COMMONWEALTH OF VIRGINIA

APPLICATION FOR A

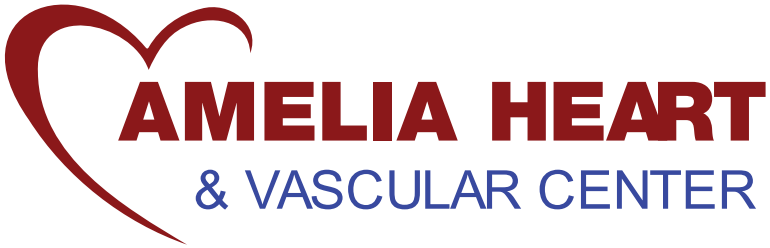
MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED

(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



Application for a Certificate of Public Need

to

Establish Cardiac PET/CT at

COPN Request No. VA-8722
Springfield, VA
Planning District 8

October 2, 2023

SECTION I **FACILITY ORGANIZATION AND IDENTIFICATION**

A. **Amelia Heart and Vascular Center, Inc.**
Official Name of Facility

6136 Brandon Ave
Address

Springfield	**VA**	**22150**
City	State	Zip

(703) 866-3131
Telephone

B. **Amelia Heart and Vascular Center, Inc.**
Legal Name of Applicant

6136 Brandon Ave
Address

Springfield	**VA**	**22150**
City	State	Zip

C. Chief Administrative Officer

Azita Moalemi M.D.
Name

6136 Brandon Ave
Address

Springfield	**VA**	**22150**
City	State	Zip

(703) 447-3749
Telephone

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

Azita Moalemi M.D.
Name

6136 Brandon Ave
Address

Springfield	**VA**	**22150**
City	State	Zip

(703) 447-3749
Telephone

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 Certificated of Incorporation	(3) _____
(4) _____	(4) Other _____ Identify	(4) _____
	Non-Profit	
(5) _____	(5) Corporation-attach copy of Articles of Incorporation and Certificated of Incorporation	(5) _____
(6) _____	(5) Other _____ Identify	(6) _____
	Governmental	
(7) _____	(7) State	(7) _____
(8) _____	(8) County	(8) _____
(9) _____	(9) City	(9) _____
(10) _____	(10) City/County	(10) _____
(11) _____	(11) Hospital Authority or Commission	(11) _____

See Attachment I.E. Articles of Incorporation and Certificated of Incorporation

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 **10** years

(4) _____ Renewable lease, renewable every _____ years

(5) _____ Other _____ (Identify)

See Attachment I.F. Lease Agreement

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.

See Attachment I.G Shareholder Agreement and Distribution

(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.

See Attachment I.G Shareholder Agreement and Distribution

2. A list of the officers of the corporation.

See Attachment I.G Shareholder Agreement and Distribution

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

See Attachment I.G Shareholder Agreement and Distribution

(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

Not Applicable

(c) In the case of a partnership also attach:
1. A list of the names and addresses of all partners.
2. The name and address of the general or managing partner.

Not Applicable

(d) In the case of other types of ownership, also attach such documents as will clearly identify the owner.

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

Not Applicable

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

Not Applicable

J. If the operator is other than the owner, attach a list of the names(s) and addresses of the operator(s) of the medical care facility project. In the case of a corporate operator, specify the name and address of the Registered Agent. In the case of the partnership operator, specify the name and address of the general or managing partner.

Not Applicable

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

Not Applicable

SECTION II **ARCHITECTURE AND DESIGN**

A. Location of the Proposed Project

1. Size of site: **2.89** acres
2. Located in **Springfield** (City) / **Fairfax** (County) / **Planning District 8** (Planning District)
3. Address or directions **6136 Brandon Ave**
   Springfield, Virginia, 22150
4. Has site been zoned for type of use proposed:

   X Yes (Attach copy of zoning or use permit)

   ____ No

   If no, explain status. ____

   See Attachment II.A.4 Certificate of Occupancy

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

1. ____ New construction
2. ____ Remodeling/modernization of an existing facility
3. ____ No construction or remodeling/modernization
4. **X** Other (Identify) **Establishment of Fixed Cardiac PET/CT imaging**

C. Design of the facility

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

   Amelia Heart and Vascular Center is a cardiovascular medicine practice with its central office located in Springfield, Virginia. We started our practice seventeen years ago. Two women cardiologists committed to service of our local community. Springfield, located in the Lee District, boasts a substantial 26.6% Latino/Hispanic population, significantly higher than Fairfax County (16.2%) and the State of Virginia (10%). 43% of Springfield's population speaks a language other than English at home, and 32% were born in another country. In particular because of our language skills, and because we sought to retain a diverse and inclusive staff, we were able to serve the socioeconomic, cultural, and linguistically diverse population of Springfield. But knowing our skills, our motto and our commitment, patients came from vicinity of Springfield as well from Annandale, Arlington, Alexandria, Woodbridge and even Maryland.

We take Medicare, most private insurances, and Medicaid. We accept self-pay, and we subsidize the cost for those in financial hardship. We have never refused care to anyone for inability to pay.

Highly aware of the fact that patients with poor access end up in facilities with substandard care, we knew our patients deserved better. We established a state of the art fully equipped office providing the entire spectrum of noninvasive cardiovascular care services as described in section IIIA. We ensured that we meet all the rigorous quality standards of accreditation agencies and became accredited in all our imaging modalities. Those are the same accreditation standards sought by our local INOVA hospitals and Virginia Hospital Center imaging departments.

We met all the requirements of the accountable care act. We were one of the first adopters of electronic health records for private practice in the area.

We ensured that we faced all the challenges inherent in caring for patients during COVID. We made our office COVID ready adhering to all policies of protection for patients and staff. At one point during the height of COVID, concerned that an elderly patient of ours may have been exposed to COVID. Knowing that she may not have the access, our cardiologist went to her house every day and tested her and her husband and her daughter for a whole week to make sure they did not turn positive and that they got the care they needed. The demographic make-up of our staff reflects the diversity of the population we serve, and we knew they depended on their income during COVID. We did not lay off a single staff in our office during COVID.

To serve our diverse patients closer to their home, we also expanded our offices to additional two locations in Alexandria and Arlington. We added four more cardiologists three of whom happen to be also women cardiologists and three Advanced Practice Providers who are aligned with our mission. We are board certified in general cardiology, nuclear cardiology, echocardiography, vascular imaging. And we have been consistently committed to the care of the rich and poor alike without regard for ethnicity, origin, language barrier, or ability to pay. And all this while staying financially solvent.

We are also very unique in our physician makeup in that we are women founded, mostly women medical staff practice. Only 10 percent of cardiologists are women in the country and in Northern Virginia in the other group practices. Our practice of six cardiologists has more than 80% women. We are inherently interested in Women and Heart Disease, a field of crucial importance in cardiovascular medicine. Sixty percent of our patients are women. Heart disease is number one killer of women, Women present differently with regards to their symptoms. They have a different anatomy.

They are more likely to be obese. They have breasts which presents a significant challenge in cardiovascular imaging. They have smaller hearts and smaller coronaries, and they are more likely to present with microvascular angina. The conventional imaging modalities in cardiology were not designed with these anatomical changes taken into consideration except cardiac PET/CT as we will explain in further details later.

Amelia Heart and Vascular (Amelia Heart) is presenting this application for a certificate of public need, seeking to establish Cardiac Positron Emission Tomography/Computed Tomography (PET/CT) imaging services at its Springfield office situated in Planning District 8. The utilization of PET/CT has become the preferred approach for conducting myocardial perfusion imaging (MPI), a pivotal diagnostic tool in the identification and management of coronary artery disease (CAD). Amelia Heart remains steadfast in its commitment to delivering the utmost in patient care quality, centered around contemporary medical standards and state-of-the-art diagnostic equipment. The incorporation of Cardiac PET/CT aligns seamlessly with our overarching mission.

