

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

January 19, 2024

RE: COPN Request No. VA-8736

Virginia Commonwealth University Health System Authority

Richmond, Virginia

Introduce mobile PET/CT imaging at the Stony Point Campus

Applicant

The Virginia Commonwealth University Health Systems Authority (VCUHS) is a public body corporate and political subdivision of the Commonwealth of Virginia, governed by the Virginia Commonwealth University Health System Authority Act of 1996-Title 23, Chapter 6.2, 23-50.16:1 of the Code of Virginia. Subsidiaries of the applicant include Aries Insurance Services, Ltd., MCV Associated Physicians, Virginia Children's Care Network, LLC, Community Memorial Hospital, University Health Services, Inc., Rehab JV, LLC, Health at Home, LLC, and Medical College of Virginia Hospitals Auxiliary of Virginia Commonwealth University Health System. VCUHS proposes to establish a mobile PET/CT site at its VCU Health Stony Point 9000 facility. The facility is in Richmond, Virginia, Planning District (PD) 15, Health Planning Region (HPR) IV.

Background

A positron emission tomography (PET) scan is an imaging test that can help reveal the metabolic or biochemical function of the tissues and organs. The PET scan uses a radioactive drug called a tracer to show both typical and atypical metabolic activity. A PET scan can often detect the atypical metabolism of the tracer in diseases before the disease shows up on other imaging tests, such as computerized tomography (CT) and magnetic resonance imaging (MRI). The tracer is most often injected into a vein within the hand or arm. The tracer will then collect into areas of the body that have higher levels of metabolic or biochemical activity. This often pinpoints the location of the disease. The PET images are typically combined with CT or MRI [to better visualize anatomical structures along with biochemical activity] and are called PET/CT or PET/MRI scans. A PET scan is an effective way to help discover a variety of conditions, including cancer, heart disease and brain disorders. Information from a PET scan is used to diagnose, monitor or treat conditions.¹ The useful life of the tracer is limited, and its availability on-site of the PET service constrains hours of operation.

¹ <https://www.mayoclinic.org/tests-procedures/pet-scan/about/pac-20385078>

There are currently no PET/MRI scanners in the PD 15 inventory, but several PET/CT scanners. Though PET/CT scanners may take CT scans separate from PET scans, most providers have acknowledged that they don't utilize the CT component in this way, but only take CT scans concurrently with PET scans. In the rare cases that do, CT volumes are counted separately. For purposes of this report, PET is the technology under evaluation and mention of the CT component may be omitted.

In 2021, the latest year for which such data are available, three fixed PET facilities in PD 15 with one scanner each, and two mobile PET sites reported volumes (**Table 1**). One of the fixed sites is limited to cardiac only PET scans. The fixed-site PET scanners in aggregate had utilization equal to 36.0% of the State Medical Facilities Plan (SMFP) volume threshold for PET. Since 2021, both of the mobile sites have received authorization to convert to fixed sites.

Table 1. PET Utilization, PD 15, 2021

Facility Name	Imaging Systems	Total Procedures	Average Procedures Per Scanner	Utilization
Fixed				
Bon Secours St. Mary's Hospital	1	1,916	1,916	31.9%
VCU Medical Center	1	2,285	2,285	38.1%
Virginia Cardiovascular Specialists (cardiac only)	1	2,286	2,286	38.1%
PD 15 Fixed	3	6,487	2,162	36.0%
Mobile				
	Vendor Half Days/ 10 Total Half Days			
Chippenham Hospital	0.5	1,365	1,916	31.9%
Henrico Doctors' Hospital - Forest	0.8	1,121	2,285	38.1%
PD 15 Mobile	1.3	2486	1912	31.9%
PD 15 PET Utilization	4.3	8,973	2,087	34.8%

Source: VHI 2021

DCOPN records show there are now six fixed-site PET scanners in PD 15 and two mobile sites (**Table 2**). The location of the proposed project, VCU Health Stony Point 9000, is an existing medical facility on VCU Health's Stony Point campus, which offers cancer, heart and vascular services, outpatient surgery, physical rehabilitation, and diagnostic imaging (including CT, MRI, ultrasound and x-ray). The applicant asserts that the proposed site is particularly important for VCUHS' oncology patients, many of whom require PET/CT in their treatment plans.

