



COMMONWEALTH of VIRGINIA

Karen Shelton, MD
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

TTY 7-1-1 OR
1-800-828-1120

August 20, 2025

Mitesh Amin, MD
445 Charles H. Dimmock Parkway, Suite 100
Colonial Heights, Virginia 23838

RE: COPN No. VA-04949 (COPN Request No. VA-8815)

James River Cardiology, LLC

Henrico County, Virginia

Establish a Center for PET/CT services with one fixed PET/CT scanner limited to cardiology

Dear Dr. Amin:

In accordance with Chapter 4, Article 1.1 of Title 32.1 of the Code of Virginia of 1950 (the Code), as amended, I reviewed the application and all supporting documents submitted by James River Cardiology, LLC to establish a specialized imaging center for the provision of PET/CT with one PET/CT scanner restricted to cardiac imaging at James River Cardiology in Henrico County, Virginia.

As required by Section 32.1-102.3B of the Code, I have considered all factors that must be taken into account in a determination of public need, and I have concluded that **conditional approval** of the request is warranted based on the following findings:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The PET/CT scanner's use will be limited solely to cardiac imaging.
3. The project will improve access to the preferred cardiac imaging modality with numerous benefits over Single Photon Emission Computed Tomography.
4. The project will not adversely affect existing providers of PET/CT services and there is no known opposition.
5. The project is more beneficial than the alternative of the status quo.

6. The capital costs are reasonable.
7. The proposal is wholly feasible in the immediate and long term.

This certificate is valid for the period August 20, 2025 through August 19, 2026. The total authorized capital cost of the project is \$1,335,285.

Please file two copies of the application for a certificate extension with the Department no later than 30 days before the expiration date of the certificate. Part VIII of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations identifies the filing requirements and review procedure for certificate extension requests.

Sincerely,



Karen Shelton, MD
State Health Commissioner

Enclosure

cc: Charis A. Mitchell, Assistant Attorney General, Commonwealth of Virginia
Erik Bodin, Director, Division of Certificate of Public Need
James Jenkins, Acting Director, VDH, Office of Licensure and Certification
Deborah K. Waite, Chief Operating Officer, Virginia Health Information
Elaine Perry, MD, MS, District Director, Henrico Health District

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH

MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED

THIS CERTIFIES THAT James River Cardiology, LLC is authorized to initiate the proposal as described below.

NAME OF FACILITY: James River Cardiology

LOCATION: 8006 Discovery Drive, Suite 130, Richmond, Virginia 23229

OWNERSHIP AND CONTROL: James River Cardiology, LLC

SCOPE OF PROJECT: Establish a specialized imaging center for the provision of PET/CT with one PET/CT scanner, restricted to cardiac imaging, at James River Cardiology in Henrico County, Virginia. Capital costs authorized for this project total \$1,335,285. The project is expected to be completed by December 1, 2025. This certificate is issued with the condition that appears on its reverse.



Pursuant to Chapter 4, Article 1:1 of Title 32.1, Sections 32.1-102.1 through 32.1-102.12 of the Code of Virginia (1950), as amended and the policies and procedures promulgated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial and continuing progress towards implementation of the proposal within twelve (12) months from the date of issuance. A progress report shall be submitted to the State Health Commissioner within twelve (12) months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Commissioner reserves the right not to renew this Certificate in the event the applicant fails to fulfill these conditions. This Certificate is non-transferable and is limited to the location, ownership, control and scope of the project shown herein.

Certificate Number: VA-04949

Date of Issuance: August 20, 2025

Expiration Date: August 19, 2026

Douglas L. Shultz, MD

Karen Shelton, MD, State Health Commissioner

James River Cardiology, LLC will provide PET/CT imaging (restricted to cardiac imaging) to all persons in need of these services, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 15 in an aggregate amount equal to at least 0.9% of James River Cardiology, LLC's gross patient revenue derived from cardiac PET/CT imaging. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. James River Cardiology, LLC will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

James River Cardiology, LLC will provide cardiac PET/CT imaging to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. James River Cardiology, LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

July 21, 2025

COPN Request No. VA-8815

James River Cardiology, LLC

Henrico, Virginia

Establish a Center for PET/CT services with one fixed PET/CT scanner limited to cardiology

Applicant

James River Cardiology, LLC (JRC) is a limited liability company formed under the laws of Delaware in 2010. Although originally formed as a Professional Corporation (P.C.) it was converted to a Limited Liability Company (LLC) in 2023. JRC is a wholly owned subsidiary of Cavalier MSO, LLC d/b/a AlignedCardio. The proposed facility, James River Cardiology, is in Henrico County, Health Planning Region (HPR) IV, Planning District (PD) 15.