The Amelia Heart Springfield office, located at 6136 Brandon Ave, Springfield, VA 22150, currently provides a comprehensive range of outpatient cardiology services, encompassing ultrasound and Single Photon Emission Tomography (SPECT) imaging. Access to the facility is facilitated through private vehicles and public transportation. The strategic location on the mixing bowl places it 2.7 miles from Exit 1B on I-395S and 5.0 miles from Exit 57A on I-495. Moreover, the Fairfax Connect and MetroBus services offer convenient transport options. Key bus stops, including Commerce and Brandon Ave (Route 321/322 Fairfax Connect), Backlick Road and Cumberland Ave (Route 401 Fairfax Connect), and Amherst Ave and Commerce (Route 18J MetroBus), are positioned for easy access. The Fairfax Connect bus stops are a mere 0.2 miles away, requiring a brief four to five-minute walk, while the MetroBus bus stop is located 0.4 miles away, an accessible eight-minute walk. The facility provides ample on-site parking, including handicapped and van accessibility.

Amelia Heart's proposal entails enhancing our imaging services at this location by introducing a Siemens Biograph 16-slice PET/CT scanner dedicated exclusively to gated cardiac MPI. Amelia Heart explicitly does not intend to perform non-cardiac studies. The CT component will be utilized solely for the attenuation correction of perfusion images. Our 60% women patient demographic population will benefit from this as the breast attenuation poses a significant challenge with conventional SPECT imaging.

The Cardiac PET/CT lab will be seamlessly integrated into currently unused space within Amelia Heart's Springfield office. The lab, spanning around 565 square feet, consists of a lead-shielded camera room and a control room, both

designed according to Nuclear Regulatory Commission guidelines. The lab will share facilities such as the existing hot lab, patient prep, and waiting areas. The proposed construction will have minimal impact on the remainder of the office, primarily necessitating minor power supply and HVAC upgrades to ensure optimal conditions for the equipment. This expansion will not impose any capacity issues in the shared office spaces.

Cardiac PET/CT constitutes a nuclear stress test similar to cardiac SPECT, commonly employed for diagnostic purposes[1]. The process involves capturing dynamic images of the heart while at rest and under stress. Skilled physicians then analyze and compare these images to ascertain myocardial perfusion, leading to diagnosis and tailored treatment plans. While SPECT has traditionally been the primary option for such studies, Cardiac PET/CT has rapidly emerged as the preferred myocardial perfusion imaging test due to its numerous advantages.

Cardiac PET/CT presents several benefits, including enhanced accuracy, reduced radiation exposure, and shorter test durations[2]. The method employs a radiotracer tagged with Rubidium-82 (Rb82), which emits positrons upon decay. These positrons interact with nearby electrons, generating photons that are counted by sensitive crystal ring detectors to create precise heart images[3]. The unique attributes of PET/CT, including its 3D imaging capability and the short half-life of Rb82, contribute to its higher resolution, sensitivity, and specificity compared to SPECT[4].

The low radioisotope dosing protocol of Cardiac PET/CT is another significant advantage. The short half-life of Rb82 (10 min) results in markedly reduced radiation exposure for patients compared to the commonly used Technetium-99 (Tc99) (halfhalf-life 6 hours) in SPECT imaging. This exposure reduction is further accentuated by PET/CT's true 3D imaging capacity compared to SPECT's 2D capabilities[5]. This is especially important as most of our staff is women of child bearing age, which will later protect them from undue radiation exposure when compared to the radiation exposure of cardiac SPECT.

The short half-life of Rb82 also translates to a rapid imaging protocol. The decay of Rb82 typically takes around 75 seconds, allowing for a swift rest and

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[1] ASNC and SNMMI Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET https://www.asnc.org/files/Guidelines%20and%20Quality/ASNCandSNMMIJointPETPositionPaper2016.pdf

[2] ASNC imaging guidelines/SNMMI procedure standard for positron emission tomography (PET) nuclear cardiology procedures https://link.springer.com/article/10.1007/s12350-016-0522-3

[3] Review: comparison of PET rubidium-82 with conventional SPECT myocardial perfusion imaging https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4204510/

[4] Cardiac PET-CT: advanced hybrid imaging for the detection of coronary artery disease https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2828569/pdf/nhj1809000.pdf

[5] Motion estimation and correction in SPECT, PET and CT (2021) https://iopscience.iop.org/article/10.1088/1361-6560/ac093b/pdf

stress image acquisition in quick succession[6]. Consequently, the total protocol time for a Cardiac PET/CT study is approximately 25 minutes, compared to SPECT's up to 3-hour study time that mandates a waiting period between rest and stress image acquisition.

Cardiac PET is more sensitive and specific and significantly safer requiring a fraction of the radiation imparted by conventional SPECT imaging. The upgrade to PET/CT is particularly advantageous for individuals with established or suspected CAD, including those who are obese, women, and those unable to undergo treadmill testing. The advantage of cardiac PET/CT in imaging women cannot be understated. The breast attenuation correction algorithm embedded in the technology leads to higher accuracy for detection of disease in women.

An appraisal of the benefits of Cardiac PET/CT wouldn't be complete without acknowledging its positive economic impact. The early and accurate detection it provides enables cost-effective management of CAD through drug therapies, reducing the need for future invasive procedures. The quantification of myocardial blood flow (MBF) by Cardiac PET/CT can potentially negate the requirement for interventional angiography, thus averting costly downstream treatments[7]. Studies indicate that Cardiac PET can decrease CAD management costs by up to 30% when compared to traditional SPECT and Computed Tomography Angiography[8].

For over a decade, Amelia Heart has been a cornerstone in delivering exceptional cardiac services to northern Virginia. We are enthusiastic about extending Cardiac PET/CT services in Springfield upon COPN approval. The integration of this advanced imaging modality, coupled with its manifold patient benefits, underpins our commitment to quality care and better health outcomes for our community. As a testament to this commitment, Amelia Heart intends to uphold a charity care requirement pertinent to this service.

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.

Amelia Heart has a strategic plan to establish a Siemens Biograph Horizon PET/CT system at their facility located at 6136 Brandon Avenue in Springfield, VA. This advanced system will be procured through a leasing arrangement with CDL Nuclear Technologies, LLC, a well-known provider of comprehensive cardiac imaging solutions on a national scale.

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[6] Radiopharmaceutical Agents for Myocardial Perfusion Imaging https://www.ahajournals.org/doi/10.1161/circulationaha.108.778860

[7] Impaired myocardial flow reserve on rubidium-82 positron emission tomography imaging predicts adverse outcomes in patients assessed for myocardial ischemia https://pubmed.ncbi.nlm.nih.gov/21816311/

[8] Impact of Myocardial Perfusion Imaging with PET and 82Rb on Downstream Invasive Procedure Utilization, Costs, and Outcomes in Coronary Disease Management https://jnm.snmjournals.org/content/48/7/1069

The proposed Cardiac PET/CT laboratory encompasses a camera room and a control room, efficiently utilizing existing space within the Springfield office. Coexisting with the established facilities, such as the hot lab and patient waiting areas, the lab's design prioritizes patient and staff safety throughout the construction phase and ongoing operational activities. Rigorous measures will be undertaken to ensure radiation shielding, and the layout will be thoughtfully designed to accommodate physicians and support staff, guaranteeing optimal care provision before, during, and after patient tests.

The strategic addition of Cardiac PET/CT at Amelia Heart's Springfield site seamlessly aligns with their overarching mission of delivering top-tier cardiac care to the citizens of central Virginia. This expansion equips the practice to offer an enhanced MPI (Myocardial Perfusion Imaging) test, surpassing the current benchmark of SPECT imaging. Notably, Cardiac PET/CT is particularly suited for patients with BMIs exceeding 30, a demographic that is consistently growing.

