

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

All applicants are reminded that a determination of Public Need results from a consideration of the factors identified in §32.1 – 102.3.B of the Virginia Medical Facilities Certificate of Public Need law.

Prior to completing the application forms, applicants are encouraged to contact the Division of Certificate of Public Need of the State Health Department and the appropriate Regional Health Planning Agency (RHPA) (if one is currently designated by the Board of Health to serve the area where the project would be located), concerning existing community health resources and the projected need for the proposed project. Of particular importance is a discussion of the required information necessary to complete the application. Copies of the appropriate State and RHPA (if one is currently designated by the Board of Health to serve the area where the project would be located) plans and policies will be made available upon request.

The Division of Public Need and the RHPA may be contacted at the following addresses, telephone and facsimile numbers:

Virginia Department of Health	(804) 367-2126
Division of Certificate of Public Need	(804) 527-4501-F
9960 Mayland Drive – Suite 401	
Henrico, Virginia 23233	

Health Systems Agency of Northern Virginia	(703) 573-3100
7245 Arlington Blvd, Suite 300	(703) 573-1276-F
Falls Church, Virginia 22042	

**INSTRUCTIONS FOR COMPLETING ESTIMATED CAPITAL COSTS
SECTION OF THE CERTIFICATE OF NEED APPLICATION**

General Instructions

1. Questions should be answered only in space provided.
2. If additional space is required, attach a separate sheet. Be sure, however, to identify your answer with the correct question number.
3. Unless otherwise indicated, answer all questions by supplying dollar (\$) amounts.
4. In certain instances, an expenditure may not be planned. In such cases, answer by placing a zero (0) in the appropriate space.
5. Proper completion of this section of the application should enable the applicant to meaningfully evaluate the costs of constructing a medical care facility and assess if such a financial commitment can realistically be undertaken.

**INSTRUCTIONS FOR COMPLETING SECTION V, PART I –
DIRECT CONSTRUCTION COSTS**

Answer to questions in this section should reflect planned expenditures for the construction of the primary structure (s) and all permanently affixed equipment. This includes construction materials (line 1) and labor (line 2) and equipment included in the construction contract which will be permanently attached to the structure (line 3). Examples of the latter include: life support systems, communications systems, central vacuuming, etc. Builder's overhead (line 4) is that portion of the builder's total overhead expenses allowable to the proposed facility and builder's profit (line 5), net earnings from the construction contract. Allocation for contingencies (line 6) is the dollar amount held in reserve for unanticipated construction expenses.

**INSTRUCTIONS FOR COMPLETING SECTION V, PART II –
EQUIPMENT NOT INCLUDED IN CONSTRUCTION CONTRACT**

List and price each piece of depreciable equipment not supplied as part of the construction contract (lines 8a through 8e). This generally includes equipment not permanently affixed to the structure. Examples include x-ray equipment, beds, freezers, etc.

INSTRUCTIONS FOR COMPLETING SECTION V, PART III – SITE ACQUISITION COSTS

Supply the acquisition price of the proposed facility site (line 10). If more than one use is planned for the site, include only that portion of the total purchase price which is allowable to the land area which will be occupied by the proposed facility. If a structure(s) currently stands on the proposed facility site and it is anticipated that this structure(s) will be used as part of the proposed facility portion, the total purchase between the value of the existing structure(s) and the value of the raw land (lines 11a and 11b), provide closing costs on line 12. These include legal fees, title fees, etc. If the site is to be leased rather than purchased, provide the sum of the lease expense over the entire term of lease on line 13. All other expense already paid or accrued should be itemized separately on lines 14a through 14c.

INSTRUCTIONS FOR COMPLETING SECTION V, PART IV – SITE PREPARATION COSTS

Supply financial data for site preparation work related solely to the proposed facility site or that portion of the total site which is to be occupied by the proposed facility. Earth work (line 16) refers primarily to land contouring. Site utilities (line 17) include the costs of installing water, electric and gas utilities. Roads and walks (line 18), lawns and planting (line 19) and unusual site conditions (lines 20a and 20b) refer to expenditures for on-site work only. Accessory structures (line 21) refer to unattached structures which are to be used in support of the primary facility; examples include garage, club house, etc. Demolition costs (line 22) are those costs incurred in clearing standing structures from the proposed facility site.

INSTRUCTIONS FOR COMPLETING SECTION V, PART V – OFF-SITE COSTS

Include only off-site construction costs for free standing structures which are to be used in support of the primary facility (lines 24 through 27). Examples might include off-site bus depots, clinics, extension of utilities to site, modification of highways for safe entrance, etc.

INSTRUCTIONS FOR COMPLETING SECTION V, PART VI – ARCHITECTURAL AND ENGINEERING FEES

Include on line 29 the architect's design fee and on line 30 the fee for supervising the implementation of the design. Engineering fees (line 31) include engineering design expenses. Consultant fees (line 32) refer only to architectural and engineering consultant fees.

INSTRUCTIONS FOR COMPLETING SECTION V, PART VII – OTHER CONSULTANT FEES

All consultant fees except for architectural and engineering consultant fees should be itemized separately on lines 34a through 34c.

INSTRUCTIONS FOR COMPLETING SECTION V, PART VIII – TAXES DURING CONSTRUCTION

Property taxes to be paid during the construction period should be listed on line 36. For multiple use sites, include only that portion of the total property allocable to the proposed facility site. Any other taxes to be paid during construction should be itemized on lines 37a and b. These, for example, might include permit fees, utility taxes, etc.

INSTRUCTIONS FOR COMPLETING SECTION V, PART IX – A- HUD SECTION 232 FINANCING

If it is expected that the proposed facility will be financed with HUD Section 232 Financing, complete and submit this section or otherwise complete either Section IX – B or IX – C. Regardless of the method of financing selected, applicants might choose to complete each of the facility financing sections. Such an exercise would permit a true comparison of the relative costs of the different methods of financing and in so doing, permit the applicant to select the least costly alternative. It is requested, however, that in submitting a Certificate of Need application, the applicant include financial data only for that financing alternative he finally selects.

On line 39 estimate the number of months required to complete construction of the proposed facility. On line 40 supply the dollar amount of the construction loan. The construction loan interest rate should be supplied on line 41 and the total interest on the construction loan for the entire construction period on line 42.

The term, in years, of the permanent mortgage loan should be provided on line 43 and the mortgage interest rate on line 44. FHA mortgage insurance (line 45) premiums equal 0.5% of the outstanding loan balance per year. Mortgage fees (line 46), for example, include examination and inspection fees and are charged at a rate of \$8 per \$1000 of mortgage value. Financing fees (line 47) are charged by the bank and may be as high as 2% of the loan. The placement fee (line 48) is a FNMA charge and is equal to 1 ½% of the loan value. The AMPO (line 49) is a reserve to make the project operational and is available to non-profit sponsors only. Up to 2% of the loan balance can be allocated to the AMPO. Title and recording fees should be supplied on line 50 and legal fees on line 51. Total mortgage interest to be paid on the permanent mortgage loan should be estimated from a book or mortgage tables and written on line 52.

