VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

January 19, 2023

COPN Request No. VA-8667
James River Cardiology, P.C.
Chesterfield, Virginia
Establishment of Fixed Cardiac PET/CT Imaging

Applicant

James River Cardiology, P.C. (JRC) is a professional corporation located in Chesterfield, Virginia, in Planning District 15 (PD 15), located within Health Planning Region IV (HPR IV). JRC is both owner and operator of the practice. JRC is neither a subsidiary nor has any subsidiaries. The application COPN Request No. VA-8667 is regarding JRC's Chesterfield location at 7300 Ashcake Parkway, Suite 100.

Background

JRC has been serving its community for over ten years with reported expertise in the following: Cardiac Electrophysiology, Cardiovascular Disease, Interventional Cardiology, and Peripheral Vascular Disease. Since its inception, JRC has grown from the primary office in Colonial Heights, Virginia to five additional locations serving the Central Virginia area.

JRC currently offers EKG stress testing, SPECT MPI (single photon emission computerized tomography; myocardial perfusion imaging), and echocardiography. JRC consists of eight board certified cardiologists and eight nurse practitioners across six office locations throughout central Virginia. Additionally, four of the eight physicians hold additional board certifications in interventional cardiology (three physicians) and clinical cardiac electrophysiology (one physician). In addition to being both board certified in cardiovascular disease and interventional cardiology, one physician is also a diplomate on the certification board of nuclear cardiology and is a registered physician in vascular interpretation.

PET/CT Technology
JRC proposes to install the Cardiac PET/CT (position emission tomography/computerized tomography) system for the purpose of MPI stress testing at its Chesterfield office. Additionally, JRC is proposing to establish the same services at their Colonial Heights location with COPN Req. No. VA-8668; the Colonial Heights location is approximately 31 minutes' drive time and 26.7 miles from the Chesterfield location (PD 19, HPR IV).

Nuclear imaging plays a pivotal role in cardiac infectious, inflammatory, infiltrative, and innervation disorders.[1] PET/CT imaging is a noninvasive diagnostic tool that allows detection of radiopharmaceutical tracer accumulation in tissues with high sensitivity and provide precise quantification of their local concentration. The tracers used accumulate in tissues proportional to their glucose utilization, whereby they reflect the glucose metabolism of cells; this glucose metabolism is increased in cancer as well as in infectious and inflammatory processes.[2] Anatomical and morphological information derived from the combination of PET with CT (PET/CT) can be used to improve the localization, extent, and characterization of lesions detected by the tracers.[3]

An advantage of using PET/CT over SPECT imaging lies in the resolution differences; PET scans are capable of 5 to 7mm resolution compared to cardiac SPECT scan resolution of 12 to 15mm.[4] Additionally, the use of X-ray CT equipment in PET/CT imaging provides routine correction of tracer attenuation (reduction of intensity of an x-ray beam as it traverses through matter); this attenuation artifact reduction reduces the rate of false-positive perfusion defects, ultimately increasing specificity.[5]

The hybrid imaging techniques of PET and CT is an advanced modality for detection of coronary artery disease; the combination allows for a single scanning session of less than 45 minutes where quantification of cardiac perfusion combines with an assessment of coronary anatomy simultaneously.[6]

In a 2010 study where researchers tested the performance of cardiac PET/CT hybrid imaging in symptomatic patients with 30% to 70% pretest probability of coronary artery disease (CAD), the accuracy of the hybrid PET/CT imaging (resulting from the combination of both anatomy and function) technique was an astounding 98% per patient per vessel.[7] Furthermore, the researchers

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[1] Slart, Riemer H. J. A, Glaudemans, Andor W. J. M, Olivier Gheysens, Mark Lubberink, Tanja Kero, Marc R. Dweck, Gilbert Habib, et al. "Procedural Recommendations of Cardiac PET/CT Imaging: Standardization in Inflammatory-, Infective-, Infiltrative-, and Innervation (4Is)-Related Cardiovascular Diseases: A Joint Collaboration of the EACVI and the EANM." European Journal of Nuclear Medicine and Molecular Imaging 48, no. 4 (2021;2020;): 1016-1039.

[2] Slart, Riemer H. J. A, Glaudemans, Andor W. J. M, Olivier Gheysens, Mark Lubberink, Tanja Kero, Marc R. Dweck, Gilbert Habib, et al. "Procedural Recommendations of Cardiac PET/CT Imaging: Standardization in Inflammatory-, Infective-, Infiltrative-, and Innervation (4Is)-Related Cardiovascular Diseases: A Joint Collaboration of the EACVI and the EANM." European Journal of Nuclear Medicine and Molecular Imaging 48, no. 4 (2021;2020;): 1016-1039.

[3] Slart, Riemer H. J. A, Glaudemans, Andor W. J. M, Olivier Gheysens, Mark Lubberink, Tanja Kero, Marc R. Dweck, Gilbert Habib, et al. "Procedural Recommendations of Cardiac PET/CT Imaging: Standardization in Inflammatory-, Infective-, Infiltrative-, and Innervation (4Is)-Related Cardiovascular Diseases: A Joint Collaboration of the EACVI and the EANM." European Journal of Nuclear Medicine and Molecular Imaging 48, no. 4 (2021;2020;): 1016-1039.

[4] Webmaster. "What's the Difference between Pet and SPECT Scans?" Cardiac Imaging, December 20, 2019. https://www.mobilecardiacpet.com/blog/whats-the-difference-between-pet-and-spect-scans/#:~:text=PET%20Scan%20Images%20are%20Clearer,flow%20at%20a%20granular%20level.

[5] Knaapen P, de Haan S, Hoekstra OS, Halbmeijer R, Appelman YE, Groothuis JG, Comans EF, Meijerink MR, Lammertsma AA, Lubberink M, Götte MJ, van Rossum AC. Cardiac PET-CT: advanced hybrid imaging for the detection of coronary artery disease. Neth Heart J. 2010 Feb;18(2):90-8. doi: 10.1007/BF03091744. PMID: 20200615; PMCID: PMC2828569.

[6] Knaapen P, de Haan S, Hoekstra OS, Halbmeijer R, Appelman YE, Groothuis JG, Comans EF, Meijerink MR, Lammertsma AA, Lubberink M, Götte MJ, van Rossum AC. Cardiac PET-CT: advanced hybrid imaging for the detection of coronary artery disease. Neth Heart J. 2010 Feb;18(2):90-8. doi: 10.1007/BF03091744. PMID: 20200615; PMCID: PMC2828569.

[7] Cardiac Positron Emission Tomography/Computed Tomography Imaging Accurately Detects Anatomically and Functionally Significant Coronary Artery Disease S. Kajander, MD , E. Joutsiniemi, MD , M. Saraste, MD , M. Pietilä, MD, PhD , H. Ukkonen, MD, PhD , A. Saraste, MD, PhD , H.T. Sipilä, PhD , M. Teräs, PhD , M. Mäki, MD, PhD , J. Airaksinen, MD, PhD , J. Hartiala, MD, PhD , and J. Knuuti, MD, PhD

found that while CT and PET stand-alone units "provided excellent exclusion of CAD, false-positive findings were not uncommon."

