

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-8731

The Rector and Visitors of the University of Virginia
on Behalf of the University of Virginia Medical Center
Charlottesville, Virginia

Establish a Medical Care Facility for PET/CT Services with One Fixed PET/CT Scanner

Applicant

The University of Virginia Medical Center (UVAMC) is a state-owned, academic healthcare center operated under the authority of The Rector and Visitors of the University of Virginia. UVAMC's University of Virginia Fontaine Research Park is at 500 Ray C. Hunt Drive, Charlottesville, Virginia, Planning District (PD) 10, Health Planning Region (HPR) I.

Background

UVAMC is a comprehensive tertiary teaching hospital. The medical center is composed of an integrated network of primary and specialty services that include the Emily Couric Clinical Cancer Center, the UVA Children's Hospital, the Heart and Vascular Center, the Digestive Health Center of Excellence, a Level I Trauma Center, the Blue Ridge Poison Center, and more than 60 outpatient clinics located on the main hospital campus and in surrounding Albemarle County.

Population and Demographics

The PD 10 population growth is projected to slow between 2020-2030, with a rate of 3.88% compared to the 2010-2020 growth rate of 8.86% (**Table 1**). Between 2010 and 2020, the PD 10 growth rate was higher than the statewide average of 7.45% for the same period (**Table 1**). For 2020-2030, the inverse is true, where the statewide average growth rate is projected to be 5.30% and is greater than the PD 10 rate (**Table 1**).

In contrast, the aged 65+ cohort of PD 10's growth is anticipated to outpace that of the statewide growth of the same demographic between 2020 -2030; the PD 10 65+ population is expecting a 22.09% increase while the statewide average for the 65+ population is expected to be 21.52% (**Table 1**). Taking note of the 65+ cohort growth rate is pertinent as this population group typically uses health care resources, including positron emission tomography/computed tomography (PET/CT) diagnostic services, at a rate much higher than those under the age of 65.

Table 1. PD 10 Population Data

Geography Name	2010	2020	% Change 2010-2020	2030	% Change 2020-2030	2020 65+	2030 65+	% Change 2020-2030 65+
Albemarle County	99,010	112,395	11.91%	124,016	9.37%	21,417	27,028	20.76%
Fluvanna County	25,691	27,249	5.72%	28,394	4.03%	5,799	7,366	21.27%
Greene County	18,403	20,552	10.46%	22,376	8.15%	3,836	5,442	29.51%
Louisa County	33,153	37,596	11.82%	41,436	9.27%	7,826	10,691	26.80%
Nelson County	15,020	14,775	-1.66%	14,322	-3.16%	4,124	4,525	8.87%
Charlottesville city	43,435	51,050	14.92%	48,920	-4.35%	4,711	6,306	25.30%
PD 10 Totals/Averages	234,712	263,617	8.86%	279,464	3.88%	47,712	61,357	22.09%
Virginia, Statewide	8,001,024	8,644,727	7.45%	9,129,002	5.30%	1,352,448	1,723,382	21.52%

Source: Weldon-Cooper Data from the UVA Weldon-Cooper Center for Public Service

The average statewide poverty rate for Virginia in 2022 (most recently available by the U.S. Census Bureau) is 10.6% (Table 2). The average PD 10 poverty rate is 11.7% (Table 2), and the weighted poverty average of PD 10 by locality is 11.5%. Albemarle and Louisa Counties and Charlottesville city account for 76.7% of the projected 2030 PD 10 population total of 279,464; the average poverty rate for these three localities is 14.3% (Table 1, Table 2). The weighted average for these three localities is 12.6%. The averages and weighted averages for PD and the largest population centers in PD 10 are all higher than the statewide average.

Table 2. Poverty Rates PD 10 (2022) and Percentage of Total PD 10 Population by Locality

Geography Name	Poverty Rate	% of Total PD 10 Population*
Albemarle County	9.0%	44.4%
Fluvanna County	4.6%	10.2%
Greene County	10.1%	8.0%
Louisa County	10.8%	14.8%
Nelson County	12.5%	5.1%
Charlottesville city	23.1%	17.5%
PD 10 Average/Total	11.7%	100%
Virginia, Statewide	10.6%	N/A

Source: U.S. Census Bureau

*2030 Projections

Positron Emission Tomography/Computed Tomography

Nuclear imaging plays a pivotal role in cardiac infectious, inflammatory, infiltrative, and innervation disorders.¹ PET/CT imaging is a noninvasive nuclear diagnostic imaging tool that allows the detection of radiopharmaceutical tracer accumulation in tissues with high sensitivity and provides precise quantification of their local concentration. The tracers used accumulate in tissues proportional to their glucose utilization, reflecting the glucose metabolism of cells; this glucose metabolism is increased in cancer as well as in infectious and inflammatory processes.² Anatomical and morphological information derived from the combination of PET with CT

¹ Slart, Riemer H. J. A, Glaudemans, Andor W. J. M, Olivier Gheysens, Mark Lubberink, Tanja Kero, Marc R. Dweck, Gilbert Habib, et al. "Procedural Recommendations of Cardiac PET/CT Imaging: Standardization in Inflammatory-, Infective-, Infiltrative-, and Innervation (4Is)-Related Cardiovascular Diseases: A Joint Collaboration of the EACVI and the EANM." European Journal of Nuclear Medicine and Molecular Imaging 48, no. 4 (2021;2020;): 1016-1039.

² Ibid.

