VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

July 20, 2026

Re: COPN Request No. VA-8888
James River Cardiology, LLC
Fredericksburg, Virginia
Establish Cardiac PET/CT Services

Applicant

James River Cardiology, LLC (James River Cardiology) is a limited liability company formed under the laws of Delaware in 2010, and wholly owned by Cavalier MSO, LLC d/b/a AlignedCardio. James River Cardiology is the sole owner of Southpark Heart & Rhythm Center, LLC, and Ashlake Heart & Rhythm Center which provide services in Virginia. The proposed facility will be located at 4604 Spotsylvania Parkway, Suite 220, Fredericksburg, Virginia, in Planning District (PD) 16, Health Planning Region (HPR) I.

Background

The location of the proposed project is in the City of Fredericksburg in PD 16. Other than the city, the PD also includes four counties: Caroline County, King George County, Spotsylvania County, and Stafford County. The total population of the PD in 2020 was 382,551 and is expected to grow by 14.7% to 438,635 by 2030 (**Table 1**). This is almost three times the expected growth rate of Virginia during the same period. The population growth estimate has increased at a higher rate than expected, with previous estimate of the PD's growth was 12.7% compared to the state's 5.0%.

Table 1: Predicted Population Change

Location	Experienced 2020			Predicted 2030			2020-2030 Change		
	Total	18+	65+	Total	18+	65+	Total	18+	65+
Caroline County	30,887	23,931	5,327	35,607	28,633	6,933	15.3%	19.6%	30.2%
King George County	26,723	20,016	3,706	29,951	23,892	5,534	12.1%	19.4%	49.3%
Spotsylvania County	140,032	105,768	20,619	160,387	127,415	31,227	14.5%	20.5%	51.4%
Stafford County	156,927	115,532	17,291	183,416	143,778	28,929	16.9%	24.4%	67.3%
Fredericksburg city	27,982	21,674	3,463	29,275	22,533	5,033	4.6%	4.0%	45.3%
PD 16	**382,551**	**286,921**	**50,406**	**438,635**	**346,251**	**77,656**	**14.7%**	**20.7%**	**54.1%**
Virginia, Statewide	**8,631,393**	**6,729,459**	**1,395,291**	**9,060,433**	**7,217,241**	**1,826,064**	**5.0%**	**7.2%**	**30.9%**

Source: Weldon-Cooper Center for Public Service (2026)

The City of Fredericksburg's population is expected to grow at a slower rate than the PD, with an increase of 4.6% to approximately 29,275 people by 2030. This is a sharp decrease in the growth rate, with previous estimates projecting a population of 31,224 (an 11.6% increase) by 2030. The population of people over the age of 65 in the City of Fredericksburg is expected to grow by a rate of 45.3%, less than the PD's expected rate (54.1%) but greater than that of the state (30.9%). The over-65 population is estimated to grow across the state at a much higher rate than any other age group.

Positron emission tomography (PET) scans use a safe, radioactive chemical that is injected, and the scanner detects diseased cells that absorb the radiotracer[1]. The specific chemical injected can change depending on the part of the body being scanned but is often a compound called fluorodeoxyglucose (FDG) which is similar to glucose and absorbed at a higher rate by more metabolically active cells, like cancerous cells. PET scans are often used to diagnose neurological conditions, brain trauma, cancers, or lung lesions[2]. All of the PET scanners in PD 16 are PET/CT scanners.

Note from the State Medical Facilities Plan (SMFP):

> 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.

A computed tomography (CT) scan is a computerized X-ray imaging tool that produces images of the body to diagnose diseases or lesions in the body. CT scanners have varying depths, usually ranging from 1 to 10 millimeters. Whereas other X-rays provide two-dimensional (2D) images, a CT scan will produce a three-dimensional (3D) image of the body and can provide a multiple-angle perspective for a scanned area[3]. When combined with PET scans, the CT scan is not the full process that occurs in an independent CT scan; instead, it is a "fast" scan simply to "delineate anatomical structures"[4].

Single Photon Emission Computer Tomography (SPECT) procedures were previously standard for providing imaging treatments for patients with heart disease. SPECT also includes a radioactive tracer and is typically used while the patient performs an exercise stress test[5]. Cardiac PET use has been recommended when possible by medical associations, instead of SPECT, due to providing

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[1]Cleveland Clinic medical. "PET Scan: What It Is, Types, Purpose, Procedure & Results." *Cleveland Clinic*, Cleveland Clinic, 19 Mar. 2025, my.clevelandclinic.org/health/diagnostics/10123-pet-scan.