By embracing Cardiac PET/CT, Amelia Heart positions itself strategically to cater to the market's demand for cost-effective, high-quality medical services. While SPECT remains a crucial component of our comprehensive imaging suite, the introduction of Cardiac PET/CT marks a significant stride in upholding Amelia Heart's tradition of continuous innovation and refinement in the realm of diagnostic imaging.

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

The Office is conveniently accessible via both private vehicles and public transportation. It is conveniently situated 2.7 miles from Exit 1B on I-395S and 5.0 miles from Exit 57A on I-495.

For those opting for public transportation, the Fairfax Connect and MetroBus services offer accessible transport options throughout the day. The Commerce and Brandon Ave (Route 321/322 Fairfax Connect), Backlick Road and Cumberland Ave (Route 401 Fairfax Connect), and Amherst Ave and Commerce (Route 18J MetroBus) bus stops are strategically located to facilitate easy access to the facility. The Fairfax Connect bus stops are just 0.2 miles away, requiring a brief four to five-minute walk, while the MetroBus bus stop is situated 0.4 miles away, a convenient eight-minute walk.

For a visual illustration of the straightforward accessibility to this facility, kindly refer to the attached diagram or map.

<u>Attachment II.C.3 Transportation Access Springfield</u>

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

   The Amelia Heart Springfield office is situated in a freestanding building with abundant on-site parking. The current facilities encompass office space, parking, and water/sewage/waste utilities, which are excellently equipped to accommodate the integration of the PET/CT system.

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.

   AHV has established a partnership with CDL Nuclear Technologies to supervise and provide expert guidance during the development and functioning of the Cardiac PET/CT lab. CDL employs its unique proprietary approach, assuring efficient acquisition of materials within stipulated timelines and cost limits, effectively maintaining project expenditures under control and on track. A comprehensive mechanical evaluation will be conducted to ascertain the seamless operation of cutting-edge HVAC and electrical systems. CDL's commitment extends to the utilization of locally procured materials and labor resources whenever feasible—encompassing elements such as drywall, flooring, and paint—further enhancing cost-effectiveness through favorable pricing arrangements.

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.

   AHV is located within a well-established medical office building, and all essential utilities are currently provided as part of the lease agreement for the space. This arrangement guarantees that the facility has uninterrupted access to the vital services necessary for its day-to-day operations.

   See Attachment I.F. Lease Agreement
   See Attachment II.D.4 Utility Data

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.)

    Not Applicable

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

    When formulating the design of the Cardiac PET/CT suite, a primary factor considered is the requirement for minimal service clearances around each camera. The dimensions of the lab are established considering these clearances and the arrangement of ancillary equipment. The PET/CT camera necessitates continuous HVAC support and 480V 3-phase power supplied to the camera room at all times. Please refer to the attached Planning Guide for a more comprehensive overview of facility construction and system prerequisites. The project's buildout plan will be strategized to minimize disturbances to the building, prioritizing minimal disruption.

    See Attachment II.E.3 Siemens Horizon PET-CT Planning Guide

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. Site-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 Drawings

H. Construction Time Estimates

1. Date of Drawings: Preliminary **01/04/23** Final **01/25/23**

2. Date of Construction: Begin **02/01/23** Completion **03/15/23**

3. Target Date of Opening: **04/01/2023**

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.

Amelia Heart presently extends an extensive array of diagnostic services at its Springfield office site, including EKG, exercise stress testing comprehensive 2-D echocardiography including strain imaging, stress echocardiography, comprehensive vascular imaging including carotid dopplers, renal dopplers, mesenteric dopplers, lower extremity arterial dopplers with segmental pressures, lower extremity venous dopplers with venous mapping, exercise stress SPECT myocardial perfusion imaging, pharmacologic stress SPECT MPI, pacemaker interrogation, Holter monitoring, mobile cardiac telemetry. Our nuclear lab is accredited by American College of Radiology (ACR). Our echocardiography lab is accredited by the Intersocietal Accreditation Commission on Echocardiography (ICAEL) and our vascular lab is accredited by the Intersocietal Accreditation Commission on Vascular Imaging (ICAVL). Obtaining accreditation from these agencies requires demonstration of rigorous quality control, performance of tests under evidence-based medicine guidelines for appropriate testing and standardized and prompt reporting.

Amelia Heart is composed of six cardiologists, five board certified and one board eligible, two skilled physician assistants, and one nurse practitioner—spanning across three office locations within Northern Virginia. Furthermore, two of the cardiologists are Diplomates on the Certification Board of Nuclear Cardiology. One of them is also a Registered Physician in Vascular Interpretation. This dedicated team possesses Alliance for Physician Certification and Advancement certifications, and two members hold dual certification from the National Board of Echocardiography, covering both Examination of Special Competence in Adult Echocardiography and Adult Comprehensive Echocardiography. Moreover, three of the cardiologists are esteemed Fellows of the American College of Cardiology. The collective experience of this proficient team has been instrumental in Amelia Heart's delivery of high-quality cardiovascular care, enriched by cutting-edge diagnostic and treatment methodologies.

The forthcoming integration of the Cardiac PET/CT system at Amelia Heart's Springfield office is purposefully aimed at gated MPI stress testing. This nuclear stress testing serves as a pivotal noninvasive tool for the identification and management of ischemic heart disease. It's important to note that the Cardiac PET/CT system will be dedicated solely to this form of imaging, with the CT element reserved for attenuation correction of the perfusion images. It is not within Amelia Heart's scope to conduct diagnostic CT scans or other non-cardiac PET/CT imaging.

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

Collaboration between cardiologists and primary care physicians plays a pivotal role in ensuring the seamless continuity of care for cardiac patients. At Amelia Heart we have always ensured prompt communication of results of diagnostic testing of our patients with primary care providers. As a medical center that is ACR, ICAEL and ICAVL certified we are bound by expedited reporting of results and plan of care. On the other end of the spectrum, we work closely with interventional cardiologists at our local hospitals where we have privileges to ensure a seamless transition if patients require acute or invasive care in follow up. We were one of the first private practices in the area to adopt and implement electronic health records. We have access to the hospital's electronic health platform- EPIC and we facilitate communications through these HIPPA protected portals.

C. What procedures are utilized in quality care assessment?

As mentioned in section II.A, all of imaging department (i.e., Echocardiography, Vascular, and SPECT) are accredited by the appropriate accredited agencies (ICAEL, ICAVL, ACR). These are the same entities that accredit imaging centers in the hospitals.

Achieving accreditation in echocardiography, vascular, nuclear SPECT Imaging from the relevant authorities signifies that we have successfully undergone a stringent evaluation process encompassing aspects of quality, reporting and appropriate selection of patients of patients for testing. The accreditation underscores our commitment to excellence in cardiovascular care. It assures our patients that our facilities meet the highest standards and adhere to rigorous protocols ensuring quality and safety.

Upon acquisition of cardiac PET/CT technology we intend to fulfill the same rigorous criteria and obtain accreditation from American College of Radiology (ACR) as we do for SPECT imaging.

In partnership with CDL, Amelia Heart will diligently oversee the alignment of all images with ACR standards and ensure proper equipment maintenance. Our internal Medical Director will actively supervise the continual competence of our physicians, staff, and technologists in their respective capacities. Supported by CDL, Amelia Heart will collaboratively formulate comprehensive policies and procedures pertaining to quality control testing.

