially owned (9.041%) by Virginia Heart. Virginia Cardiac Network, LLC negotiates insurance payments on behalf of patients and providers.

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

Not Applicable

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: **2.46** acres
- 2. Located in **Alexandria/PD 8** City/County/Planning District
- 3. Address or directions **4825 Mark Center Drive, Suite 110, Alexandria, VA 22311**
- 4. Has site been zoned for type of use proposed:

Yes (attach copy of zoning or use permit)

See Attachment II.A (Zoning Map and Ordinance)

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) _____ Other _____ (Identify)

C. Design of the facility

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

Virginia Heart does not have a written long-range plan to attach. However, as reflected in the COPN application, Virginia Heart is an independent practice owned by shareholders who are practicing cardiologists within the practice. Virginia Heart is committed to improving the health and well-being of the community through empathy, compassion, innovation, excellence, teamwork, fairness, and equality. It is the largest group of cardiologists within PD 8 representing multiple subspecialties including electrophysiology, heart failure, interventional and structural cardiology, peripheral vascular, adult congenital heart, sports cardiology, cardiomyopathy, advanced cardiovascular

imaging, cardio-obstetrics, cardio-oncology, pericardial diseases, and cardiac amyloidosis. Virginia Heart is not currently, and has no intention to be, backed by private equity. It has a 10-year professional services agreement (PSA) with Inova Health System, reflecting its commitment to remain independent. It is nationally and internationally recognized for quality, is a founding member of American College of Cardiology's (ACC) national cardiology practice consortium, MedAxiom, and strongly believes in excellence in every aspect of a patient encounter.

The addition of more capacity for Cardiovascular Positron Emission Tomography/Computed Tomography (PET/CT) to Virginia Heart's existing services aligns with its Mission, Vision, and Values to be among the Nation's most trusted partners in cardiovascular care with recognition for outstanding quality and leadership. Cardiovascular PET/CT offers patients access to the preferred and the recommended Myocardial Perfusion Imaging (MPI) test. MPI testing, which includes Single-Photon Emission Computed Tomography (SPECT) and PET/CT, is one of the fundamental cardiovascular diagnostic tools offered in the ambulatory setting by cardiology practices as a group practice operating under the Centers for Medicare & Medicaid Services (CMS) in-office ancillary service exception (See Attachment II.C).¹

SPECT has been in use for decades in the ambulatory setting and was once regulated by Virginia COPN. However, it was eventually determined that SPECT was a standard part of in-office testing for ambulatory cardiology practices and was removed from the list of technologies that require COPN. PET/CT has been used for years in hospital settings for oncology, urology, and other specialties, but it is relatively new in its use for cardiovascular diagnostic testing, and it is rarely performed in hospital settings. This is because it is not well-suited in hospital settings for cardiovascular diagnostics in that it requires unique nuclear isotopes and cardiologists to oversee the program and read the studies. Cardiovascular PET/CT is not a test that is performed in emergency situations but rather in patients who are suspected of having or have known cardiovascular disease that is relatively stable. For all of these reasons, it is more well-suited for the ambulatory environment within a cardiology practice rather than in a hospital setting.

PET/CT has demonstrated superiority over SPECT for the diagnosis of cardiovascular disease (as will be further elucidated in this application). Unfortunately, historically, the availability, logistics, and cost of the primary isotope that is used, Rb-82, along with the expense of the camera, have made it out of reach for most independent cardiology practices. However, in recent years, Rb-82 has become more readily available, and suppliers & distributors have instituted creative models, like sharing Rb-82 generators, and camera vendors have started offering long-term leases to spread the capital expense. These recent developments have made this superior technology within the reach of independent practices.

¹ Bateman, et.al. Comparison of Myocardial Perfusion SPECT and PET. Journal of Nuclear Cardiology, 2006; 13: 1;24-33

While it is understandable that PET falls under Virginia’s COPN as it relates to hospital use for oncology, urology, and other general applications, as previously noted, there is a specific use case in the ambulatory cardiology setting that makes it very different. Most cardiology practices have a panoply of in-office testing including EKGs, various heart rhythm monitoring, treadmill testing, echocardiography, and MPI. This in-office testing is used within a practice to support rapid, efficient, and cost-effective diagnoses for its patient base. The cardiologists within a practice are the predominant referring physicians for these tests, unlike hospital-based PET which is typically staffed by hospital-based radiologists who perform and read tests for outside referring providers. Thus, hospital-based PET serves an entire community, while ambulatory cardiovascular PET/CT typically serves a specific patient base within a cardiology practice. With the recent developments in isotope availability and long-term equipment financing, PET/CT is becoming a growing staple for in-office testing for cardiology practices across the country. It is strongly endorsed by the ACC/MedAxiom, and the American Society of Nuclear Cardiology (ASNC), as evidenced by letters of support to this application (Attachment IV.H.2). Therefore, offering Cardiovascular PET/CT is of critical importance and aligns with Virginia Heart’s long-range plan to continuously provide the most up-to-date, advanced care to its patients.

Locating an additional PET/CT at the Mark Center in Alexandria will enhance patient access by increasing capacity to meet existing demand and making it more accessible to patients located in Eastern & Southeastern PD 8. Virginia Heart recently opened a new clinical office in the Mark Center and is ready to offer MPI services in this location. Approval of PET/CT will allow Virginia Heart to provide the industry gold-standard for MPI to a greater number of its patients who are appropriate candidates for this service. In addition to enhancing access to Cardiovascular PET/CT for Virginia Heart patients residing closer to Alexandria, the proposed location is a unique and ideal location, as described in Section II.C.2.

This COPN application reflects Virginia Heart’s long-range plan for Cardiovascular Services and Cardiovascular PET/CT services in particular.

- (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.

Virginia Heart has a signed letter of intent (See Attachment I.F Letter of Intent to Lease) for the proposed space and is in the process of finalizing an amendment to its existing Mark Center lease agreement that will be contingent upon COPN approval of this application. Timing is of the essence because of the current availability of this unique and ideal space. Should Virginia Heart not be approved, it is expected that the proposed space will be leased long-term to another interested party. Therefore, it is highly unlikely there will be another feasible space opportunity for this project at any time in the near-to long-term without Virginia Heart moving locations. This would unnecessarily result in significant additional costs. Attachment III.K.4 demonstrates the commitment and support of Virginia Heart’s physicians to

move forward with this ideal opportunity and their confidence that Virginia Heart will fill the capacity of this service through its existing patient base.

As Virginia Heart is a private practice, not backed by private equity, any financial risk associated with this project is on the onus of its cardiologist owners. Virginia Heart has demonstrated very conservative use of ancillary testing services, including diagnostic imaging as compared to national benchmarks, thus, demonstrating their unwavering commitment to appropriate use. Their conservative use of ancillary MPI imaging services can be seen in the ACC’s national database for cardiology practices, MedAxiom. In ACC/MedAxiom’s database for 2023, Virginia Heart was in the lowest quartile of utilization nationally for the Ratio of Total Nuclear SPECT to Total New Patient Visits. Their conservative utilization is a consistent trend for the past 5 years (2019-2023).

**ACC MedAxiom National Database
Ratio of Total Nuclear SPECT to Total New Patient Visits**

	Virginia Heart	National Average	25th Percentile	50th Percentile
2019	21.95%	34.44%	< 21.78%	< 32.28%
2020	22.33%	31.19%	< 19.97%	< 29.97%
2021	20.25%	26.75%	< 18.62%	< 23.91%
2022	17.97%	26.65%	< 17.60%	< 25.18%
2023	16.43%	26.23%	< 16.73%	< 23.31%

In terms of Virginia Heart’s long-range plan for MPI testing including SPECT & PET/CT, the advent of PET/CT as a viable option for ambulatory cardiology has allowed Virginia Heart to assess and plan for adequate capacity and distribution of both technologies across its wide geographic presence in PD 8. While PET/CT is the superior technology, it has more limited and specific criteria for appropriate use. Therefore, SPECT will continue to have a significant role in MPI diagnostic testing. Depending on local geographic capacity within Virginia Heart’s footprint, some end-of-life SPECT cameras have been, or may be, decommissioned and replaced with PET/CT (if approved), and in other circumstances PET/CT would provide additive capacity.

Ideally, Virginia Heart will have adequate capacity and access to both SPECT & PET/CT that is geographically distributed to meet the needs of its patients across its footprint in PD 8. Virginia Heart currently offers PET/CT at its Telestar location in Falls Church (Central PD 8) and has recently applied for a COPN for Cardiovascular PET/CT in Loudoun (Western PD 8). This specific application for PET/CT at the Mark Center would provide more capacity and access for Eastern and Southeastern PD 8.

Virginia Heart patients in Eastern & Southeastern PD 8 will continue to have access to SPECT in Arlington (1005 N. Glebe Road, Arlington, VA, 22201) and in Alexandria (4660 Kenmore Avenue, Alexandria VA, 22304). In Central PD 8, Virginia Heart patients have access to SPECT in Falls Church (2901 Telestar Court, Falls Church VA, 22042). In Western PD 8,

SPECT is available in Loudoun (44035 Riverside Parkway, Leesburg VA, 20176), Fair Oaks (3580 Joseph Siewick Drive, Fairfax VA, 22033), and Sterling (24430 Stone Springs Boulevard, Sterling, VA 20166).

Furthermore, as evidenced in Section III.G, Virginia Heart's data shows that the addition of PET/CT fulfills unmet need because patients who are not candidates for SPECT due to various physical limitations and comorbidities can safely undergo PET/CT. Virginia Heart currently provides care for over 170,000+ patient encounters per year, and patient demand has been steadily increasing. Virginia Heart does not have nearly enough existing MPI capacity for its current patient base nor for the 94 providers in its practice, and that demand is only anticipated to increase with the growing and aging population in PD 8. It is in the best interest of public health to increase capacity and access to Cardiovascular PET/CT, as it offers significantly better diagnostic quality, dramatically increased throughput, and much lower radiation risk to patients and staff. It is also more cost-effective, provides better continuity of care, and is more convenient for patients to receive testing in the ambulatory setting with their primary cardiologists.

