VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

July 19, 2023

RE: COPN Request No. VA-8699
Cardiology Associates of Fredericksburg, Ltd.
Fredericksburg, Virginia
Establish a Specialized Center for PET/CT Imaging

Applicant

Cardiology Associates of Fredericksburg, Ltd. (CAF) is a limited company with neither subsidiaries of its own nor is it a subsidiary or wholly owned by another. CAF's office is at 9530 Cosner Drive, Suite 200, Fredericksburg, Virginia 22408, in Planning District (PD) 16, within Health Planning Region (HPR) I.

Background

Population and Demographics

PD 16 has experienced a growth in population from 2010 to the present, which is projected to continue until 2030 (**Table 1**). PD 16's growth is occurring at a rate higher than that of both HPR I and the statewide growth (**Table 1**). Contrasting this comparative growth for the entire population, the aged 65+ cohort in PD 16 is projected to grow slightly less than the statewide average for those aged 65+ between 2020 and 2030 (**Table 1**). Fredericksburg City, bolded and italicized in **Table 1**, is expecting a growth rate in those aged 65+ of 36.88%, which is much higher than the PD 16 ages 65+ projection of 22.00% growth, the HPR I age 65+ growth rate of 24.00%, and state statewide average for growth rate for ages 65+ of 27.43% growth for the same time frame.

Table 1. PD 16 Population Information

Geographic Name	2010	2020	% Change 2010-2020	2030	% Change 2020-2030	2020 65 +	2030 65+	% Change 65+
Caroline County	28,545	31,020	8.67%	32,753	5.59%	2,659	3,049	14.66%
Fredericksburg City	***24,286***	***27,905***	***14.90%***	***31,224***	***11.89%***	***23,287***	***31,875***	***36.88%***
King George County	23,584	26,783	13.56%	29,434	9.90%	8,402	10,512	25.12%
Spotsylvania County	122,397	140,356	14.67%	155,407	10.72%	2,608	2,861	9.69%
Stafford County	128,961	157,391	22.05%	182,243	15.79%	22,973	28,428	23.75%
PD 16 Totals	**327,773**	**383,455**	**15.00%**	**431,060**	**11.00%**	**59,929**	**76,726**	**22.00%**
HPR I Totals	1,237,472	1,381,669	11.65%	1,484,212	7.42%	448,386	588,893	24.00%
Virginia	8,001,024	8,646,905	8.07%	9,129,002	5.58%	1,352,448	1,723,382	27.43%

Source: Weldon-Cooper Data

PD 16's poverty rate is 8.7%, which is less than the statewide average of 10.7% (**Table 2**). The project will be located in Fredericksburg City, whose poverty rate is 14.1%, which is higher than both the PD and statewide poverty rates.

Table 2. PD 16 Poverty Rates

Geographic Name	Rate
Caroline County	9.7%
Fredericksburg City	14.1%
King George County	6.8%
Spotsylvania County	7.5%
Stafford County	5.4%
PD 16 Totals	**8.7%**
Virginia	10.7%

Source: Index Mundi

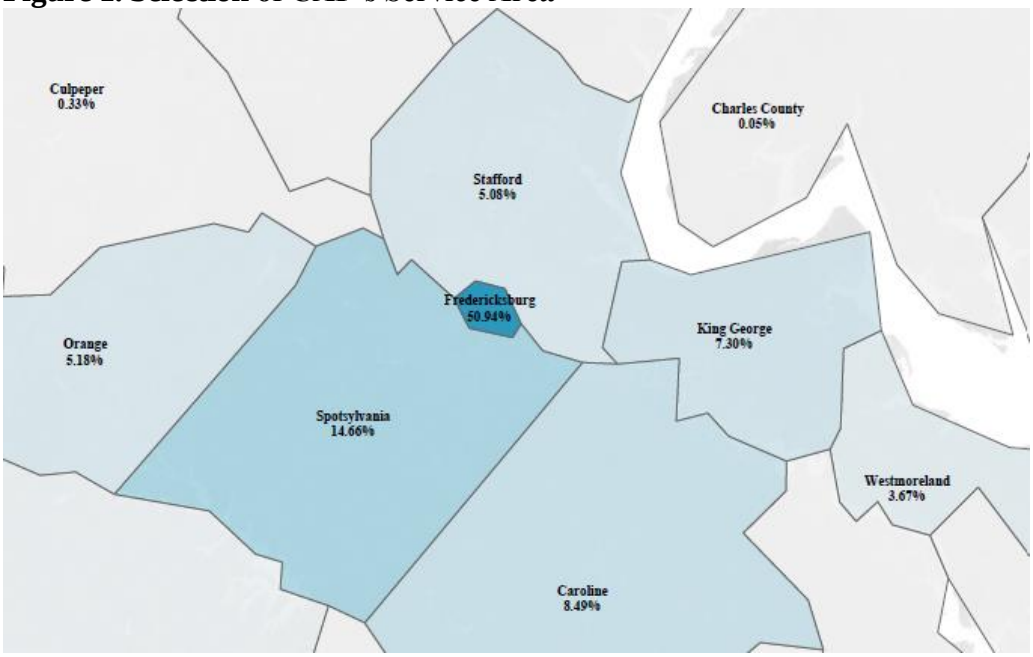
The racial demographic breakdown for 2019, the most recent data available from Weldon-Cooper, indicates that PD 16 averages are similar to those of the statewide averages (**Table 3**). PD 16 has a slightly higher White population, slightly higher African American population, and slightly lower Asian population than the statewide average in 2019 (**Table 3**). Within PD 16, Fredericksburg City and Caroline County both have a higher population of African American residents, 24.1% and 27.2%, respectively, than the PD and statewide averages (**Table 3**). **Figure 1** is an illustration of a selection of the Service Area provided by the applicant, showcasing that 50.98% of their patients reside in Fredericksburg City.