INSTRUCTIONS FOR COMPLETING SECTION V, PART IX – B
INDUSTRIAL DEVELOPMENT AUTHORITY REVENUE AND GENERAL
OBLIGATION BOND FINANCING

If it is expected that the proposed facility will be financed from the sale of industrial revenue or general obligation bonds, complete and submit this section. Otherwise, complete either Section IX – A or Section IX- C.

Specify the source of all construction capital on line 54. If construction is to be financed from the proceeds of a bond sale, do not answer questions on line 55 through 58. If construction, however, is to be financed by a separate construction loan, answer questions 56, 57 and 58. How many months will it take to complete construction of the facility (line 55)? Provide the dollar amount of the construction loan on line 56 and the construction loan interest rate on line 57. Total interest costs on the construction loan should be supplied on line 58.

On line 59 identify the nature of the bond placement, e.g., direct, underwriter, etc. Will bonds be issued before construction begins (line 60)? If yes, how many months before construction is started will the bonds be issued (line 61)? What is the dollar value of the bonds that are expected to be sold prior to the beginning of construction (line 62)? For bonds sold prior to or during construction, will interest and principal be paid or only interest (line 63)? Finally, what is the estimated pre-construction bond interest expense (line 64)? How many months after construction begins is it expected that the last bond will have been sold (line 65)? What is the estimated bond interest expense during construction (line 66)? The percentage of total construction which will be financed from the bond issue should be supplied on line 67. The expected annual interest rate, anticipated term and expected bond discount should be supplied on lines 68, 69 and 70, respectively. Legal costs, printing costs, placement fees, feasibility study costs, insurance fees, title and recording fees and other fees should be given on lines 71 through 77c, respectively. Debt service reserve, \$200,000 should be written on line 78. Life time bond should be estimated on line 79.

INSTRUCTIONS FOR COMPLETING SECTION V, PART IX – C –
CONVENTIONAL MORTGAGE LOAN FINANCING

If it is expected that the proposed facility will be financed with a conventional mortgage loan, complete and submit this section. Otherwise, complete either Section IX- A or IX-B.

Estimate the number of months required to complete construction on line 81, the dollar amount of the construction loan on line 82 and the construction loan interest rate on line 83. Total construction loan interest costs should be estimated on line 84. The terms of the permanent long term mortgage should be supplied on lines 85 through 87. On line 85 estimate the term of the loan; on line 86, its interest rate and the mortgage

discount on line 87. Estimate on lines 88 through 93 the costs for a feasibility study, finder's fees, legal fees, insurance and other fees respectively. Finally, on line 94 from a book of mortgage tables, estimate total interest for the permanent mortgage loan (line 94).

INSTRUCTIONS FOR COMPLETING THE FINANCIAL DATA SUMMARY SHEET

The Financial Data Summary Sheet provides a summary of total construction and financing costs. Financial data for lines 96 through 106 and 110 can be found by referring to the referenced line numbers. Line 96 through 103 provide a summary of direct construction costs as previously compiled in Sections I through VIII. Depending on the method of financing anticipated, the applicant should supply financial data for either lines 104, 105 or 106. These financing cost sub-totals represent construction costs and permanent loan financing fees for the selected method of financing. Total construction costs (line 107), therefore, equal the sum of lines 96 through 106. Line 108 asks for the percent of total construction costs which will be financed. The dollar value of the long-term mortgage (line 109), therefore, can be derived by multiplying line 107 times 108. Total long-term financing interest costs should be supplied for the anticipated method of financing on line 110a, b. or c. The anticipated bond discount, for the selected method of financing, should be supplied on lines 111a, b or c. Finally, total project costs (line 112), the total of construction costs, financing fees and discounts, are the total of lines 107, 110a, b or c and 111a, b or c.

SECTION I FACILITY ORGANIZATION AND IDENTIFICATION

A. Virginia Heart

Official Name of Facility

19450 Deerfield Avenue, Suite 100

Address

Leesburg

City

VA

State

20176

Zip

(703) 621-4501

Telephone

B. The Cardiovascular Group, PC

Legal Name of Applicant

2901 Telestar Court, Suite 300

Address

Falls Church

City

VA

State

22042

Zip

C. Chief Administrative Officer

Audrey L. Fisher, MPH, FACHE

Name

2901 Telestar Court, Suite 300

Address

Falls Church

City

VA

State

22042

Zip

703-621-4501

Telephone

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

Peter M. Mellette

Name

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 7 years
- (4) _____ Renewable lease, renewable every _____ years
- (5) _____ Other _____ Identify

See Attachment I.F (Lansdowne 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.

(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: **5.95** acres
2. Located in **Leesburg/Loudoun/PD 8** City/County/Planning District
3. Address or directions **19450 Deerfield Ave. Suite 100, Leesburg, VA 20176**
4. Has site been zoned for type of use proposed:

 X 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) **X** 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 strives for excellence in cardiovascular care and is committed to improving the health and well-being of the community through empathy, compassion, innovation, excellence, teamwork, fairness, and equality.

The addition of a second Cardiovascular Positron Emission Tomography/Computed Tomography (PET/CT) to Virginia Heart's existing services would align with the Mission, Vision, and Values to be among the nation's most trusted partners in cardiovascular care with recognition for quality and leadership. Cardiovascular PET/CT offers patients the access to "preferred" and the "recommended" myocardial perfusion imaging (MPI) test.¹

The Deerfield Avenue office location in Leesburg for the second PET/CT will enhance Virginia Heart patient access to needed MPI tests, making those tests more accessible to more patients located in Western PD 8. This COPN application reflects Virginia Heart's long-

¹ Bateman et. al. ASNC/SNMMI Position Statement. *Journal of Nuclear Cardiology. J Nucl Med.* 2016 Oct; 57(10):1654-1656.

range plan for cardiology 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's proposed Cardiovascular PET/CT will be located at 19450 Deerfield Avenue, Suite 100, Leesburg, VA 20176. Space within this suite will be renovated to accommodate the Cardiovascular PET/CT unit. Major design features include patient check-in and waiting room, private patient waiting space, control room, hot lab, camera room, exam room, and provider office. Sufficient lead lining and shielding will be installed at the direction of a radiation physicist. The proposed office space will be sufficient to house the Cardiovascular PET/CT unit and will support Virginia Heart's goals to provide efficient, quality care to patients with an easily accessible location.

The proposed project will provide additional capacity for high-quality diagnostic imaging needed for cardiovascular patient care in Loudoun County/Western PD 8. Given that Virginia Heart has 12 locations throughout Northern Virginia, provides over 170,000+ patient encounters a year, and has maximized capacity on its current PET/CT scanner in the Telestar Court office location in Falls Church, the additional capacity will enable Virginia Heart to better meet the demand of its approximately 170,000+ patient encounters and will make these services more accessible to the Western PD 8 community.

Myocardial Perfusion Imaging (MPI) is used in standard clinical practice for non-invasive imaging of the heart for the characterization of a variety of cardiac conditions and has been extensively reported upon in scientific literature. While Single Photon Emission Computed Tomography (SPECT) imaging has been the long-standing modality used for MPI, Cardiovascular PET/CT is a newer yet well-established technique that is superior to standard SPECT.