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

Patients will be able to easily access Virginia Heart's office at 4825 Mark Center Drive, Suite 110, Alexandria, VA 22311 as the facility in close proximity to public transportation as well as major highways. The facility is conveniently located just off the intersection of Henry G. Shirley Memorial Highway (I-395) and Seminary Road. The Mark Center is approximately 3 miles from the intersection of I-395 and Little River Turnpike and less than 2 miles from the intersection of I-395 and Route 7. Ample, free parking is available on-site for patients, including handicapped spaces closest to the building. Alexandria DASH provides fare-free bus service within Alexandria- Mark Center Station is located 0.2 miles from the proposed site and services multiple bus routes that support the Alexandria area and local metro stations.

See Attachment II.C.3 (Alexandria DASH Bus Schedule)

- (3) 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.

There are no anticipated issues related to future expansion, parking, provision of water, sewer, and solid waste services. Virginia Heart's existing Alexandria Office is located in the Mark Center across the lobby from the proposed location. The building is zoned appropriately to allow medical offices and the imaging services proposed. The building already has ample parking space for patients to have ease of access to the building. Water, sewer, and waste services are currently being provided and are adequate for the proposed project.

- (4) 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

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

The proposed location is a ground floor space which greatly minimizes structural assessment and reinforcement needs. Installing a PET/CT into a non-ground floor space is cost-prohibitive, if not impossible.

Locating the Cardiovascular PET/CT unit in the Mark Center allows for supervision of the unit by Virginia Heart cardiologists directly across the lobby, ensuring efficient use of clinical resources.

Minimal construction will occur to remodel the space and provide sufficient room for the equipment and project needs. Introducing a Cardiovascular PET/CT service in this location is a cost-effective expansion of Virginia Heart's services in PD 8 and will improve accessibility for Virginia Heart's primary service area and patients seeking services in Alexandria.

The design features required for efficient use of clinical resources, space, and funds are challenging to find in one location. The proposed location offers all required features and is unlikely to be available at a later date.

- 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 II.D (Utility Bills)

- 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.)

See Attachment II.E.2 (Tabulation of Space)

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

Design for this space is based on the projected utilization and minimum space requirements for a Siemens Biograph Cardiovascular PET/CT scanner along with all its components. The building is currently in use by Virginia Heart in an adjacent suite and is already served by all necessary utilities. A camera room, control room, hot lab, private patient waiting area, exam room, and provider office will need to be constructed. Within these rooms will be all of the necessary equipment for patient care. The Rb-82 generator will be stored in the camera room.

All design and construction will be in accordance with equipment manufacturer specifications, safety guidelines, the current requirements of the Facility Guidelines Institute (FGI) for the Design and Construction of Hospitals and Healthcare Facilities, Americans with Disabilities Act (ADA) Guidelines, the International Building Code (IBC), the National Fire Protection Association 1010 Life Safety Code (NFPA 101), the ASHRAE 90.1 Energy Conservation Code (ASHRAE), the Virginia Uniform Statewide Building Code, and applicable local codes.

- 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.

See Attachment II.F (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.

See Attachment II.G (Preliminary Design Drawing)

H. Construction Time Estimates

1. Date of Drawings: Preliminary: **August 23, 2024**
Final: **COPN Approval + 1 Month**
2. Date of Construction: Begin: **Final Drawings + 1 Month**
Completion: **2 Months from Start of Construction**
3. Target Date of Opening: **First Quarter, 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.

Virginia Heart has grown into the region's premier cardiovascular group with 94 providers who diagnose and treat the full spectrum of disorders affecting the body's heart and vascular systems. With 170,000+ patient encounters each year, patients place their trust in Virginia Heart's 60 physicians, including 56 cardiologists, 4 sleep physicians, and 34 advanced practice providers. What distinguishes Virginia Heart is a team-led, holistic approach to individualized, compassionate patient care. Virginia Heart provides the following areas of expertise on site at their outpatient offices: general cardiology, diagnostic testing, interventional cardiology, vascular disease, electrophysiology, preventative cardiology and wellness, advanced heart failure, sleep medicine, women's heart health, adult congenital heart disease, structural heart program, and research.

Virginia Heart opened its Alexandria Office in the Mark Center at the end of 2022 and has the patient volume and staff proficiency to offer MPI to its patients seeking services there. MPI is an essential mainstay in cardiology for non-invasive imaging of the heart for the characterization of a variety of cardiac conditions that has been extensively reported upon in scientific literature. While SPECT imaging has been the long-standing modality used for MPI, Cardiovascular PET/CT is a newer, yet well-established MPI modality that is superior to standard SPECT (see Section IV.A). While Virginia Heart is not currently offering MPI in this location, it would prefer to offer PET/CT (if approved). Otherwise, SPECT will be the alternative. As discussed in Section II.C.2, it is essential to Virginia Heart's long-range plan to adopt the gold standard of imaging technology in order to provide the highest level of quality care for its patients.

Furthermore, as evidenced in Section III.G, Virginia Heart's data shows that the addition of PET/CT fulfills unmet need because patients who are not candidates for SPECT due to various physical limitations and comorbidities can safely undergo PET/CT. Virginia Heart currently provides care for over 170,000+ patient encounters per year, and patient demand has been steadily increasing. Virginia Heart does not have nearly enough existing MPI capacity for its current patient base nor for the 94 providers in its practice, and that demand is only anticipated to increase with the growing and aging population in PD 8. It is in the best interest of public health to increase capacity and access to Cardiovascular PET/CT, as it offers significantly better diagnostic quality, dramatically increased throughput, and much lower radiation risk to patients and staff.

Virginia Heart will use the Cardiovascular PET/CT scanner for cardiovascular imaging procedures only. No oncological, neurological, urological, or other non-Cardiovascular PET/CT procedures will be offered.

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

The addition of another Cardiovascular PET/CT to Virginia Heart's existing

services would ensure and expand upon Virginia Heart's current continuity of care. Offering adequate ambulatory diagnostic testing within a cardiology practice allows for patients to be diagnosed and treated by their primary cardiology care team. This provides seamless continuity of care between diagnosis and treatment by a single care team. This mitigates the need for patients to visit the hospital for diagnostic testing which would result in care that is more costly and inefficient, as well as less convenient and coordinated. Patients who are appropriate candidates for Cardiovascular PET/CT would have access to diagnostic testing sooner and in a more local location. Currently, Virginia Heart is largely seeing Medicare patients due to sheer demand, and is, therefore, limited in its ability to serve all of its patients with PET/CT. With the approval of this new unit, Virginia Heart will be able to better accommodate patient demand and ensure they are receiving timely care with no interruptions due to scheduling difficulties. See Section III.G regarding current demand and the capacity an additional PET/CT scanner would provide, though this would still not suffice to address the unmet need.

This proposed project will operate pursuant to Virginia Heart's policies and procedures to ensure continuity of care. Virginia Heart cardiologists practice in all PD 8 hospitals offering advanced cardiovascular services within the practice's primary service area. Electronic Medical Records (EMR) transmitted to Virginia Heart are used to transfer patient scans to hospitals and other providers as needed. Virginia Heart utilizes Digital Imaging and Communications in Medicine (DICOM) formatted images, the international standard for communication and management of medical data. All images can be easily and quickly uploaded to compatible centers, as currently done with Virginia Heart's complex patient population.

Virginia Heart uses state-of-the-art Picture Archiving and Communications System (PACS) for storing radiological images as well as for easy remote access within partnering health care systems and providers. The Cardiovascular PET/CT scanner will interface with these systems to ensure that patient scans are quickly and easily accessible for patients and other providers.

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C. What procedures are utilized in quality care assessment?

Virginia Heart is accredited by the Intersocietal Accreditation Commission (IAC) for multiple modalities. This standard is maintained across all imaging locations and will include this proposed Cardiovascular PET/CT scanner under the Nuclear Medical Director's supervision. Virginia Heart has clinical policies and procedures in place that are followed to ensure the highest quality of care for

patients. To preserve its dedication to high-quality patient care, Virginia Heart will continue to practice IAC mandated quality assurance including, but not limited to, technical and interpretive quality assessment, appropriate use, report completion and timeliness, modality correlation, and cardiac catheterization correlation.

In addition, Virginia Heart is contracting with Molecular Imaging Services, Inc. (MIS), the industry leader specializing in ambulatory Cardiovascular PET imaging solutions. With the support of MIS and noted Cardiovascular PET/CT specialist Dr. Gary Heller, Virginia Heart has expert guidance and resources to ensure the successful expansion of its imaging program with the introduction of this new scanner. The clinical staff at MIS along with Dr. Heller will continue to work with the Nuclear Medical Director as well as the other physicians and clinical staff at Virginia Heart to maintain competencies related to Cardiovascular PET/CT. MIS and Dr. Gary Heller will continue to make quality assurance visits and provide quarterly reports on the status of the Cardiovascular PET/CT program to ensure ongoing quality.

As Virginia Heart is a private practice, not backed by private equity, any financial risk associated with this project is on the onus of its cardiologist owners. Virginia Heart has demonstrated very conservative use of ancillary testing services, including diagnostic imaging as compared to national benchmarks, thus, demonstrating their unwavering commitment to appropriate use. Their conservative use of ancillary MPI imaging services can be seen in the ACC’s national database for cardiology practices, MedAxiom. In ACC/MedAxiom’s database for 2023, Virginia Heart was in the lowest quartile of utilization for the Ratio of Total Nuclear SPECT to Total New Patient Visits. Their conservative utilization is a consistent trend for the past 5 years (2019-2023).

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2023	16.43%	26.23%	< 16.73%	< 23.31%

- 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.

Virginia Heart intends to utilize existing staff as well as hire and train a limited number of additional staff. Personnel required for this project include: 2 clinical staff and 4 technical staff. Virginia Heart currently has twelve offices across the region. Virginia Heart has several nuclear-stress-trained registered nurses (RNs) that currently work full-time in its SPECT departments that will rotate through the planned Cardiovascular PET/CT diagnostic center. Virginia Heart has 37

medical staff members trained in Nuclear Cardiology that will be reading and supervising this new diagnostic department on a rotating basis. Virginia Heart anticipates no issue in maintaining staffing levels nor impact on other providers.