In a 2020 meta-analysis, it was found that for 2016, aggregated health conditions under the umbrella of cardiovascular diseases accounted for the third highest costs to healthcare; the researchers also determined for the same year healthcare costs were funded via private insurance, which accounted for 48.0% of spending, 42.6% was by public insurance, and 9.4% from out-of-pocket payments. Finding opportunities to lower healthcare costs for both the private and public insurance spheres will also reduce spending for out-of-pocket expenses. The Medical Imaging & Technology Alliance (MITA) supports the appropriate use of diagnostic imaging to reduce healthcare costs; MITA cites a Harvard research study that found that every $1 sent on in-patient imaging correlated to approximately $3 in total savings and that every $365 spent on imaging decreases a patient's hospital stay by one day, saving approximately $3000 per patient.[8]

Regarding PET/CT specifically, cost calculations show a financial savings from the integration of PET and CT for reasons including but not limited to: (1) there are times that a PET scan results in the need for a CT scan leading to additional costs and time to perform two scans, (2) the combined scanning results in an average time savings of 20-30 minutes per patient, (3) a shorter scanning time results in more efficient use of the tracer, since it decays rapidly due to its short half-life, and (4) significantly reduces the need for invasive measures that are more costly.[9]

Regional and District Data

HPR IV has only one Cardiac PET unit, seen in **Table 1**, which is also located in PD 15. The PET units in PD 15 are bolded in **Table 1**, with only one being Cardiac PET. The standalone cardiac PET is located at Virginia Cardiovascular Specialists in Northwest Richmond, approximately a 35 minutes' drive from JRC Chesterfield and 45 minutes from the furthest town in the planning district. Being the only Cardiac PET in both the region and the district, this drive time can reasonably be expected to create hardship on patients and their ability to receive services. Additionally, while there are 6 PET/CT scanners in HPR IV, 3 of which are in PD 15, most PET scanners within the PD are "dedicated to oncology services and are not equipped for cardiac scanning"[10].

Although JRC proposes to utilize the PET/CT for cardiac scanning only, DCOPN has included the following HPR IV authorized PET scanners, which have an average of 1,229 procedures per scanner, principally outpatient, across its eight mobile and stationary units (**Table 2)**. It is worthy of note that the three units located in districts 19 and 13 had significantly less procedural volume, skewing the average. Additionally, the proposed project is specific to cardiac PET/CT scanning only and the applicant provided assurances it will not be used for any diagnostic imaging outside of cardiac services. Currently, there are no facilities offering cardiac PET/CT in PD 15. The applicant argues they should not be considered in competition with Virginia Cardiovascular Specialists' Cardiac PET as the PET is not identical to a PET/CT; however, for COPN purposes, the PET/CT need is assessed under PET standards. JRC anticipates 1,100 Cardiac PET/CT studies in Year 1, or

[8] "Mita Endorses Hausleiter Study, Appropriateness Criteria for CCTA." Imaging Technology News, October 3, 2021. https://www.itnonline.com/article/mita-endorses-hausleiter-study-appropriateness-criteria-ccta.
[9] Saif MW, Tzannou I, Makrilia N, Syrigos K. Role and cost effectiveness of PET/CT in management of patients with cancer. Yale J Biol Med. 2010 Jun;83(2):53-65. PMID: 20589185; PMCID: PMC2892773.
[10]

approximately 5 per day. JRC approximated this projection through converting about 65% of the total SPECT volume from the Chesterfield and Richmond offices, which will both use the unit, to cardiac PET/CT. Using a modest growth rate of 5% (comparable to years prior), JRC estimates reaching "full camera utilization in Year 2".

Table 1: HPR IV Authorized PET Units

Facility	PD	Total Authorized Scanners	Authorized Fixed-Site Scanners	Authorized Mobile Sites	PET Only	PET/CT	Cardiac Only
Sentara Halifax Regional Hospital	13	1	0	1	1	0	0
VCU Community Memorial Hospital	13	1	0	1	0	1	0
Bon Secours Imaging Center at Reynolds Crossing	**15**	**1**	**1**	**0**	**0**	**1**	**0**
Henrico Doctor's Hospital - Parham	**15**	**1**	**0**	**1**	**1**	**0**	**0**
Henrico Doctors' Hospital - Forest	**15**	**1**	**1**	**0**	**0**	**1**	**0**
Johnston-Willis Hospital	**15**	**1**	**1**	**0**	**0**	**1**	**0**
VCU Health System	**15**	**1**	**1**	**0**	**1**	**0**	**0**
Virginia Cardiovascular Specialists	**15**	**1**	**1**	**0**	**1**	**0**	**1***
West Creek Medical Center	**15**	**1**	**0**	**1**	**0**	**1**	**0**
Bon Secours Southside Medical Center	19	1	0	1	1	0	0
John Randolph Medical Center	19	1	0	1	0	1	0
HPR IV Total		11	5	6	5	6	1

Source: COPN Inventory
*Virginia Cardiovascular Specialists have one Cardiac-only PET scanning pursuant to COPN No. VA-04590.

Table 2: HPR IV PET Units and Procedures 2021

Facility Name	District	Class	Procedures
Bon Secours St. Mary's Hospital	15	PET - Stationary	1,916
Chippenham Hospital	15	PET - Mobile	1,365
Henrico Doctors' Hospital - Forest	15	PET - Mobile	1,121
VCU Medical Center	15	PET - Stationary	2,285
Virginia Cardiovascular Specialists / Forest Medical Plaza	**15**	**PET - Stationary**	**2,286**
Bon Secours Southside Medical Center	19	PET - Mobile	324
John Randolph Medical Center	19	PET - Mobile	289
VCU Community Memorial Hospital	13	PET - Mobile	242
Average per Unit		Mobile and Stationary	**1,229**

Source: 2021 Virginia Health Information (VHI), Diagnostic Services, Nuclear

The population data (**Tables 3 & 4**) in PD 15 shows the only decrease to be in Charles City County, with the rest of PD 15 experiencing a growth rate higher than that of the State of Virginia in not only the total population, but in the age 65+ cohort as well.

Notably, the age 65+ population for both PD 15 and the State is on the rise. In 2020, 15.62% of the total State population was 65+ in age and 15.49% of PD 15's population was 65+. The projections for the State and PD 15 in 2030 are: 18.47% and 18.40% respectively.

For 2020, the CDC listed the leading cause of death in Virginia to be heart disease. Referencing the darker colored regions in the center of **Figure 1**, one can visualize the area where there is a

higher concentration of cardiovascular disease-related mortality. Some of this higher concentrated area is within PD 15 and furthers the justification for local cardiovascular disease diagnostic and treatment capabilities.