Cardiovascular PET using Rubidium Rb 82, which 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 coronary artery disease (CAD), as indicated by the FDA in the approved prescribing information for Cardiogen-82.

In March 1995, CMS approved reimbursement for Cardiovascular PET using a Rubidium Rb 82 Generator. Cardiovascular PET/CT

can be performed using the appropriate use criteria for diagnosis and management of known or suspected CAD. Cardiovascular PET/CT has demonstrated several technical advantages over SPECT that account for improved image quality and diagnostic ability, including the following:

- (1) Routine measured (depth-independent) attenuation correction, which decreases the number of false-positive scans, and thus increases specificity;**
- (2) 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**
- (3) 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.**

Virginia Heart's ability to offer Cardiovascular PET/CT with additional capacity at another location will align with its mission to improve the well-being of the PD 8 community and provide world-class patient-centered cardiovascular care.

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

Patients will be able to easily access Virginia Heart's office at 19450 Deerfield Avenue from Riverside Parkway. The facility is conveniently located just off the State Route 901/Route 7 interchange, and approximately 5 miles from U.S. Route 15. Ample parking is available on-site for patients, including handicapped spaces closest to the building. Loudon County Transit has a public bus stop at Inova Loudoun Hospital on its Route 70 bus which is directly across the street from Virginia Heart's proposed location.

See Attachment II.C.3 (Loudoun County Transit Bus Schedule)

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

There are no anticipated issues related to future expansion, parking, provision of water, sewer, and solid waste services. The building and site are currently in use as a Virginia Heart office. 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.

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

Not Applicable

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

As the space is already controlled and utilized by Virginia Heart, there will be no acquisition or additional lease costs associated with establishing this new service. Minimal construction will occur to remodel the space and provide sufficient room for the equipment and project needs. This is a ground floor space, which minimizes structural assessment and reinforcement 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 to Virginia Heart's primary service area, in which jurisdictions proximate to the Deerfield Avenue site predominate.

- 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.

The rationale for designing the 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 and is already served by all necessary utilities. A camera room, control room, hot lab, private patient waiting room, 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 8, 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: **Third Quarter, 2025**

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.

During the past 40 years, 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+ encounters each year, patients place their trust in Virginia Heart's 60 physicians, including 52 board-certified cardiologists, 4 board-certified sleep physicians, as well as 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 proposes to acquire and utilize a Cardiovascular PET/CT scanner at the Deerfield Avenue office location exclusively for cardiovascular imaging. The capacity of the existing Cardiovascular PET/CT scanner located at the Telestar Court office location in Falls Church is currently maximized and not able to service the significant additional demand. Virginia Heart is proposing to establish a Cardiovascular PET/CT scanner at a second facility to meet the unmet needs of their referral base within the practice. Currently the volume of orders for Cardiovascular PET/CT is far greater than the capacity.

The combination of Cardiovascular PET with CT provides the patient with the most accurate study, which is significantly better than PET cameras without CT because CT provides a more rapid study with a high-quality attenuation map. The study with CT is several minutes shorter. Shorter scan times result in less motion and improved diagnostic accuracy, thereby avoiding unnecessary cardiac catheterizations.

The CT also allows for an assessment of coronary calcium simultaneously with the cardiac PET study. 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.

The combination of measuring myocardial blood flow reserve (part of the Cardiovascular PET data) and coronary calcium score by CT provides valuable information regarding the necessity for cardiac catheterization after the Cardiovascular PET/CT study. The calcium score in conjunction with blood flow results can help decide which patients do not need catheterization, and this cannot be determined by blood flow data 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 seeks COPN authorization to use the CT for the limited purpose of stand-alone cardiac calcium scoring.

Cardiovascular PET/CT also allows Virginia Heart to offer additional capacity to serve additional unmet need in a large population of patients in the Northern Virginia area. Once the Deerfield Avenue office location 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 cannot undergo testing because they ingested caffeine prior to the study.

Cardiovascular PET/CT offers a higher standard of care and lower radiation exposure for both patients and staff as compared to SPECT. The exam time of a Cardiovascular PET/CT is about 1/4 of SPECT exam time, therefore, limiting the patients' time in the medical office and greatly increasing efficiency and patient satisfaction.

Virginia Heart is dedicated to innovation, excellence, and remaining up to date with the latest technology. As cardiac imaging becomes more advanced, the practice is growing with it to bring improvements in the delivery of care to patients. The Cardiovascular PET/CT program at Virginia Heart will allow the practice to deliver new innovations and developments in the non-invasive cardiovascular testing environment.

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 a second Cardiovascular PET/CT to Virginia Heart's existing services would ensure and expand upon Virginia Heart's current

continuity of care. Patients who qualify for Cardiovascular PET/CT would have access to the service sooner and in a more local location. Currently, Virginia Heart is largely seeing Medicare patients due to sheer demand and is limited in its ability to see other patients. With the approval of this new unit, Virginia Heart will be able to better accommodate patients and ensure they are receiving timely care with no interruptions due to scheduling difficulties. The placement of the Cardiovascular PET/CT at the Deerfield Avenue office location would substantially improve access and continuity of care to Virginia Heart's patient population, 31% of which come from Loudoun County.

This proposed project will operate pursuant to Virginia Heart's policies and procedures intended to support 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 and also uses PACS for easy remote access within partnering health care systems. 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.

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 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 intra-office 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 and 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.

- 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 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 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.

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

	<u>Existing</u>	<u>This Project To be Added</u>	<u>This Project to be Discontinued</u>
1. Outpatient Surgery	_____	_____	_____
2. Post Operative Recovery Room	_____	_____	_____
3. Pharmacy with full-time pharmacists _____ part-time pharmacists _____	_____	_____	_____
4. Diagnostic Radio- logical Services			
x-ray	_____	_____	_____
radioisotope	<u> X </u>	<u> X </u>	_____
CT scanning	<u> X </u>	<u> X </u>	_____
5. Therapeutic Radio- logical Services	_____	_____	_____
Specify Source(s) or Type(s) or Equipment			

	Used			
6.	Clinical Pathology Laboratory			
7.	Blood Bank			
8.	Electroencephalography			
9.	Electrocardiography	<u> X </u>		