E. Facilities and Services to be Provided (Check)

	Existing	<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 Radiological Services			
x-ray	_____	_____	_____
radioisotope	_____ X _____	_____ X _____	_____
CT scanning	_____ X _____	_____ X _____	_____
5. Therapeutic Radiological Services Specify Source(s) or Type(s) or Equipment Used			
_____	_____	_____	_____
_____	_____	_____	_____
6. Clinical Pathology Laboratory	_____	_____	_____
7. Blood Bank	_____	_____	_____
8. Electroencephalography	_____	_____	_____
9. Electrocardiography	_____ X _____	_____	_____
10. Ultrasonography	_____ X _____	_____	_____
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	___ X ___	_____	_____
35. Pre-Discharge Planning	_____	_____	_____
36. Multiphasic Screening	_____	_____	_____
37. Other (Identify)			
<u>PET/CT</u>	___ X ___	___ X ___	_____

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?

Yes (Give name of hospital) **Affiliated with Inova Alexandria 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)?

Yes (give name of facility)

Virginia Heart uses EPIC for electronic medical records which communicates with regional medical systems (Inova Alexandria Hospital, other Inova facilities, and other PD 8 hospitals), both inpatient and outpatient.

No

4. Outpatient services are (will be) available from **8:00 am to 4:30 pm, 5** days of week.

5. Does (will) the facility operate scheduled clinics?

Yes (Attach clinic schedule list)

No

6. Are there other organized outpatient services in your primary service area?

Yes No

7. The outpatient facility is (will be) staffed:

(a) Only by physicians on call: Yes No

(b) By full time physicians: Yes No

(c) By physicians who limit their practice to this outpatient service? Yes No

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

Virginia Heart is dedicated to the appropriate use of all services it provides. Anticipated restrictions and or limitations include patients who do not meet appropriate use criteria for Cardiovascular PET/CT imaging and patients who cannot tolerate imaging (i.e., claustrophobia, severe back pain, difficulty lying flat, etc.). Absolute restrictions (e.g., stress imaging specifically) are indicated in the Exemption and Exclusion Criteria for Pharmacological Stress Testing found in section 12.2 of Virginia Heart's procedure manuals.

See Attachment III.F.8 (Pharmacological Stress Testing Procedure)

There are no other limitations or restrictions for participation. All patients are served regardless of socioeconomic status, race, ethnicity, or their ability to pay as long as they meet the appropriate use criteria.

Virginia Heart will use the Cardiovascular PET/CT scanner for cardiovascular imaging procedures only. No oncological, neurological, urological, or other non-Cardiovascular PET/CT procedures will be offered.

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.

Virginia Heart Overall Practice Volumes (2021-2024)				
	2024 (Annualized)	2023	2022	2021
Patient Encounters	171,184	162,134	157,029	151,633
Caths/PCI	3,440	3,165	3,396	3,213
Ambulatory Echocardiograms	30,404	26,886	24,582	22,190
Ambulatory SPECT	5,258	6,211	5,986	5,999
Ambulatory PET/CT	2,363	718	NA	NA

Virginia Heart Volumes for Alexandria & Arlington (2021-2024)				
	2024 (Annualized)	2023	2022	2021
Patient Encounters	41,893	40,339	38,024	38,884
Ambulatory SPECT	1,643	1,831	1,657	1,552

Virginia Heart serves 170,000+ patient encounters per year across 12 locations in the Northern Virginia region, and currently utilizes SPECT in multiple locations and Cardiovascular PET/CT in one location at its Falls Church office. In Alexandria and Arlington, Virginia Heart serves over 40,000 patient encounters per year, representing approximately one-quarter of the total encounters, and 20% of the practice’s MPI tests.

From Virginia Heart’s initiation of Cardiovascular PET/CT in August 2023 through July 2024, 6,012 SPECT studies and 2,181 Cardiovascular PET/CT studies were completed, for a total of 8,193 MPI studies. This represents an increase of 37% in total MPI studies from the 2021-2022 annual average. This demonstrates that Cardiovascular PET/CT is not merely replacing SPECT volume significantly, but rather filling unmet need for patients who are not candidates for SPECT due to physical limitations and/or comorbidities.

From August 2023 through July 2024, 3,328 orders were placed for Cardiovascular PET/CT scans. Only 2,181 studies were performed because there was insufficient capacity to meet the demand. This equated to an average of 100 patients per month in

excess demand. Therefore, Virginia Heart has not been able to provide the preferred method of testing to these patients. Additionally, Virginia Heart has been serving predominantly Medicare Fee For Service (FFS) patients while pursuing contracting with private payers. Medicare FFS represents only 35% of Virginia Heart’s patient population. Once Virginia Heart begins utilizing Cardiovascular PET/CT for privately insured patients, it estimates a minimum additional demand of 65%, or 6,180 additional orders per year. Accounting for the 1,200 annual orders that are currently not able to be met, this equates to an additional total estimated demand of 7,380 per year. This is a conservative estimate because as demonstrated, the addition of Cardiovascular PET/CT capacity fills unmet need that is not yet quantified.

Utilization statistics demonstrate demand has far outstripped capacity while being primarily limited to Medicare FFS. In order to adequately serve patients, significant additional Cardiovascular PET/CT capacity is needed. See Section IV.B.2 for further information on utilization statistics of SPECT and PET/CT.

Virginia Heart has thoroughly and carefully analyzed their ability to utilize the proposed additional capacity at the Mark Center location, as well as the Lansdowne location.² Virginia Heart has full confidence that both sites will be used at the proposed capacity and would otherwise not be willing to take on the financial risk of such projects.

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 Time	Vacant Positions	Full Time	Total
Total number of Full- time staff	4		2	6
Administration- Business Office				
Registered Nurses	1		1	2
Licensed Practical Nurses, Nurses Aides, Orderlies/Attendants				
Registered Medical Records Librarian				
Registered Pharmacists				
Laboratory Medical Technologists				
ADA Dieticians				

² COPN Request No. VA-8782 to introduce PET/SCT services with one fixed PET/CT scanner limited to cardiology at Virginia Heart’s Lansdowne facility was filed in the previous review cycle and is currently pending.

Radiologic Technologists	<u>3</u>	<u> </u>	<u>1</u>	<u>4</u>
Occupational Therapists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Physical Therapists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Psychologists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Psychiatric Social Workers	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Recreational Therapists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Inhalation Therapists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Medical Social Workers	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Other Health Professionals, Identify	<u> </u>	<u> </u>	<u> </u>	<u> </u>
All Other Personnel (Exclude Physicians and Dentists)	<u> </u>	<u> </u>	<u> </u>	<u> </u>

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.

Virginia Heart will utilize existing staff as well as hire and train a limited number of new staff for the proposed project.

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

Given the minimal additional staff required, there is no anticipated 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).

See Attachment III.K.1 (Radioactive Materials License)

The Radioactive Materials (RAM) License for the Mark Center is currently being worked on. Once all the appropriate information is gathered, a shielding plan will be calculated by the health physicist. Once the shielding plan is completed, the appropriate documents will be submitted to the Virginia Department of Health, Office of Radiological Health, and Radioactive Materials Program to amend the existing RAM License to add the Mark Center.

2. Current accreditation status and copy of latest accreditation report from Joint Commission on Accreditation of Hospitals (existing facilities excluding public health centers).

See Attachment III.K.2 (IAC Accreditation Certificate)

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

See Attachment III.K.3 (Medical Staff Roster)

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).

See Attachment III.K.4 (VAH Physician Letters of Commitment)

SECTION IV PROJECT JUSTIFICATION AND IDENTIFICATION OF COMMUNITY NEED

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

For over 40 years, Virginia Heart has been a nationally recognized leader in providing cardiovascular care to the Northern Virginia community. Virginia Heart dedicates itself to providing the highest quality of care with the most advanced diagnostic procedures and treatments to ensure patients receive equitable treatment and the best possible outcomes and quality of life.

Through the proposed project, Virginia Heart seeks to add cardiovascular PET/CT capacity at a location that will serve a significant portion of its current patients' needs for MPI services, specifically for those Virginia Heart patients residing in Eastern and Southeastern PD 8. As discussed in Section II.C.2, the Mark Center offers an ideal location for the proposed project. If Virginia Heart does not move forward with installing a Cardiovascular PET/CT within this space, there will likely not be another opportunity for at least 11 years when the Alexandria Office lease is complete and a new space for both the office and a Cardiovascular PET/CT could be pursued. Not only would this be much more expensive to completely relocate to another location, this delay would reduce the accessibility for patients from Eastern & Southeastern PD 8 to this superior modality and result in a continued unmet need (as discussed in Section III.G). This unmet need will only grow with Virginia Heart's increase in providers and the growing elderly population in PD 8 (see Section IV.C.2.c). Additionally, the project would likely come at a significant increase in cost as waiting would likely require Virginia Heart to move an entire clinical office in addition to the costs associated with the Cardiovascular PET/CT project.

Approval of the proposed project will allow Virginia Heart to provide the highest quality of imaging services to its patient population, provide a higher quality of care, work towards addressing a significant unmet need in Cardiovascular PET/CT capacity, and take advantage of an ideal geographical opportunity that will likely not be available again in the near future.

MPI is used in standard clinical practice for non-invasive imaging of the heart for the characterization of a variety of cardiac conditions that has been extensively reported upon in scientific literature. Traditionally, cardiologists have used SPECT to non-invasively evaluate diminished blood flow to the heart muscle from Coronary Artery Disease (CAD), also known as myocardial ischemia. Patients with a SPECT result that indicates the presence of CAD are then referred for invasive cardiac catheterization and potential intervention via stent or open-heart surgery.

While SPECT imaging has been the long-standing modality used for MPI, Cardiovascular PET/CT is a newer, yet well-established, MPI modality that is superior to standard SPECT. Combining CT with PET is significantly better than PET alone. The addition of CT provides a more rapid study with a high-quality attenuation map. The study with CT is several minutes shorter, resulting in less motion and improved diagnostic accuracy, thereby avoiding unnecessary cardiac

catheterizations.

Virginia Heart’s facilities are accredited by the Intersocietal Accreditation Commission (IAC), the gold standard for SPECT quality. While even adhering to the highest standards, SPECT is inherently limited by less than desirable sensitivity and specificity. However, until PET/CT became an option, SPECT has been the predominant non-invasive diagnostic test for myocardial ischemia.