Background

A positron emission tomography (PET) scan is an imaging test that can help reveal the metabolic or biochemical function of tissues and organs. The PET scan uses a radioactive drug called a tracer to show both typical and atypical metabolic activity. A PET scan can often detect the atypical metabolism of the tracer in diseases before the disease shows up on other imaging tests, such as computerized tomography (CT) and magnetic resonance imaging (MRI). The tracer is most often injected into a vein in the hand or arm. The tracer will then collect into areas of the body that have higher levels of metabolic or biochemical activity. This often pinpoints the location of the disease. The PET images are typically combined with CT or MRI and are called PET/CT or PET/MRI scans.¹ All but three of the PET units in PD 15 are PET/CT scanners.

Regarding cardiac PET/CT, the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging published a joint position paper in 2016 (Society Joint Position Statement) stating:

The purpose of this joint Society Position Statement is to highlight the attributes that make rest/stress myocardial perfusion PET both **Preferred** and **Recommended** in the era of high value initiatives for appropriate patients. Myocardial perfusion PET image quality, high diagnostic accuracy that is relatively independent of body habitus, ability to accurately risk

¹ <https://www.mayoclinic.org/tests-procedures/pet-scan/about/pac-20385078>

stratify patients with a wide array of clinical presentations, short acquisition times, safety by virtue of low radiation exposure, and its unique ability to quantify myocardial blood flow are all significant and clinically important properties. The properties of myocardial perfusion PET according to the published literature are sufficient to advance recommendations for its use in clinical practice. There are no clinical scenarios where PET should not be considered a preferred test for patients who meet appropriate criteria for a stress imaging test and who require pharmacologic stress.²

According to Virginia Health Information (VHI) there were seven PET scanners in PD 15 in 2023, the latest year for which data are available, four fixed site units and three mobile units. Utilization of the fixed site PET scanners averaged 2,120 per scanner (Table 1). This is 35.3% of the volume standard of 6,000 average procedures per fixed site unit that is set forth in the State Medical Facilities Plan (SMFP).

Table 1. 2023 PET Data, PD 15

Facility Name	Imaging Systems	Procedures	Procedures per Unit	% of SMFP
Fixed Site				
Bon Secours St. Mary's Hospital	1	2,286	2,286	38.1%
Henrico Doctors' Hospital - Forest	1	774	774	12.9%
VCU Medical Center	1	3,179	3,179	53.0%
Virginia Cardiovascular Specialists, PC	1	2,241	2,241	37.4%
PD 15 Total and Average	4	8,480	2,120	35.3%

Source: 2023 VHI

Since the 2023 volumes were submitted by providers, one mobile PET scanner was authorized to convert to a fixed site scanner, one new fixed PET was authorized and one new mobile unit was authorized. There are currently nine PET scanners in PD 15, six fixed and three mobile units. Two of the fixed PET scanners are restricted to cardiac use (Table 2).

² Bateman et.al. *American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET*. Journal of nuclear cardiology (2016): official publication of the American Society of Nuclear Cardiology. <https://pubmed.ncbi.nlm.nih.gov/27528255/> (accessed December 17, 2024).

Table 2. Inventory of Authorized PET Scanners, PD 15

Facility	Total Authorized Scanners	Cardiac Only
Fixed Site		
Bon Secours Imaging Center at Reynolds Crossing	1	0
Henrico Doctors' Hospital - Forest	1	0
Johnston-Willis Hospital ³	1	0
VCU Health System	1	0
Virginia Cardiovascular Specialists	1	1
James River Cardiology - Chesterfield ⁴	1	1
	6	2
Mobile		
Henrico Doctor's Hospital - Parham Doctors' Hospital	1	0
Med-Atlantic	1	0
VCU at Stony Point ⁵	1	0
Source: DCOPN Records	3	0

Proposed Project

JRC proposes to establish a PET/CT service restricted to cardiac studies, by installing one PET/CT scanner at its existing practice at 8006 Discovery Drive, Suite 130, Richmond, Virginia in Henrico County leased from CDL Nuclear Technologies. JRC states that the CT component will serve solely for attenuation correction and will not perform diagnostic CT scans. The cardiac PET/CT lab, including both the camera room and control room will fit into existing unused space. Little renovation is required other than installation of rigorous radiation shielding. Projected capital costs are \$1,335,285 (Table 3). The applicant asserts that no third-party financing is necessary to execute the proposed project as equipment and facility renovations are included in JRC's service agreement with CDL Nuclear Technologies, LLC and facility costs will be paid from operating capital revenues. Should the proposed project be approved, the target date of opening is prior to December 1, 2025.