- | | | | | |
|-----|-----------------------------------|-------------------|-------------------|-------------------|
| 10. | Ultrasonography | <u> X </u> | <u> </u> | <u> </u> |
| 11. | Respiratory Therapy | <u> </u> | <u> </u> | <u> </u> |
| 12. | Renal Dialysis | | | |
| | chronic outpatient | <u> </u> | <u> </u> | <u> </u> |
| | home dialysis training | <u> </u> | <u> </u> | <u> </u> |
| 13. | Alcoholism Service | <u> </u> | <u> </u> | <u> </u> |
| 14. | Drug Addiction Service | <u> </u> | <u> </u> | <u> </u> |
| 15. | Physical Therapy Department | <u> </u> | <u> </u> | <u> </u> |
| 16. | Occupational Therapy Department | <u> </u> | <u> </u> | <u> </u> |
| 17. | Medical Rehabilitation outpatient | <u> </u> | <u> </u> | <u> </u> |
| 18. | Psychiatric Service | <u> </u> | <u> </u> | <u> </u> |
| | outpatient | <u> </u> | <u> </u> | <u> </u> |
| | emergency service | <u> </u> | <u> </u> | <u> </u> |
| 19. | Clinical Psychology | <u> </u> | <u> </u> | <u> </u> |
| 20. | Outpatient Emergency Service | <u> </u> | <u> </u> | <u> </u> |
| 21. | Social Service | <u> </u> | <u> </u> | <u> </u> |
| 22. | Family Planning Service | <u> </u> | <u> </u> | <u> </u> |
| 23. | Genetic Counseling Service | <u> </u> | <u> </u> | <u> </u> |
| 24. | Abortion Service | <u> </u> | <u> </u> | <u> </u> |
| 25. | Pediatric Service | <u> </u> | <u> </u> | <u> </u> |
| 26. | Obstetric Service | <u> </u> | <u> </u> | <u> </u> |

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	<u> X </u>	_____	_____
35.	Pre-Discharge Planning	_____	_____	_____
36.	Multiphasic Screening	_____	_____	_____
37.	Other (Identify)	_____	_____	_____
	<u>PET/CT</u>	<u> X </u>	<u> X </u>	_____
	_____	_____	_____	_____
	_____	_____	_____	_____

F. Program

1. Is (will) this outpatient facility (be) a department, unit or satellite of a hospital?
 _____ Yes (Give name of hospital) _____
 X No

2. Is this outpatient facility affiliated with or does it have a transfer agreement with a hospital?
 X Yes (Give name of hospital) **Affiliated with Inova Loudoun Hospital**

_____ No

3. Is (will) there (be) an arrangement whereby medical records can readily be transferred between this outpatient facility and an inpatient facility (ies)?
____**X**____ Yes (give name of facility)

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

_____ No

4. Outpatient services are (will be) available from **8:00 a.m. to 4:30 p.m., 5** days of week.
5. Does (will) the facility operate scheduled clinics?
_____ Yes (Attach clinic schedule list)
____**X**____ No
6. Are there other organized outpatient services in your primary service area?
____**X**____ Yes _____ No
7. The outpatient facility is (will be) staffed:

- (a) Only by physicians on call: _____ Yes ____**X**____ No
- (b) By full time physicians: ____**X**____ Yes _____ No
- (c) By physicians who limit their practice to this outpatient service? _____ Yes ____**X**____ No

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

Virginia Heart is dedicated to the appropriate use of each service line 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.

- 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.

	2024 (Annualized)	2023	2022	2021
Outpatient Visits	135,350	124,684	120,006	114,466
Inpatient Visits	35,834	37,450	37,023	37,167
Caths/PCI	3,440	3,165	3,396	3,213
Office Echos/ Stress Echos	30,404	26,886	24,582	22,190
Office MPI	5,258	6,211	5,986	5,999
Cardiovascular PET/CT	2,363	718	NA	NA

Virginia Heart currently utilizes SPECT and Cardiovascular PET/CT imaging. From initiation of Cardiovascular PET/CT in August 2023 through July 2024 6,012 SPECT studies were completed and 2,181 Cardiovascular PET/CT studies, for a total of 8,193 MPI studies. This represents an increase of 37% in MPI studies from the 2021/2022 annual average. This demonstrates that Cardiovascular PET/CT is not replacing SPECT volume significantly, but rather filling unmet need. Virginia Heart has been serving predominately Medicare Fee For Service (FFS) patients while pursuing contracting with private payers. Medicare FFS represents only 35% of Virginia Heart's patient population. In the time from initialization of Cardiovascular PET/CT at Virginia Heart, 3,328 orders were placed for Cardiovascular PET/CT scans, which equated to an average of 100 orders per month for which there was no capacity to schedule those patients. Therefore, Virginia Heart has not been able to provide the preferred method of testing to these patients.

Demand has far outstripped capacity at the existing Telestar Court office location while being primarily limited to Medicare FFS patients. In order to serve these patients and the remaining 65% of Virginia Heart's 170,000+ patient encounters per year, significant additional capacity is needed. Establishing the proposed Cardiovascular PET/CT scanner at the Deerfield Avenue office location will provide the ability to serve a larger fraction of the patients, although it will still be insufficient.

Virginia Heart now has contracts with two major private payers (which includes Medicare Managed Care Plans) and is in negotiations with two others. Once Virginia Heart starts utilizing Cardiovascular PET/CT for privately insured patients, it estimates an additional demand of approximately 65%, or 6,180 additional orders per year. Accounting for the 1,200 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. This data demonstrates an ongoing unmet need for Cardiovascular PET/CT in the practice's referral base and the community at large. The proposed scanner will primarily be utilized by this current patient population, and its placement at the Deerfield Avenue office location would substantially improve access to Virginia Heart's patients, 31% of which come from Loudoun County.

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	<u>4</u>	<u> </u>	<u>2</u>	<u>6</u>
Administration-Business Office	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Registered Nurses	<u>1</u>	<u> </u>	<u>1</u>	<u>2</u>
Licensed Practical Nurses, Nurses Aides, Orderlies/Attendants	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Registered Medical Records Librarian	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Registered Pharmacists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Laboratory Medical Technologists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
ADA Dieticians	<u> </u>	<u> </u>	<u> </u>	<u> </u>
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 _____

All Other Personnel (Exclude Physicians and Dentists)

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

Virginia Heart will utilize existing staff as well as hire and train 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 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 Deerfield Avenue office location 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 Deerfield Avenue office location.

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

Traditionally, cardiologists have used SPECT to non-invasively evaluate diminished blood flow to the heart muscle from CAD, also known as myocardial ischemia. Patients with a positive SPECT result are then referred for invasive cardiac catheterization and potential intervention via stent or open-heart surgery. However, SPECT has many disadvantages to newer technology (specifically PET/CT) including large amounts of radiation exposure to both patients and staff¹⁻⁵ and, most importantly, much lower sensitivity and specificity. Thus, the number of false negative & positive results is quite high with SPECT. For example, a SPECT result may appear negative in the setting of multiple differential diagnoses which actually do require treatment, such as significant three vessel disease or other critical conditions like left main obstruction. This can result in delayed or inadequate diagnosis and/or treatment of serious cardiovascular disease. Cardiovascular PET/CT offers the advantage of non-invasively quantifying coronary flow to sort out these and other differential diagnoses to provide more specific treatment for patients. Offering more targeted and specialized treatment plans results in better outcomes for patients. Thus, Cardiovascular PET/CT is the preferred, recommended first line evaluation in many cardiac patients to evaluate the presence of myocardial ischemia. As compared to SPECT, Cardiovascular PET/CT offers 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 have in the past advocated for SPECT now advocate for PET/CT due to its high sensitivity/specificity and tremendous clinical utility.¹⁻⁵

¹⁻⁵

1. Bateman, [et.al.](#) Comparison of Myocardial Perfusion SPECT and PET. *Journal of Nuclear Cardiology*, 2006; 13: 1;24- 33
2. 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)
3. 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
4. Bateman et. al. ASNC/SNMMI Position Statement, *Journal of Nuclear Cardiology*, Oct 2016; 57 (10):1654-1656
5. 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

In line with its mission, Virginia Heart now seeks to expand its Cardiovascular PET/CT service with one scanner at its Deerfield Avenue office location in Loudoun County. Virginia Heart's Telestar Court office location's Cardiovascular PET/CT is currently operating at full capacity and has significant demand that cannot be fulfilled. Since 31% of Virginia Heart's patient base originates from Loudoun County, the Deerfield Avenue office location was selected not only to help address the additional unmet need of the practice's referral base, but to make this service more geographically accessible to the medically underserved area of Western PD 8 [(See attachment IV.A (Loudoun County MUA – Medically Underserved Population))].

