VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

September 18, 2023

RE: COPN Request No. VA-8709
Virginia Cancer Institute, Inc.
Henrico, Virginia
Addition of PET/CT services via 1 Fixed Site PET/CT Scanner with No Independent Use of CT

Applicant

Virginia Cancer Institute, Inc. (VCI) is a for-profit corporation that is neither partially or wholly owned by another entity nor wholly or partially owns any subsidiaries. VCI owns and operates six physician office locations; this project is for the VCI-West End location, located at 8007 Discovery Drive, Richmond, Virginia 23229. VCI-West End is within the boundaries of Planning District (PD) 15, which is within the greater boundaries of Health Planning Region (HPR) IV.

Background

Planning District 15 Population and Demographics

PD 15 is located in central Virginia and includes the counties of Charles City, Chesterfield, Goochland, Hanover, Henrico, New Kent, and Powhatan as well as Richmond City. The overall population in PD 15 in 2020 was 1,120,304, making PD 15 representative of approximately 13% of the statewide population (**Table 1**).

PD 15 is projected to experience a population growth of 6.6% between 2020-2030, which is greater than the statewide average of 5.3% for Virginia (**Table 1**). This trend of population growth occurring at a rate faster than the statewide average was also seen between 2010-2020, with growth rates of 9.1% and 7.4%, respectively (**Table 1**).

The projected population growth rate of the age 65+ cohort between 2020 and 2030 is also projected to be higher for PD 15 than the statewide average; PD 15 is projected to have a 25.1% increase in the 65+ population, while the statewide average projection for this age group is 21.5% (**Table 1**). The growth in the senior population for PD 15 is specifically relevant to this analysis due to the increased risk of cancer diagnoses (and thus increased use of positron emission tomography /computed tomography, or PET/CT, services) increase with age; the average age for cancer

diagnosis in America is 66 years old and less than 1% of all cancer diagnoses in America are attributable to individuals under the age of 20 years old.[1]

Table 1. PD 15 Population Data

Locality Name	2010	2020	% Change 2010-2020	2030	% Change 2020-2030	2020 65+	2030 65+	% Change 2020-2030 65+
Charles City County	7,256	6,773	-7.1%	6,200	-9.2%	1,773	2,189	19.0%
Chesterfield County	316,236	364,548	13.3%	406,942	10.4%	55,297	72,476	23.7%
Goochland County	21,717	24,727	12.2%	27,339	9.6%	5,420	7,421	27.0%
Hanover County	99,863	109,979	9.2%	118,374	7.1%	19,807	27,456	27.9%
Henrico County	306,935	334,389	8.2%	356,656	6.2%	53,255	68,003	21.7%
New Kent County	18,429	22,945	19.7%	27,067	15.2%	4,303	6,663	35.4%
Powhatan County	28,046	30,333	7.5%	32,152	5.7%	6,041	8,552	29.4%
Richmond City	204,214	226,610	9.9%	245,437	7.7%	26,352	31,657	16.8%
PD 15 Total	**1,002,696**	**1,120,304**	**9.1%**	**1,220,168**	**6.6%**	**172,249**	**224,417**	**25.1%**
Virginia, Statewide	**8,001,024**	**8,644,727**	**7.4%**	**9,129,002**	**5.3%**	**1,352,448**	**1,723,382**	**21.5%**

Source: Weldon-Cooper Data

PD 15 is an area with a stratified composition of income levels. Richmond City had a poverty rate of 26.2% in 2016 (the most recent data available on the Virginia Department of Health website), while the surrounding areas had an average poverty rate of 7.6% for the same year (**Table 2**). The effects of poverty on health outcomes have been studied extensively from local to global scales. With regard to cancer mortality rates, a 2020 study found that counties and cities in the United States facing persistent poverty (defined as counties or cities with poverty rates ≥20% since 1980) face social, structural, and behavioral challenges that increase residents' vulnerabilities to cancer; the researchers found that cancer mortality was higher in localities facing persistent poverty than in other localities at a statistically significant level.[2]

Table 2. PD 15 Poverty Rates, 2016

Locality Name	Poverty Rate
Charles City County	12.4%
Chesterfield County	7.0%
Goochland County	6.4%
Hanover County	5.8%
Henrico County	9.2%
New Kent County	5.9%
Powhatan County	6.6%
Richmond City	26.2%
PD 15 Average	**10.0%**
Virginia, Statewide Average	**11.0%**

Source: vdh.virginia.gov/data/social-determinants-of-health/poverty/

[1] https://www.cancercenter.com/community/blog/2023/06/cancer-risk-by-age#:~:text=The%20average%20age%20of%20individuals,continues%20to%20increase%20with%20age.
[2] Jennifer L. Moss, Casey N. Pinto, Shobha Srinivasan, Kathleen A. Cronin, Robert T. Croyle; Persistent Poverty and Cancer Mortality Rates: An Analysis of County-Level Poverty Designations. Cancer Epidemiol Biomarkers Prev 1 October 2020; 29 (10): 1949–1954.

The overall cancer incidence rate in PD 15 is higher than the statewide average; the PD 15 incidence rate is 494.7 incidences per 100,000 people while the statewide average is 434.1 (**Table 3**). The incidence rate in PD 15 is:

- 9.5% higher than the statewide average overall;
- 10.0% higher for White residents than for White residents statewide;
- 6.9% higher for Black residents than for Black residents statewide; and
- 12.3% higher for Black residents than the overall statewide average incidence rate (**Table 3**).

Table 3. PD Cancer Incidence Rates Utilizing 2011-2020 Data

Locality	Overall Cancer Incidence Rate[1]	White	% Population White (2019)	Black	% Population Black (2019)
Charles City County	408.2	383.5	44.8%	437.1	44.4%
Chesterfield County	483.3	487.3	68.2%	443.1	24.5%
Goochland County	579.9	556.6	80.4%	665.3	15.8%
Hanover County	481.4	487.6	86.0%	461.8	9.5%
Henrico County	466.1	475.1	57.0%	453.5	30.9%
New Kent County	448.3	493.5	80.8%	N/A[2]	13.9%
Powhatan County	478.1	488.0	88.0%	484.8	9.2%
Richmond City	492.3	469.2	***47.7%***	519.4	***46.9%***
PD 15 Average	479.7	480.1	***69.1%***	495.0[3]	***24.4%***
Virginia, Statewide Average	434.1	432.1	***69.4%***	460.9	***19.9%***

Source: https://www.vdh.virginia.gov/virginia-cancer-registry/data/ and Weldon-Cooper Data
[1]Rates per 100,000 people of all racial demographics, male and female, and for all cancer types.
[2]Data not provided due to less than 16 cases available.
[3]Calculated without New Kent County.