(PET/CT) improves the localization, extent, and characterization of lesions detected by the tracers.³

An advantage of using PET/CT over SPECT imaging lies in the resolution differences; PET scans are capable of 5 to 7mm resolution compared to cardiac SPECT scan resolution of 12 to 15mm.⁴ Additionally, the use of X-ray CT equipment in PET/CT imaging provides routine correction of tracer attenuation (reduction of the intensity of an X-ray beam as it traverses through matter creating noise in the image); this attenuation artifact reduction reduces the rate of false-positive perfusion defects, ultimately increasing specificity.⁵ The hybrid imaging techniques of PET and CT are an advanced modality for the detection of coronary artery disease; the combination allows for a single scanning session of less than 45 minutes where cardiac perfusion (physiology) combines with an assessment of coronary anatomy simultaneously.⁶

In a 2020 meta-analysis of 2016 data, aggregated health conditions under the umbrella of cardiovascular diseases accounted for the third highest costs to healthcare; the researchers also determined for the same year healthcare costs were funded via private insurance, which accounted for 48.0% of spending, 42.6% of spending was by public insurance, and 9.4% of spending was from out-of-pocket payments. Finding opportunities to lower healthcare costs for both the private and public insurance spheres will also reduce spending for out-of-pocket expenses. The Medical Imaging & Technology Alliance (MITA) supports the appropriate use of diagnostic imaging to reduce healthcare costs; MITA cites a Harvard research study that found that every \$1 sent on in-patient imaging correlated to approximately \$3 in total savings and that every \$365 spent on imaging decreases a patient's hospital stay by one day, saving approximately \$3,000 per patient.⁷

Regarding PET/CT specifically, cost calculations show financial savings from the integration of PET and CT for reasons including but not limited to: (1) there are times that a PET scan results in the need for a CT scan leading to additional costs and time to perform two scans, (2) the combined scanning results in an average time savings of 20-30 minutes per patient, (3) a shorter scanning time results in more efficient use of the tracer, since it decays rapidly due to its short half-life, and (4) significantly reduces the need for invasive measures that are more costly.⁸

Cardiac and Solid Organ Transplant PET/CT

Myocardial perfusion imaging (MPI) is an assessment tool for known or suspected coronary artery disease (CAD). Single photon emission computed tomography (SPECT) has historically

³ Slart, Riemer H. J. A, Glaudemans, Andor W. J. M, Olivier Gheysens, Mark Lubberink, Tanja Kero, Marc R. Dweck, Gilbert Habib, et al. "Procedural Recommendations of Cardiac PET/CT Imaging: Standardization in Inflammatory-, Infective-, Infiltrative-, and Innervation (4Is)-Related Cardiovascular Diseases: A Joint Collaboration of the EACVI and the EANM." *European Journal of Nuclear Medicine and Molecular Imaging* 48, no. 4 (2021;2020): 1016-1039.

⁴ Webmaster. "What's the Difference between Pet and SPECT Scans?" *Cardiac Imaging*, December 20, 2019. <https://www.mobilecardiacpet.com/blog/whats-the-difference-between-pet-and-spect-scans/#:~:text=PET%20Scan%20Images%20are%20Clearer,flow%20at%20a%20granular%20level.>

⁵ Knaapen P, de Haan S, Hoekstra OS, Halbmeijer R, Appelman YE, Groothuis JG, Comans EF, Meijerink MR, Lammertsma AA, Lubberink M, Götte MJ, van Rossum AC. Cardiac PET-CT: advanced hybrid imaging for the detection of coronary artery disease. *Neth Heart J*. 2010 Feb;18(2):90-8. doi: 10.1007/BF03091744. PMID: 20200615; PMCID: PMC2828569.

⁶ Ibid.

⁷ "Mita Endorses Hausleiter Study, Appropriateness Criteria for CCTA." *Imaging Technology News*, October 3, 2021. <https://www.itnonline.com/article/mita-endorses-hausleiter-study-appropriateness-criteria-ccta.>

⁸ Saif MW, Tzannou I, Makrilia N, Syrigos K. Role and cost effectiveness of PET/CT in management of patients with cancer. *Yale J Biol Med*. 2010 Jun;83(2):53-65. PMID: 20589185; PMCID: PMC2892773.

been the modality for MPI assessment; however, Cardiac PET, using tracers such as rubidium-82, is available and yields a much more accurate and detailed image.⁹ SPECT images give useful information, but PET images provide cardiologists with much more useful information and a clearer image. Additionally, PET positron emission tracers usually lead to lower radiation exposure than SPECT tracers, mostly attributable to the shorter half-life of PET tracers.¹⁰

Solid organ transplant patients are at a higher risk for developing infections and malignancies (cancers) as a result of the chronic requirement of immunosuppressant medications used following the transplant. PET/CT is “an accurate diagnostic tool for the work-up of diagnostic unresolved [solid organ transplant] recipients suspected of malignancy or infection.”¹¹ UVAMC participates in organ transplantation screening procedures, treatment, and research. Organ transplant patients require invasive catheterization procedures and SPECT imaging to provide medical professionals with information that would be more accurate, less invasive, have less radiation exposure, and be more cost-effective if gathered by a PET/CT procedure instead.

PET and PET/CT in PD 10

Table 3. PET and PET/CT Units in PD 10 and 2021 VHI Volumes and Utilization

Facility	Total Authorized Scanners	Fixed / Mobile	PET or PET/CT	Procedures	Utilization
Sentara Martha Jefferson Hospital	1	Mobile	PET	588	9.8%
UVAMC	1	Fixed	PET/CT ¹	2,601	43.4%
Total/Average	2 Total	N/A	N/A	3,189 Total	26.6% Avg

Sources: DCOPN Records, VHI Data 2021

¹PET/CT was a PET only in 2021. UVAMC upgraded their PET to a PET/CT via VA-R-015-22.