Table 2. Authorized PET Sites, PD 15

Facility	Authorized Fixed-Site Scanners
Fixed	
Bon Secours Imaging Center at Reynolds Crossing	1
Henrico Doctors' Hospital - Forest ²	1
Johnston-Willis Hospital ³	1
VCU Health System	1
Virginia Cardiovascular Specialists (cardiac only)	1
James River Cardiology - Chesterfield (cardiac only) ⁴	1
Mobile	
Henrico Doctor's Hospital - Parham Doctors' Hospital	1
Med-Atlantic (prostate only)	1

Source: DCOPN Records

Proposed Project

The applicant proposes to add a 585-square foot mobile pad for PET/CT services with minimal reconfiguration of parking spaces. Square footage within the existing VCU Health Stony Point 9000 facility will not change. The applicant states that parking is plentiful and sufficient for patients and the proposal will not impact overall availability of parking for patients. Projected capital costs for the proposed project are \$267,000, funded with accumulated reserves such that no financing costs will be incurred (**Table 3**).

Table 3. Capital Costs, VCU Health Stony Point 9000

Direct Construction Costs	\$ 128,810
Site Preparation Cost	\$ 52,262
Architectural and Engineering fees	\$ 40,928
Other Consulting Fees	\$ 45,000
TOTAL CAPITAL COST	\$ 267,000

Source: COPN Request No. VA-8736

VCUHS intends to enter a leasing contract for a new state-of-the-art mobile PET/CT unit to provide care at three other VCUHS sites outside of PD 15. The scanner has capability for high-quality imaging on complex patients with shorter scanning times, providing better operational efficiency and reducing patient exposure times. The proposed project is in the City of Richmond and, if approved, the target date to begin operations is about nine months after COPN issuance.

² Conversion from mobile to fixed site, authorized by COPN No. VA-04733, was expected complete 7/2023.

³ Conversion from mobile to fixed site authorized by COPN No. VA-04756, expected complete 1/2024.

⁴ Expected operational 11/2023.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the “introduction into an existing medical care facility described in subsection A of any positron emission tomographic (PET) scanning... when such medical care facility has not provided such service in the previous 12 months.” A medical care facility includes “any specialized center or clinic or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, computed tomographic (CT) scanning, magnetic resonance imaging (MRI)...”.

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.

- 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.**

PD 15 had a population just over 1.1 million in 2020 and is projected to add nearly 100,000 to its population by 2030. Its projected growth of 8.6% by the end of the decade is a higher growth rate than that of Virginia’s population, 5.6% (**Table 4**). The City of Richmond, where the proposed project is located, represents about 20% of the PD 15 population (**Chart 1**) and is projected to grow at about the same rate as PD15 as a whole, and add over 26,000 to its population between 2020 and 2030.

