



Application for a Certificate of Public Need

to

**Establish Cardiac PET/CT at
Cardiac Care Associates, P.C.**

**COPN Request No. VA-8754
Reston, VA
Planning District 8**

April 1, 2024

SECTION I

FACILITY ORGANIZATION AND IDENTIFICATION

A. **Cardiac Care Associates, P.C.**

Official Name of Facility

1830 Town Center Drive, Suite 402

Address

Reston**VA****20190**

City

State

Zip

(703) 481-9191

Telephone

B. **Cardiac Care Associates, P.C.**

Legal Name of Applicant

1830 Town Center Drive, Suite 405

Address

Reston**VA****20190**

City

State

Zip

C. Chief Administrative Officer

Young Park, MD

Name

1830 Town Center Drive, Suite 405

Address

Reston**VA****20190**

City

State

Zip

(410) 963-1435

Telephone

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

Sarah Oliver

Name

1830 Town Center Drive, Suite 405

Address

Reston**VA****20190**

City

State

Zip

(571) 271-7496

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

<u>Owner of the Facility</u> (Check one)	<u>Proprietary</u>	<u>Operator of Facility</u> (Check one)
(1) _____	(1) Individual	(1) _____
(2) <u>X</u>	(2) Partnership-attach copy of Partnership Agreement and receipt showing that agreement has been recorded	(2) _____
(3) _____	(3) Corporate attach copy of Articles of Incorporation and 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

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) <u>X</u>	Leasehold interest for not less than <u>7</u> 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. Virginia SCC Entity Information

(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. Virginia SCC Entity Information

2. A list of the officers of the corporation.

See Attachment I.G. Virginia SCC Entity Information

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

See Attachment I.G. Virginia SCC Entity Information

(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: 0.85 acres
2. Located in Reston Fairfax Planning District 8
City / County / Planning District
3. Address or directions 1830 Town Center Drive, Suite 402
Reston, VA 20190

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.

Cardiac Care Associates, hereinafter referred to as CCA, is actively pursuing the addition of a Cardiac PET/CT system to enhance their current facility as part of a long-range strategy to deliver superior cardiac care. With a commitment to improving health and clinical outcomes within the community, CCA provides a comprehensive suite of cardiac care services, incorporating advanced imaging technology to detect and address Coronary Artery Disease (CAD) at an early stage.

For the past 38 years, CCA has been dedicated to serving its community, leveraging the expertise of its seven physicians and two advanced practice providers who undergo extensive training in a broad spectrum of heart and cardiovascular conditions. The specialization areas include Cardiovascular Diseases, Interventional Cardiology, Peripheral Vascular Diseases, and Sleep

Medicine. Since its establishment, CCA has expanded from its original office in Reston to four additional locations catering to the broader Fairfax and Loudoun County areas. This expansion has granted the region access to innovative services and treatments for the care and management of coronary artery disease. Furthermore, the office is set to bring on board two additional physicians in the fall as part of its continued growth.

With the incorporation of Cardiac PET/CT at CCA, the standard of care and quality of care in the region will experience a notable improvement, offering patients within the Planning District access to high-quality and more readily available imaging. The utilization of cardiac PET/CT will enable patients to benefit from a preferred method for imaging myocardial perfusion, aligning with recommended practices by CMS¹, ASNC and SNMMI².

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.

CCA is putting forth a proposal to install a Siemens Biograph Horizon PET/CT system at their office, situated at 1830 Town Center Drive Suite 402, Reston, VA 20190. The system is set to be leased from CDL Nuclear Technologies, LLC, a nationwide provider specializing in cardiac imaging services.

The cardiac PET/CT lab will comprise a lead-shielded camera room and an adjoining control room, where Certified Nuclear Medicine Technologists (CNMTs) will operate the camera and process images. These rooms will be constructed utilizing existing square footage within the CCA office. Other shared spaces for the cardiac PET/CT lab include a hot lab, patient waiting areas, and restrooms. The integration of the cardiac PET/CT lab is carefully planned to ensure an efficient workflow for both patients and staff, maintaining a comfortable and safe environment throughout the office.

The incorporation of cardiac PET/CT into CCA's cardiovascular service line aligns with the practice's mission to deliver high-quality cardiac care to the residents of Northern Virginia. Cardiac PET/CT serves as a valuable tool for the early and precise detection of coronary artery disease (CAD), particularly in individuals unable to exercise or with a high BMI. The demand for such a test is on the rise, with an increasing number of patients who stand to benefit from its capabilities each year.

With the integration of cardiac PET/CT, CCA is strategically positioned to meet the market demand for high-value, low-cost providers. While nuclear

¹ NCD 220.6.1 PET for Perfusion of the Heart. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=292&ncdver=2>

² ASNC and SNMMI Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET <https://www.asnc.org/files/Guidelines%20and%20Quality/ASNCandSNMMIJointPETPositionPaper2016.pdf>

SPECT, a legacy nuclear stress test modality, will continue to be part of CCA's imaging suite, the addition of cardiac PET/CT plays a pivotal role in upholding CCA's dedication to continuous innovation and advancement in diagnostic imaging.

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

CCA is easily accessible by both car and public transportation. The office is conveniently situated right off Fairfax County Parkway (Highway 286), offering convenient access for patients using various modes of transportation.