Table 3. Capital Costs, JRC PET/CT

Direct Construction Costs	\$256,000
Equipment not included in construction costs	\$824,000
Site Acquisition Costs	\$245,285
Architectural and Engineering fees	\$10,000
TOTAL CAPITAL COST	\$1,335,285

Source: COPN Request No. VA-8815

³ COPN No. VA-04756 authorized the conversion of a mobile PET to a fixed PET August 2021, completed April 2024.

⁴ COPN No. VA-04844 authorized this fixed PET scanner in June 2023, completed December 2023.

⁵ COPN No. VA-04875 authorized is mobile PET scanner February 2024, expected complete November 2024.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the “[e]stablishment of a medical care facility described in subsection A.” A medical care facility includes “[a]ny specialized center or clinic or that portion of a physician's office developed for the provision of... positron emission tomographic (PET) scanning...”

Required Considerations -- § 32.1-102.3, of the Code of Virginia

In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable.

- 1. The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.**

PD 15 had a population of over 1.1 million in 2020 and is projected to add nearly 100,000 to its population by 2030. Its projected growth rate of 8.9% by the end of the decade is a higher growth rate than that projected for Virginia's population, 5.8% (Table 4). Henrico County, where the proposed project is located, is projected to grow by 6.7%, less than the growth rate of PD15. Henrico County is projected to add nearly 23,000 to its population between 2020 and 2030 (Table 4).

People aged 65 and older have a higher utilization rate for advanced imaging services than younger individuals,⁶ so they are an important demographic in projects involving PET imaging. The population over age 65 is expected to grow at a higher rate in PD 15 (31.7%) than that of Virginia (26.3%), and this age cohort is projected to grow in Henrico County at 28.9%. Henrico County is projected to add 16,084 people over age 65 between 2020 and 2030 through aging and in-migration (Table 4).

⁶ <https://jamanetwork.com/journals/jama/fullarticle/2749213>

Table 4. PD 15 Population Data

Locality	2020 Population	2030 Projected Population	Projected Growth 2020-2030	Percent Growth 2020-2030	65+ 2020 Population	Projected 65+ 2030 Population	Projected Growth 65+	Percent Growth 65+
Charles City	6,773	6,200	-573	-8.5%	1,776	2,184	408	23.0%
Chesterfield	364,548	406,942	42,394	11.6%	58,200	78,858	20,658	35.5%
Goochland	24,727	27,339	2,612	10.6%	5,721	7,865	2,144	37.5%
Hanover	109,979	118,374	8,395	7.6%	20,688	28,681	7,993	38.6%
Henrico	334,389	356,656	22,267	6.7%	55,596	71,680	16,084	28.9%
New Kent	22,945	27,067	4,122	18.0%	4,405	6,216	1,811	41.1%
Powhatan	30,333	32,152	1,819	6.00%	5,848	8,085	2,237	38.3%
Richmond	226,610	245,437	18,827	8.3%	29,874	36,307	6,433	21.5%
PD 15	1,120,304	1,220,167	99,863	8.9%	182,108	239,876	57,768	31.7%
Virginia	8,631,393	9,129,002	497,609	5.8%	1,395,291	1,762,641	367,350	26.3%

Source: Weldon Cooper Intercensal Estimates

Table 5 shows that PD 15 has a poverty rate just below that of Virginia (10.7%). The poverty rate in Henrico County is lower still at 9%. As to transportation barriers, none is identified. The proposed site is off Forest Avenue, approximately 1.4 miles from the I-64 interchange. The office is 0.1 miles from the Greater Richmond Transit Company (GRTC) bus stop on Route 79. The GRTC also offers a CARE service tailored to patients aged 80 years and older and patients with disabilities. This service provides door-to-door transportation.

Table 5. PD 15 Poverty Rates

Geographic Name	Poverty Rate
Charles City County	12.3%
Chesterfield County	7.6%
Colonial Heights City	13.5%
Goochland County	6.7%
Hanover County	5.2%
Henrico County	9.0%
New Kent County	5.2%
Powhatan County	6.9%
Richmond City	24.5%
PD 15 Totals	10.1%
Virginia	10.7%

Source: Weldon Cooper Census Data

2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following:
 - (i) The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served.