Table 3. Racial Demographics for PD 16, 2019 Data

Geographic Name	White	African American	Asian	Other	Two or More Races
Caroline County	67.2%	27.2%	1.1%	0.9%	3.6%
Fredericksburg City	67.5%	24.1%	3.1%	1.0%	4.3%
King George County	77.9%	16.1%	1.6%	0.9%	3.5%
Spotsylvania County	75.4%	17.5%	2.8%	0.6%	3.6%
Stafford County	70.9%	20.0%	3.6%	0.9%	4.5%
PD 16 Totals	71.8%	21.0%	2.4%	0.9%	3.2%
Virginia	69.4%	19.9%	6.9%	0.7%	3.2%

Source: Weldon-Cooper Data

Figure 1. Selection of CAF's Service Area



Source: COPN Req. VA-8699, Attachment IV.B.1

The Centers for Disease Control and Prevention lists heart disease as the leading cause of death nationally, with the most common type of heart disease being coronary artery disease (CAD).[1] In 2019, African Americans were 30% more likely to die from heart disease than non-Hispanic Whites; African American adults are 30% more likely to have high blood pressure, though less likely than non-Hispanic Whites to have their blood pressure under control.[2] Furthermore, African American women are nearly 50% more likely to have high blood pressure compared to non-Hispanic White women.[3] While these differences are a result of a variety of factors, two of the factors considered to negatively impact the African American community with heart disease are access to care and a diverse, trustworthy healthcare team[4].

Cardiac PET/CT

CAF proposes to install the Cardiac PET/CT (positron emission tomography/computerized tomography) system to be exclusively used for cardiac imaging and procedures. Nuclear imaging plays a pivotal role in diagnosing cardiac infectious, inflammatory, infiltrative, and innervation disorders.[5] PET/CT imaging is a noninvasive diagnostic tool that allows the detection of

[1] Minorityhealth.hhs/gov/omh/browse .aspx?lvl=4&lvlid=19

[2] Ibid.

[3] Ibid.

[4] Ogunniyi MO, Mahmoud Z, Commodore-Mensah Y, Fleg JL, Fatade YA, Quesada O, Aggarwal NR, Mattina DJ, Moraes De Oliveira GM, Lindley KJ, Ovbiagele B, Roswell RO, Douglass PL, Itchhaporia D, Hayes SN; American College of Cardiology Cardiovascular Disease in Women Committee and the American College of Cardiology Health Equity Taskforce. Eliminating Disparities in Cardiovascular Disease for Black Women: JACC Review Topic of the Week. J Am Coll Cardiol. 2022 Nov 1;80(18):1762-1771. doi: 10.1016/j.jacc.2022.08.769. PMID: 36302590; PMCID: PMC10278154.

[5] 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.

radiopharmaceutical tracer accumulation in tissues with high sensitivity and provides 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.[6] 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.[7]

An advantage of using PET/CT over SPECT imaging lies in the resolution differences, with PET offering significantly better resolution than SPECT. Additionally, the use of X-ray CT equipment in PET/CT imaging provides correction of tracer attenuation (reduction of the intensity of an X-ray beam as it penetrates through matter); this attenuation reduction reduces the rate of false-positive results, ultimately increasing specificity.[8]

The hybrid imaging techniques of PET and CT are an advanced modality for the 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.[9]

In a 2010 study where researchers tested the performance of cardiac PET/CT hybrid imaging in symptomatic patients with a 30% to 70% pretest probability of CAD, the accuracy of the hybrid PET/CT imaging technique was 98% per patient per vessel.[10] Furthermore, the researchers 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 nationally; the researchers also determined that 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.

Regarding PET/CT, 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

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[6] 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.

[7] Ibid.

[8] 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.

[9] Ibid.

[10] 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

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.[11]

Cardiology Associates of Fredericksburg, Ltd.

CAF offers a variety of cardiac care services including imaging technology to detect and mitigate coronary artery disease at an early stage. CAF specializes in cardiac electrophysiology, cardiovascular diseases, interventional cardiology, and peripheral vascular diseases. CAF has been providing cardiology specialty healthcare since 1978. CAF offers both in-office and hospital services (at Mary Washington Hospital):

In-office Services

- Cardiology Consultation
- Electrophysiology Consultation
- Pre-operative Evaluation
- 24-hour Holter Monitor
- 30-day Arrhythmia Monitor
- Carotid Duplex
- Echocardiogram
- Saline Contrast Echocardiogram
- Electrocardiogram (EKG)
- Exercise Stress Test
- Nuclear Stress Test – Cardiac Perfusion Scan
- Stress Echocardiogram
- Pacemaker and Defibrillator Clinic
- Remote Monitoring of Pacemakers and Defibrillators (ICDs)
- Vascular Imaging

Hospital Services

- Advanced Complex Coronary Interventions
- Cardiac Catheterization
- Cardioversion
- Balloon Aortic Valvuloplasty
- Transcatheter Aortic Valve Replacement (TAVR)
- ASD and PFO Closures
- Peripheral Angiography and Intervention
- Tilt Table Test
- Transesophageal Echocardiogram (TEE)
- Advanced Electrophysiology Procedures/Complex Ablations
- Pacemaker and Defibrillator (ICD) Implantation[12]

Proposed Project

CAF is proposing to establish a specialized center for PET/CT imaging through the addition of one PET/CT scanner to be used exclusively for cardiac imaging and procedures. The CT portion of the PET/CT will not be used independently, but rather will only be used for enhancing the PET imaging. The specific imaging unit proposed to be purchased is a Siemens Biograph Horizon PET/CT system; the system will be leased from CDL Nuclear Technologies, LLC, a supplier of nuclear technologies.

The PET/CT unit's lead-shielded camera room and an adjacent control room will be built within the existing square footage of the suite. Utilities are current and operational at the facility. The total capital cost for the project is anticipated to be $1,354,647, with $754,000 attributable to the rental agreement with CDL Nuclear Technologies, LLC ($15,900 per month for the duration of the rental contract, the full length of which is 60 months).