The Fairfax Connector Service offers transportation via routes 552, and 950, throughout the day, with stops at the Town Center Parkway and Town Center Drive intersection, located just 0.2 miles from the CCA office. Additionally, there is an additional stop (RIBS 3) in front of Reston Hospital Center, providing a very brief walk of about 0.02 miles to the CCA office.

To visually depict the convenience of reaching this facility, please see:

See Attachment II.C.3 Transportation Access

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 CCA offices are situated within an office building that offers abundant on-site parking. The current facilities, encompassing office space, parking, and water/sewage/waste utilities, are well-equipped to seamlessly accommodate the addition of the PET/CT system.

The entire Cardiac PET/CT lab will occupy approximately 800 square feet within the existing CCA office space. CCA plans to reallocate existing square footage within the facility to accommodate the lab.

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.

CCA has entered into a contract with CDL Nuclear Technologies for oversight and consultation in the construction and operation of the Cardiac PET/CT lab. CDL employs a proprietary model to ensure timely and cost-effective sourcing of materials, keeping the project costs within budget and on schedule. A comprehensive mechanical review will be conducted to ensure that HVAC

and electrical components incorporate the latest and most efficient technology. CDL is committed to utilizing locally sourced materials and labor, including drywall, flooring, paint, etc., whenever possible, contributing to better pricing for the project.

- 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.

CCA is situated within an existing medical office building, which is currently equipped with all necessary utilities.

See attachment II.D.4 Utility Receipts

- 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.

In the design of the Cardiac PET/CT suite, a primary consideration is the minimal service clearances around each camera. The dimensions of the lab are determined by these clearances and the arrangement of ancillary equipment. A PET/CT camera necessitates continuous 24/7 HVAC and 480V 3-phase power into the camera room. For more detailed information on facility construction and system requirements, please refer to the attached Planning Guide. The project's buildout plan aims to minimize disruption to the building as much as possible.

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 Drawings

- H. Construction Time Estimates

1. Date of Drawings: Preliminary 06/05/24 Final 06/26/24
2. Date of Construction: Begin 08/01/24 Completion 09/15/24
3. Target Date of Opening: 10/01/2024

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.

Cardiac Care Associates stands as a prominent healthcare provider in the Reston area, delivering a comprehensive spectrum of cardiology services to patients. Our offerings encompass diagnostic testing, treatment, and the effective management of diverse heart conditions. Our team consists of seasoned cardiac physicians, advanced practice providers, nurses, and dedicated healthcare professionals committed to delivering the utmost quality care to each patient. This team also incorporates a sleep medicine physician, recognizing the impact of sleep health on cardiac well-being.³

At present, CCA provides a diverse array of non-invasive and invasive diagnostic tests, encompassing electrocardiograms (ECG), stress tests, echocardiograms, sleep studies, and cardiac catheterization procedures to name a few. These tests serve the purpose of identifying and assessing various heart conditions, including arrhythmias, heart disease, and valve problems. The dedicated team at CCA not only conducts thorough diagnostic assessments but also formulates comprehensive treatment and management plans for patients with heart conditions. This includes medication management and lifestyle counseling to ensure holistic care.

The introduction of a cardiac PET/CT scanner at CCA will enhance the provision of advanced imaging services to patients with known or suspected coronary artery disease (CAD). This cutting-edge technology empowers the cardiology team to capture detailed images of the heart, facilitating earlier and more accurate identification and diagnosis of heart conditions. Cardiac PET/CT imaging will also furnish the team with crucial insights into the extent and severity of heart disease, allowing for the development of more effective and tailored treatment plans for patients.

Beyond its diagnostic and treatment offerings, CCA is dedicated to delivering quality patient-centered care. The team invests time in understanding each patient and their unique needs, collaborating closely to formulate personalized treatment plans. The incorporation of cardiac PET/CT imaging further reinforces CCA's commitment to offering high-quality, patient-centered care to individuals dealing with heart disease.

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

The medical providers at CCA hold admitting privileges at four local community hospitals. In the event that patients require acute care, they can be seamlessly

³ Sleep Deprivation Is Associated With Increased Risk for Hypertensive Heart Disease: A Nationwide Population-Based Cohort Study <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9879308/>

transferred to the various hospitals, along with all necessary medical records to ensure continuity of care. This office is dedicated to serving as an advocate for patients' needs and is committed to providing reliable support to their primary care physicians or any additional members of the medical care team.

The introduction of Cardiac PET/CT will play a crucial role in the robust care continuum established at CCA. Patients undergoing a PET/CT stress test will receive immediate results from the interpreting physician. These test results will guide decisions on whether the patient may require treatment within the CCA facility, administered by our qualified staff.

C. What procedures are utilized in quality care assessment?

At the heart of CCA's operational principles is a commitment to quality patient care. The current SPECT modality at CCA has received accreditation from the Intersocietal Accreditation Commission (IAC), and the same accreditation process will be pursued for the PET/CT scanner. The Intersocietal Accreditation Commission (IAC) is an organization responsible for accrediting and certifying imaging facilities and hospitals that specialize in nuclear cardiology, nuclear medicine, and PET/CT. The IAC's role is crucial in promoting high-quality imaging and ensuring patient safety. To maintain accreditation, CCA will adhere to IAC guidelines, engaging in ongoing quality assurance and performance improvement. The CCA Nuclear laboratory has consistently achieved certification from ICANL, the VA Radiation Agency, and the Nuclear Regulatory Commission on an annual basis.