Amelia Heart is equipped with well-defined appropriate use criteria and has established robust policies and procedures that encompass quality control testing. At Amelia Heart, every patient is assured of receiving exceptional care services. Our nuclear technologists hold certifications from NMTCB and/or AART, and each undergoes training and certification on the Bracco generator cart, housing radioactive materials. We also have for years retained the services of an experienced radiation safety physicist who overseas safety protocols and

procedures for staff and patients alike. This comprehensive approach underscores our unwavering dedication to providing top-tier care while maintaining stringent quality and safety standards.

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

The staffing needs for this project will involve a Certified Nuclear Medicine/CT Technologist and a Registered Nurse. There is no requirement for external staffing resources. All necessary staff will be drawn from the existing resources within the office.

E. Facilities and Services to be Provided (Check)

	Existing	This Project To be Added	This Project to be Discontinued
1. Outpatient Surgery			
2. Post Operative Recovery Room			
3. Pharmacy with:			
full-time pharmacists			
part-time pharmacists			
4. Diagnostic Radiological Services	**X**		
x-ray			
radioisotope	**X**	**X**	
CT scanning			
5. Therapeutic Radiological Services			
Specify Source(s) or Type(s) or Equipment Used			
6. Clinical Pathology Laboratory			
7. Blood Bank			
8. Electroencephalography			
9. Electrocardiography	**X**		
10. Ultrasonography	**X**		
11. Respiratory Therapy			
12. Renal Dialysis:			
Chronic outpatient			
Home dialysis training			
13. Alcoholism Service			
14. Drug Addiction Service			
15. Physical Therapy Department			
16. Occupational Therapy Department			
17. Medical Rehabilitation Outpatient			

18. Psychiatric Service:			
Outpatient			
Emergency Service			
19. Clinical Psychology			
20. Outpatient Emergency Service			
21. Social Service			
22. Family Planning Service			
23. Genetic Counseling Service			
24. Abortion Service			
25. Pediatric Service			
26. Obstetric Service			
27. Gynecological Service			
28. Home Care Service			
29. Speech Pathology Service			
30. Audiology Service			
31. Paramedical Training Program			
32. Dental Service			
33. Podiatric Service			
34. Pre-Admission Testing			
35. Pre-Discharge Planning			
36. Multiphasic Screening			
37. Other (Identify)			

F. Program

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

   _____ Yes (Give name of hospital) _____

   X No

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

   X Yes (Give name of hospital) **INOVA Fairfax Hospital**

   _____ 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) **INOVA Fairfax Hospital**

   _____ No

Amelia Heart utilizes the Athena One electronic medical records system. All study images will be seamlessly integrated into the EMR alongside the final report. To facilitate swift information exchange with inpatient medical facilities, we employ both fax communication and an HL-7 interface with the hospital, particularly once patients are designated under our care as consulting physicians. Amelia Heart providers also have access to EPIC electronic system at INOVA Hospitals and can provide internal HIPPA protected messaging to the care team at the hospitals. Our practice maintains ongoing communication with the following facilities:

INOVA Alexandria Hospital
INOVA Fairfax Hospital
Virginia Hospital Center

4. Outpatient services are (will be) available from **8:00** a.m. to **4:30** p.m. **six** days of the week. **(Monday through Saturday)**

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

   X Yes (Attach clinic schedule list)

   _____ No

Location Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
08:00 a.m.						
09:00 a.m.						
10:00 a.m.						
11:00 a.m.						
12:00 p.m.	Emergency Slot	Emergency Slot	Emergency Slot	Emergency Slot	Emergency Slot	Emergency Slot
1:00 p.m.						
2:00 p.m.						
3:00 p.m.						
4:30 p.m.						

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 _____ No

   b) By full time physicians: **X** Yes _____ No

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

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

Amelia Heart is committed to service of our community. Presently, Amelia Heart is an active participant with major insurers and Medicare, and most Medicaid products ensuring access. We also have programs for self-pay patients and subsidized care for at risk patients in financial hardship. We have never refused care to a patient because of inability to pay.

Clinical considerations that could impose limitations include:

1. **Patient Size: In instances where a patient's dimensions exceed the capacity of the camera's field of view.**
2. **Unstable Angina: Cases involving patients with unstable angina, where the cardiac condition's volatility might interfere with the accuracy of the test.**
3. **Uncontrolled Systemic Hypertension: Patients with unregulated systemic hypertension, where the elevated blood pressure might affect the test's reliability.**
4. **2nd or 3rd AV Block without Pacemaker: Patients with 2nd or 3rd degree atrioventricular (AV) block who do not have a pacemaker, as the block might pose challenges during the testing process.**
5. **Non-Adherence to Preparation Instructions: Instances where patients have not followed the prescribed preparation guidelines for the examination.**

These limitations are in place to ensure the integrity and precision of the diagnostic process, while AHV remains committed to offering its services in a wide-ranging and inclusive manner, guided by clinical necessity and adherence to best practices.

<u>See Attachment III.F.8 AUC For Cardiac Radionuclide Imaging 2009</u>

<u>See Attachment III.F.8 AUC Cardiac PET 2020</u>

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.

Amelia Heart lacks historical data regarding Cardiac PET/CT procedures, as this service has not been previously conducted. Furthermore, other providers offering Cardiac PET/CT within Planning District 8 have reached their capacity as addressed in Section IV.2.B. The remaining PET/CT systems in the district are

primarily utilized for non-cardiac purposes, rendering historical statistics irrelevant in assessing accurate volumes for cardiac needs or indications.

The following table presents service volume records for the calendar years 2021, 2022 and an annualized 2023

Procedure / Visit Type	2021	2022	Variance 2022
SPECT & STRESS ECHO	1,859	1,367	-26.47%
PERIPHERAL ULTRASOUND	1,838	2074	12.84%
ROUTINE TREADMILL STRESS	3,462	3,022	-12.71%
ECHO	7,188	7,392	2.84%
NEW PATIENT VISIT	2,939	3208	9.15%
HOLTER MONITOR	2,939	3208	9.15%
ESTABLISHED PATIENT VISIT	11,286	13,943	23.54%
EKG COMPLETE	5,528	6,744	22.00%

The table below illustrates the quantities of SPECT and Stress Echo procedures during the calendar years 2021, 2022, and an annualized projection for 2023.

CPT Description	SPECT	Stress Echo	Total	% Increase
2021	926	933	1,859	
2022	660	707	1,367	-26%
(Annualized) 2032	1,006	576	1,582	16%

The decline in volumes between 2021 and 2022 can be attributed to the unforeseen significant sewage issue occurred on the floor above, resulting in damage to equipment, walls, and ceilings within the office. Subsequently, the office had to temporarily for about a month to conduct sanitation, replace damaged equipment, and carry out necessary repairs. Unfortunately, during this period, the office was unable to provide Cardiac SPECT services. Moreover, given that a significant portion of our patient demographic comprises women (60%), who tend to experience more breast attenuation artifacts, our office conducts fewer Cardiac SPECT scans on this population. This approach helps avoid inconclusive or false-positive results, which, in turn, would necessitate further testing or potentially unwarranted cardiac catheterizations.

The Cardiac PET/CT service will cater to patients for whom SPECT is not suitable due to factors like body habitus (BMI 35 or higher), large breasts or implants, previous inconclusive SPECT results owing to attenuation artifact, confirmed pericardial or pleural effusion, prior mastectomy, and patients with SPECT studies that did not align with coronary angiographic findings (resulting in false positives or false negatives).

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).

		Additional		Needed
	Current Full Time	Vacant Positions	Full Time	TOTAL
Total number of Full-Time staff	**32**			**33**
Administration-Business Office	**5**			**5**
Registered Nurses	**1**			**1**
Licensed Practical Nurses, Nurses Aides, Orderlies/Attendants	**13**	**1**	**1**	**14**
Registered Medical Records Librarian				
Registered Pharmacists				
Laboratory Medical Technologists				
ADA Dieticians				
Radiologic Technologists	**7**			**7**
Occupational Therapists				
Physical Therapists				
Psychologists				
Psychiatric Social Workers				
Recreational Therapists				
Inhalation Therapists				
Medical Social Workers				
Other Health Professionals, Identify				
All Other Personnel (Exclude Physicians and Dentists)				
Front Desk/Reception	**6**			**6**

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.