[11] 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.
[12] https://www.fredcardio.com/services-procedures/

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 taken into account when applicable.

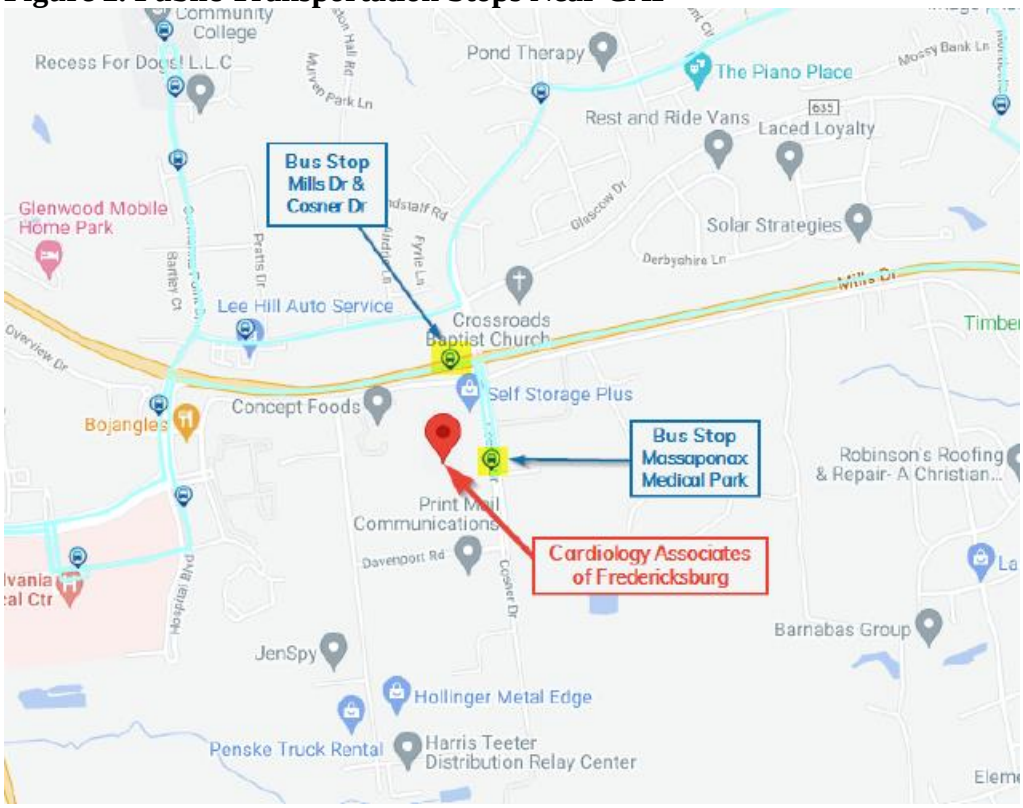
1. **The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic,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

   Cardiology Associates of Fredericksburg can be accessed by car or public transportation. The office is located 2.8 miles from exits 126 and 126B via I-95 North and South. Additionally, the office is located 0.2 miles south of Highway 17.

   Fredericksburg Regional Transit (FRED) provides transportation via route S5 throughout the day to the Mills Drive/Cosner Drive intersection which is 0.3 miles from the CAF office and an additional stop at Massaponax Medical Park which is a very brief walk of about 0.09 miles from the CAF office (**Figure 2**). Currently, FRED is fare free; the Free Fare initiative is being reviewed yearly to ensure viability of the service remaining available without fares.[13] **Figure 3** details the areas covered by FRED which include parts of Stafford and Spotsylvania Counties in addition to the City of Fredericksburg.

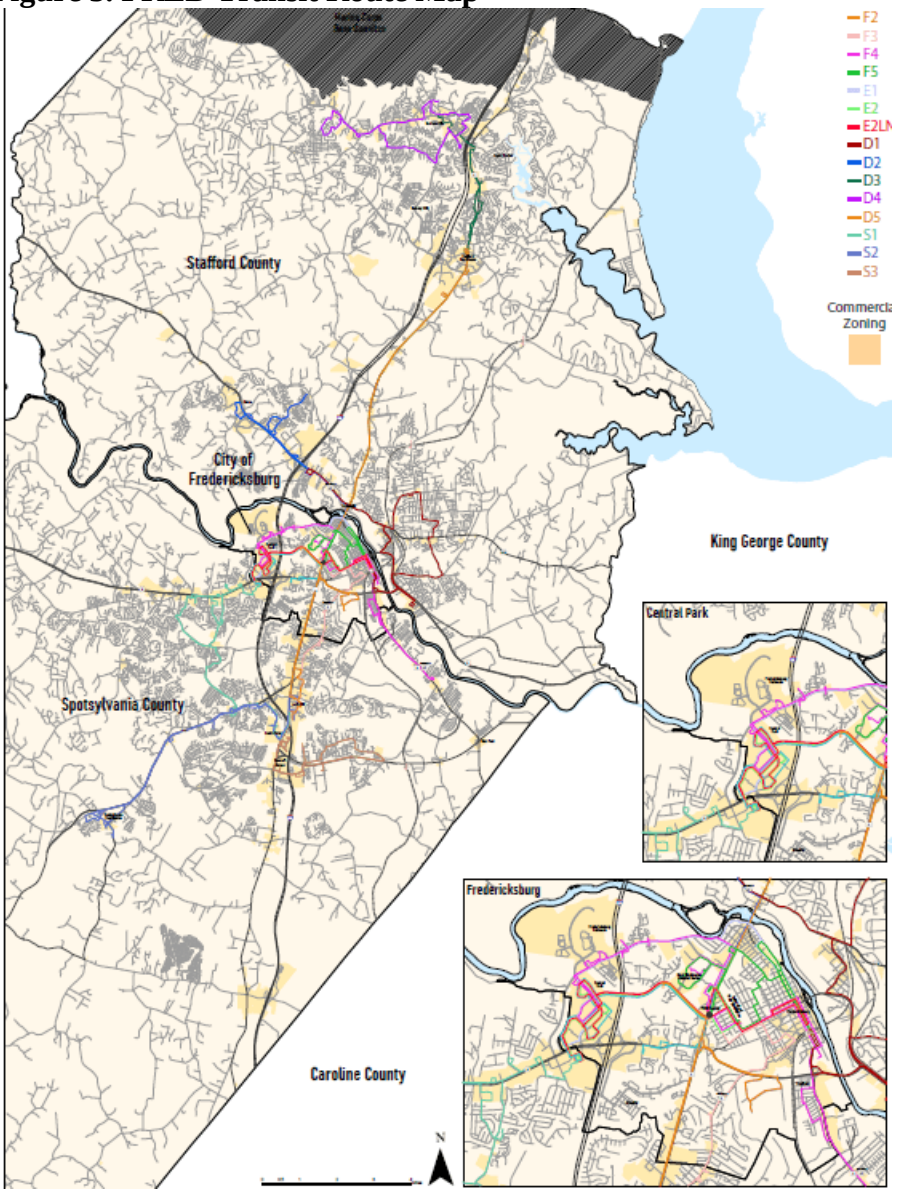
[13] https://www.fredericksburgva.gov/1684/Fares