There are only two PET scanners in PD 10, only one of which has the CT portion that provides attenuation correction and advanced imaging. Sentara Martha Jefferson Hospital is located 4.4 miles, or 15¹² minutes driving time, from UVAMC and has one mobile PET unit with a utilization of 9.8% of the State Medical Facilities Plan (SMFP) threshold of 6,000 procedures; UVAMC has one fixed site PET unit operating at 43.4% of the SMFP threshold (**Table 3**). The average of the two units is 26.6% of the SMFP threshold (**Table 3**). UVAMC’s PET/CT is located at the Emily Couric Clinical Cancer Care Center (ECCCC), which is located on the UVAMC campus. UVAMC upgraded their PET to a PET/CT via registration VA-R-015-22.

Proposed Project

UVAMC proposes to establish a specialized center for outpatient PET/CT services with one PET/CT scanner at the University of Virginia Fontaine Research Park. The specific location within the research park is in the UVA Health Heart and Vascular Center Fontaine (**Figure 1**). The space within the UVA Health Heart and Vascular Center being remodeled to house the proposed PET/CT is currently housing the SPECT equipment.

⁹ Ghotbi AA, Kjaer A, Hasbak P. Review: comparison of PET rubidium-82 with conventional SPECT myocardial perfusion imaging. Clin Physiol Funct Imaging. 2014 May;34(3):163-70. doi: 10.1111/cpf.12083. Epub 2013 Sep 13. PMID: 24028171; PMCID: PMC4204510.

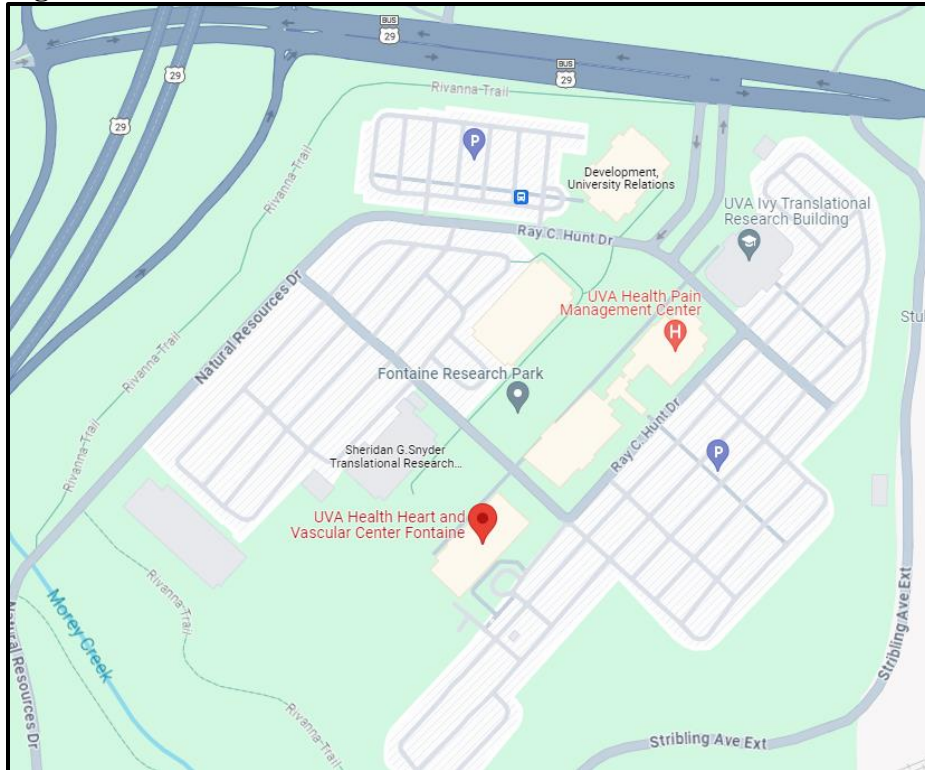
¹⁰ Ibid.

¹¹ Wareham NE, Lundgren JD, Da Cunha-Bang C, Gustafsson F, Iversen M, Johannesen HH, Kjaer A, Rasmussen A, Sengeløv H, Sørensen SS, Fischer BM. The clinical utility of FDG PET/CT among solid organ transplant recipients suspected of malignancy or infection. Eur J Nucl Med Mol Imaging. 2017 Mar;44(3):421-431. doi: 10.1007/s00259-016-3564-5. Epub 2016 Nov 12. PMID: 27838763; PMCID: PMC5281676.

¹² Distance and time calculated by Google Maps.

The project will not require new construction but will require remodeling of an existing building. University property is not subject to local zoning and use permit requirements as it is a state agency. The property is presently affixed with appropriate and operational utilities. The applicant provides assurances that the CT portion of the PET/CT will not be used independently of the PET portion of the equipment.