DCOPN received five letters of commitment from physicians of JRC and a letter of support from a referring physician in PD 15. These letters expressed the benefits of cardiac PET/CT over SPECT with its superior diagnostic accuracy, reduced radiation exposure and quicker turnaround times. They assert that the only two PET/CTs in PD 15 with the ability to perform cardiac PET/CT are at capacity, with no availability to accommodate additional cardiac imaging patients. This lack of capacity in advanced cardiac imaging causes significant delays for patients. The letters state that the proposed project will provide access and benefit many patients in the area with or suspected of having coronary artery disease.

Public Hearing

§32.1-102.6B of the Code of Virginia directs DCOPN to hold one public hearing on each application in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8815 is not competing with another project and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held. DCOPN provided notice to the public on May 15, 2025 regarding this project and inviting public comment. The public comment period closed on June 29, 2025. Other than the letters of support referenced above, no members of the public commented. There is no known opposition to the project.

(ii) The availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner.

Initially, in Virginia, PET scanners were envisioned for cardiac imaging and the criteria for their review under COPN reflected that. However, utilization of cardiac PET did not initially advance as expected but PET was found to be a useful tool in neurology and in the treatment and staging of cancers. While some PET scanners in the Commonwealth are used for cardiac, neurologic and cancer imaging, the first PET scanner dedicated to cardiac imaging became operational in PD 15 in 2018 (Virginia Cardiovascular Specialists, PC). The applicant also has one cardiac-only PET/CT scanner in PD 15 already, in Chesterfield County approximately 25 miles/34 minutes from the proposed site.

The two cardiac PET scanners in PD 15 are operated by individual cardiology practices and are used primarily for their own patients. PET/CT is developing into a significant technology for cardiac diagnostics. It is the preferred and recommended modality for myocardial perfusion by the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging.

JRC has 12 board-certified cardiologists and 18 advanced care practitioners across six offices in central Virginia. Its Discovery office at the proposed site saw over 10,000 patient visits in 2024 and projects over 11,000 in 2025, a 9.9% increase. The applicant asserts an inability to refer patients to the two dedicated cardiac PET/CT units in PD 15, including its own JRC cardiac PET/CT in Chesterfield County due to lack of capacity. DCOPN did not identify any reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner. Moreover, the proposed project is a preferable

alternative to the status quo. JRC seeks to offer an emerging technology which provides higher quality, faster imaging and exposes patients to less radiation when compared to Single Photon Emission Computed Tomography (SPECT). PET/CT is becoming the standard of care for cardiac imaging.

As discussed in detail throughout this staff analysis report, cardiac PET/CT imaging offers several important advantages over SPECT. The American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging have issued a joint Society Position Statement “to highlight the attributes that make rest/stress myocardial perfusion PET both Preferred and Recommended in the era of high value initiative for appropriate patients.”⁷ According to this Society Position Statement, “[m]yocardial perfusion PET image quality, high diagnostic accuracy that is relatively independent of body habitus, ability to accurately risk stratify patients with a wide array of clinical presentations, short acquisition times, safety by virtue of low radiation exposure, and its unique ability to quantify myocardial blood flow are all significant and clinically important properties.”⁸

Furthermore, the applicant proposes to use the PET/CT unit to serve its existing patient population. Therefore, DCOPN concludes that the proposed project is unlikely to adversely affect the utilization and efficiency of existing services.

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

Currently there is no organization in HPR IV designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 15. Therefore, this consideration is not applicable to the review of the proposed project.

(iv) Any costs and benefits of the project.

Total projected capital costs for the proposed project are \$1,335,285, funded by operating revenues and a service contract with CDL Nuclear Technologies. The estimated costs are slightly higher than other recently approved projects to establish cardiac PET/CT, but reasonable. For example, COPN No. VA-04590 was issued to Virginia Cardiac Specialists authorizing a capital cost of \$576,719 and COPN No. VA-04844 was issued to JRC in Chesterfield with a capital cost of just over \$1 million.

The applicant has described several benefits to cardiac PET/CT over SPECT based studies. PET/CT based cardiac studies are more accurate than SPECT based studies. The combination of cardiovascular PET with CT provides the patient with the most accurate study, which is significantly better than PET cameras without CT because CT provides a more rapid study with a high-quality attenuation map. The study with CT is several minutes shorter. Shorter scan times

⁷ Bateman et.al. *American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET*. Journal of nuclear cardiology (2016): official publication of the American Society of Nuclear Cardiology. <https://pubmed.ncbi.nlm.nih.gov/27528255/> (accessed March 5, 2024).