Table 3. PD 15 and Statewide Total Population Projections, 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Charles City	7,256	6,982	-3.8%	6,941	-0.6%	-4.3%
Chesterfield	316,236	353,841	11.9%	396,647	12.1%	25.4%
Goochland	21,717	23,547	8.4%	26,702	13.4%	23.0%
Hanover	99,863	109,244	9.4%	119,360	9.3%	19.5%
Henrico	306,935	332,103	8.2%	363,259	9.4%	18.4%
New Kent	18,429	23,474	27.4%	28,104	19.7%	52.5%
Powhatan	28,046	29,909	6.6%	33,440	11.8%	19.2%
Richmond City	204,214	232,533	13.9%	245,483	5.6%	20.2%
Total PD 15	**1,002,696**	**1,111,633**	**10.9%**	**1,219,936**	**9.7%**	**21.7%**
Virginia	8,001,024	8,655,021	8.2%	9,331,666	7.8%	16.6%

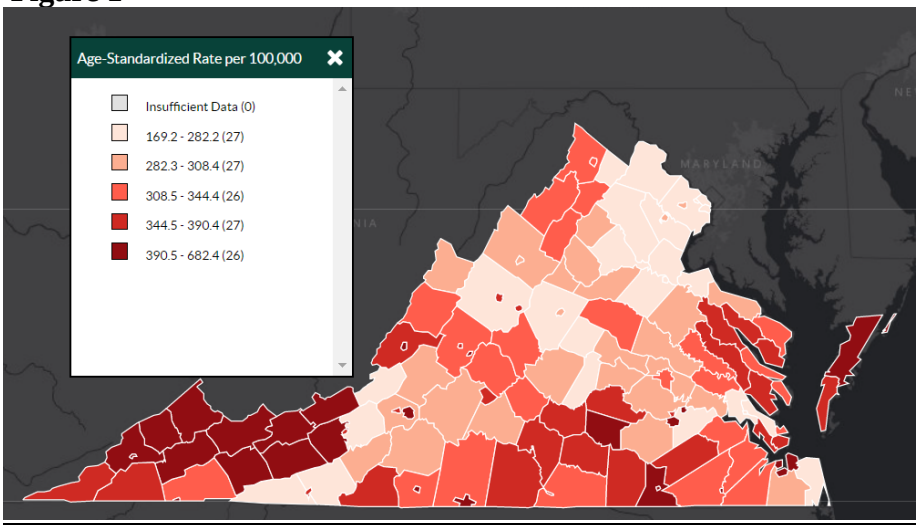
Source: U.S. Census, Weldon Cooper Center Projections (August 2019) and DCOPN (interpolations)

Table 4. PD 15 Population Projections for 65+ Age Cohort, 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Charles City	1,214	1,773	46.1%	2,189	23.4%	80.3%
Chesterfield	32,878	55,297	68.2%	72,476	31.1%	120.4%
Goochland	3,237	5,420	67.4%	7,421	36.9%	129.3%
Hanover	13,104	19,807	51.2%	27,456	38.6%	109.5%
Henrico	37,924	53,255	40.4%	68,003	27.7%	79.3%
New Kent	2,226	4,303	93.3%	6,663	54.8%	199.3%
Powhatan	3,407	6,041	77.3%	8,552	41.5%	151.0%
Richmond City	22,619	26,352	16.5%	31,657	20.1%	40.0%
Total PD 15	**116,609**	**172,249**	**47.7%**	**224,417**	**30.3%**	**92.5%**
Virginia	976,937	1,352,448	38.4%	1,723,382	27.4%	76.4%

Source: U.S. Census, Weldon Cooper Center Projections (August 2019) and DCOPN (interpolations)

Figure 1



***Source:** CDC 2018-2020 Data for Heart Disease Deaths

Due to the nature of this proposal being requested for COPN approval along with COPN Req. No. VA-8668 at JRC's Colonial Heights location, it is important to review utilization and population data for PD 19, also located within HPR IV.

Table 5 indicates that the population centers are concentrated in Dinwiddie, Prince George, Colonial Heights, Hopewell, and Petersburg. The entire PD has experienced a stable population with the projection to only see about 0.51% of growth across the PD from 2020-2030. While Dinwiddie and Prince George are projected to experience some positive growth (6.29% and 4.77% respectively), Colonial Height's growth projection is only 0.77% and the other localities are expected to experience a decline in population.

The 65+ year old cohort, most likely to utilize Cardiac PET/CT services, PD 19 is projected to see a 21.43% increase in population. In regards to the addition of services being requested in this area, it can be seen that while PD 19's population is stable, the 65+ cohort is increasing, which can reasonably indicate a need for an increase in service provisions for them.

Table 5. Statewide and PD 19 Total Population Projections, 2010-2030

Locality	2010	2020	% Change 2010-2020	Avg Ann % Change 2010-2020	2030	% Change 2020-2030	Avg Ann % Change 2020-2030	% Change 2010-2030
Dinwiddie	28,001	28,669	2.39%	0.23%	30,473	6.29%	0.61%	8.83%
Greensville	12,243	11,340	-7.38%	-0.75%	11,144	-1.72%	-0.17%	-8.98%
Prince George	35,725	37,613	5.28%	0.50%	39,408	4.77%	0.47%	10.31%
Surry	7,058	6,501	-7.89%	-0.80%	6,282	-3.37%	-0.34%	-10.99%
Sussex	12,087	11,370	-5.93%	-0.59%	10,657	-6.27%	-0.65%	-11.83%
Colonial Heights	17,411	17,631	1.26%	0.12%	17,766	0.77%	0.08%	2.04%
Emporia City	5,927	5,462	-7.85%	-0.79%	5,317	-2.65%	-0.27%	-10.29%
Hopewell City	22,591	22,852	1.16%	0.11%	22,781	-0.31%	-0.03%	0.84%
Petersburg City	32,420	31,671	-2.31%	-0.23%	30,166	-4.75%	-0.49%	-6.95%
Total PD 19	**173,463**	**173,109**	**-0.20%**	**-0.20%**	**173,995**	**0.51%**	**0.05%**	**0.31%**
PD 19 65+	**24,581**	**30,488**	**24.03%**	**2.12%**	**37,022**	**21.43%**	**1.96%**	**50.61%**
Virginia	8,001,024	8,655,021	8.17%	0.77%	9,331,666	7.82%	0.76%	16.63%
Virginia 65+	976,937	1,352,448	38.44%	3.22%	1,723,382	27.43%	2.45%	76.41%

Source: U.S. Census, Weldon Cooper Center Projections (August 2019) and DCOPN (interpolations)

Proposed Project

JRC proposes to establish cardiac PET/CT imaging services at its Chesterfield office location. JRC Chesterfield is located at 7300 Ashlake Parkway, Suite 100, Chesterfield, Virginia 23838, approximately 30 minutes southwest of Richmond. The target date of opening is July 6, 2023.

JRC proposes to further its imaging capabilities (beyond SPECT, which is no longer subject to COPN) at the Chesterfield location with the addition of a Siemens Biograph 16-slice PET/CT for use in gated cardiac MPI only; the applicant gives assurances that "JRC has neither the desire nor the ability to perform non-cardiac studies, and the CT will be used solely for attenuation correction of the perfusion images."

The cardiac PET/CT lab will be built within the existing office in currently unused space. The lab itself will consist of 546 square feet for a camera room and control room, both to be lead-shielded in compliance with Nuclear Regulatory Commission guidelines, and it will share the existing hot lab, patient preparation, and waiting areas.