Figure 1. UVA Fontaine Research Park



Source: Google Maps

The construction time estimates, assuming COPN approval in February 2024, are the following:

Date of Drawings:	Preliminary: April 2024	Final: July 2024
Date of Construction:	Begin: September 2024	Completion: August 2025
Target Opening:	August 2025	

Project Definition

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

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

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

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

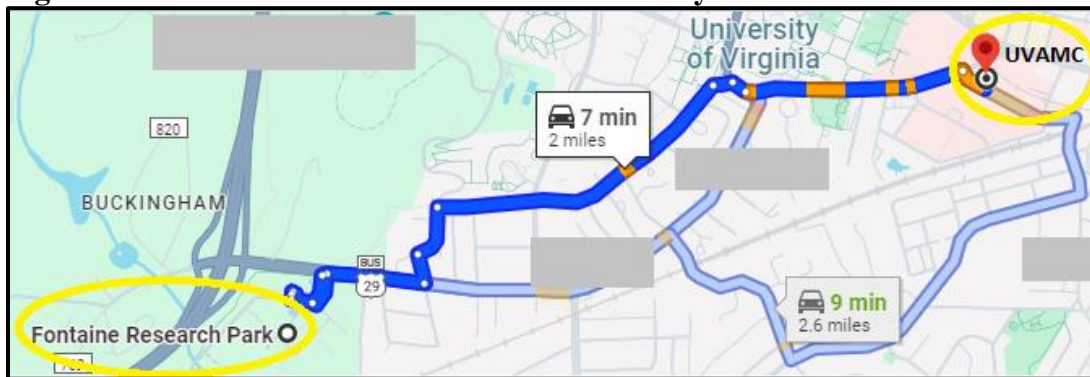
Geographically, UVAMC is readily accessible from I-64, US-29 and US-250. Additionally, public transportation is available via the Charlottesville Transit Service and Jefferson Area United Transit, Inc. (JAUNT). The applicant reports that there is ample public parking at the research park (denoted in **Figure 1** with the purple “P” marking). Additionally, there is a “frequent and regular shuttle service” available from the “University Hospital to the UVA Heart and Vascular Center at Fontaine where the new PET/CT will be situated.”¹³

The applicant reports a current two-week backlog in scheduling cancer patients, and a six-week backlog in scheduling cardiac patients, limiting PET/CT scans for cardiac patients to only 5 scans per week. UVAMC states a generator for rubidium-82 (tracer for cardiac imaging with a half-life of 75 seconds) is anticipated to be added to the University in the “very near future”. Currently, they have a cyclotron for N-Ammonia, the tracer being used for their MPI PET/CT imaging needs at present, whose half-life is only 10 minutes long. Once the rubidium-82 generator is acquired, the applicant expects approximately 60% of MPI studies will be performed with this tracer (with even less radiation exposure than N-Ammonia), but 40% will still require the N-Ammonia tracer. Having a PET/CT closer to the N-Ammonia cyclotron would make it easier for transporting the tracer to the patient.

The N-Ammonia cyclotron is located directly next to the proposed project location at the Fontaine Research Park. The proposed location (and cyclotron) is approximately 2 miles, or 7 minutes driving distance, from the ECCCC. This distance is making it difficult for patients needing MPI/Cardiac studies at the only PET/CT on campus difficult as there are only minutes in which to get the tracer into the patient and the imaging completed before the half-life point. This difficulty, along with the demands for cancer-related imaging, has extremely limited the scheduling time for cardiac purposes (and other imaging purposes such as organ transplants which require pre- and post-operative PET/CT imaging). Instead of PET/CT scanning availability, some patients have to undergo catheterization procedures, which are more costly and invasive. Having a PET/CT directly adjacent to the cyclotron will allow for the cardiac and organ transplant imaging demands to be met, as well as to decant some of the cancer imaging volumes.

¹³ COPN Request No. VA-8731, page 6 of the application

Figure 2. Distance from ECCCC to N-Ammonia Cyclotron



Source: Google Maps

2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following:

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

DCOPN did not receive any letters of opposition and received ten letters of support for the proposed project from medical professionals and leaders of UVAMC. Collectively, these letters articulate several benefits of the project, including:

- With the growth of UVAMC’s cardiac and transplant (particularly heart transplant) programs, increased PET/CT imaging access will provide a less invasive, more comfortable, more diagnostically accurate mode of diagnostic capabilities compared to other methods. For example, PET/CT is effective in showing any abnormalities or graft dysfunction of transplants earlier, allowing for treatment to happen timely.
- Cardiac PET/CT is the “standard of care for functional assessment of ischemic heart disease, replacing SPECT imaging as the preferred modality for ... MPI.”¹⁴ Technical advantages of PET imaging include: “better spatial resolution..., temporal resolution (ability to identify precise timing of the image), high count sensitivity (capture and use more radioactive signal to improve the picture), and incorporated attenuation correction...”¹⁵
- PET/CT is cost-effective, reducing costs by reducing the use of coronary angiography and CABG (coronary artery bypass graft), as well as reducing the costs associated with managing CAD.
- The benefits of PET/CT and the radionuclide tracers allow for many other diseases and conditions to be observed, many of which would otherwise not be discovered or treated timely.

¹⁴ Support Letter from Jamieson Bourque, MD, MHS, Professor of Medicine and Radiology, Medical Director of Nuclear Cardiology

¹⁵ Ibid.