This new scanner will provide additional capacity for 2,500 appointment slots per year and is anticipated to perform approximately 2,000 Cardiovascular PET/CT scans per year based upon a projected utilization of 80%. 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. Virginia Heart has added 21 providers over the last two years and 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.

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.

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 myocardial blood flow (MBF) to sort out these and other differential diagnoses to provide more specific treatment for patients. 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).

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).

Virginia Heart’s own experience demonstrates these known benefits. They performed 2,180 PET/CTs from August 2023-July 2024, and they compared these results to 5,986 SPECTS performed at Virginia Heart 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 Catheterization	Required Intervention (Stent/Surgery)	False Positive Rate
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%

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.

Furthermore, the assessment of myocardial blood flow, not traditionally available in other imaging techniques, has allowed for diagnosis of pathology

such as microvascular disease. Additionally, the CT portion of the PET/CT identified incidental pathology such as increased pulmonary artery size associated with pulmonary hypertension, tumors or cancers in the lung, hiatal hernias, etc., that allowed for patients to be treated for conditions that were otherwise undiagnosed.

Finally, when identified via PET/CT, the presence of coronary calcification frequently led 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.

Cardiovascular PET/CT also 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.

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. Cardiovascular PET/CT offers superior image resolution, increased sensitivity and diagnostic accuracy, greater interpretation certainty, and decreased radiation exposure by a factor of 75% compared to traditional SPECT imaging. The approval of this project would improve access to this critical tool in cardiovascular imaging.

Cardiovascular PET/CT also offers significant cost savings. 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.

While Virginia Heart has one Cardiovascular PET/CT scanner at the Telestar Court office location, the practice is unable to meet the demand of patients who qualify for the superior diagnostic imaging exam. The addition of a Cardiovascular PET/CT scanner to Virginia Heart's Deerfield Avenue office location will allow access to this preferred method of testing for more patients eligible under Appropriate Use Criteria and expand the geographical availability of Cardiovascular PET/CT to the Loudoun Country area. This project will make this improved technology, which is critical to efficient and effective cardiac care, more accessible to all individuals who receive care in PD 8.

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 Deerfield Avenue office location, Virginia Heart expects that this project will serve northern PD 8, specifically in the northern and western areas including Loudoun County and western Fairfax County. Its primary service areas include Loudoun, Fairfax, Arlington, and Alexandria counties. Prince William County forms a secondary service area. Virginia Heart will be the most accessible Cardiovascular PET/CT provider for its primary service area residents.

See Attachment IV.B.1 (Patient Origin by Zip Code)

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

Historic patient origin data for Virginia Heart's patient population is presented in Attachment IV.B.1 (Patient Zip Code Origin). The data shows that over 75% of Virginia Heart's patients originate in Northern PD 8, 31% from Loudoun County specifically. Virginia Heart has SPECT services available at 6 locations. It is presumed that a portion of patients who would undergo SPECT now have access to 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 Telestar Court office location.

Based on utilization data from the existing Cardiovascular PET/CT, 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.

Virginia Heart anticipates the capability of filling the schedule for this additional Cardiovascular PET/CT scanner with its current patient population, and the placement of the Cardiovascular PET/CT at the Deerfield Avenue office location would substantially improve access for Virginia Heart’s patient population in PD 8 and Loudoun County.

The SPECT and Cardiovascular PET/CT units at Virginia Heart have experienced the following historic utilization:

Virginia Heart SPECT and Cardiovascular PET/CT Data 2020-2024

Imaging Type	Imaging Systems	Total Procedures 2024 YTD (July)	Total Procedures 2023	Total Procedures 2022	Total Procedures 2021	Total Procedures 2020	Grand Total
SPECT	7	3,116	6,212	5,985	5,999	5,195	26,507
PET/CT	1	1,404	705	-	-	-	2,109
Total	8	4,520	6,917	5,985	5,999	5,195	28,616

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. 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 myocardial blood flow 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. The following ICD-10 codes are typically seen for Cardiovascular PET/CT services:

ICD-10	Common ICD-10 Diagnosis Codes- Cardiovascular PET/CT (78431) with Supporting Medical Necessity
I20.0	Unstable Angina
I21.01	ST elevation (STEMI) myocardial infarction involving Left Main of coronary artery
I25.10	Atherosclerotic heart disease of native artery without angina pectoris
I42.0	Cardiomyopathy
I48.2	Chronic Atrial Fibrillation
R06.02	Shortness of Breath
R07.9	Chest Pain, Unspecified
R55.0	Syncope
R94.31	Abnormal Electrocardiogram
Z01.810	Encounter for preprocedural cardiovascular examination

- 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 the Telestar Court office location 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, with two others approved in other PD 8 locations to serve a particular cardiology practice's patients due to the need for physician supervision during the test. All 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:**
 - o **8100 Ashton Ave., Manassas, VA**
 - o **415 Church Street NE, Vienna, VA**
- **NOVA Cardiovascular Care, Inc.: 1190 Old Bridge Rd., Woodbridge, VA**

The closest of these sites to the proposed Deerfield Avenue office location is Carient Heart & Vascular located at 415 Church

Street, NE, which is approximately 23 miles away. Additionally, Virginia Heart and Carient Heart & Vascular have different referral bases.

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

The current Cardiovascular PET/CT scanner at Virginia Heart's Telestar Court office 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. Other existing and approved Cardiovascular PET/CTs are meeting the needs of the cardiology practices' own patients but cannot address Virginia Heart patient needs and the needs of other PD 8 residents not tied into a particular cardiology practice.

Virginia Heart's patient population data shows that over 75% of Virginia Heart's patients originate in Northern PD 8 and 31% from Loudoun County specifically. Due to Virginia Heart's existing Cardiovascular PET/CT schedule capacity and the unmet need of the practice's referral base in the Loudoun County area, the second scanner will provide capacity for approximately 2,500 additional scans per year with an expected utilization of 80% (2,000 scans) due to cancellations, no-shows, and patients who cannot undergo testing because they ingested caffeine prior to the study. While this does not address the full unmet demand (estimated to be 7,380 per year), it will significantly increase access to this superior modality.