⁸ Id.

result in less motion and improved diagnostic accuracy, thereby avoiding unnecessary cardiac catheterizations. Cardiac PET/CT scans also expose patients to less radiation than SPECT.

The addition of a cardiac PET/CT by JRC is unlikely to produce a reduction in utilization of existing cardiac PET/CT services within PD 15. Given the strong and growing demand for cardiac PET/CT services and limited availability, the proposed project is beneficial to the population, particularly JRC's patient base. Other providers of cardiac PET/CT serve their own distinct patient population and given the population and relatively high growth in PD 15, no reduction in services is anticipated.

(v) The financial accessibility of the project to the residents of the area to be served, including indigent residents.

JRC states that it participates in all major insurance plans and Medicare, ensuring broad accessibility to its patients. The applicant did not include a charity care breakout in its proforma (**Table 7**). In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care based on gross patient revenues derived from cardiac PET/CT imaging that is no less than the equivalent average for charity care contributions in HPR IV of 0.9%. Pursuant to Code of Virginia language any COPN issued for this project will also be conditioned on the applicant's agreement to accept patients who are the recipients of Medicare and Medicaid.

Table 6. HPR IV Charity Care Contributions: 2023

HPR IV	2023 at 200%		
	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Inpatient Hospitals			
Encompass Health Rehab Hosp of Petersburg	\$31,902,584	\$1,128,654	3.5%
Bon Secours Southern Virginia Regional Medical Center	\$250,713,603	\$5,572,556	2.2%
Sentara Halifax Regional Hospital	\$341,148,455	\$6,200,157	1.8%
Bon Secours St. Francis Medical Center	\$1,479,291,082	\$24,657,029	1.7%
Bon Secours Richmond Community Hospital	\$1,241,191,742	\$16,711,399	1.3%
Bon Secours St. Mary's Hospital	\$2,762,282,294	\$34,017,353	1.2%
Sheltering Arms Institute	\$186,535,950	\$2,177,014	1.2%
Bon Secours Southside Regional Medical Center	\$2,565,858,345	\$28,890,515	1.1%
CJW Medical Center HCA	\$10,527,250,615	\$100,362,996	1.0%
VCU Health System	\$8,145,377,150	\$66,362,509	0.8%
TriCities Hospital HCA	\$1,371,999,484	\$10,527,708	0.8%
Henrico Doctors' Hospital HCA	\$6,907,258,982	\$38,780,978	0.6%
Bon Secours Memorial Regional Medical Center	\$1,828,188,155	\$9,964,617	0.5%
Centra Southside Community Hospital	\$384,039,049	\$1,652,238	0.4%
Poplar Springs Hospital UHS	\$88,939,433	\$376,070	0.4%
VCU Community Memorial Hospital	\$421,895,877	\$1,677,139	0.4%
Encompass Health Rehab Hosp of Virginia	\$28,432,919	\$13,720	0.0%
Select Specialty Hospital - Richmond	\$53,310,288	\$0	0.0%
Cumberland Hospital for Children and Adolescents UHS	\$30,897,129	\$0	0.0%
Total Inpatient Hospitals:			19
HPR IV Total Inpatient \$ & Mean %	\$38,646,513,136	\$349,072,652	0.9%
Outpatient Centers			
Boulders Ambulatory Surgery Center HCA	\$178,430,144	\$2,835,945	1.6%
American Access Care of Richmond	\$5,614,196	\$78,601	1.4%
Urosurgical Center of Richmond	\$46,830,464	\$384,074	0.8%
Virginia Eye Institute, Inc.	\$51,667,075	\$387,608	0.8%
VCU Health Neuroscience, Orthopedic and Wellness Center	\$67,292,975	\$414,824	0.6%
St. Mary's Ambulatory Surgery Center	\$54,839,934	\$252,107	0.5%
MEDRVA Surgery Center @ West Creek	\$12,554,561	\$20,580	0.2%
Virginia ENT Surgery Center	\$25,926,435	\$10,589	0.0%
MEDRVA Stony Point Surgery Center	\$64,547,579	\$0	0.0%
Cataract and Refractive Surgery Center	\$7,916,214	\$0	0.0%
Virginia Beach Health Center VLPP	\$2,270,805	\$0	0.0%
Skin Surgery Center of Virginia	\$1,542,518	\$0	0.0%
Total Outpatient Hospitals:			12
HPR IV Total Outpatient Hospital \$ & Mean %	\$519,432,900	\$4,384,328	0.8%
Total Hospitals:			31
HPR IV Total \$ & Mean %	\$39,165,946,036	\$353,456,980	0.9%

Source: VHI 2023

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

There are no other factors, not addressed elsewhere in the analysis, relevant to the determination of a public need for either project.