- Cardiac (and cancer) patients who come to UVAMC are the “sickest of the sick.”¹⁶ Because of this, the demand and length of time of imaging studies differ from that of a typical community or local outpatient imaging center. In addition to being able to scan more than 5 cardiac patients a week, approximately 60% of patients receiving SPECT imaging will be able to have access to the PET/CT preferred imaging.
- The PET/CT in the proposed location would foster further collaborative research opportunities, medical education, and training initiatives. Additionally, the “...UVA Cardiovascular program is known for academic excellence in cardiovascular imaging. [UVAMC has] a NIH [National Institute of Health]-funded T32 training grant for advanced cardiovascular imaging that is one of only a few in the country. These trainees need extensive exposure to advanced PET/CT cardiovascular imaging. General cardiovascular fellows and other housestaff need exposure to this rapidly expanding modality.”¹⁷
- The PET/CT was placed at ECCCC because it was expected to be used primarily for oncological imaging; however, clinical care in other medical disciplines (like cardiology, neurology, and transplantation) has been evolving and now use PET/CT imaging as a core function of diagnosis and treatment monitoring. The expanded use of PET/CT imaging has created the need for additional capacity at UVAMC.
- The methodology for calculating PET and PET/CT procedures in the SMFP is not reflective of the scanning done at UVAMC. Their scans average 45 minutes per scan. The demands for lengthier scanning have created a scheduling backlog of 2 weeks for cancer patients, six weeks for cardiac patients, and virtually no capacity for transplant patients.
- PET/CT has become essential for the diagnosis and treatment of neurocognitive disorders, such as dementia, as well. PET/CT is quickly replacing cardiac catheterization and SPECT as a higher-quality, less invasive standard of care for pre-transplant cardiac screening as well as for determining recurrent cancer post-transplant versus reactive tissue related to an autoimmune response to the transplant.
- PET perfusion imaging has been shown to increase diagnostic accuracy specifically in the women’s cardiac community while reducing the radiation exposure this community faces. Reducing radiation exposure is imperative in this population.
- In just the Kidney-Pancreas transplant programs, there have been over 1,400 referrals in the past year, many of whom require pre-transplant PET/CT screening that presently must be done at other facilities. Having the pre-transplant screening done at other locations can result in delays in obtaining results, interpreting results, and coordinating care.

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 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-8731 is

¹⁶ Support Letter from Jamieson Bourque, MD, MHS, Professor of Medicine and Radiology, Medical Director of Nuclear Cardiology.

¹⁷ Ibid.

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.

DCOPN did not identify any reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner. Relocating the currently operable PET/CT closer to the cyclotron would not alleviate the demands placed on the PET/CT by oncological needs and would not increase scanning time to allow for transplant screenings.

(iii) Any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6.

Currently, there is no organization in HPR I designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 10. Therefore, this consideration does not apply to the review of the proposed project.

(iv) Any costs and benefits of the project.

The total capital cost is anticipated to be \$4,000,000, 100% of which is to be paid through accumulated reserves. The project will result in a need for 5.0 full-time equivalent (FTE) staff members: one registered nurse, one licensed practical nurse, two radiologic technologists, and one front-door team member. The applicant reports that several current employees can be readily deployed to support the service if hiring staff proves difficult. The staffing needs are relatively minimal and can be recruited from within the University graduate pool if needed. DCOPN finds it unlikely that the staffing will have a detrimental impact on other area providers.

Benefits to the project include increased capacity and time for conducting longer-than-typical PET/CT scans, increased teaching & research opportunities, and an ability to conduct pre-and post-transplant screening at UVAMC.

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

The applicant has provided assurances that PET/CT services will be accessible to all patients, regardless of financial considerations. In 2021, the most recent data available, UVAMC reports 2.98% of their gross revenues to be charity, which is greater than the average of HPR I of 1.92% (**Table 4**). Furthermore, as previously discussed, the Pro Forma Income Statement provided by the applicant anticipates a charity care contribution equal to 4.5% of gross revenues derived from PET/CT services at UVAMC, an amount consistent with the average HPR I contribution from 2020. Recent changes to §32.16-102.4B of the Code of Virginia

now require DCOPN to place a charity care condition on all applicants seeking a COPN. For this reason, DCOPN recommends that the proposed project, if approved, be subject to a 1.92% charity care condition, to be derived from total PET/CT gross patient services revenues, consistent with the HPR I average as of 2021, the most recent data available. DCOPN recommends a 1.92% charity condition rather than the projected 4.5% by the applicant as UVAMC has historically provided charitable care beyond the HPR average and the 4.5% was likely proposed as a reflection of previous data that is no longer the most current data available. DCOPN again notes that its recommendation includes a provision allowing for the reassessment of the charity care rate at such time as more reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

Table 4. VHI 2021 Reported Charity Care for HPR I

Health Planning Region I			
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:
UVA Transitional Care Hospital	\$ 53,021,859	\$3,256,725	6.14%
Encompass Health Rehab Hosp of Fredericksburg	\$ 42,215,195	\$1,984,765	4.70%
Culpeper Regional Hospital	\$ 445,240,580	\$15,076,533	3.39%
University of Virginia Medical Center	\$ 6,669,433,774	\$198,965,329	2.98%
Sentara RMH Medical Center	\$ 993,414,446	\$18,657,804	1.88%
Carilion Rockbridge Community Hospital	\$ 180,498,750	\$2,600,213	1.44%
Sentara Martha Jefferson Hospital	\$ 825,488,467	\$11,009,327	1.33%
UVA Encompass Health Rehabilitation Hospital	\$ 36,000,152	\$373,808	1.04%
Stafford Hospital Center	\$ 337,420,833	\$3,079,852	0.91%
Augusta Health	\$ 1,232,396,858	\$10,863,652	0.88%
Page Memorial Hospital	\$ 75,441,642	\$592,000	0.78%
Shenandoah Memorial Hospital	\$ 150,943,059	\$1,183,240	0.78%
Mary Washington Hospital	\$ 1,548,595,215	\$11,288,574	0.73%
Winchester Medical Center	\$ 1,541,736,262	\$10,319,447	0.67%
Spotsylvania Regional Medical Center	\$ 681,942,940	\$4,520,886	0.66%
Fauquier Hospital	\$ 462,729,762	\$2,463,787	0.53%
Warren Memorial Hospital	\$ 196,713,548	\$977,784	0.50%
Bath Community Hospital	\$ 25,547,880	\$73,591	0.29%
Total Inpatient Hospitals:			18
HPR I Inpatient Hospital Median			0.90%
HPR I Total Inpatient \$ & Mean %			1.92%
	\$ 15,498,781,222	\$ 297,287,317	

Source: 2021 VHI Data

(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).