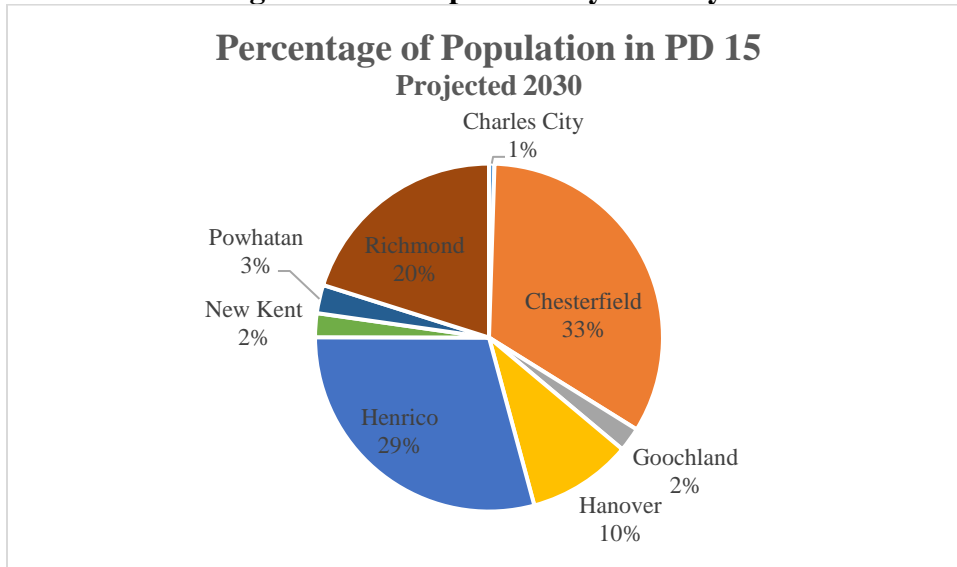
Table 4. PD 15 Population Data

	2020 Population	2030 Projected Population	Proj. Population Change 2020-2030	Proj. Percent Change 2020-2030	2020 65+ Population	Proj. 2030 65+ Population	Proj. 65+ Population Change 2020-2030	Proj. 65+ Percent Change 2020-2030
Charles City	6,758	6,200	-558	-8.30%	1,773	2,189	416	23.40%
Chesterfield	365,627	406,942	41,315	11.30%	55,297	72,476	17,179	31.10%
Goochland	24,809	27,339	2,530	10.20%	5,420	7,421	2,001	36.90%
Hanover	110,164	118,374	8,210	7.50%	19,807	27,456	7,649	38.60%
Henrico	334,756	356,656	21,900	6.50%	53,255	68,003	14,748	27.70%
New Kent	23,069	27,067	3,998	17.30%	4,303	6,663	2,360	54.80%
Powhatan	30,355	32,152	1,797	5.90%	6,041	8,552	2,511	41.50%
Richmond	226,613	245,437	18,824	8.30%	26,352	31,657	5,305	20.10%
PD 15	1,140,301	1,238,825	98,524	8.60%	176,028	228,611	52,583	29.90%
<i>Virginia</i>	<i>8,646,905</i>	<i>9,129,002</i>	<i>482,097</i>	<i>5.60%</i>	<i>1,352,448</i>	<i>1,723,382</i>	<i>370,934</i>	<i>27.40%</i>

Source: Weldon Cooper Intercensal Estimates

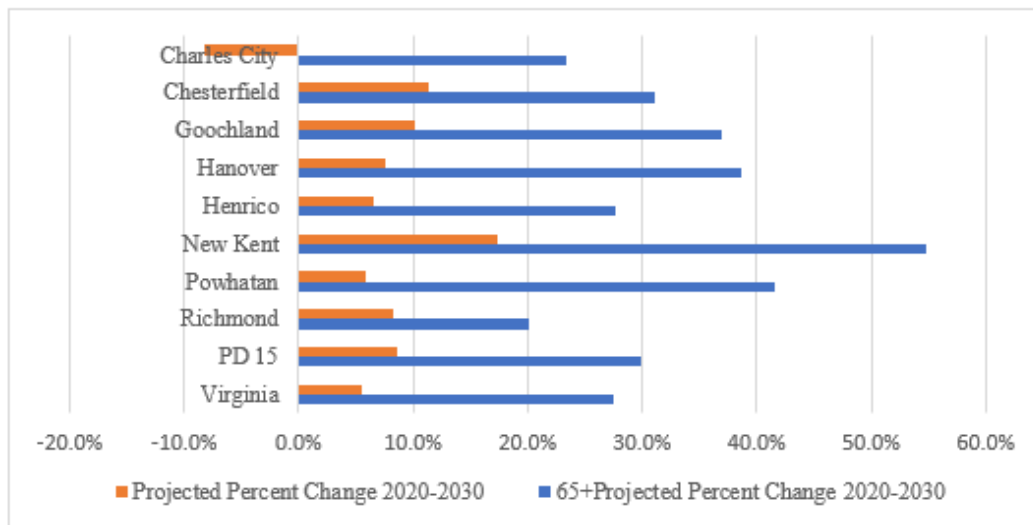
People aged 65 and older, have a higher utilization rate for advanced imaging services than younger individuals,⁵ so they are an important demographic in projects involving PET imaging. Though the population over age 65 is expected to grow at a higher rate in PD 15 (29.9%) than that of Virginia (27.4%), this age cohort is projected to grow more slowly in Richmond. At 20.1%, Richmond has the slowest increase in the 65 and older age cohort of all other localities in PD 15, projected to add 5,305 people over age 65 between 2020 and 2030 through aging and in migration (Table 1/Chart 2).