As discussed in Section II.C.1 and II.C.2, Virginia Heart's long-range plan is to provide patients with excellent diagnosis and care using the most appropriate and highest-quality MPI technology. Cardiovascular PET/CT is the preferred, recommended first line modality in many patients to evaluate the presence of myocardial ischemia. As compared to SPECT, Cardiovascular PET/CT offers high sensitivity and specificity, high-diagnostic accuracy, consistent high-quality images, low-radiation exposure, short acquisition protocols, ability to quantify myocardial blood flow (MBF), and tremendous prognostic power. Medical societies who have in the past advocated for SPECT now advocate for PET/CT due to its high sensitivity/specificity and tremendous clinical utility (See Attachment II.C).¹³⁴⁵⁶

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

Cardiovascular PET using Rubidium (Rb-82) as the radioactive tracer was approved by the U.S. Food and Drug Administration (FDA) in 1989, has been demonstrated to be effective for the evaluation of regional myocardial perfusion in adult patients with suspected or existing CAD, as indicated by the FDA in the approved prescribing information for Cardiogen-82. The higher energy of Rb-82 with the spatial resolution of Cardiovascular PET/CT and the attenuation correction provided by the CT portion of the Cardiovascular PET/CT scanner is even more beneficial for patients who are larger/obese, have large breasts or breast implants, are barrel-chested,

¹ Bateman, et.al. Comparison of Myocardial Perfusion SPECT and PET. Journal of Nuclear Cardiology, 2006: 13: 1;24-33

³ Chow, et.al. Prognostic Significance of Dipyridamole-induced ST Depression in Patients with Normal 82Rb PET Myocardial Perfusion Imaging. Journal of Nuclear Medicine, 2005; 46(7)

⁴ Yoshinaga K et.al. What is the Prognostic Value of Myocardial Perfusion Imaging Using Rubidium-82 Positron Emission Tomography? Journal of the American College of Cardiology, 2006; 48:1029-1039

⁵ Bateman et. al. ASNC/SNMMI Position Statement, Journal of Nuclear Cardiology, Oct 2016; 57 (10):1654-1656

⁶ Schleipman R. et. al. Occupational Radiation Dose Associated with Rb-82 Myocardial Perfusion Positron Emission Tomography Imaging. Journal of Nuclear Cardiology, May/June 2006; 13: 3;378-84

and/or have had previous surgical intervention of the chest. Cardiovascular PET/CT is covered by Medicare and most private insurers when their appropriate use criteria is met.

Cardiovascular PET/CT has demonstrated several technical advantages over SPECT that account for improved image quality, diagnostic ability, and efficiency including the following:

- Routine measured (depth-independent) attenuation correction, which decreases the number of false-positive scans, and thus increases specificity;
- High spatial and contrast resolution (heart-to-background ratio) that allows for improved detection of small perfusion defects, thereby decreasing the number of false-negative scans, and increasing sensitivity; and
- High temporal resolution that allows fast dynamic imaging of tracer kinetics, making absolute quantification of myocardial perfusion (in milliliters per minute per gram of tissue) possible.

Cardiovascular PET/CT offers decreased radiation exposure by ~75% compared to traditional SPECT imaging. Additionally, Cardiovascular PET/CT is more efficient than SPECT. The tracer Cardiovascular PET/CT uses is injected into the patient during the scan, unlike the SPECT tracer which requires an injection and a substantial waiting period before the scan. This not only limits radiation exposure for patients and staff, but also eliminates the waiting period, therefore significantly reducing the time it takes for the procedure. A SPECT scan appointment takes approximately 3 hours while a Cardiovascular PET/CT scan appointments are typically 45-60 minutes and the scan itself takes less than 30 minutes.

The CT portion also allows for an assessment of coronary calcium simultaneously with the cardiac PET study. Cardiovascular PET/CT provides incremental prognostic value, and therefore, therapeutic opportunities with concomitant coronary artery calcium scoring. Calcium scoring plus MPI with MBF using Cardiovascular PET/CT has been found to be more predictive of future major adverse cardiovascular and cerebrovascular events than the classic Framingham CAD risk factors of hypertension, diabetes mellitus, hypercholesterolemia, smoking, and family history of premature CAD. The presence or absence of calcium in a patient's coronary arteries can be easily determined with no additional radiation exposure or time. This information is very important in treating patients, especially those with no known diagnosis of CAD. For example, a patient with no coronary calcium is in a lower risk category for CAD. If a patient does have calcium seen on CT, their risk of CAD and CAD-related events is higher and can be predicted by how severe the calcium is. This data is routinely used by healthcare providers in the management of patients, which increases the value of Cardiovascular PET/CT over Cardiovascular PET alone. Additionally, the ability to assess cardiovascular risk by standalone calcium scoring via CT is an important component of diagnosing cardiovascular disease and stroke risk. Virginia Heart also seeks COPN authorization to use the CT for the limited purpose of stand-alone cardiac calcium scoring.

When identified via PET/CT, the presence of coronary calcification frequently

leads to therapeutic changes including initiation of antiplatelets like aspirin, statins or other lipid-lowering agents, and lifestyle interventions such as diet, exercise, smoking cessation, etc. It is notable how informative and educational the results of a PET/CT are for patients when showing their actual pictures during a follow up office visit. The presence of calcium along with a “negative” test means they have started to develop plaque in their arteries that can be medically treated to prevent further progression of the disease. This goes a long way towards patient education and preventative measures.

Unlike traditional SPECT, PET/CT with the addition of MBF quantification has numerous benefits in diagnosing triple-vessel disease and left main disease, conditions commonly missed with myocardial SPECT. It also improves survival rates and identifies patients who could benefit from early revascularization before any further irreversible damage to heart muscle occurs. Furthermore, MBF, not traditionally available in other imaging techniques, allows for diagnosis of pathology such as microvascular disease. Additionally, the CT portion of the PET/CT captures anatomy beyond the heart which results in additional “incidental” pathology findings such as pulmonary hypertension, tumors or cancers in the lung, hiatal hernias, etc. Such identification allows patients to be treated for conditions otherwise undiagnosed.

With SPECT alone, one scan could indicate a wide range of differential outcomes. This would then require follow up tests, procedures, and scans to diagnose the problem. Cardiovascular PET/CT with MBF can differentiate all of these results in one scan and reduce the need for follow up testing, thus saving time, money, and producing better health care results. The combination of MBF reserve and coronary calcium scoring by CT provides valuable information regarding the necessity for cardiac catheterization after the Cardiovascular PET/CT study that a SPECT or PET alone would not provide. The calcium score in conjunction with blood flow results can help decide which patients do not need catheterization, which cannot be determined by blood flow data alone. Unlike traditional SPECT imaging, Cardiovascular PET/CT can identify patients with positive calcium score despite unremarkable perfusion images. The management of those patients would be significantly different, and a more aggressive approach is warranted to decrease their risk factors.

Data shows that rates of heart attack and cardiac catheterization are significantly lower after 1 year in patients managed by Cardiovascular PET/CT. In addition, there was a decrease in the number of angiograms, balloon angioplasty with stenting, and coronary artery bypass graft surgeries (CABG). One study suggested a greater than 50% reduction in coronary angiography and CABG in those who underwent Cardiovascular PET/CT compared with SPECT, without a change in mortality at year one. That same study indicated that total costs of management of CAD were reduced by about 30% compared to SPECT (See Attachment II.C).⁷ The valuable information Cardiovascular PET/CT scans provide can obviate the need for further cardiac tests, reduce unnecessary medical expenses, lead to expeditious referrals for assessment of other causes of symptoms, and relieve anxiety over potential life-threatening etiologies for

⁷ M. Merhige et. al, Impact of PET MPI on CAD Management. J Nucl Med 2007; 48: 1069-1076.

symptoms.

More accurate diagnoses with PET/CT allow for improved treatment through much greater sensitivity (capturing patients with CAD who would otherwise be missed by SPECT) and by reducing risks and costs through increased specificity (decreasing patients unnecessarily sent for additional procedures such as cardiac catheterization). Cardiovascular PET/CT with MBF has been proven to reduce the number of patients who are unnecessarily referred for cardiac catheterization (false positives), and to improve the sensitivity for referring patients who actually need cardiac catheterization and subsequent intervention (false negatives).

The number of false negative and positive results is much higher with SPECT. For example, a SPECT result may appear negative in the setting of multiple differential diagnoses which actually do require treatment. This can result in delayed or inadequate diagnosis and/or treatment of serious cardiovascular disease. In analyzing the data of patients who underwent SPECT and went on to have a cardiac catheterization, Virginia Heart’s cardiac catheterization correlations to SPECT test results continue to have false negative and false positive rates consistent with those reported by other accredited SPECT facilities. SPECT may yield a false negative result in certain circumstances such as diffuse/balanced ischemia seen with either multi-vessel disease and/or high-grade left main/proximal left anterior descending artery disease; or microvascular disease/endothelial dysfunction essentially behaving like symptomatic CAD but without the epicardial coronary arterial stenosis; or a non-responder to the vasodilator. Unfortunately, it is impossible to discern with SPECT if one of these conditions is present or if the result is truly negative. Cardiovascular PET/CT offers the advantage of non-invasively quantifying MBF to sort out these and other differential diagnoses to provide more specific treatment for patients.

Virginia Heart’s own experience demonstrates these known benefits. 2,180 PET/CTs were performed at Virginia Heart from August 2023-July 2024, and 5,986 SPECTS were performed in 2022 (the most recent year for which accurate cardiac catheterization and intervention data are available). Among the SPECT patients, 5% were referred for cardiac catheterization and only 43% of those had confirmed CAD requiring intervention (via stent or cardiac surgery). This equates to a false positive rate of 57%. By contrast, among the PET/CT patients, a higher percentage (7%) were referred for cardiac catheterization, demonstrating the higher specificity in identifying treatable CAD. Of those 7%, 75% were confirmed to have CAD requiring intervention which equates to a false positive rate of only 25%. Of this 25%, a majority were determined to have other cardiovascular diagnoses. Thus, PET/CT resulted in a 32% reduction of false positives or unnecessary cardiac catheterizations.

Virginia Heart SPECT vs PET/CT Patient Results			
	Referred for Cardiac	Required Intervention	False Positive Rate
	Catheterization	(Stent/Surgery)	
SPECT Jan-Dec 2022 (N=5,986)	5% (292)	43% (126)	57%

PET/CT Aug 2023-July 2024 (N=2,180)	7% (157)	75% (117)	25%
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Taken together, when compared with PET, a larger number of SPECT studies are false positives and likely to get a catheterization, but do not go on to have any intervention. A higher percentage of PET/CT studies undergo catheterization, but of those who do, they are more likely to get revascularized, i.e., real disease that needed stents or open-heart surgery.