[2] "Positron Emission Tomography (PET)." *Hopkins Medicine*, Johns Hopkins Medicine, 20 Aug. 2021, www.hopkinsmedicine.org/health/treatment-tests-and-therapies/positron-emission-tomography-pet.

[3] Fayad, Laura M. "CT Scan versus MRI versus X-Ray: What Type of Imaging Do I Need?" *Johns Hopkins Medicine*, Johns Hopkins Medicine, 29 Aug. 2025, www.hopkinsmedicine.org/health/treatment-tests-and-therapies/ct-vs-mri-vs-xray.

[4] Ahmed I, Devulapally P. Nuclear Medicine PET Scan Cardiovascular Assessment, Protocols, and Interpretation. [Updated 2023 Jul 30]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK570631/

[5] "Myocardial Perfusion Imaging Test: Pet and SPECT | American Heart Association." *Myocardial Perfusion Imaging Test: PET and SPECT*, American Heart Association, 26 Feb. 2025, www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/myocardial-perfusion-imaging.

higher quality of images and lower radiation exposure[6]. When PET can be combined with CT, the image quality improves further and allows for more accurate diagnosis and treatment.

There is currently one PET/CT scanner in PD 16 reporting services to Virginia Health Information (VHI) in the most recent year of data available, 2024 (**Table 2**). The scanner does not have a restriction on use, and the CT portion is authorized to provide imaging independently from the PET portion of the scanner.

Table 2: PET/CT Reported Utilization in PD 16 (2024)

Facility	Scanners	Scans	Utilization
Medical Imaging of Fredericksburg	1	2,686	44.8%

Source: VHI Data

COPN No. VA-04852 authorized one PET/CT scanner restricted to cardiac imaging services for Cardiology Associates of Fredericksburg (Cardiology Associates) in August of 2023. The scanner was expected to be providing services starting in November of that year. Data for the site was not reported for 2023 or 2024, nor was there an annual or indefinite extension filed with DCOPN at the time this report was written[7]. DCOPN has no documentation that this authorized scanner is operational. The CT portion of the PET/CT is not authorized for independent use.

COPN No. VA-04971 authorized Oracle Heart and Vascular to establish a specialized imaging center for cardiac PET/CT scans with one PET/CT scanner in March 2026. The facility is expected to begin providing services on June 16, 2026. It is restricted to cardiac imaging services. The CT portion of the scanner is not authorized for independent use.

There are two COPN requests for PET/CT scanners in PD 16 that are currently being analyzed. The competing projects are COPN Request No. VA-8850 and VA-8864. COPN Request No. VA-8850 is applying for an unrestricted PET/CT scanner, while the proposed PET/CT scanner for COPN Request No. VA-8864 will be restricted to oncological imaging. An Informal Fact-Finding Conference (IFFC) for the projects was held on April 20, 2026, and the Health Commissioner's decision is expected by August 1, 2026. Should the projects be approved, the total number of PET/CT scanners in the PD will be five, with two restricted to cardiac scans and one restricted to oncological use (**Figure 1**).

[6] Bateman, Timothy M. "Advantages and disadvantages of pet and SPECT in a busy clinical practice." *Journal of Nuclear Cardiology*, vol. 19, Feb. 2012, pp. 3–11, https://doi.org/10.1007/s12350-011-9490-9.

[7] In a phone call on March 2, 2026, staff at the facility stated that there was a PET/CT scanner providing services but could not confirm when these services started. DCOPN is waiting for the formal Indefinite Extension.

Figure 1: Proposed and Authorized PET/CT Inventory (PD 15)

Authorized Facility	CT Units	Restriction	Certificate No.
Medical Imaging of Fredericksburg	1	Unrestricted	VA-03953
Cardiology Associates of Fredericksburg	1	Cardiac imaging	VA-04852
Oracle Heart and Vascular	1	Cardiac imaging	VA-04971
Authorized PET/CT Scanners	**3**		

Applying Facility	CT Units	Restriction	Request No.
Reston Radiology Advanced Imaging Centers, LLC	1	Unrestricted	VA-8850
Hemotology-Oncology Associates of Fredericksburg	1	Hemotology-Oncology	VA-8864
Other Proposed PET/CT Scanners	**2**		

Source: DCOPN Inventory and Records

AlignedCardio does not have existing COPN certificates in PD 16 under the name of James River Cariology or other subsidiaries, although the applicant does have certificates in other PDs. Since February 2025, the applicant has been authorized for three certificates, with two in the neighboring PD 15. One certificate is for the establishment of a specialized imaging center with one PET/CT scanner restricted to cardiology[8], and the other is for the establishment of a cardiac catheterization laboratory under the subsidiary of Ashlake Heart & Rhythm Center[9]. James River Cardiology is also authorized as a specialized imaging center with one PET/CT in PD 5[10] and is applying for the establishment of another in PD 20[11].

