VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

January 19, 2026

RE: COPN Request No. VA-8845
Oracle Heart & Vascular, Inc.
Fredericksburg, Virginia
Establish a New Medical Care Facility for PET/CT Services with One Fixed PET/CT Scanner Limited to Cardiology

Applicant

Oracle Heart & Vascular Inc, (hereafter known as "Oracle") is a Virginia professional stock corporation. Previously known as Oracle Heart & Vascular, PLLC, the practice has two established locations. The proposed project will be the first established medical facility and is located at 412 Park Hill Drive, Fredericksburg, Virginia in Planning District (PD) 16, Health Planning Region (HPR) I.

Background

The location of the project is in the City of Fredericksburg and in PD 16, along with four other 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 12.7% to 431,060 by 2030 (**Table 1**). This is more than double the expected population growth rate of Virginia during the same period. While Fredericksburg's population has a growth rate slightly less of the PD (11.6% compared to the PD rate of 12.7%), the actual increase is approximately 3,242 people which brings the population of the count to 31,224 people in 2030. This increase will make the population of the county approximately 7.2% of the total population in the PD. The growth rate of the population over the age of 65 in the city is less than half of the projected growth rate of the age group for the PD.

Table 1: Predicted Population Change of PD 16

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	32,753	25,369	6,470	6.0%	6.0%	21.5%
King George County	26,723	20,016	3,706	29,434	22,265	5,146	10.1%	11.2%	38.9%
Spotsylvania County	140,032	105,768	20,619	155,407	118,822	29,311	11.0%	12.3%	42.2%
Stafford County	156,927	115,532	17,291	182,243	135,993	26,858	16.1%	17.7%	55.3%
City of Fredericksburg	27,982	21,674	3,463	31,224	24,142	4,158	11.6%	11.4%	20.1%
PD16	**382,551**	**286,921**	**50,406**	**431,060**	**326,590**	**71,943**	**12.7%**	**13.8%**	**42.7%**
Virginia	**8,631,393**	**6,729,459**	**1,395,291**	**9,129,002**	**7,173,130**	**1,762,641**	**5.8%**	**6.6%**	**26.3%**

Source: Weldon-Cooper Center for Public Service

Positron emission tomography (PET) scans use a safe, radioactive chemical that is injected and detect diseased cells that absorb the chemical in scans[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]. PET images can be combined with CT scans to produce more precise information about the areas scanned. 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 1-10 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 it will be alone, instead a "fast" scan to "delineate anatomical structures"[4].

PET/CT machines allow for both scans to occur simultaneously. The hybrid scans are endorsed by the American Heart Association and are a growing trend in the diagnosis of cardiovascular disease (CVD). A 2017 study also determined that PET/CT scans "significantly shorten imaging protocols, reduce radiation exposure, and increase its application in CVD" when compared to the previous standard of single photon emission computer tomography (SPECT).[5]

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**). It is located at 1201 Sam Perry Boulevard in Fredericksburg and is approximately 0.2 miles away from the proposed site. The currently existing PET/CT scanner does not have a restriction on its use[6]. The applicant has stated

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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] Li Z, Gupte AA, Zhang A, Hamilton DJ. Pet Imaging and its Application in Cardiovascular Diseases. Methodist DeBakey Cardiovasc J. 2017 Jan-Mar;13(1):29-33. doi: 10.14797/mdcj-13-1-29. PMID: 28413580; PMCID: PMC5385792.

[6] In DCOPN Staff Report for COPN Request No. VA-8866, it was incorrectly stated that the PET/CT scanner at the facility was restricted to oncological services. The certificate does not have any restrictions or conditions beyond the 2.8% charity care stipulated.

that the scanner will be used for cardiac services, primarily for the "early detection of coronary artery disease (CAD)".