The following chart details the difference in quality between SPECT, PET, and PET/CT:

Comparison of Cardiac 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
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

Virginia Heart's offices 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 transplant program. The ability to have adequate Cardiovascular PET/CT capacity for these patients is imperative.

Accurate, cost-efficient, and patient-centered diagnosis and management of cardiovascular care in this region is crucial. The current capacity of Cardiovascular PET/CT services in PD 8 does not satisfy the demand and is not geographically accessible nor convenient for patients in the western region of PD 8.

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 myocardial blood flow 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.

Cardiovascular PET/CT offers lower radiation to the patient as well as the staff performing the scan while yielding higher quality images. Cardiovascular PET/CT provides a 75% reduction in radiation compared to SPECT and approximately the same amount of radiation exposure as PET alone.

Higher resolution and image quality allows Cardiovascular PET/CT to offer superior quality in identifying the correct area of ischemia as opposed to traditional SPECT imaging with lower specificity.

Unlike with traditional SPECT, the addition of myocardial blood flow quantification has numerous benefits in diagnosing triple vessel disease and left main disease, conditions commonly missed with myocardial SPECT. It will also improve survival rates and can identify patients who could benefit from early revascularization.

The higher energy of Rubidium-82, the radioactive tracer used, with spatial resolution of Cardiovascular PET/CT and the attenuation correction provided by the CT portion of the Cardiovascular PET/CT scanner is beneficial for larger/obese patients, large breasts or breast implants, barrel-chested patients, and patients with 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 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 negative predictive value for all cardiac death is 98.8% over 3 years post normal Cardiovascular PET/CT.³ Negative predictive value (NPV) is a measure of how likely a person is to not have a disease or condition after receiving a negative test result. The proven accuracy of PET/CT along with this NPV data provides confidence for Virginia Heart physicians to confidently medically treat patients who have a PET/CT that is negative for cardiac disease. The NPV can also lead to patients not being referred for unnecessary testing such as cardiac catheterizations. A normal PET MPI confers a very low risk of cardiac death of 0.4% per year which is close to that of a normal age matched population.

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

As detailed above, the current available services are unable to meet the demand for care. Virginia Heart anticipates a continued increase in demand with projected growth of 15% in 2025 and is planning for the current and future needs of

3. 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.

patients. The current Cardiovascular PET/CT schedule is full with a consistent backlog of several weeks, impeding patients' access to timely scans. The patient population of the practice would benefit from the availability of a second Cardiovascular PET/CT scanner that would provide the opportunity for more readily available appointments, especially in the case of patients who are in immediate need of the service due to cardiac-related symptoms or pre-surgical clearance. Virginia Heart has added 21 providers over the last two years and anticipates adding 20 more providers in the next 5 years. Virginia Heart anticipates a 30% growth in the number of patient encounters over the next 5 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.

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. The best way to diagnose and identify these at-risk CAD populations is with Cardiovascular PET/CT that provides equitable, timely, and accurate diagnoses. The approval of this second scanner would improve Virginia Heart's ability to offer these improvements to a higher volume of patients.

- 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 coronary artery disease, 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 timely schedule a significant number of patients who would be better served with this type of

imaging. Introducing another Cardiovascular PET/CT to Western PD 8 would better support the care of residents seeking cardiovascular treatment in this area.

Cardiovascular PET/CT, unlike simple PET, allows for coronary artery calcium evaluation and is also able to produce more accurate and higher quality images. Thus, Cardiovascular PET/CT reduces the need for additional follow up testing, which saves time and money. Data shows that rates of heart attack and cardiac catheterization are significantly lower after 1 year in patents managed by Cardiovascular PET/CT. In addition, in patients managed by Cardiovascular PET/CT, 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.⁶ 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 symptoms.

In addition to being safer, more sensitive, more specific, and producing higher quality images, 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 waiting period before the scan. This not only limits radiation exposure for patients and staff, but also eliminates the waiting period, reducing the time it takes for the procedure. A SPECT scan usually lasts three hours while a Cardiovascular PET/CT examination only takes 30 minutes. The scheduled appointment slots are typically 45-60 minutes depending on whether the patient is ambulatory or not.

Locating the Cardiovascular PET/CT in the Deerfield Avenue office location places it within Virginia Heart's primary service area. The site is readily accessible from major thoroughfares and has plenty of parking, including handicapped access. This location will add more convenient and accessible care for residents of PD 8. With the growing population and consistent heavy commuter traffic in the area, the patient population needs access to additional Cardiovascular PET/CT locations to service their needs. The introduction of a Cardiovascular PET/CT to the Deerfield Avenue office location would assist Virginia Heart patients travelling from Loudoun County to overcome the hurdle of geographical barriers such as travel time of 40-60 minutes, heavy traffic, and tolls on the Greenway toll road and

⁶ M. Merhige et. al, Impact of PET MPI on CAD Management. *J Nucl Med* 2007; 48: 1069-1076.

Dulles toll road, a total of \$23.40 based on Attachment IV.D(1) (Toll Rates - Dulles Toll Road) to get to a Cardiovascular PET/CT appointment at the Telestar Court office location. See also Attachment IV.D(2) (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 practice has a primary service area of almost 2 million people in PD 8, a region which serves some of the most complicated cardiac patients due to its proximity to a large transplant center. Virginia Heart represents 1/4 of PD 8's cardiologists. The available SPECT services in the area are not comparable to Cardiovascular PET/CT because Cardiovascular PET/CT provides clearer, more accurate images than SPECT and provides additional functions that SPECT does not, like calcium scoring. The superior diagnostic functions Cardiovascular PET/CT performs allows Virginia Heart to better serve patients because it reduces the need for follow-up testing in patients who would have had a false positive SPECT result. This in turn expands access to health care by reducing costs. Cardiovascular PET/CT is also significantly faster than SPECT, which allows for more efficiency.

The current SPECT systems in Virginia Heart are aging and have older technology that is 'end of life' from respective manufacturers. See Attachment IV.E.1 (Phillips End of Support Notification for CardioMD). Rather than re-investing in newer SPECT cameras with the same diagnostic limitations, Virginia Heart is electing to replace these systems with the superior imaging technology that Cardiovascular PET/CT offers to increase access to superior health care service for patients. In keeping with this strategy, Virginia Heart recently decommissioned a very old SPECT camera at its Vienna location in anticipation of additional Cardiovascular PET/CT capacity.

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 improved technology, Virginia Heart has been

constrained in its ability to meet patient demand with only one unit. The introduction of a second unit within Virginia Heart's primary service area will improve accessibility for residents of Western PD 8 and will ensure that patients have better access and scheduling availability to access this improved imaging offering.

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, there is significant community support for the addition of a Cardiovascular PET/CT scanner at Virginia Heart. In particular, Inova Health System and many referring physicians have confirmed that the addition would better serve their patients.

(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 Deerfield Avenue office location is a cost-efficient, incremental option to ensure the needs of PD 8 residents are efficiently met.