Proposed Project

James River Cardiology is proposing the establishment of a specialized imaging facility with one PET/CT scanner restricted to cardiovascular imaging. The proposed location is currently a Virginia Cardiovascular Specialists facility, which is performing SPECT scans for patients, along with other cardiovascular services not regulated by DCOPN. Upon authorization of the proposed project, James River Cardiology will take ownership of the facility, with Virginia Cardiovascular Consultants becoming part of James River Cardiology. Physicians and staff currently working at Virginia Cardiovascular Specialists will continue to provide care to patients, with the addition of PET/CT imaging services from the James River Cardiology staff[12]. The proposed PET/CT scanner will be located in 720 square feet of existing clinical space in the facility and will not require expanding the facility's footprint. Capital costs for the proposed project are estimated at $1,180,926 (**Table 3**). This includes renovations of existing interior space and purchasing the equipment.

[8] COPN No. VA-04949
[9] COPN No. VA-04959
[10] COPN No. VA-04975
[11] COPN Request No. VA-8885 is also in Batch Cycle D/G that began May 10, 2026. The COPN recommendation is due July 20, 2026.
[12] Email from M. Amin. "Existing Location COPN Request No. VA-8888." 2 July 2026.

Table 3: Capital Cost

Direct Construction Cost	$	256,000
Equipment not Included in Construction	$	824,000
Site Acquisition Cost	$	100,926
Architectural, Engineering, and Consultant Fees	$	-
Capital Cost	**$**	**1,180,926**

Source: COPN Request No. VA-8888

Imaging services will be provided on site Monday through Friday, from 8 am to 5 pm. Emergency slots will be held during the noon hour and from 4 pm to 5 pm each weekday. Should the proposed project be approved, the applicant projects that services will begin on December 11, 2026.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project as the "[e]stablishment of a medical care facility described in subsection A;" medical care facilities are defined, in part, as "[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.**

Table 4: PD 16 Estimated Population in Poverty (2024)

Location	Population in Poverty	Total Population	Poverty Percentage
Caroline County	3,403	32,721	10.4%
King George County	1,870	28,333	6.6%
Spotsylvania County	10,604	151,486	7.0%
Stafford County	8,873	164,315	5.4%
City of Fredericksburg	3,377	27,680	12.2%
PD 16	**28,127**	**404,535**	**7.0%**
Virginia	**839,669**	**8,568,051**	**9.8%**

Source: US Census SIAPE (2024)

The proposed project is in the City of Fredericksburg, in PD 16. The city is located on the border of Spotsylvania County and Stafford County and has a poverty rate of 12.2% (**Table 4**). This rate is higher than that of the PD and the state. The 2024 poverty rate in the City of Fredericksburg increased 7.4% between 2023 and 2024, which was similar to the PD 16 increase within that time period (6.7%). This increase is not reflected in the state of Virginia's poverty rate, which

decreased from 10.2% to 9.8%. The City of Fredericksburg has the highest rate of poverty in the PD, as of the 2024 data.

The City of Fredericksburg has a public transit system called Fredericksburg Regional Transit System (FRED or FXBGO!). FRED provides transportation with no fare, as part of a trial that began in 2022, which has not announced an end date[13]. The currently free transportation is available to anyone in the city, Monday through Friday. There are four bus stops within a fifteen-minute walk, including one at the opposite end of the parking lot from where the proposed facility's entrance is.

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 letters of support from current doctors and staff at existing James River Cardiology facilities. There were also seven letters of support for the project from physicians in the area and in the current James River Cardiology practices. The letters in aggregate expressed:

- The rate of cardiovascular disease in the PD, and Fredericksburg in particular, is increasing. This causes the demand for cardiac PET/CT scans to increase, which impacts PET/CT scanner availability.
- Patients are having to travel to the Richmond area for cardiac imaging scans, creating barriers and delays in care.
- In cardiac care, immediate care is necessary.
- Cardiac PET/CT scans allow for non-invasive imaging with improved accuracy and accessibility, "particularly valuable" among patients with comorbidities.