No additional staff will be required.

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

Amelia Heart foresees no repercussions on staffing at other facilities within the service area. Any added staffing necessities will be met using our existing internal personnel and will not affect the current staff of other facilities.

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

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 ACR Accreditation

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 Staff Roster Springfield

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 Physician Statement

SECTION IV **PROJECT JUSTIFICATION AND IDENTIFICATION OF COMMUNITY NEED**

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

Amelia Heart and Vascular Center, a cardiovascular practice founded by two women cardiologists Dr. Azita Moalemi and Dr. Naghmeh Tebyanian in 2007, has since flourished into a thriving healthcare hub with three locations, a team of six cardiologists, and three Advanced Practice Providers. Our journey has been marked by an unwavering commitment to serving a remarkably diverse patient population across Springfield, Alexandria, and Arlington. This diversity spans not only socio-economic backgrounds but also ethnicity and language, reflecting the rich tapestry of our community.

Springfield, located in the Lee District, boasts a substantial 26.6% Latino/Hispanic population, significantly higher than Fairfax County (16.2%) and the State of Virginia (10%). In response to this demographic reality, Dr. Moalemi, a fluent Spanish speaker with South American roots, leads our team, alongside two advanced practice providers proficient in Spanish. This linguistic competency has allowed us to become the primary providers of cardiovascular care in Springfield for the past 16 years, attracting Latino patients from Alexandria and Arlington. Furthermore, a staggering 43% of Springfield's population speaks a language other than English at home, and 32% were born in another country. Our diverse team and staff are equipped to accommodate the unique needs of these patients, ensuring access to care regardless of their ability to pay.

The growth of our practice is not only attributed to our diversity, which resonates with patients seeking culturally sensitive care, but also to the rising prevalence of cardiovascular disease in our region and the nation. As cardiologists, we are constantly challenged to provide the safest, most sensitive, and accurate diagnostic tests to our patients. In many medical conditions, missing a diagnosis may result in delayed treatment, but early coronary artery disease detection is paramount in cardiology. False-negative results can lead to sudden cardiac death, while false positives necessitate further, often invasive, testing with potential risks.

This is where Cardiac Positron Emission Tomography (PET) emerges as a transformative technology. PET imaging offers unparalleled sensitivity, specificity, and accuracy in noninvasively assessing blood flow to the heart, enabling the detection of blockages in blood vessels. It elevates image quality by reducing artifacts and minimizes radiation exposure compared to conventional SPECT imaging. This technological advancement is a game-changer in our mission to provide precise diagnoses swiftly, saving lives and reducing the burden of unnecessary testing on our patients, many of whom come from disadvantaged backgrounds. It has superb diagnostic value in women with different anatomy.

The acquisition of a new CT/PET Scanner at Amelia Heart and Vascular Center is not merely a step forward in healthcare technology but a commitment to our diverse and underserved communities. Our longstanding dedication to inclusivity

and cutting-edge diagnostic tools position us as the ideal provider to address the unique healthcare needs of minority and underprivileged populations. This investment will enhance the quality of care and contribute to the overall well-being of the communities we proudly serve.

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.)

   The core service region of AHV is concentrated within Northern Virginia. A comprehensive analysis based on zip codes reveals that a substantial 76% of the patient population hails from the specific zip codes highlighted in Attachment IV.B.1. This distribution underscores the significant presence of AHV within these designated areas, reinforcing the practice's integral role in serving the healthcare needs of the Northern Virginia community.

   <u>See Attachment IV.B.1 Zip Code Analysis</u>

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

   The primary source of patients will predominantly be internal referrals from AHV's team of physicians. The majority of referred patients are expected to display the following characteristics or medical history:

   1. **<u>Unstable Angina Pectoris:</u> Individuals with ongoing, unstable chest pain due to inadequate blood flow to the heart.**
   2. **<u>Post-Acute Myocardial Infarction:</u> Patients who have experienced a recent heart attack and require detailed evaluation of their cardiac function.**
   3. **<u>Sarcoid Myocarditis:</u> Individuals with sarcoidosis, a condition causing inflammation, potentially affecting the heart.**
   4. **<u>Abnormal Electrocardiograms:</u> Patients with irregular heart rhythms or other electrical abnormalities in the heart's activity.**
   5. **<u>CAD Symptoms in Females with Large Breasts/Breast Implants:</u> Females with substantial breast size or breast implants, who might experience challenges with accurate imaging using traditional methods due to interference.**
   6. **<u>Large Body Habitus:</u> Individuals with a significant body size, where conventional testing could yield suboptimal image quality.**

   The list provided includes primary diagnosis codes for Cardiac PET/CT, but it is not exhaustive and might encompass:

ICD-10 Code	ICD-10 Code Description	ICD-10 Code	ICD-10 Code Description
D86.85	Sarcoid myocarditis	I20.0 - I20.9	Angina pectoris
I21.01 - I22.2	STEMI involving LM or LAD	I21.09	Acute Myocardial Infarction
I25.10	CAD of native artery w/o angina pectoris	I35.0	Nonrheumatic aortic (valve) stenosis
I42.0	Dilated Cardiomyopathy	I47.1	Supraventricular Tachycardia
I48.0 - I48.92	Atrial fibrillation/Atrial Flutter	I49.49	Other premature depolarization
I50.1 - I50.9	Heart failure	N62	Hypertrophy of breast
R07.9	Chest Pain, Unspecified	R55	Syncope
R94.31	Abnormal Electrocardiogram	R94.39	Abnormal Stress Test
Z01.810	Encounter for pre-op cardiac exam	Z68.41 - Z68.45	Body mass index [BMI] 40.0->70, adult
Z95.1	Presence of aortocoronary bypass graft	Z95.5	S/P coronary angioplasty implant and graft

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

Carient Heart & Vascular currently offers fixed Cardiac PET/CT services in Planning District 8 in two locations listed below. Virginia Heart was approved for a fixed cardiac PET, but it is unclear if they started seeing patients.

2. If Yes,

a. Identify the facility(ies)

Carient Heart & Vascular
8100 Ashton Avenue, Suite 200
Manassas, VA 20109

Carient Heart & Vascular
415 Church St NE, Suite 101
Vienna, VA 22180

Virginia Heart
2901 Telestar Court, Suite 300
Falls Church, VA 22042

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

Both Carient Heart & Vascular's Cardiac PET labs are currently operating at their maximum capacity, leading to the absence of available slots for non-Carient patients seeking cardiac PET services. Moreover, as indicated in application VA-8626, the initial PET scanner at Carient reached its operational limits, resulting in the

requirement for a second scanner. This second scanner received approval on February 9, 2023, with COPN No. VA-04825. This expansion underscores the heightened demand for these services.

An approval was granted for Virginia Heart to possess a Cardiac PET/CT scanner; however, it remains uncertain whether they have initiated their program at this juncture.

The landscape of cardiac myocardial perfusion imaging (MPI) has shifted, favoring the adoption of Cardiac PET/CT as the new standard of care. The distinct benefits it offers over traditional SPECT imaging have substantially increased the demand for this innovative approach.

Furthermore, we have received a letter of support from Dr. Merdod Ghafouri at Carient, affirming the community's potential benefits from this program. This collective evidence emphasizes the significance of the proposed Cardiac PET/CT services and the pressing need for their provision within the community.