Table 2: PET/CT Reported Utilization in PD16 (2024)

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

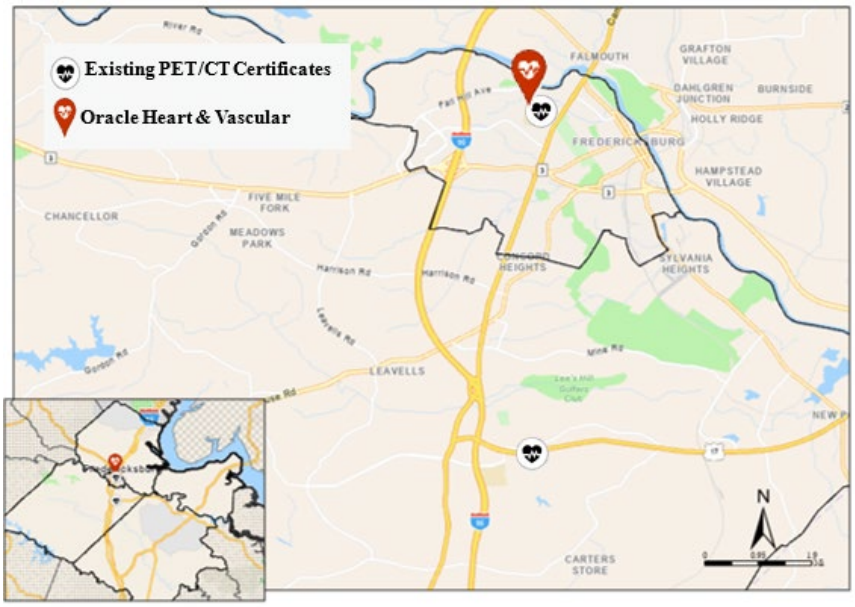
Source: VHI Data

COPN No. VA-04253 authorized one PET/CT scanner for Spotsylvania Regional Medical Center in 2010, but the facility has not reported PET/CT data to VHI from receiving the certificate to the most recent year of data available and has not filed for an indefinite extension with DCOPN.

COPN No. VA-04852 authorized one PET/CT scanner for Cardiology Associates of Fredericksburg (Cardiology Associates) in August of 2023 and was expected to be providing services starting in November of that year. Data was not reported for 2023 or 2024, nor was there an annual or indefinite extension filed with DCOPN[7].

As stated above, there is only one PET/CT scanner that reported data in 2024 in PD 16. The other two locations which hold certificates are not reporting data but are included in **Map 1** for reference. To show where the facilities are in relation to each other, the main picture in the map is zoomed into the rectangle outlined in the smaller picture.

Map 1: Locations with PET/CT COPN Certificates,



Source: ArcGIS, DCOPN Inventory, VHI Records

This project is the first requested by Oracle. The applicant has three office locations, all in PD 16. The first is in King George and the others are in Fredericksburg. Its Park Hill address is the first

[7] In a phone call on November 18, 2025, staff at the facility stated that there was a PET/CT scanner providing services but could not confirm when these services started. DCOPN formally reached out to the facility's representative listed on the application regarding the status of the project, but there was no response.

medical facility as none of the others have COPN regulated equipment or services. Oracle applied for a zoning change on September 29, 2025, to the appropriate zone.

Proposed Project

Oracle is proposing to establish a medical facility through the introduction of PET/CT scanner restricted to cardiovascular use. The facility at Park Hill Drive is currently providing "a comprehensive suite of cardiac services, that include but are not limited to blood tests, electrocardiograms, chest x-rays, echocardiograms, peripheral vascular ultrasounds and nuclear stress tests, in order to diagnose and treat coronary artery disease (CAD) in its early stages." The practice has an existing patient base and are providing care for patients at this location currently.

The project will include the addition of the PET/CT machine and system, as well as the construction of a hot lab and patient waiting areas. The construction will occur in the already rented facility and is expected to include a renovation of approximately 525 square feet. With the direct construction costs estimated to be approximately $420,000, the cost per square foot will equate to an estimated $800 (**Table 3**). This cost is appropriate when compared to other similar, recently authorized projects. In **Table 3**, the cost of site acquisition includes the rent for the facility for the term of the lease, which is renewed every three years.