On June 22, 2026, DCOPN received a letter of opposition from Medical Imaging of Fredericksburg (MIF). The letter stated that:

- PD 16 has enough PET/CT services, restricted and unrestricted.
- PD 16 operates at 45% of the SMFP threshold and can increase volumes without needing an additional facility.
- MIF is currently one of the few facilities to offer "Class-1, Level-A testing, the highest recommendation available by the American Heart Association and American College of Cardiology, for high quality, non-invasive coronary CTA testing with non-invasive FFR-CT (HeartFlow)."

Also on June 22, 2026, DCOPN received a letter from James River Cardiology responding to the letter of opposition from MIF. The letter stated that:

[13] https://www.fredericksburgva.gov/1684/Fares

- The authorized PET/CT scanners restricted to cardiological scans in PD 16 are not providing services for patients receiving care at "community cardiologists".
- The HeartFlow program that MIF cites is not the same as the fractional flow reserve derived CT (FFR-CT) that the applicant will provide.

Other than the letters written above, there were no other comments.

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-8888 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 regarding this project, inviting public comments on May 10, 2026. The public comment period closed on June 24, 2026. Other than the letters of commitment 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.

The status quo is a reasonable alternative to the proposed project. There are currently two authorized cardiac PET/CTs in the PD and one current provider with an unrestricted PET/CT scanner. The operator of the existing unrestricted scanner, MIF, has stated that the facility is able to have further volumes prior to the need for an additional PET/CT scanner in the PD. As the two cardiac-restricted PET/CT imaging providers are not reporting data, a reasonable alternative is to wait for volumes prior to the authorization of additional scanners in the PD.

However, the location of the proposed project has an existing patient base under Virginia Cardiologist Specialists and is providing SPECT services. While SPECT imaging is still a valid and accurate method of diagnosis and can assist in treatment, PET/CT imaging has been determined to be a more accurate method for certain cardiac diseases.

(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 I designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 16. Therefore, this consideration does not apply to the review of either proposed project.

(iv) Any costs and benefits of the project.

Capital costs of the proposed project are estimated to be $1,180,926. This is comparable with similar projects that have been recently authorized. A certificate issued in August of 2025 for the establishment of a center for PET/CT services with one scanner limited to cardiology was estimated to cost $1,335,285[14] and a similar certificate in April 2025 was issued to a project with a cost estimation of $3,807,237[15]. The applicant states that starting funds will be provided through a service agreement with CDL Nuclear Technology which "will be funded throughout the agreement's terms."

Table 3: Capital Cost *(as shown above)*

Direct Construction Cost	$	256,000
Equipment not Included in Construction	$	824,000
Site Acquisition Cost	$	100,926
Architectural, Engineering, and Consultant Fees	$	-
Capital Cost	**$**	**1,180,926**

Source: COPN Request No. VA-8888

A benefit to the proposed project is that patients currently receiving SPECT imaging services at Virginia Cardiologist Specialists will be able to receive PET/CT imaging without needing to travel to a separate location. This will increase comprehensive care for the patients and provide imaging services recommended for cardiac care.

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

In accordance with Section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project will be conditioned to provide a level of charity care based on gross patient revenues derived from PET/CT imaging services that is no less than the equivalent average for charity care contributions in HPR I, currently 2.0% (**Table 5**). Pursuant to the 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.

James River Cardiology has proffered a charity care rate of 3.1%, which is higher than the HPR average of 2.0%. Should the project be approved, there will be a charity care condition of 3.1% on the certificate.