During construction, the applicant states there will be little, if any, construction impact to the rest of the office, ensuring its other service provisions for the community are not interrupted. Aside from general carpentry considerations, the facility will require minor power supply and HVAC upgrades to maintain proper conditions for the sensitive instrumentation within the camera.

The costs of the project are expected to total $1,001,700, with the details of the total cost available in **Table 6.** JRC has entered into a services agreement with CDL Nuclear Technologies through which all capital expenditures, including all facility renovations, will be paid over the term of the agreement. JRC plans to satisfy the terms of the lease through operating capital revenues. Additionally, the office location's rent starting on or around August 1, 2021, is detailed in the chart captured from the lease agreement (**Figure 2**). The applicant states the lease rate for JRC with CDL Nuclear Technologies is $15,000 per month for one PET/CT system, and it includes the following:

- PET/CT system and ancillary equipment such as leaded storage and EKG
- System service, including bi-annual preventive maintenance
- Facility buildout allowance
- Ancillary services such as ongoing clinical support and billing consultation[11].

The applicant verified that costs outlined in **Table 6** will be- paid through the $15,000 per month lease, and that there will be no up-front costs. JRC plans to satisfy the terms of the lease through operating capital revenues. Due to not needing to expend capital up-front, JC does not anticipate an adverse effect on the cost to provide care to its patients.

DCOPN finds the projected costs reasonable when compared to similar project COPN VA-04806 issued August 22, 2022, to The Cardiovascular Group, PC to establish PET/CT services with one fixed scanner limited to cardiovascular use whose associated costs were $2,491,617, with leased equipment. Semi-comparably, considering COPN VA-04805 issued to Med Atlantic, Inc., the lease for a mobile PET/CT lease would be $23,646 per month with start-up costs needed, for a total of $2,320,184. Another example is found in COPN VA- 04152 issued to Alliance Imaging, Inc. to add a mobile PET/CT scanner, which cost approximately $2,369,184 with leased equipment. While the second two examples are for mobile units, the leasing and lower renovation needs made the projects comparable in price to the current proposal.

[11] DCOPN verified that CDL Nuclear Facilities offers services inclusive of all aspects listed in the application as there was no confirming paperwork attached with the application.

Figure 2: Site Lease Agreement Costs

Lease Year	Annual Base Rent	Monthly Base Rent
1	$156,000.00	$13,000.00
2	$187,200.00	$15,600.00
3	$216,164.00	$18,013.67
4	$221,568.10	$18,464.01
5	$227,107.30	$18,925.61
6	$232,784.99	$19,398.75
7	$238,604.61	$19,883.72
8	$244,569.72	$20,380.81
9	$250,683.97	$20,890.33
10	$256,951.07	$21,412.59

Source: COPN Req. No. VA-8667 Attachment I.F.4, Deed of Lease Agreement

Table 6. Detailed Costs of Project

I. Direct Construction Costs	
Cost of Materials	$65,000
Cost of Labor	$67,000
Equipment Included in Construction Contract	$3,000
Builder's Overhead	$12,500
Builder's Profit	$12,500
Part I Subtotal	$160,000
II. Equipment Not Included in Construction Contract	
Siemen's Biograph Horizon 16-Slice PET/CT	$747,500
GE CardioSoft 12-Lead EKG	$11,200
Part II Subtotal	$758,700
III. Site Preparation Costs	
Site Utilities	$20,000
Part III Subtotal	$20,000
IV. Architectural and Engineering Fees	
Architect's Design Fee	$13,000
Engineering Fees	$10,000
Part IV. Subtotal	$23,000
V. Other Consultant Fees	
Attorney's Fee	$35,000
Part V Subtotal	$35,000
VI. Taxes During Construction	
Property Taxes During Construction	$5,000
Part VI Subtotal	$5,000
Total Capital and Financing Costs	**$1,001,700**
Estimated Costs of Modernization and Renovation (Excluding Site Acquisition Costs)	**$203,000**

*__Source__: COPN Req. VA-8667

Additionally, it is important to note that the applicant also proposes the same project with the same costs for their Colonial Heights office, PD 19, via COPN Req. No. VA-8668.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "Establishment of a medical care facility described in subsection A …Any specialized center or clinic or that portion of a physician's office developed for the provision of computed tomographic (CT) scanning…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 considered when applicable.

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

Patients can access JRC's Chesterfield office location by car or public transportation. The facility is located just off US-360, approximately 4 miles from the VA-288 interchange. There is plenty of on-site parking for patients, including numerous handicapped spaces nearest to the building. The facility also has van access. The GRTC Transit System also offers a CARE service for patients 80 years or older and patients with disabilities, which provides origin-to-destination service to JRC Chesterfield. Additionally, JRC's Chesterfield office is currently located in a stand-alone building with ample parking.

Within the HPD and PD where JRC-Chesterfield is located, there are no cardiac PET/CT units available; however, Virginia Cardiovascular Specialists, PC (VCS) has a cardiac PET in PD 15 located approximately 24.7 miles, or approximately 35 minutes' drive from the proposed location. The only other two cardiac PET/CT scanners in Virginia, according to DCOPN Inventory, are at Carilion Roanoke Memorial Hospital and Virginia Heart in Falls Church, neither of which are in HPR IV nor are they within a reasonable driving distance from PD 15. Aside from transportation time and costs, patients are reportedly choosing smaller clinics, microhospitals, freestanding Emergency Departments, etc. to meet their needs as they are easier to navigate than larger hospitals.[12] Access to cardiac PET/CT imaging in a freestanding clinic form may increase the odds of patients actively participating in their diagnostic and treatment needs.

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

[12] Heath, Sara. "Top Challenges Impacting Patient Access to Healthcare." PatientEngagementHIT, February 17, 2022. https://patientengagementhit.com/news/top-challenges-impacting-patient-access-to-healthcare.

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

DCOPN received four letters of support for the proposed project from the medical community, two of which were local, to include: President of the Cardiac PET Industry Coalition, Physician and Faculty at John Ochsner Heart and Vascular Institute, a Physician with Advance Care Partners, and a Physician with Vital Care Family Practice. Collectively, these letters articulate several benefits of the project, including:

- Coronary artery disease (CAD) is the leading cause of death in the United States for both men and women.
- PET is a powerful, non-invasive, quantitative imaging modality that has been shown to benefit physicians in the investigation, treatment, and diagnosis of cardiovascular biology and physiology. In recent years, increasing diversity of therapeutic options for CAD and increasing specificity of novel therapies for certain biological pathways have resulted in a clinical need for more accurate and specific cardiovascular diagnostic techniques.
- "In a study of 2,159 patients to determine the downstream savings Cardiac PET has on the healthcare system, it was shown conclusively that in patients being evaluated for suspected coronary artery disease, Cardiac PET results in a 50% reduction in the use of coronary arteriography (cardiac catheterization) and CABG (Coronary Bypass Surgery) and a 30% reduction in direct patient management costs, while maintaining excellent patient outcomes and minimizing indirect costs."[13]
- The Medicare and Medicaid "Triple Aim" of "Better outcomes, better patient satisfaction, and cost savings" are achieved when incorporating Cardiac PET in the diagnostic algorithm for patients undergoing testing for CAD.
- Cardiac PET is the best modality for the diagnosis of significant CAD.
- The increasing popularity of Cardiac PET nationally and globally has allowed for a copious amount of data to support its clinical use and its advantages over SPECT. Some advantages include attenuation correction, high count densities, and better radiotracers. These advantages translate into better image quality, higher sensitivity, and higher specificity for detecting significant coronary disease.
- Cardiac PET also allows for quantifying regional absolute myocardial blood flow (MBF); these measurements correlate with whether invasive revascularization procedures will yield statistically likely successful outcomes.
- Nearly 85% of Advance Care Partners' patients have cardiac conditions and they play a particular focus on prevention of avoidable hospitalizations. The addition of a Cardiac PET/CT unit will assist them in providing prompt care to their mutual patients.
- Vital Care Family Practice "have worked closely with James River Cardiology for more than 10 years and appreciate the group's effort to provide quality cardiovascular care using the best technology to benefit our patients."
- Cardiac PET/CT scanning is not readily available to their patients at any other facility in the community.

[13] Merhige, M.E. (2007). Impact of Myocardial Perfusion Imaging with PET and 82Rb on Downstream Invasive Procedure Utilization, Costs, and Outcomes in Coronary Disease Management. 48(7), referenced within Letter of Endorsement from President of Cardiac PET Industry Coalition, Wilson, Lon, BS, ASNE, RSO, provided with application.

DCOPN did not receive any letters in opposition to the proposed project.

Public Hearing
Section 32.1-102.6 B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city 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-8667 is not competing with another project in this batch cycle and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

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

While the applicant did not identify a reasonable alternative to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner, DCOPN advises that the approval of COPN Req. No. VA-8668 and the denial of the current proposal would better serve the community at this time. While the proposal of JRC to add a cardiac PET/CT unit at their Chesterfield location (in addition to their request for a Colonial Heights location in PD 19, COPN Req. VA-8668) will satisfy a need for both the district and the region, the current data suggests establishing PET/CT services at the Colonial Heights location will serve more of the rural population in the south, infringe less on the pool of patients for VCS (illustrated below and expanded on in **Figure 4** below), all while adequately meeting the needs of the community.

In HPR IV there are no Cardiac PET/CT units and within District 15, there is only one fixed Cardiac PET unit, located at Virginia Cardiovascular Specialists, PC (VCS), 8001 Franklin Farm Drive, Suite 130, Richmond, VA 23229. While VCS has a cardiac PET[14], their PET does not have the attenuation correction that yields higher resolution imaging accompanied by CT. The proposed project offers an enhanced PET service through the addition of the CT mechanism, however, COPN guidelines dictate that the PET/CT and PET be considered together.

JRC could opt for mobile PET/CT services; however, the monthly lease cost would likely be higher than the proposed cost per month. The projected quantity of procedures makes a fixed unit more time-efficient, too. Considering COPN VA-04805 issued to Med Atlantic, Inc., the lease for a mobile PET/CT lease would be $23,646 per month with start-up costs needed. Another example is found in COPN VA- 04152 issued to Alliance Imaging, Inc. to add a mobile PET/CT scanner, which cost approximately $2,369,184.

While the applicant and prior precedent by DCOPN call for leeway in the SMFP's 6,000 procedure thresh-hold for establishing new PET services as 6,000 procedures is not an

[14] Analysis regarding the only comparable competition to JRC's proposal in the district appears in the report in section: Required Consideration 4.

accurate reflection of procedural volume for PET, the PET/CT has been shown to cut down time needed for scans, reasonably allowing for more scans in the same period as a PET. In addition, other PET/Cardiac PET and PET/CTs in the region have been able to accommodate over one-third of the SMFP's 6,000 threshold for procedural volume needed before the addition of a new fixed-site PET service.

The applicant reports calculating projected PET/CT utilization for their Chesterfield and Richmond location by approximating 65% of SPECT being appropriate for PET/CT studies, yielding approximately 1,100 procedures, based on 2022 annualized data and their "modest 5% growth rate." Also important to note, the service will be provided to patients not appropriate for SPECT, namely those patients whose BMI is 35 or greater, those with breast implants or large breasts, those with a previous inconclusive SPECT study due to attenuation artifact, known pericardial or pleural effusion, prior mastectomy, and patients with previous SPECT studies that were discordant with coronary angiographic findings (either false positive or false negative). The applicant anticipates being at full-camera utilization by Year 2.

For the Colonial Heights location, using 2022 annualized SPECT data, with 50% of SPECT considered appropriate for PET/CT, the applicant anticipates 970 Cardiac PET/CT studies and to reach full utilization by Year 3 (assuming the same growth rate of 5%).

Combined for both projects, the utilization would be approximately 2,070, which is comparable to three other well-utilized PET scanners in HPR IV (**Table 1**).

The addition of the PET/CT machine in PD 19 at JRC's Colonial Heights location can reasonably be expected to perform needed scans for JRC Chesterfield (and Richmond per the applicant), and Colonial Heights patient pool. Recommended approval of COPN Req. No. VA-8668 and recommended denial of COPN Req. VA-8667 would allow for VCS to experience less impact from the new PET/CT, while still allowing for an increase in services for those in HPR IV. As utilization increases, it may be more appropriate to add an additional PET/CT to the service area.

(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 proposed project;

The financial costs of this project (totaled at an estimated $1,001,700 total that is included in the $15,000 per month lease for 5 years) are reasonable and consistent with previously approved projects to establish fixed PET/CT services. For example, COPN VA- 04152 issued to Alliance Imaging, Inc. to add a mobile PET/CT scanner, which cost approximately

$2,369,184. An additional example is COPN VA-04806 issued August 22, 2022, to The Cardiovascular Group, PC to establish PET/CT services with one fixed scanner limited to cardiovascular use whose associated costs were $2,491,617, with leased equipment. Semi-comparably, considering COPN VA-04805 issued to Med Atlantic, Inc., the lease for a mobile PET/CT lease would be $23,646 per month with start-up costs needed, for a total of $2,320,184.

A potential loss from the proposal materializing is a potential for hospitals with PET/CT services in the region to lose cardiac specific patients they may have; however, the PET/CT services currently in use are focusing on non-cardiac indications such as oncology, neurology, and urology. Currently, to confirm cardiac disease, patients may have to undergo more invasive procedures such as cardiac catheterizations since there is a lack of PET/CT technology directed towards the cardiac patients' needs.[15] As previously discussed, patients of all ages, but more concentrated in the older population with higher rates of cardiac-based medical concerns, are preferring smaller clinics and microhospitals to trying to navigate large hospital sites. The potential cost loss is balanced by the benefit the project would bring to the community and patients being served.

Additionally, there are no solely cardiac PET/CT scanners in either the PD or within the HPR. While there is a currently unrivaled cardiac PET on the opposite end of PD 15, this PET does not have the benefit of attenuation correction from the combined CT that JRC would be bringing to the PD. As discussed in the background section, the third highest spending category in 2016 in the United States was in the aggregated healthcare category of cardiovascular diseases[16]; PET/CT accuracy will be able to assist in reducing these costs through its accuracy and reduction of invasive measures needed for patients.