Table 3: Project Estimated Capital Costs

Direct Construction	$ 420,000.00
Site Acquisition	$ 143,136.08
Site Preparation	$ 85,000.00
Architecture and Engineering Fees	$ 22,000.00
Equipment Lease (CDL Nuclear)	$ 492,750.00
Total Capital Cost	**$ 1,162,886.08**
Cost after Allowance	**$ 862,886.08**

Source: COPN Request No. VA-8845

The applicant is not applying to use the CT component of the PET/CT independently, but rather to enhance the images resulting from the PET scan; therefore, the staff report will focus on the PET inventory, utilization, and State Medical Facilities Plan (SMFP) criteria.

Project Definition

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

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

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

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

Oracle is located in the City of Fredericksburg, in PD 16. Fredericksburg is located on the border of Spotsylvania County and Stafford County and has a poverty rate of 7.4% (**Table 4**). This rate is slightly higher than that of the PD and lower than the state.

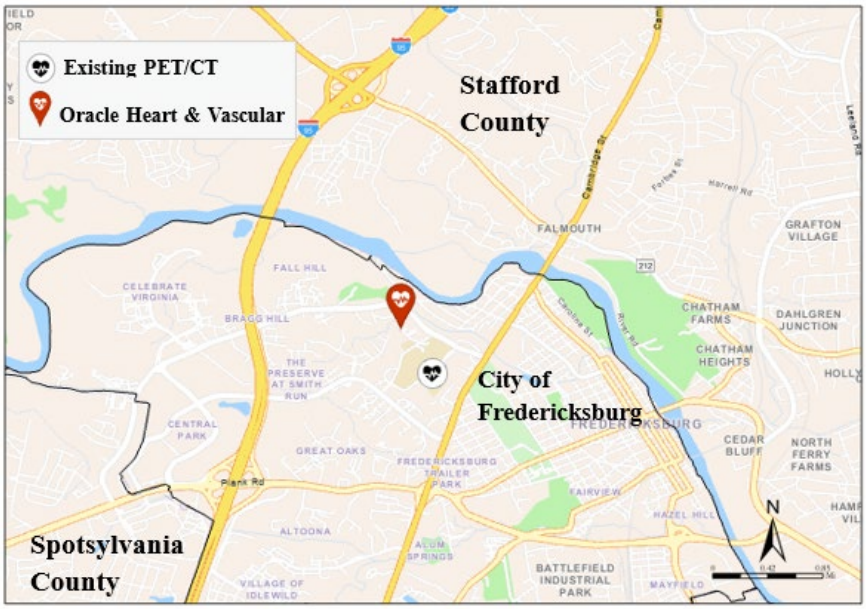
Table 4: Poverty Rate in PD16 (2023)

Location	Poverty Rate
Caroline County	9.3%
King George County	10.6%
Spotsylvania County	6.6%
Stafford County	5.3%
City of Fredericksburg	7.4%
PD16	**6.7%**
Virginia, Statewide	**10.2%**

Source: US Census SIAPE (2023)

The proposed facility is located in a medical office park and near multiple highways, including but not limited to, I-95, Hwy-3, Hwy-208, and Jefferson Davis Highway (**Map 2**). Oracle stated in the application that "[proximity] to Mary Washington Hospital further enhances road connectivity and supports seamless transfers, emergency access, and collaboration with neighboring providers." The applicant does not have a formal transfer agreement with the hospital. On **Map 2**, the hospital can be seen adjacent to the existing PET/CT scanner as the Medical Imaging of Fredericksburg is part of the hospital and on the main campus.

Map 2: Oracle Interstate Access



Source: ArcGIS, DCOPN Inventory, VHI Records

The City of Fredericksburg has a public-transit system called Fredericksburg Regional Transit system (FRED or FXBGO!) which has a stop approximately 0.02 miles from the facility and has lines into neighboring counties. FRED is providing transportation with no fare, as part of a trial that began in 2022 and has not announced an end date[8]. The currently free transportation is available to anyone in the city, Monday through Friday.