Figure 2. Public Transportation Stops Near CAF



Sources: COPN Req. VA-8699 (Attachment II.C.3) and Google Maps

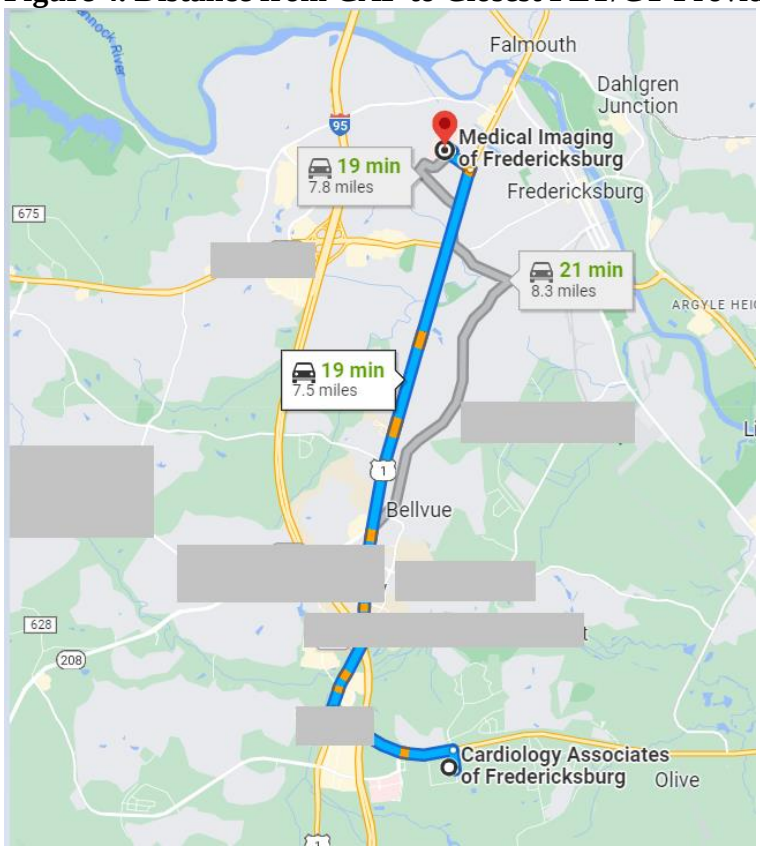
Figure 3. FRED Transit Route Map



Source: fredericksburgva.gov/1761/Service-map

CAF is located approximately 20 minutes driving time, or approximately 7.5-8.3 miles, from Medical Imaging of Fredericksburg, LLC, who is the only other provider of any PET and PET/CT imaging in PD 16 (**Figure 4**).

Figure 4. Distance from CAF to Closest PET/CT Provider



Source: Google Maps

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 three letters of support for the proposed project from a local medical provider (outside of CAF), the President of the Cardiac PET Industry Coalition, and from Faculty at the John Ochsner Heart and Vascular Institute, New Orleans, Louisiana. Collectively, these letters articulate several benefits of the project, including:

- Cardiac PET/CT services are not readily available anywhere elsewhere in the Fredericksburg area. (Note: It is unclear what is specifically meant by "readily available" in the support letter.)
- CAF's seeking of new, proven technology is in line with their mission.
- It is hoped that the addition of the cardiac PET/CT will help improve co-managing of their own patients with heart disease who also see CAF.
- One person dies every 36 seconds in the United States of heart disease, according to the CDC. Furthermore, approximately 1 in 4 deaths in the United States is related to heart disease. Moreover, between 2016 and 2017, heart disease cost an estimated $36

billion in the Unites States between healthcare services, medications, and the loss of productivity as a result of deaths.

- There are new and emerging cardiovascular therapies that are requiring more specified, accurate diagnostic technologies.
- Cardiac PET imaging reduces healthcare costs as there is a reduction in radiation required for the imaging and the ability of PET to measure myocardial blood flow in a non-invasive manner.
- It is proven that the Centers for Medicare and Medicaid Services "Triple Aim" of "Better outcomes, better patient satisfaction and cost savings" is clearly achieved when incorporating Cardiac PET in the diagnostic algorithm for patients undergoing testing for coronary artery disease.
- "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."

DCOPN received no 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.

DCOPN does not find reasonable alternatives to the proposed project available that would meet the needs of the population in a less costly, more efficient, or more effective manner.

CAF 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 precedent of COPN approvals call for leeway in the SMFP's 6,000 procedure thresh-hold for establishing new PET services as 6,000 procedures does not appear to be an accurate reflection of procedural volume for PET, the PET/CT has been shown to cut down the time needed for scans, reasonably allowing for more scans in the same period as a PET.