Chart 1. Percentage of PD 15 Population by Locality



Source: Weldon Cooper Intercensal Estimates

Chart 2. Projected Growth Rates 2020 to 2030 & 65+ Projected Growth Rates



Source: Weldon Cooper Intercensal Estimates

⁵ <https://jamanetwork.com/journals/jama/fullarticle/2749213>

Table 5. PD 15 Poverty Rates

Geographic Name	Poverty Rate
Charles City County	12.30%
Chesterfield County	7.60%
Colonial Heights City	13.50%
Goochland County	6.70%
Hanover County	5.20%
Henrico County	9.00%
New Kent County	5.20%
Powhatan County	6.90%
<i>Richmond City</i>	<i>24.50%</i>
PD 15 Totals	10.10%
Virginia	10.70%

Source: Weldon-Cooper Census Data

Table 5 shows that PD 15 has a poverty rate just under that of Virginia (10.7%), but the poverty rate in Richmond is over double those at 24.5%. The effects of poverty on health outcomes have been studied extensively from local to global scales. Regarding 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 $\geq 20\%$ 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.⁶

The overall cancer incidence rate in PD 15 is higher than the statewide average; the PD 15 incidence rate is 494.7 per 100,000 people while the statewide average is 434.1. 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

As to transportation barriers, none are identified. VCU Health Stony Point is off Chippenham Parkway. Several major roadways including Parham Road and Powhite Parkway provide convenient access. The location is also accessible by public transportation, the Greater Richmond Transit Company (GRTC).

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:

⁶ 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.

(i) The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served.

DCOPN received a letter of commitment from the Interim Chief Medical Officer on behalf of the VCUHS medical staff and two letters of support from VCUHS' Chair of Radiology and Deputy Director and Senior VP of its cancer service line. These letters, in aggregate, expressed the following:

- The VCUHS medical staff strongly supports the addition of a PET/CT at Stony Point.
- The proposed project will greatly improve access to a critical imaging modality for many existing VCUHS patients.
- VCUHS operates only one PET/CT unit (fixed) in PD 15, on its downtown campus.
- Trying to accommodate all VCUHS patients that require a PET/CT on a single scanner has created operational, scheduling, and patient care challenges.
- The Stony Point campus is an important care location for VCUHS' Richmond-based patients and is home to a Massey Cancer Center site.
- Adding a supplemental mobile PET/CT unit at an existing, well-utilized VCUHS site of care will improve access, timeliness of care and patient experience.
- More timely care leads to quicker diagnosis and treatment, resulting in improvement in quality of care.
- PET/CT has played an increasingly pivotal role in the lives of patients, guiding therapeutic decisions of physicians, "often the next step in a therapeutic algorithm hinges upon the PET/CT findings."
- Indications for PET/CT have grown from primarily oncologic to cardiac, suspected infection, sarcoidosis and dementia.
- The number of patients seeking care at VCU has also grown.
- Massey Cancer Center has recently received designation by the National Cancer Institute. This combined with growth of VCU's organ transplant program and the opening of the Stravitz-Sanyal Liver Institute at VCU are all expected to increase the number of patients coming to VCU requiring a PET scan.
- A single PET/CT scanner cannot accommodate the need.
- Patients battling cancer or other debilitating conditions need a more convenient PET/CT site (than downtown Richmond).
- The fragmentation in access to care at different sites is challenging for patients navigating demanding treatment schedules, side effects, complex comorbidities, pain and fatigue.
- Patients rely on family members for transportation.
- The downtown PET/CT is highly utilized, causing delays in care.
- The proposed project will enhance accessibility, availability and delivery of care.

Public Hearing

§32.1-102.6B of the Code of Virginia directs DCOPN to hold one public hearing on each application in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8736 is not competing with

another project and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

DCOPN provided notice to the public regarding this project inviting public comment on November 9, 2023. The public comment period closed on December 26, 2023. Other than the letters of support referenced above, no members of the public commented. There is no known opposition to the project.

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

There appears to be no reasonable alternative to the proposed project. VCUHS' fixed PET/CT scanner in downtown Richmond has wait times exceeding three weeks despite extending operating hours into early mornings, late evenings, and weekends. There is a window for utilizing the isotopes necessary for PET imaging that constrains the extension of hours further. The options for serving the growing PET/CT patient base at VCUHS is longer wait times or added PET/CT capacity. Rather than expand the PET/CT service at its downtown location, VCU is proposing the establishment of mobile PET/CT at the Massey Cancer Center site at VCUHS' Stony Point location. This proposal will decompress volumes at the downtown fixed PET/CT and provide more convenient access for cancer patients already going to Stony Point for cancer care, as well as other patients of the Stony Point campus in need of PET imaging.