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 two letters of commitment. The president of Oracle wrote on behalf of the medical staff, stating staff support for the project and dedication to the provision of the additional services if approved. He stated that the establishment of PET/CT services will be more accurate than the current Single Photon Emission Computed Tomography (SPECT) scans, which will remain as a support in the facility. A doctor from a separate facility located within the same medical complex as Oracle also wrote in support of the project and complimented Oracle's patient care.

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

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-8845 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 November 10, 2025. The public comment period closed on December 24, 2025. 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 not a reasonable alternative. There is currently only one facility in the PD reporting that PET/CT scans were provided to patients in 2024, Medical Imaging of Fredericksburg. The imaging center is primarily used for oncological services, but there is no restriction on the scanner. However, in 2024, the center reported 2,686 scans, which while approximately 44.8% of the SMFP expansion threshold, is a higher utilization than the average PET/CT scanner in Virginia[9]. Cardiology Associates received a certificate for a cardiological PET/CT scanner in 2023 and was expected to begin services in November the same year. The facility did not report data to VHI in 2023 or 2024.

As numerous organizations, such as the American Heart Association, have determined cardiology PET/CT scans a more effective manner of determining heart health than the current SPECT that the applicant is using, the addition of the scanner would be more advantageous than the status quo.

(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 is not applicable to the review of the proposed project.

(iv) Any costs and benefits of the project.

As shown in **Table 3** above and repeated below, the projected capital costs for the project are $670,136.08 which represents the costs for the PET/CT machine, related software, rent, and

[9] DCOPN has acknowledged in previous reports that the SMFP's utilization standards for PET/CT services require updating to determine a more appropriate measurement threshold for utilization.

construction. The facility signed a five-year lease in 2023 and has an agreement with CDL Nuclear Technologies (CDL Nuclear), the company leasing the equipment that provides Oracle with an allowance of $300,000 to be used in the design and construction of the space where the equipment will be placed. With this allowance, the remaining costs are $370,136.08 (**Table 3**). The applicant stated that the remaining amount will be paid through its "own resources and/or financing agreements."[10] The financing agreements were not specified.

The project will include the addition of the PET/CT machine and system, as well as the construction of a hot lab and patient waiting areas. The construction will occur in the already rented facility of which 525 square feet will be renovated. With the direct construction costs estimated to be approximately $420,000, the cost per square foot will equate to an estimated $800 (**Table 3**). The cost of site acquisition includes the rent for the facility for the term of the lease, which is renewed every three years.

Table 3: Project Estimated Capital Costs *(as shown above)*

Direct Construction	$ 420,000.00
Site Acquisition	$ 143,136.08
Site Preparation	$ 85,000.00
Architecture and Engineering Fees	$ 22,000.00
Equipment Lease (CDL Nuclear)	$ 492,750.00
Total Capital Cost	**$ 1,162,886.08**
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Source: COPN Request No. VA-8845

The construction costs are comparable with other projects, but the overall cost is significantly less. For example, a certificate awarded 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[11]; a similar certificate in April 2025 was awarded to a project with cost estimation of $3,807,237[12].

There are currently two PET/CT scanners providing services in PD 16. The approval of Oracle's project will provide a second PET/CT scanner restricted to the provision of cardiac scans. The applicant stated that patients are facing waiting up to two weeks before receiving scans, which can contribute to "significant stress and anxiety." An additional PET/CT scanner in the district can also decrease travel time for patients who are currently traveling outside of the PD for care.

Oracle will have the PET/CT scanner providing services Monday through Friday, 8:30am to 4:30pm, with emergency slots each day from 12:30pm to 1:20pm. Oracle has a current patient base and provides SPECT scans for patients. The applicant stated that PET/CT would be for patients for whom SPECT is not best practice. Oracle estimates that there will be approximately 720 PET/CT scans in the first year, with a 5% growth rate annually for the next five years.