Another advantage of Cardiovascular PET/CT is that it accommodates and allows all body types and limitations to be tested and accurately diagnosed, whether obese, large breasted, breast implants, central abdominal fat, inability to raise arms, chest wall defects, etc. Traditional SPECT imaging is hampered by artifacts from these body types and can lead to false diagnoses, resulting in further downstream testing.

Cardiovascular PET/CT also offers significant cost savings in overall healthcare costs. The Center for Disease Control (CDC) states that 1 person dies every 33 seconds from cardiovascular disease. The American Heart Association reports that the current cost of America’s cardiovascular disease totals more than \$555 billion, and that number is expected to reach \$1.1 trillion by 2035 when nearly half of all Americans will have some form of cardiovascular disease (see Attachment IV.A: Cardiovascular Disease Burden Report). In Virginia, heart disease is the number one leading cause of death according to the CDC. Virginia Heart wants to better service patients by continuing to take advantage of cost-saving cardiovascular imaging tests that can provide information regarding the presence, extent, and severity of CAD, estimate the risk for early and late major adverse cardiovascular events, and assist in determining the most important treatment, including medical therapy versus coronary revascularization. The way to do that is through expanding capacity for and access to Cardiovascular PET/CT. Currently, Virginia Heart cannot meet its patient population’s need for Cardiovascular PET/CT imaging, and additional capacity is warranted.

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.)

Through its 12 existing locations, including the proposed Mark Center location, Virginia Heart expects that this project will primarily serve Eastern & Southeastern PD 8, specifically in the areas including Arlington, Alexandria, and eastern Fairfax counties. Virginia Heart’s primary service areas include Alexandria, Arlington, Fairfax, and Loudoun counties. Prince William County forms a secondary service area. Primary service area for the Mark Center within PD 8 includes Alexandria, Arlington, and portions of Fairfax.

Virginia Heart will be the most accessible Cardiovascular PET/CT

provider for its primary service area residents in Eastern and Southeastern PD 8.

See Attachment IV.B.1 (Patient Origin by Zip Code for both the Alexandria and Arlington offices of Virginia Heart)

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

Cardiovascular PET/CT is a first-line, preferred test for patients who are unable to complete a diagnostic-level exercise stress imaging study, who have known or suspected CAD, or who meet appropriate use criteria for a stress imaging test. Cardiovascular PET/CT is the preferred test in all clinical scenarios for patients who meet appropriate criteria for a stress imaging test and who require pharmacologic stress testing. Cardiovascular PET/CT is also recommended for patients with suspected CAD who meet appropriate criteria for stress imaging tests and who also meet one or more of the following criteria: poor quality prior SPECT MPI study, young patients with known CAD, body characteristics that cause attenuation and commonly affect image quality, high-risk patients, and patients in whom MBF quantification is needed. Thus, many patients who are referred for SPECT imaging would be eligible for Cardiovascular PET/CT. Virginia Heart has a significant number of patients with these characteristics and strives to provide the best diagnostic option for these patients’ cardiovascular health care.

Historic patient origin data for Virginia Heart’s Alexandria & Arlington patient population is presented in Attachment IV.B.1 (Patient Zip Code Origin for both the Alexandria and Arlington offices of Virginia Heart). Over 75% of Virginia Heart’s patients originate in Northern PD 8, and of those, 35% originate from Alexandria and Arlington. Virginia Heart patients have access to SPECT at 6 locations. It is presumed that a portion of patients who would normally undergo SPECT will be referred for Cardiovascular PET/CT; however, that access is limited due to the demand for this service and the strain on the one existing Cardiovascular PET/CT unit at the Falls Church location. Based on utilization data (see Section III.G), it is expected that there is also a large additional pool of patients who are not candidates for SPECT and would benefit from Cardiovascular PET/CT.

The table below represents Virginia Heart’s utilization for MPI over the past 5 years.

		Virginia Heart MPI Tests by Year (2020-24)					
Imaging Type	Imaging Systems	2024 Annualized	2023	2022	2021	2020	Grand Total
SPECT	7	5,342	6,212	5,985	5,999	5,195	28,733
PET/CT	1	2,407	705	-	-	-	3,112
Total	8	7,749	6,917	5,985	5,999	5,195	31,845

Virginia Heart anticipates the capability of filling the schedule for this additional Cardiovascular PET/CT scanner with its current patient population (see Sections IV.C.2.b and IV.C.2.c on capacity and demand), and the placement of the Cardiovascular PET/CT at the Mark Center would substantially improve access for Virginia Heart’s patient population in PD 8 and specifically the Alexandria/Arlington area.

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

Virginia Heart has only one existing Cardiovascular PET/CT scanner, located at Telestar Court in Falls Church. There are only three other dedicated Cardiovascular PET/CT scanners being used to perform Cardiovascular PET for the diagnosis of CAD in PD 8. All four Cardiovascular PET/CT scanners approved in PD 8 primarily serve a particular cardiology practice’s patients due to the need for physician supervision during the test and the fact that it is an in-office ancillary service with referrals predominately coming from within each practice.

All of the other PET/CT scanners in PD 8 are used for oncology, neurology, or urology purposes. Virginia Heart will not use the proposed Cardiovascular PET/CT scanner for oncology, neurology, or urology purposes; Virginia Heart only intends to use the proposed Cardiovascular PET/CT scanner for cardiovascular indications to diagnose and assist with CAD evaluation for its 170,000+ patient encounters per year.

2. If Yes,

- a. Identify the facility(ies)

There are four facilities approved and performing Cardiovascular PET for the diagnosis of CAD in PD 8:

- **Virginia Heart: 2901 Telestar Court, Falls Church, VA**
- **Carient Heart & Vascular:**
 - **8100 Ashton Ave., Manassas, VA**
 - **415 Church Street NE, Vienna, VA**
- **NOVA Cardiovascular Care, Inc.: 1190 Old Bridge Rd., Woodbridge, VA**

The closest site to the proposed Mark Center location is Virginia Heart’s Falls Church location at 2901 Telestar Court, which is approximately 9 miles away and 25 minutes’ travel time depending on varying traffic conditions. The other three practices have different referral and patient bases.

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

Existing and approved Cardiovascular PET/CTs outside Virginia

Heart are meeting the needs of those cardiology practices' own patients but cannot address Virginia Heart patient needs and the needs of other PD 8 residents who are not tied to a particular cardiology practice.

Virginia Heart's offices primarily serve Northern PD 8, which is made up of the following major counties and cities: Arlington, Alexandria, Fairfax, Loudoun, Fairfax City, and Falls Church. PD 8 has over 2.5 million people, and Virginia Heart's primary service area comprises almost 2 million people. Virginia Heart represents 1/4 of the PD 8 cardiologists and supports these cardiologists' provision of care to patients. Additionally, healthcare facilities in these counties draw from well beyond PD 8 for referrals of some of the most complicated cardiac patients because they offer a robust cardiac surgery and transplant program. The ability to have adequate Cardiovascular PET/CT capacity for these patients is imperative.

The current Cardiovascular PET/CT scanner at Virginia Heart's Falls Church location is operating at full capacity and is therefore unable to meet the need for all Virginia Heart patients who are candidates to have the preferred and recommended test for MPI. The current Cardiovascular PET/CT schedule is full with a consistent backlog of several weeks, impeding patients' access to timely scans (see Section III.G for capacity and utilization statistics).

In addition, the Falls Church office is not an optimal geographic location to serve the significant number of patients originating in Alexandria and Arlington. These patients would be better served and have improved access with the establishment of Cardiovascular PET/CT services at the Mark Center office.

The available SPECT services in the area are not comparable to the service Cardiovascular PET/CT offers. Cardiovascular PET/CT is the "preferred" and "recommended" MPI test. Cardiovascular PET/CT offers superior technology for non- invasive evaluation of ischemic heart disease. In addition to being safer for staff and patients, it also provides much higher image quality than SPECT or PET alone. With SPECT alone, one scan could indicate a wide range of differential outcomes. This would then require follow up tests, procedures, and scans to diagnose the problem. Cardiovascular PET/CT with MBF can differentiate all of these results in one scan and reduce the need for follow up testing, saving time, money, and producing better health care results (see Section IV.A on benefits of Cardiovascular PET/CT over SPECT).

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

Demand for healthcare services in PD 8 is primarily driven by a combination of aging demographics and overall population growth. From 2020 to 2025, the population of those over the age of 65 years is expected to grow 18.8%. See Attachment IV.C.2.c (Projected Population Growth in PD 8). Attendant with age is a concomitant increase in cardiovascular disease. PD 8's growing elderly population needs accurate diagnoses with low radiation and potential downstream savings, all of which would be offered through the addition of the proposed Cardiovascular PET/CT (see Section IV.A).

Additionally, Virginia Heart continues to grow, adding 21 providers over the last two years and it anticipates adding at least 20 more providers, with a concomitant 30% growth in the number of patient encounters, over the next 5 years. Therefore, demand for this service is expected to continue to increase.

Once the Mark Center scanner is fully staffed and has optimal operational efficiencies, it is expected to have capacity for up to 2,500 scans per year. Virginia Heart is a strictly outpatient facility with operating hours from Monday through Friday, 8:00am – 4:30pm. Therefore, capacity is dictated by the operating hours. However, maximum utilization is expected to be approximately 80% (2,000) due to cancellations, no-shows, and patients who have to be rescheduled for testing because they ingested caffeine prior to the study, despite proper education and reminders prior to the scan. While this does not address the full unmet demand (conservatively estimated to be 7,380 per year), it will significantly increase access to this superior modality. Based on existing volumes, projected increase in demand, and greater proximity to a significant number of Virginia Heart's patients, this unit will not be underutilized (see Section III.G).

- 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 current availability of Cardiovascular PET/CT in PD 8 does not meet the demand to diagnose complex CAD, guide medical management and/or revascularization. As discussed throughout this application, Virginia Heart has experienced high utilization of its one Cardiovascular PET/CT scanner and is unable to schedule a significant number of patients who would be better served with this type of imaging. Introducing another Cardiovascular PET/CT to Eastern PD 8 would better support the care of residents seeking cardiovascular treatment in this area. A significant number of patients in the Virginia Heart network originate from Alexandria and Arlington and would be better served by this service at the Mark Center versus traveling to another location.