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

Anticipated growth in the demand for Cardiac PET/CT imaging is projected to persist steadily over the coming five years. Given that Carient's existing labs are operating at maximum capacity, the inclusion of PET/CT services at AHV's Springfield facility will not only enhance accessibility but also alleviate the need for extensive patient commutes, particularly for individuals residing in Northern Virginia. This expansion will contribute to reducing inconveniences for a considerable number of patients by providing convenient access to advanced diagnostic capabilities closer to home.

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

As of the date of this application, Planning District 8 faces a notable deficit in accessible cardiac PET/CT services, with both existing fixed Cardiac PET/CT systems operating at maximum capacity. This initiative seeks to address an unmet demand within the Planning District, where access to this level of advanced care remains largely insufficient, not only within the district but across the state as well. With the traffic and congestion and substantial cost of express lanes (the cost of transportation becomes prohibitive for patients. As discussed in the physician statement our location in Springfield has been crucial in reaching out to a socioeconomically diverse population of patients. We find transportation costs for a noninvasive test prohibitive for our patient population.

The current state of affairs underscores a significant gap in cardiac care provision. Presently, the two Cardiac PET/CT labs in Planning District 8 are exclusively operated by Carient Heart & Vascular, situated 37-43 minutes away from Amelia Heart Springfield's location in Manassas, and 23 minutes away from the Vienna location. These distances also represent geographical barriers to care, particularly for individuals like the elderly, who might find extended drives uncomfortable or challenging. This highlights the urgency of introducing a Cardiac PET/CT program to Planning District 8, thereby offering advanced technology and fostering health equity in an underserved region.

The incorporation of Cardiac PET/CT is poised to provide Amelia Heart physicians with a powerful tool for diagnosing complex coronary artery disease with unparalleled precision and localization. It will facilitate the development of treatment strategies that don't necessarily entail medical interventions, thereby elevating patient care outcomes. Beyond patients, the system will also contribute to reduced radiation exposure for staff. Most of our staff are young women of child bearing age and we are keenly aware of the risk of exposure to radiation from patient source. Technetium used in cardiac SPECT has a half-life of 6 hours. Rubidium used in cardiac PET has a half-life of 10 min. Additionally, the implementation of Cardiac PET/CT will significantly curtail waiting periods for patients between scans. This transition will slash the usual three to four-hour duration required for SPECT scans down to a mere 30-60 minutes for Cardiac PET/CT scans.

In summary, the introduction of this project within Planning District 8 will effectively eliminate the necessity for patients to seek care in distant parts of the state, providing a local and accessible solution. This proximity to home will significantly alleviate the travel burden that often accompanies the pursuit of high-quality cardiovascular care, consequently enhancing patient experience, reducing stress, and ultimately fostering improved health outcomes for the communities we serve.

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

12VAC5-230-200. Travel time.

PET services should be within 60 minutes driving time one way under normal conditions of 95% of the health planning district using a mapping software as determined by the commissioner.

The availability of Cardiac PET or PET/CT services within Planning District 8 remains notably constrained. As a result, all PET/CT services offered within the district are allocated to non-cardiac applications such as oncology, neurology, and urology. Regrettably, the limited availability of advanced cardiac imaging options often necessitates patients to undergo more invasive procedures, such as cardiac

catheterizations, to confirm cardiac diseases due to the absence of cutting-edge PET/CT technology.

Despite the fixed Cardiac PET/CT scanners at Carient Heart & Vascular's Manassas and Vienna locations being situated within a 60-minute driving distance for certain patients in the Planning District, a significant underserved area within the district persists. The proposed establishment of a Cardiac PET/CT facility at AHV Springfield holds the promise of not only enhancing access to the central regions of the Planning District but also offering more advanced Cardiac PET/CT technology compared to a standalone Cardiac PET. As expounded upon in Section II.C.3, AHV Springfield enjoys convenient accessibility via Virginia state highways and public transportation. Furthermore, historical approvals of COPN applications have demonstrated a willingness to grant approvals that facilitate swifter access to additional planning districts, even when driving standards are met[9].

In essence, the proposed initiative seeks to bridge the gap in cardiac imaging services within the underserved regions of Planning District 8. By introducing state-of-the-art Cardiac PET/CT technology and streamlining access to advanced cardiac diagnostics, this undertaking will markedly enhance patient care, reduce the need for invasive procedures, and tangibly contribute to better health outcomes for the population served by AHV Springfield.

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 as this facility is an outpatient facility.

B. No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such health planning district.

[9] DCOPN Staff Report, COPN Request No. VA-8699 Cardiology Associates of Fredericksburg, Request to Establish a Specialized Center for PET/CT Imaging, approved via COPN No. 04844 As the commissioner has previously found, the presence of a PET scanner in the district does not preclude approval of this COPN for a cardiac PET/CT scanner. There, as here, the PET/CT scanner was dedicated exclusively for cardiac disease management. More specifically, the commissioner found that: "Cardiac Pet/CT represents a significant new technological approach to addressing cardiac disease and is not presently accessible in PD 15."

Note: For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as one PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as individual PET procedures and CT procedures respectively, unless those images are made concurrently.

Using the Inventory of Equipment and Services data from the DCOPN requested on 08/16/2023, the two Cardiac PET/CT labs in Planning District 8 are exclusively operated by Carient Heart & Vascular, situated approximately 37-43 minutes away from AHV Springfield's location in Manassas, and 23 minutes away from the Vienna location. A third scanner at Virginia Heart, which is 14 minutes away from AHV Springfield, remains unknown if they have initiated their program. A total of seven scanners (two mobile scanners and five fixed scanners) are used in the Planning District for non-cardiac purposes. However, these remaining scanners are not suitable for performing Cardiac PET/CT scans to detect coronary artery disease. The proposed addition of Cardiac PET/CT at AHV Springfield will not lead to any reduction in other types of PET scanning within the district, as the facility will solely utilize the PET/CT for cardiac purposes. Presently, this planning district lacks wide access to state-of-the-art technology of this nature.

AHV Springfield intends to adhere to the Appropriate Use Criteria (AUC) for cardiac radionuclide imaging (2009) and PET myocardial perfusion imaging (2020). If approved, the facility anticipates conducting an average of 1,006 scans per year based on these criteria.

Within the Planning District, the AHV Springfield campus does not foresee a decline in the utilization of existing mobile PET and PET CT scanners, primarily employed for noncardiac imaging. Most referrals for PET CT scans performed at the facility will come from the clinic's own physicians. Additionally, referrals will be received from external cardiac physicians situated in the campus area but not affiliated with AHV.

AHV Springfield anticipates that the Cardiac PET/CT scanner will be fully utilized. In 2023, the facility is projected to carry out 1,006 SPECT scans, equivalent to around 84 patient scans per month. As per the above-mentioned AUCs, it's expected that 55% of these patients will meet the qualifications for Cardiac PET/CT based solely on Medicare and Aetna[10] criteria. The remaining patients will meet the criteria based on their insurance plans in accordance with the aforementioned AUCs. The shorter acquisition time of this test will also allow AHV to reduce radiation exposure to patients and minimize the time patients spend at the office.

[10] Aetna Medical Policy 0071 on Positron Emission Tomography
https://www.aetna.com/cpb/medical/data/1_99/0071.html

Most fixed PET sites within Virginia's Planning Districts have not achieved the utilization rates of 6,000[11] procedures outlined by the SMFP. DCOPN has recommended in multiple cases that the Commissioner disregard the PET SMFP utilization provisions due to their outdated and unattainable nature, as they do not accurately quantify the actual need. Currently, only one provider in Planning District 8 offers Cardiac PET, with no providers capable of providing Cardiac PET/CT. Upon approval, AHV's Springfield campus would become the sole provider of fixed Cardiac PET/CT services in this Planning District. The facility is expected to operate at full capacity in its second year of operation.