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

JRC does not foresee any restrictions or limitations to the scope of services unless the patient does not have clinical indications supporting the necessity for the test. The applicant states it currently participates in "all major insurers and Medicare". Clinical limitations per the applicant include: (1) patient size, unable to fit in the camera field of view, (2) unstable angina, (3) uncontrolled systemic hypertension, (4) 2nd or 3rd AV block without pacemaker, and (5) patients who did not follow the preparation instructions for the exam.

According to regional and statewide data regularly collected by VHI for 2020, the average amount of charity care provided by the facilities in HPR IV that reported such charity care for that year was 1.3% of all reported total gross patient revenues (**Table 7**). In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive

[15] Cardiac Positron Emission Tomography/Computed Tomography Imaging Accurately Detects Anatomically and Functionally Significant Coronary Artery Disease S. Kajander, MD , E. Joutsiniemi, MD , M. Saraste, MD , M. Pietilä, MD, PhD , H. Ukkonen, MD, PhD , A. Saraste, MD, PhD , H.T. Sipilä, PhD , M. Teräs, PhD , M. Mäki, MD, PhD , J. Airaksinen, MD, PhD , J. Hartiala, MD, PhD , and J. Knuuti, MD, PhD

[16] Dieleman JL, Cao J, Chapin A, et al. US Health Care Spending by Payer and Health Condition, 1996-2016. JAMA. 2020;323(9):863–884. doi:10.1001/jama.2020.0734

approval, the applicant is expected to provide a level of charity care for total gross patient revenues that is no less than the equivalent average for charity care contributions in HPR IV.

Table 7. 2020 Charity Care Contributions

Health Planning Region IV			
2020 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**Percent of Gross Patient Revenue**
Bon Secours St. Francis Medical Center	$909,600,664	$28,930,399	3.18%
Bon Secours Richmond Community Hospital	$916,350,189	$28,612,659	3.12%
Bon Secours St. Mary's Hospital	$2,028,786,995	$51,459,409	2.54%
Bon Secours Memorial Regional Medical Center	$1,425,167,696	$28,386,279	1.99%
Centra Southside Community Hospital	$324,125,273	$5,447,210	1.68%
Sentara Halifax Regional Hospital	$279,469,170	$3,668,115	1.31%
CJW Medical Center	$7,560,037,769	$86,592,596	1.15%
VCU Health System	$6,172,966,084	$69,698,687	1.13%
John Randolph Medical Center	$1,032,491,952	$10,903,791	1.06%
Henrico Doctors' Hospital	$4,859,466,138	$51,444,601	1.06%
VCU Community Memorial Hospital	$317,168,977	$1,932,837	0.61%
Bon Secours Southern Virginia Regional Medical Center	$183,898,466	$1,059,319	0.58%
Bon Secours Southside Regional Medical Center	$1,875,804,250	$5,837,542	0.31%
Vibra Hospital of Richmond LLC	$145,408,947	$0	0.00%
Cumberland Hospital for Children and Adolescents	$54,279,874	$0	0.00%
Total Facilities			15
Median			1.1%
Total $ & Mean %	**$28,085,022,444**	**$373,973,444**	**1.3%**

Source: VHI 2020 Charity Care Contribution Data

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

DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant to determining a public need for the proposed project.

3. The extent to which the application is consistent with the State Health Services 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, these regulations provide the best available criteria and DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

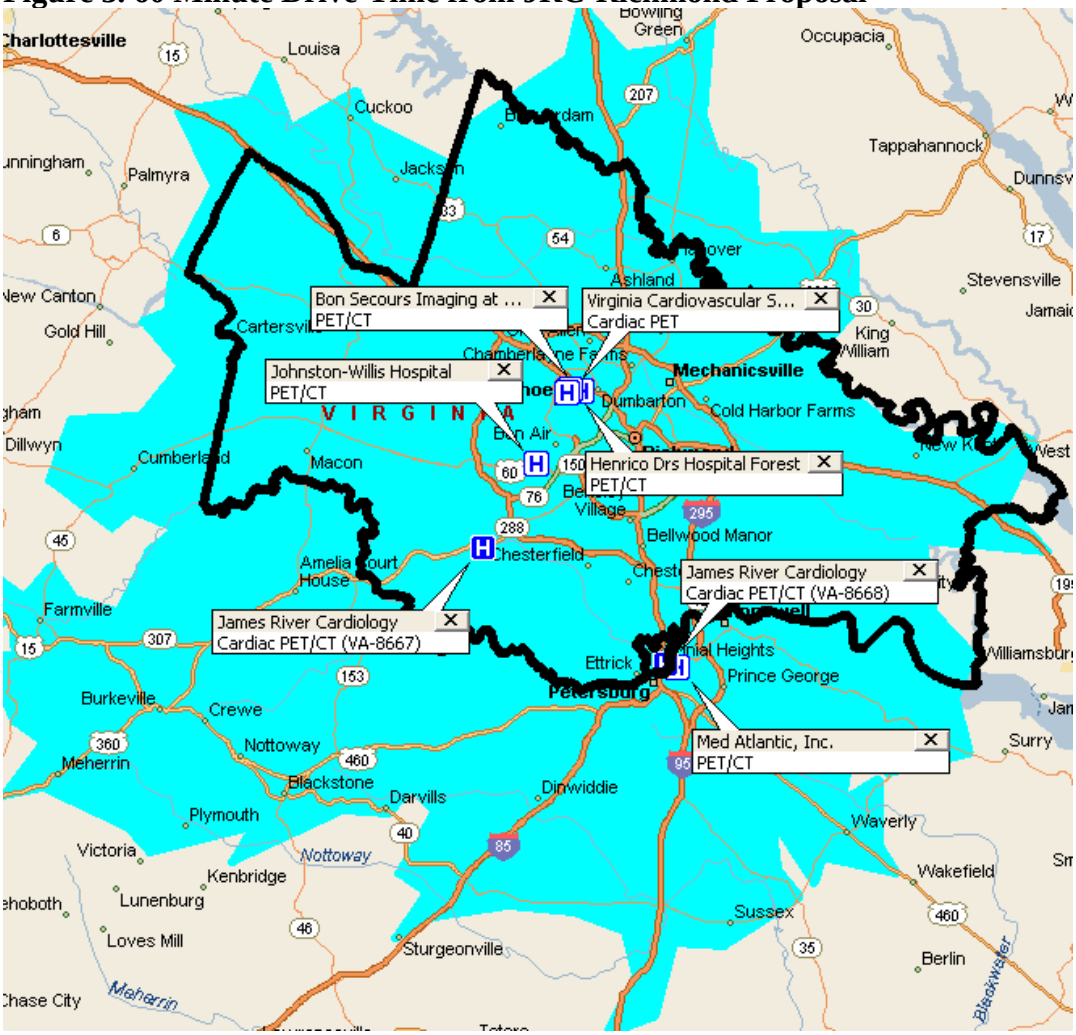
The SMFP contains criteria/standards for the establishment of PET services. They are as follows:

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.