See Section II.C.3 for details regarding accessibility to the proposed Mark Center location via private and public transportation options. This location is inside the 495 Beltway and offers more convenient and accessible care for residents of

Eastern & Southeastern PD 8, including Alexandria, Arlington, and portions of Fairfax County such as Springfield, Franconia, Fort Belvoir, and Occoquan.

Virginia Heart's only operational Cardiovascular PET/CT unit is located in the Falls Church office on Telestar Court. With the growing population in the Northern Virginia region and consistent heavy commuter traffic, driving times from the Alexandria and Arlington areas can be as much as 45 minutes long. Locating a Cardiovascular PET/CT unit at the proposed Mark Center location would assist in overcoming boundaries such as travel time and heavy traffic for patients in Eastern & Southeastern PD 8 while also allowing additional capacity for Virginia Heart patients served at the Falls Church location, where the current unit has a backlog of several weeks.

See Attachment IV.D (Virginia Heart Offices and Driving Times to Current PET/CT).

- 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.

Criteria for Determining Need – Virginia Code § 32.1-1.2.3

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

Virginia Heart's current Cardiovascular PET/CT unit has resulted in significant improvements in care and has brought access to this preferred imaging to PD 8. However, due to the sheer volume of patients and demand for this superior technology, Virginia Heart has been constrained in its ability to meet patient demand with only one operational PET/CT unit (see Sections III.G and IV.B.2 on capacity and utilization). The introduction of another unit in Alexandria within Virginia Heart's primary service area will improve accessibility for residents of Eastern & Southeastern PD 8 and will ensure that patients have better access and scheduling availability to this recommended imaging offering. See Sections II.C.3 and IV.D regarding geographical increase in access to Cardiovascular PET/CT.

Virginia Heart will continue to serve all patients equitably and effectively using Cardiovascular PET/CT, as it has with its current Cardiovascular PET/CT unit at Telestar Court. Currently, Virginia Heart's Cardiovascular PET/CT program does not have the capacity to meet the demand of every patient who qualifies under Appropriate Use Criteria for Cardiovascular PET/CT due to sheer demand.

2. *The extent to which the proposed project will meet the needs of people in the area to be served, as demonstrated by each of the following:*

(i) the level of community support for the proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;

As demonstrated in the letters of support, in particular from Inova Health System, there is significant community support for the addition of a Cardiovascular PET/CT scanner at Virginia Heart.

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

Virginia Heart has not identified any alternatives to the project that would provide the same benefits and superior technology that Cardiovascular PET/CT provides, as discussed throughout this application. The status quo is no longer a reasonable alternative to meet demand due to the limitations of SPECT imaging, a greater demand than capacity for current Cardiovascular PET/CT resources, and the downstream testing and costs that could be prevented by using Cardiovascular PET/CT. The addition of a Cardiovascular PET/CT service at the Virginia Heart Mark Center is a cost-efficient, incremental option to ensure the needs of PD 8 residents are efficiently met. The Mark Center is an ideal location as it is a ground floor unit and across the lobby from Virginia Heart's Alexandria Office. The Mark Center is an appropriate location to add this new service, as it improves geographic access to a large number of Virginia Heart patients located in Alexandria and Arlington. It is unlikely that Virginia Heart will find another suitable location in this area that is in proximity to their cardiologists if they do not receive approval for the Cardiovascular PET/CT at the Mark Center in Alexandria.

See Section II.C.3 and Section IV.D regarding information on drive time and public transportation options that make the proposed location more accessible, and therefore less costly, than the Virginia Heart Falls Church location for patients in Eastern & Southeastern PD 8.

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

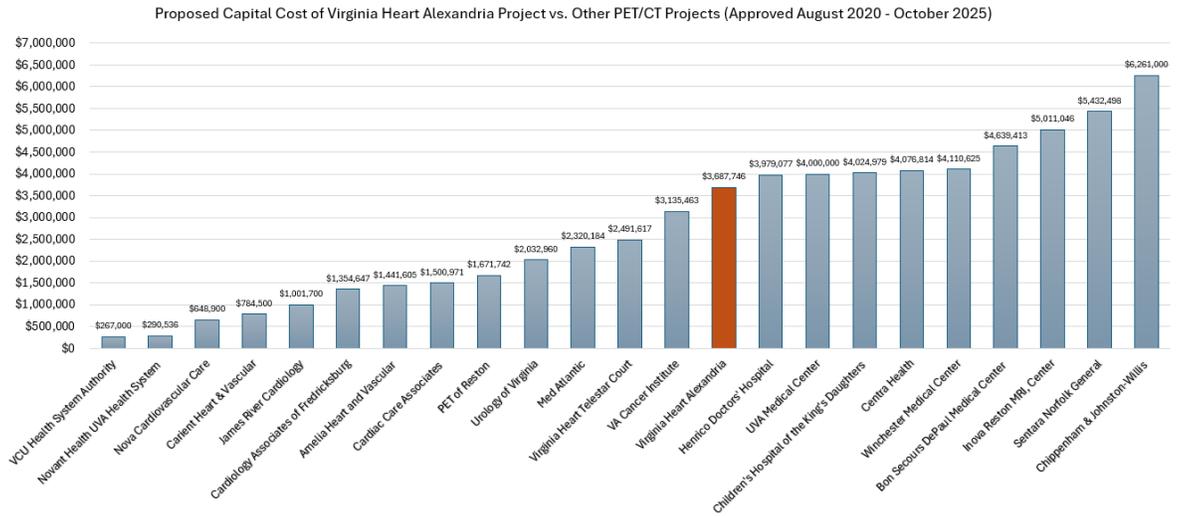
HSANV has not yet issued a recommendation or report on this project.

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

The costs of this project are far outweighed by its extensive benefits. The total capital and financing costs are \$3,807,237. The numerous benefits are discussed in detail throughout this application but include improved image resolution, increased sensitivity and specificity leading to greater interpreter certainty and better diagnostics, decreased radiation exposure, better efficiency, and reduced downstream costs. Overall, the project will improve care and outcomes for cardiovascular patients as referenced

earlier. Virginia Heart’s internal statistics show a reduction in normal cardiac catheterization when Cardiovascular PET/CT is utilized versus SPECT imaging, leading to downstream cost savings.

The costs of the project are related to remodeling of the site and the use of state-of-the-art, digital PET/CT equipment and are consistent with similar projects reviewed over the past 5 years.



The benefits of bringing another unit capable of providing this preferred cardiovascular imaging technology to Eastern PD 8 far outweigh the limited, reasonable capital costs.

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

Virginia Heart will provide its Cardiovascular PET/CT service to patients regardless of ability to pay or payor source. It expects and will comply with a charity care condition related to the service. Cardiovascular PET/CT use based on appropriate use criteria offers patients access to the preferred and recommended test regardless of socioeconomic status, race, or ethnicity. As mentioned in this application, Cardiovascular PET/CT results in more accurate diagnosis that prevents subsequent follow-up testing and minimizes downstream costs for patients.

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

There are no other factors that are relevant to the review of this project. Virginia Heart has demonstrated a public need exists for this project and that its proposal is the most cost-effective and appropriate way to improve the quality, cost, and efficiency of the provision of cardiac care service to residents of PD 8.

3. The extent to which the proposed project is consistent with the State

Health Services Plan;

12VAC5-230-30. Guiding Principles in the Development of Project Review

- 1. The COPN program is based on the understanding that excess capacity or underutilization of medical facilities are detrimental to both cost effectiveness and quality of medical services in Virginia.*

Utilization, capacity, and demand statistics outlined in Sections III.G and IV.B.2 clearly demonstrate the significant unmet need for access to this preferred imaging technology. Due to Virginia Heart's existing Cardiovascular PET/CT schedule capacity and the unmet need of the practice's referral base, this scanner will provide approximately 2,500 additional Cardiovascular PET/CT appointment slots per year. While this does not address the full unmet demand (estimated to be a minimum of 7,380 per year), it will significantly increase access to this superior modality. Based on existing volumes and projected increase in demands, this unit will not be underutilized or reduce the utilization of other Cardiovascular PET units in PD 8.

- 2. The COPN program seeks the geographical distribution of medical facilities and to promote the availability and accessibility of proven technologies.*

Historically, PET scanners in PD 8 were used primarily for oncology, neurology, and urology purposes. Recently, a number of Cardiovascular PET programs have been established, but they primarily service each practices' independent referral base (see Section IV.C).

The addition of a Cardiovascular PET/CT scanner at the proposed location will provide greater geographical distribution/coverage for Virginia Heart patients to access the proven technology of testing such as MPI, myocardial viability imaging, and calcium scoring to more patients, especially in Eastern & Southeastern PD 8. This combination of testing, which is unique to a Cardiovascular PET/CT scanner, has the capacity to serve an ongoing need in a large population of patients in the Northern Virginia area, and specifically the large number of patients seeking services in Alexandria and Arlington. Patients in the area would not have to combat heavy commuter traffic in Northern Virginia to get to the Falls Church location. Also, it will provide faster availability of appointments and fewer scheduling delays and will not reduce utilization in existing PET/CT sites. Currently, there is a several week backlog for Cardiovascular PET/CT imaging at the Virginia Heart Falls Church location.

- 3. The COPN program seeks to promote the development and maintenance of services and access to those services by every person who needs them without respect to their ability to pay.*

Virginia Heart currently offers and will continue to offer services to patients regardless of ability to pay.

- 4. The COPN program seeks to encourage the conversion of facilities to new and efficient uses and the reallocation of resources to meet evolving community needs.*

The proposed project will add a Cardiovascular PET/CT scanner at Virginia Heart's Mark Center location. The benefits of a Cardiovascular PET/CT scanner compared to a SPECT scanner are detailed throughout this application. This proposed service will be able to offer better imaging, improved diagnostic accuracy, less radiation exposure, lower downstream costs, and will improve access to Cardiovascular PET/CT services in an area that continues to need access to such services and technology.