(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.

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-8699 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.

(iv) Any costs and benefits of the project.

The project would benefit PD 16 by making PET/CT services available to the cardiac population, ultimately increasing diagnostic accuracy, reducing radiation exposure, reducing invasive diagnostic procedures, and decreasing healthcare costs. The project will also allow for cardiac imaging in an outpatient, comfortable location for patients, rather than in a higher-cost, more difficult-to-navigate, hospital setting.

The project anticipates a total capital cost of $1,354,647, with $$754,000 dedicated to the rental agreement with CDL Nuclear Technologies, LLC ($15,900 per month for the duration of the rental contract). Additionally, CAF expects to hire one additional certified nuclear medicine technologist; the applicant does not intend to poach resources from neighboring healthcare facilities and intends to source the additional staff member from a variety of sources, including professional societies, local colleges/trade schools, or online job boards if necessary.

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

The applicant has provided assurances that PET/CT services will be accessible to all patients, regardless of financial considerations. In 2020, the most recent data available, CAF was not required to submit their Charity Care Contributions to VHI; however, the overall average Charity Care Contribution rate for HPR I was 2.1%. The Pro Forma Income Statement provided by the applicant anticipates a charity care contribution equal to 2.1% of gross revenues derived from PET/CT services of CAF, an amount consistent with the average HPR I contribution. However, recent changes to §32.16-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on all applicants seeking a COPN. For this reason, DCOPN recommends that the proposed project, if approved, be subject to a 2.1% charity care condition, to be derived from total PET/CT gross patient services revenues, consistent with the HPR I average. DCOPN again notes that its recommendation includes a provision allowing for the reassessment of the charity care rate at such time as more reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

Table 4. 2020 Charity Care Contributions in HPR I

2020 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**% of Gross Patient Revenue:**
Culpeper Regional Hospital	$359,182,141	$12,102,933	3.37%
University of Virginia Medical Center	$5,962,089,202	$186,745,010	3.13%
UVA Transitional Care Hospital	$66,296,097	$2,047,513	3.09%
Sentara RMH Medical Center	$918,098,298	$22,656,844	2.47%
Carilion Stonewall Jackson Hospital	$137,363,522	$2,944,339	2.14%
Martha Jefferson Hospital	$731,733,007	$11,500,103	1.57%
Page Memorial Hospital	$63,530,998	$792,862	1.25%
Augusta Medical Center	$1,059,370,204	$12,042,914	1.14%
Shenandoah Memorial Hospital	$121,946,999	$1,321,088	1.08%
Warren Memorial Hospital	$150,609,573	$1,621,917	1.08%
Stafford Hospital Center	$287,238,184	$3,044,975	1.06%
Winchester Medical Center	$1,433,802,000	$14,305,992	1.00%
Spotsylvania Regional Medical Center	$589,741,098	$5,843,457	0.99%
Mary Washington Hospital	$1,429,424,065	$13,513,637	0.95%
Bath Community Hospital	$23,228,689	$145,250	0.63%
Fauquier Hospital	$412,365,921	$1,528,892	0.37%
Total Facilities			16
Median			1.1%
Total $ & Mean %	**$13,386,837,857**	**$280,054,793**	**2.1%**

Source: VHI 2020 Data

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

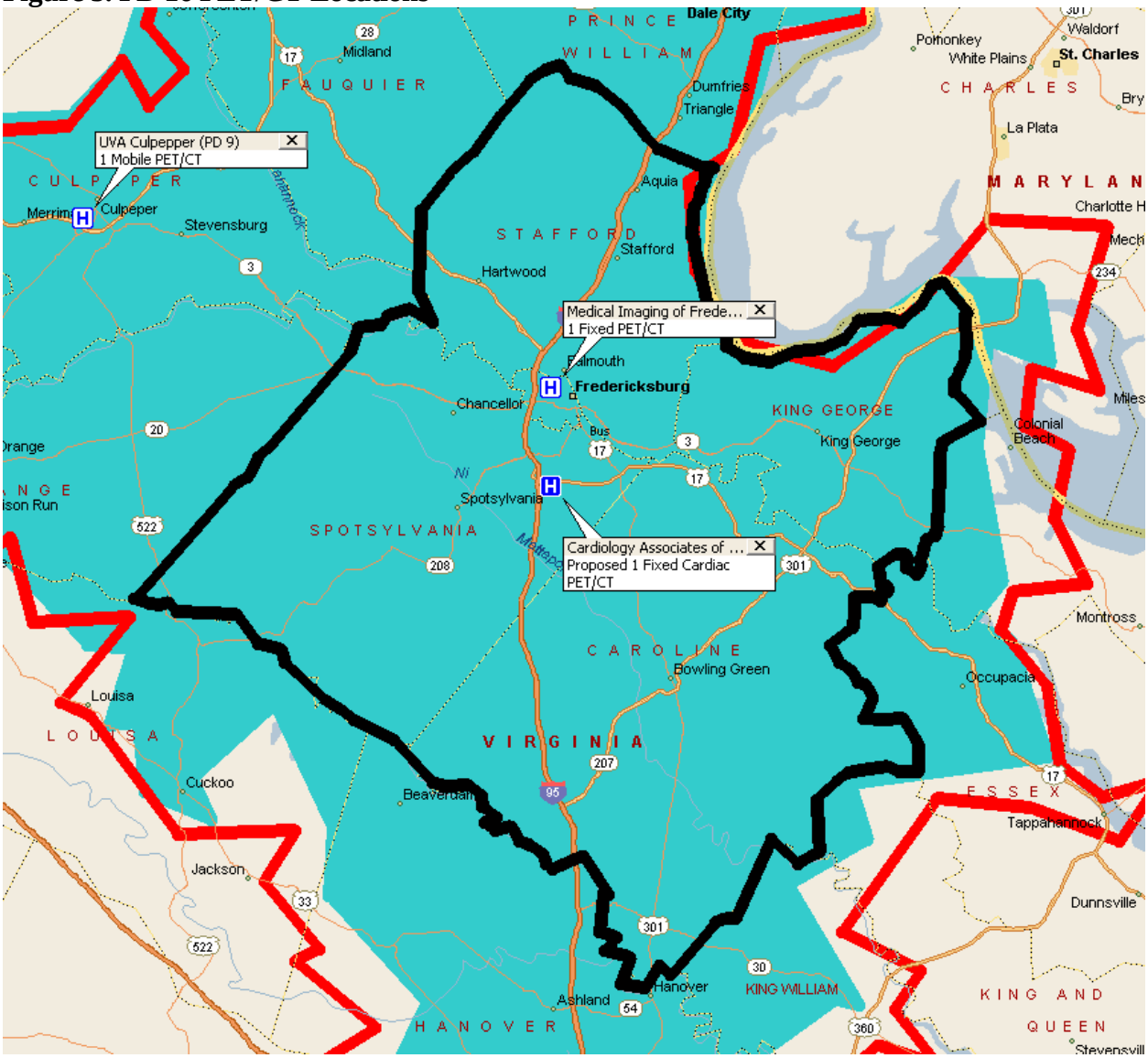
3. The extent to which the application is consistent with the State Medical Facilities Plan.