CCA is committed to collaborating with CDL Nuclear Technologies to ensure that all images adhere to the standards set by the IAC, and the equipment is meticulously maintained. Within the purview of CCA's internal Medical Director's responsibilities, regular assessments will be conducted for all physicians, staff, and technologists to ensure they maintain qualifications in their respective roles. With CDL's support, CCA will establish policies and procedures pertaining to quality control testing.

CCA has implemented appropriate use criteria, coupled with policies and procedures governing quality control testing. The paramount focus at CCA is to deliver high-quality medical care to every patient. Moreover, CCA's nuclear technologists, in addition to being NMTCB and/or AART certified, are mandated to undergo training and certification on the Bracco infusion system, which generates the radioisotope utilized for the cardiac PET/CT test.

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 personnel required for this project will include a Certified Nuclear Medicine/CT Technologist. There is no need for additional external staffing resources, as all staffing requirements will be fulfilled using existing resources within the office.

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 Radiological Services			
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)			
Cardiac Monitoring	X		

F. Program

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

_____ Yes (Give name of hospital) _____
 _____ **X** No

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

_____ Yes (Give name of hospital) _____
 _____ **X** 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) _____
 _____ No

CCA employs Athena Health for Electronic Medical Records (EMR) storage. Cardiac PET/CT images and final reports from interpreting physicians are promptly uploaded into the EMR. Immediate sharing of all documentation with inpatient medical facilities is facilitated through facsimile. Ongoing communication regarding admitted patients is consistently provided to the following facilities by our practice:

Reston Hospital Center
Inova Loudoun Hospital
Inova Fairfax Hospital
Inova Fair Oaks Hospital

4. Outpatient services are (will be) available from 9:00 a.m. to 5:00 p.m.
5 (five) days of the week.

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

X Yes (Attach clinic schedule list)

 No

Location Times	Monday	Tuesday	Wednesday	Thursday	Friday
09:00 a.m.					
10:00 a.m.					
11:00 a.m.					
12:00 p.m.					
1:00 p.m.	Emergency Slot	Emergency Slot	Emergency Slot	Emergency Slot	Emergency Slot
2:00 p.m.					
3:00 p.m.					
4:00 p.m.					
5:00 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.

CCA may impose restrictions or limitations on the scope of services, except in cases where there are clinical indications supporting the necessity of the test. Clinical limitations include: (1) patient size, if they cannot fit in the camera FOV, (2) unstable angina, (3) uncontrolled

systemic hypertension, (4) 2nd and 3rd AV blocks without a pacemaker, and (5) patients who fail to comply with the preparation instructions.

Additionally, CCA actively participates in all major insurance plans and Medicare.

See Attachment III.F.8 AUC For Cardiac Radionuclide Imaging 2009

See Attachment III.F.8 AUC Cardiac PET 2020

- 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.

Currently, CCA has not performed Cardiac PET/CT, and as a result, there is no historical information available. Within the Planning District, there are six providers offering PET/CT services, but these are primarily for oncologic indications. Based on Staff Report 8626 and COPN No. VA-04825, Carient Heart and Vascular sought to establish a Cardiac PET/CT scanner in Vienna, suggesting that their Manassas location may have reached its capacity. This inference leads to the assumption that Carient might have capacity limitations and primarily serves its own patient base.

The following table presents service volume records for the calendar years of 2021 and 2022.

Procedure / Visit Type	2022	2023	Variance 2023
SPECT & STRESS ECHO	2,514	2,714	7.96%
ECHO	7,218	7,853	8.80%
CARDIAC MONITORING	1,455	1,125	-22.68%
CAROTID ULTRASOUND	1,757	1,997	13.66%
ENDOVENOUS LASER TREATMENT	7	11	57.14%
LOWER EXTREMITY VENOUS	142	80	-43.66%
LOWER EXTREMITY ARTERIAL/ABI	53	65	22.64%

The following table illustrates the amounts of SPECT observed in the calendar years 2022 and 2023, along with an annualized projection for the year 2024.

Procedure / Visit Type	SPECT	% Increase
2022	2,514	
2023	2,699	7%
(Annualized) 2024	2,846	5%

The cardiac PET/CT service is designed for patients who are considered unsuitable for SPECT based on various factors. These include body habitus (BMI 35 or greater), large breasts or implants, prior inconclusive SPECT studies due to attenuation artifacts, known pericardial or pleural effusion, previous mastectomy, and patients with prior SPECT studies that exhibited discrepancies with coronary angiographic findings (either false positive or false negative).

Approximately 52% of the SPECT volumes are expected to transition to Cardiac PET/CT, considering factors such as patient population, payer mix, and appropriateness utilization criteria (AUC). In Year 1, the projection is for approximately seven PET/CT scans per day, resulting in 1,680 cardiac PET/CT studies. Conservative estimates based on regional demographics and standard of care criteria anticipate an annual growth rate of cardiac PET/CT volume at 5% year over year for the next 5 years.