- 5. The COPN program discourages the proliferation of services that would undermine the ability of essential community providers to maintain their financial viability.*

Virginia Heart's primary service area is almost 2 million people in PD 8, while PD 8 itself has over 2.5 million people and is rapidly growing. Virginia Heart employs ¼ of the cardiologists in the region and will only use the Cardiovascular PET/CT modality for cardiology indications, which will ensure that it does not disrupt the practice of current PET/CT services in PD 8.

Recently approved Cardiovascular PET/CT programs primarily service their unique referral base and are not able to take on additional patients. Given this, Virginia Heart does not anticipate that the addition of a Cardiovascular PET/CT will negatively impact any essential community providers.

12VAC5-230-50. Project Costs. The capital development costs of a facility and the operating expenses of providing the authorized services should be comparable to the costs and expenses of similar facilities with the health planning region.

As shown in Section IV.E.2.iv, the proposed capital costs of adding a Cardiovascular PET/CT service are reasonable and consistent with the costs and expenses of similar facilities within the state.

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.

Travel time to existing PET/CT services within PD 8 should be within 60 minutes' travel time, but driving conditions within PD 8 can extend travel

times well beyond “normal conditions.” Normal driving conditions in PD 8 are notoriously congested roads with long travel delays. The 2023 Urban Mobility report published by the Texas A&M Transportation Institute found Northern Virginia to be in the top four most congested areas in the United States, causing the average commuter to spend an extra 85 hours in traffic. The report also states, *“The COVID-19 pandemic had a profound impact on travel behavior and patterns. While on one hand the rise of telecommuting options and work-from-home (WFH) trends have cushioned the burden on the transportation system on at least some days of the work week, the evolving impacts on public transportation and increased work schedule flexibility have resulted in more traffic during mid-day periods and more non-transit traffic on the road in general. The complex dynamics resulting from increased vehicle miles traveled, auto ownership, and shift in transit ridership pose significant challenges for traffic congestion”*.⁸ This heavy off-peak congestion and long delays require travelers planning to arrive at their destination at a scheduled time to set aside over twice as much time for trips as would be typical in light traffic to account for potential delays and backups. The approval of a Cardiovascular PET/CT at Virginia Heart’s Mark Center, where many patients already receive services, will align with this provision and will limit extensive travel and costs associated with travel for patients.

As demonstrated in Attachment IV.D (Virginia Heart Offices and Driving Times to Current PET/CT), the proposed Cardiovascular PET/CT in the Mark Center is approximately 9 miles and approximately 25 minutes in ideal traffic conditions (and up to 45 minutes) from Virginia Heart’s only existing Cardiovascular PET/CT in the Falls Church location. Installing another Cardiovascular PET/CT would allow Virginia Heart’s patient population and the community of Eastern & Southeastern PD 8 easier and more convenient access to this preferred cardiac imaging modality. Past COPN cases have approved projects that would increase timely access to portions of a planning district, even when the driving standard is already met.⁹

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. Virginia Heart is an outpatient facility.

⁸ David Schrank, et al; “2023 Urban Mobility Report,” The Texas A&M Transportation Institute (June 2024) (available at <https://static.tti.tamu.edu/tti.tamu.edu/documents/mobility-report-2023.pdf>).

⁹ DCOPN Staff Report, COPN Request No. VA-8381, Bon Secours Request to Convert Mobile PET/CT to Fixed PET/CT, at 7 (approved via COPN No. VA-4619). The Commissioner has also recently noted that the SMFP was last substantively revised in 2009, resulting in many provisions and computational methods being outdated and less than helpful in gauging whether public need exists for certain services. Commissioner Decision re: COPN Request No. VA-8573, Riverside Smithfield Hospital (Mar. 18, 2022), at 6.

b. No new fixed site PET services shall 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.

With the exception of the original Carient PET, the reported utilization of PET/CT scanners only measure utilization based on oncology, neurology, and urology patients, not cardiovascular patients. Similar to Virginia Heart’s current Cardiovascular PET/CT service, this proposed Cardiovascular PET/CT unit will serve a specific patient type, cardiovascular patients, not oncology, neurology, and urology patients. Recently several Cardiovascular PET/CT programs have been established that only service each practices’ independent referral base, limiting these units’ availability to serve other patient needs. The best data available that is comparable to Cardiovascular PET/CT is SPECT data from 2022 VHI reports and Virginia Heart’s internal SPECT data. Virginia Heart’s Cardiovascular PET/CT at the Falls Church location is at full capacity.

COPN decisions have approved multiple fixed PET scanners in PD 8 and in other Virginia planning districts, despite none of the existing fixed-site PET services reaching utilization rates anywhere near the annual 6,000-procedure threshold advocated by the SMFP. Indeed, recent COPN applications on Cardiovascular PET/CT in PD 8 have been approved despite existing scanners not reaching utilization of a 6,000-procedure threshold.¹⁰

The approval of this project is unlikely to affect existing providers in PD 8. Virginia Heart will only use Cardiovascular PET/CT to perform procedures to diagnose and assist with the treatment of coronary artery disease. Its current volumes and expected growth will result in sufficient utilization with little likelihood of diverting patients from other providers.

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

a. 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

¹⁰ See, e.g., Commissioner Decision re: COPN Request No. VA-8722, Amelia Heart and Vascular Center, Inc. (Apr. 15, 2024). This decision approved a fixed PET/CT application despite the recognition that existing PET and PET/CT scanners in the planning districts performed significantly below the SMFP’s threshold of 6,000 procedures per scanner per year.

would not significantly reduce the utilization of existing fixed providers in the health planning district.

Virginia Heart is not proposing to expand Cardiovascular PET/CT services at the fully utilized Falls Church location. Instead, Virginia Heart proposes to acquire and utilize a Cardiovascular PET/CT scanner at the Mark Center exclusively for cardiac imaging to address the unmet patient demand for MPI with additional capacity at a more convenient location.

As demonstrated in Sections III.G, IV.2.b, and IV.2.c, there is a significant unmet need for this superior imaging technology. The addition of a Cardiovascular PET/CT at the Mark Center will provide additional capacity and better distribution of services for Virginia Heart's patient base, though there will still be excess demand. Virginia Heart does not anticipate any significant reduction in the utilization of existing Cardiovascular PET/CT units.

Recent COPN applications on Cardiovascular PET/CT in PD 8 have approved expansion of services at Carient Heart & Vascular at another facility, despite existing cardiovascular scanners not reaching utilization of a 6,000- procedure threshold.¹¹

- 12 VAC5-230-230. 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. Virginia Heart is not proposing to add or expand an existing mobile PET/CT service.

12VAC5-230-240 Staffing. PET services should be under the direction or supervision of one or more qualified physicians. Such physicians shall be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

The proposed fixed Cardiovascular PET/CT service will be under the

¹¹ Commissioner Decision re: COPN Request No. VA-8626, Carient Heart & Vascular, P.C. (Feb. 9, 2023).

direction of appropriately qualified and licensed cardiologists.

4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served;

The addition of a fixed Cardiovascular PET/CT service to Virginia Heart's Mark Center location will allow the preferred and recommended cardiac imaging modality to be offered to more patients (see Section IV.A for benefits of Cardiovascular PET/CT) in an area that does not have access to this well-established technology that is critical to efficient and effective cardiac diagnosis and treatment. Virginia Heart serves a significant volume of patients in this specific area of PD 8. While the project will improve competition in the area by offering another Cardiovascular PET/CT unit to the planning district, due to existing services primarily serving their own independent patient bases, it is unlikely that this project will compete with other existing services.

5. The relationship of the proposed project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities;

Virginia Heart will only use the Cardiovascular PET/CT modality for cardiology indications, which will ensure that it does not disrupt the practice of current PET/CT services in PD 8. Recently approved Cardiovascular PET/CT programs primarily serve their unique referral bases. Given this, Virginia Heart does not anticipate that the addition of a Cardiovascular PET/CT unit to serve its existing patients will negatively impact any essential community providers.

Given the need for cardiologist supervision of the service, approval of a Cardiovascular PET/CT at the proposed location, which is across the lobby from Virginia Heart's Alexandria Office, is the most efficient and effective use of the service.

6. The feasibility of the proposed project, including the financial benefits of the proposed project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital;

As detailed in Section V, the capital costs of this project are reasonable, and the project is financially feasible. Construction costs will be limited, and additional staffing requirements are minimal.

7. The extent to which the proposed project provides improvements or innovations in the financing and delivery of health care services, as demonstrated by (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) the potential for provision of health care services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be

appropriate; and

Throughout this application, Virginia Heart has demonstrated how Cardiovascular PET/CT is the preferred first line evaluation modality in many cardiac patients due to its high-diagnostic accuracy, consistent high-quality images, low-radiation exposure, short-acquisition protocols, ability to quantify myocardial blood flow, and tremendous prognostic power. Medical societies who once advocated for SPECT now advocate for PET/CT due to its tremendous clinical utility. By adding a fixed Cardiovascular PET/CT unit at the Mark Center, Virginia Heart will be able to improve access to this preferred cardiac technology, eliminate the need for downstream testing, and reduce costs to a greater number of patients in the community.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served, (i) the unique research, training, and clinical mission of the teaching hospital or medical school and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care services for citizens of the Commonwealth, including indigent or underserved populations.

Not applicable. This project is not proposed by, nor does it affect a teaching hospital.

- 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.

Virginia Heart proposes to acquire and utilize a Cardiovascular PET/CT scanner at the Mark Center exclusively for cardiac imaging. The existing Cardiovascular PET/CT scanner located at the Falls Church location is currently at capacity and not able to meet its demand. Virginia Heart is proposing to establish another Cardiovascular PET/CT scanner to meet the needs of the referral base and the outstanding necessity within the practice. See Sections III.G, IV.C.2.b, and IV.C.2.c on capacity, demand, and utilization.

Virginia Heart will follow the national Appropriate Use Criteria for Cardiovascular PET/CT if the project is approved. These criteria were established by the American College of Cardiology, the American Heart Association, the American College of Physicians, the American Society of Nuclear Cardiology, the Society of Cardiovascular CT, the Canadian Cardiovascular Society, the Canadian Society of Cardiovascular Nuclear and CT Imaging, the Society of Nuclear Medicine and Molecular Imaging, and the European Association of Nuclear Medicine. These criteria were developed to avoid inappropriate use of this technology and avoid unnecessary financial burden on the healthcare system. See Attachment IV.F (Appropriate Use Criteria).