Part II, Article 1 of the State Medical Facilities Plan (SMFP) contains the standards and criteria for the establishment of diagnostic services. They are as follows:

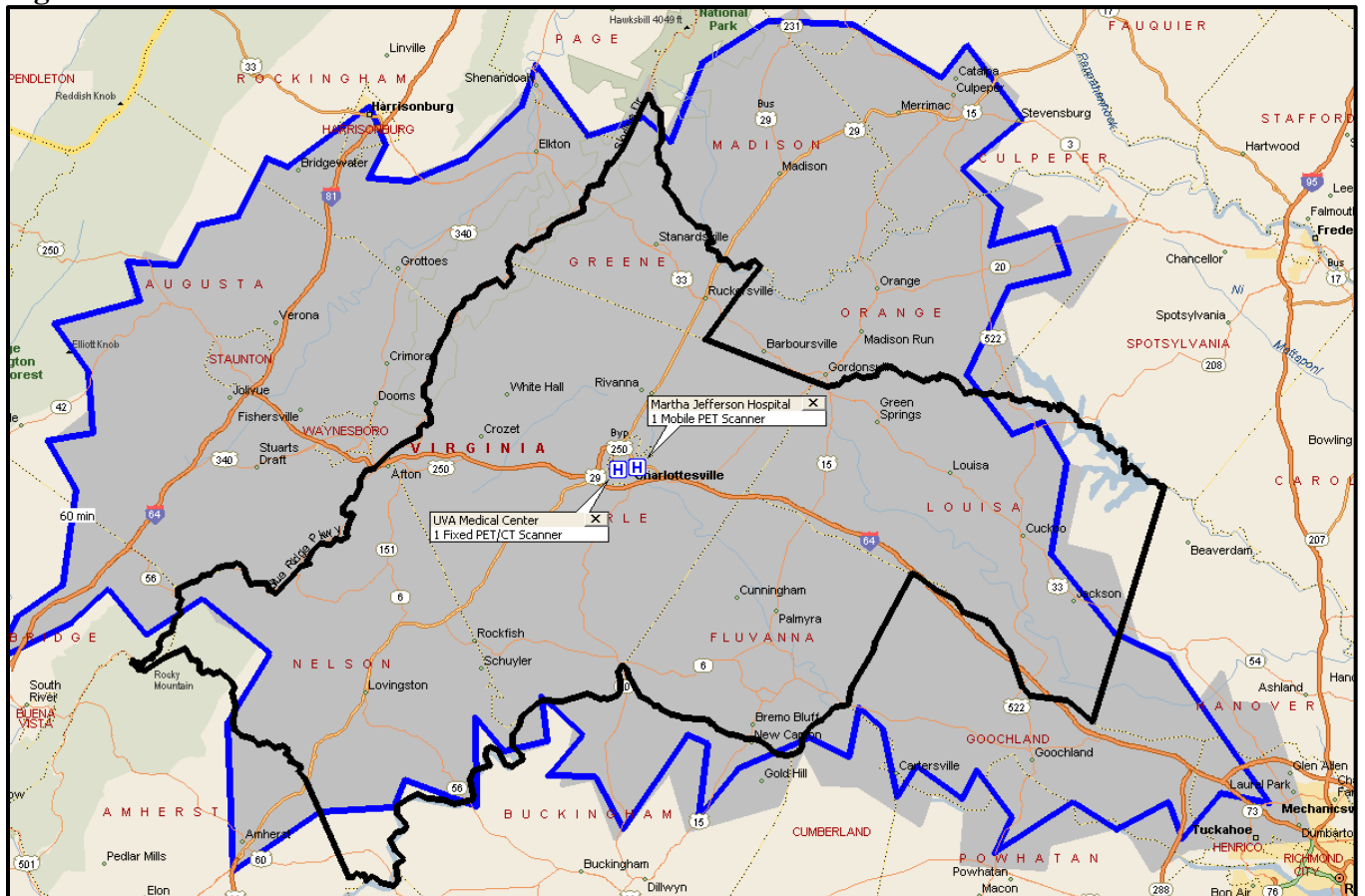
Part II. Diagnostic Imaging Services
Article 4. Positron Emission Tomography

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.

The black outline in **Figure 3** illustrates the boundary of PD 10, the blue outline represents the 60-minute driving distance radius from UVAMC, and the grey shaded area indicates the geographic area within the 60-minute driving distance from PET or PET/CT services in PD 10. As indicated in **Figure 3**, it is reasonable to conclude that 95% or more of PD 10 has access to PET services within a 60-minute driving time one way under normal conditions.

Figure 3. PD 10 PET & PET/CT Provider Locations



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

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

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

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.

As discussed in the **Background**, **PET and PET/CT in PD 10** section of this staff report, using the SMFP procedure threshold, the average utilization in PD 10 is 26.6%, with Sentara Martha Jefferson operating at 9.8% and UVAMC operating at 43.4% of the SMFP threshold of 6,000 procedures per year (**Table 3**).

The Recommended Case Decision that was 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:

*“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 1,916 to 2,286 annual procedures is discernible**¹⁸.”*

UVAMC’s established fixed PET/CT in 2021 was operating at 135.8% to 113.8% of the operational peak range of 1,916 - 2,286 procedures per year as determined by the Adjudication Officer in the decision referenced above (**Table 3**).