(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.

Projected capital costs for the proposed project are \$267,000, funded with accumulated reserves such that no financing costs will be incurred (**Table 3**). The estimated costs are modest and reasonable when compared with other recently approved projects to establish a mobile PET/CT service, for example, COPN No. VA-04805 was authorized for \$1.4 million.

The applicant has described several benefits to the proposed project. It is intended to decompress the highly utilized PET/CT at VCUHS' downtown location where volumes are creating operational challenges and wait times exceed three weeks, despite extended hours. VCUHS expects this to be especially helpful as expected volume increases occur. The applicant reports that a Stony Point PET/CT site is easier to access and navigate, and co-located with other services for which PET is required for diagnosis, staging and treatment. The applicant asserts the proposal will create a better patient experience, less travel and shorter wait times for PET studies, overall, a better quality of care.

In addition, the proposal will enhance efficiencies with an additional site to rotate a new mobile PET/CT unit.

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

The applicant states that the proposed project will be financially accessible to all patients that need PET/CT services. It asserts it is the largest safety net provider in Virginia with a commitment to ensuring high-quality and affordable care for all patients.

VCUHS provided charity care in the amount of 0.9% in 2021, the latest year for which such data are available. This is just below the HPR IV average of 1.0%. MEDRVA Stony Point provided 0.0% charity the same year (**Table 6**). In accordance with section 32.1-102.4. B of the Code of Virginia should the proposed project receive approval, it would be conditioned to provide a level of charity care based on gross patient revenues derived from PET imaging that is no less than the equivalent average for charity care contributions in HPR IV. Pursuant to Code of Virginia language any COPN issued for this project will also be conditioned on the applicant's agreement to accept patients who are the recipients of Medicare and Medicaid. The proforma provided by the applicant projects a charity care percentage of 1.0% of patient revenues, consistent with the HPR IV average.

Table 6. 2021 Charity Care, HPR IV

Health Planning Region IV			
2021 Charity Care Contributions at or below 200% of Federal Poverty Level			
HPR IV	2021 at 200%		
	Gross Pt Rev	Adjusted Charity Care	%
Encompass Health Rehab Hosp of Petersburg	\$ 26,851,240	\$ 1,046,165	3.9%
Southern Virginia Regional Medical Center	\$ 193,424,382	\$ 6,462,541	3.3%
Sentara Halifax Regional Hospital	\$ 305,216,000	\$ 5,567,790	1.8%
Bon Secours St. Francis Medical Center	\$ 1,075,574,864	\$ 15,314,171	1.4%
Southside Regional Medical Center	\$ 2,000,593,397	\$ 27,695,403	1.4%
Bon Secours Richmond Community Hospital	\$ 991,036,257	\$ 11,039,087	1.1%
CJW Medical Center	\$ 8,975,939,621	\$ 87,710,457	1.0%
Henrico Doctors' Hospital	\$ 5,763,604,659	\$ 52,734,748	0.9%
VCU Health System	\$ 6,809,570,615	\$ 61,295,221	0.9%
Bon Secours St. Mary's Hospital	\$ 2,358,088,813	\$ 20,998,912	0.9%
TriCities Hospital	\$ 1,324,643,208	\$ 9,600,576	0.7%
Sheltering Arms Institute	\$ 137,252,572	\$ 970,918	0.7%
Bon Secours Memorial Regional Medical Center	\$ 1,614,325,924	\$ 9,753,218	0.6%
Community Memorial Hospital	\$ 343,583,756	\$ 1,572,169	0.5%
Encompass Health Rehab Hosp of Virginia	\$ 25,150,781	\$ 107,359	0.4%
Southside Community Hospital	\$ 383,098,711	\$ 1,431,006	0.4%
Cumberland Hospital for Children and Adolescents	\$ 39,513,361	\$ -	0.0%
Select Specialty Hospital - Richmond	\$ 141,742,321	\$ -	0.0%
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%
Boulders Ambulatory Surgery Center	\$ 108,434,022	\$ 3,555,600	3.3%
St. Mary's Ambulatory Surgery Center	\$ 44,154,385	\$ 634,846	1.4%
Urosurgical Center of Richmond	\$ 41,571,274	\$ 544,435	1.3%
Virginia Eye Institute, Inc.	\$ 35,627,224	\$ 308,496	0.9%
MEDRVA Surgery Center @ West Creek	\$ 9,492,898	\$ 7,975	0.1%
American Access Care of Richmond	\$ 5,226,209	\$ -	0.0%
Cataract and Refractive Surgery Center	\$ 9,247,035	\$ -	0.0%
MEDRVA Stony Point Surgery Center	\$ 58,223,076	\$ -	0.0%
Skin Surgery Center of Virginia	\$ 1,454,451	\$ -	0.0%
Virginia Beach Health Center VLPP	\$ 2,651,434	\$ -	0.0%
Total Outpatient Hospitals:			10
HPR IV Total Outpatient Hospital \$ & Mean %	\$ 316,082,008	\$ 5,051,352	1.6%
Total Hospitals:			28
HPR IV Total Hospital \$ & Mean %	\$ 32,825,292,490	\$ 318,351,093	1.0%