The Centers for Disease Control and Prevention report that Black Americans have the highest death rate for cancer overall, have a lower overall 5-year cancer survival rate compared to White Americans, and are more likely than White Americans to be diagnosed with female breast, lung, and colorectal cancers at a late stage (which is harder to treat as it spreads throughout the body).[3] The American Cancer Society lists structural racism, socioeconomic status, access to care, comorbidities, and medical mistrust and health system implications as factors that influence cancer disparities.[4]

Also worthy of consideration are the population percentages configuration comparisons for Richmond City, the PD 15 average, and the statewide average (***bolded and italicized*** in **Table 3)**. The PD 15 and statewide population composition averages are relatively similar; however, an inverse relationship exists with the PD 15 and statewide averages with the Richmond City averages with a significantly higher proportion of Black residents than White residents concentrated in the city. The Richmond City incidence rate is 50.2/100,000 people higher for Black residents compared to White residents (**Table 3**). Comparatively, the incidence rate is 14.9/100,000 people and 28.8/100,000 people higher for Black residents than White residents for the PD 15 average and statewide average, respectively (**Table 3**). Further, the Centers for Disease Control report that Black

[3]https://www.cdc.gov/cancer/healthequity/groups/africanamerican.htm#:~:text=Compared%20to%20members%20of%20other,survival%20rate%20than%20White%20people.
[4] American Cancer Society. Cancer Facts & Figures for African American/Black People 2022-2024.

Americans have the highest death rate for cancer across the nation.[5] Inductive reasoning would conclude that Richmond City would have a greater need than the statewide average to have oncological imaging and tools for treatment as the composition of Richmond City has a greater ratio of Black residents with higher death rates from cancer in addition to Richmond City having a higher poverty rate, which is also a factor in poor health outcomes. The disparity between Richmond City and both the PD and HPR average incidence rates is evident.

PET/CT and PET/CT Use in Cancer Diagnostics and Treatment (Theranostics)

A PET scanner is an imaging tool that produces images of organs and tissues at work using an injectable radioactive chemical (radiotracer) in conjunction with the PET scanner. The scanner detects diseased cells that absorb large amounts of the radiotracer, indicating potential health problems; the PET is able to illustrate metabolism, blood flow, and oxygen use of the tissues being scanned. The imaging of the metabolic rection of tissues to the radiotracers shows the physiological difference of the cancer cells, while the CT portion illustrates an anatomical view of the cells behaving as cancer cells.[6] CT is a service that is able to render anatomical imaging of the body. PET/CT scanners are capable of producing a 3D image by combining the PET and CT capabilities, allowing for a more accurate diagnosis. The PET portion of the PET/CT is able to give clinicians a physiological portrayal (view of the *functioning* of tissues) while the CT is simultaneously giving a more accurate anatomical (shapes and placement of tissues) image.

The radiotracers used in PET and PET/CT imaging can be very specialized to specific types of cells, or can be a broad radiotracer, such as F-18 fluorodeoxyglucose (FDG), a molecule similar to glucose (sugar).[7] This molecule is utilized by cancer cells (metabolized at a rate much faster than regular, healthy cells). Clinical research has shown that the PET/CT technology is able to alter a patient's treatment plan to better target cancer in approximately one-third of cases when compared to PET alone, likely attributable to the CT anatomical overlay supplementing the PET imaging.[8]

Some common uses of PET/CT diagnostic imaging specific to oncology include:

- detect cancer and/or make a diagnosis;
- determine whether a cancer has spread in the body;
- assess the effectiveness of treatment;
- determine if a cancer has returned after treatment;
- evaluate prognosis;
- assess tissue metabolism and viability;
- evaluate brain abnormalities, such as tumors, memory disorders, seizures, and other central nervous system disorders; and
- map normal human brain and heart function.[9]

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[5] https://www.cdc.gov/cancer/health-equity/groups/african-american.htm
[6] https://my.clevelandclinic.org/health/diagnostics/10123-pet-scan
[7]https://www.radiologyinfo.org/en/info/pet#:~:text=The%20most%20common%20radiotracer%20is,seen%20on%20other%20imaging%20tests.
[8] https://stanfordhealthcare.org/medical-tests/p/pet-ct-scan/what-to-expect.html#:~:text=Better%20data%2C%20better%20treatment%20plans,one%2Dthird%20of%20the%20cases.
[9]https://www.radiologyinfo.org/en/info/pet#:~:text=The%20most%20common%20radiotracer%20is,seen%20on%20other%20imaging%20tests.

In addition to the diagnostic uses of PET/CT imaging in the oncological field, a developing discipline of therapeutic intervention utilizing PET/CT imaging is growing rapidly, called theranostics. The impact factor for "theranostics" (the average times an average research paper is cited during a year for a particular subject) was 7.806 in 2014 and only rose to 8.579 in 2021; in 2022, the impact factor for "theranostics" had risen to 11.556, with the 2023 impact factor being 12.4.[10] This marked, exponential increase in the impact factor is indicative of the swiftly increasing interest in this field and the benefits it has for patients.

Theranostics is the combination of diagnostics and therapy, where the imaging shows where the cancer cells are, followed by a targeted, specific radiopharmaceutical to kill those specific cells.[11] This focused approach of delivering radiopharmaceuticals to only the cancer cells reduce radiation exposure by combining the imaging modality with the simultaneous precise delivery of radiation to the intended cells.[12] In Virginia, there are only two locations (not in PD 15) that currently offer theranostics: Carilion Clinic in Roanoke and University of Virginia Medical Center in Charlottesville.

Virginia Cancer Institute, Inc.

VCI operates the following six physician office locations within the greater Richmond area:

- West End (at Discovery Drive in Henrico County);
- Johnston-Willis Hospital campus (at the Sarah Cannon Cancer Institute);
- Harbourside (Midlothian);
- Southside Regional Medical Center campus (Petersburg);
- Hanover County (Mechanicsville); and
- Prince George County.

VCI staffs 23 full-time oncologists and hematologists and more than 300 non-physician staff members. Additionally, VCI has a surgical division, Virginia Surgical Institute, which is staffed by eight surgeons who perform surgical services, including oncological surgical procedures, at VCI's Midlothian office. The services available at VCI include:

- lab services, biopsies, therapeutic procedures, chemotherapy and therapeutic infusion therapy, pharmacy, licensed clinical social worker services and patient education services (as well as financial coordinator services), and CT services (at VCI- West End and Harbourside offices).

Proposed Project

VCI is seeking to introduce PET/CT services to complement its currently available CT services at the West End location on Discovery Drive. The CT portion of the PET/CT will not be used independently, but rather exclusively in conjunction with the PET imaging. The PET/CT will be in

[10]https://www.thno.org/indexrank#:~:text=Impact%20factor%20of%20the%20journal%20is%2011.556%2C%20according%20to%20the,Reports%C2%AE%20released%20in%202022.

[11] https://www.uchicagomedicine.org/cancer/types-treatments/theranostics#:~:text=forefront%20of%20Theranostics.-,What%20is%20theranostics%3F,specific%20target%20in%20the%20body.