¹⁸ Emphasis added by DCOPN.

The applicant provided the data observed in **Table 5** regarding their 2022 and 2023 PET/CT volumes. The volume totals show a substantial increase in procedural volumes. While the cardiac imaging studies appear relatively low, UVAMC is limited in the number of cardiac studies it can perform as the tracer cyclotron is not located nearby and the time on the scanner used by cancer patients does not allow for any additional cardiac studies to be completed on this machine.

Table 5. Total PET/CT Volumes for 2022 and 2023 at UVAMC

Fiscal Year	PET/CT Non-cardiac	PET/CT Cardiac	Total
2022	2,725	248	2,973
2023	3,253	353	3,606

Source: COPN Request No. VA-8731

Additionally, there would be an increase in cardiac studies through the conversion of approximately 60% of patients receiving SPECT studies and through the addition of transplant patients requiring screening who are currently seeking scanning elsewhere or are undergoing invasive catheterization and SPECT studies. In 2022, UVAMC performed 2,155 outpatient SPECT studies; 60% of this would be approximately 1,293 studies. Not only would approval of this project result in additional PET/CT volumes to support the need, but it would reduce radiation exposure associated with SPECT and would allow for less invasive diagnostics for transplant referrals and patients. Furthermore, the project would easily have the volumes to support a second scanner within the first year of operation when compared to projects such as the Adjudication Officer's recommendation above. The project does not meet this provision of the SMFP, but it does meet the application of this provision in recently approved projects of similar size and scope.

12VAC5-230-220. Expansion of fixed site services.

Proposals to increase the number of PET scanners in an existing PET service should be approved only when the existing scanners performed an average of 6,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing fixed site providers in the health planning district.

This provision is not applicable as the applicant is not seeking to expand an existing fixed-site service.

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

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

B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district .

This provision of the SMFP is not applicable as the applicant is not proposing to add or expand mobile PET or mobile PET/CT services.

12VAC5-230-240. Staffing.

PET services should be under the direction or supervision of one or more qualified physicians. Such physicians shall be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

The applicant provides assurances that the PET/CT services would be under the direction of supervision of one or more qualified physicians designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

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 project is not anticipated to improve geographic access to essential healthcare services as it is creating services near established PET/CT services. Furthermore, as one of only two PET services providers in PD 10, the project is not likely to foster beneficial institutional competition by establishing another PET/CT location. However, the project will increase access concerning the time waiting for patients to be scanned, reducing the wait time for therapeutic medical decisions to be made/treatment plans to be formulated.

- 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.**

In relation to the current SMFP threshold for procedure volumes, the project would decrease the efficiency of existing services or facilities; however, as noted in multiple PET and PET/CT projects recently, the SMFP utilization threshold is not an accurate reflection of the present use of these diagnostic tools. With a revised understanding of the time for scanning using PET and PET/CT scanners, DCOPN concludes that the project would reasonably support the UVAMC strategic goals for healthcare provision and would create efficiency in the timeliness of patients being scanned and treatment beginning. The only other PET scanner in the PD is a mobile PET and does not have the CT-supporting capabilities that are needed for UVAMC's purposes. DCOPN finds it unlikely that the project would have a substantial influence on the PET procedure volumes of Sentara Martha Jefferson Hospital.

- 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 \$4,000,000, all of which is to be paid through accumulated reserves (**Table 6**). Of the total capital cost, 27.25% is allocated to direct construction costs, 62.50% is allocated to equipment not included in the construction contract, and 10.25% is allocated to architectural and engineering fees (**Table 6**).

Table 6. Total Capital Cost Summary

Direct Construction Costs Sub-total		\$1,090,000
	Cost of materials and labor	\$900,000
	Builder's overhead	\$72,000
	Builder's profit	\$18,000
	Allocation for contingencies	\$100,000
Equipment Not Included in the Construction Contract Sub-total		\$2,500,000
	PET scanner	\$2,500,000
Architectural and Engineering Fees Sub-total		\$410,000
	Consultant's fees	\$410,000
Total Capital Cost		\$4,000,000

Source: COPN Request No. VA-8731

Table 7 shows three projects that the State Health Commissioner recently approved of a similar size and scope. The total capital costs range from \$2,491,617 to \$4,110,625 (Table 7); the total capital costs for the project being reviewed in this staff report falls on the higher end of this spectrum but appears reasonable due to the specific software packaging needed for the diagnostic imaging UVAMC desires to perform.

Table 7. Comparable Projects and Associated Capital Costs

COPN No. Issued	Total Authorized Capital Cost
COPN No. VA-04861 issued October 13, 2023, authorizing Virginia Cancer Institute, Inc. to establish PET/CT services with 1 fixed-site PET/CT scanner	\$3,135,463 (moderate renovation)
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)
COPN No. VA-04806 issued on 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)
Average of Recent, Similar Projects	\$3,245,902

Source: DCOPN Records

The applicant asserts that the fiscal year 2022 Net Income for the PET/CT they have at ECCCC was \$7,293,022 (2,973 procedures) and the fiscal year 2023 Net Income for the same scanner was \$8,813,400 (3,606 procedures) (Table 5). The applicant anticipates that the addition of the second PET/CT location and scanner at UVAMC will result in a Net Income of \$12,258,982 in Year 1 and \$12,580,875 in Year 2 (Table 8). Based upon the increase in procedures between 2021 to 2023 (2,601 to 3,606 procedures, respectively), the additional cardiac patients they will be able to support with scanning that currently receive SPECT imaging, along with the transplant patients they will be able to support, DCOPN finds the projected volumes and Net Income projections to be reasonable. Furthermore, the projections indicate a continuation of the PET/CT imaging services at UVAMC to be viable in both the short and long term.