Source: VHI

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

There are no other factors, not addressed elsewhere in the analysis, relevant to the determination of a public need for either project.

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

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

The State Medical Facilities Plan (SMFP) contains the criteria and standards for PET services. They are as follows:

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

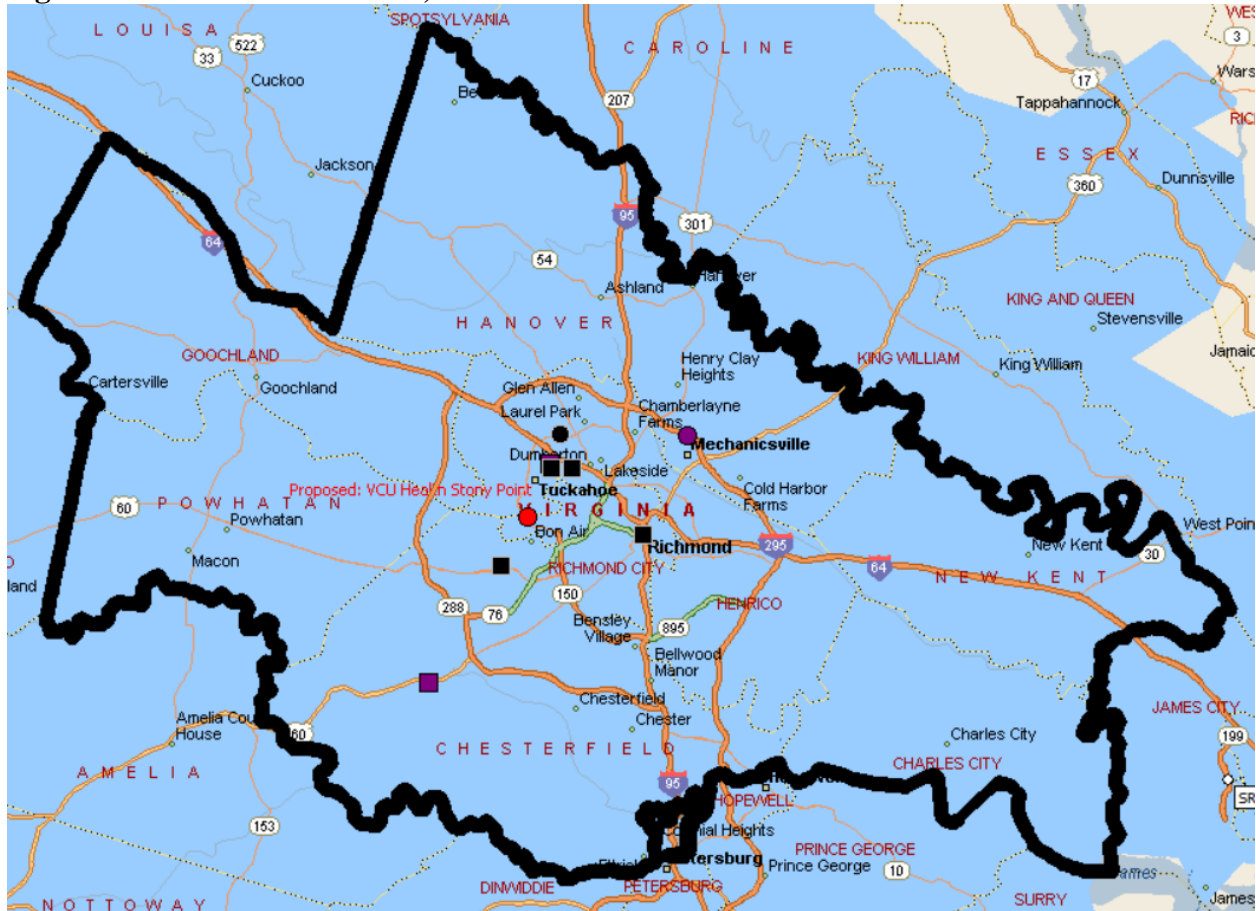
Article 4. Positron Emission Tomography

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 1** are the locations of the PET sites in PD 15. The black outline represents the PD 15 boundary, the blue shaded area represents the geographic area within 60-minutes' driving distance to current providers, consistent with the Travel Time provision for PET imaging services. DCOPN notes the entirety of PD 15 is within 60 minutes of a PET service. In fact, the area within 60 minutes of PD 15 PET services extends beyond the boundary of PD 15 on all sides and the proposed facility (the red circle on the map) does not improve geographic access in the PD. Squares on the map are fixed PET sites; circles are mobile PET sites; purple icons represent limited use sites (two cardiac-only and one prostate-only).

Figure 1. Authorized PET Sites, PD 15



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.

This provision of the SMFP is not applicable as the applicant is not seeking to establish a fixed site PET service.

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 a fixed site PET service; however, the proposed mobile PET/CT service is expected to decant volumes from the applicant's highly utilized fixed site.

The SMFP volume per unit threshold originally set for PET services has been discussed in previous applications and determined to be inconsistent with current technology and applications of the modality.⁷ PD 15 had an average utilization rate of 34.8% in 2021 and VCUHS' utilization that year was higher than the average, at 38.1%. As discussed previously, the fixed PET/CT unit at VCUHS has found it necessary to expand hours of operation and its patients are still experiencing wait times exceeding three weeks, to the detriment of optimal care, even at this utilization well below the SMFP threshold. COPN Request No. VA-8736 proposes a mobile site at Stony Point 9000 to supplement VCUHS' fixed PET/CT.

12VAC5-230-230. Adding or expanding mobile PET or PET/CT services.

A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.