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 Full Time	Vacant Positions	Additional Full Time	Needed TOTAL
Total number of Full-Time staff	43	0		43
Administration-Business Office	15	0		15
Registered Nurses				
Licensed Practical Nurses, Nurses Aides, Orderlies/Attendants	13	0		13
Registered Medical Records Librarian				
Registered Pharmacists				
Laboratory Medical Technologists				
ADA Dieticians				
Radiologic Technologists	9	0		9
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)				
Prior Auth Specialist	2	0		2
Hospital Scheduler	1	0		1
Cardiac Technologist	3	0		3

- 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 personnel will be required.

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

No impact.

- 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 RAM License

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

See Attachment III.K.2 IAC 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 Physician Roster

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

This application is being submitted by Cardiac Care Associates (CCA) to obtain a certificate of public need for the establishment of Cardiac Positron Emission Tomography/Computed Tomography (PET/CT) imaging services at its Reston office in Planning District 8. In the diagnosis and management of coronary artery disease (CAD), PET/CT has emerged as the preferred method for myocardial perfusion imaging (MPI)⁴, additionally guidelines for Chest Pain and Chronic CAD (the ACC/AHA 2021 Chest Pain and 2023 chronic coronary artery disease guidelines) have integrated PET as a preferred approach to SPECT when available in the management of patients with angina without obstructive coronary arteries and in patients with known coronary artery disease with new/changing symptoms. The guidelines specifically mentioned the higher accuracy of PET and the use of quantitative blood flow data to understand the nature of patients' symptoms.⁵ Upholding its commitment to providing the highest-quality, value-based healthcare, CCA adheres to the latest medical standards. The addition of cardiac PET/CT aligns seamlessly with this mission.

Cardiac Care Associates is situated at 1830 Town Center Drive Suite 402, Reston, VA 20190. At CCA, a comprehensive array of outpatient cardiology services is offered, including ultrasound imaging and single photon emission tomography (SPECT) imaging as integral components of the cardiovascular service line. The office is conveniently located off Fairfax County Parkway, also known as Highway 286. The Fairfax Connector Service provides transportation via routes 552, 950, and RIBS 3 throughout the day, with stops at the Town Center Parkway and Town Center Drive intersection, merely 0.2 miles from the CCA office. An additional stop in front of Reston Hospital Center offers a brief walk of about 0.02 miles to the CCA office. The office building provides ample on-site parking, including designated spaces for wheelchairs and vans. CCA is proposing the addition of a Siemens Biograph 16-slice PET/CT exclusively for use in gated cardiac MPI to enhance imaging services. CCA specifically focuses on cardiac studies and does not intend to perform non-cardiac studies, utilizing the CT scan solely to correct for attenuation of the perfusion images taken during the study.

In the Reston office, a cardiac PET/CT lab is planned to be constructed within existing unused space. The lab encompasses approximately 800 square feet, comprising a lead-shielded camera room and a control room, both designed in adherence to Nuclear Regulatory Commission guidelines. This lab will have its own hot lab space, patient prep, and waiting areas within the office. The construction process is expected to have minimal, if any, impact on the rest of the office. Aside from general carpentry considerations, the facility will undergo minor

⁴ ASNC and SNMMI Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET <https://www.asnc.org/files/Guidelines%20and%20Quality/ASNCandSNMMIJointPETPositionPaper2016.pdf>

⁵ How is positron emission tomography/computed tomography imaging revolutionizing cardiac care: Let me count the ways <https://www.sciencedirect.com/science/article/pii/S1071358124004720?via%3Dihub>

electrical and HVAC upgrades to ensure the sensitive instrumentation inside the camera is maintained in proper conditions safely and efficiently. Patient study volumes on the PET/CT system will primarily be derived from existing SPECT volumes in accordance with appropriate use criteria. Importantly, the introduction of the PET/CT will not create capacity issues in the shared office spaces.

Concerning nuclear stress tests, cardiac PET/CT shares similarities with the widely used cardiac SPECT.⁶ Typically, the protocols involve capturing dynamic images of the patient's heart twice: once at rest and again during stress. The interpreting physician analyzes and compares these two images to assess myocardial perfusion and formulate a diagnosis and treatment plan. Historically, SPECT imaging was the primary viable option for this type of study. However, in recent years, cardiac PET has gained prominence as the preferred MPI test over traditional SPECT, owing to its numerous advantages over the latter.

An assessment of the benefits of Cardiac PET/CT would not be complete without acknowledging its downstream economic benefits. Early and accurate detection enables physicians to manage CAD with cost-effective drug therapies and reduces the need for future expensive and invasive procedures. Cardiac PET/CT further mitigates costly downstream treatments via the quantification of myocardial blood flow (MBF), which can obviate the need for interventional angiography.⁷ Analysis has shown that Cardiac PET reduces the overall cost of managing CAD by as much as 30% over traditional SPECT and Computed Tomography Angiography.⁸

Cardiac PET/CT is a more precise, lower-radiation, and quicker test compared to traditional SPECT imaging.⁹ This is mainly because of two unique components of the test: the radiotracer and the sensitive crystal ring detectors. To image an internal organ such as the heart, the organ must emit light that a specialized camera can “see.” Cardiac PET/CT imaging utilizes an electrolyte analogue that is tagged with Rubidium-82 (Rb-82) which, when administered intravenously, is taken up by the heart tissue for a brief period of time. The Rb-82 naturally decays by emitting positrons. These positrons interact with nearby electrons which produces a pair of 511keV photons. The energetic photons escape the body at 180 degrees relative to each other and are simultaneously counted by the ring detector to produce an accurate image of the heart.¹⁰