[10] Springs, Kim. "COPN Request No. VA-8845." Received by DCOPN 1 Dec. 2025
[11] COPN VA-04949
[12] COPN VA-04930

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

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

HPR IV	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%**

	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%
Culpeper Surgery Center, LLC			
University of Virginia Medical Center--Battle Building (Outpatient Children's Hospital)			
University of Virginia Musculoskeletal Center at Ivy Mountain			
Monticello Community Surgery Center			
Total Outpatient Hospitals:			**9**
HPR I Total Outpatient Hospital $ & Mean %	**$ 392,232,354**	**$ 3,536,494**	**0.9%**
Total Hospitals:			**21**
HPR I Total Hospital $ & Mean %	**$ 20,550,893,515**	**$ 410,785,406**	**2.0%**

Section 32.1-102.4. B of the Code of Virginia indicates that, should the proposed project receive approval, it will be conditioned to provide a level of charity care. 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. Oracle stated a commitment to providing equitable access to care in PD 16 and proffered a charity care rate of 2.5%. This is higher than the average rate in the HPR of 2.0% (**Table 5**).

(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.

2. 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 SMFP.

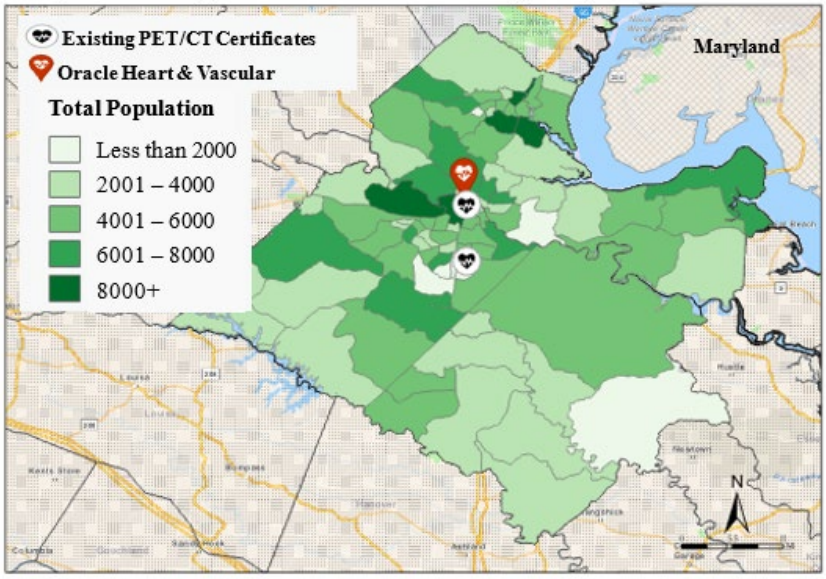
The SMFP contains the criteria and standards for PET/CT[13] imaging services. They are as follows:

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.

[13] As the facility is applying for a PET/CT without the separate use of the CT scanner, the SMFP regulations specific for the establishment or expansion of CT services (ex: 12VAC5-230-120) are not included.

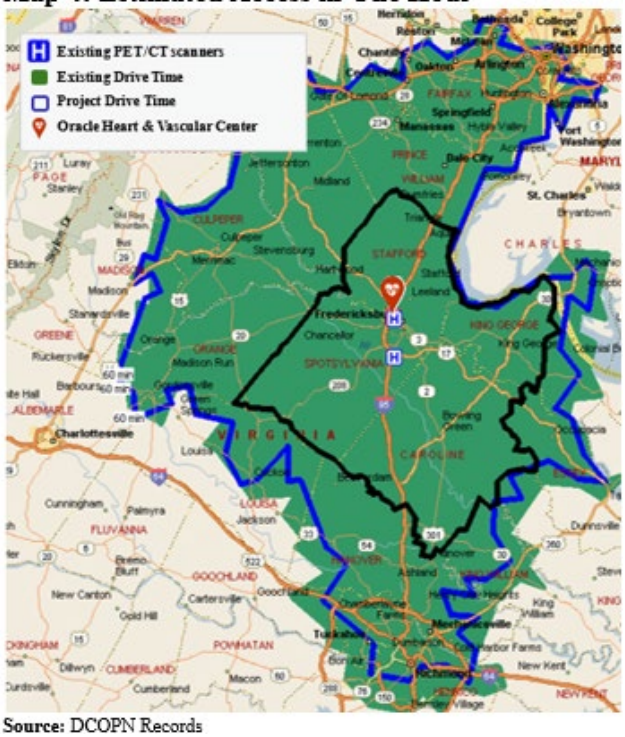
Map 3: 2020 Population of Census Tracts (PD16)