As **Figure 3** shows, there are many PET/CT services within PD 15 (outlined in black); the light blue indicates 60 minutes' drive from the proposal site. The closest service provider to the services being offered would be Virginia Cardiovascular Associates, who have a cardiac PET. As seen below in **Figure 3**, this location is in a different section of the district, in the Richmond area. Additionally, JRC has an application for another PET/CT in its' Colonial Heights office in PD 19, HPR IV.

Figure 3. 60 Minute Drive-Time from JRC-Richmond Proposal



***Source:** DCOPN Generated

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

The only cardiac PET, according to 2021 data from VHI outlined in **Table 2**, shows Virginia Cardiovascular Specialists performed 2,286 procedures. The SMFP states "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." As the applicant states, DCOPN has recommended several cases, including but not limited to: COPN Nos. VA-04740 and VA-04715 where the decision included the PET SMFP utilization provisions are outdated and do not quantify the actual need. Additionally, COPN Req. No. VA-7191, ultimately resulting in COPN No. VA-04151, states:

> "[T]here are few PET services in the state that have actually met [the SMFP's] goal[s]" which reflect "a misconception about the utilization of this modality at the time the SMFP was written."'

In its Year 1 alone, JRC anticipates 1,100 procedures, with increasing patient volume moving forward. JRC's projection places the proposed unit in a similar realm as the hospitals who have mobile PET services. As previously discussed, mobile services would not be as cost effective, and more importantly, PET in conjunction with CT delivers superior accuracy to PET alone. Most notably is consideration of the volumes depicted in **Table 2** being from units that are not cardiac PET/CT.

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 as applicant does not currently operate a 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 as applicant does not have Mobile PET services.

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.

JRC consists of eight board certified cardiologists and eight nurse practitioners across six office locations throughout central Virginia. Additionally, four of the eight physicians hold additional board certifications in interventional cardiology (three physicians) and clinical cardiac electrophysiology (one physician). In addition to being both board certified in cardiovascular disease and interventional cardiology, one physician is also a diplomate on the certification board of nuclear cardiology and is a registered physician in vascular interpretation.

Required Considerations Continued

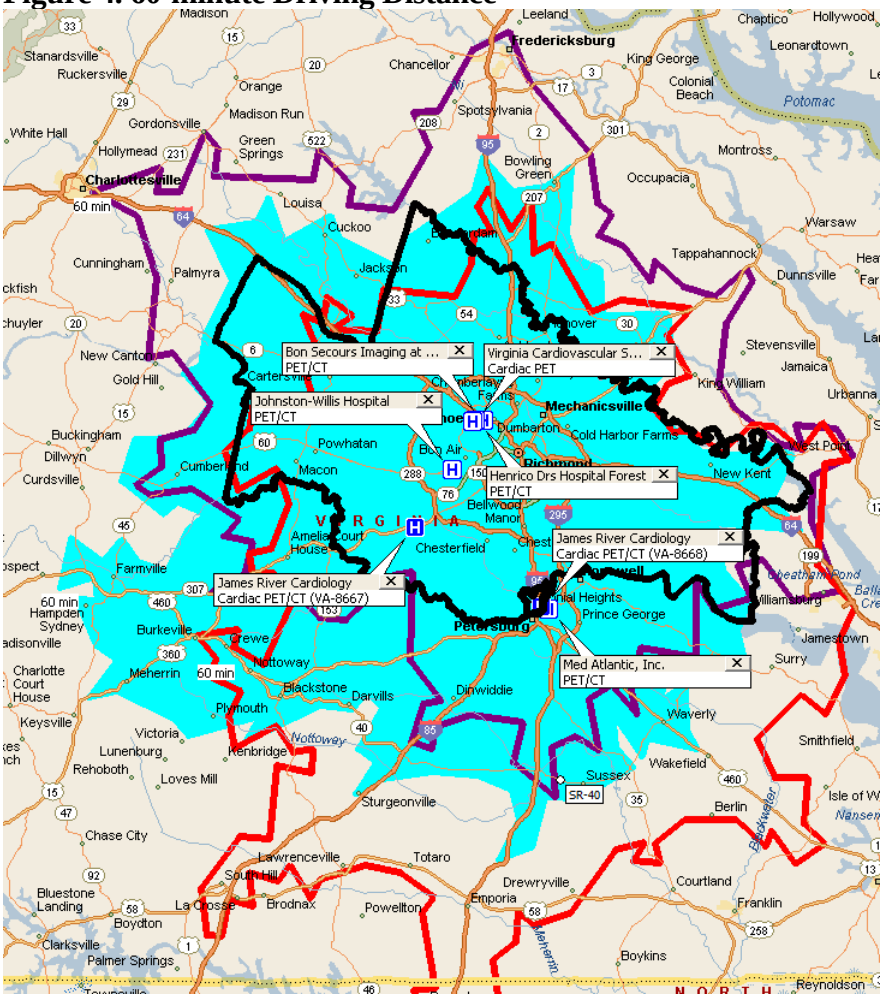
4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served;

Though the applicant argues there is no direct competitor to the proposal as it will be the only cardiac PET/CT in PD 15, Virginia Cardiovascular Associates is a competitor providing similar services in a similar setting who may be impacted as they have a cardiac PET (**Figure 3**). For COPN purposes, as outlined in the SFMP language above, the PET and PET/CT are considered the same even though the PET/CT is an enhanced version. The proposed location is in a different area

of the district, and the addition of a PET/CT scanner fosters competition and may stimulate additional locations advancing their technologies to better meet patient needs. Per the applicant, VCS' cardiac-PET is being used to its full capacity; therefore, there is no current availability for cardiac PET for non-VCS patients. However, DCOPN understands that the VCS 2021 VHI data shows 2,286 scans for the year (only one more scan than VCU Medical Center).

Furthermore, consider the light blue shaded are indicating JRC's proposed location and a 60-minute driving radius in comparison to the purple outline of VCS's 60 minute driving radius; while there is a substantial overlap, there is also opportunity for each location independently. The overlapping area is a densely populated area, which can foster competition and allow for patient choice in providers. The area in lavender exclusive to JRC allows for additional communities to have access to cardiac PET/CT services. The red outline is indicative of the additional PET/CT request by JRC for its Colonial Heights location (COPN Req. VA-8668). While this request is in PD 19, which also has no direct Cardiac PET or Cardiac PET/CT, the overlap may have a significantly negative impact both JRC's Chesterfield location and VCS's Richmond location. JRC's request for its Colonial Heights location, if it was the only application covers less of the same area regarding driving time as VCS, while also allowing access for those in the rural southern portion of the state.

Figure 4. 60-minute Driving Distance



***Source:** DCOPN Generated

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

Given the proffered limited scope of the proposed PET/CT scanner for cardiac purposes exclusively, the highly specialized nature of the scope of the scanner's use, the lack of opposition from existing providers of PET services, and the only reasonably comparable cardiac PET being utilized extensively, DCOPN concludes that the proposed project would not adversely affect the utilization and efficiency of existing PET providers in the planning district.