3. The extent to which the application is consistent with the State Medical Facilities Plan.

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

The SMFP contains criteria/standards for the establishment or expansion of PET services. They are as follows:

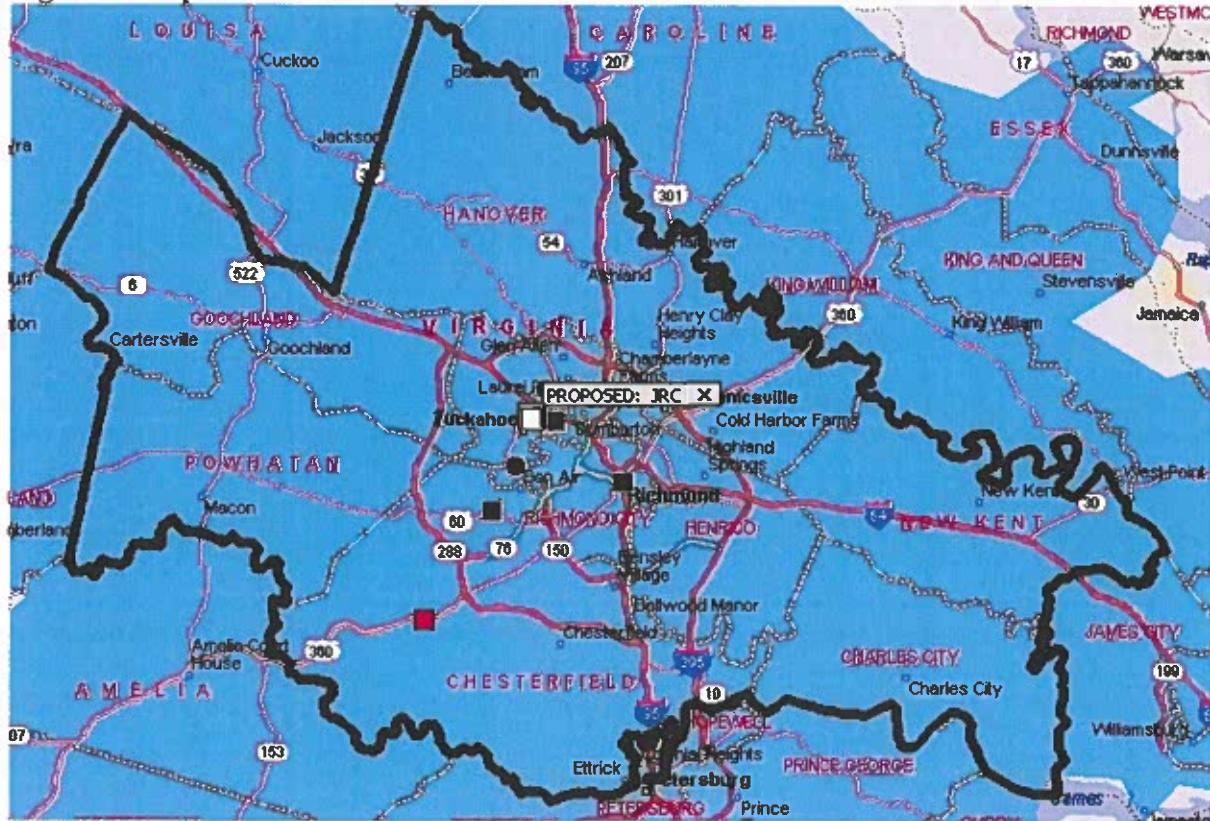
Part II
Diagnostic Imaging Services
Article 4 Criteria and Standards for Positron Emission Tomography

12VAC5-230-200. Travel Time.

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

The heavy black line in **Figure 1** is the boundary of PD 15. The squares on the map represent fixed site PET scanners while the circles are mobile sites. The red squares indicate PET scanners restricted to cardiac-only studies and the white square is the proposed site. It is important to note that the SMFP does not distinguish between cardiac-specific PET services and all other PET services. The blue shaded area includes the area that is within 60 minutes driving time one-way under normal conditions of existing cardiac specific PET services in PD 15. The drive time availability for existing cardiac specific PET overlaps and covers the area that is within a 60-minute drive of all PET. **Figure 1** clearly illustrates that PET services are available within 60 minutes' driving time of the entire population in PD 15.