The proposed project fulfills this standard for adding a mobile PET/CT service. VCUHS has submitted patient origin data and demonstrates that over 800 PET/CT scans have been performed on patients that reside closer to Stony Point 9000 than to VCUHS' downtown PET/CT site in 2022. The applicant states that this number of scans reflects unique patients well above the 230 patients referenced in this standard. VCUHS predicts 628 PET/CT scans at the proposed mobile Stony Point site in its first year of operation and 697 PET/CT scans in its second.

With high utilization on the VCUHS' fixed PET/CT that would benefit operationally from shifting a portion of PET/CT patients to its Stony Point site, as well as reasonable expectations of high growth in demand for the PET/CT modality, these volumes can be accomplished with existing VCUHS patients and will not significantly reduce utilization of other existing providers in PD 15.

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.

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

⁷ For example, DCOPN Staff reports for COPN Request Nos. VA-8507 and VA-8327.

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 imaging service will be under the direct supervision of one or more qualified physicians.

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 project does not foster beneficial competition but is intended to supplement a highly utilized fixed site service for better accommodation and care of the applicant's existing patient base.

- 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.**

Each of the three major health systems, in PD 15, as well as some independent providers, offers PET services. As discussed, VCUHS has a single fixed-site service. The proposed mobile PET site, co-located at a facility that offers services that require PET imaging for diagnosis, staging and treatment, is a complementary service, convenient for the growing number of cancer patients as well as others requiring PET scans. VCUHS intends to enter into a lease arrangement for a new state-of-the-art mobile PET/CT scanner that will rotate to three other sites outside of PD 15, and the proposed project would provide a fourth site and more fully utilized the new scanner.

- 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.**

Capital costs are modest and reasonable, and the proforma provided by the applicant projects a positive net income beginning the first year (**Table 7**). VCUHS intends to enter a leasing contract for a new state-of-the-art mobile PET/CT unit providing care at three other VCUHS sites outside of PD 15. Introducing the proposed fourth mobile PET/CT at VCUHS Stony Point 9000 would more fully utilize the scanner and spread costs of the leasing arrangement, improving the financial benefits of the leasing agreement overall, and financially benefiting the projected costs of the proposed project. Additional staffing required is minimal at 1.5 FTEs, of which VCUHS will provide 0.5 and the equipment vendor 1.0.