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

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

Not applicable.

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

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

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

Statutory Authority
§ 32.1-102.2 of the Code of Virginia.

Not applicable.

12VAC5-230-240. Staffing.

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

[11] Commissioner Decision re: COPN Request No. VA-8537, PET of Reston (Feb. 15, 2021) (approving a fixed PET/CT scanner in PD 8); Commissioner Decision re: COPN Request No. VA-8508, Children's Hospital of .the King's Daughters (July 20, 2020) (approving a fixed PET/CT scanner in PD 20); Commissioner's Decision re: COPN Request No. VA-8510, HCA Henrico Doctors' Hospital (January 19, 2021) (approving a fixed PET/CT scanner in PD 15). Despite recognizing 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, all of the PET/CT applications were approved.

Statutory Authority
§ 32.1-102.2 of the Code of Virginia.

The administration of the proposed fixed Cardiac PET/CT service will be under the supervision of qualified physicians with the necessary training and licensure. Dr. Azita Moalemi will assume the role of Nuclear Medicine Director for the Cardiac PET/CT service. Dr. Moalemi, along with other cardiologists at AHV, possesses specialized training in the delivery and interpretation of Cardiac PET/CT.

– End of State Medical Facilities Plan Analysis –

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.

Considering that 60% of our patient population comprises women, the current standard of care, which involves Cardiac SPECT, frequently yields inconclusive outcomes. Breast attenuation typically results in a fixed defect, and in cases of larger breasts, positioning differences between rest and stress images can lead to a reversible defect. A 2006 study disclosed that the positioning of the left breast differed between the two studies, with the stress images covering more of the heart due to breast placement, possibly leading to a misleading reversible defect. Additionally, the study highlighted quantitative analysis disparities between rest and stress scans, emphasizing the risk of misinterpreting anterior wall ischemia. Maintaining identical patient positioning for rest and stress imaging is crucial,[12] which becomes challenging as patients need to move multiple times during a Cardiac SPECT procedure. Due to this fact, Amelia Heart does not perform as many Cardiac SPECT's as other similar practices.

Given these challenges, Cardiac PET/CT emerges as the preferable alternative for women. This is attributed to the fact that patients remain in the same position for both rest and stress images, thus mitigating the issues associated with varied positioning during the procedure.

As detailed in Sections IV.A and IV.E of this application, the proposed project aims to grant patients access to superior cardiac imaging services within the Planning District. This initiative is intended to ensure such access without diminishing the utilization of the current PET/CT system or impeding other providers' capacity to deliver non-cardiac related services within the District.

G. Coordination and Affiliation with Other Facilities.

[12] Artifacts and Pitfalls in Myocardial Perfusion Imaging Steven Burrell and Anita MacDonald Journal of Nuclear Medicine Technology December 2006, 34 (4) 193-211.
https://tech.snmjournals.org/content/34/4/193

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

Not applicable.

H. Attach copies of the following documents:

1. A map of the service area indicating:

    a. Location of proposed project.

        See Attachment IV.H.1 Location

    b. Location of other existing medical facilities (by name, type (hospital, nursing home, outpatient clinic, etc.) and number of beds in each inpatient facility).

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.

    See Attachment IV.H.2 LOE (3)

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

    See Attachment IV.H.3 Letter of Notice (7)

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.

Not applicable.

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 _____ No

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

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	$ **120,000.00**
2.	Cost of labor	$ **50,600.00**
3.	Equipment included in construction contract	$ **35,000.00**
4.	Builder's overhead	$ **18,700.00**
5.	Builder's profit	$ **18,700.00**
6.	Allocation for contingencies	$ **20,000.00**
7.	Sub-total (add lines 1 thru 6)	$ **263,000.00**

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

8.	a.	**Equipment Rentral Agreement with CDL of $11,214.29 per month**	$ **942,000.00**
	b.		$ **0**
	c.		$ **0**
	d.		$ **0**
	e.		$ **0**

9. Sub-total (add lines 8a thru 8e) $ **942,000.00**

Part III – Site Acquisition Costs

10. Full purchase price $ **0**
11. For sites with standing structures $ **0**
    a. purchase price allocable to structures $ **0**
    b. purchase price allocable to land $ **0**
12. Closing costs $ **0**
13. If leasehold, lease expense for the entire term of the initial lease $ **218,105.10**
14. Additional expenses paid or accrued: $ **0**
    a. _____ $ **0**
    b. _____ $ **0**
    c. _____ $ **0**
15. Sub-total (add lines 10 thru 14c) $ **$218,105.10**

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: $ **0**
    a. _____ $ **0**
    b. _____ $ **0**
21. Accessory structures $ **0**
22. Demolition costs $ **0**
23. Sub-total (add lines 16 thru 22) $ **0.00**

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 $ **8,000.00**
30. Architect's supervision fee $ **2,000.00**

31.	Engineering fees	$ **8,500.00**
32.	Consultant's fees	$ **0**
33.	Sub-total (add lines 29 thru 32)	$ **18,500.00**

Part VII – Other Consultant Fees (List each separately)

34.	a. _____	$ **0**
	b. _____	$ **0**
	c. _____	$ **0**
35.	Sub-total (add lines 34a thru 34c)	$ **0**

Part VIII – Taxes During Construction

36.	Property taxes during construction	$ **0**
37.	List other taxes:	
	a. _____	$ **0**
	b. _____	$ **0**
38.	Sub-total (add lines 36 thru 37b)	$ **0**

Part IX-A – HUD Section 232 Financing

39.	Estimated construction time(in months)	**0**
40.	Dollar amount of construction loan	$ **0**
41.	Construction loan interest rate	**0 %**
42.	Estimated construction loan interest costs	$ **0**
43.	Term of financing (in years)	**0**
44.	Interest rate on permanent loan	**0 %**
45.	FHA mortgage insurance premium	$ **0**
46.	FHA mortgage fees	$ **0**
47.	Financing fees	$ **0**
48.	Placement fees	$ **0**
49.	AMPO (non-profit only)	$ **0**
50.	Title and recording fees	$ **0**
51.	Legal fees	$ **0**
52.	Total interest expense on permanent mortgage loan	$ **0**
53.	Sub-total Part IX-A HUD Section 232 Financing (add lines 42, 45, 46, 47, 48, 49, 50 and 51)	$ **0**

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

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

_____

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

55. Estimated construction time (in months) _____
56. Dollar amount of construction loan $ **0**
57. Construction loan interest rate **0** %
58. Estimated construction loan interest cost $ **0**
59. Nature of bond placement (direct, underwriter, if other, specify)

_____

60. Will bonds be issued prior to the beginning of construction? _____ Yes _____ No
61. If the answer to question 60 is yes, how long before (in months)? _____
62. Dollar amount of bonds expected to be sold prior to the beginning of construction $ **0**
63. Will principal and interest be paid during construction or only interest? $ **0**
64. Bond interest expense prior to the beginning of construction (in dollars) $ **0**
65. How many months after construction begins will last bond be sold? $ **0**
66. Bond interest expense during construction $ **0**
67. What percent of total construction will be financed from bond issue? $ **0**
68. Expected bond interest rate **0** %
69. Anticipated term of bond issued (in years) **0**
70. Anticipated bond discount (in dollars) $ **0**
71. Legal costs $ **0**
72. Printing costs $ **0**
73. Placement fee $ **0**
74. Feasibility study $ **0**
75. Insurance $ **0**
76. Title and recording fees $ **0**
77. Other fees (list each separately) $ **0**
    a. _____ $ **0**
    b. _____ $ **0**
    c. _____ $ **0**
78. Sinking fund reserve account (Debt Service Reserve) $ **0**
79. Total bond interest expenses (in dollars) $ **0**