Virginia Heart does not foresee a reduction in utilization of existing fixed site PET/CT services within PD 8. As other providers serve a distinct patient population and given the large population of the Northern Virginia area, no

reduction in services is anticipated.

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.)

Virginia Heart has a ten-year affiliation agreement with Inova Health System. See Attachment IV.G (Affiliation Press Release). There are other working relationships with HCA facilities and with Virginia Hospital Center, at which Virginia Heart physicians are credentialed and/or have active offices.

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).

See Attachment IV.H.1 (Service Area Map)

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.

Attachment IV.H.2 (Letters of Support)

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

See Attachment IV.H.3 (Proposed Project Notification Letters)

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.

There are no existing per diem rates. Virginia Heart participates in multiple payor relationships including Medicare, Medicaid, Anthem, Aetna, and other payors who insure its patients. Virginia Heart anticipates no unusual difficulty in negotiating contract amendments for additional Cardiovascular PET/CT services at this location due to its diagnostic benefits.

- 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 VHI
 Provide a copy of report(s) which provide(s) the basis for comparison. **Not yet reported for Falls Church office.**

Virginia Heart will participate in VHI reporting once Cardiovascular PET/CT services for cardiovascular patients are initiated at the proposed office.

- 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>264,835</u>
2.	Cost of labor	\$ <u>243,266</u>
3.	Equipment included in construction contract	\$ <u>130,000</u>
4.	Builder’s overhead	\$ <u>0</u>
5.	Builder’s profit	\$ <u>44,667</u>

6.	Allocation for contingencies	\$ <u>34,138</u>
7.	Sub-total (add lines 1 thru 6)	\$ <u>716,906</u>

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

8.	a. PET/CT _____	\$ <u>2,146,020</u>
	b. Hot Lab _____	\$ <u>73,765</u>
	c. _____	\$ <u>0</u>
	d. _____	\$ <u>0</u>
	e. _____	\$ <u>0</u>
9.	Sub-total (add lines 8a thru 8e)	\$ <u>2,219,785</u>

Part III – Site Acquisition Costs

10.	Full purchase price	\$ <u>0</u>
11.	For sites with standing structures	\$ <u>0</u>
	a. purchase price allocable to structures	\$ <u>0</u>
	b. purchase price allocable to land	\$ <u>0</u>
12.	Closing costs	\$ <u>0</u>
13.	If leasehold, lease expense over entire term of lease	\$ <u>681,123</u>
14.	Additional expenses paid or accrued:	
	a. _____	\$ <u>0</u>
	b. _____	\$ <u>0</u>
	c. _____	\$ <u>0</u>
15.	Sub-total (add lines 10 thru 14c)	\$ <u>681,123</u>

Part IV – Site Preparation Costs

16.	Earth work	\$0
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.	_____	\$0
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	\$ <u>21,500</u>
30.	Architect’s supervision fee	\$ <u>8,140</u>
31.	Engineering fees	\$ <u>25,000</u>
32.	Consultant’s fees	\$0
33.	Sub-total (add lines 29 thru 32)	\$ <u>54,640</u>

Part VII – Other Consultant Fees (List each separately)

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

Part VIII – Taxes During Construction

36.	Property taxes during construction		<u>\$ 15,292</u>
37.	List other taxes:		
	a. _____		<u>\$0</u>
	b. _____		<u>\$0</u>
38.	Sub-total (add lines 36 thru 37b)		<u>\$ 15,292</u>

Part IX-A – HUD Section 232 Financing
Not Applicable

39.	Estimated construction time(in months)		_____
40.	Dollar amount of construction loan		\$ _____
41.	Construction loan interest rate		_____ %
42.	Estimated construction loan interest costs		\$ _____
43.	Term of financing (in years)		_____
44.	Interest rate on permanent loan		_____ %
45.	FHA mortgage insurance premium		\$ _____
46.	FHA mortgage fees		\$ _____
47.	Financing fees		\$ _____
48.	Placement fees		\$ _____
49.	AMPO (non-profit only)		\$ _____

- 50. Title and recording fees \$ _____
- 51. Legal fees \$ _____
- 52. Total interest expense on permanent mortgage loan \$ _____
- 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)

Not Applicable

- 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 \$ _____
- 57. Construction loan interest rate _____%
- 58. Estimated construction loan interest cost \$ _____
- 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 \$ _____
- 63. Will principal and interest be paid during construction or only interest? _____

- 64. Bond interest expense prior to the beginning of construction(in dollars) \$ _____
- 65. How many months after construction begins will last bond be sold? _____
- 66. Bond interest expense during construction \$ _____
- 67. What percent of total construction will be financed from bond issue? \$ _____
- 68. Expected bond interest rate _____%
- 69. Anticipated term of bond issued (in years) _____
- 70. Anticipated bond discount (in dollars) _____
- 71. Legal costs \$ _____
- 72. Printing costs \$ _____
- 73. Placement fee \$ _____
- 74. Feasibility study \$ _____
- 75. Insurance \$ _____
- 76. Title and recording fees \$ _____
- 77. Other fees (list each separately)
 - a. _____ \$ _____
 - b. _____ \$ _____
 - c. _____ \$ _____
- 78. Sinking fund reserve account (Debt Service Reserve) \$ _____
- 79. Total bond interest expenses (in dollars) \$ _____
- 80. Sub-total Part IX_B (add lines 58, 64, 66, 71, 72, 73, 74, 75, 76, 77a, b, c and 78) **\$0**

Part IX_C – Conventional Mortgage Loan Financing

81.	Estimated construction time (in months)	<u>2.5 months</u>
82.	Dollar amount of construction loan	<u>\$0</u>
83.	Construction loan interest rate	_____ %
84.	Estimated construction loan interest cost (in dollars)	<u>\$0</u>
85.	Term of long-term financing (in years)	<u>5 years</u>
86.	Interest rate on long term loan	<u>6.24%</u>
87.	Anticipated mortgage discount (in dollars)	<u>\$0</u>
88.	Feasibility study	<u>\$0</u>
89.	Finder's fee	<u>\$0</u>
90.	Legal fees	<u>\$0</u>
91.	Insurance	<u>\$0</u>
92.	Other fees (list each separately)	
	_____	<u>\$0</u>
93.	_____	<u>\$0</u>
94.	Total permanent mortgage loan interest expense (in dollars)	<u>\$119,491</u>
	<i>*Amount to financed for permanent mortgage loan</i>	<i>\$716,906</i>
95.	Sub-total Part IX_C (add lines 84 & 88 thru 93)	<u>\$0</u>

Financial Data Summary Sheet

96.	Sub-total Part I	Direct Construction Cost (line 7)	<u>\$ 716,906</u>
97.	Sub-total Part II	Equipment not included in construction contract (line 9)	<u>\$ 2,219,785</u>
98.	Sub-total Part III	Site Acquisition Costs (line 15)	<u>\$ 681,123</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>\$ 54,640</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>\$ 15,292</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)		<u>\$ 3,687,746</u>
108.	Percent of total capital costs to be financed _ 19.44%		
109.	Dollar amount of long term mortgage (line 107 x 108)		<u>\$ 716,906</u>
110.	Total Interest Cost on Long Term Financing		<u>\$0</u>
	a.	HUD-232 Financing (line 53)	<u>\$0</u>
	b.	Industrial Development Authority Revenue & General Revenue Bond Financing (line 79)	<u>\$0</u>
	c.	Conventional Loan Financing (line 94)	<u>\$ 119,491</u>
111.	Anticipated Bond discount		
	a.	HUD-232 Financing (line 53)	<u>\$0</u>
	b.	Industrial Development Authority Revenue & General Revenue Bond Financing (line 70)	<u>\$0</u>
	c.	Conventional Loan Financing (line 87)	<u>\$0</u>
112.	TOTAL CAPITAL AND FINANCING COST (ADD LINES 107, 110a, b or c AND 111a, b or c)		<u>\$ 3,807,237</u>

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>\$716,906</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>\$716,906</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	<u>\$0</u>
	10. Other (Identify) <u>Operations</u>	<u>\$3,090,331</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 paid for from a combination of existing and future operating income. Virginia Heart anticipates borrowing the cost of leasehold improvements rather than using reserves for that purpose. This is a prudent use of existing resources while allowing other reserves to be used for operating expenses.

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 debt service cost per patient day is not relevant to an outpatient service; the allocated debt service will be about \$83 per projected procedure in year 2. Given the anticipated use, the proposed use of loan funds will not substantially affect the costs of patient care. See Attachment V.G (Amortization Schedule)

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

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.

See Attachment V.H.2 (Audited Financial Statement)

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.

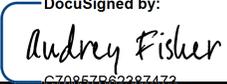
See Attachment V.H.3 (Pro Forma)

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.

DocuSigned by:

 Signature of Authorizing Officer

2901 Telestar Court
 Address – Line1

Audrey L. Fisher, MPH, FACHE
 Type/Print Name of Authorizing Officer

Suite 300
 Address – Line 2

CEO
 Title of Authorizing Officer

Falls Church, VA 22042
 City/State/Zip

(703) 621-4501
 Telephone

12/2/2024
 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.**



PET/CT Proforma
Alexandria, Virginia

Annual Estimated Volume	1,702	2,016
Average Daily Volume	7	8

INCOME STATEMENT	Year 1	Year 2
Projected Revenue	\$4,634,052	\$5,487,693
Compensation Staff	1,061,238	1,097,331
Benefits	265,309	274,333
Legal Fees	60,000	5,000
Bank Fees	5,040	6,000
Contracted Services	89,122	102,058
Training	50,925	50,000
Patient Supplies	161,728	191,520
Patient Education	5,000	6,000
Office Supplies	9,000	6,500
Maintenance	194,078	178,812
Marketing	25,000	10,000
Rent Expense	56,522	57,935
Utilities	7,218	7,416
BPOL Taxes	15,292	18,109
Personal Property Taxes	70,954	45,871
Operating Lease Equipment	592,404	592,404
Software License Fees	92,031	92,031
Bad Debt Expense	162,844	227,477
Charitable Donations	240,114	284,346
Depreciation & Amortization	82,545	82,545
Interest Expense	41,168	33,072
Total Expenses	3,287,532	3,368,759
Profit (Loss)	\$1,346,520	\$2,118,935