[12] Duan H, Iagaru A, Aparici CM. Radiotheranostics - Precision Medicine in Nuclear Medicine and Molecular Imaging. Nanotheranostics. 2022 Jan 1;6(1):103-117. doi: 10.7150/ntno.64141. PMID: 34976584; PMCID: PMC8671964.

remodeled, existing space and will not require extensive construction. The total capital cost associated with the project is $3,135,463, to be paid for using accumulated reserves (**Table 7**).

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "[i]ntroduction into an existing medical care facility described in subsection A [including… a]ny specialized center or clinic or that portion of a physician's office developed for the provision of outpatient or ambulatory… 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.

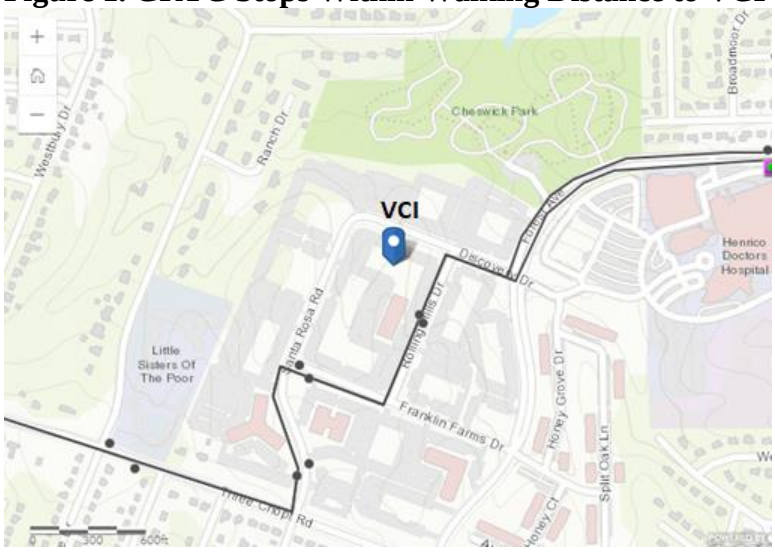
1. **The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic,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

   VCI's West End location is located less than 1.6 miles from Exit 183A off of Interstate-64, along a public transportation route. The Roland Hills and the 1602 Bus Stop of the 79 Bus Route provided by Greater Richmond Transit Company (GRTC) is directly across the street from the building entrance (**Figure 1**). Particularly for patients lacking vehicle transportation or who are unable to drive themselves, this location would be beneficial for those needing outpatient oncological PET/CT services.

   Relation to public transportation is relevant to the population VCI serves as approximately 20.1% of their patient population originates from the City of Richmond, where the poverty rate is 26.2%; comparably, Henrico County's poverty rate of approximately 9.2%, and the PD 15 average and statewide averages of 10.0% and 11.0%, respectively (**Table 2**).

   While there are available PET and PET/CT imaging elsewhere in the PD, the units available for oncological needs are limited to acute care hospitals; this project would provide access to an outpatient PET/CT imaging option for oncological patients. Furthermore, through the location is in Henrico County, the public transportation option increases access for those in the City of Richmond.

Figure 1. GRTC Stops Within Walking Distance to VCI



Source: http://ridegrtc.com/planning-your-trip/new-bus-signs/

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 no letters of opposition for the proposed project. DCOPN received seven letters of support for the proposed project from the local medical community and [Radiology Associates of Richmond, Inc. (RAR) Access Now: A Program of the Richmond Academy of Medicine, Anthem, Commonwealth Primary Care, Inc. (CPC), Pulmonary Associates of Richmond (PAR), and Virginia Physicians for Women (VPW)] and the Nebraska Cancer Specialists/ Systemic Radiation Therapy and Theranostics Center. Collectively, these letters articulate several benefits of the project, including:

- RAR is "proud to collaborate with VCI on its existing CT services, providing interpretations of CT scans performed at VCI's offices" and they support VCI's proposal to expand their imaging services to include PET/CT. RAR is "committed to continuing to provide radiology services for VCI's imaging services, to include the new PET/CT service."

- "PET/CT has brought revolutionary changes in improving cancer care for patients. Its benefits include detection of previously unrecognizable cancerous activity, better definition of treatment targets, optimization of treatment decisions, and ability to monitor treatment responses early, thus optimizing use of early interventions for non-responding tumors" (RAR's support letter).

- Current Medical Director of Nebraska Cancer Specialists' Systemic Radiation Therapy and Theranostics Center (the nation's first dedicated Community Oncology Theranostics Center) stated: "Theranostics…. combines specific targeted diagnostic tests with specific targeted therapy." Rather than a broad treatment, theranostics allows oncologists to conduct a "highly targeted attack directly and exclusively on cancerous cells and tissues, based on the individual characteristics of the particular tumor…PET/CT services, the gold standard in cancer imaging, is an essential component of [theranostics]." Further, "Unquestionably, the availability of in-house PET/CT services will enhance VCI's ability to diagnose early-stage cancer, more definitively identify, locate, and stage tumors, and enhance its delivery of timely and effective care to its patients. It will also allow VCI to provide Theranostics to its patients, significantly expanding treatment options for many patients and making it eligible for many clinical trials and research opportunities." To conclude, "I believe the project will significantly improve outcomes for patients an reduce the costs and other burdens of cancer care."

- Access Now, which ensures free specialty care for those who have no health insurance through a complex network of practices pledging to treat a certain number of uninsured patients and uncompensated visits per year, states: "VCI and its physicians have long been a critical component of this volunteer network, providing comprehensive specialized cancer care services to uninsured patients suffering from cancer throughout Central Virginia. Those patients are not only financially disadvantaged but also frequently severely ill, fragile, and immunocompromised; many navigate complex and busy medical appointment schedules across numerous providers and facilities and often depend on family members or friends for transportation. VCI offers these patients a patient-centered one-stop model of care, tremendously enhancing access to high-quality integrated cancer services."

- Anthem supports the project stating "[w]e believe that the Central Virginia market, and particularly cancer patients residing in VCI's service area, would greatly benefit from PET/CT services in a lower-cost specialized setting and we urge your approval of VCI's application." Further, cancer care requires some of the most expensive treatments over a long duration of time. "Frequently, those services are fragmented throughout various providers and care settings in the community, not only delaying timely access but also undermining outcomes and increasing costs and the overall burden of cancer disease for patient." Moreover, "[a]pproval of VCI's proposal would further expand VCI's cancer treatment resources to allow better care, thus lowering costs for patients and payors alike."