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) **0**
82. Dollar amount of construction loan $ **0**
83. Construction loan interest rate **0** %
84. Estimated construction loan interest cost (in dollars) $ **0**
85. Term of long term financing (in years) **0**
86. Interest rate on long term loan **0** %
87. Anticipated mortgage discount (in dollars) $ **0**
88. Feasibility study $ **0**
89. Finder's fee $ **0**
90. Legal fees $ **0**
91. Insurance $ **0**
92. Other fees (list each separately) $ **0**
    _____ $ **0**
93. _____ $ **0**
94. Total permanent mortgage loan interest expense (in dollars) $ **0**
95. Sub-total Part IX_C (add lines 84 & 88 thru 93) $ **0**

Financial Data Summary Sheet

96.	Sub-total Part I	Direct Construction Cost (line 7)	$ **263,000.00**
97.	Sub-total Part II	Equipment not included in construction contract (line 9)	$ **942,000.00**
98.	Sub-total Part III	Site Acquisition Costs (line 15)	$ **218,105.10**
99.	Sub-total Part IV	Site Preparation Cost (line 23)	$ **0**
100.	Sub-total Part V	Off-Site Costs (line 28)	$ **0**
101.	Sub-total Part VI	Architectural and Engineering fees (line 33)	$ **18,500.00**
102.	Sub-total Part VII	Other Consultant fees (line 35)	$ **0**
103.	Sub-total Part VIII	Taxes During Construction (line 38)	$ **0**
104.	Sub-total Part IX-A	HUD-232 Financing (line 53)	$ **0**
105.	Sub-total Part IX-B	Industrial Development Authority Revenue & General Revenue Bond Financing (line 80)	$ **0**
106.	Sub-total Part IX-C	Conventional Loan Financing (line 95)	$ **0**
107.	TOTAL CAPITAL COST (lines 96 thru 106)		$ **0**
108.	Percent of total capital costs to be financed		**0 %**

109. Dollar amount of long term mortgage (line 107 x 108) $ **0**

110. Total Interest Cost on Long Term Financing $ **0**

a. HUD-232 Financing (line 53) $ **0**

b. Industrial Development Authority Revenue & General Revenue Bond Financing (line 79) $ **0**

c. Conventional Loan Financing (line 94) $ **0**

111. Anticipated Bond discount $ **0**

a. HUD-232 Financing (line 53) $ **0**

b. Industrial Development Authority Revenue & General Revenue Bond Financing (line 70) $ **0**

c. Conventional Loan Financing (line 87) $ **0**

112. TOTAL CAPITAL AND FINANCING COST (ADD LINES 107, 110a, b or c AND 111a, b or c) $ **1,441,605.10**

D. 1. Estimated costs for new construction (excluding site acquisition costs) $ **0**

2. Estimated costs of modernization and renovation (excluding site acquisition costs) $ **0**

E. Anticipated Sources of Funds for Proposed Project — Amount

1. Public Campaign $ **0**
2. Bond Issue (Specify Type) _____ $ **0**
3. Commercial Loans $ **0**
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) _____ $ **0**

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.

AHV will not require third-party financing for the execution of the proposed project. A service agreement has been established between AHV and CDL Nuclear Technologies, outlining the payment of capital expenditures, including facility renovations, throughout the agreement's term, provided they meet the criteria of capital expenditures. Utilizing operating capital revenues, AHV

intends to fulfill the lease terms and meet lease obligations as stipulated in the agreement.

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.

As elaborated in Section V.F. earlier, the services agreement established with CDL will enable AHV to operate the proposed project without the need for a significant upfront capital investment. Therefore, AHV foresees no negative impact on the cost of providing care to its patients.

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.

   AHV has not undergone an audit within the last two years. However, for reference, the 2021 and 2022 balance sheet and income statement have been submitted as Attachment V.H.2 Balance Sheet and Income Statement.

   See Attachment V.H. 2 Balance Sheet and Income 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.

MD Signature of Authorizing Officer	Amelia Heart & Vascular Center Address – Line 1
Azita Miakmi, MD Type/Print Name of Authorizing Officer	6136 Brandon Ave Address – Line 2
President, Amelia Heart and Vascular Center Title of Authorizing Officer	Springfield, VA 22150 City/State/Zip
7034473749 Telephone	9/29/2023 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.**

AMELIA HEART
& VASCULAR CENTER

PET/CT MPI Pro Forma

Medicare Locality - Virginia

Assumed variables		
Monthly Volume		100
Scanning days/mo		20
PET/CT Equipment Lease/mo	$	13,000.00
Rb82 isotope per dose	$	291.88
LexiScan	$	62.28
Disposables/pt	$	25.00
Expected growth/yr		5.00%

2023 Medicare (Part B) PET/CT Reimbursement		
78431 - PET/CT Perfusion	$	2,337.64
93015 - Stress Test	$	70.48
A9555 - Rb-82 Isotope (2 doses)	$	583.76
78434 - Coronary Flow Reserve ("CRF")	$	29.76
J2785 - LexiScan (4 doses)	$	249.12
Total reimbursement per exam	$	3,270.76
Total reimbursement after isotope cost	**$**	**2,687.00**

Customer Revenue (PET/CT)		**Year 1**		**Year 2**		**Year 3**		**Year 4**		**Year 5**
Monthly Volume		100.0		105.0		110.3		115.8		121.6
Annual volume		1200.0		1260.0		1323.0		1389.2		1458.6
Net reimbursement per pt after isotope cost	$	2,687.00	$	2,687.00	$	2,687.00	$	2,687.00	$	2,687.00
Annual revenue after Rb82 isotope cost	$	3,224,400.00	$	3,385,620.00	$	3,554,901.00	$	3,732,646.05	$	3,919,278.35

Operating Expenses (PET/CT)										
Yearly equipment lease w/ maintenance	$	207,000.00	$	207,000.00	$	207,000.00	$	207,000.00	$	207,000.00
Registered Nurse	$	95,000.00	$	98,800.00	$	102,752.00	$	106,862.08	$	111,136.56
Technologist (yearly)	$	96,000.00	$	99,840.00	$	103,833.60	$	107,986.94	$	112,306.42
Disposables (yearly)	$	74,736.00	$	78,472.80	$	82,396.44	$	86,516.26	$	90,842.08
Facility lease (PET lab only)	$	21,932.07	$	22,372.48	$	22,821.76	$	23,279.36	$	23,745.28
Utilities (PET lab only)	$	1,614.02	$	1,694.72	$	1,779.45	$	1,868.43	$	1,961.85
Other shared employee costs	$	215,000.00	$	221,450.00	$	228,093.50	$	234,936.31	$	241,984.39
Practice overhead	$	548,148.00	$	575,555.40	$	604,333.17	$	634,549.83	$	666,277.32
Charitable contributions (3.5% allocation)	$	112,854.00	$	118,496.70	$	124,421.54	$	130,642.61	$	137,174.74
Insurance	$	6,500.00	$	1,800.00	$	1,800.00	$	1,800.00	$	1,800.00
Licensure/Accreditation	$	2,000.00	$	2,000.00	$	2,000.00	$	2,000.00	$	2,000.00
Stress agent (Lexiscan)	$	298,944.00	$	313,891.20	$	329,585.76	$	346,065.05	$	363,368.30
Total operating expenses / year	$	1,679,728.08	$	1,741,373.30	$	1,810,817.22	$	1,883,506.86	$	1,959,596.95
Estimated NET annual profit (PET/CT)	$	1,544,671.92	$	1,644,246.70	$	1,744,083.78	$	1,849,139.19	$	1,959,681.40

*DISCLAIMER: This pro forma is based on current (CY 2023) Medicare rates and may or may not be an accurate reflection of the actual reimbursement received from other insurance providers or future CY reimbursements.