Chapter 230. State Medical Facilities Plan (SMFP); Part I. Definitions and General Information; 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.

Shaded in teal in **Figure 5**, it is evident that 95% or more of PD 16 (black outline) is within 60 minutes of driving time from PET or PET/CT services. The red outline indicates the area within 60 minutes driving distance from the proposed project location. However, the PET/CT at Medical Imaging of Fredericksburg (MIF) is utilized for mainly oncological purposes and is not able to conduct the cardiac tests that a cardiac PET/CT is able to perform (more detail regarding PET/CT capability to be presented below).

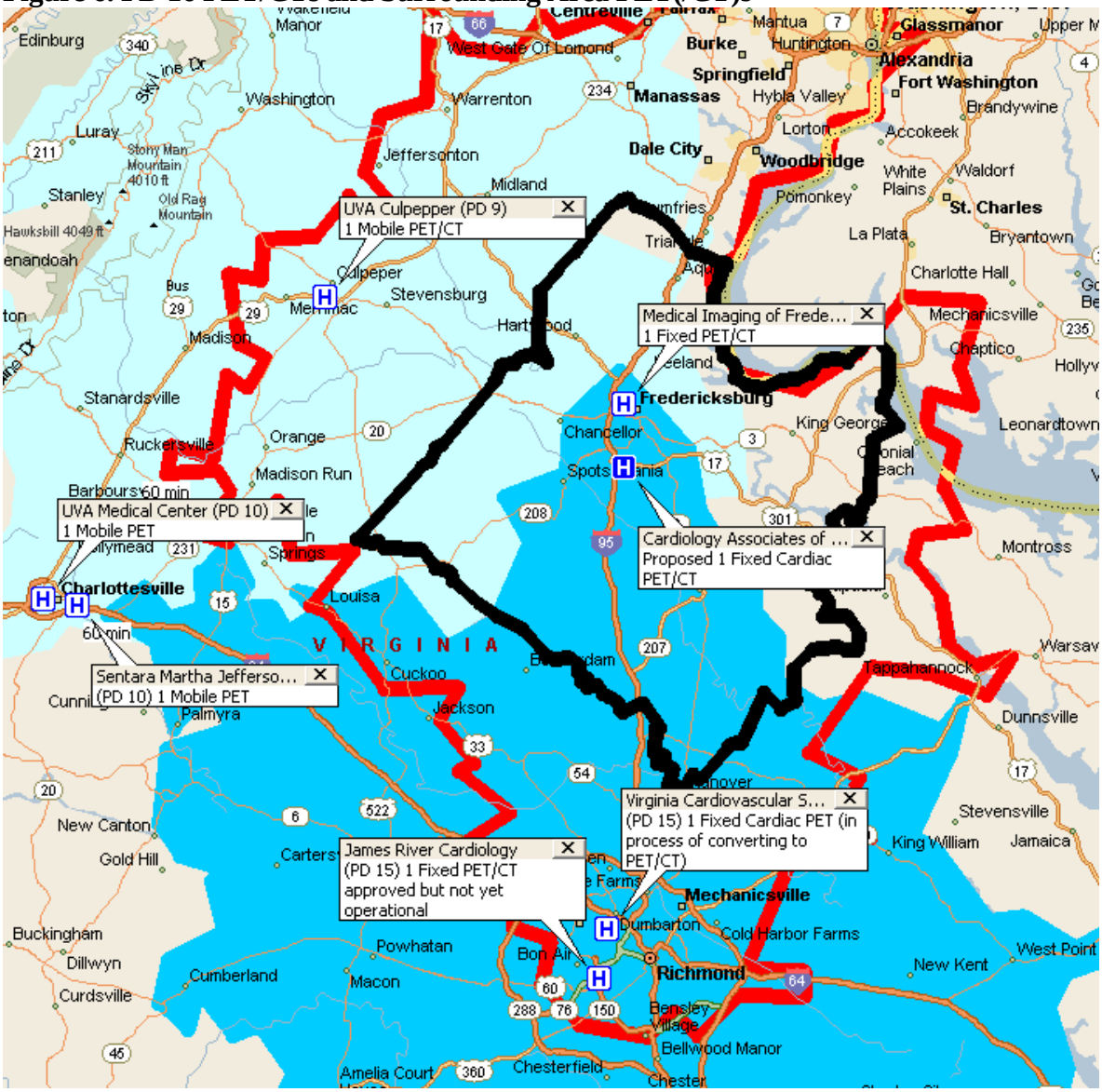
Figure 5. PD 16 PET/CT Locations



Source: Google Maps, DCOPN Records, and Microsoft Streets and Trips

The light blue shaded area **(Figure 6)** is indicative of the 60-minute driving distance from UVA Culpepper's PET/CT in PD 9 (which does offer heart imaging services), while the darker blue shaded area illustrates the 60-minute driving distance from Virginia Cardiovascular Specialists in PD 15 and their cardiac PET, converting to cardiac PET/CT unit through Registration VA-R-014-23. Based upon SMFP guidelines, Virginia Cardiovascular Specialists is providing services within an appropriate driving distance for parts of PD 16 (**Figure 6**). However, the Commissioner issued COPN No. VA-04844 on June 1, 2023, authorizing James River Cardiology, P.C. to establish a specialized center for cardiac PET/CT imaging. During the course of the review, it was noted that the cardiac PET/CT at Virginia Cardiovascular Specialists is operating at capacity with their own patient population. Therefore, at this time, there are no cardiac PET/CT services within PD 16.

Figure 6. PD 16 PET/CTs and Surrounding Area PET(/CT)s



Source: Google Maps, DCOPN Records, and Microsoft Streets and Trips

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 neither a hospital nor a free-standing hospital or within a hospital system; therefore, this provision is not applicable.

B. No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such health planning district.
Note: For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as one PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as individual PET procedures and CT procedures respectively, unless those images are made concurrently.

There are no additional PET or PET/CT units in PD 16 outside of the one PET/CT unit located at Medical Imaging of Fredericksburg, LLC (MIF) (**Table 5**). While the PET/CT operated by MIF is underutilized with respect to the SMFP, operating at only 31.93% according to 2021 data reported to VHI, this has been an increase compared to prior years.

Table 5. PD 16 PET/CT Utilization

Facility	Total Authorized PET/CT[1] Scanners	2021	Utilization
Medical Imaging of Fredericksburg	1	1,916	31.93%

Sources: VHI Data 2021 and DCOPN Records
[1] There are no PET units in PD 16 without the CT attached.

MIF operated at the following utilizations, respective to the 6,000-procedure threshold per year standard outlined in the SMFP:

- 26.4% (1,584 procedures) in 2020
- No data was available in VHI for 2019
- 19.0% (1,142 procedures) in 2018
- 18.7% (1,122 procedures) in 2017.

Furthermore, the MIF PET/CT scanner, pursuant to COPN VA-03953 issued on August 20, 2005, authorized MIF to utilize the CT portion of the unit independently of the PET/CT, which is indicative of the machine itself likely being utilized at a higher utilization for the CT portion. MIF's PET/CT unit is also utilized exclusively for oncological purposes and is not available to accommodate CAF's cardiac diagnostic imaging needs for the following reasons:

- A PET/CT that is used for oncology is typically not outfitted with the correct software and hardware to perform gated cardiac myocardial perfusion imaging.

These are significant cost add-ons that a radiology group not performing cardiac imaging would not need.[14]

- Cardiac imaging protocols differ greatly from oncology, requiring a different staffing configuration to perform the test.[15]
- Differing protocols make it difficult to perform oncology and cardiology studies intermittently on the same PET/CT system.[16]
- The radioisotope required for cardiac PET imaging cannot be purchased per dose as needed as in oncology. The isotope must either be generated on-site via a rubidium generator or via an ammonia cyclotron in the immediate vicinity of the facility. The economics of sourcing rubidium or ammonia make cardiac PET unviable at low volumes.[17]

CAF intends to utilize the PET/CT scanning exclusively for cardiac patients who are not appropriate for SPECT imaging, such as those whose body mass index is higher than 35, patients with large breasts or implants, previous inconclusive SPECT study due to attenuation artifacts, 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). CAF expects that approximately 52% of SPECT and Stress Echo volumes will convert to Cardiac PET/CT. In Year 1, CAF projects five scans per day, or 1,204 cardiac PET/CT procedures per year, or 20.1% utilization. While this is under the 6,000-procedure threshold, the PET/CT is to be limited to cardiac PET/CT use exclusively, with a volume of existing patients utilizing the procedure.

Moreover, DCOPN has indicated in multiple Staff Reports, including but not limited to staff reports for COPN Nos. VA-04740 and VA-04715, where the recommendation indicated 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."'

Relatively recently, on June 1, 2023, the Commissioner approved James River Cardiology, P.C.'s COPN No. VA-04844 to establish PET/CT services with a projected utilization of 1,100 procedures (18.3% utilization) in PD 15. PD 15 had a PET unit, but not a PET/CT unit in the PD at the time of the COPN approval. Although PD 16 has another PET/CT unit approximately 7.5-8.3 miles (or approximately 20 minutes of driving time) away from CAF, the proposed unit would be exclusively for cardiac PET/CT imaging and the existing PET/CT is not able to accommodate cardiac-specific imaging. One of the cited reasons for

[14] Applicant provided information and Anand SS, Singh H, Dash AK. Clinical Applications of PET and PET-CT. Med J Armed Forces India. 2009 Oct;65(4):353-8. doi: 10.1016/S0377-1237(09)80099-3. Epub 2011 Jul 21. PMID: 27408291; PMCID: PMC4921358.
[15] Ibid.
[16] Ibid.
[17] Ibid.

the Commissioner's approval of COPN No. VA-04844 includes the following, which is also applicable to this project:

> "Cardiac PET/CT reflects an important new application of technology for combatting cardiac disease and is not currently available in PD 15…"

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 provision is not applicable as the applicant is not proposing to expand fixed-site services.

12VAC5-230-230. Adding or expansing 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 provision is not applicable as the applicant is not proposing to add or expand mobile PET or 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 provided assurances that the PET(/CT) services will be under the direction of one or more qualified physicians.

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.**

The proposed PET/CT services will be proved for exclusively cardiac purposes and is not otherwise available within PD 16. The project is not likely to foster institutional competition

that would either benefit or harm area providers. The project will, however, improve access to an essential healthcare service that is not currently available within the PD.