- CPC states the following in support of the applicant's proposal: "Primary care providers play an active and important role in cancer patient management." Following a diagnosis, "primary care practitioners often manage cancer patients as they navigate the complex and often fragmented cancer experience, for example by managing comorbid conditions, chronic pain, malnutrition, and depression." CPC reports referring numerous patients to VCI for specialized cancer services. Furthermore, "…it is critical that VCI is able to expand its service offering to include PET/CT, the

current standard of care in cancer imaging… PET/CT is able to detect and identify cancer earlier and much more accurately than CT."

- PAR states: "[for a] better characterization of those lesions as benign or coordination of care for those patients, VCI must be allowed to integrate PET/CT services with its existing services. Doing so will ensure continued speedy access to the most clinically appropriate, efficient, and cost-effective imaging, delivered in a setting entirely geared toward the special needs of cancer patients."

- VPW states the following in support of the proposal: "VCI is well-known and trusted for its comprehensive high-quality oncology care, and we often entrust VCI physicians with the care of our patients." Incidence rates for breast cancer has risen in recent years, with an average risk of 1-in-8 women developing the disease. Breast cancer is also the second leading cause of death for women in the United States. Furthermore, "a PET/CT study is more specific and accurate than CT or PET alone for the revelation of breast lesions and distant metastases, believed to be responsible for the vast majority of deaths caused by breast cancer. More recently, novel radiotracers and imaging applications have further expanded – and continue to expand – the PET/CT's utility and importance for patients with breast cancer as the theranostic approach to treatment is quickly gaining ground."

- VPW also states: "Theranostics refers to a combination approach of using one radioactive drug to diagnose cancer and a second radioactive drug to deliver therapy to the main tumor and any metastatic tumors. Just last year, the United States Food and Drug Administration approved the first theranostic treatment for patients with unresectable (unable to be removed) or metastatic (spread to other parts of the body) HER2-low breast cancer – a type of breast cancer that accounts for at least 55% of all breast cancers and, thus far treated with chemotherapy, has had a poor prognosis." VPW believes "VCI's proposal will ensure that cancer patients have more timely and convenient access to PET/CT services, facilitating more expeditious and specific diagnoses and allowing better management of cancer throughout the patient's experience with cancer."

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-8709 is not competing with another project in this batch cycle and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

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

Maintaining the status quo would continue to meet the basic needs of VCI patients, however, project approval would open options for treatment and imaging that are not currently

available due to the complexity in radiotracer availability and scheduling and the imaging availability of the hospitals. Further, not all of the area hospitals have both PET & CT imaging (PET/CT scanner) that can occur simultaneously, that provide clearer and more useful imaging for VCI practitioners. The project would also reduce fragmentation of care for many VCI cancer patients as they would be able to have the PET/CT scanning done in a location they are familiar with. The project would also reduce costs by providing imaging at an outpatient reimbursement price point rather than the acute care hospital price point. Moreover, as discussed previously, there are only two locations in Virginia that offer theranostics; this project would bring this innovative imaging and treatment modality to PD 15. The status quo would not be able to fully meet the needs of the population in a less costly, more efficient, or more effective manner than the proposed project.

(iii) Any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6.
Currently there is no organization in HPR IV designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 15. Therefore, this consideration is not applicable to the review of the proposed project.

(iv) Any costs and benefits of the project.
The financial cost of the project is $3,135,463 (**Table 7**). There will be a cost to area providers from the reduction in referrals to their locations from VCI. However, benefits of the project include the introduction to imaging combined with treatment that the acute care area hospitals are not currently able to provide. Additionally, the project will benefit patients and the healthcare sector by providing lower-cost imaging in an outpatient setting. Furthermore, VCI's addition of a PET/CT scanner and establishment of associated services being in an outpatient setting is more in line with the current trend towards patients preferring care in outpatient settings (as opposed to trying to navigate large, complex, ambiguous acute care hospital halls and parking).

(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 will be accessible to all patients, regardless of financial considerations. In 2021, the most recent data available, VCI did not have any charity care reported. The Pro Forma Income Statement provided by the applicant anticipates a charity care contribution equal to 1.0% of gross revenues derived from PET/CT services at VCI, an amount consistent with the average HPR IV contribution. However, recent changes to §32.16-102.4B of the Code of Virginia now require the State Health Commissioner to condition the approval of all COPNs. For this reason, DCOPN recommends that the proposed project, if approved, be subject to a 1.0% charity care condition, to be derived from total PET/CT gross patient services revenues, consistent with the HPR IV average (**Table 4**). The DCOPN charity care 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. HPR IV 2021 Charity Care Contributions

Health Planning Region IV			
2021 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**Percent of Gross Patient Revenue**
Encompass Health Rehab Hosp of Petersburg	$ 26,851,240	$ 1,046,165	3.90%
Southern Virginia Regional Medical Center	$ 193,424,382	$ 6,462,541	3.34%
Sentara Halifax Regional Hospital	$ 305,216,000	$ 5,567,790	1.82%
Bon Secours St. Francis Medical Center	$ 1,075,574,864	$ 15,314,171	1.42%
Southside Regional Medical Center	$ 2,000,593,397	$ 27,695,403	1.38%
Bon Secours Richmond Community Hospital	$ 991,036,257	$ 11,039,087	1.11%
CJW Medical Center	$ 8,975,939,621	$ 87,710,457	0.98%
Henrico Doctors' Hospital	$ 5,763,604,659	$ 52,734,748	0.91%
VCU Health System	$ 6,809,570,615	$ 61,295,221	0.90%
Bon Secours St. Mary's Hospital	$ 2,358,088,813	$ 20,998,912	0.89%
TriCities Hospital	$ 1,324,643,208	$ 9,600,576	0.72%
Sheltering Arms Institute	$ 137,252,572	$ 970,918	0.71%
Bon Secours Memorial Regional Medical Center	$ 1,614,325,924	$ 9,753,218	0.60%
Community Memorial Hospital	$ 343,583,756	$ 1,572,169	0.46%
Encompass Health Rehab Hosp of Virginia	$ 25,150,781	$ 107,359	0.43%
Southside Community Hospital	$ 383,098,711	$ 1,431,006	0.37%
Cumberland Hospital for Children and Adolescents	$ 39,513,361	$ -	0.00%
Select Speciality Hospital - Richmond	$ 141,742,321	$ -	0.00%
Total Inpatient Hospitals:			18
HPR IV Inpatient Hospital Median			0.9%
HPR IV Total Inpatient $ & Mean %	**$ 32,509,210,482**	**$ 313,299,741**	**1.0%**

Source: VHI Data and DCOPN Extrapolations

(vi) At the discretion of the Commissioner, any other factors as may be relevant to the determination of 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.
Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop, by November 1, 2022, recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, these regulations provide the best available criteria and DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

Chapter 230. State Medical Facilities Plan (SMFP), Part I. Definitions and General Information
Article 4. Positron Emission Tomography