⁶ ASNC and SNMMI Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET <https://www.asnc.org/files/Guidelines%20and%20Quality/ASNCandSNMMIJointPETPositionPaper2016.pdf>

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>

⁹ 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>

¹⁰ Review: comparison of PET rubidium-82 with conventional SPECT myocardial perfusion imaging <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4204510/>

The capability of PET/CT to utilize two counts for retracing back to a decay event and the short distance of interaction between positron and electron lead to a superior level of spatial resolution, sensitivity, and specificity when compared to SPECT imaging.¹¹

Cardiac PET/CT also provides the advantage of a low radioisotope dosing protocol. The 75-second half-life of Rb82 leads to considerably reduced radiation exposure for the patient compared to Technetium-99 (Tc99), which has a half-life of 6 hours¹² and is commonly used in SPECT imaging. Exposure is further reduced by PET/CT's ability to image in true 3D versus SPECT which can only capture counts across a 2D plane.¹³

The short half-life of Rb82 offers the additional benefit of enabling a brief imaging protocol. The average patient dose of Rb82 fully decays in approximately 10-12 minutes¹⁴ allowing for the acquisition of rest and stress images in rapid succession. The total protocol time for a Cardiac PET/CT study is approximately 45 minutes. In SPECT imaging, patients are often required to wait as long as 2.5 hours between rest and stress image acquisition for the Tc99 dose to decay, resulting in a total study time of up to 3-4 hours.

An evaluation of the benefits of Cardiac PET/CT is incomplete without recognizing its downstream economic advantages. Early and accurate detection empowers physicians to manage Coronary Artery Disease (CAD) with cost-effective drug therapies, thereby diminishing the necessity for future expensive and invasive procedures. Cardiac PET/CT not only provides valuable diagnostic information but also helps mitigate downstream treatments costs through the quantification of myocardial blood flow (MBF), potentially eliminating the need for interventional angiography.¹⁵ Analysis indicates that Cardiac PET reduces the overall cost of managing Coronary Artery Disease (CAD) by as much as 30% compared to traditional SPECT and Computed Tomography Angiography.¹⁶

For 38 years, Cardiac Care Associates has been a stalwart provider of exceptional cardiac services to Northern Virginia. We are delighted to extend our offerings to include Cardiac PET/CT in Reston, following approval from DCOPN. The addition of this advanced imaging modality reinforces our commitment to

¹¹ 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>

¹² Radiopharmaceutical Agents for Myocardial Perfusion Imaging <https://www.ahajournals.org/doi/10.1161/circulationaha.108.778860>

¹³ Motion estimation and correction in SPECT, PET and CT (2021) <https://iopscience.iop.org/article/10.1088/1361-6560/ac093b/pdf>

¹⁴ CardioGen-82 full Prescribing Information https://imaging.bracco.com/sites/braccoimaging.com/files/technica_sheet_pdf/us-en-2020-11-24-spc-cardiogen-82.pdf

¹⁵ 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/>

¹⁶ 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>

delivering quality care and enhancing health outcomes for our community. To fulfill this commitment, CCA intends to implement a charity care requirement specific to this service, further emphasizing our dedication to the well-being of the community we 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 primary service area for CCA is in Northern Virginia. A zip code analysis reveals that 75% of the patients originate from thirty specific zip codes, as identified in Attachment IV.B.1.

See Attachment IV.B.1 Zip Code Analysis

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

The primary source of patient referrals to the cardiac PET/CT clinic will be internal, with CCA physicians being the majority referrers. Patients referred to us commonly exhibit or have a history of conditions such as unstable angina pectoris, post-acute myocardial infarction, sarcoid myocarditis, abnormal electrocardiograms, CAD symptoms in females with large breasts/breast implants, and large body habitus, where traditional testing may result in poor imaging quality. The following is a list of primary diagnosis codes that can be utilized for Cardiac PET/CT, though it is not exhaustive by any means:

<u>ICD-10 Code</u>	<u>ICD-10 Code Description</u>	<u>ICD-10 Code</u>	<u>ICD-10 Code Description</u>
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 presently provides fixed Cardiac PET/CT services in Planning District 8 at two listed locations. Virginia Heart received approval for a fixed cardiac PET; however, it is unclear whether they have commenced 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 of Carient Heart & Vascular's Cardiac PET labs are currently operating at maximum capacity, resulting in no available slots for non-Carient patients seeking cardiac PET services. Furthermore, as outlined in application VA-8626, the initial PET scanner at Carient reached its operational limits, necessitating the acquisition of a second scanner. The approval for this second scanner was granted on February 9, 2023, under COPN No. VA-04825. This expansion underscores the heightened demand for these services.

Although Virginia Heart received approval for a Cardiac PET/CT scanner, it remains uncertain whether they have initiated their program at this juncture.

The landscape of cardiac myocardial perfusion imaging (MPI) has shifted from the antiquated cardiac SPECT to 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.