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

The costs of the project are expected to total $1,001,700 (**Table 4)**. JRC has entered into a services agreement with CDL Nuclear Technologies through which all capital expenditures, including all facility renovations, will be paid over the term of the agreement. JRC plans to satisfy the terms of the lease through operating capital revenues.

The office location's rent starting on or around August 1, 2021, is detailed in the chart captured from the lease agreement (**Figure 2**). The applicant states the lease rate for JRC with CDL Nuclear Technologies is $15,000.00 per month for one PET/CT system, and it includes the following:

- PET/CT system and ancillary equipment such as leaded storage and EKG
- System service, including bi-annual preventive maintenance
- Facility buildout allowance
- Ancillary services such as ongoing clinical support and billing consultation[17].

Applicant confirmed that costs outlined in **Table 5** will be- paid through the $15,000 per month lease, and that there will be no up-front costs. JRC plans to satisfy the terms of the lease through operating capital revenues. Due to not needing to expend capital up-front, JC does not anticipate an adverse effect on the cost to provide care to its patients.

The Pro Forma Income Statement **(Table 8)** provided by the applicant assumes the 2022 Medicare Part B Reimbursement Rate for PET/CT Perfusion, with a total reimbursement after isotope costs to be $2,460.12 per procedure. As depicted below, beginning in Year 1 and extending through the lease of the PET/CT unit, the project is anticipated to have profitable returns. Additionally, the monthly lease cost of $15,000 will easily be covered when considering the projected monthly returns, even with the inclusion of other operating expenses.

[17] DCOPN verified that CDL Nuclear Facilities offers services inclusive of all aspects listed in the application as there was no confirming paperwork attached with the application.

Table 8. Pro Forma Income Statement

	Year 1	Year 2	Year 3	Year 4	Year 5
Estimated Monthly Volume	92	97	102	107	112
Annual Net Revenue After Isotope Cost	$2,715,972	$2,851,771	$2,994,360	$3,144,078	$3,301,282
Monthly Net Revenue After Isotope Cost	$226,331	$237,648	$249,530	$262,006	$275,107
Total Annual Operating Expenses	$1,296,373	$1,306,017	$1,357,699	$1,411,832	$1,468,535
Estimated Net Annual Profit	**$1,419,599**	**$1,545,754**	**$1,636,661**	**$1,732,246**	**$1,832,747**

Source: COPN Req. No. VA-8667

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

The project brings a vital new technology to not only the planning district, but the region. The applicant is proposing an additional, equivalent project in PD 19, which would lead to two of these units being able to provide services to a growing community. PET/CT brings a technology that is able to perform precision imaging with much greater accuracy than that of PET alone. CT is able to provide attenuation correction in PET images, leading to clearer, more accurate images with less risk of false positives. The cost of the fixed unit rather than the mobile units utilized by hospitals is lower with the lease proposed in this project. Additionally, the increase in accuracy of the images yields reduction in invasive catheterizations and an increase in appropriate diagnoses, ultimately decreasing healthcare costs for both the patient and healthcare system. The project will be for the provision of services solely on an outpatient basis.

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

The applicant is not a teaching hospital or affiliated with public institutions of higher education or medical schools in the area to be served. Approval of the proposed projects would not contribute to the unique research, training or clinical mission of a teaching hospital or medical school.

DCOPN Findings and Conclusions

DCOPN finds that the proposed project to establish a specialized center for imaging with one PET/CT scanner limited to cardiac PET/CT imaging at their Chesterfield location on Ashcake Parkway is not generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. While the SMFP's 6,000-procedure threshold for fixed PET units has not been met and there is an established precedent and sensical disregard of the 6,000-procedure threshold as a rigid boundary, the Chesterfield location proposal in addition to the Colonial Heights proposal would add two scanners well below the SMFP threshold.

The applicant reasonably projects to have a volume of 1,100 procedures in the first year. Affording the community of the opportunity to access these services to reduce the need for invasive procedures is in line with the SMFP's over-arching guiding principles in the development of project review criteria and standards found in 12VAC5-230-30 which include, in part, "The COPN program is based on the understanding that excess capacity or underutilization ….are detrimental to both cost effectiveness and quality of medical services…, COPN…seeks the geographical distribution of medical facilities and to promote the availability and accessibility of proven technologies…" The Colonial Heights location reasonably projects 970 procedures and is located further south in the Region, right on the edge of PD 15, but within PD 19. Combined, the procedures projected would be reasonable for the addition of one scanner, not two.

While there is no other current PET/CT available in PD 15 or HPR IV being utilized specifically for cardiac purposes, there is one fixed cardiac PET in PD 15 whose provider did not oppose the project. The PET/CT technology has been shown the provide more accurate, precision imaging than PET, resulting in better patient outcomes that have been documented and researched extensively in the scientific and medical communities and referenced throughout this report. Due to the innovative nature of the technology coupled with the reasonable costs and lack of this technology for use in cardiology, DCOPN finds the addition of one of the scanners to be more favorable than maintaining the status quo. Considering Figure 4 again, one can see that the Colonial Heights location would likely have less impact than the Chesterfield location on VCS and would allow for easier access for the southern, rural communities in Virginia.

The total costs and capital estimated at $1,001,700 is not only reasonable when compared to relatively similar projects, but there are no up-front costs for installation as the applicant will be leasing the PET/CT unit from CDL Nuclear Technologies for $15,000 a month, for 5 years, with the costs of installation, training, the unit itself, and preventative maintenance included. The project from the first year of operation is predicted to be profitable, with the profit margin increasing with increasing volume. Although the costs are reasonable, DCOPN recommends the conditional approval of VA-8668, but not VA-8667 and finds the duplication of costs for two projects unnecessary.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **denial** of James River Cardiology, P.C.'s COPN request number VA-8667 to establish a specialized center for PET/CT services with one leased PET/CT scanner for the following reasons, assuming **conditional approval** of COPN request number VA-8668:

1. The proposed project is not 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 project brings innovative technology to HPR IV not readily available or easily accessible for cardiology elsewhere in the HPR, however, COPN Req. VA-8668 would better serve the community.

3. The project is not more favorable than maintaining the status quo.

4. The capital costs are unnecessarily duplicated if COPN VA-8668 is approved.

5. It is reasonable to suggest the project could negatively impact VCS' service area.

The Division of Certificate of Public Need recommends **conditional approval** of James River Cardiology, P.C.'s COPN request number VA-8668 to establish a specialized center for PET/CT services with one leased PET/CT scanner for the following reasons:

1. The proposed 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 project brings innovative technology to HPR IV not readily available or easily accessible for cardiology elsewhere in the HPR.

3. The project is more favorable than maintaining the status quo.

4. The capital costs are reasonable.

5. There is no known opposition to the project.

6. The project appears economically viable in the long term and short term.

Recommended Condition

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

James River Cardiology, P.C. will provide PET services 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 facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount equal to at least 1.3% of James River Cardiology, P.C.'s total patient services revenue derived from PET services as 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. 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, P.C. 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 to 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, P.C. will provide PET care 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. Additionally James River Cardiology, P.C. will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.