[14] COPN VA-04949
[15] COPN VA-04930

Table 5: 2024 Charity Care Contributions at or below 200% of Federal Poverty Level

HPR I	Gross Patient Revenues	Charity Care	% of Gross Patient Revenues
Inpatient Hospitals			
UVA Health Culpeper Medical Center	608,478,177	34,259,884	5.6%
University of Virginia Medical Center	8,921,363,447	267,814,182	3.0%
Sentara RMH Medical Center	1,299,093,095	34,179,211	2.6%
UVA Encompass Health Rehabilitation Hospital	47,227,845	2,302,674	4.9%
Sentara Martha Jefferson Hospital	976,480,538	17,411,990	1.8%
Carilion Rockbridge Community Hospital	245,348,553	2,154,977	0.9%
Spotsylvania Regional Medical Center	1,018,743,482	8,957,162	0.9%
Augusta Health	1,602,399,846	12,298,471	0.8%
Bath Community Hospital	29,576,578	172,931	0.6%
Valley Health Winchester Medical Center	2,123,358,824	11,908,546	0.6%
Stafford Hospital Center	370,363,474	1,843,906	0.5%
Mary Washington Hospital	1,802,440,824	8,931,031	0.5%
Valley Health Shenandoah Memorial Hospital	211,090,921	1,039,184	0.5%
Fauquier Hospital	502,348,786	2,450,797	0.5%
Valley Health Warren Memorial Hospital	265,287,099	1,197,376	0.5%
Valley Health Page Memorial Hospital	95,416,374	314,135	0.3%
Encompass Health Rehab Hosp of Fredericksburg	39,643,298	12,455	0.0%
UVA Transitional Care Hospital			
HPR I Inpatient Hospital Median			0.9%
HPR I Total Inpatient $ & Mean %	**$ 20,158,661,161**	**$ 407,248,912**	**2.0%**

HPR I	Gross Patient Revenues	Charity Care	% of Gross Patient Revenues
Outpatient Centers			
Martha Jefferson Outpatient Surgery Center	27,600,926	837,961	3.0%
UVA Health Surgical Care Riverside	39,804,288	921,933	2.3%
UVA Orthopedic Center	98,920,765	1,552,249	1.6%
Fredericksburg Ambulatory Surgery Center	71,232,608	178,939	0.3%
Surgery Center of Central Virginia	113,613,804	40,762	0.0%
Rockingham Eye Surgery Center	13,818,185	4,650	0.0%
Soaring Surgery Center	2,677,434	0	0.0%
Valley Health Surgery Center	19,528,899	0	0.0%
Winchester Eye Surgery Center, LLC	5,035,445	0	0.0%
HPR I Outpatient Hospital Median			0.0%
HPR I Total Outpatient Hospital $ & Mean %	**$ 392,232,354**	**$ 3,536,494**	**0.9%**
HPR I Hospital Median			1.22%
HPR I Total Hospital $ & Mean %	**$ 20,550,893,515**	**$ 410,785,406**	**2.0%**

Source: VHI Data (2024)

(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).

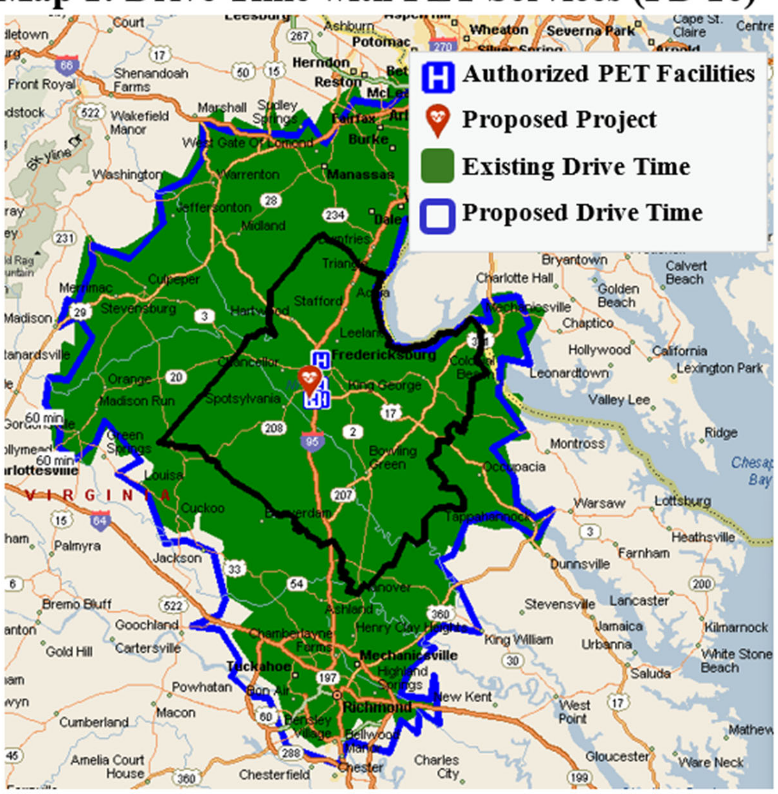
The SMFP contains criteria/standards for the establishment or expansion of cardiac catheterization services. They are as follows:

Article 4
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.