Patients who use public transportation would need to utilize multiple bus routes or the Loudoun transit to the Metro to travel to the current Cardiovascular PET/CT scanner located at Virginia Heart's Telestar Court office location. Patients who drive themselves to appointments would incur tolls on the Dulles Toll Road or increase their travel time to use local routes. Northern Virginia is also well known to have ample commuter congestion on the roads which further increases travel time for patients. Having a Cardiovascular PET/CT scanner at the Deerfield Avenue office location would provide an alternative to patients who are located closer to Loudoun County and in Western PD 8 who are seeking these services.

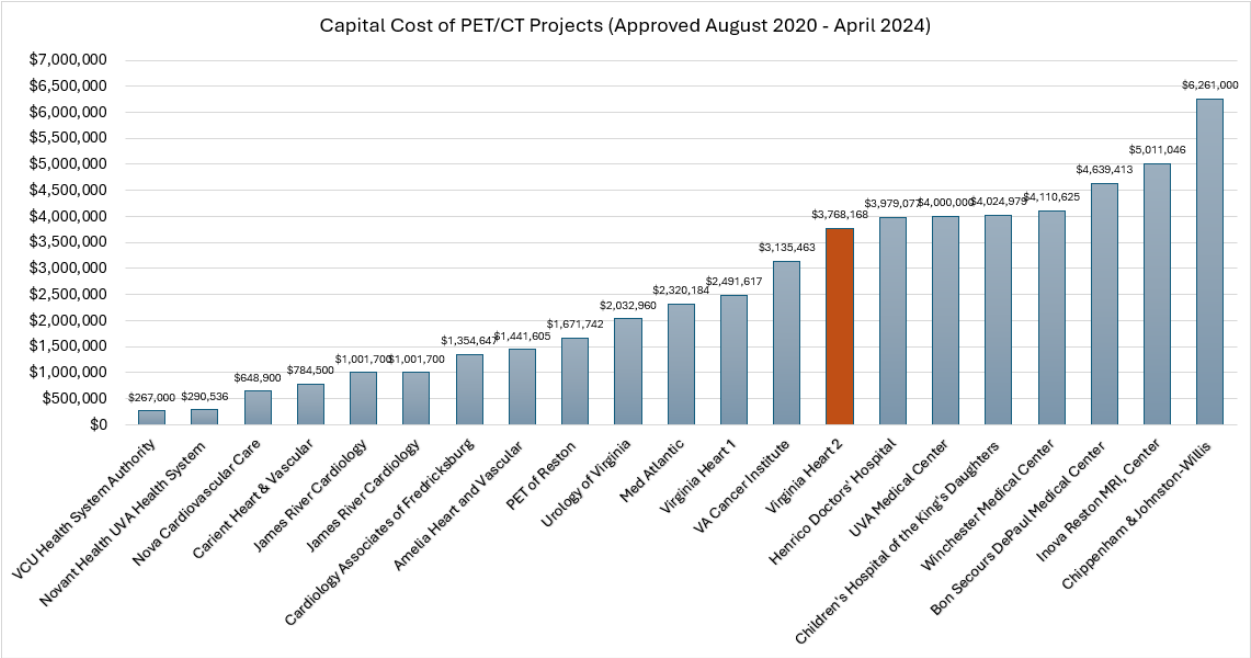
(iii) any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;

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 \$3,941,734. 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 this medically underserved area of PD 8 far outweigh the limited, reasonable 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.*

This project will establish a Cardiovascular PET/CT service at Virginia Heart's Deerfield Avenue office location. Virginia Heart's current demand for Cardiovascular PET/CT and large patient base shows that it can support Cardiovascular PET/CT services at this location. As discussed in this application, many patients who are candidates for SPECT would also be appropriate candidates (and would be better served) by Cardiovascular PET/CT imaging. Additionally, there is a large population of patients who are not candidates for SPECT that will also be served by Cardiovascular PET/CT. Virginia Heart will maximize productivity and ensure

appropriate volumes to support the project at the Deerfield Avenue office location.

Virginia Heart's patient population data shows that over 75% of its patients originate in Northern PD 8, and 31% from Loudoun County specifically. Due to Virginia Heart's existing Cardiovascular PET/CT schedule capacity and the unmet need of the practice's referral base, the second 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 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.

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

Historically, PET/CT scanners in PD 8 were used primarily for oncology, neurology, and urology purposes. Recently, several Cardiovascular PET/CT programs have been established, but they primarily service each practices' independent referral base.

The addition of a Cardiovascular PET/CT scanner at Virginia Heart's Deerfield Avenue office location will provide easier accessibility to this proven technology for patients in Loudoun County. Patients in the Loudoun County area would not have to combat heavy commuter traffic in Northern Virginia and pay tolls to get to the Telestar Court office location.

The addition of Cardiovascular PET/CT in the Deerfield Avenue office location will provide faster availability of appointments and fewer scheduling delays. Currently, there is a several week backlog for Cardiovascular PET/CT imaging at the Telestar Court office location.

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 myocardial perfusion imaging, myocardial viability imaging, and calcium scoring to more patients in the greater Loudoun County area. 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.

Placing a Cardiovascular PET/CT unit at Virginia Heart's Deerfield Avenue office location will expand the geographic accessibility of Cardiovascular PET/CT and allow the residents in PD 8 to have more access to this well-established technology, without a reduction in utilization of existing PET/CT sites. It will especially provide a better geographic distribution of Cardiovascular PET/CT units for Virginia Heart's patients by providing a more geographically convenient location for Western PD 8.

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 Deerfield Avenue office 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 discourse 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. PD 8 itself has over 2.5 million people and is rapidly growing. Virginia Heart employs 1/4 of the cardiologists in the region. 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 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.

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 region.

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.

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.”⁷ 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 Deerfield Avenue office location, 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 Deerfield Avenue office location is approximately 28 miles from Virginia Heart’s only existing Cardiovascular PET/CT in the Telestar Court office location. Installing a second Cardiovascular PET/CT would allow Virginia Heart’s patient population and the

⁷ 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>).

community of 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.⁸

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.

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 measures utilization based on oncology, neurology, and urology patients not cardiovascular patients. Similar to its 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. 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 Telestar Court office 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

⁸ 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.

Cardiovascular PET/CT in PD 8 have been approved despite existing scanners not reaching utilization of a 6,000-procedure threshold.⁹

Historically, PET/CT scanners in PD 8 were used primarily for oncology, neurology and urology purposes. 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 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 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 Telestar Court office location.

Instead, Virginia Heart proposes to acquire and utilize a Cardiovascular PET/CT scanner at the Deerfield Avenue office location exclusively for cardiac imaging. The existing Cardiovascular PET/CT scanner located at the Telestar Court office location is currently at capacity. Virginia Heart is proposing to launch a second Cardiovascular PET/CT scanner to meet the unmet needs of the practice's referral base and the outstanding necessity within the practice. However, Virginia Heart believes that placing the second unit at another existing facility in PD 8 will better meet patient needs by distributing these imaging services throughout its primary service area, resulting in better access for its patients. The approval of this project is unlikely to affect or reduce the utilization of existing providers in PD 8.