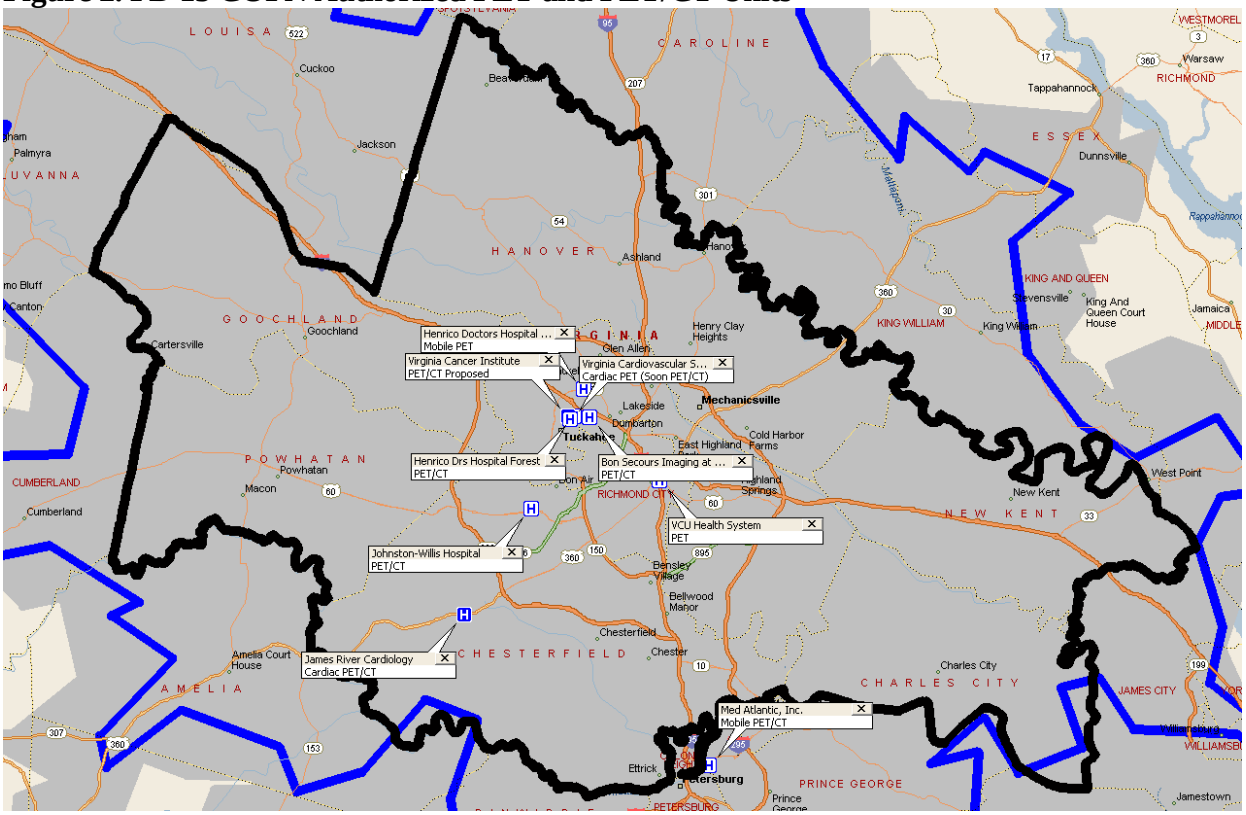
12VAC5-230-200. Travel time.
PET services should be within 60 minutes driving time one way under normal conditions of 95% of the health planning district using a mapping software as determined by the commissioner.

Illustrated in **Figure 2** are the locations of the PET and PET/CT units in PD 15. The black outline represents the PD 15 boundary, the grey shaded area represents the geographic area within 60-

minutes' driving distance to current providers (excluding cardiac-exclusive PET and PET/CT units), and the blue line represents the 60-minutes' driving distance from the proposed VCI PET/CT unit location. Cardiac-exclusive PET and PET/CT units were not considered with regard to geographic area covered (grey shaded area) because the cancer patients the applicant is proposing to provide services for are not able to use units that are COPN limited to cardiac units excusively.

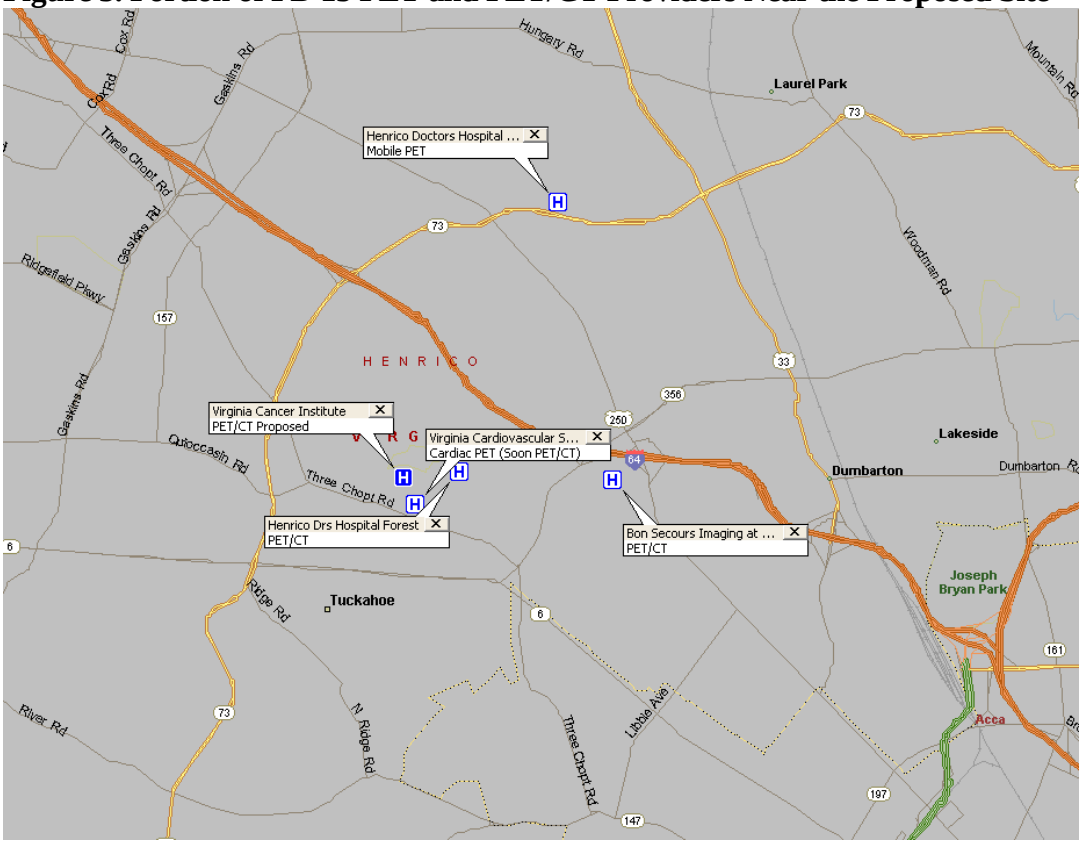
The entirety of PD 15 has access to PET and PET/CT services within a 60-minutes' driving distance (the SMFP threshold). Therefore, the proposed site does not add access to PET or PET/CT services to any geographic area within the PD that are not already covered. The project will provide access for theranostics that is not currently available within the PD; the closest providers able to deliver theranostic treatment are the University of Virginia Medical Center, Johns Hopkins Medical Center in Baltimore, Maryland, or Carilion in Roanoke, Virginia. In addition to theranostics, VCI reports that the local PD 15 providers are not able to provide the specific contrast studies needed by VCI for some patients. The PET/CT equipment proposed at VCI and the accompanying staff and pharmaceutical arrangements would allow for these tests to be scheduled and completed.