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

The anticipated growth in demand for Cardiac PET/CT imaging is projected to persist steadily over the next five years. Considering that Carient's existing labs are operating at maximum capacity, the addition of PET/CT services at CCA's Reston office aims to enhance accessibility and alleviate the need for extensive patient commutes, especially for individuals residing in Northern Virginia. This expansion is poised to significantly reduce 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 confronts a significant deficit in accessible cardiac PET/CT services, as both existing fixed Cardiac PET/CT systems are operating at maximum capacity. This initiative aims to tackle an unmet demand within the Planning District, where access to this advanced level of care remains largely insufficient, not only within the district but across the state as well. With traffic congestion and the substantial cost of express lanes, transportation costs become prohibitive for patients.

The current scenario highlights a significant gap in the provision of cardiac care. Currently, the two Cardiac PET/CT labs in Planning District 8 are exclusively operated by Carient Heart & Vascular. CCA Reston is located 40-42 minutes away (or 1 hour and 47 minutes via public transportation) from CCA's Manassas location. This distance poses a geographical barrier to care, especially for individuals such as the elderly who might find extended drives uncomfortable or challenging or patients who rely on public transportation services. This emphasizes the pressing need to introduce more Cardiac PET/CT programs in Planning District 8, aiming to provide advanced technology and foster health equity in an underserved region.

The integration of Cardiac PET/CT is poised to equip CCA physicians with a potent tool for diagnosing complex coronary artery disease with unparalleled precision and localization. This advancement will facilitate the formulation of treatment strategies that may not necessarily involve medical interventions, thereby enhancing patient care outcomes. Beyond benefiting patients, the system will also contribute to reducing radiation exposure for staff. Notably, Technetium, used in cardiac SPECT, has a half-life of 6 hours, while Rubidium, used in cardiac PET, has a half-life of 10 minutes. Additionally, the implementation of Cardiac PET/CT will significantly reduce waiting periods for patients between scans. This transition will shorten the typical three to four-hour duration required for SPECT scans to a mere 30-60 minutes for Cardiac PET/CT scans.

In summary, the implementation of this project in Planning District 8 will eliminate the need for patients to seek care in distant parts of the state, offering a local and accessible solution. This proximity to home will greatly alleviate the travel burden associated with the pursuit of high-quality cardiovascular care, ultimately enhancing patient experience, reducing stress, and 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 accessibility of Cardiac PET or PET/CT services in Planning District 8 is significantly limited. Currently, all other PET/CT services provided within the district are allocated to non-cardiac applications, including oncology, neurology, and urology. Unfortunately, the restricted availability of advanced cardiac imaging options often compels patients to undergo more invasive procedures, like 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 located within a 60-minute driving distance for certain patients in the Planning District, there remains a significant underserved area within the district. The proposed establishment of a Cardiac PET/CT facility at CCA Reston not only promises to enhance access to the central regions of the Planning District but also offers more advanced Cardiac PET/CT technology compared to a standalone Cardiac PET. As detailed in Section II.C.3, CCA Reston enjoys convenient accessibility via Virginia state highways and public transportation. Furthermore, historical approvals of COPN applications have shown a willingness to grant approvals that facilitate swifter access to additional planning districts, even when driving standards are met.¹⁷

Fundamentally, the proposed initiative aims to fill the void in cardiac imaging services within the underserved regions of Planning District 8. Introducing state-of-the-art Cardiac PET/CT technology and streamlining access to advanced cardiac diagnostics, this endeavor will significantly improve patient care, diminish

¹⁷ 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). A recent report by the Commissioner noted that the SMFP was last substantively revised in 2009, leading to many provisions and computational methods that are outdated and less than helpful in gauging whether public need exists for particular services. Commissioner Decision re: COPN Request No. VA-8573, Riverside Smithfield Hospital (Mar. 18, 2022), at 6.

the requirement for invasive procedures, and tangibly contribute to better health outcomes for the population served by CCA Reston.

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.

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.

Utilizing data from the DCOPN Inventory of Equipment and Services from date 04/15/2022 that is on the COPN website, the two Cardiac PET/CT labs in Planning District 8 are solely operated by Carient Heart & Vascular. These labs are situated approximately 40-42 minutes away from CCA Reston's location in Manassas and 22 minutes away from the Vienna location. The status of a third scanner at Virginia Heart remains unknown regarding the initiation of its program. In total, there are seven scanners (one mobile scanner and six fixed scanners) 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 CCA Reston will not result in any reduction in other types of PET scanning within the district, as the facility will exclusively utilize the PET/CT for cardiac purposes. Currently, this planning district lacks widespread access to state-of-the-art technology of this nature.

CCA aims to follow the Appropriate Use Criteria (AUC) for cardiac radionuclide imaging (2009) and PET myocardial perfusion imaging (2020).

Pending approval, the facility projects an average of 1,680 scans per year in accordance with these criteria.

In the Planning District, the CCA Reston campus does not anticipate a decrease in the usage of current mobile PET and PET CT scanners primarily employed for noncardiac imaging. The majority of referrals for PET CT scans conducted at the facility will originate from the clinic's own physicians. Moreover, external cardiac physicians in the campus area, unaffiliated with CCA, will also provide referrals.

CCA Reston anticipates that the Cardiac PET/CT scanner will be fully utilized. In 2024, the facility is projected to carry out 2,846 SPECT scans, equivalent to around 237 patient scans per month. As per the above-mentioned AUCs, it's expected that 52% of these patients will meet the qualifications for Cardiac PET/CT based solely on Medicare and Aetna 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 CCA to reduce radiation exposure to patients and minimize the time patients spend at the office.