Map 1: Drive Time with PET Services (PD 16)



Source: Microsoft Streets and Trips (2008), DCOPN Inventory

Map 1 shows the geographic accessibility from the proposed site. The black outline is the boundary of the PD. The dark green is the existing drive time from the authorized facilities, marked with the blue "H". The proposed drive time from the proposed facility, marked with the red pin, is shown with the dark blue outline. The projects that are being considered outside of this batch cycle for the PD are shown with the blue and white "H" but are not included in the existing drive time as the projects are not currently authorized. The proposed project does not add geographic accessibility to the PD.

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.

This criterion does not apply as the applicant is not a hospital or within a hospital system.

B. No new fixed site PET services should be approved unless an average of 6,000 procedures[16] 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.

6,000 PET procedures are not currently being performed in the PD. In 2024, the last year for which data is available, the reported volume was 2,686 scans on one authorized PET/CT. This is well under the SMFP threshold.

While the utilization of existing authorized scanners must be considered in the analysis of public need, DCOPN has previously stated that the threshold for the maximum utilization needs updating. The highest performing PET scanner in Virginia for 2024, the latest year for which such data is available, performed 5,448 procedures (90.8% of the utilization standard[17]); the second highest utilized scanner performed 4,139 procedures (69.0% of the standard[18]). The

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

[17] This was performed by Virginia Heart in Falls Church, Virginia. The facility is authorized for one scanner by COPN VA-04806.

[18] This was performed by Fairfax PET/CT Center in Fairfax, Virginia. The facility is authorized for one scanner per COPN VA-04132.

average number of PET scans performed in Virginia was 2,372 procedures in 2024. The only reporting PET/CT scanner in PD 16 is operating at a higher utilization than the state average. There are two cardiac PET/CT scanners that have been authorized for the PD but are not yet reporting volumes to VHI. DCOPN notes that the SMFP does not make a distinction between unrestricted and restricted PET scanners.

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.

This criterion does not apply as the proposed project is for the establishment of a fixed site and not the expansion of services.

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.**

This criterion does not apply as the proposed project is for the establishment of a fixed site and does not involve the addition or expansion of mobile PET/CT 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.

The applicant stated:

> "The proposed fixed Cardiac PET/CT service will be overseen by physicians who possess the requisite training and licensure. Dr. Jaspreet Singh will serve as the Nuclear Medicine Director of the Cardiac PET/CT service at James River Cardiology. Dr. Singh holds specialized training in the performance and interpretation of Cardiac PET/CT and is supported by additional board-certified cardiologists within the practice who contribute to the delivery of comprehensive cardiovascular care."

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.**

Approval of the proposed project would add a third cardiac-restricted PET/CT to PD 16. As stated previously, the two authorized PET/CTs with cardiac restrictions are not reporting volumes to VHI so the need for the specific imaging services cannot be compared with existing volumes from providers. DCOPN notes that the SMFP does not make a distinction between unrestricted and restricted PET scanners. The applicant has an existing patient base for SPECT imaging services at the proposed location and the applicant stated that the purpose of the proposed project is to convert "existing nuclear cardiology (SPECT) capacity to PET/CT, allowing the practice to enhance diagnostic capabilities without expanding its physical footprint or shifting volumes from other providers." The applicant estimates approximately 96 scans per month in the first year, 1,152 within the year, and 100.8 scans per month in the second year, 1,209 within the year. Conversion of existing SPECT volumes to PET/CT scans is unlikely to impact volumes of existing providers.

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.**

The proposed location is on the campus of Spotsylvania Regional Medical Center's campus. The medical center is an acute hospital with 133 beds and is a designated Level 3 trauma center. The facility is not authorized for a PET/CT scanner, so the proposed project is not expected to impact care provided by the center, and the center has not provided comment to DCOPN in support or opposition.

Two cardiac PET/CT scanners have been authorized in PD 16 that DCOPN does not have volumes for. Neither has filed for indefinite extensions, and so, due to the lack of available data on the volumes needed for cardiac PET/CT scanners, DCOPN cannot accurately determine the impact that the proposed project will have specifically on cardiac PET/CT imaging. As stated previously, the sole authorized non-restricted provider, MIF, has stated concerns that the proposed project will impact its volumes at its existing facility. This was taken into consideration, along with the fact that SPECT imaging is currently being provided at the facility, but PET/CT imaging is the recommended imaging service for several cardiac diseases.