Figure 2. PD 15 COPN Authorized PET and PET/CT Units



Sources: DCOPN Inventory Data, Google Maps, and Microsoft Office Streets & Trips

Figure 3. Portion of PD 15 PET and PET/CT Providers Near the Proposed Site



Sources: DCOPN Inventory Data, Google Maps, and Microsoft Office Streets & Trips

Figure 3 is a magnified image extracted from **Figure 2** of a concentrated area of PET and PET/CT providers within close proximity to the proposed location. While the proposed site is within minutes of other providers for PET and PET/CT services, DCOPN has not received any letters of opposition from these providers. Furthermore, the applicant provided assurances to DCOPN during a facility tour associated with the project (in addition to providing assurances within the application) that VCI would still be referring approximately 50% of their patients requiring PET and PET/CT scans to area providers.

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.
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.

Table 5. COPN-Authorized PD 15 PET and PET/CT Units

Facility	Total Authorized Scanners	Fixed-Site Scanners	Mobile-Site Scanners	PET Only	PET/CT	Cardiac Only
Bon Secours Imaging Center at Reynolds Crossing	1	1	0	0	1	0
Henrico Doctor's Hospital - Parham Doctors' Hospital	1	0	1	1	0	0
Henrico Doctors' Hospital - Forest	1	1	0	0	1[1]	0
Johnston-Willis Hospital	1	1	0	0	1[2]	0
Med-Atlantic	1	0	1	0	1	0
VCU Health System	1	1	0	1	0	0
Virginia Cardiovascular Specialists	1	1	0	1[3]	0	1
James River Cardiology - Chesterfield	1	1	0	0	1[4]	1
PD 15 Totals	**8**	**6**	**2**	**3**	**5**	**2**

Sources: COPN Inventory and VHI Data
[1]COPN VA-04733 converts existing mobile PET/CT to a fixed PET/CT (projected completion July 15, 2023).
[2]COPN VA-04756 converts existing mobile PET/CT to a fixed PET/CT (projected completion January 31, 2024).
[3]Registration VA-R-014-23 replaces existing PET with PET/CT exclusively for cardiac use and without CT being used independently.
[4]COPN VA-04844 authorizes fixed PET/CT (projected completion November 15, 2023).

Table 6. 2021 PD 15 VHI Reported PET Volumes and Utilization

Facility	Stationary or Mobile	Procedures	Utilization
Bon Secours St. Mary's Hospital[1]	1 PET-Stationary	1,916	31.9%
Chippenham Hospital	1 PET-Mobile	1,365	22.8%
Henrico Doctors' Hospital – Forest	1 PET-Mobile	1,121	18.7%
VCU Medical Center	1 PET-Stationary	2,285	38.1%
Virginia Cardiovascular Specialists / Forest Medical Plaza	1 PET-Stationary (Cardiac Exclusive)	2,286	38.1%
PD 15 Total	**5[2]**	**8,973**	**22.9%**

Sources: 2021 VHI Data and DCOPN Inventory
[1]COPN No. VA-04619 converted mobile PET/CT at Bon Secours St. Mary's Hospital to stationary PET/CT located at the Bon Secours Imagin Center at Reynolds Crossing
2Total Based on VHI 2021 available inventory and data

Table 5 illustrates the current authorized PET and PET/CT units in PD 15; there are eight total authorized units, one unit of which (James River Cardiology – Chesterfield) is not operational as of the time of the writing of this Staff Report. Three units of the eight authorized are PET only, five units are PET/CT, two of the eight units are relegated to cardiac-only imaging, and only two of the eight scanners are mobile.

Table 6 summarizes the most recently available utilization data for PET scanning in PD 15 available to DCOPN as reported by Virginia Health Information (VHI); the most recently available data is

from 2021. In conjunction with the established inaccuracy of the SMFP threshold for PET and PET/CT scanning at present, it is important to note that much of the elective services' utilization in Virginia decreased from the previously established norms during the 2020 and 2021 years as a response to the Covid-19 pandemic.

The Recommended Case Decision written by the Adjudication Officer and adopted by the State Health Commissioner resulting in the June 1, 2023, issuance of COPN No. VA-04844 to James River Cardiology to establish a specialized center for cardiac PET/CT imaging stated the following regarding the same data presented above:

> "A review of 2021 data shows that, in HPR IV, (i) 91.3 percent of PET scanning (for all medical indications) was provided at one of five hospital-based sites or in a specialists' office located in PD 15 (consisting of Bon Secours St. Mary's Hospital, HCA Chippenham Hospital, HCA Henrico Doctors' Hospital, Virginia Commonwealth University Hospital Authority, and Virginia Cardiovascular Specialists), (ii) less than nine percent of PET scanning was provided at mobile, rural sites, and (iii) clearly, the 6000-procedure standard adopted for inclusion in the SMFP years ago is not a reliable indicator of an operational level that reasonably reflects rational resourcing. Significantly, among the five busier PET service providers, an operational peak range of 1916 to 2286 annual procedures is discernible."

While COPN No. VA-04844 was for a cardiac-specific PET/CT unit, this particular excerpt is relevant to the current application under review as the data used to analyze is the same and the project is also seeking to create a lower-cost, less-difficult-to-navigate PET/CT option for a specific subset of patients.

Historically, VCI reports having referred 3,003 PET/CT scans to outside providers in 2022. The applicant anticipates only 1,800 scans in Year 1 and 1,854 scans in Year 2 of the total scans needed for patients to be provided at VCI following project completion; VCI still anticipates referring a significant portion of scans to area providers as appropriate. Again, DCOPN did not receive any opposition communications from area providers who may be concerned about the reduction in referrals from VCI.

While the project does not meet subsection B of this section of the SMFP, the Commissioner and DCOPN have recognized that the 6,000 procedural volume threshold outlined in the SMFP does not accurately reflect the current capacity of PET and PET/CT services as evidenced in approximately the last 19 PET and PET/CT applications (minus one application- COPN Request No. VA-8541 which was denied).