Table 7. Proforma Mobile PET/CT-Stony Point Location

	Year 1	Year 2
Gross Revenue	\$ 7,265,332	\$ 8,305,501
Charity Care	\$ 72,653	\$ 83,055
Other Deductions	\$ 5,491,427	\$ 6,277,628
Net Revenue	\$ 1,701,252	\$ 1,944,818
Expenses	\$ 1,186,933	\$ 1,298,658
Net Income/Loss	\$ 514,319	\$ 646,160

Source: COPN Request No. VA-8736

- 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 proposal includes the introduction of latest PET/CT technology, for shorter patient scanning times and less patient exposure, and establishes an outpatient mobile site co-located with existing patient services, including a newly National Cancer Institute (NCI)-designated Comprehensive Cancer Center. It is the proposed fourth site for a new mobile PET/CT lease that provides care within the VCUHS system to multiple PDs.

- 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.

VCUHS is the only academic medical center in Central Virginia. It has a three-part mission to preserve and restore health for all people of Virginia and beyond, through innovation in service, research, and education. The proposal co-locates PET/CT services with a site of the Massey Cancer Center, recently designated by the NCI as a Comprehensive Cancer Center.

DCOPN Staff Findings and Conclusions

VCUHS proposes to introduce mobile PET/CT at VCUHS Stony Point 9000, a site that already provides patient services, including cancer care and other imaging modalities. The proposal integrates an imaging modality that complements services already on-site for a higher level of patient convenience and care quality. It will decant volumes from VCUHS’ fixed site in downtown Richmond that has experienced operational issues from over utilization, including extended patient waits, despite hours of operation expanded to the time frame to useful life of required radiation isotopes. The proposal is the fourth rotation in a new leasing contract VCUHS plans to enter for a new, up-to-date mobile PET/CT scanner.

The proposed project improves access for disadvantaged populations where PET services are needed. The City of Richmond where the proposed site is located has a higher than state average growth rate, though a slower than average growth rate in the 65 and older population. The poverty rate in the area is nearly 25% and the cancer incidence is above state averages. The proposal has community support, especially among the medical staff referring to and supporting existing services at the proposed site. There is no known opposition to the proposed project.

There is no reasonable more beneficial alternative to the proposed project. Costs are quite modest and reasonable, and benefits are substantial for efficiency, providing for a growing patient base, patient convenience and care quality, integrating a necessary imaging modality at an existing patient care site. The proposal does not improve geographic access but 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. It is wholly feasible and will improve the delivery of patient care, specifically for cancer care patients at a newly designated Comprehensive Cancer Center and support the mission of an academic medical center.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends conditional approval of the Virginia Commonwealth University Health Systems Authority's COPN Request number VA-8736 to introduce a mobile PET/CT service at it VCUHS Stony Point 9000 facility in Richmond, Virginia for the following reasons:

1. The proposal will improve access to PET/CT services in a PD with an above average poverty rate and cancer incidence.
2. The proposal 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.
3. There is no reasonable alternative to the proposed project, and it is more beneficial than the status quo.
4. The capital costs of the proposed project are modest and reasonable.
5. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of PET services in PD 15.
6. The proposed project is financially viable in the immediate and long-term.
7. It represents an improvement in the delivery of health services and supports the mission of a Virginia academic medical center.
8. There is no known opposition to the project.

DCOPN's recommendation is contingent upon the Virginia Commonwealth University Health Systems Authority's agreement to the following charity care condition:

The Virginia Commonwealth University Health Systems Authority will provide PET/CT imaging 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 will facilitate the development and operation of primary medical care services to medically underserved persons in PD 15 in an aggregate amount equal to at least 1.0% of the Virginia Commonwealth University Health Systems Authority's gross patient revenue derived from PET/CT services at the VCU Health Stony Point 9000 site. 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. The Virginia Commonwealth University Health Systems Authority will accept the revised charity condition based on 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 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.

The Virginia Commonwealth University Health Systems Authority will provide PET/CT services at VCU Health Stony Point 9000 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, The Virginia Commonwealth University Health Systems Authority will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.