Most fixed PET facilities within Virginia's Planning Districts fall short of the utilization rates of 6,000¹⁸ procedures outlined by the SMFP. DCOPN, in multiple instances, has recommended that the Commissioner dismiss the PET SMFP utilization provisions, deeming them outdated and unattainable as they fail to accurately gauge the actual need. Presently, only one provider in Planning District 8 offers Cardiac PET at multiple locations, and no providers are equipped to offer Cardiac PET/CT. Upon approval, CCA's Reston campus would stand as the exclusive provider of fixed Cardiac PET/CT services in this part of the Planning District, with full operational capacity anticipated in its second year.

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.

¹⁸ 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.

- 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.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Cardiac PET/CT services will be overseen by physicians with appropriate training and licensure. Dr. Bhanu Krishnan will serve as the Nuclear Medicine Director for the Cardiac PET/CT service and also serves as the office's Radiation Safety Officer. In addition to other cardiologists at CCA, Dr. Krishnan has received special training in the delivery and interpretation of Cardiac PET/CT.

Additionally, there are two other providers that are also board certified in Nuclear Cardiology.

– 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.

Projected by the United States Census Bureau, by the year 2060, almost one in four Americans will be 65 years or older.¹⁹ The expansion of this demographic underscores the demand for advanced cardiac imaging, given the inherent risk factors associated with cardiovascular disease and aging.²⁰

¹⁹ The U.S. Joins Other Countries With Large Aging Populations
<https://www.census.gov/library/stories/2018/03/graying-america.html>

²⁰ Cardiovascular Risks Associated with Gender and Aging
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616540/pdf/jcdd-06-00019.pdf>

As outlined in Section IV.E. of this proposal, the project aims to offer patients access to high-quality cardiac imaging services within the Planning District without diminishing the utilization of the existing PET/CT system or impacting the ability of other providers to deliver non-cardiac related services within the District

G. Coordination and Affiliation with Other Facilities.

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

Not Applicable.

H. Attach copies of the following documents:

1. A map of the service area indicating:

a. Location of proposed project.

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.

**Letter from Carient Heart and Vascular
Letter from Internal Medicine Associates of Reston
Letter from Reston Ear, Nose and Throat
Letter from Heart & Vascular Specialist
Letter from Loudoun Internal Medicine Associates**

See Attachment IV.H.2 Letters of Endorsement (5)

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

**Letter Sent to Carient Heart and Vascular
Letter Sent to Virginia Hospital Center
Letter Sent to Sentara Northern Virginia Medical Center
Letter Sent to PET of Reston
Letter Sent to Novant Health UVA Cancer Center – Lake Manassas
Letter Sent to Metro Region PET Center
Letter Sent to Kaiser Permanente Woodbridge Imaging Center**

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 **X** _____ 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	\$ <u>150,000.00</u>
2. Cost of labor	\$ <u>85,000.00</u>
3. Equipment included in construction contract	\$ <u>0</u>
4. Builder's overhead	\$ <u>10,000.00</u>
5. Builder's profit	\$ <u>5,000.00</u>
6. Allocation for contingencies	\$ <u>0</u>
7. Sub-total (add lines 1 thru 6)	\$ <u>250,000.00</u>

Part II – Equipment Not Included in Construction Contract (List each separately)

If leasehold, lease expense for the entire term of the initial lease

Equipment Rental Agreement	
8. a. <u>with CDL of \$11,733.33 per month</u>	\$ <u>704,000.00</u>
b. _____	\$ _____
c. _____	\$ _____
d. _____	\$ _____
e. _____	\$ _____

9. Sub-total (add lines 8a thru 8e) \$ 704,000.00

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 \$ 528,971.26

14. Additional expenses paid or accrued: \$ 0

a. _____ \$ 0

b. _____ \$ 0

c. _____ \$ 0

15. Sub-total (add lines 10 thru 14c) \$ 528,971.26

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	\$ <u>8,000.00</u>
32. Consultant's fees	\$ <u>0</u>
33. Sub-total (add lines 29 thru 32)	\$ <u>18,000.00</u>

Part VII – Other Consultant Fees (List each separately)

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

Part VIII – Taxes During Construction

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

Part IX-A – HUD Section 232 Financing

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

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

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

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

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)	\$ <u>250,000.00</u>
97.	Sub-total Part II	Equipment not included in construction contract (line 9)	\$ <u>704,000.00</u>
98.	Sub-total Part III	Site Acquisition Costs (line 15)	\$ <u>528,971.26</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>18,000.00</u>
102.	Sub-total Part VII	Other Consultant fees (line 35)	\$ <u>0</u>
103.	Sub-total Part VIII	Taxes During Construction (line 38)	\$ <u>0</u>
104.	Sub-total Part IX-A	HUD-232 Financing (line 53)	\$ <u>0</u>
105.	Sub-total Part IX-B	Industrial Development Authority Revenue & General Revenue Bond Financing (line 80)	\$ <u>0</u>
106.	Sub-total Part IX-C	Conventional Loan Financing (line 95)	\$ <u>0</u>
107.	TOTAL CAPITAL COST (lines 96 thru 106)		\$ <u>1,500,971.26</u>
108.	Percent of total capital costs to be financed		<u>0</u> %