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 only PET/CT unit available in the PD does not have the cardiac imaging software on their unit to accommodate the cardiac imaging needs of CAF patients. Furthermore, a support letter indicated that patients co-managed under their and CAF's care would benefit the patients and their outcomes.

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 project's total capital cost of $1,354,647 (**Table 6**) appears reasonable compared to:

- COPN No. VA-04844, issued June 1, 2023, authorizing a fixed-site cardiac PET/CT for a total capital cost of $1,001,700;
- COPN No. VA-04827, issued February 9, 2023, authorizing a fixed-site cardiac PET/CT for a total capital cost of $1,001,700; and
- COPN No. VA-04806, issued August 22, 2022, authorizing a fixed-site cardiac PET/CT for a total capital cost of $2,491,617.

Table 6. Total Capital Cost Summary

Direct Construction Costs	$194,500
Equipment Not Included in Construction Contract	$754,000
Site Acquisition Costs	$392,147
Architectural and Engineering fees	$14,000
Total Capital Cost	**$1,354,647**

Source: COPN Req. VA-8699

There will be no third-party financing. CAF has entered into a service agreement under which capital expenditures, including facility renovations, will be paid throughout the term of the agreement as appropriate. CAF will utilize operating capital revenues to satisfy the terms of the lease.

Table 7. Pro Forma Summary

	Year 1	Year 2	Year 3	Year 4	Year 5
Annual Volume	1,200	1,260	1,323	1,389	1,458
Annual Revenue	$2,925,546	$3,071,729	$3,255,316	$3,386,581	$3,555,911
Total Operating Expenses	$1,548,270	$1,603,358	$1,666,285	$1,731,944	$1,800,651
Estimated Net Annual Profit	$1,377,187	$1,468,192	$1,559,031	$1,654,638	$1,755,260

Source: COPN Req. VA-8699

As illustrated in **Table 7**, the project appears to be viable in the long term, with a consistent, moderate increase in estimated net annual profit each year. The applicant used a growth rate of 5% for patients.

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 healthcare needs. (iv) At the discretion of the Commissioner, any other factors as may be appropriate.**

   The project increases access to vital new technology. PET/CT 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 the accuracy of the images yields a reduction in invasive catheterizations and an increase in appropriate diagnoses, ultimately decreasing healthcare costs for both the patient and the 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. (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 affiliated with a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

DCOPN Staff Summary and Findings

The overall PD 16 population is projected to grow at a rate that is approximately double that of the statewide average between 2020 and 2030 (11.00% and 5.58%, respectively). Although the PD 16 projected growth rate specifically for the age 65+ cohort (22.0%) is projected to be less than the statewide average (10.7%), the primary service area, including Fredericksburg city (36.88%), is projected to grow much higher than the statewide average between 2020-2030.

PD 16's poverty rate is less than the statewide poverty rate of 10.7%, but the Fredericksburg city poverty rate is 14.1%. Furthermore, Fredericksburg City and Caroline County are composed of a higher percentage of their population of historically marginalized (including healthcare marginalization) racial demographic groups.

In PD 16, the one available PET/CT unit is not capable of cardiac PET/CT diagnostic imaging at this time. While there is a cardiac PET located in PD 15 (within 60-minute driving distance from about half of PD 16), Virginia Cardiovascular Specialists, this PET is being utilized at capacity, as indicated in the recently approved COPN No. VA-04844 authorizing James River Cardiology, P.C. to establish cardiac PET/CT services in PD 15. The project appears generally consistent with the SMFP guidelines. Approval of the project would increase access for the entire PD to cardiac PET/CT imaging.

There was no opposition to the project. DCOPN did not discover any reasonable alternatives that would meet the needs of the population in a less costly, more efficient, or more effective manner. The total capital cost of $1,354,647 is reasonable in comparison to similar projects in the state and the project appears viable over the short and long term as outlined in the Pro Forma Summary (**Table 7**).

Approval of this project would increase access for the entire PD but also would increase access for populations that face more difficulty with access to healthcare (those in poverty and those in marginalized racial groups, such as African Americans). PET/CT has been shown to be of great benefit to cardiology through reducing radiation exposure with comparison to SPECT imaging, greater accuracy compared to both SPECT and cardiac PET, decreased need for invasive diagnostics like cardiac catheterization procedures, and an overall decrease in healthcare costs from a combination of the aforementioned benefits.

DCOPN Staff Recommendations

COPN Request No. VA-8699 – Cardiology Associates of Fredericksburg, Ltd.
The Division of Certificate of Public Need recommends the **conditional approval** of Cardiology Associates of Fredericksburg, Inc's COPN Request no. VA-8699 to establish a specialized center for cardiac PET/CT imaging for the following reasons:

1. The proposal is consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia;

2. There does not appear to be any less costly alternative to the proposed project;

3. The capital costs of the proposed project are reasonable;

4. The proposed project is unlikely to have a significant negative impact on the utilization, costs, or charges of other providers of PET(/CT) in the PD or surrounding areas;

5. The proposed project appears to be financially viable in the immediate and long term;

6. Cardiac PET/CT reflects an important new application of technology for combatting cardiac disease and is not currently available in PD 16; and

7. There is no known opposition to the project.

Charity Conditions

DCOPN's recommendation is contingent upon Cardiology Associates of Fredericksburg, Inc.'s agreement to the following charity care condition:

Cardiology Associates of Fredericksburg, Ltd. will provide positron emission tomography/computed tomography (PET/CT) services to all persons in need of this service, 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 2.1% of Cardiology Associates of Fredericksburg, Ltd.'s total patient services revenue derived from PET/CT 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. Cardiology Associates of Fredericksburg, Ltd. 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.

Cardiology Associates of Fredericksburg, Ltd. will provide PET/CT 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, Cardiology Associates of Fredericksburg, Ltd. will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.