Table 8. Pro Forma Summary (Both PET/CT Units)

	Year 1	Year 2
Procedures	5,829	5,978
Net Revenue	\$14,213,753	\$14,563,418
Total Expenses	\$1,854,772	\$1,982,543
Net Income	\$12,358,982	\$12,580,875

Source: COPN Request No. VA-8731

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.**

While PET/CT is not a new technology, the application of this diagnostic tool in cardiology, transplantation, and oncology is innovative and exponentially growing as new radiotracers and applications are being discovered. PET/CT is becoming the standard of care in disciplines such as cardiac MPI imaging. PET/CT is less invasive than catheterization techniques and involves less radiation exposure (for both patients and staff) than SPECT imaging. PET/CT imaging for both cardiac and transplantation (the main use for the proposed unit) results in cost-effectiveness by reducing the need for invasive, expensive techniques as well as increasing timeliness and accuracy in diagnosing and treatment. The PET/CT services will be provided on an outpatient basis, reducing the costs of the imaging and increasing comfort for patients, as well. 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.

UVAMC is a state-owned academic medical center. UVAMC asserts that they have a tripartite mission to provide research, training, and clinical care to benefit the citizens of the Commonwealth. The applicant additionally asserts that approval of the project inherently enhances their ability to carry out their clinical mission. Moreover, UVAMC asserts that their research and teaching missions will be aided and enhanced. Additionally, the applicant states that innovations in inpatient services are intended to reach indigent and underserved populations and that the research, training, and clinical care at UVAMC will undoubtedly lead to innovation in the provision of healthcare for all citizens of the Commonwealth.

DCOPN Staff Summary and Findings

The PD 10 population is projected to grow at a rate of 3.88% between 2020-2030, which is slower than the statewide average; however, the 65+ population in PD 10 is projected to increase by 22.09%, which is higher than the statewide average, for the same period (**Table 1**). The statewide average poverty rate in Virginia in 2022 was 10.6% and the averages and weighted averages of PD 10 (and the population centers in PD 10) are higher than the statewide average (**Table 2**).

PET/CT combines PET and CT imaging for a more accurate picture than incorporates anatomy and the physiology of what is being imaged. Compared with SPECT, an imaging modality being

replaced by PET/CT, PET/CT enacts substantially less radiation exposure for the patients and staff, results in cost savings, and results in more effective diagnostic capabilities and treatment plans. Furthermore, the PET/CT scanning reduces the need for invasive diagnostic techniques such as catheterization and CABG, also resulting in a cost savings.

DCOPN did not receive any letters of opposition for the project and received 10 letters of support for the project. The total capital cost is \$4,000,000, which appears reasonable compared to other projects of a similar size and scope. The project also appears viable in the short and long term. UVAMC anticipates needing an additional 5.0 FTE staff, which DCOPN finds to be relatively minimal and does not anticipate this hiring need to have a detrimental effect on other area providers. The project is neither likely to increase geographic access nor foster beneficial institutional competition for the area; however, the project is not anticipated to have a negative effect on either geographic access or competition. The project would aid in training of students and support the NIH grant for cardiac imaging that UVAMC is currently awarded.

It appears that 95% or more of the population has access to PET services within 60-minute driving distance from their homes (**Figure 3**). The project does not meet the SMFP procedure threshold for approval, however, the project does meet the threshold generally adopted by the State Health Commissioner in recent PET and PET/CT projects of a similar size and scope. Furthermore, UVAMC has seen a substantial increase in PET/CT procedure volumes that would be exacerbated (and support efficiency) by the project as they would be able to support all PET/CT cardiac needs that they currently must triage and limit as well as the transplantation specialty PET/CT imaging that they are not currently able to support. The procedure volumes, reduction in radiation exposure, reduction of invasive diagnostic procedures, reduction in healthcare costs, increase in patient comfort and satisfaction, and increase in diagnostic accuracy all support the approval of the project despite the SMFP threshold not being met. Furthermore, the other PET service in PD 10 (a mobile unit at Sentara Martha Jefferson Hospital) is not likely to be adversely affected by the project as UVAMC is needing the CT-support to the PET, which the mobile PET is not able to perform. DCOPN did not receive any opposition from Sentara Martha Jefferson Hospital.

DCOPN Staff Recommendations

COPN Request No. VA-8731 – The Rector and Visitors of the University of Virginia on Behalf of the University of Virginia Medical Center

The Division of Certificate of Public Need recommends the **conditional approval** of this project for the following reasons:

1. The proposal to establish a specialized center for PET/CT imaging at the University of Virginia Fontaine Research Park 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.
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 10.
5. The proposed project appears to be financially viable in the immediate and long-term.
6. There is no known opposition to the project.
7. The project would support the teaching hospital and medical school associated with UVAMC via education and research opportunities.

Charity Conditions

DCOPN's recommendation is contingent upon The Rector and Visitors of the University of Virginia on Behalf of the University of Virginia Medical Center's agreement to the following charity care condition:

The Rector and Visitors of the University of Virginia on Behalf of the University of Virginia Medical Center 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 1.92% of The Rector and Visitors of the University of Virginia on Behalf of the University of Virginia Medical Center'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. The Rector and Visitors of the University of Virginia on Behalf of the University of Virginia Medical Center 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.

The Rector and Visitors of the University of Virginia on Behalf of the University of Virginia Medical Center 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, The Rector and Visitors of the University of Virginia on Behalf of the University of Virginia Medical Center will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.