109.	Dollar amount of long term mortgage (line 107 x 108)	\$ <u>0</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>0</u>
111.	Anticipated Bond discount	\$ <u>0</u>
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>0</u>
D.	1. Estimated costs for new construction (excluding site acquisition costs)	\$ <u>0</u>
	2. Estimated costs of modernization and renovation (excluding site acquisition costs)	\$ <u>0</u>
E.	Anticipated Sources of Funds for Proposed Project	Amount
1.	Public Campaign	\$ <u>0</u>
2.	Bond Issue (Specify Type) _____	\$ <u>0</u>
3.	Commercial Loans	\$ <u>0</u>
4.	Government Loans (Specify Type) _____	\$ <u>0</u>
5.	Grants (Specify Type) _____	\$ <u>0</u>
6.	Bequests	\$ <u>0</u>
7.	Private Foundations	\$ <u>0</u>
8.	Endowment Income	\$ <u>0</u>
9.	Accumulated Reserves	\$ <u>0</u>
10.	Other (Identify) _____	\$ <u>0</u>
F.	Describe in detail the proposed method of financing the proposed project, including the various alternatives considered. Attach any documents which indicate the financial feasibility of the project.	

CCA will not require third-party financing for the execution of the proposed project. A service agreement has been established between CCA 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, CCA

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.

Not Applicable.

- 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.

CCA has not been subject to an audit in the past two years. Nonetheless, for your reference, the balance sheet and Profit and Loss for the years 2022 and 2023 have been submitted as Attachment V.H.2 Balance Sheet and Profit and Loss.

See Attachment V.H. 2 Balance Sheet and Profit and Loss

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.



 Signature of Authorizing Officer

Young Park, MD

 Type/Print Name of Authorizing Officer

Managing Partner

 Title of Authorizing Officer

(410) 963-1435

 Telephone

1830 Town Center Drive

Address – Line 1

Suite 405

Address – Line 2

Reston, VA 20190

City/State/Zip

3/22/2024

Date

Copies of this request should be sent to:

**A. Virginia Department of Health
 Division of Certificate of Public Need
 9960 Mayland Drive – Suite 401
 Henrico, Virginia 23233**

B. The Regional Health Planning Agency if one is currently designated by the Board of Health to serve the area where the project would be located.



PET/CT MPI Pro Forma
Medicare Locality - Washington DC

Assumed variables		2024 Medicare (Part B) PET/CT Reimbursement					
Monthly Volume	140	78431 - PET/CT Perfusion	\$ 2,944.55				
Scanning days/mo	20	93015 - Stress Test	\$ 82.40				
PET/CT Equipment Lease/mo	\$ 11,733.33	A9555 - Rb-82 Isotope (2 doses)	\$ 850.00				
Rb82 isotope per dose	\$ 425.00	78434 - Coronary Flow Reserve ("CRF")	\$ 220.98				
LexiScan	\$ 14.28	J2785 - LexiScan (4 doses)	\$ 57.12				
Disposables/pt	\$ 25.00	Total reimbursement per exam	\$ 4,155.05				
Expected growth/yr	5.00%	Total reimbursement after isotope cost	\$ 3,305.05				

Customer Revenue (PET/CT)	Year 1	Year 2	Year 3	Year 4	Year 5
Monthly Volume	140.0	147.0	154.4	162.1	170.2
Annual volume	1680.0	1764.0	1852.2	1944.8	2042.1
Net reimbursement per pt after isotope co: \$	\$ 3,305.05	\$ 3,305.05	\$ 3,305.05	\$ 3,305.05	\$ 3,305.05
Annual revenue after Rb82 isotope cost	\$ 5,552,484.00	\$ 5,830,108.20	\$ 6,121,613.61	\$ 6,427,694.29	\$ 6,749,079.01

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)	\$ 23,990.40	\$ 25,189.92	\$ 26,449.42	\$ 27,771.89	\$ 29,160.48
Facility lease (PET lab only)	\$ 63,175.99	\$ 63,175.99	\$ 65,071.27	\$ 67,023.41	\$ 69,034.11
Utilities (PET lab only)	\$ 5,166.16	\$ 5,424.47	\$ 5,695.70	\$ 5,980.48	\$ 6,279.50
Other shared employee costs	\$ 215,000.00	\$ 221,450.00	\$ 228,093.50	\$ 234,936.31	\$ 241,984.39
Practice overhead	\$ 943,922.28	\$ 991,118.39	\$ 1,040,674.31	\$ 1,092,708.03	\$ 1,147,343.43
Charitable contributions (3.5% allocation)	\$ 194,336.94	\$ 204,053.79	\$ 214,256.48	\$ 224,969.30	\$ 236,217.77
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)	\$ 95,961.60	\$ 100,759.68	\$ 105,797.66	\$ 111,087.55	\$ 116,641.92
Total operating expenses / year	\$ 1,948,053.37	\$ 2,020,612.24	\$ 2,103,423.94	\$ 2,190,125.98	\$ 2,280,904.60
Estimated NET annual profit (PET/CT)	\$ 3,604,430.63	\$ 3,809,495.96	\$ 4,018,189.67	\$ 4,237,568.31	\$ 4,468,174.41

*DISCLAIMER: This pro forma is based on current (CY 2024) Medicare rates and may or may not be an accurate reflection of the actual reimbursement received from other insurance providers or future CY reimbursements.