Figure 1. Map of Authorized PET Scanners in PD 15



Note: Squares are fixed sites; circles are mobile sites; red squares are cardiac-only; the white square is the proposed site.

Figure 2 is provided to visualize both of the existing cardiac PET services in PD 15 (the red squares) in relation to the proposed cardiac PET site (the white square). JRC's existing cardiac PET service in Chesterfield is about 35 minutes from the proposed site. Due to proximity to Virginia Cardiovascular Specialists' PET site, the proposed project does not improve geographic access to cardiac PET services beyond what is already available, but the travel time standard is already met, and the purpose of the proposed project is primarily access for JRC's patient base.

Figure 2. Proximity of Cardiac PET/CT to Applicant's Site



Note: Squares are fixed sites; circles are mobile sites; red squares are cardiac-only; the white square is the proposed site.

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.

The applicant is not a hospital.

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 one individual PET procedure and one CT procedure respectively, unless those images are made concurrently.

In 2023, the latest year for which VHI has reported utilization data, PD 15 had PET scanners at 7 authorized sites, three mobile and four stationary units. Utilization of the four stationary scanners for 2023 is presented in **Table 1**. These scanners performed an average of 2,120 procedures, 35.3% of the SMFP standard that year.

DCOPN notes that there are now six fixed site PET scanners in PD 15, included in **Table 2**, two of them restricted to cardiac use. Only one of these cardiac only PET units was open and reporting in 2023. Virginia Cardiovascular Specialists, PC reported 2,241 procedures on its PET scanner, 37.4% of the SMFP standard.

Calculated Needed Fixed PET Scanners in PD 15

2025 COPN authorized fixed PET scanners = 6

Calculated Needed Fixed PET scanners = $8,480 \text{ (2023 PET procedures)} \div 6,000 = 1.4 \text{ (2)}$
scanners needed

PD 15 Calculated Need = 2 PET scanners

PD 15 Calculated Surplus = 4 PET scanners (2025 PET Scanners (6) – Calculated Need (2))

The SMFP does not distinguish between cardiac PET and PET used for other clinical uses. As shown above, there is a calculated surplus of 4 PET scanners in PD 15. DCOPN notes, as shown in **Table 1**, no PET services in PD 15 surpassed the SMFP's volume threshold in 2023. In fact, according to VHI data for 2023, the average number of PET procedures performed across all PET providers in the entire Commonwealth was 2,221. The only cardiac-restricted PET scanner operational in PD 15 in 2023 exceeded this. The applicant reports that JRC Chesterfield performed 1,328 PET studies its first year of operation.

DCOPN has previously acknowledged the SMFP's utilization standards for PET/CT services are outdated and that expecting a PET service to reach the threshold suggested by the SMFP amounts to a misconception about the utilization of this modality at the time the SMFP was written and should be treated as such. Based on converting 65% of its SPECT volumes to cardiac PET/CT, the proposed JRC PET scanner is expected to perform 1,529 its first year.

With regard to the effect that the proposed project would have on existing providers, JRC has stated that the primary purpose of the proposed PET/CT service will be to serve its existing patient base. Because of the distinct nature of the patient base and the restricted scope of the PET/CT service to only cardiac procedures, DCOPN does not anticipate that approval of the proposed project would negatively affect utilization of other PET services in PD 15. Instead, approval of the proposed project would create an overall improvement in access to cardiac PET/CT for JRC's patients.

While the applicant does not meet the computational analysis of this SMFP standard, DCOPN recommends that the Commissioner, in this specific instance, does not allow this standard to bar the establishment of this cardiac PET/CT service.

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

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

Not applicable. The applicant is not proposing to expand an existing fixed-site PET service.

12VAC5-230-230. Adding or Expanding Mobile PET or PET/CT Services.

- A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.**
- B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district.**

Not applicable. The applicant is not proposing to add or expand an existing mobile PET/CT service.

12VAC5-230-240. Staffing.

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

The applicant has confirmed that PET services would be under the direct supervision of certified and trained radiologists.

Required Considerations Continued

- 4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served.**

Two of the six authorized fixed site PET services in PD 15 are cardiac-only, each owned by a cardiology group and each providing PET imaging primarily to (or prioritizing) that cardiology group's patients, as would JRC's proposed scanner such that little to no competition would result from the proposed project.