Source: ArcGIS, DCOPN Inventory, VHI Records

Map 3 shows the population of PD16, with the darker green indicating higher population density. The location of the proposed facility is in a higher population density area of the PD. **Map 4** shows the access to facilities within a 60-minute dive highlighted green. The blue outline is the drive-time accessibility from Oracle. The proposed project of establishing a medical care facility through the introduction of PET/CT imaging services will not improve travel time to PET/CT scanners in the PD. The existing facilities provide service-coverage to all of the PD.

Map 4: Estimated Access in One Hour



Source: DCOPN Records

12VAC5-230-210. Need for new fixed site service.

A. If the applicant is a hospital, whether free-standing or within a hospital system, 850 new PET appropriate cases shall have been diagnosed and the hospital shall have provided radiation therapy services with specific ancillary services suitable for the equipment before a new fixed site PET service should be approved for the health planning district.

The applicant is not a hospital, nor connected to a hospital system. The criterion does not apply to this project.

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.

There were 2,686 reported PET/CT procedures in the PD in 2024. As stated before, Cardiology Associates of Fredericksburg has not yet reported PET/CT services. The approval of an additional PET/CT scanner could significantly impact the utilization of the existing scanners as the current reported utilization is approximately 44.8% of the 6,000 procedure SMFP expansion threshold required.

As stated above, DCOPN has previously acknowledged the SMFP's utilization standards for PET/CT services need updating to create a more appropriate threshold to determine utilization of scanners. The average of all PET scanners in Virginia was 2,372 in 2024, the latest year for which such data are available. The reported PD average of 2,686 is higher than the state average.

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 the applicant is not proposing the expansion of an existing PET service. The PD had 2,686 scans reported in 2024. This is below the SMFP expansion threshold of 6,000 scans.

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 is not applicable. The applicant is not applying to add or expand mobile PET/CT services but is looking to establish a fixed site.

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 PET/CT services will be supervised by the facility's Nuclear Medicine Director for Cardiac PET/CT, Dr. Raushan Abdula. Dr. Abdula, and other cardiologists at Orache, have been trained in the "delivery and interpretation of cardiac PET/CT."

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.**

There is currently one facility in the PD reporting that PET/CT scans were provided to patients in 2024, with one other facility holding a certificate without data reported. The approval of Oracle for a PET scanner will increase patient choice in the city as well as in the PD, connectedly increasing beneficial competition as well.

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.**

Approval of the proposed project will mean the addition of a third PET/CT in PD 16. Only one facility with a PET/CT scanner reported utilization to VHI in 2024, so the total number of scans in the PD was 2,686 (**Table 6**). The SMFP threshold for the expansion of PET services is 6,000, making the utilization of the reporting scanner only 44.8%. The addition of a third scanner with the current utilization could impact existing providers.

Table 6: PET/CT Utilization in PD16 (2024)

Facility	Scanners	Scans	Utilization
Medical Imaging of Fredericksburg	1	2,686	44.8%
Cardiology Associates of Fredericksburg	1	-	-
PD 16 Total	2	2,686	22.4%

Source: VHI Data, DCOPN Inventory

However, Oracle has three existing locations, including the Park Hill Drive location, and has an existing patient base. The applicant stated in the application that the focus would not be to gain additional patients for the scans but provide scans to the patients already being served.

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 first year of the project, the applicant estimated a net profit of approximately $697,594.16 for the first year (**Table 7**). The net profit is expected to increase each year by a feasible amount. The project will require the hiring of a certified nuclear medicine/CT technologist as well as a registered nurse. Neither annual costs nor additional staff required are expected to negatively impact the provision of care in the PD.