Utilizing the 850 procedures threshold described in subsection A (although VCI is not a hospital, DCOPN is addressing this calculation for the Commissioner's consideration), the following information is worthy of consideration:

- In 2021, VCI referred 1,979 of their patients to area hospitals for 2,728 PET and PET/CT studies (about 321% of the 850 threshold of PET appropriate cases for hospitals to add fixed site PET services)

- In 2022, VCI referred 2,118 of their patients to area hospitals for 3,003 PET and PET/CT studies (about 353% of the 850 threshold of PET appropriate cases for hospitals to add fixed site PET services)

These trends show that, although not a hospital, VCI has 2.21-2.53 times more than the 850-threshold delineated in subsection A.

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 of the SMFP is not applicable as the applicant is not seeking to expand established fixed site PET (or PET/CT) 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 of the SMFP is not applicable as the applicant is neither seeking to expand nor add 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 provides assurances that the PET/CT services will be under the direction or supervision of one or more qualified physicians that will be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health.

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.**
   The proposed service would foster institutional competition benefitting PD 15 while improving access to essential healthcare services for all appropriate patients in the area. Not yet available within the PD and only available at two locations in Virginia, the University of

Virginia Medical Center campus and Carilion Clinic, the project would meaningfully increase access to theranostics and expand clinical trial capabilities for PD 15 cancer patients. A portion of the referrals from VCI to area hospitals will decrease; however, the applicant proposes to focus on providing imaging for those patients who need scanning that is not available at other locations (such as theranostics), while still referring appropriate patients to outside 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.**
Based on SMFP utilization, the PD is vastly underutilizing its PET services; however, the Commissioner and DCOPN have recognized that the 6,000 procedural volume threshold outlined in the SMFP does not accurately reflect the current capacity of PET and PET/CT services.

6. **The feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital.**
The total capital cost of the project is $3,135,463, of which 100% of the cost is to be paid through accumulated reserves. The scanner cost (Equipment Not Included in Construction Contract) is $1,848,500 while the remaining cost, $1,286,963, is associated with the construction and leasing price (**Table 7**).

Table 7. Total Capital Cost Summary

Direct Construction Costs		
Cost of materials	$398,124	
Cost of labor	$197,925	
Builder's Overhead	$27,300	
Builder's Profit	$27,300	
Allocation for contingencies	$61,425	
Sub-Total		*$712,074*
Equipment Not Included in Construction Contract		
IT (Information Technology)	$3,500	
Furniture	$25,000	
Injector	$120,000	
PET/CT Scanner	$1,700,000	
Sub-Total		*$1,848,500*
Site Acquisition Costs		
Lease Expense for Project Space	$532,889	
Sub-Total		*$532,889*
Architectural and Engineering Fees		
Architect's Design Fee	$10,000	
Architect's Supervision Fee	$10,000	
Engineering Fee	$20,000	
Consultant Fee	$2,000	
Sub-Total		*$42,000*
Total Capital Cost (Paid through Accumulated Reserves, no Financing Costs)		**$3,135,463**

Source: COPN Req. VA-8709

The applicant anticipates a Revenue in Excess of Expenses for Year 1 to be $260,468 and for Year 2, $297,510 (**Table 8**).

Table 8. Pro Forma Summary

	Year 1	Year 2
PET/CT Scans Per Year	**1,800**	**1,854**
Total Gross Revenue	$3,897,000	$4,013,910
Net Revenue (Total Gross Revenue minus contractual adjustments and charity care adjustments)	$2,121,030	$2,184,661
Total Expenses (Total Expenses includes salaries & benefits, building rent, equipment lease, equipment maintenance, leasehold improvement amortization, supplies, IT associated expenses, regulatory & certification, G&A, bad debt expense)	$1,849,514	$1,875,772
Revenue in Excess of Expenses	**$271,516**	**$308,889**

Source: COPN Req. VA-8710

Table 9. Comparable Projects and Associated Capital Costs and Revenue Projections

COPN No. Issued	Total Authorized Capital Cost	Year 1 Revenue over Expenses Projection	Year 2 Revenue over Expenses Projection
COPN No. VA-04836 issued April 11, 2023, authorizing Nova Cardiovascular Care, Inc. to establish cardiac-exclusive PET services with 1 fixed-site PET scanner	$648,900 (minimal renovation)	$480,400	$557,205
COPN No. VA-04841 issued April 11, 2023, authorizing Urology of Virginia, PLLC to establish a site for mobile PET/CT with independent use of the CT, exclusively for urological imaging	$2,032,960 (moderate renovation/support pad addition)	$40,440	$271,550
COPN No. VA-04844 issued June 1, 2023, authorizing James River Cardiology, P.C. to establish a site for cardiac-exclusive PET/CT imaging with 1 PET/CT scanner	$1,001,700 (minimal renovation)	$1,419,599	$1,545,754
COPN No. VA-04827 issued February 9, 2023, authorizing James River Cardiology, P.C. to establish a site for cardiac-exclusive PET/CT imaging with 1 PET/CT scanner	$1,001,700 (minimal renovation)	$1,019,738	$1,129,900
COPN No. VA-04828 issued February 9, 2023, authorizing Winchester Medical Center to convert its mobile PET scanning service to a fixed-site scanning service	$4,110,625 (extensive renovation of existing space)	$311,970	$649,694
COPN No. VA-04826 issued February 9, 2023, authorizing Carient Heart & Vascular, P.C. to establish PET/CT services exclusively for cardiac imaging	$784,500 (minimal renovations)	$4,844,984	$4,045,849
COPN No. VA-04806 issued August 22, 2022, authorizing The Cardiovascular Group, P.C. to establish PET/CT services limited to cardiovascular use with 1 fixed-site PET/CT scanner	$2,491,617 (moderate renovations)	$1,009,897	$1,446,066
Average of Recent, Similar Projects	**$1,724,572**	**$1,303,856**	**$1,378,003**

Source: DCOPN Records

Compared to the average cost of similar projects ($1,724,572), the project has a much higher capital cost projection at $3,135,463 (**Table 9**). However, many of the recently approved projects, such as the James River Cardiology, P.C. projects, are leasing the units from a

company who has included the cost of space renovations into the lease. Contrarily, projects like the Winchester Medical Center conversion of a mobile PET to fixed PET site includes construction costs outside of the equipment, resulting in a total capital cost of more than $4 million (**Table 9**). Most specifically, COPN VA-04828, with an authorized capital cost of $4,110,625, is most similar to the project being analyzed in this report; the VCI project is less than the COPN VA-04828 project capital cost.

The average Year 1 and Year 2 projections for Revenue over Expenses for similar projects ($1,303,856 and $1,378,003, respectively) are higher than the projected Revenue over Expenses for the project; however, the range of data creating the average varied widely (**Table 9**). For example, the Year 1 data ranged from a low of $40,440 to a high of $4,844,984 (**Table 9**). The project's anticipated Year 1 and Year 2 Revenues over Expenses fall within the range associated with similar projects.