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 applicant is projecting a net income of $1,461,453 for the first year of operation and $1,556,553 for the second year (**Table 6**). The projections show a net profit made for both years, and the applicant provided information showing further profit for the first five years of operation.

Table 6: Pro Forma Projection

	Year 1	Year 2
Gross Patient Revenue[19]	**$ 3,321,953**	**$ 3,488,051**
Isotope Cost	$ (576,000)	$ (604,800)
Charity Care	$ (35,697)	$ (37,482)
Total Deductions	$ (611,697)	$ (642,282)
Operating Revenue	**$ 2,710,256**	**$ 2,845,769**
Operating Expenses	$ (1,248,803)	$ (1,289,216)
Net Income (Before Taxes)	**$ 1,461,453**	**$ 1,556,553**

Source: COPN Request No. VA-8888

Two additional full-time equivalent (FTE) staff will be hired for the proposed project. This includes: one administrator, one radiologic technologist. The applicant states that most of the staff providing care will be people already working at the location under the current owner of Virginia Cardiology Specialists. Additional personal, such as nuclear medical technologists, will "either be recruited locally or trained from existing staff where appropriate".

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.

(i) The proposed project will not introduce new technology. PET/CT services are already being provided in the PD; the proposed project is the establishment of an additional cardiac PET/CT provider. (ii) All services will be provided on an outpatient basis. (iii) The applicant did not identify any cooperative efforts. (iv) There were no additional factors deemed appropriate.

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 nor is it connected to one.

DCOPN Staff Findings and Conclusions

James River Cardiology, LLC (James River Cardiology) is proposing the establishment of a specialized imaging facility with one PET/CT scanner restricted to cardiological imaging in PD 16. The proposed location is currently a Virginia Cardiovascular Specialists facility, which is

[19] This cost was determined by DCOPN per the information provided on the Pro Forma. The original estimations did not have the revenue prior to the isotope costs.

performing SPECT scans for patients, along with other cardiovascular services not regulated by DCOPN. Capital costs of the proposed project are estimated to be $1,180,926. The applicant states that starting funds will be provided through a service agreement with CDL Nuclear Technology, which "will be funded throughout the agreement's terms." James River Cardiology has proffered a charity care rate of 3.1%, which is higher than the HPR average of 2.0%. Should the project be approved, there will be a charity care condition of 3.1% on the certificate.

DCOPN received letters of support from current doctors and staff at existing James River Cardiology facilities; there was also one letter of opposition from an existing PET/CT provider in the PD. The status quo is a reasonable alternative to the proposed project; however, the location is currently providing SPECT imaging for patients and PET/CT imaging has been determined to be a more accurate method with certain cardiac diseases by industry standards. The proposed project does not add geographic accessibility to the PD. It also would not meet the 6,000 procedures of the SMFP threshold of PD expansion for PET/CT scanners. However, as DCOPN has stated in previous reports, the exact threshold for the maximum utilization needs updating as there is no PET scanner in the state that is operating equal to or above the threshold. The applicant estimates approximately 96 scans per month in the first year, 1,152 within the year, and 100.8 scans per month in the second year, 1,209 within the year. The project is feasible in terms of financial and human resources. No new technology will be added to the PD through the proposed project, and James River Cardiology is not a teaching hospital.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends **conditional approval** of James River Cardiology, LLC's Certificate of Public Need Request number VA-8888 to establish a specialized care facility for the provision of PET/CT imaging services for the following reasons:

1. James River Cardiology, LLC's proposal 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 existing patient base and cardiovascular restriction make it unlikely that the proposal will negatively impact existing providers.
3. There is an existing patient base receiving SPECT, which would transition to the superior PET/CT modality.
4. Projected costs are reasonable, and the proposal is wholly feasible.

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

James River Cardiology, LLC will provide PET/CT imaging services to all persons in need of this service, regardless of their ability to pay, and will facilitate the development and operation of primary medical care services to medically underserved persons in an aggregate amount equal to at least 2.0% of James River Cardiology, LLC's gross patient revenue derived from PET/CT

imaging services. 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.

James River Cardiology, LLC will provide PET/CT imaging services 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, 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.