⁹ 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.

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.¹⁰

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 direction of appropriately qualified and licensed physicians.

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 Deerfield Avenue office location will allow the preferred and recommended cardiac imaging modality to be offered to more patients with improved accuracy, sensitivity and specificity, lower radiation, efficiency, and improved downstream costs and savings in an area that does not have access to this well-established technology that is critical to efficient and effective cardiac treatment. While the project will improve competition in the area by offering another Cardiovascular PET/CT unit to the planning district, due to existing

¹⁰ Commissioner Decision re: COPN Request No. VA-8626, Carient Heart & Vascular, P.C. (Feb. 9, 2023).

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 serves PD 8, a rapidly growing area, and employs a significant portion of the cardiologists in the area. Virginia Heart's primary service area encompasses almost 2 million people in PD 8, which has over 2.5 million people. Due to its existing Cardiovascular PET/CT unit being at full capacity and not meeting current demand at the Telestar Court office location, Virginia Heart needs additional capacity to meet its patient needs.

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 busy practice sites which can serve PD 8 patients 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 Deerfield Avenue office location, 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 Deerfield Avenue office location exclusively for cardiac imaging. The existing Cardiovascular PET/CT scanner located at the Telestar Court office location is currently at capacity and not able to meet its demand. Virginia Heart is proposing to establish a second Cardiovascular PET/CT scanner to meet the needs of the referral base and the outstanding necessity within the practice.

Furthermore, demand has far outstripped capacity at the existing Telestar Court office location while being primarily limited to Medicare FFS which represent 35% of the practice's patients. In order to serve these patients and the remaining 65% of Virginia Heart's 170,000+ patient encounters per year, significant additional capacity is needed as noted earlier. Establishing the proposed Cardiovascular PET/CT scanner at the Deerfield Avenue office location will provide the ability to serve a larger fraction of the patients, although it will still be insufficient.

Once the Deerfield Avenue office location 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 cannot undergo testing because they ingested caffeine prior to the study. Virginia Heart expects to perform approximately 1,687 scans in the first year of operation and 2,000 by the second year.

Virginia Heart will follow the Appropriate Use Criteria for Cardiovascular PET/CT if the project is approved. This criteria was 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. The goal of this criteria's creation was 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. Given the size of Virginia Heart's patient population and service area, Virginia Heart's additional Cardiovascular PET/CT scanner is expected to be fully utilized within 1-2 years.

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 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?

_____ Yes **X** No

If yes, specify program _____
Provide a copy of report(s) which provide(s) the basis for comparison.

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>221,864</u>
2.	Cost of labor	\$ <u>265,801</u>
3.	Equipment included in construction contract	\$ <u>125,000</u>
4.	Builder’s overhead	\$ <u>0</u>
5.	Builder’s profit	\$ <u>46,912</u>

- | | | |
|----|--------------------------------|--------------------------|
| 6. | Allocation for contingencies | \$ <u>65,000</u> |
| 7. | Sub-total (add lines 1 thru 6) | \$ <u>724,576</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>2,360,310</u> |
| | b. Hot Lab _____ | \$ <u>73,159</u> |
| | c. _____ | \$ <u>0</u> |
| | d. _____ | \$ <u>0</u> |
| | e. _____ | \$ <u>0</u> |
| 9. | Sub-total (add lines 8a thru 8e) | \$ <u>2,433,469</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>588,621</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>588,621</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	\$ 18,500
30.	Architect's supervision fee	\$ 6,500
31.	Engineering fees	\$ 25,000
32.	Consultant's fees	\$0
33.	Sub-total (add lines 29 thru 32)	\$ 50,000.00

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>20,236</u>
37.	List other taxes:	
	a. _____	\$<u>0</u>
	b. _____	\$<u>0</u>
38.	Sub-total (add lines 36 thru 37b)	\$ <u>20,236</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>6.44%</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>\$124,832</u>
	<i>*Amount to financed for permanent mortgage loan \$724,576</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>\$ 724,576</u>
97.	Sub-total Part II	Equipment not included in construction contract (line 9)	<u>\$ 2,433,469</u>
98.	Sub-total Part III	Site Acquisition Costs (line 15)	<u>\$ 588,621</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>\$ 50,000</u>
102.	Sub-total Part VII	Other Consultant fees (line 35)	<u>\$0</u>
103.	Sub-total Part VIII	Taxes During Construction (line 38)	<u>\$ 20,236</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>\$ 3,816,902</u>
108.	Percent of total capital costs to be financed _ 19%		
109.	Dollar amount of long term mortgage (line 107 x 108)		<u>\$ 724,576</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>\$ 124,832</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>\$ 3,941,734</u>

- D. 1. Estimated costs for new construction (excluding site acquisition costs) \$0
2. Estimated costs of modernization and renovation (excluding site acquisition costs) \$724,576
- E. Anticipated Sources of Funds for Proposed Project Amount
1. Public Campaign \$0
2. Bond Issue (Specify Type) _____ \$0
3. Commercial Loans \$724,576
4. Government Loans (Specify Type) _____ \$0
5. Grants (Specify Type) _____ \$0
6. Bequests \$0
7. Private Foundations \$0
8. Endowment Income \$0
9. Accumulated Reserves \$0
10. Other (Identify) Operations \$3,092,326
- 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 day will be \$68.40. 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)

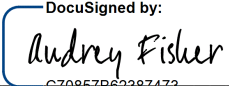
SECTION VI

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:

C70857B63287473...

Signature of Authorizing Officer

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

CEO
Title of Authorizing Officer

(703) 621-4501
Telephone

2901 Telestar Court
Address – Line 1

Suite 300
Address – Line 2

Falls Church, VA 22042
City/State/Zip


10/1/2024

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.**

Revised 02/24/2015

 VIRGINIA HEART Excellence in Cardiovascular Care		
PET/CT Proforma		
Lansdowne, Virginia		
Annual Estimated Volume	1,687	2,008
Average Daily Volume	7	8
INCOME STATEMENT	Year 1	Year 2
Projected Revenue	\$3,710,828	\$4,416,395
Compensation Staff	969,485	998,569
Benefits	242,371	249,642
Legal Fees	60,000	5,000
Bank Fees	4,800	6,000
Contracted Services	104,469	121,750
Training	50,000	50,000
Patient Supplies	168,720	200,800
Patient Education	5,000	6,000
Office Supplies	9,000	6,500
Maintenance	194,078	178,812
Marketing	25,000	10,000
Rent Expense	59,254	60,609
Utilities	8,706	8,945
BPOL Taxes	12,246	14,574
Personal Property Taxes	4,929	4,929
Operating Lease Equipment	337,188	337,188
Software License Fees	106,545	106,545
Bad Debt Expense	132,341	184,593
Charitable Donations	193,878	230,741
Depreciation & Amortization	97,524	97,524
Interest Expense	42,958	34,538
Total Expenses	2,828,492	2,913,261
Profit (Loss)	\$ 882,336	\$ 1,503,134