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

As the existing cardiac PET/CT services are established to serve the needs of the individual cardiology groups that operate them, as would the applicant's cardiac PET/CT service, it appears there will be little impact on the health care system as a whole in PD 15, other than making cardiac PET/CT imaging available to the patients of one of the cardiology groups in the area.

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

The total capital costs of the proposed project are \$1,335,285 of which approximately 19.1% represents direct construction costs (Table 3). As already discussed, DCOPN concludes that when compared to similar projects, these costs are slightly higher than recently approved similar projects, but reasonable. The applicant states that the proposed project will be funded through operating revenues and a service contract with the equipment vendor. The proforma income statement provided by the applicant (Table 7) projects a net profit of \$1,461,453 in the first year of operation, and a net profit of \$1,556,553 in the second year of operation.

Table 7. Proforma, JRC PET Scanner

	Year 1	Year 2
Revenue	\$2,745,953	\$2,883,251
Total Expenses	\$1,284,500	\$1,326,698
Net Profit	\$1,461,453	\$1,556,553

Source: COPN Request No. VA-8815

Regarding staffing, the applicant anticipates the need to hire four full time equivalent employees (FTEs), a modest and attainable recruitment.

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

Cardiac PET has been found to reduce the overall cost of managing coronary artery disease by approximately 30% when it is used routinely as compared with SPECT.⁹ Though there are existing and authorized providers of cardiac PET/CT scanning services in PD 15, PET/CT seems to be available only to cardiac patients whose cardiologists have an authorized service. The proposed project provides access to the latest, more accurate technology for the applicant's patients on an outpatient basis. The applicant does not make any arguments regarding

⁹ Merhige, M. E., Breen, W. J., Shelton, V., Houston, T., D'Arcy, B. J., & Perna, A. F. (2007, July 1). Impact of myocardial perfusion imaging with pet and 82RB on downstream invasive procedure utilization, costs, and outcomes in coronary disease management. *Journal of Nuclear Medicine*.

<https://jnm.snmjournals.org/content/48/7/1069>

cooperative efforts to meet regional health care needs. DCOPN did not identify any other factors as may be appropriate to bring to the Commissioner's attention.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

(i) The unique research, training, and clinical mission of the teaching hospital or medical school. (ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

Not applicable. The applicant is not a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

DCOPN Staff Findings and Conclusions

DCOPN finds that James River Cardiology's proposed project to establish PET/CT restricted to cardiac studies at its Discovery office by installing one PET/CT is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. The applicant has stated that the PET/CT scanner would be used solely for cardiac imaging. While the planning district does not meet the utilization threshold for the establishment of a new PET service, DCOPN notes that precedent has been established by the Commissioner regarding this threshold not barring the establishment of new PET/CT services when sufficiently compelling circumstances exist. As such compelling reasons exist, such as the unique population of patients the PET/CT will serve, and the clinical advantages of PET/CT over SPECT, DCOPN recommends that the Commissioner, in this specific instance, not allow this standard to bar the establishment of cardiac PET/CT services at this location.

Additionally, DCOPN finds that the proposed project is more beneficial than the alternative of the status quo. Furthermore, the proposed project is unlikely to negatively affect the utilization of existing providers. Finally, DCOPN finds that the total capital costs of the proposed project are reasonable, and the proposal is wholly feasible in the immediate and long run.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends **conditional approval** of James River Cardiology, LLC's COPN Request Number VA-8815 to establish a specialized center for cardiac PET/CT imaging with one PET/CT unit located at 8806 Discovery Drive, Suite 130, Richmond, Virginia in Henrico County for the following reasons:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The PET/CT scanner's use will be limited solely to cardiac imaging.
3. The project will improve access to the preferred cardiac imaging modality with numerous benefits over SPECT.

4. The project will not adversely affect existing providers of PET/CT services and there is no known opposition.
5. The project is more beneficial than the alternative of the status quo.
6. The capital costs are reasonable.
7. The proposal is wholly feasible in the immediate and long term.

DCOPN's recommendation is contingent upon James River Cardiology, LLC's agreement to the following charity care condition:

James River Cardiology, LLC will provide cardiac PET/CT imaging to all persons in need of these services, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 15 in an aggregate amount equal to at least 0.9% of James River Cardiology, LLC's gross patient revenue derived from cardiac PET/CT imaging. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. James River Cardiology, LLC will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

James River Cardiology, LLC will provide cardiac PET/CT imaging to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. James River Cardiology, LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.