Table 7: Estimated PET/CT Profit for First 5 Years

	Year 1	Year 2	Year 3	Year 4	Year 5
Annual Revenue Expected	$1,712,700.00	$1,798,335.00	$1,888,251.75	$1,982,664.34	$2,081,797.55
Charity Care *(2.5%)*	$ 42,817.50	$ 44,958.38	$ 47,206.29	$ 49,566.61	$ 52,044.94
Total Annual Expenses	$ 972,288.34	$ 981,639.52	$ 927,475.61	$1,045,282.49	$1,079,164.53
Estimated Net Profit	**$ 697,594.16**	**$ 771,737.10**	**$ 913,569.85**	**$ 887,815.24**	**$ 950,588.08**

Source: COPN Request No. VA-8845 Application

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 project will introduce PET/CT for cardiology, which is recommended by the American Heart Association for reasons including, but not limited to, lower radiation doses, higher accuracy, and shorter imaging times than the SPECT scans[14]. (ii) Oracle will provide services on an outpatient basis. Of the two existing PET/CT scanners in the PD, both belong to outpatient clinics. (iii) There are no cooperative efforts to meet regional health care needs specified in the

[14] Bourque JM, Beller GA. Nuclear Cardiology: The Past, Present, and Future. Circ Cardiovasc Imaging. 2024. doi: 10.1161/CIRCIMAGING.124.016875. Epub 2024 May 21. PMID: 38771905.

project. (iv.) The project is for the approval of a PET/CT scanner restricted to cardiological uses. It will be the second restricted-use cardiac PET/CT scanner in the PD.

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.

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

DCOPN Staff Findings and Conclusions

Oracle Heart & Vascular (Oracle) is applying to establish a specialized center for the provision of cardiac PET/CT imaging services with one fixed PET/CT scanner restricted to cardiological services. The scanner will be added to the 412 Park Hill Drive location in Fredericksburg, Virginia in which Oracle has a cardiac practice and other services not regulated by COPN. There are currently two PET/CT scanners in PD 16, although only one reported data in 2024. The CT portion of the scanner will not be authorized to be used independently without further COPN certification.

There is community support for the project with two members of the public writing letters of support and no known opposition. Of the data reported to VHI in 2024, the last year for which data is available, the utilization of the existing PET/CT scanner in PD 16 was 44.8% of the SMFP expansion threshold but was performing a higher number of scans than the state average. Due to the higher number of scans, the status quo is not a reasonable alternative.

While approval of the project will not enhance geographic access to cardiac PET/CT imaging services in the PD, the additional cardiac PET/CT scanner will allow more efficient access to diagnostic services. Oracle will be providing PET/CT services to an existing patient base restricted to cardiac imaging; the approval of the project is not expected to impact existing providers. Cardiac PET/CT is technology that is more efficient and effective than the current technology (SPECT) in use. The project total is estimated at $1,162,886.08; Oracle has a $300,000 allowance from CDL Nuclear Technologies which the applicant is leasing equipment with. The rest of the cost will be paid for through income reserves. The applicant has proffered a charity rate of 2.5%, which is higher than the PD average.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends **conditional approval** of Oracle Heart & Vascular, Inc.'s Certificate of Public Need Request number VA-8845 to establish a new medical care facility for the provision of PET/CT services with one fixed PET/CT scanner limited to cardiology for the following reasons:

1. The proposal to introduce cardiac PET/CT services into an existing medical facility is generally consistent with the standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
2. Capital costs for the proposed project are reasonable.
3. The PET/CT scanner's use will be restricted to cardiac imaging.
4. The project will improve access to the preferred cardiac imaging modality with numerous benefits over SPECT.
5. The project is more beneficial than the alternative of the status quo.
6. The project is feasible in the immediate and long term.
7. There is no known opposition to the proposed project.

DCOPN's recommendation is contingent upon Oracle Heart & Vascular, Inc.'s agreement to the following charity conditions:

Oracle Heart & Vascular, Inc.'s will provide PET/CT 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 2.5% of Oracle Heart & Vascular, Inc.'s total patient services revenue derived from cardiac PET/CT 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 documenting compliance with the preceding requirement. Oracle Heart & Vascular, Inc. 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.

Oracle Heart & Vascular, Inc. will provide cardiac 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 Oracle Heart & Vascular, Inc. will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.