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.**
The project will bring theranostics to PD 15. The only other theranostics programs available in the state are at the University of Virginia Medical Center and Carilion Clinic. The field of theranostics is growing and innovatively combines diagnostic imaging with precision treatment for appropriate patients. Furthermore, the project would provide the service at a lower-cost, outpatient setting. The applicant physician team meets regularly with other area physicians for case discussions and collaborations, encouraging a cooperative effort to meet the needs of PD 15's vulnerable cancer patients. Specifically, VCI has longstanding relationships with Bon Secours Mercy Health, HCA, and VCU Health facilities in PD 15. 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 the extent to which the project provides improvements or innovations in the financing and delivery of health services.

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.**
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; however, the applicant participates in clinical research trials. The clinical research trial opportunities would be expanded greatly if the project was to be approved, specifically for theranostic clinical research.

DCOPN Staff Summary and Findings

The population for PD 15, in addition to the 65+ specific cohort, are growing at rates faster than that of the statewide average (**Table 1**). Richmond city has a poverty rate over 2.5 times that of the statewide average and nearing 2.5 times the PD 15 average (**Table 2**). Richmond city is also the third largest locality within PD 15 (**Table 1**). Within PD 15, the entire population is composed of approximately 69.4% White residents and approximately 19.9% Black residents (**Table 3**). For both the statewide and PD 15 averages, Black residents have a higher cancer incidence rate than White residents.

Two factors leading to higher rates of cancer mortality are racial demographics (Black Americans face the highest rates of cancer mortality) and economic factors (those in poverty face higher rates of cancer mortality). Richmond city has a different proportion of racial demographics than the statewide and PD 15 averages, with White residents being approximately 47.7% of the total city population and approximately 46.9% of the total city population being Black residents (**Table 3**). Richmond city, which has public transportation that accesses the proposed location, has a greater ratio of two different groups of residents who face higher mortality with regard to cancer (and more healthcare disparity in general). This project would provide a convenient access point for PD 15 residents as a whole, but particularly for those who need public transportation to access cancer treatments. Currently, there is not public transportation easily linking Richmond city residents to lifesaving and life-prolonging theranostic treatments as the only other two locations offering theranostic treatment in the state are located in Charlottesville and Roanoke.

The applicant is proposing to add the PET/CT combination in order to provide more accurate imaging that can show metabolically which cells are likely cancerous in addition to creating an anatomical image that further aids physicians in treatment design and implementation. The applicant is also anticipating referring approximately 50% of its PET scanning needs to local area hospitals, reducing the impact this project will have on area providers. The patients the applicant anticipates serving at the proposed location are those who would not be able to have their imaging or treatment needs conducted at the hospitals (such as theranostics).

There was no opposition to the project received by DCOPN. There was support from area providers, Anthem health insurance, a leader in theranostics research (Nebraska Cancer Specialists), and a non-profit that assists residents in Central Virginia who are in need of healthcare and do not have insurance themselves. The support praised the project for bringing an innovative theranostics modality to the area, that PET/CT combination scanning has brought positive change to the oncological community by being able to identify cancerous activity that was previously undetectable (allowing for earlier treatment and more effective treatment outcomes), that VCI has been a critical volunteer provider for those who struggle to pay for healthcare services, and that the PET/CT in an outpatient setting would reduce costs to the healthcare system from both an imaging reimbursement perspective as well as from an earlier intervention standpoint.

There were no reasonable alternatives to the project that would meet the needs of the population in a less costly, more efficient, or more effective manner. While the status quo would continue to serve patients with the basic needs, the project implementation would add another imaging unit that combines the PET and CT modalities, which is becoming a new standard for oncology.

Moreover, the status quo would not add theranostic treatment that would directly target cancerous cells at a location that is not more than 60-minutes' driving distance from their homes. Patients who are appropriate for theranostic treatment and who cannot get the treatment scheduled or obtain transportation would be able to receive the treatment instead of chemotherapy (which targets both healthy and unhealthy cells as opposed to theranostics targeting only unhealthy cells).

There would be a negative cost of the project for area providers, but the project will only be redirecting approximately 50% of VCI's imaging needs to VCI and would also be adding an innovative treatment option not currently available in the PD. The benefits of theranostics can provide appear to outweigh the cost to area providers. Additionally, there was no opposition by these local area providers who would be affected by the project received by DCOPN. The project would not create access to any location within the PD to PET (or PET/CT) services as the PD already has access to services within a 60-minutes' driving time.

Utilization for currently available PET and PET/CT services is well below the SMFP threshold of 6,000 scans per unit (the average for 2021 data was only 1,795 scans per unit, or 22.9% utilization. However, for 18 of the last 19 projects for PET services, the Commissioner has recognized the inadequacy of the SMFP standards for PET and PET/CT services for determining procedural capacity. In 2022, VCI referred patients for 3,003 PET and PET/CT procedures to area providers. The applicant only anticipates to have about 50% of the PET and PET/CT scanning completed at the VCI location and will continue to refer to area providers for the other 50%.

The capital cost of the project is $3,135,463 (**Table 7**), which is higher than the average for similar, recently approved projects ($1,724,572) (**Table 9**). However, the capital cost is within the range of other similar projects ($784,500 - $4,110,625) (**Table 9**). The project most closely similar to the VCI proposal was approved for a COPN with the authorized capital cost of $4,110,625, which is more than the presently analyzed proposal. The revenue over expenses anticipated for Years 1 and 2 (**Table 8**) are less than the averages for similar projects (Table 9), but like the capital cost, the project revenue over expenses is within the range of similar projects that have been approved recently. **Tables 7 - 9** and the associated analysis are indicative of a reasonable capital cost as well as short and long-term viability of the project.

While VCI is not affiliated with a specific teaching hospital, VCI actively participates in clinical research trials; approval of this project would expand opportunities for clinical research trial participation.

DCOPN Staff Recommendations

COPN Request No. VA-8709 – Virginia Cancer Institute, Inc.

The Division of Certificate of Public Need recommends the **conditional approval** of Virginia Cancer Institute, Inc.'s COPN Request No. VA-8709 to establish a specialized center for PET/CT imaging for the following reasons:

1. The proposal to add PET/CT imaging services to the Virginia Cancer Institute – West End location by Virginia Cancer Institute, Inc. is generally 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 that would be as effective to meet the needs of the population to be served.

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

4. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of PET/CT services in PD 15.

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

6. There is no known opposition to the project.

Charity Conditions

DCOPN's recommendation is contingent upon Virginia Cancer Institute, Inc.'s agreement to the following charity care condition:

Virginia Cancer Institute, Inc. 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 1.0% of Virginia Cancer Institute, Inc.'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. Virginia Cancer Institute, 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.

Virginia Cancer Institute, Inc. 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, Virginia Cancer Institute, 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.